

NOVEMBER 25, 2016

RULES COMMITTEE PRINT 114-67
TEXT OF HOUSE AMENDMENT TO THE SENATE
AMENDMENT TO H.R. 34, TSUNAMI WARNING,
EDUCATION, AND RESEARCH ACT OF 2015
[Showing the text of the 21st Century Cures Act.]

In lieu of the matter proposed to be added after the enacting clause, insert the following:

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

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

Sec. 1. Short title; table of contents.

DIVISION A—21ST CENTURY CURES

Sec. 1000. Short title.

TITLE I—INNOVATION PROJECTS AND STATE RESPONSES TO
OPIOID ABUSE

Sec. 1001. NIH innovation projects.

Sec. 1002. FDA innovation projects.

Sec. 1003. Account for the state response to the opioid abuse crisis.

Sec. 1004. Budgetary treatment.

TITLE II—DISCOVERY

Subtitle A—National Institutes of Health Reauthorization

Sec. 2001. National Institutes of Health Reauthorization.

Sec. 2002. EUREKA prize competitions.

Subtitle B—Advancing Precision Medicine

- Sec. 2011. Precision Medicine Initiative.
- Sec. 2012. Privacy protection for human research subjects.
- Sec. 2013. Protection of identifiable and sensitive information.
- Sec. 2014. Data sharing.

Subtitle C—Supporting Young Emerging Scientists

- Sec. 2021. Investing in the next generation of researchers.
- Sec. 2022. Improvement of loan repayment program.

Subtitle D—National Institutes of Health Planning and Administration

- Sec. 2031. National Institutes of Health strategic plan.
- Sec. 2032. Triennial reports.
- Sec. 2033. Increasing accountability at the National Institutes of Health.
- Sec. 2034. Reducing administrative burden for researchers.
- Sec. 2035. Exemption for the National Institutes of Health from the Paperwork Reduction Act requirements.
- Sec. 2036. High-risk, high-reward research.
- Sec. 2037. National Center for Advancing Translational Sciences.
- Sec. 2038. Collaboration and coordination to enhance research.
- Sec. 2039. Enhancing the rigor and reproducibility of scientific research.
- Sec. 2040. Improving medical rehabilitation research at the National Institutes of Health.
- Sec. 2041. Task force on research specific to pregnant women and lactating women.
- Sec. 2042. Streamlining National Institutes of Health reporting requirements.
- Sec. 2043. Reimbursement for research substances and living organisms.
- Sec. 2044. Sense of Congress on increased inclusion 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.
- Sec. 2052. Compliance activities reports.
- Sec. 2053. Updates to policies to improve data.
- Sec. 2054. Consultation.

Subtitle F—Facilitating Collaborative Research

- Sec. 2061. National neurological conditions surveillance system.
- Sec. 2062. Tick-borne diseases.
- Sec. 2063. Accessing, sharing, and using health data for research purposes.

Subtitle G—Promoting Pediatric Research

- Sec. 2071. National pediatric research network.
- Sec. 2072. Global pediatric clinical study network.

TITLE III—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

- Sec. 3001. Patient experience data.
- Sec. 3002. Patient-focused drug development guidance.
- Sec. 3003. Streamlining patient input.
- Sec. 3004. Report on patient experience drug development.

Subtitle B—Advancing New Drug Therapies

- Sec. 3011. Qualification of drug development tools.
- Sec. 3012. Targeted drugs for rare diseases.
- Sec. 3013. Reauthorization of program to encourage treatments for rare pediatric diseases.
- Sec. 3014. GAO study of priority review voucher programs.
- Sec. 3015. Amendments to the Orphan Drug grants.
- Sec. 3016. Grants for studying continuous drug manufacturing.

Subtitle C—Modern Trial Design and Evidence Development

- Sec. 3021. Novel clinical trial designs.
- Sec. 3022. Real world evidence.
- Sec. 3023. Protection of human research subjects.
- Sec. 3024. Informed consent waiver or alteration for clinical investigations.

Subtitle D—Patient Access to Therapies and Information

- Sec. 3031. Summary level review.
- Sec. 3032. Expanded access policy.
- Sec. 3033. Accelerated approval for regenerative advanced therapies.
- Sec. 3034. Guidance regarding devices used in the recovery, isolation, or delivery of regenerative advanced therapies.
- Sec. 3035. Report on regenerative advanced therapies.
- Sec. 3036. Standards for regenerative medicine and regenerative advanced therapies.
- Sec. 3037. Health care economic information.
- Sec. 3038. Combination product innovation.

Subtitle E—Antimicrobial Innovation and Stewardship

- Sec. 3041. Antimicrobial resistance monitoring.
- Sec. 3042. Limited population pathway.
- Sec. 3043. Prescribing authority.
- Sec. 3044. Susceptibility test interpretive criteria for microorganisms; antimicrobial susceptibility testing devices.

Subtitle F—Medical Device Innovations

- Sec. 3051. Breakthrough devices.
- Sec. 3052. Humanitarian device exemption.
- Sec. 3053. Recognition of standards.
- Sec. 3054. Certain class I and class II devices.
- Sec. 3055. Classification panels.
- Sec. 3056. Institutional review board flexibility.
- Sec. 3057. CLIA waiver improvements.
- Sec. 3058. Least burdensome device review.
- Sec. 3059. Cleaning instructions and validation data requirement.
- Sec. 3060. Clarifying medical software regulation.

Subtitle G—Improving Scientific Expertise and Outreach at FDA

- Sec. 3071. Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service.
- Sec. 3072. Hiring authority for scientific, technical, and professional personnel.
- Sec. 3073. Establishment of Food and Drug Administration Intercenter Institutes.

- Sec. 3074. Scientific engagement.
- Sec. 3075. Drug surveillance.
- Sec. 3076. Reagan-Udall Foundation for the Food and Drug Administration.

Subtitle H—Medical Countermeasures Innovation

- Sec. 3081. Medical countermeasure guidelines.
- Sec. 3082. Clarifying BARDA contracting authority.
- Sec. 3083. Countermeasure budget plan.
- Sec. 3084. Medical countermeasures innovation.
- Sec. 3085. Streamlining Project BioShield procurement.
- Sec. 3086. Encouraging treatments for agents that present a national security threat.
- Sec. 3087. Paperwork Reduction Act waiver during a public health emergency.
- Sec. 3088. Clarifying Food and Drug Administration emergency use authorization.

Subtitle I—Vaccine Access, Certainty, and Innovation

- Sec. 3091. Predictable review timelines of vaccines by the Advisory Committee on Immunization Practices.
- Sec. 3092. Review of processes and consistency of Advisory Committee on Immunization Practices recommendations.
- Sec. 3093. Encouraging vaccine innovation.

Subtitle J—Technical Corrections

- Sec. 3101. Technical corrections.
- Sec. 3102. Completed studies.

TITLE IV—DELIVERY

- Sec. 4001. Assisting doctors and hospitals in improving quality of care for patients.
- Sec. 4002. Transparent reporting on usability, security, and functionality.
- Sec. 4003. Interoperability.
- Sec. 4004. Information blocking.
- Sec. 4005. Leveraging electronic health records to improve patient care.
- Sec. 4006. Empowering patients and improving patient access to their electronic health information.
- Sec. 4007. GAO study on patient matching.
- Sec. 4008. GAO study on patient access to health information.
- Sec. 4009. Streamlining transfers used for educational purposes.
- Sec. 4010. Improving Medicare local coverage determinations.
- Sec. 4011. Medicare pharmaceutical and technology ombudsman.
- Sec. 4012. Medicare site-of-service price transparency.
- Sec. 4013. Telehealth services in Medicare.

TITLE V—SAVINGS

- Sec. 5001. Savings in the Medicare Improvement Fund.
- Sec. 5002. Medicaid reimbursement to States for durable medical equipment.
- Sec. 5003. Penalties for violations of grants, contracts, and other agreements.
- Sec. 5004. Reducing overpayments of infusion drugs.
- Sec. 5005. Increasing oversight of termination of Medicaid providers.
- Sec. 5006. Requiring publication of fee-for-service provider directory.
- Sec. 5007. Fairness in Medicaid supplemental needs trusts.

- Sec. 5008. Eliminating Federal financial participation with respect to expenditures under Medicaid for agents used for cosmetic purposes or hair growth.
- Sec. 5009. Amendment to the Prevention and Public Health Fund.
- Sec. 5010. Strategic Petroleum Reserve drawdown.
- Sec. 5011. Rescission of portion of ACA territory funding.
- Sec. 5012. Medicare coverage of home infusion therapy.

DIVISION B—HELPING FAMILIES IN MENTAL HEALTH CRISIS

- Sec. 6000. Short title.

TITLE VI—STRENGTHENING LEADERSHIP AND ACCOUNTABILITY

Subtitle A—Leadership

- Sec. 6001. Assistant Secretary for Mental Health and Substance Use.
- Sec. 6002. Strengthening the leadership of the Substance Abuse and Mental Health Services Administration.
- Sec. 6003. Chief Medical Officer.
- Sec. 6004. Improving the quality of behavioral health programs.
- Sec. 6005. Strategic plan.
- Sec. 6006. Biennial report concerning activities and progress.
- Sec. 6007. Authorities of centers for mental health services, substance abuse prevention, and substance abuse treatment.
- Sec. 6008. Advisory councils.
- Sec. 6009. Peer review.

Subtitle B—Oversight and Accountability

- Sec. 6021. Improving oversight of mental and substance use disorders programs through the Assistant Secretary for Planning and Evaluation.
- Sec. 6022. Reporting for protection and advocacy organizations.
- Sec. 6023. GAO study.

Subtitle C—Interdepartmental Serious Mental Illness Coordinating Committee

- Sec. 6031. Interdepartmental Serious Mental Illness Coordinating Committee.

TITLE VII—ENSURING MENTAL AND SUBSTANCE USE DISORDERS PREVENTION, TREATMENT, AND RECOVERY PROGRAMS KEEP PACE WITH SCIENCE AND TECHNOLOGY

- Sec. 7001. Encouraging innovation and evidence-based programs.
- Sec. 7002. Promoting access to information on evidence-based programs and practices.
- Sec. 7003. Priority mental health needs of regional and national significance.
- Sec. 7004. Priority substance use disorder treatment needs of regional and national significance.
- Sec. 7005. Priority substance use disorder prevention needs of regional and national significance.

TITLE VIII—SUPPORTING STATE PREVENTION ACTIVITIES AND RESPONSES TO MENTAL HEALTH AND SUBSTANCE USE DISORDER NEEDS

- Sec. 8001. Community mental health services block grant.

- Sec. 8002. Substance abuse prevention and treatment block grant.
- Sec. 8003. Additional provisions related to the block grants.
- Sec. 8004. Study of distribution of funds under the substance abuse prevention and treatment block grant and the community mental health services block grant.

TITLE IX—PROMOTING ACCESS TO MENTAL HEALTH AND
SUBSTANCE USE DISORDER CARE

Subtitle A—Helping Individuals and Families

- Sec. 9001. Grants for treatment and recovery for homeless individuals.
- Sec. 9002. Grants for jail diversion programs.
- Sec. 9003. Promoting integration of primary and behavioral health care.
- Sec. 9004. Projects for assistance in transition from homelessness.
- Sec. 9005. National Suicide Prevention Lifeline Program.
- Sec. 9006. Connecting individuals and families with care.
- Sec. 9007. Strengthening community crisis response systems.
- Sec. 9008. Garrett Lee Smith Memorial Act reauthorization.
- Sec. 9009. Adult suicide prevention.
- Sec. 9010. Mental health awareness training grants.
- Sec. 9011. Sense of Congress on prioritizing American Indians and Alaska Native youth within suicide prevention programs.
- Sec. 9012. Evidence-based practices for older adults.
- Sec. 9013. National violent death reporting system.
- Sec. 9014. Assisted outpatient treatment.
- Sec. 9015. Assertive community treatment grant program.
- Sec. 9016. Sober truth on preventing underage drinking reauthorization.
- Sec. 9017. Center and program repeals.

Subtitle B—Strengthening the Health Care Workforce

- Sec. 9021. Mental and behavioral health education and training grants.
- Sec. 9022. Strengthening the mental and substance use disorders workforce.
- Sec. 9023. Clarification on current eligibility for loan repayment programs.
- Sec. 9024. Minority fellowship program.
- Sec. 9025. Liability protections for health professional volunteers at community health centers.
- Sec. 9026. Reports.

Subtitle C—Mental Health on Campus Improvement

- Sec. 9031. Mental health and substance use disorder services on campus.
- Sec. 9032. Interagency Working Group on College Mental Health.
- Sec. 9033. Improving mental health on college campuses.

TITLE X—STRENGTHENING MENTAL AND SUBSTANCE USE
DISORDER CARE FOR CHILDREN AND ADOLESCENTS

- Sec. 10001. Programs for children with a serious emotional disturbance.
- Sec. 10002. Increasing access to pediatric mental health care.
- Sec. 10003. Substance use disorder treatment and early intervention services for children and adolescents.
- Sec. 10004. Children's recovery from trauma.
- Sec. 10005. Screening and treatment for maternal depression.
- Sec. 10006. Infant and early childhood mental health promotion, intervention, and treatment.

TITLE XI—COMPASSIONATE COMMUNICATION ON HIPAA

- Sec. 11001. Sense of Congress.
- Sec. 11002. Confidentiality of records.
- Sec. 11003. Clarification on permitted uses and disclosures of protected health information.
- Sec. 11004. Development and dissemination of model training programs.

TITLE XII—MEDICAID MENTAL HEALTH COVERAGE

- Sec. 12001. Rule of construction related to Medicaid coverage of mental health services and primary care services furnished on the same day.
- Sec. 12002. Study and report related to Medicaid managed care regulation.
- Sec. 12003. Guidance on opportunities for innovation.
- Sec. 12004. Study and report on Medicaid emergency psychiatric demonstration project.
- Sec. 12005. Providing EPSDT services to children in IMDs.
- Sec. 12006. Electronic visit verification system required for personal care services and home health care services under Medicaid.

TITLE XIII—MENTAL HEALTH PARITY

- Sec. 13001. Enhanced compliance with mental health and substance use disorder coverage requirements.
- Sec. 13002. Action plan for enhanced enforcement of mental health and substance use disorder coverage.
- Sec. 13003. Report on investigations regarding parity in mental health and substance use disorder benefits.
- Sec. 13004. GAO study on parity in mental health and substance use disorder benefits.
- Sec. 13005. Information and awareness on eating disorders.
- Sec. 13006. Education and training on eating disorders.
- Sec. 13007. Clarification of existing parity rules.

TITLE XIV—MENTAL HEALTH AND SAFE COMMUNITIES

Subtitle A—Mental Health and Safe Communities

- Sec. 14001. Law enforcement grants for crisis intervention teams, mental health purposes.
- Sec. 14002. Assisted outpatient treatment programs.
- Sec. 14003. Federal drug and mental health courts.
- Sec. 14004. Mental health in the judicial system.
- Sec. 14005. Forensic assertive community treatment initiatives.
- Sec. 14006. Assistance for individuals transitioning out of systems.
- Sec. 14007. Co-occurring substance abuse and mental health challenges in drug courts.
- Sec. 14008. Mental health training for Federal uniformed services.
- Sec. 14009. Advancing mental health as part of offender reentry.
- Sec. 14010. School mental health crisis intervention teams.
- Sec. 14011. Active-shooter training for law enforcement.
- Sec. 14012. Co-occurring substance abuse and mental health challenges in residential substance abuse treatment programs.
- Sec. 14013. Mental health and drug treatment alternatives to incarceration programs.
- Sec. 14014. National criminal justice and mental health training and technical assistance.

- Sec. 14015. Improving Department of Justice data collection on mental illness involved in crime.
- Sec. 14016. Reports on the number of mentally ill offenders in prison.
- Sec. 14017. Department of Veterans Affairs patients' rights.
- Sec. 14018. Reauthorization of appropriations.

Subtitle B—Comprehensive Justice and Mental Health

- Sec. 14021. Sequential intercept model.
- Sec. 14022. Prison and jails.
- Sec. 14023. Allowable uses.
- Sec. 14024. Law enforcement training.
- Sec. 14025. Federal law enforcement training.
- Sec. 14026. GAO report.
- Sec. 14027. Evidence based practices.
- Sec. 14028. Transparency, program accountability, and enhancement of local authority.
- Sec. 14029. Grant accountability.

DIVISION C—INCREASING CHOICE, ACCESS, AND QUALITY IN HEALTH CARE FOR AMERICANS

- Sec. 15000. Short title.

TITLE XV—PROVISIONS RELATING TO MEDICARE PART A

- Sec. 15001. Development of Medicare HCPCS version of MS-DRG codes for similar hospital services.
- Sec. 15002. Establishing beneficiary equity in the Medicare hospital readmission program.
- Sec. 15003. Five-year extension of the rural community hospital demonstration program.
- Sec. 15004. Regulatory relief for LTCHs.
- Sec. 15005. Savings from IPPS MACRA pay-for through not applying documentation and coding adjustments.
- Sec. 15006. Extension of certain LTCH Medicare payment rules.
- Sec. 15007. Application of rules on the calculation of hospital length of stay to all LTCHs.
- Sec. 15008. Change in Medicare classification for certain hospitals.
- Sec. 15009. Temporary exception to the application of the Medicare LTCH site neutral provisions for certain spinal cord specialty hospitals.
- Sec. 15010. Temporary extension to the application of the Medicare LTCH site neutral provisions for certain discharges with severe wounds.

TITLE XVI—PROVISIONS RELATING TO MEDICARE PART B

- Sec. 16001. Continuing Medicare payment under HOPD prospective payment system for services furnished by mid-build off-campus outpatient departments of providers.
- Sec. 16002. Treatment of cancer hospitals in off-campus outpatient department of a provider policy.
- Sec. 16003. Treatment of eligible professionals in ambulatory surgical centers for meaningful use and MIPS.
- Sec. 16004. Continuing Access to Hospitals Act of 2016.

- Sec. 16005. Delay of implementation of Medicare fee schedule adjustments for wheelchair accessories and seating systems when used in conjunction with complex rehabilitation technology (CRT) wheelchairs.
- Sec. 16006. Allowing physical therapists to utilize locum tenens arrangements under Medicare.
- Sec. 16007. Extension of the transition to new payment rates for durable medical equipment under the Medicare program.
- Sec. 16008. Requirements in determining adjustments using information from competitive bidding programs.

TITLE XVII—OTHER MEDICARE PROVISIONS

- Sec. 17001. Delay in authority to terminate contracts for Medicare Advantage plans failing to achieve minimum quality ratings.
- Sec. 17002. Requirement for enrollment data reporting for Medicare.
- Sec. 17003. Updating the Welcome to Medicare package.
- Sec. 17004. No payment for items and services furnished by newly enrolled providers or suppliers within a temporary moratorium area.
- Sec. 17005. Preservation of Medicare beneficiary choice under Medicare Advantage.
- Sec. 17006. Allowing end-stage renal disease beneficiaries to choose a Medicare Advantage plan.
- Sec. 17007. Improvements to the assignment of beneficiaries under the Medicare Shared Savings Program.

TITLE XVIII—OTHER PROVISIONS

- Sec. 18001. Exception from group health plan requirements for qualified small employer health reimbursement arrangements.

DIVISION D—CHILD AND FAMILY SERVICES AND SUPPORT

- Sec. 19000. Short title.

TITLE XIX—INVESTING IN PREVENTION AND FAMILY SERVICES

- Sec. 19001. Purpose.

Subtitle A—Prevention Activities Under Title IV–E

- Sec. 19011. Foster care prevention services and programs.
- Sec. 19012. Foster care maintenance payments for children with parents in a licensed residential family-based treatment facility for substance abuse.
- Sec. 19013. Title IV–E payments for evidence-based kinship navigator programs.

Subtitle B—Enhanced Support Under Title IV–B

- Sec. 19021. Elimination of time limit for family reunification services while in foster care and permitting time-limited family reunification services when a child returns home from foster care.
- Sec. 19022. Reducing bureaucracy and unnecessary delays when placing children in homes across State lines.
- Sec. 19023. Enhancements to grants to improve well-being of families affected by substance abuse.

Subtitle C—Miscellaneous

- Sec. 19031. Reviewing and improving licensing standards for placement in a relative foster family home.
- Sec. 19032. Development of a statewide plan to prevent child abuse and neglect fatalities.
- Sec. 19033. Modernizing the title and purpose of title IV–E.
- Sec. 19034. Effective dates.

TITLE XX—ENSURING THE NECESSITY OF A PLACEMENT THAT IS NOT IN A FOSTER FAMILY HOME

- Sec. 20001. Limitation on Federal financial participation for placements that are not in foster family homes.
- Sec. 20002. Assessment and documentation of the need for placement in a qualified residential treatment program.
- Sec. 20003. Protocols to prevent inappropriate diagnoses.
- Sec. 20004. Additional data and reports regarding children placed in a setting that is not a foster family home.
- Sec. 20005. Effective dates; application to waivers.

TITLE XXI—CONTINUING SUPPORT FOR CHILD AND FAMILY SERVICES

- Sec. 21001. Supporting and retaining foster families for children.
- Sec. 21002. Extension of child and family services programs.
- Sec. 21003. Improvements to the John H. Chafee foster care independence program and related provisions.

TITLE XXII—CONTINUING INCENTIVES TO STATES TO PROMOTE ADOPTION AND LEGAL GUARDIANSHIP

- Sec. 22001. Reauthorizing adoption and legal guardianship incentive programs.

TITLE XXIII—TECHNICAL CORRECTIONS

- Sec. 23001. Technical corrections to data exchange standards to improve program coordination.
- Sec. 23002. Technical corrections to State requirement to address the developmental needs of young children.

TITLE XXIV—ENSURING STATES REINVEST SAVINGS RESULTING FROM INCREASE IN ADOPTION ASSISTANCE

- Sec. 24001. Delay of adoption assistance phase-in.
- Sec. 24002. GAO study and report on State reinvestment of savings resulting from increase in adoption assistance.

TITLE XXV—SOCIAL IMPACT PARTNERSHIPS TO PAY FOR RESULTS

- Sec. 25001. Short title.
- Sec. 25002. Social Impact Partnerships to Pay for Results.
- Sec. 25003. Extension of TANF program.
- Sec. 25004. Strengthening welfare research and evaluation and development of a What Works Clearinghouse.
- Sec. 25005. Technical corrections to data exchange standards to improve program coordination.

1 **DIVISION A—21ST CENTURY**
2 **CURES**

3 **SECTION 1000. SHORT TITLE.**

4 This Division may be cited as the “21st Century
5 Cures Act”.

6 **TITLE I—INNOVATION**
7 **PROJECTS AND STATE RE-**
8 **SPONSES TO OPIOID ABUSE**

9 **SEC. 1001. NIH INNOVATION PROJECTS.**

10 (a) IN GENERAL.—The Director of the National In-
11 stitutes of Health (referred to in this section as the “Di-
12 rector of NIH”) shall use any funds appropriated pursu-
13 ant to the authorization of appropriations in subsection
14 (b)(3) to carry out the National Institutes of Health inno-
15 vation projects described in subsection (b)(4) (referred to
16 in this section as the “NIH Innovation Projects”).

17 (b) NATIONAL INSTITUTES OF HEALTH INNOVATION
18 ACCOUNT.—

19 (1) ESTABLISHMENT OF NIH INNOVATION AC-
20 COUNT.—There is established in the Treasury an ac-
21 count, to be known as the “NIH Innovation Ac-
22 count” (referred to in this subsection as the “Ac-
23 count”), for purposes of carrying out the NIH Inno-
24 vation Projects described in paragraph (4).

1 (2) TRANSFER OF DIRECT SPENDING SAV-
2 INGS.—

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

6 (i) For fiscal year 2017,
7 \$372,000,000.

8 (ii) For fiscal year 2018,
9 \$526,000,000.

10 (iii) For fiscal year 2019,
11 \$721,000,000.

12 (iv) For fiscal year 2020,
13 \$507,000,000.

14 (v) For fiscal year 2021,
15 \$424,000,000.

16 (vi) For fiscal year 2022,
17 \$496,000,000.

18 (vii) For fiscal year 2023,
19 \$1,085,000,000.

20 (viii) For fiscal year 2024,
21 \$407,000,000.

22 (ix) For fiscal year 2025,
23 \$107,000,000.

24 (x) For fiscal year 2026,
25 \$151,000,000.

1 (B) AMOUNTS DEPOSITED.—Any amounts
2 transferred under subparagraph (A) shall re-
3 main unavailable in the Account until such
4 amounts are appropriated pursuant to para-
5 graph (3).

6 (3) APPROPRIATIONS.—

7 (A) AUTHORIZATION OF APPROPRIA-
8 TIONS.—For each of the fiscal years 2017
9 through 2026, there is authorized to be appro-
10 priated from the Account to the Director of
11 NIH, for the purpose of carrying out the NIH
12 Innovation Projects, an amount not to exceed
13 the total amount transferred to the Account
14 under paragraph (2)(A), to remain available
15 until expended.

16 (B) OFFSETTING FUTURE APPROPRIA-
17 TIONS.—For any of fiscal years 2017 through
18 2026, for any discretionary appropriation under
19 the heading “NIH Innovation Account” pro-
20 vided to the Director of NIH pursuant to the
21 authorization of appropriations under subpara-
22 graph (A) for the purpose of carrying out the
23 NIH Innovation Projects, the total amount of
24 such appropriations for the applicable fiscal
25 year (not to exceed the total amount remaining

1 in the Account) shall be subtracted from the es-
2 timate of discretionary budget authority and
3 the resulting outlays for any estimate under the
4 Congressional Budget and Impoundment Con-
5 trol Act of 1974 or the Balanced Budget and
6 Emergency Deficit Control Act of 1985, and
7 the amount transferred to the Account shall be
8 reduced by the same amount.

9 (4) NIH INNOVATION PROJECTS.—NIH Inno-
10 vation Projects authorized to be funded under this
11 section shall consist of the following and, of the total
12 amounts authorized to be appropriated under para-
13 graph (3), there are authorized to be appropriated to
14 each such project a total amount not to exceed the
15 following, over the period of fiscal years 2017
16 through 2026:

17 (A) For the Precision Medicine Initiative,
18 including for the advancement of a cohort of in-
19 dividuals to support the goals of the Precision
20 Medicine Initiative, not to exceed a total of
21 \$1,400,000,000, as follows:

22 (i) For fiscal year 2017, \$0.

23 (ii) For fiscal year 2018,
24 \$114,000,000.

1 (iii) For fiscal year 2019,
2 \$23,000,000.

3 (iv) For fiscal year 2020,
4 \$136,000,000.

5 (v) For fiscal year 2021, \$78,000,000.

6 (vi) For fiscal year 2022,
7 \$245,000,000.

8 (vii) For fiscal year 2023,
9 \$580,000,000.

10 (viii) For fiscal year 2024,
11 \$180,000,000.

12 (ix) For fiscal year 2025,
13 \$30,000,000.

14 (x) For fiscal year 2026,
15 \$14,000,000.

16 (B) For the Brain Research through Ad-
17 vancing Innovative Neurotechnologies Initiative
18 (known as the “BRAIN Initiative”), not to ex-
19 ceed a total of \$1,564,000,000, as follows:

20 (i) For fiscal year 2017, \$0.

21 (ii) For fiscal year 2018,
22 \$124,000,000.

23 (iii) For fiscal year 2019,
24 \$25,000,000.

1 (iv) For fiscal year 2020,
2 \$135,000,000.

3 (v) For fiscal year 2021, \$83,000,000.

4 (vi) For fiscal year 2022,
5 \$251,000,000.

6 (vii) For fiscal year 2023,
7 \$505,000,000.

8 (viii) For fiscal year 2024,
9 \$227,000,000.

10 (ix) For fiscal year 2025,
11 \$77,000,000.

12 (x) For fiscal year 2026,
13 \$137,000,000.

14 (C) To support cancer research, such as
15 the development of cancer vaccines, the develop-
16 ment of more sensitive diagnostic tests for can-
17 cer, immunotherapy and the development of
18 combination therapies, and research that has
19 the potential to transform the scientific field,
20 that has inherently higher risk, and that seeks
21 to address major challenges related to cancer,
22 not to exceed a total of \$1,802,000,000, as fol-
23 lows:

24 (i) For fiscal year 2017,
25 \$372,000,000.

1 (ii) For fiscal year 2018,
2 \$278,000,000.

3 (iii) For fiscal year 2019,
4 \$663,000,000.

5 (iv) For fiscal year 2020,
6 \$226,000,000.

7 (v) For fiscal year 2021,
8 \$263,000,000.

9 (D) For the National Institutes of Health,
10 in coordination with the Food and Drug Admin-
11 istration, to award grants and contracts for
12 clinical research to further the field of regenera-
13 tive medicine using adult stem cells, including
14 autologous stem cells, for which grants and con-
15 tracts shall be contingent upon the recipient
16 making available non-Federal contributions to-
17 ward the costs of such research in an amount
18 not less than \$1 for each \$1 of Federal funds
19 provided in the award, not to exceed a total of
20 \$30,000,000, as follows:

21 (i) For fiscal year 2017, \$0.

22 (ii) For each of fiscal years 2018
23 through 2020, \$10,000,000.

24 (iii) For each of fiscal years 2021
25 through 2026, \$0.

1 (c) ACCOUNTABILITY AND OVERSIGHT.—

2 (1) WORK PLAN.—

3 (A) IN GENERAL.—Not later than 180
4 days after the date of enactment of this Act,
5 the Director of NIH shall submit to the Com-
6 mittee on Health, Education, Labor, and Pen-
7 sions and the Committee on Appropriations of
8 the Senate and the Committee on Energy and
9 Commerce and the Committee on Appropria-
10 tions of the House of Representatives, a work
11 plan including the proposed allocation of funds
12 authorized to be appropriated pursuant to sub-
13 section (b)(3) for each of fiscal years 2017
14 through 2026 for the NIH Innovation Projects
15 and the contents described in subparagraph
16 (B).

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

19 (i) recommendations from the Advi-
20 sory Committee described in subparagraph
21 (C);

22 (ii) the amount of money to be obli-
23 gated or expended in each fiscal year for
24 each NIH Innovation Project;

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

3 (iv) a description of how each such
4 project supports the strategic research pri-
5 orities identified in the NIH Strategic Plan
6 under subsection (m) of section 402 of the
7 Public Health Service Act (42 U.S.C.
8 282), as added by section 2031.

9 (C) RECOMMENDATIONS.—Prior to sub-
10 mitting the work plan under this paragraph,
11 the Director of NIH shall seek recommenda-
12 tions from the Advisory Committee to the Di-
13 rector of NIH appointed under section 222 of
14 the Public Health Service Act (42 U.S.C. 217a)
15 on—

16 (i) the allocations of funds appro-
17 priated pursuant to the authorization of
18 appropriations under subsection (b)(3) for
19 each of fiscal years 2017 through 2026;
20 and

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

23 (2) REPORTS.—

24 (A) ANNUAL REPORTS.—Not later than
25 October 1 of each of fiscal years 2018 through

1 2027, the Director of NIH shall submit to the
2 Committee on Health, Education, Labor, and
3 Pensions and the Committee on Appropriations
4 of the Senate and the Committee on Energy
5 and Commerce and the Committee on Appro-
6 priations of the House of Representatives, a re-
7 port including—

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

11 (ii) a description of any such project
12 using funds provided pursuant to the au-
13 thorization of appropriations under sub-
14 section (b)(3); and

15 (iii) whether such projects are advanc-
16 ing the strategic research priorities identi-
17 fied in the NIH Strategic Plan under sub-
18 section (m) of section 402 of the Public
19 Health Service Act (42 U.S.C. 282), as
20 added by section 2031.

21 (B) **ADDITIONAL REPORTS.**—At the re-
22 quest of the Committee on Health, Education,
23 Labor, and Pensions or the Committee on Ap-
24 propriations of the Senate, or the Committee on
25 Energy and Commerce or the Committee on

1 Appropriations of the House of Representatives,
2 the Director of NIH shall provide an update in
3 the form of testimony and any additional re-
4 ports to the respective congressional committee
5 regarding the allocation of funding under this
6 section or the description of the NIH Innova-
7 tion Projects.

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

13 (e) SUNSET.—This section shall expire on September
14 30, 2026.

15 **SEC. 1002. FDA INNOVATION PROJECTS.**

16 (a) IN GENERAL.—The Commissioner of Food and
17 Drugs (referred to in this section as the “Commissioner”)
18 shall use any funds appropriated pursuant to the author-
19 ization of appropriations under subsection (b)(3) to carry
20 out the activities described in subsection (b)(4).

21 (b) FDA INNOVATION ACCOUNT.—

22 (1) ESTABLISHMENT OF FDA INNOVATION AC-
23 COUNT.—There is established in the Treasury an ac-
24 count, to be known as the “FDA Innovation Ac-
25 count” (referred to in this subsection as the “Ac-

1 count’), for purposes of carrying out the activities
2 described in paragraph (4).

3 (2) TRANSFER OF DIRECT SPENDING SAV-
4 INGS.—

5 (A) IN GENERAL.—For each of fiscal years
6 2018 through 2026, the following amounts shall
7 be transferred to the Account from the general
8 fund of the Treasury:

9 (i) For fiscal year 2018, \$30,000,000.

10 (ii) For fiscal year 2019,
11 \$60,000,000.

12 (iii) For fiscal year 2020,
13 \$60,000,000.

14 (iv) For fiscal year 2021,
15 \$50,000,000.

16 (v) For fiscal year 2022, \$50,000,000.

17 (vi) For fiscal year 2023,
18 \$50,000,000.

19 (vii) For fiscal year 2024,
20 \$50,000,000.

21 (viii) For fiscal year 2025,
22 \$75,000,000.

23 (ix) For fiscal year 2026,
24 \$75,000,000.

1 (B) AMOUNTS DEPOSITED.—Any amounts
2 transferred under subparagraph (A) shall re-
3 main unavailable in the Account until such
4 amounts are appropriated pursuant to para-
5 graph (3).

6 (3) APPROPRIATIONS.—

7 (A) AUTHORIZATION OF APPROPRIA-
8 TIONS.—For each of the fiscal years 2018
9 through 2026, there is authorized to be appro-
10 priated from the Account to the Commissioner,
11 for the purpose of carrying out the activities de-
12 scribed in paragraph (5), an amount not to ex-
13 ceed the total amount transferred to the Ac-
14 count under paragraph (2)(A), to remain avail-
15 able until expended.

16 (B) OFFSETTING FUTURE APPROPRIA-
17 TIONS.—For any of fiscal years 2018 through
18 2026, for any discretionary appropriation under
19 the heading “FDA Innovation Account” pro-
20 vided to the Commissioner pursuant to the au-
21 thorization of appropriations under subpara-
22 graph (A) for the purpose of carrying out the
23 projects activities described in paragraph (4),
24 the total amount of such appropriations in the
25 applicable fiscal year (not to exceed the total

1 amount remaining in the Account) shall be sub-
2 tracted from the estimate of discretionary budg-
3 et authority and the resulting outlays for any
4 estimate under the Congressional Budget and
5 Impoundment Control Act of 1974 or the Bal-
6 anced Budget and Emergency Deficit Control
7 Act of 1985, and the amount transferred to the
8 Account shall be reduced by the same amount.

9 (4) FDA ACTIVITIES.—The activities authorized
10 to be funded under this section are the activities
11 under subtitles A through F (including the amend-
12 ments made by such subtitles) of title III, section
13 565A of the Federal Food, Drug, and Cosmetic Act,
14 as added by section 3086 of this Act, and section
15 1014 of such Act, as added by section 3073 of this
16 Act.

17 (c) ACCOUNTABILITY AND OVERSIGHT.—

18 (1) WORK PLAN.—

19 (A) IN GENERAL.—Not later than 180
20 days after the date of enactment of this Act,
21 the Commissioner shall submit to the Com-
22 mittee on Health, Education, Labor, and Pen-
23 sions and the Committee on Appropriations of
24 the Senate and the Committee on Energy and
25 Commerce and the Committee on Appropria-

1 tions of the House of Representatives, a work
2 plan including the proposed allocation of funds
3 appropriated pursuant to the authorization of
4 appropriations under subsection (b)(3) for each
5 of fiscal years 2018 through 2026 and the con-
6 tents described in subparagraph (B).

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

9 (i) recommendations from the Advi-
10 sory Committee described in subparagraph
11 (C);

12 (ii) the amount of money to be obli-
13 gated or expended in each fiscal year for
14 each activity described in subsection (b)(4);
15 and

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

18 (C) RECOMMENDATIONS.—Prior to sub-
19 mitting the work plan under this paragraph,
20 the Commissioner shall seek recommendations
21 from the Science Board to the Food and Drug
22 Administration, on the proposed allocation of
23 funds appropriated pursuant to the authoriza-
24 tion of appropriations under subsection (b)(3)

1 for each of fiscal years 2018 through 2026 and
2 on the contents of the proposed work plan.

3 (2) REPORTS.—

4 (A) ANNUAL REPORTS.—Not later than
5 October 1 of each of fiscal years 2019 through
6 2027, the Commissioner shall submit to the
7 Committee on Health, Education, Labor, and
8 Pensions and the Committee on Appropriations
9 of the Senate and the Committee on Energy
10 and Commerce and the Committee on Appro-
11 priations of the House of Representatives, a re-
12 port including—

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

16 (ii) a description of all such activities
17 using funds provided pursuant to the au-
18 thorization of appropriations under sub-
19 section (b)(3); and

20 (iii) how the activities are advancing
21 public health.

22 (B) ADDITIONAL REPORTS.—At the re-
23 quest of the Committee on Health, Education,
24 Labor, and Pensions or the Committee on Ap-
25 propriations of the Senate, or the Committee on

1 Energy and Commerce or the Committee on
2 Appropriations of the House of Representatives,
3 the Commissioner shall provide an update in
4 the form of testimony and any additional re-
5 ports to the respective congressional committee
6 regarding the allocation of funding under this
7 section or the description of the activities un-
8 dertaken with such funding.

9 (d) LIMITATIONS.—Notwithstanding any transfer au-
10 thority authorized by this Act or any appropriations Act,
11 any funds made available pursuant to the authorization
12 of appropriations in subsection (b)(3) shall not be used
13 for any purpose other than an activity described in sub-
14 section (b)(4).

15 (e) SUNSET.—This section shall expire on September
16 30, 2026.

17 **SEC. 1003. ACCOUNT FOR THE STATE RESPONSE TO THE**
18 **OPIOID ABUSE CRISIS.**

19 (a) IN GENERAL.—The Secretary of Health and
20 Human Services (referred to in this section as the “Sec-
21 retary”) shall use any funds appropriated pursuant to the
22 authorization of appropriations under subsection (b) to
23 carry out the grant program described in subsection (c)
24 for purposes of addressing the opioid abuse crisis within
25 the States.

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

3 (1) ESTABLISHMENT.—There is established in
4 the Treasury an account, to be known as the “Ac-
5 count For the State Response to the Opioid Abuse
6 Crisis” (referred to in this subsection as the “Ac-
7 count”), to carry out the opioid grant program de-
8 scribed in subsection (c).

9 (2) TRANSFER OF DIRECT SPENDING SAV-
10 INGS.—

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

14 (i) For fiscal year 2017,
15 \$500,000,000.

16 (ii) For fiscal year 2018,
17 \$500,000,000.

18 (B) AMOUNTS DEPOSITED.—Any amounts
19 transferred under subparagraph (A) shall re-
20 main unavailable in the Account until such
21 amounts are appropriated pursuant to para-
22 graph (3).

23 (3) APPROPRIATIONS.—

24 (A) AUTHORIZATION OF APPROPRIA-
25 TIONS.—In each of the fiscal years 2017 and

1 2018, there is authorized to be appropriated
2 from the Account to the Secretary, for the
3 grant program described in subsection (c), an
4 amount not to exceed the total amount trans-
5 ferred to the Account under paragraph (2)(A),
6 to remain available until expended.

7 (B) OFFSETTING FUTURE APPROPRIA-
8 TIONS.—In each of fiscal years 2017 and 2018,
9 for any discretionary appropriation under the
10 heading “Account For the State Response to
11 the Opioid Abuse Crisis” for the grant program
12 described in subsection (c), the total amount of
13 such appropriations in the applicable fiscal year
14 (not to exceed the total amount remaining in
15 the Account) shall be subtracted from the esti-
16 mate of discretionary budget authority and the
17 resulting outlays for any estimate under the
18 Congressional Budget and Impoundment Con-
19 trol Act of 1974 or the Balanced Budget and
20 Emergency Deficit Control Act of 1985, and
21 the amount transferred to the Account shall be
22 reduced by the same amount.

23 (c) OPIOID GRANT PROGRAM.—

24 (1) STATE RESPONSE TO THE OPIOID ABUSE
25 CRISIS.—Subject to the availability of appropria-

1 tions, the Secretary shall award grants to States for
2 the purpose of addressing the opioid abuse crisis
3 within such States, in accordance with subparagraph
4 (B). In awarding such grants, the Secretary may
5 give preference to States with an incidence or preva-
6 lence of opioid use disorders that is substantially
7 higher relative to other States.

8 (2) OPIOID GRANTS.—Grants awarded to a
9 State under this subsection shall be used for car-
10 rying out activities that supplement activities per-
11 taining to opioids undertaken by the State agency
12 responsible for administering the substance abuse
13 prevention and treatment block grant under subpart
14 II of part B of title XIX of the Public Health Serv-
15 ice Act (42 U.S.C. 300x–21 et seq.), which may in-
16 clude public health-related activities such as the fol-
17 lowing:

18 (A) Improving State prescription drug
19 monitoring programs.

20 (B) Implementing prevention activities,
21 and evaluating such activities to identify effec-
22 tive strategies to prevent opioid abuse.

23 (C) Training for health care practitioners,
24 such as best practices for prescribing opioids,
25 pain management, recognizing potential cases

1 of substance abuse, referral of patients to treat-
2 ment programs, and overdose prevention.

3 (D) Supporting access to health care serv-
4 ices, including those services provided by Feder-
5 ally certified opioid treatment programs or
6 other appropriate health care providers to treat
7 substance use disorders.

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

12 (d) ACCOUNTABILITY AND OVERSIGHT.—A State re-
13 ceiving a grant under subsection (c) shall include in a re-
14 port related to substance abuse submitted to the Secretary
15 pursuant to section 1942 of the Public Health Service Act
16 (42 U.S.C. 300x–52), a description of—

17 (1) the purposes for which the grant funds re-
18 ceived by the State under such subsection for the
19 preceding fiscal year were expended and a descrip-
20 tion of the activities of the State under the program;
21 and

22 (2) the ultimate recipients of amounts provided
23 to the State in the grant.

1 (e) LIMITATIONS.—Any funds made available pursu-
2 ant to the authorization of appropriations under sub-
3 section (b)—

4 (1) notwithstanding any transfer authority in
5 any appropriations Act, shall not be used for any
6 purpose other than the grant program in subsection
7 (c); and

8 (2) shall be subject to the same requirements as
9 substance abuse prevention and treatment programs
10 under titles V and XIX of the Public Health Service
11 Act (42 U.S.C. 290aa et seq., 300w et seq.).

12 (f) SUNSET.—This section shall expire on September
13 30, 2026.

14 **SEC. 1004. BUDGETARY TREATMENT.**

15 (a) STATUTORY PAYGO SCORECARDS.—The budg-
16 etary effects of division A of this Act shall not be entered
17 on either PAYGO scorecard maintained pursuant to sec-
18 tion 4(d) of the Statutory Pay-As-You-Go Act of 2010.

19 (b) SENATE PAYGO SCORECARDS.—The budgetary
20 effects of division A of this Act shall not be entered on
21 any PAYGO scorecard maintained for purposes of section
22 201 of S. Con. Res. 21 (110th Congress).

23 (c) RESERVATION OF SAVINGS.—None of the funds
24 in the NIH Innovation Account, the FDA Innovation Ac-
25 count, or the Account For the State Response to the

1 Opioid Abuse Crisis established by this title shall be made
2 available except to the extent provided in advance in ap-
3 propriations Acts, and legislation or an Act that rescinds
4 or reduces amounts in such accounts shall not be esti-
5 mated as a reduction in direct spending under the Con-
6 gressional Budget and Impoundment Control Act of 1974
7 or the Balanced Budget and Emergency Deficit Control
8 Act of 1985.

9 **TITLE II—DISCOVERY**
10 **Subtitle A—National Institutes of**
11 **Health Reauthorization**

12 **SEC. 2001. NATIONAL INSTITUTES OF HEALTH REAUTHOR-**
13 **IZATION.**

14 Section 402A(a)(1) of the Public Health Service Act
15 (42 U.S.C. 282a(a)(1)) is amended—

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

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

20 (3) by adding at the end the following new sub-
21 paragraphs:

22 “(D) \$34,851,000,000 for fiscal year
23 2018;

24 “(E) \$35,585,871,000 for fiscal year 2019;

25 and

1 “(F) \$36,472,442,775 for fiscal year
2 2020.”.

3 **SEC. 2002. EUREKA PRIZE COMPETITIONS.**

4 (a) IN GENERAL.—Pursuant to the authorities and
5 processes established under section 24 of the Stevenson-
6 Wydler Technology Innovation Act of 1980 (15 U.S.C.
7 3719), the Director of the National Institutes of Health
8 shall support prize competitions for one or both of the fol-
9 lowing goals:

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

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

15 (A) for which public and private invest-
16 ment in research is disproportionately small rel-
17 ative to Federal Government expenditures on
18 prevention and treatment activities with respect
19 to such diseases and conditions, such that Fed-
20 eral expenditures on health programs would be
21 reduced;

22 (B) that are serious and represent a sig-
23 nificant disease burden in the United States; or

24 (C) for which there is potential for signifi-
25 cant return on investment to the United States.

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

3 (1) collect information on—

4 (A) the effect of innovations funded
5 through the prize competitions under this sec-
6 tion in advancing biomedical science or improv-
7 ing health outcomes pursuant to subsection (a);
8 and

9 (B) the effect of the innovations on Fed-
10 eral expenditures; and

11 (2) include the information collected under
12 paragraph (1) in the triennial report under section
13 403 of the Public Health Service Act (42 U.S.C.
14 283) (as amended by section 2032).

15 **Subtitle B—Advancing Precision** 16 **Medicine**

17 **SEC. 2011. PRECISION MEDICINE INITIATIVE.**

18 Part H of title IV of the Public Health Service Act
19 (42 U.S.C. 289 et seq.) is amended by adding at the end
20 the following:

21 **“SEC. 498E. PRECISION MEDICINE INITIATIVE.**

22 “(a) IN GENERAL.—The Secretary is encouraged to
23 establish and carry out an initiative, to be known as the
24 ‘Precision Medicine Initiative’ (in this section referred to

1 as the ‘Initiative’), to augment efforts to address disease
2 prevention, diagnosis, and treatment.

3 “(b) COMPONENTS.—The Initiative described under
4 subsection (a) may include—

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

7 “(2) developing new approaches for addressing
8 scientific, medical, public health, and regulatory
9 science issues;

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

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

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

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

20 “(1) coordinate with the Secretary of Energy,
21 private industry, and others, as the Secretary deter-
22 mines appropriate, to identify and address the ad-
23 vanced supercomputing and other advanced tech-
24 nology needs for the Initiative;

1 “(2) develop and utilize public-private partner-
2 ships; and

3 “(3) leverage existing data sources.

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

6 “(1) ensure the collaboration of the National
7 Institutes of Health, the Food and Drug Adminis-
8 tration, the Office of the National Coordinator for
9 Health Information Technology, and the Office for
10 Civil Rights of the Department of Health and
11 Human Services;

12 “(2) comply with existing laws and regulations
13 for the protection of human subjects involved in re-
14 search, including the protection of participant pri-
15 vacy;

16 “(3) implement policies and mechanisms for ap-
17 propriate secure data sharing across systems that
18 include protections for privacy and security of data;

19 “(4) consider the diversity of the cohort to en-
20 sure inclusion of a broad range of participants, in-
21 cluding consideration of biological, social, and other
22 determinants of health that contribute to health dis-
23 parities;

24 “(5) ensure that only authorized individuals
25 may access controlled or sensitive, identifiable bio-

1 logical material and associated information collected
2 or stored in connection with the Initiative; and

3 “(6) on the appropriate Internet website of the
4 Department of Health and Human Services, identify
5 any entities with access to such information and pro-
6 vide information with respect to the purpose of such
7 access, a summary of the research project for which
8 such access is granted, as applicable, and a descrip-
9 tion of the biological material and associated infor-
10 mation to which the entity has access.

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

21 **SEC. 2012. PRIVACY PROTECTION FOR HUMAN RESEARCH**
22 **SUBJECTS.**

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

1 “(d)(1)(A) If a person is engaged in biomedical, be-
2 havioral, clinical, or other research, in which identifiable,
3 sensitive information is collected (including research on
4 mental health and research on the use and effect of alcohol
5 and other psychoactive drugs), the Secretary, in coordina-
6 tion with other agencies, as applicable—

7 “(i) shall issue to such person a certificate of
8 confidentiality to protect the privacy of individuals
9 who are the subjects of such research if the research
10 is funded wholly or in part by the Federal Govern-
11 ment; and

12 “(ii) may, upon application by a person engaged
13 in research, issue to such person a certificate of con-
14 fidentiality to protect the privacy of such individuals
15 if the research is not so funded.

16 “(B) Except as provided in subparagraph (C), any
17 person to whom a certificate is issued under subparagraph
18 (A) to protect the privacy of individuals described in such
19 subparagraph shall not disclose or provide to any other
20 person not connected with the research the name of such
21 an individual or any information, document, or biospeci-
22 men that contains identifiable, sensitive information about
23 such an individual and that was created or compiled for
24 purposes of the research.

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

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

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

9 “(iii) made with the consent of the individual to
10 whom the information, document, or biospecimen
11 pertains; or

12 “(iv) made for the purposes of other scientific
13 research that is in compliance with applicable Fed-
14 eral regulations governing the protection of human
15 subjects in research.

16 “(D) Any person to whom a certificate is issued
17 under subparagraph (A) to protect the privacy of an indi-
18 vidual described in such subparagraph shall not, in any
19 Federal, State, or local civil, criminal, administrative, leg-
20 islative, or other proceeding, disclose or provide the name
21 of such individual or any such information, document, or
22 biospecimen that contains identifiable, sensitive informa-
23 tion about the individual and that was created or compiled
24 for purposes of the research, except in the circumstance
25 described in subparagraph (C)(iii).

1 “(E) Identifiable, sensitive information protected
2 under subparagraph (A), and all copies thereof, shall be
3 immune from the legal process, and shall not, without the
4 consent of the individual to whom the information per-
5 tains, be admissible as evidence or used for any purpose
6 in any action, suit, or other judicial, legislative, or admin-
7 istrative proceeding.

8 “(F) Identifiable, sensitive information collected by a
9 person to whom a certificate has been issued under sub-
10 paragraph (A), and all copies thereof, shall be subject to
11 the protections afforded by this section for perpetuity.

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

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

21 “(3) Nothing in this subsection shall be construed to
22 limit the access of an individual who is a subject of re-
23 search to information about himself or herself collected
24 during such individual’s participation in the research.

1 “(4) For purposes of this subsection, the term ‘identi-
2 fiable, sensitive information’ means information that is
3 about an individual and that is gathered or used during
4 the course of research described in paragraph (1)(A)
5 and—

6 “(A) through which an individual is identified;
7 or

8 “(B) for which there is at least a very small
9 risk, as determined by current scientific practices or
10 statistical methods, that some combination of the in-
11 formation, a request for the information, and other
12 available data sources could be used to deduce the
13 identity of an individual.”.

14 (b) APPLICABILITY.—Beginning 180 days after the
15 date of enactment of this Act, all persons engaged in re-
16 search and authorized by the Secretary of Health and
17 Human Services to protect information under section
18 301(d) of the Public Health Service Act (42 U.S.C.
19 241(d)) prior to the date of enactment of this Act shall
20 be subject to the requirements of such section (as amend-
21 ed by this Act).

1 **SEC. 2013. PROTECTION OF IDENTIFIABLE AND SENSITIVE**
2 **INFORMATION.**

3 Section 301 of the Public Health Service Act (42
4 U.S.C. 241) is amended by adding at the end the fol-
5 lowing:

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

11 “(A) an individual is identified; or

12 “(B) there is at least a very small risk, as de-
13 termined by current scientific practices or statistical
14 methods, that some combination of the information,
15 the request, and other available data sources could
16 be used to deduce the identity of an individual.

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

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

25 “(3) Nothing in this subsection shall be construed to
26 limit a research participant’s access to information about

1 such participant collected during the participant’s partici-
2 pation in the research.”.

3 **SEC. 2014. DATA SHARING.**

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

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

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

10 (3) by inserting after paragraph (24) the fol-
11 lowing:

12 “(25) may require recipients of National Insti-
13 tutes of Health awards to share scientific data, to
14 the extent feasible, generated from such National In-
15 stitutes of Health awards in a manner that is con-
16 sistent with all applicable Federal laws and regula-
17 tions, including such laws and regulations for the
18 protection of—

19 “(A) human research participants, includ-
20 ing with respect to privacy, security, informed
21 consent, and protected health information; and

22 “(B) proprietary interests, confidential
23 commercial information, and the intellectual
24 property rights of the funding recipient.”.

1 (b) CONFIDENTIALITY.—Nothing in the amendments
2 made by subsection (a) authorizes the Secretary of Health
3 and Human Services to disclose any information that is
4 a trade secret, or other privileged or confidential informa-
5 tion, described in section 552(b)(4) of title 5, United
6 States Code, or section 1905 of title 18, United States
7 Code, or be construed to require recipients of grants or
8 cooperative agreements through the National Institutes of
9 Health to share such information.

10 **Subtitle C—Supporting Young**
11 **Emerging Scientists**

12 **SEC. 2021. INVESTING IN THE NEXT GENERATION OF RE-**
13 **SEARCHERS.**

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

17 **“SEC. 404M. NEXT GENERATION OF RESEARCHERS.**

18 **“(a) NEXT GENERATION OF RESEARCHERS INITIA-**
19 **TIVE.—**There shall be established within the Office of the
20 Director of the National Institutes of Health, the Next
21 Generation of Researchers Initiative (referred to in this
22 section as the ‘Initiative’), through which the Director
23 shall coordinate all policies and programs within the Na-
24 tional Institutes of Health that are focused on promoting

1 and providing opportunities for new researchers and ear-
2 lier research independence.

3 “(b) ACTIVITIES.—The Director of the National In-
4 stitutes of Health, through the Initiative shall—

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

10 “(2) develop, modify, or prioritize policies, as
11 needed, within the National Institutes of Health to
12 promote opportunities for new researchers and ear-
13 lier research independence, such as policies to in-
14 crease opportunities for new researchers to receive
15 funding, enhance training and mentorship programs
16 for researchers, and enhance workforce diversity;

17 “(3) coordinate, as appropriate, with relevant
18 agencies, professional and academic associations,
19 academic institutions, and others, to improve and
20 update existing information on the biomedical re-
21 search workforce in order to inform programs re-
22 lated to the training, recruitment, and retention of
23 biomedical researchers; and

24 “(4) carry out other activities, including evalua-
25 tion and oversight of existing programs, as appro-

1 appropriate, to promote the development of the next gen-
2 eration of researchers and earlier research independ-
3 ence.”.

4 (b) CONSIDERATION OF RECOMMENDATIONS.—In
5 carrying out activities under section 404M(b) of the Public
6 Health Service Act, the Director of the National Institutes
7 of Health shall take into consideration the recommenda-
8 tions made by the National Academies of Sciences, Engi-
9 neering, and Medicine as part of the comprehensive study
10 on policies affecting the next generation of researchers
11 under the Department of Health and Human Services Ap-
12 propriations Act, 2016 (Public Law 114–113), and submit
13 a report to the Committee on Health, Education, Labor,
14 and Pensions and the Committee on Appropriations of the
15 Senate, and the Committee on Energy and Commerce and
16 the Committee on Appropriations of the House of Rep-
17 resentatives, with respect to any actions taken by the Na-
18 tional Institutes of Health based on the recommendations
19 not later than 2 years after the completion of the study
20 required pursuant to the Department of Health and
21 Human Services Appropriations Act, 2016.

22 **SEC. 2022. IMPROVEMENT OF LOAN REPAYMENT PROGRAM.**

23 (a) INTRAMURAL LOAN REPAYMENT PROGRAM.—
24 Section 487A of the Public Health Service Act (42 U.S.C.
25 288–1) is amended—

1 (1) by amending the section heading to read as
2 follows: “**INTRAMURAL LOAN REPAYMENT PRO-**
3 **GRAM**”;

4 (2) in subsection (a)—

5 (A) by striking “The Secretary shall carry
6 out a program” and inserting “The Director of
7 the National Institutes of Health shall, as ap-
8 propriate and based on workforce and scientific
9 priorities, carry out a program through the sub-
10 categories listed in subsection (b)(1) (or modi-
11 fied subcategories as provided for in subsection
12 (b)(2))”;

13 (B) by striking “conduct” and inserting
14 “conduct research”;

15 (C) by striking “research with respect to
16 acquired immune deficiency syndrome”; and

17 (D) by striking “\$35,000” and inserting
18 “\$50,000”;

19 (3) by redesignating subsection (b) as sub-
20 section (d);

21 (4) by inserting after subsection (a), the fol-
22 lowing:

23 “(b) SUBCATEGORIES OF RESEARCH.—

1 “(1) IN GENERAL.—In carrying out the pro-
2 gram under subsection (a), the Director of the Na-
3 tional Institutes of Health—

4 “(A) shall continue to focus on—

5 “(i) general research;

6 “(ii) research on acquired immune de-
7 ficiency syndrome; and

8 “(iii) clinical research conducted by
9 appropriately qualified health professional
10 who are from disadvantaged backgrounds;
11 and

12 “(B) may focus on an area of emerging
13 scientific or workforce need.

14 “(2) ELIMINATION OR ESTABLISHMENT OF
15 SUBCATEGORIES.—The Director of the National In-
16 stitutes of Health may eliminate one or more subcat-
17 egories provided for in paragraph (1) due to changes
18 in workforce or scientific needs related to biomedical
19 research. The Director may establish other sub-
20 category areas based on workforce and scientific pri-
21 orities if the total number of subcategories does not
22 exceed the number of subcategories listed in para-
23 graph (1).

24 “(c) LIMITATION.—The Director of the National In-
25 stitutes of Health may not enter into a contract with a

1 health professional pursuant to subsection (a) unless such
2 professional has a substantial amount of education loans
3 relative to income (as determined pursuant to guidelines
4 issued by the Director).”; and

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

6 “(e) AVAILABILITY OF APPROPRIATIONS.—Amounts
7 available for carrying out this section shall remain avail-
8 able until the expiration of the second fiscal year begin-
9 ning after the fiscal year for which such amounts are made
10 available.”.

11 (b) EXTRAMURAL LOAN REPAYMENT PROGRAM.—
12 Section 487B of the Public Health Service Act (42 U.S.C.
13 288–2) is amended—

14 (1) by amending the section heading to read as
15 follows: “**EXTRAMURAL LOAN REPAYMENT PRO-**
16 **GRAM**”;

17 (2) in subsection (a)—

18 (A) by striking “The Secretary, in con-
19 sultation with the Director of the Eunice Ken-
20 nedy Shriver National Institute of Child Health
21 and Human Development, shall establish a pro-
22 gram” and inserting “IN GENERAL.—The Di-
23 rector of the National Institutes of Health
24 shall, as appropriate and based on workforce
25 and scientific priorities, carry out a program

1 through the subcategories listed in subsection
2 (b)(1) (or modified subcategories as provided
3 for in subsection (b)(2)),”;

4 (B) by striking “(including graduate stu-
5 dents)”;

6 (C) by striking “with respect to contracep-
7 tion, or with respect to infertility,”; and

8 (D) by striking “service, not more than
9 \$35,000” and inserting “research, not more
10 than \$50,000”;

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

13 (4) by inserting after subsection (a), the fol-
14 lowing:

15 “(b) SUBCATEGORIES OF RESEARCH.—

16 “(1) IN GENERAL.—In carrying out the pro-
17 gram under subsection (a), the Director of the Na-
18 tional Institutes of Health—

19 “(A) shall continue to focus on—

20 “(i) contraception or infertility re-
21 search;

22 “(ii) pediatric research, including pe-
23 diatric pharmacological research;

24 “(iii) minority health disparities re-
25 search;

1 “(iv) clinical research; and

2 “(v) clinical research conducted by ap-
3 propriately qualified health professional
4 who are from disadvantaged backgrounds;
5 and

6 “(B) may focus on an area of emerging
7 scientific or workforce need.

8 “(2) ELIMINATION OR ESTABLISHMENT OF
9 SUBCATEGORIES.—The Director of the National In-
10 stitutes of Health may eliminate one or more subcat-
11 egories provided for in paragraph (1) due to changes
12 in workforce or scientific needs related to biomedical
13 research. The Director may establish other sub-
14 category areas based on workforce and scientific pri-
15 orities if the total number of subcategories does not
16 exceed the number of subcategories listed in para-
17 graph (1).

18 “(c) LIMITATION.—The Director of the National In-
19 stitutes of Health may not enter into a contract with a
20 health professional pursuant to subsection (a) unless such
21 professional has a substantial amount of education loans
22 relative to income (as determined pursuant to guidelines
23 issued by the Director).”;

24 (5) in subsection (d) (as so redesignated), by
25 striking “The provisions” and inserting “APPLICA-

1 BILITY OF CERTAIN PROVISIONS REGARDING OBLI-
2 GATED SERVICE.—The provisions’; and

3 (6) in subsection (e) (as so redesignated), by
4 striking “Amounts” and inserting “AVAILABILITY
5 OF APPROPRIATIONS.—Amounts”.

6 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

7 Title IV of the Public Health Service Act is amended—

8 (1) by striking section 464z-5 (42 U.S.C.
9 285t-2);

10 (2) by striking section 487C (42 U.S.C. 288-
11 3);

12 (3) by striking section 487E (42 U.S.C. 288-
13 5);

14 (4) by striking section 487F (42 U.S.C. 288-
15 5a), as added by section 205 of Public Law 106-
16 505, relating to loan repayment for clinical research-
17 ers; and

18 (5) by striking section 487F (42 U.S.C. 288-
19 6), as added by section 1002(b) of Public Law 106-
20 310 relating to pediatric research loan repayment.

21 (d) GAO REPORT.—Not later than 18 months after
22 the date of enactment of this Act, the Comptroller General
23 of the United States shall submit to Congress a report
24 on the efforts of the National Institutes of Health to at-
25 tract, retain, and develop emerging scientists, including

1 underrepresented individuals in the sciences, such as
2 women, racial and ethnic minorities, and other groups.
3 Such report shall include an analysis of the impact of the
4 additional authority provided to the Secretary of Health
5 and Human Services under this Act to address workforce
6 shortages and gaps in priority research areas, including
7 which centers and research areas offered loan repayment
8 program participants the increased award amount.

9 **Subtitle D—National Institutes of**
10 **Health Planning and Adminis-**
11 **tration**

12 **SEC. 2031. NATIONAL INSTITUTES OF HEALTH STRATEGIC**
13 **PLAN.**

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

16 (1) in subsection (b)(5), by inserting before the
17 semicolon the following: “, and through the develop-
18 ment, implementation, and updating of the strategic
19 plan developed under subsection (m)”;

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

21 “(m) NATIONAL INSTITUTES OF HEALTH STRATEGIC
22 PLAN.—

23 “(1) IN GENERAL.—Not later than 2 years
24 after the date of enactment of the 21st Century
25 Cures Act, and at least every 6 years thereafter, the

1 Director of the National Institutes of Health shall
2 develop and submit to the appropriate committees of
3 Congress and post on the Internet website of the
4 National Institutes of Health, a coordinated strategy
5 (to be known as the ‘National Institutes of Health
6 Strategic Plan’) to provide direction to the bio-
7 medical research investments made by the National
8 Institutes of Health, to facilitate collaboration across
9 the institutes and centers, to leverage scientific op-
10 portunity, and to advance biomedicine.

11 “(2) REQUIREMENTS.—The strategy under
12 paragraph (1) shall—

13 “(A) identify strategic research priorities
14 and objectives across biomedical research, in-
15 cluding—

16 “(i) an assessment of the state of bio-
17 medical and behavioral research, including
18 areas of opportunity with respect to basic,
19 clinical, and translational research;

20 “(ii) priorities and objectives to ad-
21 vance the treatment, cure, and prevention
22 of health conditions;

23 “(iii) emerging scientific opportuni-
24 ties, rising public health challenges, and
25 scientific knowledge gaps; and

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

3 “(B) consider, in carrying out subpara-
4 graph (A)—

5 “(i) disease burden in the United
6 States and the potential for return on in-
7 vestment to the United States;

8 “(ii) rare diseases and conditions;

9 “(iii) biological, social, and other de-
10 terminants of health that contribute to
11 health disparities; and

12 “(iv) other factors the Director of Na-
13 tional Institutes of Health determines ap-
14 propriate;

15 “(C) include multi-institute priorities, in-
16 cluding coordination of research among insti-
17 tutes and centers;

18 “(D) include strategic priorities for fund-
19 ing research through the Common Fund, in ac-
20 cordance with section 402A(c)(1)(C);

21 “(E) address the National Institutes of
22 Health’s proposed and ongoing activities related
23 to training and the biomedical workforce; and

1 “(F) describe opportunities for collabora-
2 tion with other agencies and departments, as
3 appropriate.

4 “(3) USE OF PLANS.—Strategic plans developed
5 and updated by the national research institutes and
6 national centers of the National Institutes of Health
7 shall be prepared regularly and in such a manner
8 that such plans will be informed by the strategic
9 plans developed and updated under this subsection.
10 Such plans developed by and updated by the na-
11 tional research institutes and national centers shall
12 have a common template.

13 “(4) CONSULTATION.—The Director of Na-
14 tional Institutes of Health shall develop the strategic
15 plan under paragraph (1) in consultation with the
16 directors of the national research institutes and na-
17 tional centers, researchers, patient advocacy groups,
18 and industry leaders.”.

19 (b) CONFORMING AMENDMENT.—Section
20 402A(c)(1)(C) of the Public Health Service Act (42
21 U.S.C. 282a(c)(1)(C)) is amended by striking “Not later
22 than June 1, 2007, and every 2 years thereafter,” and
23 inserting “As part of the National Institutes of Health
24 Strategic Plan required under section 402(m),”.

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

4 “(3) STRATEGIC PLANNING.—

5 “(A) IN GENERAL.—The directors of the
6 national institutes and national centers shall
7 consult at least once annually with the Director
8 of the National Institute on Minority Health
9 and Health Disparities and the Director of the
10 Office of Research on Women’s Health regard-
11 ing objectives of the national institutes and na-
12 tional centers to ensure that future activities by
13 such institutes and centers take into account
14 women and minorities and are focused on re-
15 ducing health disparities.

16 “(B) STRATEGIC PLANS.—Any strategic
17 plan issued by a national institute or national
18 center shall include details on the objectives de-
19 scribed in subparagraph (A).”.

20 **SEC. 2032. TRIENNIAL REPORTS.**

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

23 (1) in the section heading, by striking “**BIEN-**
24 **NIAL**” and inserting “**TRIENNIAL**” ; and

25 (2) in subsection (a)—

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

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

5 “(3) A description of intra-National Institutes
6 of Health activities, including—

7 “(A) identification of the percentage of
8 funds made available by each national research
9 institute and national center with respect to
10 each applicable fiscal year for conducting or
11 supporting research that involves collaboration
12 between the institute or center and 1 or more
13 other national research institutes or national
14 centers; and

15 “(B) recommendations for promoting co-
16 ordination of information among the centers of
17 excellence.”;

18 (C) in paragraph (4)—

19 (i) in subparagraph (B), by striking
20 “demographic variables and other vari-
21 ables” and inserting “demographic vari-
22 ables, including biological and social vari-
23 ables and relevant age categories (such as
24 pediatric subgroups), and determinants of
25 health,”; and

1 (ii) in subparagraph (C)(v)—

2 (I) by striking “demographic
3 variables and such” and inserting
4 “demographic variables, including rel-
5 evant age categories (such as pediatric
6 subgroups), information submitted by
7 each national research institute and
8 national center to the Director of Na-
9 tional Institutes of Health under sec-
10 tion 492B(f), and such”; and

11 (II) by striking “(regarding in-
12 clusion of women and minorities in
13 clinical research)” and inserting “and
14 other applicable requirements regard-
15 ing inclusion of demographic groups”;
16 and

17 (D) in paragraph (6)—

18 (i) in the matter preceding subpara-
19 graph (A), by striking “the following:” and
20 inserting “the following—”;

21 (ii) in subparagraph (A)—

22 (I) by striking “An evaluation”
23 and inserting “an evaluation”; and

24 (II) by striking the period and
25 inserting “; and”;

1 (iii) by striking subparagraphs (B)
2 and (D);
3 (iv) by redesignating subparagraph
4 (C) as subparagraph (B); and
5 (v) in subparagraph (B), as redesign-
6 nated by clause (iv), by striking “Rec-
7 ommendations” and inserting “rec-
8 ommendations”.

9 **SEC. 2033. INCREASING ACCOUNTABILITY AT THE NA-**
10 **TIONAL INSTITUTES OF HEALTH.**

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

15 “(a) APPOINTMENT.—

16 “(1) IN GENERAL.—The Director of the Na-
17 tional Cancer Institute shall be appointed by the
18 President, and the Directors of the other national
19 research institutes and national centers shall be ap-
20 pointed by the Secretary, acting through the Direc-
21 tor of National Institutes of Health. Each Director
22 of a national research institute or national center
23 shall report directly to the Director of National In-
24 stitutes of Health.

25 “(2) APPOINTMENT.—

1 “(A) TERM.—A Director of a national re-
2 search institute or national center who is ap-
3 pointed by the Secretary, acting through the
4 Director of National Institutes of Health, shall
5 be appointed for 5 years.

6 “(B) REAPPOINTMENT.—At the end of the
7 term of a Director of a national research insti-
8 tute or national center, the Director may be re-
9 appointed in accordance with standards applica-
10 ble to the relevant appointment mechanism.
11 There shall be no limit on the number of terms
12 that a Director may serve.

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

19 “(D) CURRENT DIRECTORS.—Each Direc-
20 tor of a national research institute or national
21 center who is serving on the date of enactment
22 of the 21st Century Cures Act shall be deemed
23 to be appointed for a 5-year term under this
24 subsection beginning on such date of enact-
25 ment.

1 “(E) RULE OF CONSTRUCTION.—Nothing
2 in this subsection shall be construed to limit the
3 authority of the Secretary or the Director of
4 National Institutes of Health to terminate the
5 appointment of a director referred to in sub-
6 paragraph (A) before the expiration of such di-
7 rector’s 5-year term.

8 “(F) NATURE OF APPOINTMENT.—Ap-
9 pointments and reappointments under this sub-
10 section shall be made on the basis of ability and
11 experience as it relates to the mission of the
12 National Institutes of Health and its compo-
13 nents, including compliance with any legal re-
14 quirement that the Secretary or Director of Na-
15 tional Institutes of Health determines relevant.

16 “(3) NONAPPLICATION OF CERTAIN PROVI-
17 SION.—The restrictions contained in section 202 of
18 the Departments of Labor, Health and Human
19 Services, and Education, and Related Agencies Ap-
20 propriations Act, 1993 (Public Law 102–394; 42
21 U.S.C. 238f note) related to consultants and indi-
22 vidual scientists appointed for limited periods of
23 time shall not apply to Directors appointed under
24 this subsection.”.

1 (b) REVIEW OF CERTAIN AWARDS BY DIRECTORS.—
2 Section 405(b) of the Public Health Service Act (42
3 U.S.C. 284(b)) is amended by adding at the end the fol-
4 lowing:

5 “(3) Before an award is made by a national research
6 institute or by a national center for a grant for a research
7 program or project (commonly referred to as an ‘R-series
8 grant’), other than an award constituting a noncompeti-
9 tive renewal of such a grant, or a noncompetitive adminis-
10 trative supplement to such a grant, the Director of such
11 national research institute or national center shall, con-
12 sistent with the peer review process—

13 “(A) review and make the final decision with
14 respect to making the award; and

15 “(B) take into consideration, as appropriate—

16 “(i) the mission of the national research
17 institute or national center and the scientific
18 priorities identified in the strategic plan under
19 section 402(m);

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

22 “(iii) advice by staff and the advisory
23 council or board of such national research insti-
24 tute or national center.”.

1 (c) REPORT ON DUPLICATION IN FEDERAL BIO-
2 MEDICAL RESEARCH.—The Secretary of Health and
3 Human Services (referred to in this subsection as the
4 “Secretary”), shall, not later than 2 years after the date
5 of enactment of this Act, submit a report to Congress on
6 efforts to prevent and eliminate duplicative biomedical re-
7 search that is not necessary for scientific purposes. Such
8 report shall—

9 (1) describe the procedures in place to identify
10 such duplicative research, including procedures for
11 monitoring research applications and funded re-
12 search awards to prevent unnecessary duplication;

13 (2) describe the steps taken to improve the pro-
14 cedures described in paragraph (1), in response to
15 relevant recommendations made by the Comptroller
16 General of the United States;

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

20 (4) provide examples of instances where the
21 Secretary has identified unnecessarily duplicative re-
22 search and the steps taken to eliminate the unneces-
23 sary duplication.

1 **SEC. 2034. REDUCING ADMINISTRATIVE BURDEN FOR RE-**
2 **SEARCHERS.**

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

5 (1) IN GENERAL.—Not later than 2 years after
6 the date of enactment of this Act, the Secretary of
7 Health and Human Services (referred to in this sec-
8 tion as the “Secretary”) shall—

9 (A) lead a review by research funding
10 agencies of all regulations and policies related
11 to the disclosure of financial conflicts of inter-
12 est, including the minimum threshold for re-
13 porting financial conflicts of interest;

14 (B) make revisions, as appropriate, to har-
15 monize existing policies and reduce administra-
16 tive burden on researchers while maintaining
17 the integrity and credibility of research findings
18 and protections of human participants; and

19 (C) confer with the Office of the Inspector
20 General about the activities of such office re-
21 lated to financial conflicts of interest involving
22 research funding agencies.

23 (2) CONSIDERATIONS.—In updating policies
24 under paragraph (1)(B), the Secretary shall con-
25 sider—

1 (A) modifying the timelines for the report-
2 ing of financial conflicts of interest to just-in-
3 time information by institutions receiving grant
4 or cooperative agreement funding from the Na-
5 tional Institutes of Health;

6 (B) ensuring that financial interest dislo-
7 sure reporting requirements are appropriate for,
8 and relevant to, awards that will directly fund
9 research, which may include modification of the
10 definition of the term “investigator” for pur-
11 poses of the regulations and policies described
12 in subparagraphs (A) and (B) of paragraph (1);
13 and

14 (C) updating any applicable training mod-
15 ules of the National Institutes of Health related
16 to Federal financial interest disclosure.

17 (b) MONITORING OF SUBRECIPIENTS OF FUNDING
18 FROM THE NATIONAL INSTITUTES OF HEALTH.—The Di-
19 rector of the National Institutes of Health (referred to in
20 this section as the “Director of National Institutes of
21 Health”) shall implement measures to reduce the adminis-
22 trative burdens related to monitoring of subrecipients of
23 grants by primary awardees of funding from the National
24 Institutes of Health, which may incorporate findings and

1 recommendations from existing and ongoing activities.

2 Such measures may include, as appropriate—

3 (1) an exemption from subrecipient monitoring
4 requirements, upon request from the primary award-
5 ees, provided that—

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

10 (B) the primary awardee conducts, pursu-
11 ant to guidance of the National Institutes of
12 Health, a pre-award evaluation of each sub-
13 recipient's risk of noncompliance with Federal
14 statutes and regulations, the conditions of the
15 subaward, and any recurring audit findings;
16 and

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

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

24 (c) REPORTING OF FINANCIAL EXPENDITURES.—

25 The Secretary, in consultation with the Director of Na-

1 tional Institutes of Health, shall evaluate financial expend-
2 iture reporting procedures and requirements for recipients
3 of funding from the National Institutes of Health and take
4 action, as appropriate, to avoid duplication between de-
5 partment and agency procedures and requirements and
6 minimize burden to funding recipients.

7 (d) ANIMAL CARE AND USE IN RESEARCH.—Not
8 later than 2 years after the date of enactment of this Act,
9 the Director of National Institutes of Health, in collabora-
10 tion with the Secretary of Agriculture and the Commis-
11 sioner of Food and Drugs, shall complete a review of ap-
12 plicable regulations and policies for the care and use of
13 laboratory animals and make revisions, as appropriate, to
14 reduce administrative burden on investigators while main-
15 taining the integrity and credibility of research findings
16 and protection of research animals. In carrying out this
17 effort, the Director of the National Institutes of Health
18 shall seek the input of experts, as appropriate. The Direc-
19 tor of the National Institutes of Health shall—

20 (1) identify ways to ensure such regulations
21 and policies are not inconsistent, overlapping, or un-
22 necessarily duplicative, including with respect to in-
23 spection and review requirements by Federal agen-
24 cies and accrediting associations;

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

4 (3) take other actions, as appropriate, to im-
5 prove the coordination of regulations and policies
6 with respect to research with laboratory animals.

7 (e) DOCUMENTATION OF PERSONNEL EXPENSES.—

8 The Secretary shall clarify the applicability of the require-
9 ments under the Office of Management and Budget Uni-
10 form Guidance for management and certification systems
11 adopted by entities receiving Federal research grants
12 through the Department of Health and Human Services
13 regarding documentation of personnel expenses, including
14 clarification of the extent to which any flexibility to such
15 requirements specified in such Uniform Guidance applies
16 to entities receiving grants through the Department of
17 Health and Human Services.

18 (f) RESEARCH POLICY BOARD.—

19 (1) ESTABLISHMENT.—Not later than 1 year
20 after the date of enactment of this Act, the Director
21 of the Office of Management and Budget shall es-
22 tablish an advisory committee, to be known as the
23 “Research Policy Board” (referred to in this sub-
24 section as the “Board”), to provide Federal Govern-

1 ment officials with information on the effects of reg-
2 ulations related to Federal research requirements.

3 (2) MEMBERSHIP.—

4 (A) IN GENERAL.—The Board shall in-
5 clude not more than 10 Federal members, in-
6 cluding each of the following Federal members
7 or their designees:

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

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

13 (iii) The Secretary of Health and
14 Human Services.

15 (iv) The Director of the National
16 Science Foundation.

17 (v) The secretaries and directors of
18 other departments and agencies that sup-
19 port or regulate scientific research, as de-
20 termined by the Director of the Office of
21 Management and Budget.

22 (B) NON-FEDERAL MEMBERS.—The Board
23 shall be comprised of not less than 9 and not
24 more than 12 representatives of academic re-
25 search institutions, other private, nonprofit re-

1 search institutions, or other nonprofit organiza-
2 tions with relevant expertise. Such members
3 shall be appointed by a formal process, to be es-
4 tablished by the Director of the Office of Man-
5 agement and Budget, in consultation with the
6 Federal membership, and that incorporates—

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

11 (ii) procedures to fill membership po-
12 sitions vacated before the end of a mem-
13 ber's term.

14 (3) PURPOSE AND RESPONSIBILITIES.—The
15 Board shall make recommendations regarding the
16 modification and harmonization of regulations and
17 policies having similar purposes across research
18 funding agencies to ensure that the administrative
19 burden of such research policy and regulation is
20 minimized to the greatest extent possible and con-
21 sistent with maintaining responsible oversight of fed-
22 erally funded research. Activities of the Board may
23 include—

24 (A) providing thorough and informed anal-
25 ysis of regulations and policies;

1 (B) identifying negative or adverse con-
2 sequences of existing policies and making ac-
3 tionable recommendations regarding possible
4 improvement of such policies;

5 (C) making recommendations with respect
6 to efforts within the Federal Government to im-
7 prove coordination of regulation and policy re-
8 lated to research;

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

13 (E) conducting ongoing assessment and
14 evaluation of regulatory burden, including de-
15 velopment of metrics, periodic measurement,
16 and identification of process improvements and
17 policy changes.

18 (4) EXPERT SUBCOMMITTEES.—The Board
19 may form temporary expert subcommittees, as ap-
20 propriate, to develop timely analysis on pressing
21 issues and assist the Board in anticipating future
22 regulatory challenges, including challenges emerging
23 from new scientific advances.

24 (5) REPORTING REQUIREMENTS.—Not later
25 than 2 years after the date of enactment of this Act,

1 and once thereafter, the Board shall submit a report
2 to the Director of the Office of Management and
3 Budget, the Administrator of the Office of Informa-
4 tion and Regulatory Affairs of the Office of Manage-
5 ment and Budget, the Director of the Office of
6 Science and Technology Policy, the heads of relevant
7 Federal departments and agencies, the Committee
8 on Health, Education, Labor, and Pensions of the
9 Senate, and the Committee on Energy and Com-
10 merce of the House of Representatives containing
11 formal recommendations on the conceptualization,
12 development, harmonization, and reconsideration of
13 scientific research policy, including the regulatory
14 benefits and burdens.

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

17 (7) GAO REPORT.—Not later than 4 years
18 after the date of enactment of this Act, the Comp-
19 troller General of the United States shall conduct an
20 independent evaluation of the activities carried out
21 by the Board pursuant to this subsection and submit
22 to the appropriate committees of Congress a report
23 regarding the results of the independent evaluation.
24 Such report shall review and assess the Board's ac-

1 activities with respect to the responsibilities described
2 in paragraph (3).

3 **SEC. 2035. EXEMPTION FOR THE NATIONAL INSTITUTES OF**
4 **HEALTH FROM THE PAPERWORK REDUCTION**
5 **ACT REQUIREMENTS.**

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

9 “(g) Subchapter I of chapter 35 of title 44, United
10 States Code, shall not apply to the voluntary collection of
11 information during the conduct of research by the Na-
12 tional Institutes of Health.”.

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

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

17 “(n) **UNIQUE RESEARCH INITIATIVES.**—

18 “(1) **IN GENERAL.**—The Director of NIH may
19 approve, after consideration of a proposal under
20 paragraph (2)(A), requests by the national research
21 institutes and centers, or program officers within the
22 Office of the Director to engage in transactions
23 other than a contract, grant, or cooperative agree-
24 ment with respect to projects that carry out—

1 “(A) the Precision Medicine Initiative
2 under section 498E; or

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

9 “(2) REQUIREMENTS.—The authority provided
10 under this subsection may be used to conduct or
11 support high impact cutting-edge research described
12 in paragraph (1) using the other transactions au-
13 thority described in such paragraph if the institute,
14 center, or office—

15 “(A) submits a proposal to the Director of
16 NIH for the use of such authority before con-
17 ducting or supporting the research, including
18 why the use of such authority is essential to
19 promoting the success of the project;

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

22 “(C) for each year in which the institute,
23 center, or office has used such authority in ac-
24 cordance with this subsection, submits a report
25 to the Director of NIH on the activities of the

1 institute, center, or office relating to such re-
2 search.”.

3 (b) REPORT TO CONGRESS.—Not later than Sep-
4 tember 30, 2020, the Secretary of Health and Human
5 Services, acting through the Director of the National In-
6 stitutes of Health, shall conduct an evaluation of the ac-
7 tivities under subsection (n) of section 402 of the Public
8 Health Service Act (42 U.S.C. 282), as added by sub-
9 section (a), and submit a report to the Committee on
10 Health, Education, Labor, and Pensions of the Senate and
11 the Committee on Energy and Commerce of the House
12 of Representatives on the results of such evaluation.

13 (c) DUTIES OF DIRECTORS OF INSTITUTES.—Section
14 405(b)(1) of the Public Health Service Act (42 U.S.C.
15 284(b)(1)) is amended—

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

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

21 “(C) shall, as appropriate, conduct and support
22 research that has the potential to transform the sci-
23 entific field, has inherently higher risk, and that
24 seeks to address major current challenges;”.

1 **SEC. 2037. NATIONAL CENTER FOR ADVANCING**
2 **TRANSLATIONAL SCIENCES.**

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

5 (1) in paragraph (1), by striking “phase IIA”
6 and inserting “phase IIB”; and

7 (2) in paragraph (2)—

8 (A) in the matter preceding subparagraph
9 (A), by striking “phase IIB” and inserting
10 “phase III”;

11 (B) in subparagraph (A), by striking
12 “phase IIB” and inserting “phase III”;

13 (C) in subparagraph (B), by striking
14 “phase IIA” and inserting “phase IIB”; and

15 (D) in subparagraph (C), by striking
16 “phase IIB” and inserting “phase III”.

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

19 (1) in subsection (c)—

20 (A) in paragraph (4)(D), by striking
21 “and” at the end;

22 (B) in paragraph (5), by striking the pe-
23 riod and inserting a semicolon; and

24 (C) by adding at the end the following:

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

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

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

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

14 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion shall be construed as authorizing the Secretary to dis-
16 close any information that is a trade secret, or other privi-
17 leged or confidential information subject to section
18 552(b)(4) of title 5, United States Code, or section 1905
19 of title 18, United States Code.”.

20 **SEC. 2038. COLLABORATION AND COORDINATION TO EN-**
21 **HANCE RESEARCH.**

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

1 (1) by amending paragraph (4) to read as fol-
2 lows:

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

5 “(A) information to better evaluate sci-
6 entific opportunity, public health burdens, and
7 progress in reducing health disparities; and

8 “(B) data on study populations of clinical
9 research, funded by or conducted at each na-
10 tional research institute and national center,
11 which—

12 “(i) specifies the inclusion of—

13 “(I) women;

14 “(II) members of minority
15 groups;

16 “(III) relevant age categories, in-
17 cluding pediatric subgroups; and

18 “(IV) other demographic vari-
19 ables as the Director of the National
20 Institutes of Health determines appro-
21 priate;

22 “(ii) is disaggregated by research
23 area, condition, and disease categories; and

1 “(iii) is to be made publicly available
2 on the Internet website of the National In-
3 stitutes of Health;”; and

4 (2) in paragraph (8)—

5 (A) in subparagraph (A), by striking
6 “and” at the end; and

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

8 “(C) foster collaboration between clinical
9 research projects funded by the respective na-
10 tional research institutes and national centers
11 that—

12 “(i) conduct research involving human
13 subjects; and

14 “(ii) collect similar data; and

15 “(D) encourage the collaboration described
16 in subparagraph (C) to—

17 “(i) allow for an increase in the num-
18 ber of subjects studied; and

19 “(ii) utilize diverse study populations,
20 with special consideration to biological, so-
21 cial, and other determinants of health that
22 contribute to health disparities;”.

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

1 (1) by striking “biennial” each place such term
2 appears and inserting “triennial”;

3 (2) by striking “The advisory council” and in-
4 sserting the following:

5 “(1) IN GENERAL.—The advisory council”; and

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

7 “(2) CONTENTS.—Each triennial report pre-
8 pared by an advisory council of each national re-
9 search institute as described in paragraph (1) shall
10 include each of the following:

11 “(A) The number of women included as
12 subjects, and the proportion of subjects that are
13 women, in any project of clinical research con-
14 ducted during the applicable reporting period,
15 disaggregated by categories of research area,
16 condition, or disease, and accounting for single-
17 sex studies.

18 “(B) The number of members of minority
19 groups included as subjects, and the proportion
20 of subjects that are members of minority
21 groups, in any project of clinical research con-
22 ducted during the applicable reporting period,
23 disaggregated by categories of research area,
24 condition, or disease and accounting for single-
25 race and single-ethnicity studies.

1 “(C) For the applicable reporting period,
2 the number of projects of clinical research that
3 include women and members of minority groups
4 and that—

5 “(i) have been completed during such
6 reporting period; and

7 “(ii) are being carried out during such
8 reporting period and have not been com-
9 pleted.

10 “(D) The number of studies completed
11 during the applicable reporting period for which
12 reporting has been submitted in accordance
13 with subsection (c)(2)(A).”.

14 (c) COORDINATION.—Section 486(c)(2) of the Public
15 Health Service Act (42 U.S.C. 287d(c)(2)) is amended by
16 striking “designees” and inserting “senior-level staff des-
17 ignees”.

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

22 **“SEC. 404N. POPULATION FOCUSED RESEARCH.**

23 “The Director of the National Institutes of Health
24 shall, as appropriate, encourage efforts to improve re-

1 search related to the health of sexual and gender minority
2 populations, including by—

3 “(1) facilitating increased participation of sex-
4 ual and gender minority populations in clinical re-
5 search supported by the National Institutes of
6 Health, and reporting on such participation, as ap-
7 plicable;

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

11 “(3) addressing methodological challenges.”.

12 (e) REPORTING.—

13 (1) IN GENERAL.—The Secretary, in collabora-
14 tion with the Director of the National Institutes of
15 Health, shall as appropriate—

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

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

23 (2) NATIONAL ACADEMY OF MEDICINE REC-
24 OMMENDATIONS.—In developing the measures de-
25 scribed in paragraph (1)(A), the Secretary shall take

1 into account recommendations made by the National
2 Academy of Medicine.

3 (f) IMPROVING COORDINATION RELATED TO MINOR-
4 ITY HEALTH AND HEALTH DISPARITIES.—Section 464z-
5 3 of the Public Health Service Act (42 U.S.C. 285t) is
6 amended—

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

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

11 (A) in the subsection heading, by striking
12 “INTERAGENCY” and inserting “INTRA-NA-
13 TIONAL INSTITUTES OF HEALTH”;

14 (B) by striking “as the primary Federal
15 officials” and inserting “as the primary Federal
16 official”;

17 (C) by inserting a comma after “review”;

18 (D) by striking “Institutes and Centers of
19 the National Institutes of Health” and inserting
20 “national research institutes and national cen-
21 ters”; and

22 (E) by adding at the end the following:
23 “The Director of the Institute may foster part-
24 nerships between the national research insti-
25 tutes and national centers and may encourage

1 the funding of collaborative research projects to
2 achieve the goals of the National Institutes of
3 Health that are related to minority health and
4 health disparities.”.

5 (g) BASIC RESEARCH.—

6 (1) DEVELOPING POLICIES.—Not later than 2
7 years after the date of enactment of this Act, the
8 Director of the National Institutes of Health (re-
9 ferred to in this section as the “Director of the Na-
10 tional Institutes of Health”), taking into consider-
11 ation the recommendations developed under section
12 2039, shall develop policies for projects of basic re-
13 search funded by National Institutes of Health to
14 assess—

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

17 (B) how differences between male and fe-
18 male cells, tissues, or animals may be examined
19 and analyzed.

20 (2) REVISING POLICIES.—The Director of the
21 National Institutes of Health may update or revise
22 the policies developed under paragraph (1) as appro-
23 priate.

24 (3) CONSULTATION AND OUTREACH.—In devel-
25 oping, updating, or revising the policies under this

1 section, the Director of the National Institutes of
2 Health shall—

3 (A) consult with—

4 (i) the Office of Research on Women’s
5 Health;

6 (ii) the Office of Laboratory Animal
7 Welfare; and

8 (iii) appropriate members of the sci-
9 entific and academic communities; and

10 (B) conduct outreach to solicit feedback
11 from members of the scientific and academic
12 communities on the influence of sex as a vari-
13 able in basic research, including feedback on
14 when it is appropriate for projects of basic re-
15 search involving cells, tissues, or animals to in-
16 clude both male and female cells, tissues, or
17 animals.

18 (4) ADDITIONAL REQUIREMENTS.—The Direc-
19 tor of the National Institutes of Health shall—

20 (A) ensure that projects of basic research
21 funded by the National Institutes of Health are
22 conducted in accordance with the policies devel-
23 oped, updated, or revised under this section, as
24 applicable; and

1 (B) encourage that the results of such re-
2 search, when published or reported, be
3 disaggregated as appropriate with respect to
4 the analysis of any sex differences.

5 (h) CLINICAL RESEARCH.—

6 (1) IN GENERAL.—Not later than 1 year after
7 the date of enactment of this Act, the Director of
8 the National Institutes of Health, in consultation
9 with the Director of the Office of Research on Wom-
10 en’s Health and the Director of the National Insti-
11 tute on Minority Health and Health Disparities,
12 shall update the guidelines established under section
13 492B(d) of Public Health Service Act (42 U.S.C.
14 289a–2(d)) in accordance with paragraph (2).

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

17 (A) reflect the science regarding sex dif-
18 ferences;

19 (B) improve adherence to the requirements
20 under section 492B of the Public Health Serv-
21 ice Act (42 U.S.C. 289a–2), including the re-
22 porting requirements under subsection (f) of
23 such section; and

24 (C) clarify the circumstances under which
25 studies should be designed to support the con-

1 duct of analyses to detect significant differences
2 in the intervention effect due to demographic
3 factors related to section 492B of the Public
4 Health Service Act, including in the absence of
5 prior studies that demonstrate a difference in
6 study outcomes on the basis of such factors and
7 considering the effects of the absence of such
8 analyses on the availability of data related to
9 demographic differences.

10 (i) APPROPRIATE AGE GROUPINGS IN CLINICAL RE-
11 SEARCH.—

12 (1) INPUT FROM EXPERTS.—Not later than
13 180 days after the date of enactment of this Act, the
14 Director of the National Institutes of Health shall
15 convene a workshop of experts on pediatric and older
16 populations to provide input on—

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

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

23 (2) POLICY UPDATES.—Not later than 180
24 days after the conclusion of the workshop under
25 paragraph (1), the Director of the National Insti-

1 tutes of Health shall make a determination with re-
2 spect to whether the policies of the National Insti-
3 tutes of Health on the inclusion of relevant age
4 groups in clinical studies need to be updated, and
5 shall update such policies as appropriate. In making
6 the determination, the Director of the National In-
7 stitutes of Health shall take into consideration
8 whether such policies—

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

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

14 (3) PUBLIC AVAILABILITY OF FINDINGS AND
15 CONCLUSIONS.—The Director of the National Insti-
16 tutes of Health shall—

17 (A) make the findings and conclusions re-
18 sulting from the workshop under paragraph (1)
19 and updates to policies in accordance with para-
20 graph (2), as applicable, available to the public
21 on the Internet website of the National Insti-
22 tutes of Health; and

23 (B) ensure that age-related data reported
24 in the triennial report under section 403 of the
25 Public Health Service Act (42 U.S.C. 283) (as

1 amended by section 2032) are made available to
2 the public on the Internet website of the Na-
3 tional Institutes of Health.

4 **SEC. 2039. ENHANCING THE RIGOR AND REPRODUCIBILITY**
5 **OF SCIENTIFIC RESEARCH.**

6 (a) ESTABLISHMENT.—Not later than 1 year after
7 the date of enactment of this Act, the Secretary of Health
8 and Human Services, acting through the Director of the
9 National Institutes of Health, shall convene a working
10 group under the Advisory Committee to the Director of
11 the National Institutes of Health (referred to in this sec-
12 tion as the “Advisory Committee”), appointed under sec-
13 tion 222 of the Public Health Service Act (42 U.S.C.
14 217a), to develop and issue recommendations through the
15 Advisory Committee for a formal policy, which may incor-
16 porate or be informed by relevant existing and ongoing
17 activities, to enhance rigor and reproducibility of scientific
18 research funded by the National Institutes of Health.

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

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

25 (2) clinical experiment design, including—

1 (A) the diversity of populations studied for
2 clinical research, with respect to biological, so-
3 cial, and other determinants of health that con-
4 tribute to health disparities;

5 (B) the circumstances under which sum-
6 mary information regarding biological, social,
7 and other factors that contribute to health dis-
8 parities should be reported; and

9 (C) the circumstances under which clinical
10 studies, including clinical trials, should conduct
11 an analysis of the data collected during the
12 study on the basis of biological, social, and
13 other factors that contribute to health dispari-
14 ties;

15 (3) applicable levels of rigor in statistical meth-
16 ods, methodology, and analysis;

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

19 (5) any other matter the working group deter-
20 mines relevant.

21 (c) POLICIES.—Not later than 18 months after the
22 date of enactment of this Act, the Director of the National
23 Institutes of Health shall consider the recommendations
24 developed by the working group and issued by the Advi-

1 sory Committee under subsection (a) and develop or up-
2 date policies as appropriate.

3 (d) REPORT.—Not later than 2 years after the date
4 of enactment of this Act, the Director of the National In-
5 stitutes of Health shall issue a report to the Secretary of
6 Health and Human Services, the Committee on Health,
7 Education, Labor, and Pensions of the Senate, and the
8 Committee on Energy and Commerce of the House of
9 Representatives regarding recommendations developed
10 under subsection (a) and any subsequent policy changes
11 implemented, to enhance rigor and reproducibility in sci-
12 entific research funded by the National Institutes of
13 Health.

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

20 **SEC. 2040. IMPROVING MEDICAL REHABILITATION RE-**
21 **SEARCH AT THE NATIONAL INSTITUTES OF**
22 **HEALTH.**

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

1 (1) in subsection (b), by striking “conduct and
2 support” and inserting “conduct, support, and co-
3 ordination”;

4 (2) in subsection (c)(1)(C), by striking “of the
5 Center” and inserting “within the Center”;

6 (3) in subsection (d)—

7 (A) by striking “(d)(1) In consultation”
8 and all that follows through the end of para-
9 graph (1) and inserting the following:

10 “(d)(1) The Director of the Center, in consultation
11 with the Director of the Institute, the coordinating com-
12 mittee established under subsection (e), and the advisory
13 board established under subsection (f), shall develop a
14 comprehensive plan (referred to in this section as the ‘Re-
15 search Plan’) for the conduct, support, and coordination
16 of medical rehabilitation research.”;

17 (B) in paragraph (2)—

18 (i) in subparagraph (A), by striking “;
19 and” and inserting a semicolon;

20 (ii) in subparagraph (B), by striking
21 the period and inserting “; and”; and

22 (iii) by adding at the end the fol-
23 lowing:

24 “(C) include goals and objectives for con-
25 ducting, supporting, and coordinating medical reha-

1 bilitation research, consistent with the purpose de-
2 scribed in subsection (b).”;

3 (C) by striking paragraph (4) and insert-
4 ing the following:

5 “(4) The Director of the Center, in consultation with
6 the Director of the Institute, the coordinating committee
7 established under subsection (e), and the advisory board
8 established under subsection (f), shall revise and update
9 the Research Plan periodically, as appropriate, or not less
10 than every 5 years. Not later than 30 days after the Re-
11 search Plan is so revised and updated, the Director of the
12 Center shall transmit the revised and updated Research
13 Plan to the President, the Committee on Health, Edu-
14 cation, Labor, and Pensions of the Senate, and the Com-
15 mittee on Energy and Commerce of the House of Rep-
16 resentatives.”; and

17 (D) by adding at the end the following:

18 “(5) The Director of the Center, in consultation with
19 the Director of the Institute, shall, prior to revising and
20 updating the Research Plan, prepare a report for the co-
21 ordinating committee established under subsection (e) and
22 the advisory board established under subsection (f) that
23 describes and analyzes the progress during the preceding
24 fiscal year in achieving the goals and objectives described
25 in paragraph (2)(C) and includes expenditures for reha-

1 bilitation research at the National Institutes of Health.
2 The report shall include recommendations for revising and
3 updating the Research Plan, and such initiatives as the
4 Director of the Center and the Director of the Institute
5 determine appropriate. In preparing the report, the Direc-
6 tor of the Center and the Director of the Institute shall
7 consult with the Director of the National Institutes of
8 Health.”;

9 (4) in subsection (e)—

10 (A) in paragraph (2), by inserting “peri-
11 odically host a scientific conference or workshop
12 on medical rehabilitation research and” after
13 “The Coordinating Committee shall”; and

14 (B) in paragraph (3), by inserting “the Di-
15 rector of the Division of Program Coordination,
16 Planning, and Strategic Initiatives within the
17 Office of the Director of the National Institutes
18 of Health,” after “shall be composed of”;

19 (5) in subsection (f)(3)(B)—

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

23 (B) by inserting after clause (viii) the fol-
24 lowing:

1 “(ix) The Director of the Division of Program
2 Coordination, Planning, and Strategic Initiatives.”;
3 and

4 (6) by adding at the end the following:

5 “(g)(1) The Secretary and the heads of other Federal
6 agencies shall jointly review the programs carried out (or
7 proposed to be carried out) by each such official with re-
8 spect to medical rehabilitation research and, as appro-
9 priate, enter into agreements preventing duplication
10 among such programs.

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

16 “(h) For purposes of this section, the term ‘medical
17 rehabilitation research’ means the science of mechanisms
18 and interventions that prevent, improve, restore, or re-
19 place lost, underdeveloped, or deteriorating function.”.

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

23 (1) in subsection (a), by striking “IN GEN-
24 ERAL.—”; and

25 (2) by striking subsection (b).

1 **SEC. 2041. TASK FORCE ON RESEARCH SPECIFIC TO PREG-**
2 **NANT WOMEN AND LACTATING WOMEN.**

3 (a) **TASK FORCE ON RESEARCH SPECIFIC TO PREG-**
4 **NANT WOMEN AND LACTATING WOMEN.—**

5 (1) **ESTABLISHMENT.—**Not later than 90 days
6 after the date of enactment of this Act, the Sec-
7 retary of Health and Human Services (referred to in
8 this section as the “Secretary”) shall establish a
9 task force, in accordance with the Federal Advisory
10 Committee Act (5 U.S.C. App.), to be known as the
11 “Task Force on Research Specific to Pregnant
12 Women and Lactating Women” (in this section re-
13 ferred to as the “Task Force”).

14 (2) **DUTIES.—**The Task Force shall provide ad-
15 vice and guidance to the Secretary regarding Fed-
16 eral activities related to identifying and addressing
17 gaps in knowledge and research regarding safe and
18 effective therapies for pregnant women and lactating
19 women, including the development of such therapies
20 and the collaboration on and coordination of such
21 activities.

22 (3) **MEMBERSHIP.—**

23 (A) **FEDERAL MEMBERS.—**The Task Force
24 shall be composed of each of the following Fed-
25 eral members, or the designees of such mem-
26 bers:

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

3 (ii) The Director of the National In-
4 stitutes of Health, the Director of the Eu-
5 nice Kennedy Shriver National Institute of
6 Child Health and Human Development,
7 and the directors of such other appropriate
8 national research institutes.

9 (iii) The Commissioner of Food and
10 Drugs.

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

13 (v) The Director of the National Vac-
14 cine Program Office.

15 (vi) The head of any other research-
16 related agency or department not described
17 in clauses (i) through (v) that the Sec-
18 retary determines appropriate, which may
19 include the Department of Veterans Af-
20 fairs and the Department of Defense.

21 (B) NON-FEDERAL MEMBERS.—The Task
22 Force shall be composed of each of the fol-
23 lowing non-Federal members, including—

24 (i) representatives from relevant med-
25 ical societies with subject matter expertise

1 on pregnant women, lactating women, or
2 children;

3 (ii) nonprofit organizations with ex-
4 pertise related to the health of women and
5 children;

6 (iii) relevant industry representatives;
7 and

8 (iv) other representatives, as appro-
9 priate.

10 (C) LIMITATIONS.—The non-Federal mem-
11 bers described in subparagraph (B) shall—

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

15 (ii) be appointed by the Secretary.

16 (4) TERMINATION.—

17 (A) IN GENERAL.—Subject to subpara-
18 graph (B), the Task Force shall terminate on
19 the date that is 2 years after the date on which
20 the Task Force is established under paragraph
21 (1).

22 (B) EXTENSION.—The Secretary may ex-
23 tend the operation of the Task Force for one
24 additional 2-year period following the 2-year pe-
25 riod described in subparagraph (A), if the Sec-

1 retary determines that the extension is appro-
2 priate for carrying out the purpose of this sec-
3 tion.

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

8 (6) TASK FORCE REPORT TO CONGRESS.—Not
9 later than 18 months after the date on which the
10 Task Force is established under paragraph (1), the
11 Task Force shall prepare and submit to the Sec-
12 retary, the Committee on Health, Education, Labor,
13 and Pensions of the Senate, and the Committee on
14 Energy and Commerce of the House of Representa-
15 tives a report that includes each of the following:

16 (A) A plan to identify and address gaps in
17 knowledge and research regarding safe and ef-
18 fective therapies for pregnant women and lac-
19 tating women, including the development of
20 such therapies.

21 (B) Ethical issues surrounding the inclu-
22 sion of pregnant women and lactating women in
23 clinical research.

24 (C) Effective communication strategies
25 with health care providers and the public on in-

1 formation relevant to pregnant women and lac-
2 tating women.

3 (D) Identification of Federal activities, in-
4 cluding—

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

7 (ii) recommendations for the coordina-
8 tion of, and collaboration on research re-
9 lated to pregnant women and lactating
10 women;

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

15 (iv) existing Federal efforts and pro-
16 grams to improve the scientific under-
17 standing of the health impacts on pregnant
18 women, lactating women, and related birth
19 and pediatric outcomes, including with re-
20 spect to pharmacokinetics,
21 pharmacodynamics, and toxicities.

22 (E) Recommendations to improve the de-
23 velopment of safe and effective therapies for
24 pregnant women and lactating women.

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

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

9 (1) IN GENERAL.—Not later than 2 years after
10 the date of enactment of this Act, the Secretary,
11 considering any recommendations of the Task Force
12 available at such time and in consultation with the
13 heads of relevant agencies of the Department of
14 Health and Human Services, shall, as appropriate,
15 update regulations and guidance, as applicable, re-
16 garding the inclusion of pregnant women and lac-
17 tating women in clinical research.

18 (2) CRITERIA FOR EXCLUDING PREGNANT OR
19 LACTATING WOMEN.—In updating any regulations or
20 guidance described in paragraph (1), the Secretary
21 shall consider any appropriate criteria to be used by
22 institutional review boards and individuals reviewing
23 grant proposals for excluding pregnant women or
24 lactating women as a study population requiring ad-

1 ditional protections from participating in human
2 subject research.

3 **SEC. 2042. STREAMLINING NATIONAL INSTITUTES OF**
4 **HEALTH REPORTING REQUIREMENTS.**

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

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

10 “(B) REPORTING.—Not later than 2 years
11 after the date of enactment of 21st Century
12 Cures Act, the head of each national research
13 institute or national center shall submit to the
14 Director of the National Institutes of Health a
15 report, to be included in the triennial report
16 under section 403, on the amount made avail-
17 able by the institute or center for conducting or
18 supporting research that involves collaboration
19 between the institute or center and 1 or more
20 other national research institutes or national
21 centers.”; and

22 (2) in subparagraphs (D) and (E) by striking
23 “(B)(i)” each place it appears and inserting “(B)”.

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

4 (1) by striking subsection (b);

5 (2) by redesignating subsection (c) as sub-
6 section (b); and

7 (3) in subsection (b) (as so redesignated), by
8 striking “subsections (a) and (b)” and inserting
9 “subsection (a)”.

10 (c) DOCTORAL DEGREES REPORTING.—Section
11 403C(a)(2) of the Public Health Service Act (42 U.S.C.
12 283a–2(a)(2)) is amended by striking “(not including any
13 leaves of absence)”.

14 (d) VACCINE REPORTING.—Section 404B of the Pub-
15 lic Health Service Act (42 U.S.C. 283d) is amended—

16 (1) by striking subsection (b); and

17 (2) by striking “(a) DEVELOPMENT OF NEW
18 VACCINES.—The Secretary” and inserting “The
19 Secretary”.

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

23 (1) in the subsection heading, by striking “AN-
24 NUAL” and inserting “BIENNIAL”; and

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

4 (f) REVIEW OF CENTERS OF EXCELLENCE.—

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

7 (2) CONFORMING AMENDMENT.—Section
8 399EE(e) of the Public Health Service Act (42
9 U.S.C. 280–4(c)) is amended by striking “399CC,
10 404H,” and inserting “399CC”.

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

14 (1) by striking paragraph (2); and

15 (2) by redesignating paragraph (3) as para-
16 graph (2).

17 (h) NATIONAL INSTITUTE OF NURSING RE-
18 SEARCH.—

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

21 (2) CONFORMING AMENDMENT.—Section
22 464X(g) of the Public Health Service Act (42
23 U.S.C. 285q–2(g)) is amended by striking “biennial
24 report made under section 464Y,” and inserting
25 “triennial report made under section 403”.

1 **SEC. 2043. REIMBURSEMENT FOR RESEARCH SUBSTANCES**
2 **AND LIVING ORGANISMS.**

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

6 (1) in the flush matter at the end of subsection

7 (a)—

8 (A) by redesignating such matter as sub-
9 section (h)(1); and

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

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

14 “(2) Where research substances and living organisms
15 are made available under paragraph (1) through contrac-
16 tors, the Secretary may direct such contractors to collect
17 payments on behalf of the Secretary for the costs incurred
18 to make available such substances and organisms and to
19 forward amounts so collected to the Secretary, in the time
20 and manner specified by the Secretary.

21 “(3) Amounts collected under paragraph (2) shall be
22 credited to the appropriations accounts that incurred the
23 costs to make available the research substances and living
24 organisms involved, and shall remain available until ex-
25 pended for carrying out activities under such accounts.”.

1 **SEC. 2044. SENSE OF CONGRESS ON INCREASED INCLUSION**
2 **OF UNDERREPRESENTED POPULATIONS IN**
3 **CLINICAL TRIALS.**

4 It is the sense of Congress that the National Institute
5 on Minority Health and Health Disparities should include
6 within its strategic plan under section 402(m) of the Pub-
7 lic Health Service Act (42 U.S.C. 282(m)) ways to in-
8 crease representation of underrepresented populations in
9 clinical trials.

10 **Subtitle E—Advancement of the**
11 **National Institutes of Health Re-**
12 **search and Data Access**

13 **SEC. 2051. TECHNICAL UPDATES TO CLINICAL TRIALS**
14 **DATABASE.**

15 Section 402(j)(2)(D) of the Public Health Service Act
16 (42 U.S.C. 282(j)(2)(D)) is amended—

17 (1) in clause (ii)(I), by inserting before the
18 semicolon “, unless the responsible party affirma-
19 tively requests that the Director of the National In-
20 stitutes of Health publicly post such clinical trial in-
21 formation for an applicable device clinical trial prior
22 to such date of clearance or approval”; and

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

24 “(iii) OPTION TO MAKE CERTAIN
25 CLINICAL TRIAL INFORMATION AVAILABLE
26 EARLIER.—The Director of the National

1 Institutes of Health shall inform respon-
2 sible parties of the option to request that
3 clinical trial information for an applicable
4 device clinical trial be publicly posted prior
5 to the date of clearance or approval, in ac-
6 cordance with clause (ii)(I).

7 “(iv) COMBINATION PRODUCTS.—An
8 applicable clinical trial for a product that
9 is a combination of drug, device, or biologi-
10 cal product shall be considered—

11 “(I) an applicable drug clinical
12 trial, if the Secretary determines
13 under section 503(g) of the Federal
14 Food, Drug, and Cosmetic Act that
15 the primary mode of action of such
16 product is that of a drug or biological
17 product; or

18 “(II) an applicable device clinical
19 trial, if the Secretary determines
20 under such section that the primary
21 mode of action of such product is that
22 of a device.”.

23 **SEC. 2052. COMPLIANCE ACTIVITIES REPORTS.**

24 (a) DEFINITIONS.—In this section:

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

5 (2) SECRETARY.—The term “Secretary” means
6 the Secretary of Health and Human Services.

7 (b) REPORT ON ACTIVITIES TO ENCOURAGE COMPLI-
8 ANCE.—Not later than 2 years after the date of enactment
9 of this Act, the Secretary, acting through the Director of
10 the National Institutes of Health and in collaboration with
11 the Commissioner of Food and Drugs, shall submit to the
12 Committee on Health, Education, Labor, and Pensions of
13 the Senate and the Committee on Energy and Commerce
14 of the House of Representatives, a report that describes
15 education and outreach, guidance, enforcement, and other
16 activities undertaken to encourage compliance with section
17 402(j) of the Public Health Service Act (42 U.S.C.
18 282(j)).

19 (c) REPORTS ON CLINICAL TRIALS.—

20 (1) IN GENERAL.—Not later than 2 years after
21 the final compliance date under the final rule imple-
22 menting section 402(j) of the Public Health Service
23 Act, and every 2 years thereafter for the next 4
24 years, the Secretary, acting through the Director of
25 the National Institutes of Health and in collabora-

1 tion with the Commissioner of Food and Drugs,
2 shall submit to the Committee on Health, Edu-
3 cation, Labor, and Pensions of the Senate and the
4 Committee on Energy and Commerce of the House
5 of Representatives, a report describing—

6 (A) the total number of applicable clinical
7 trials with complete data bank registration in-
8 formation registered during the period for
9 which the report is being prepared (broken
10 down by each year of such reporting period);

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

16 (C) the activities undertaken by the Sec-
17 retary to educate responsible persons about
18 data bank registration and results submission
19 requirements, including through issuance of
20 guidance documents, informational meetings,
21 and training sessions; and

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

24 (2) ACTIONS TO ENFORCE COMPLIANCE.—After
25 the Secretary has undertaken the educational activi-

1 ties described in paragraph (1)(C), the Secretary
2 shall include in subsequent reports submitted under
3 paragraph (1) the number of actions taken by the
4 Secretary during the period for which the report is
5 being prepared to enforce compliance with data bank
6 registration and results submission requirements.

7 **SEC. 2053. UPDATES TO POLICIES TO IMPROVE DATA.**

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

10 (1) by striking “In the case” and inserting the
11 following:

12 “(1) IN GENERAL.—In the case”; and

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

14 “(2) REPORTING REQUIREMENTS.—For any
15 new and competing project of clinical research sub-
16 ject to the requirements under this section that re-
17 ceives a grant award 1 year after the date of enact-
18 ment of the 21st Century Cures Act, or any date
19 thereafter, for which a valid analysis is provided
20 under paragraph (1)—

21 “(A) and which is an applicable clinical
22 trial as defined in section 402(j), the entity con-
23 ducting such clinical research shall submit the
24 results of such valid analysis to the clinical trial
25 registry data bank expanded under section

1 402(j)(3), and the Director of the National In-
2 stitutes of Health shall, as appropriate, con-
3 sider whether such entity has complied with the
4 reporting requirement described in this sub-
5 paragraph in awarding any future grant to such
6 entity, including pursuant to section
7 402(j)(5)(A)(ii) when applicable; and

8 “(B) the Director of the National Insti-
9 tutes of Health shall encourage the reporting of
10 the results of such valid analysis described in
11 paragraph (1) through any additional means
12 determined appropriate by the Director.”.

13 **SEC. 2054. CONSULTATION.**

14 Not later than 90 days after the date of enactment
15 of this Act, the Secretary of Health and Human Services
16 shall consult with relevant Federal agencies, including the
17 Food and Drug Administration, the Office of the National
18 Coordinator for Health Information Technology, and the
19 National Institutes of Health, as well as other stake-
20 holders (including patients, researchers, physicians, indus-
21 try representatives, and developers of health information
22 technology) to receive recommendations with respect to
23 enhancements to the clinical trial registry data bank under
24 section 402(j) of the Public Health Service Act (42 U.S.C.

1 282(j)), including with respect to usability, functionality,
2 and search capability.

3 **Subtitle F—Facilitating**
4 **Collaborative Research**

5 **SEC. 2061. NATIONAL NEUROLOGICAL CONDITIONS SUR-**
6 **VEILLANCE SYSTEM.**

7 Part P of title III of the Public Health Service Act
8 (42 U.S.C. 280g et seq.) is amended by inserting after
9 section 399S the following:

10 **“SEC. 399S-1. SURVEILLANCE OF NEUROLOGICAL DIS-**
11 **EASES.**

12 “(a) IN GENERAL.—The Secretary, acting through
13 the Director of the Centers for Disease Control and Pre-
14 vention and in coordination with other agencies as the Sec-
15 retary determines, shall, as appropriate—

16 “(1) enhance and expand infrastructure and ac-
17 tivities to track the epidemiology of neurological dis-
18 eases; and

19 “(2) incorporate information obtained through
20 such activities into an integrated surveillance sys-
21 tem, which may consist of or include a registry, to
22 be known as the National Neurological Conditions
23 Surveillance System.

24 “(b) RESEARCH.—The Secretary shall ensure that
25 the National Neurological Conditions Surveillance System

1 is designed in a manner that facilitates further research
2 on neurological diseases.

3 “(c) CONTENT.—In carrying out subsection (a), the
4 Secretary—

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

8 “(2) to the extent practicable, shall provide for
9 the collection and storage of other available informa-
10 tion on neurological diseases, including information
11 related to persons living with neurological diseases
12 who choose to participate, such as—

13 “(A) demographics, such as age, race, eth-
14 nicity, sex, geographic location, family history,
15 and other information, as appropriate;

16 “(B) risk factors that may be associated
17 with neurological diseases, such as genetic and
18 environmental risk factors and other informa-
19 tion, as appropriate; and

20 “(C) diagnosis and progression markers;

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

24 “(A) the natural history of the diseases;

25 “(B) the prevention of the diseases;

1 “(C) the detection, management, and
2 treatment approaches for the diseases; and

3 “(D) the development of outcomes meas-
4 ures;

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

7 “(5) initially may address a limited number of
8 neurological diseases.

9 “(d) CONSULTATION.—In carrying out this section,
10 the Secretary shall consult with individuals with appro-
11 priate expertise, which may include—

12 “(1) epidemiologists with experience in disease
13 surveillance or registries;

14 “(2) representatives of national voluntary
15 health associations that—

16 “(A) focus on neurological diseases; and

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

19 “(3) health information technology experts or
20 other information management specialists;

21 “(4) clinicians with expertise in neurological
22 diseases; and

23 “(5) research scientists with experience con-
24 ducting translational research or utilizing surveil-
25 lance systems for scientific research purposes.

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

5 “(f) COORDINATION WITH OTHER FEDERAL, STATE,
6 AND LOCAL AGENCIES.—Subject to subsection (h), the
7 Secretary shall—

8 “(1) make information and analysis in the Na-
9 tional Neurological Conditions Surveillance System
10 available, as appropriate—

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

14 “(B) to State and local agencies; and

15 “(2) identify, build upon, leverage, and coordi-
16 nate among existing data and surveillance systems,
17 surveys, registries, and other Federal public health
18 infrastructure, wherever practicable.

19 “(g) PUBLIC ACCESS.—Subject to subsection (h), the
20 Secretary shall ensure that information and analysis in the
21 National Neurological Conditions Surveillance System are
22 available, as appropriate, to the public, including research-
23 ers.

24 “(h) PRIVACY.—The Secretary shall ensure that in-
25 formation and analysis in the National Neurological Con-

1 ditions Surveillance System are made available only to the
2 extent permitted by applicable Federal and State law, and
3 in a manner that protects personal privacy, to the extent
4 required by applicable Federal and State privacy law, at
5 a minimum.

6 “(i) REPORTS.—

7 “(1) REPORT ON INFORMATION AND ANAL-
8 YSES.—Not later than 1 year after the date on
9 which any system is established under this section,
10 the Secretary shall submit an interim report to the
11 Committee on Health, Education, Labor, and Pen-
12 sions of the Senate and the Committee on Energy
13 and Commerce of the House of Representatives re-
14 garding aggregate information collected pursuant to
15 this section and epidemiological analyses, as appro-
16 priate. Such report shall be posted on the Internet
17 website of the Department of Health and Human
18 Services and shall be updated biennially.

19 “(2) IMPLEMENTATION REPORT.—Not later
20 than 4 years after the date of the enactment of this
21 section, the Secretary shall submit a report to the
22 Congress concerning the implementation of this sec-
23 tion. Such report shall include information on—

1 “(A) the development and maintenance of
2 the National Neurological Conditions Surveil-
3 lance System;

4 “(B) the type of information collected and
5 stored in the surveillance system;

6 “(C) the use and availability of such infor-
7 mation, including guidelines for such use; and

8 “(D) the use and coordination of databases
9 that collect or maintain information on neuro-
10 logical diseases.

11 “(j) DEFINITION.—In this section, the term ‘national
12 voluntary health association’ means a national nonprofit
13 organization with chapters, other affiliated organizations,
14 or networks in States throughout the United States with
15 experience serving the population of individuals with neu-
16 rological disease and have demonstrated experience in neu-
17 rological disease research, care, and patient services.

18 “(k) AUTHORIZATION OF APPROPRIATIONS.—To
19 carry out this section, there is authorized to be appro-
20 priated \$5,000,000 for each of fiscal years 2018 through
21 2022.”.

22 **SEC. 2062. TICK-BORNE DISEASES.**

23 (a) IN GENERAL.—The Secretary of Health and
24 Human Services (referred to in this section as “the Sec-
25 retary”) may continue to conduct or support epidemiolog-

1 ical, basic, translational, and clinical research related to
2 vector-borne diseases, including tick-borne diseases.

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

9 (c) TICK-BORNE DISEASES WORKING GROUP.—

10 (1) ESTABLISHMENT.—The Secretary may es-
11 tablish a working group, to be known as the Tick-
12 Borne Disease Working Group (referred to in this
13 section as the “Working Group”), comprised of rep-
14 resentatives of appropriate Federal agencies and
15 other non-Federal entities, as appropriate, to provide
16 expertise and to review all efforts within the Depart-
17 ment of Health and Human Services related to tick-
18 borne diseases, to help ensure interagency coordina-
19 tion and minimize overlap, and to examine research
20 priorities.

21 (2) RESPONSIBILITIES.—The working group
22 shall—

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

1 (i) ongoing tick-borne disease re-
2 search, including research related to
3 causes, prevention, treatment, surveillance,
4 diagnosis, diagnostics, duration of illness,
5 and intervention for individuals with tick-
6 borne diseases;

7 (ii) advances made pursuant to such
8 research;

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

11 (I) epidemiological activities re-
12 lated to tick-borne diseases; and

13 (II) basic, clinical, and
14 translational tick-borne disease re-
15 search related to the pathogenesis,
16 prevention, diagnosis, and treatment
17 of tick-borne diseases;

18 (iv) gaps in tick-borne disease re-
19 search described in clause (iii)(II);

20 (v) the Working Group's meetings re-
21 quired under paragraph (4); and

22 (vi) the comments received by the
23 Working Group;

24 (B) make recommendations to the Sec-
25 retary regarding any appropriate changes or

1 improvements to such activities and research;
2 and

3 (C) solicit input from States, localities, and
4 nongovernmental entities, including organiza-
5 tions representing patients, health care pro-
6 viders, researchers, and industry regarding sci-
7 entific advances, research questions, surveil-
8 lance activities, and emerging strains in species
9 of pathogenic organisms.

10 (3) MEMBERSHIP.—The members of the work-
11 ing group shall represent a diversity of scientific dis-
12 ciplines.

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

15 (5) REPORTING.—Not later than 2 years after
16 the date of enactment of this Act, and every 2 years
17 thereafter until termination of the Working Group
18 pursuant to paragraph (6), the Working Group
19 shall—

20 (A) submit a report on its activities under
21 paragraph (2)(A) and any recommendations
22 under paragraph (2)(B) to the Secretary, the
23 Committee on Energy and Commerce of the
24 House of Representatives, and the Committee

1 on Health, Education, Labor, and Pensions of
2 the Senate; and

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

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

9 **SEC. 2063. ACCESSING, SHARING, AND USING HEALTH DATA**
10 **FOR RESEARCH PURPOSES.**

11 (a) GUIDANCE RELATED TO REMOTE ACCESS.—Not
12 later than 1 year after the date of enactment of this Act,
13 the Secretary of Health and Human Services (referred to
14 in this section as the “Secretary”) shall issue guidance
15 clarifying that subparagraph (B) of section
16 164.512(i)(1)(ii) of part 164 of the Rule (prohibiting the
17 removal of protected health information by a researcher)
18 does not prohibit remote access to health information by
19 a researcher for such purposes as described in section
20 164.512(i)(1)(ii) of part 164 of the Rule so long as—

21 (1) at a minimum, security and privacy safe-
22 guards, consistent with the requirements of the
23 Rule, are maintained by the covered entity and the
24 researcher; and

1 (2) the protected health information is not cop-
2 ied or otherwise retained by the researcher.

3 (b) GUIDANCE RELATED TO STREAMLINING AU-
4 THORIZATION.—Not later than 1 year after the date of
5 enactment of this Act, the Secretary shall issue guidance
6 on the following:

7 (1) AUTHORIZATION FOR USE AND DISCLOSURE
8 OF HEALTH INFORMATION.—Clarification of the cir-
9 cumstances under which the authorization for the
10 use or disclosure of protected health information,
11 with respect to an individual, for future research
12 purposes contains a sufficient description of the pur-
13 pose of the use or disclosure, such as if the author-
14 ization—

15 (A) sufficiently describes the purposes such
16 that it would be reasonable for the individual to
17 expect that the protected health information
18 could be used or disclosed for such future re-
19 search;

20 (B) either—

21 (i) states that the authorization will
22 expire on a particular date or on the occur-
23 rence of a particular event; or

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

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

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

12 (3) REVOCATION OF AUTHORIZATION.—Clari-
13 fication of appropriate mechanisms by which an in-
14 dividual may revoke an authorization for future re-
15 search purposes, such as described in paragraph
16 (1)(C).

17 (c) WORKING GROUP ON PROTECTED HEALTH IN-
18 FORMATION FOR RESEARCH.—

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

1 (2) MEMBERS.—The working group shall in-
2 clude representatives of—

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

8 (B) the research community;

9 (C) patients;

10 (D) experts in civil rights, such as privacy
11 rights;

12 (E) developers of health information tech-
13 nology;

14 (F) experts in data privacy and security;

15 (G) health care providers;

16 (H) bioethicists; and

17 (I) other experts and entities, as the Sec-
18 retary determines appropriate.

19 (3) REPORT.—Not later than 1 year after the
20 date on which the working group is convened under
21 paragraph (1), the working group shall conduct a re-
22 view and submit a report to the Secretary containing
23 recommendations on whether the uses and disclo-
24 sures of protected health information for research
25 purposes should be modified to allow protected

1 health information to be available, as appropriate,
2 for research purposes, including studies to obtain
3 generalizable knowledge, while protecting individuals'
4 privacy rights. In conducting the review and making
5 recommendations, the working group shall—

6 (A) address, at a minimum—

7 (i) the appropriate manner and timing
8 of authorization, including whether addi-
9 tional notification to the individual should
10 be required when the individual's protected
11 health information will be used or disclosed
12 for such research;

13 (ii) opportunities for individuals to set
14 preferences on the manner in which their
15 protected health information is used in re-
16 search;

17 (iii) opportunities for patients to re-
18 voke authorization;

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

21 (v) existing gaps in statute, regula-
22 tion, or policy related to protecting the pri-
23 vacy of individuals, and

24 (vi) existing barriers to research re-
25 lated to the current restrictions on the

1 uses and disclosures of protected health in-
2 formation; and

3 (B) consider, at a minimum—

4 (i) expectations and preferences on
5 how an individual's protected health infor-
6 mation is shared and used;

7 (ii) issues related to specific sub-
8 groups of people, such as children, incar-
9 cerated individuals, and individuals with a
10 cognitive or intellectual disability impact-
11 ing capacity to consent;

12 (iii) relevant Federal and State laws;

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

16 (v) potential impacts of disclosure and
17 non-disclosure of protected health informa-
18 tion on access to health care services; and

19 (vi) the potential uses of such data.

20 (4) REPORT SUBMISSION.—The Secretary shall
21 submit the report under paragraph (3) to the Com-
22 mittee on Health, Education, Labor, and Pensions
23 of the Senate and the Committee on Energy and
24 Commerce of the House of Representatives, and
25 shall post such report on the appropriate Internet

1 website of the Department of Health and Human
2 Services.

3 (5) TERMINATION.—The working group con-
4 vened under paragraph (1) shall terminate the day
5 after the report under paragraph (3) is submitted to
6 Congress and made public in accordance with para-
7 graph (4).

8 (d) DEFINITIONS.—In this section:

9 (1) THE RULE.—References to “the Rule” refer
10 to part 160 or part 164, as appropriate, of title 45,
11 Code of Federal Regulations (or any successor regu-
12 lation).

13 (2) PART 164.—References to a specified section
14 of “part 164”, refer to such specified section of part
15 164 of title 45, Code of Federal Regulations (or any
16 successor section).

17 **Subtitle G—Promoting Pediatric**
18 **Research**

19 **SEC. 2071. NATIONAL PEDIATRIC RESEARCH NETWORK.**

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

22 (1) in paragraph (1), by striking “in consulta-
23 tion with the Director of the Eunice Kennedy Shriv-
24 er National Institute of Child Health and Human
25 Development and in collaboration with other appro-

1 appropriate national research institutes and national cen-
2 ters that carry out activities involving pediatric re-
3 search, may provide for the establishment of” and
4 inserting “in collaboration with the national research
5 institutes and national centers that carry out activi-
6 ties involving pediatric research, shall support”; and

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

10 **SEC. 2072. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK.**

11 It is the sense of Congress that—

12 (1) the National Institutes of Health should en-
13 courage a global pediatric clinical study network by
14 providing grants, contracts, or cooperative agree-
15 ments to support new and early stage investigators
16 who participate in the global pediatric clinical study
17 network;

18 (2) the Secretary of Health and Human Serv-
19 ices (referred to in this section as the “Secretary”)
20 should engage with clinical investigators and appro-
21 priate authorities outside of the United States, in-
22 cluding the European Union, during the formation
23 of the global pediatric clinical study network to en-
24 courage the participation of such investigator and
25 authorities; and

1 (3) once a global pediatric clinical study net-
2 work is established and becomes operational, the
3 Secretary should continue to encourage and facili-
4 tate the participation of clinical investigators and
5 appropriate authorities outside of the United States,
6 including in the European Union, to participate in
7 the network with the goal of enhancing the global
8 reach of the network.

9 **TITLE III—DEVELOPMENT**

10 **Subtitle A—Patient-Focused Drug** 11 **Development**

12 **SEC. 3001. PATIENT EXPERIENCE DATA.**

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

15 (1) in subsection (a)—

16 (A) in the subsection heading, by striking
17 “IN GENERAL” and inserting “PATIENT EN-
18 GAGEMENT IN DRUGS AND DEVICES”;

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

23 (C) by striking “The Secretary” and in-
24 serting the following:

25 “(1) IN GENERAL.—The Secretary”;

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

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

5 “(b) STATEMENT OF PATIENT EXPERIENCE.—

6 “(1) IN GENERAL.—Following the approval of
7 an application that was submitted under section
8 505(b) of this Act or section 351(a) of the Public
9 Health Service Act at least 180 days after the date
10 of enactment of the 21st Century Cures Act, the
11 Secretary shall make public a brief statement re-
12 garding the patient experience data and related in-
13 formation, if any, submitted and reviewed as part of
14 such application.

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

17 “(A) patient experience data;

18 “(B) information on patient-focused drug
19 development tools; and

20 “(C) other relevant information, as deter-
21 mined by the Secretary.

22 “(c) PATIENT EXPERIENCE DATA.—For purposes of
23 this section, the term ‘patient experience data’ includes
24 data that—

1 “(1) are collected by any persons (including pa-
2 tients, family members and caregivers of patients,
3 patient advocacy organizations, disease research
4 foundations, researchers, and drug manufacturers);
5 and

6 “(2) are intended to provide information about
7 patients’ experiences with a disease or condition, in-
8 cluding—

9 “(A) the impact of such disease or condi-
10 tion, or a related therapy, on patients’ lives;
11 and

12 “(B) patient preferences with respect to
13 treatment of such disease or condition.”.

14 **SEC. 3002. PATIENT-FOCUSED DRUG DEVELOPMENT GUID-**
15 **ANCE.**

16 (a) PUBLICATION OF GUIDANCE DOCUMENTS.—Not
17 later than 180 days after the date of enactment of this
18 Act, the Secretary of Health and Human Services (re-
19 ferred to in this section as the “Secretary”), acting
20 through the Commissioner of Food and Drugs, shall de-
21 velop a plan to issue draft and final versions of one or
22 more guidance documents, over a period of 5 years, re-
23 garding the collection of patient experience data, and the
24 use of such data and related information in drug develop-
25 ment. Not later than 18 months after the date of enact-

1 ment of this Act, the Secretary shall issue a draft version
2 of at least one such guidance document. Not later than
3 18 months after the public comment period on the draft
4 guidance ends, the Secretary shall issue a revised draft
5 guidance or final guidance.

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

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

12 (1) methodological approaches that a person
13 seeking to collect patient experience data for submis-
14 sion to, and proposed use by, the Secretary in regu-
15 latory decisionmaking may use, that are relevant
16 and objective and ensure that such data are accurate
17 and representative of the intended population, in-
18 cluding methods to collect meaningful patient input
19 throughout the drug development process and meth-
20 odological considerations for data collection, report-
21 ing, management, and analysis;

22 (2) methodological approaches that may be used
23 to develop and identify what is most important to
24 patients with respect to burden of disease, burden of

1 treatment, and the benefits and risks in the manage-
2 ment of the patient's disease;

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

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

10 (5) how a person seeking to develop and submit
11 proposed draft guidance relating to patient experi-
12 ence data for consideration by the Secretary may
13 submit such proposed draft guidance to the Sec-
14 retary;

15 (6) the format and content required for submis-
16 sions under this section to the Secretary, including
17 with respect to the information described in para-
18 graph (1);

19 (7) how the Secretary intends to respond to
20 submissions of information described in paragraph
21 (1), if applicable, including any timeframe for re-
22 sponse when such submission is not part of a regu-
23 latory application or other submission that has an
24 associated timeframe for response; and

1 (8) how the Secretary, if appropriate, antici-
2 pates using relevant patient experience data and re-
3 lated information, including with respect to the
4 structured risk-benefit assessment framework de-
5 scribed in section 505(d) of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 355(d)), to inform reg-
7 ulatory decisionmaking.

8 **SEC. 3003. STREAMLINING PATIENT INPUT.**

9 Chapter 35 of title 44, United States Code, shall not
10 apply to the collection of information to which a response
11 is voluntary, that is initiated by the Secretary under sec-
12 tion 569C of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 360bbb–8c) (as amended by section 3001) or
14 section 3002.

15 **SEC. 3004. REPORT ON PATIENT EXPERIENCE DRUG DEVEL-**
16 **OPMENT.**

17 Not later than June 1 of 2021, 2026, and 2031, the
18 Secretary of Health and Human Services, acting through
19 the Commissioner of Food and Drugs, shall prepare and
20 publish on the Internet website of the Food and Drug Ad-
21 ministration a report assessing the use of patient experi-
22 ence data in regulatory decisionmaking, in particular with
23 respect to the review of patient experience data and infor-
24 mation on patient-focused drug development tools as part
25 of applications approved under section 505(c) of the Fed-

1 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(e))
2 or section 351(a) of the Public Health Service Act (42
3 U.S.C. 262(a)).

4 **Subtitle B—Advancing New Drug**
5 **Therapies**

6 **SEC. 3011. QUALIFICATION OF DRUG DEVELOPMENT**
7 **TOOLS.**

8 (a) IN GENERAL.—Chapter V of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
10 ed by inserting after section 506F the following new sec-
11 tion:

12 **“SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT**
13 **TOOLS.**

14 “(a) PROCESS FOR QUALIFICATION.—

15 “(1) IN GENERAL.—The Secretary shall estab-
16 lish a process for the qualification of drug develop-
17 ment tools for a proposed context of use under
18 which—

19 “(A)(i) a requestor initiates such process
20 by submitting a letter of intent to the Sec-
21 retary; and

22 “(ii) the Secretary accepts or declines to
23 accept such letter of intent;

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

4 “(ii) the Secretary accepts or declines to
5 accept the qualification plan; and

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

9 “(ii) the Secretary determines whether to
10 accept such qualification package for review;
11 and

12 “(iii) if the Secretary accepts such quali-
13 fication package for review, the Secretary con-
14 ducts such review in accordance with this sec-
15 tion.

16 “(2) ACCEPTANCE AND REVIEW OF SUBMIS-
17 SIONS.—

18 “(A) IN GENERAL.—Subparagraphs (B),
19 (C), and (D) shall apply with respect to the
20 treatment of a letter of intent, a qualification
21 plan, or a full qualification package submitted
22 under paragraph (1) (referred to in this para-
23 graph as ‘qualification submissions’).

24 “(B) ACCEPTANCE FACTORS; NONACCEPT-
25 ANCE.—The Secretary shall determine whether

1 to accept a qualification submission based on
2 factors which may include the scientific merit of
3 the qualification submission. A determination
4 not to accept a submission under paragraph (1)
5 shall not be construed as a final determination
6 by the Secretary under this section regarding
7 the qualification of a drug development tool for
8 its proposed context of use.

9 “(C) PRIORITIZATION OF QUALIFICATION
10 REVIEW.—The Secretary may prioritize the re-
11 view of a full qualification package submitted
12 under paragraph (1) with respect to a drug de-
13 velopment tool, based on factors determined ap-
14 propriate by the Secretary, including—

15 “(i) as applicable, the severity, rarity,
16 or prevalence of the disease or condition
17 targeted by the drug development tool and
18 the availability or lack of alternative treat-
19 ments for such disease or condition; and

20 “(ii) the identification, by the Sec-
21 retary or by biomedical research consortia
22 and other expert stakeholders, of such a
23 drug development tool and its proposed
24 context of use as a public health priority.

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

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

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

17 “(B) determine whether the drug develop-
18 ment tool at issue is qualified for its proposed
19 context of use.

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

25 “(b) EFFECT OF QUALIFICATION.—

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

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

9 “(A) supporting or obtaining approval or
10 licensure (as applicable) of a drug or biological
11 product (including in accordance with section
12 506(c)) under section 505 of this Act or section
13 351 of the Public Health Service Act; or

14 “(B) supporting the investigational use of
15 a drug or biological product under section
16 505(i) of this Act or section 351(a)(3) of the
17 Public Health Service Act.

18 “(3) RESCISSION OR MODIFICATION.—

19 “(A) IN GENERAL.—The Secretary may re-
20 scind or modify a determination under this sec-
21 tion to qualify a drug development tool if the
22 Secretary determines that the drug development
23 tool is not appropriate for the proposed context
24 of use specified by the requestor. Such a deter-
25 mination may be based on new information that

1 calls into question the basis for such qualifica-
2 tion.

3 “(B) MEETING FOR REVIEW.—If the Sec-
4 retary rescinds or modifies under subparagraph
5 (A) a determination to qualify a drug develop-
6 ment tool, the requestor involved shall, on re-
7 quest, be granted a meeting with the Secretary
8 to discuss the basis of the Secretary’s decision
9 to rescind or modify the determination before
10 the effective date of the rescission or modifica-
11 tion.

12 “(c) TRANSPARENCY.—

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

18 “(A) Information with respect to each
19 qualification submission under the qualification
20 process under subsection (a), including—

21 “(i) the stage of the review process
22 applicable to the submission;

23 “(ii) the date of the most recent
24 change in stage status;

1 “(iii) whether external scientific ex-
2 perts were utilized in the development of a
3 qualification plan or the review of a full
4 qualification package; and

5 “(iv) submissions from requestors
6 under the qualification process under sub-
7 section (a), including any data and evi-
8 dence contained in such submissions, and
9 any updates to such submissions.

10 “(B) The Secretary’s formal written deter-
11 minations in response to such qualification sub-
12 missions.

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

16 “(D) Summary reviews that document con-
17 clusions and recommendations for determina-
18 tions to qualify drug development tools under
19 subsection (a).

20 “(E) A comprehensive list of—

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

23 “(ii) all surrogate endpoints which
24 were the basis of approval or licensure (as
25 applicable) of a drug or biological product

1 (including in accordance with section
2 506(e)) under section 505 of this Act or
3 section 351 of the Public Health Service
4 Act.

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

10 “(3) APPLICABILITY.—Nothing in this section
11 shall be construed as authorizing the Secretary to
12 disclose any information contained in an application
13 submitted under section 505 of this Act or section
14 351 of the Public Health Service Act that is con-
15 fidential commercial or trade secret information sub-
16 ject to section 552(b)(4) of title 5, United States
17 Code, or section 1905 of title 18, United States
18 Code.

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

21 “(1) to alter the standards of evidence under
22 subsection (c) or (d) of section 505, including the
23 substantial evidence standard in such subsection (d),
24 or under section 351 of the Public Health Service
25 Act (as applicable); or

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

6 “(e) DEFINITIONS.—In this section:

7 “(1) BIOMARKER.—The term ‘biomarker’—

8 “(A) means a characteristic (such as a
9 physiologic, pathologic, or anatomic char-
10 acteristic or measurement) that is objectively
11 measured and evaluated as an indicator of nor-
12 mal biologic processes, pathologic processes, or
13 biological responses to a therapeutic interven-
14 tion; and

15 “(B) includes a surrogate endpoint.

16 “(2) BIOMEDICAL RESEARCH CONSORTIA.—The
17 term ‘biomedical research consortia’ means collabo-
18 rative groups that may take the form of public-pri-
19 vate partnerships and may include government agen-
20 cies, institutions of higher education (as defined in
21 section 101(a) of the Higher Education Act of
22 1965), patient advocacy groups, industry representa-
23 tives, clinical and scientific experts, and other rel-
24 evant entities and individuals.

1 “(3) CLINICAL OUTCOME ASSESSMENT.—The
2 term ‘clinical outcome assessment’ means—

3 “(A) a measurement of a patient’s symp-
4 toms, overall mental state, or the effects of a
5 disease or condition on how the patient func-
6 tions; and

7 “(B) includes a patient-reported outcome.

8 “(4) CONTEXT OF USE.—The term ‘context of
9 use’ means, with respect to a drug development tool,
10 the circumstances under which the drug development
11 tool is to be used in drug development and regu-
12 latory review.

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

15 “(A) a biomarker;

16 “(B) a clinical outcome assessment; and

17 “(C) any other method, material, or meas-
18 ure that the Secretary determines aids drug de-
19 velopment and regulatory review for purposes of
20 this section.

21 “(6) PATIENT-REPORTED OUTCOME.—The term
22 ‘patient-reported outcome’ means a measurement
23 based on a report from a patient regarding the sta-
24 tus of the patient’s health condition without amend-

1 ment or interpretation of the patient’s report by a
2 clinician or any other person.

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

9 “(8) REQUESTOR.—The term ‘requestor’ means
10 an entity or entities, including a drug sponsor or a
11 biomedical research consortia, seeking to qualify a
12 drug development tool for a proposed context of use
13 under this section.

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

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

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

1 (b) GUIDANCE.—

2 (1) IN GENERAL.—The Secretary of Health and
3 Human Services (referred to in this section as the
4 “Secretary”) shall, in consultation with biomedical
5 research consortia (as defined in subsection (e) of
6 section 507 of the Federal Food, Drug, and Cos-
7 metic Act (as added by subsection (a)) and other in-
8 terested parties through a collaborative public proc-
9 ess, issue guidance to implement such section 507
10 that—

11 (A) provides a conceptual framework de-
12 scribing appropriate standards and scientific
13 approaches to support the development of bio-
14 markers delineated under the taxonomy estab-
15 lished under paragraph (3);

16 (B) with respect to the qualification proc-
17 ess under such section 507—

18 (i) describes the requirements that en-
19 tities seeking to qualify a drug develop-
20 ment tool under such section shall observe
21 when engaging in such process;

22 (ii) outlines reasonable timeframes for
23 the Secretary’s review of letters, qualifica-
24 tion plans, or full qualification packages
25 submitted under such process; and

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

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

11 (2) TIMING.—Not later than 3 years after the
12 date of the enactment of this Act, the Secretary
13 shall issue draft guidance under paragraph (1) on
14 the implementation of section 507 of the Federal
15 Food, Drug, and Cosmetic Act (as added by sub-
16 section (a)). The Secretary shall issue final guidance
17 on the implementation of such section not later than
18 6 months after the date on which the comment pe-
19 riod for the draft guidance closes.

20 (3) TAXONOMY.—

21 (A) IN GENERAL.—For purposes of in-
22 forming guidance under this subsection, the
23 Secretary shall, in consultation with biomedical
24 research consortia and other interested parties
25 through a collaborative public process, establish

1 a taxonomy for the classification of biomarkers
2 (and related scientific concepts) for use in drug
3 development.

4 (B) PUBLIC AVAILABILITY.—Not later
5 than 2 years after the date of the enactment of
6 this Act, the Secretary shall make such tax-
7 onomy publicly available in draft form for pub-
8 lic comment. The Secretary shall finalize the
9 taxonomy not later than 1 year after the close
10 of the public comment period.

11 (c) MEETING AND REPORT.—

12 (1) MEETING.—Not later than 2 years after the
13 date of the enactment of this Act, the Secretary
14 shall convene a public meeting to describe and solicit
15 public input regarding the qualification process
16 under section 507 of the Federal Food, Drug, and
17 Cosmetic Act, as added by subsection (a).

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

1 (A) the number of requests submitted, as
2 a letter of intent, for qualification of a drug de-
3 velopment tool (as defined in subsection (e) of
4 such section 507);

5 (B) the number of such requests accepted
6 and determined to be eligible for submission of
7 a qualification plan or full qualification package
8 (as such terms are defined in subsection (e) of
9 such section 507), respectively;

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

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

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

22 **SEC. 3012. TARGETED DRUGS FOR RARE DISEASES.**

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

1 **“SEC. 529A. TARGETED DRUGS FOR RARE DISEASES.**

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

4 “(1) facilitate the development, review, and ap-
5 proval of genetically targeted drugs and variant pro-
6 tein targeted drugs to address an unmet medical
7 need in one or more patient subgroups, including
8 subgroups of patients with different mutations of a
9 gene, with respect to rare diseases or conditions that
10 are serious or life-threatening; and

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

14 “(b) LEVERAGING OF DATA FROM PREVIOUSLY AP-
15 PROVED DRUG APPLICATION OR APPLICATIONS.—The
16 Secretary may, consistent with applicable standards for
17 approval under this Act or section 351(a) of the Public
18 Health Service Act, allow the sponsor of an application
19 under section 505(b)(1) of this Act or section 351(a) of
20 the Public Health Service Act for a genetically targeted
21 drug or a variant protein targeted drug to rely upon data
22 and information—

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

1 “(2) submitted by a sponsor described in para-
2 graph (1) in support of one or more previously ap-
3 proved applications that were submitted under sec-
4 tion 505(b)(1) of this Act or section 351(a) of the
5 Public Health Service Act,
6 for a drug that incorporates or utilizes the same or similar
7 genetically targeted technology as the drug or drugs that
8 are the subject of an application or applications described
9 in paragraph (2) or for a variant protein targeted drug
10 that is the same or incorporates or utilizes the same vari-
11 ant protein targeted drug, as the drug or drugs that are
12 the subject of an application or applications described in
13 paragraph (2).

14 “(c) DEFINITIONS.—For purposes of this section—

15 “(1) the term ‘genetically targeted drug’ means
16 a drug that—

17 “(A) is the subject of an application under
18 section 505(b)(1) of this Act or section 351(a)
19 of the Public Health Service Act for the treat-
20 ment of a rare disease or condition (as such
21 term is defined in section 526) that is serious
22 or life-threatening;

23 “(B) may result in the modulation (includ-
24 ing suppression, up-regulation, or activation) of

1 the function of a gene or its associated gene
2 product; and

3 “(C) incorporates or utilizes a genetically
4 targeted technology;

5 “(2) the term ‘genetically targeted technology’
6 means a technology comprising non-replicating nu-
7 cleic acid or analogous compounds with a common or
8 similar chemistry that is intended to treat one or
9 more patient subgroups, including subgroups of pa-
10 tients with different mutations of a gene, with the
11 same disease or condition, including a disease or
12 condition due to other variants in the same gene;
13 and

14 “(3) the term ‘variant protein targeted drug’
15 means a drug that—

16 “(A) is the subject of an application under
17 section 505(b)(1) of this Act or section 351(a)
18 of the Public Health Service Act for the treat-
19 ment of a rare disease or condition (as such
20 term is defined in section 526) that is serious
21 or life-threatening;

22 “(B) modulates the function of a product
23 of a mutated gene where such mutation is re-
24 sponsible in whole or in part for a given disease
25 or condition; and

1 “(C) is intended to treat one or more pa-
2 tient subgroups, including subgroups of patients
3 with different mutations of a gene, with the
4 same disease or condition.

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

7 “(1) alter the authority of the Secretary to ap-
8 prove drugs pursuant to this Act or section 351 of
9 the Public Health Service Act (as authorized prior
10 to the date of enactment of the 21st Century Cures
11 Act), including the standards of evidence, and appli-
12 cable conditions, for approval under such applicable
13 Act; or

14 “(2) confer any new rights, beyond those au-
15 thorized under this Act or the Public Health Service
16 Act prior to enactment of this section, with respect
17 to the permissibility of a sponsor referencing infor-
18 mation contained in another application submitted
19 under section 505(b)(1) of this Act or section 351(a)
20 of the Public Health Service Act.”.

21 **SEC. 3013. REAUTHORIZATION OF PROGRAM TO ENCOUR-**
22 **AGE TREATMENTS FOR RARE PEDIATRIC DIS-**
23 **EASES.**

24 (a) IN GENERAL.—Section 529(b) of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(b)) is

1 amended by striking paragraph (5) and inserting the fol-
2 lowing:

3 “(5) **TERMINATION OF AUTHORITY.**—The Sec-
4 retary may not award any priority review vouchers
5 under paragraph (1) after September 30, 2020, un-
6 less the rare pediatric disease product application—

7 “(A) is for a drug that, not later than Sep-
8 tember 30, 2020, is designated under sub-
9 section (d) as a drug for a rare pediatric dis-
10 ease; and

11 “(B) is, not later than September 30,
12 2022, approved under section 505(b)(1) of this
13 Act or section 351(a) of the Public Health
14 Service Act.”.

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

17 **SEC. 3014. GAO STUDY OF PRIORITY REVIEW VOUCHER**
18 **PROGRAMS.**

19 (a) **STUDY.**—The Comptroller General of the United
20 States (referred to in this section as the “Comptroller
21 General”) shall conduct a study addressing the effective-
22 ness and overall impact of the following priority review
23 voucher programs, including any such programs amended
24 or established by this Act:

1 (1) The neglected tropical disease priority re-
2 view voucher program under section 524 of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C.
4 360n).

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

8 (3) The medical countermeasure priority review
9 voucher program under section 565A of the Federal
10 Food, Drug, and Cosmetic Act, as added by section
11 3086.

12 (b) ISSUANCE OF REPORT.—Not later than January
13 31, 2020, the Comptroller General shall submit to the
14 Committee on Health, Education, Labor, and Pensions of
15 the Senate and the Committee on Energy and Commerce
16 of the House of Representatives a report containing the
17 results of the study under subsection (a).

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

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

23 (A) the indications for which the drug is
24 approved under section 505(c) of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C.

1 355(c)), pursuant to an application under sec-
2 tion 505(b)(1) of such Act, or licensed under
3 section 351(a) of the Public Health Service Act
4 (42 U.S.C. 262(a));

5 (B) whether, and to what extent, the
6 voucher impacted the sponsor's decision to de-
7 velop the drug; and

8 (C) whether, and to what extent, the ap-
9 proval or licensure of the drug, as applicable
10 and appropriate—

11 (i) addressed a global unmet need re-
12 lated to the treatment or prevention of a
13 neglected tropical disease, including wheth-
14 er the sponsor of a drug coordinated with
15 international development organizations;

16 (ii) addressed an unmet need related
17 to the treatment of a rare pediatric dis-
18 ease; or

19 (iii) affected the Nation's prepared-
20 ness against a chemical, biological, radio-
21 logical, or nuclear threat, including natu-
22 rally occurring threats;

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

1 (A) the indications for which such drug is
2 approved under section 505(c) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(c)), pursuant to an application under sec-
5 tion 505(b)(1) of such Act, or licensed under
6 section 351(a) of the Public Health Service Act
7 (42 U.S.C. 262);

8 (B) the value of the voucher, if trans-
9 ferred; and

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

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

15 (A) the resources used by the Food and
16 Drug Administration in reviewing drugs for
17 which vouchers were used, including the effect
18 of the programs on the Food and Drug Admin-
19 istration's review of drugs for which priority re-
20 view vouchers were not awarded or used;

21 (B) whether any improvements to such
22 programs are necessary to appropriately target
23 incentives for the development of drugs that
24 would likely not otherwise be developed, or de-

1 veloped in as timely a manner, and, as applica-
2 ble and appropriate—

3 (i) address global unmet needs related
4 to the treatment or prevention of neglected
5 tropical diseases, including in countries in
6 which neglected tropical diseases are en-
7 demic; or

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

11 (C) whether the sunset of the rare pedi-
12 atric disease program and medical counter-
13 measure program has had an impact on the
14 program, including any potential unintended
15 consequences.

16 (d) PROTECTION OF NATIONAL SECURITY.—The
17 Comptroller General shall conduct the study and issue re-
18 ports under this section in a manner that does not com-
19 promise national security.

20 **SEC. 3015. AMENDMENTS TO THE ORPHAN DRUG GRANTS.**

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

23 (1) in subsection (a), by striking paragraph (1)
24 and inserting the following: “(1) defraying the costs

1 of developing drugs for rare diseases or conditions,
2 including qualified testing expenses,”; and

3 (2) in subsection (b)(1)—

4 (A) in subparagraph (A)(ii), by striking
5 “and” after the semicolon;

6 (B) in subparagraph (B), by striking the
7 period and inserting “; and”; and

8 (C) by adding at the end the following:

9 “(C) prospectively planned and designed
10 observational studies and other analyses con-
11 ducted to assist in the understanding of the
12 natural history of a rare disease or condition
13 and in the development of a therapy, including
14 studies and analyses to—

15 “(i) develop or validate a drug devel-
16 opment tool related to a rare disease or
17 condition; or

18 “(ii) understand the full spectrum of
19 the disease manifestations, including de-
20 scribing genotypic and phenotypic varia-
21 bility and identifying and defining distinct
22 subpopulations affected by a rare disease
23 or condition.”.

1 **SEC. 3016. GRANTS FOR STUDYING CONTINUOUS DRUG**
2 **MANUFACTURING.**

3 (a) IN GENERAL.—The Secretary of Health and
4 Human Services may award grants to institutions of high-
5 er education and nonprofit organizations for the purpose
6 of studying and recommending improvements to the proc-
7 ess of continuous manufacturing of drugs and biological
8 products and similar innovative monitoring and control
9 techniques.

10 (b) DEFINITIONS.—In this section—

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

14 (2) the term “biological product” has the mean-
15 ing given such term in section 351(i) of the Public
16 Health Service Act (42 U.S.C. 262(i)); and

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

21 **Subtitle C—Modern Trial Design**
22 **and Evidence Development**

23 **SEC. 3021. NOVEL CLINICAL TRIAL DESIGNS.**

24 (a) PROPOSALS FOR USE OF NOVEL CLINICAL TRIAL
25 DESIGNS FOR DRUGS AND BIOLOGICAL PRODUCTS.—For
26 purposes of assisting sponsors in incorporating complex

1 adaptive and other novel trial designs into proposed clin-
2 ical protocols and applications for new drugs under section
3 505 of the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 355) and biological products under section 351 of
5 the Public Health Service Act (42 U.S.C. 262), the Sec-
6 retary of Health and Human Services (referred to in this
7 section as the “Secretary”) shall conduct a public meeting
8 and issue guidance in accordance with subsection (b).

9 (b) GUIDANCE ADDRESSING USE OF NOVEL CLIN-
10 ICAL TRIAL DESIGNS.—

11 (1) IN GENERAL.—The Secretary, acting
12 through the Commissioner of Food and Drugs, shall
13 update or issue guidance addressing the use of com-
14 plex adaptive and other novel trial design in the de-
15 velopment and regulatory review and approval or li-
16 censure for drugs and biological products.

17 (2) CONTENTS.—The guidance under para-
18 graph (1) shall address—

19 (A) the use of complex adaptive and other
20 novel trial designs, including how such clinical
21 trials proposed or submitted help to satisfy the
22 substantial evidence standard under section
23 505(d) of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 355(d));

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

4 (i) completion of such modeling or
5 simulations; or

6 (ii) the submission of resulting infor-
7 mation to the Secretary;

8 (C) the types of quantitative and quali-
9 tative information that should be submitted for
10 review; and

11 (D) recommended analysis methodologies.

12 (3) PUBLIC MEETING.—Prior to updating or
13 issuing the guidance required by paragraph (1), the
14 Secretary shall consult with stakeholders, including
15 representatives of regulated industry, academia, pa-
16 tient advocacy organizations, consumer groups, and
17 disease research foundations, through a public meet-
18 ing to be held not later than 18 months after the
19 date of enactment of this Act.

20 (4) TIMING.—The Secretary shall update or
21 issue a draft version of the guidance required by
22 paragraph (1) not later than 18 months after the
23 date of the public meeting required by paragraph (3)
24 and finalize such guidance not later than 1 year

1 after the date on which the public comment period
2 for the draft guidance closes.

3 **SEC. 3022. REAL WORLD EVIDENCE.**

4 Chapter V of the Federal Food, Drug, and Cosmetic
5 Act is amended by inserting after section 505E (21 U.S.C.
6 355f) the following:

7 **“SEC. 505F. UTILIZING REAL WORLD EVIDENCE.**

8 “(a) IN GENERAL.—The Secretary shall establish a
9 program to evaluate the potential use of real world evi-
10 dence—

11 “(1) to help to support the approval of a new
12 indication for a drug approved under section 505(e);
13 and

14 “(2) to help to support or satisfy postapproval
15 study requirements.

16 “(b) REAL WORLD EVIDENCE DEFINED.—In this
17 section, the term ‘real world evidence’ means data regard-
18 ing the usage, or the potential benefits or risks, of a drug
19 derived from sources other than randomized clinical trials.

20 “(c) PROGRAM FRAMEWORK.—

21 “(1) IN GENERAL.—Not later than 2 years
22 after the date of enactment of the 21st Century
23 Cures Act, the Secretary shall establish a draft
24 framework for implementation of the program under
25 this section.

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

3 “(A) the sources of real world evidence, in-
4 cluding ongoing safety surveillance, observa-
5 tional studies, registries, claims, and patient-
6 centered outcomes research activities;

7 “(B) the gaps in data collection activities;

8 “(C) the standards and methodologies for
9 collection and analysis of real world evidence;
10 and

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

15 “(3) CONSULTATION.—

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

23 “(B) PROCESS.—The consultation under
24 subparagraph (A) may be carried out through
25 approaches such as—

1 “(i) a public-private partnership with
2 the entities described in such subparagraph
3 in which the Secretary may participate;

4 “(ii) a contract, grant, or other ar-
5 rangement, as the Secretary determines
6 appropriate, with such a partnership or an
7 independent research organization; or

8 “(iii) public workshops with the enti-
9 ties described in such subparagraph.

10 “(d) PROGRAM IMPLEMENTATION.—The Secretary
11 shall, not later than 2 years after the date of enactment
12 of the 21st Century Cures Act and in accordance with the
13 framework established under subsection (c), implement
14 the program to evaluate the potential use of real world
15 evidence.

16 “(e) GUIDANCE FOR INDUSTRY.—The Secretary
17 shall—

18 “(1) utilize the program established under sub-
19 section (a), its activities, and any subsequent pilots
20 or written reports, to inform a guidance for industry
21 on—

22 “(A) the circumstances under which spon-
23 sors of drugs and the Secretary may rely on
24 real world evidence for the purposes described

1 in paragraphs (1) and (2) of subsection (a);
2 and

3 “(B) the appropriate standards and meth-
4 odologies for collection and analysis of real
5 world evidence submitted for such purposes;

6 “(2) not later than 5 years after the date of en-
7 actment of the 21st Century Cures Act, issue draft
8 guidance for industry as described in paragraph (1);
9 and

10 “(3) not later than 18 months after the close
11 of the public comment period for the draft guidance
12 described in paragraph (2), issue revised draft guid-
13 ance or final guidance.

14 “(f) RULE OF CONSTRUCTION.—

15 “(1) IN GENERAL.—Subject to paragraph (2),
16 nothing in this section prohibits the Secretary from
17 using real world evidence for purposes not specified
18 in this section, provided the Secretary determines
19 that sufficient basis exists for any such nonspecified
20 use.

21 “(2) STANDARDS OF EVIDENCE AND SEC-
22 RETARY’S AUTHORITY.—This section shall not be
23 construed to alter—

24 “(A) the standards of evidence under—

1 “(i) subsection (c) or (d) of section
2 505, including the substantial evidence
3 standard in such subsection (d); or

4 “(ii) section 351(a) of the Public
5 Health Service Act; or

6 “(B) the Secretary’s authority to require
7 postapproval studies or clinical trials, or the
8 standards of evidence under which studies or
9 trials are evaluated.”.

10 **SEC. 3023. PROTECTION OF HUMAN RESEARCH SUBJECTS.**

11 (a) **IN GENERAL.**—In order to simplify and facilitate
12 compliance by researchers with applicable regulations for
13 the protection of human subjects in research, the Sec-
14 retary of Health and Human Services (referred to in this
15 section as the “Secretary”) shall, to the extent practicable
16 and consistent with other statutory provisions, harmonize
17 differences between the HHS Human Subject Regulations
18 and the FDA Human Subject Regulations in accordance
19 with subsection (b).

20 (b) **AVOIDING REGULATORY DUPLICATION AND UN-**
21 **NECESSARY DELAYS.**—The Secretary shall, as appro-
22 priate—

23 (1) make such modifications to the provisions of
24 the HHS Human Subject Regulations, the FDA

1 Human Subject Regulations, and the vulnerable pop-
2 ulations rules as may be necessary—

3 (A) to reduce regulatory duplication and
4 unnecessary delays;

5 (B) to modernize such provisions in the
6 context of multisite and cooperative research
7 projects; and

8 (C) to protect vulnerable populations, in-
9 corporate local considerations, and support
10 community engagement through mechanisms
11 such as consultation with local researchers and
12 human research protection programs, in a man-
13 ner consistent with subparagraph (B); and

14 (2) ensure that human subject research that is
15 subject to the HHS Human Subject Regulations and
16 to the FDA Human Subject Regulations may—

17 (A) use joint or shared review;

18 (B) rely upon the review of—

19 (i) an independent institutional review
20 board; or

21 (ii) an institutional review board of an
22 entity other than the sponsor of the re-
23 search; or

24 (C) use similar arrangements to avoid du-
25 plication of effort.

1 (c) CONSULTATION.—In harmonizing or modifying
2 regulations or guidance under this section, the Secretary
3 shall consult with stakeholders (including researchers, aca-
4 demic organizations, hospitals, institutional research
5 boards, pharmaceutical, biotechnology, and medical device
6 developers, clinical research organizations, patient groups,
7 and others).

8 (d) TIMING.—The Secretary shall complete the har-
9 monization described in subsection (a) not later than 3
10 years after the date of enactment of this Act.

11 (e) PROGRESS REPORT.—Not later than 2 years after
12 the date of enactment of this Act, the Secretary shall sub-
13 mit to Congress a report on the progress made toward
14 completing such harmonization.

15 (f) DEFINITIONS.—

16 (1) HUMAN SUBJECT REGULATIONS.—In this
17 section:

18 (A) FDA HUMAN SUBJECT REGULA-
19 TIONS.—The term “FDA Human Subject Reg-
20 ulations” means the provisions of parts 50, 56,
21 312, and 812 of title 21, Code of Federal Regu-
22 lations (or any successor regulations).

23 (B) HHS HUMAN SUBJECT REGULA-
24 TIONS.—The term “HHS Human Subject Reg-
25 ulations” means the provisions of subpart A of

1 part 46 of title 45, Code of Federal Regulations
2 (or any successor regulations).

3 (C) VULNERABLE POPULATION RULES.—

4 The term “vulnerable population rules”
5 means—

6 (i) except in the case of research de-
7 scribed in clause (ii), the provisions of sub-
8 parts B through D of part 46, Code of
9 Federal Regulations (or any successor reg-
10 ulations); and

11 (ii) in the case of research that is sub-
12 ject to FDA Human Subject Regulations,
13 the provisions applicable to vulnerable pop-
14 ulations under part 56 of title 21, Code of
15 Federal Regulations (or any successor reg-
16 ulations) and subpart D of part 50 of such
17 title 21 (or any successor regulations).

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

19 (A) INSTITUTIONAL REVIEW BOARD.—The
20 term “institutional review board” has the mean-
21 ing that applies to the term “institutional re-
22 view board” under the HHS Human Subject
23 Regulations.

24 (B) LEAD INSTITUTIONAL REVIEW
25 BOARD.—The term “lead institutional review

1 board” means an institutional review board that
2 otherwise meets the requirements of the HHS
3 Human Subject Regulations and enters into a
4 written agreement with an institution, another
5 institutional review board, a sponsor, or a prin-
6 cipal investigator to approve and oversee human
7 subject research that is conducted at multiple
8 locations. References to an institutional review
9 board include an institutional review board that
10 serves a single institution and a lead institu-
11 tional review board.

12 **SEC. 3024. INFORMED CONSENT WAIVER OR ALTERATION**
13 **FOR CLINICAL INVESTIGATIONS.**

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

17 (1) in subparagraph (D), by striking “except
18 where subject to such conditions as the Secretary
19 may prescribe, the investigator” and inserting the
20 following: “except where, subject to such conditions
21 as the Secretary may prescribe—

22 “(i) the proposed clinical testing poses no
23 more than minimal risk to the human subject
24 and includes appropriate safeguards to protect

1 the rights, safety, and welfare of the human
2 subject; or

3 “(ii) the investigator”; and

4 (2) in the matter following subparagraph (D),
5 by striking “subparagraph (D)” and inserting “sub-
6 paragraph (D)(ii)”.

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

17 **Subtitle D—Patient Access to**
18 **Therapies and Information**

19 **SEC. 3031. SUMMARY LEVEL REVIEW.**

20 (a) FFDCA.—Section 505(c) of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 355(c)) is amended
22 by adding at the end the following:

23 “(5)(A) The Secretary may rely upon qualified data
24 summaries to support the approval of a supplemental ap-
25 plication, with respect to a qualified indication for a drug,

1 submitted under subsection (b), if such supplemental ap-
2 plication complies with subparagraph (B).

3 “(B) A supplemental application is eligible for review
4 as described in subparagraph (A) only if—

5 “(i) there is existing data available and accept-
6 able to the Secretary demonstrating the safety of the
7 drug; and

8 “(ii) all data used to develop the qualified data
9 summaries are submitted to the Secretary as part of
10 the supplemental application.

11 “(C) The Secretary shall post on the Internet website
12 of the Food and Drug Administration and update annu-
13 ally—

14 “(i) the number of applications reviewed solely
15 under subparagraph (A) or section 351(a)(2)(E) of
16 the Public Health Service Act;

17 “(ii) the average time for completion of review
18 under subparagraph (A) or section 351(a)(2)(E) of
19 the Public Health Service Act;

20 “(iii) the average time for review of supple-
21 mental applications where the Secretary did not use
22 review flexibility under subparagraph (A) or section
23 351(a)(2)(E) of the Public Health Service Act; and

24 “(iv) the number of applications reviewed under
25 subparagraph (A) or section 351(a)(2)(E) of the

1 Public Health Service Act for which the Secretary
2 made use of full data sets in addition to the quali-
3 fied data summary.

4 “(D) In this paragraph—

5 “(i) the term ‘qualified indication’ means an in-
6 dication for a drug that the Secretary determines to
7 be appropriate for summary level review under this
8 paragraph; and

9 “(ii) the term ‘qualified data summary’ means
10 a summary of clinical data that demonstrates the
11 safety and effectiveness of a drug with respect to a
12 qualified indication.”.

13 (b) PHSA.—Section 351(a)(2) of the Public Health
14 Service Act (42 U.S.C. 262(a)(2)) is amended by adding
15 at the end the following:

16 “(E)(i) The Secretary may rely upon qualified data
17 summaries to support the approval of a supplemental ap-
18 plication, with respect to a qualified indication for a drug,
19 submitted under this subsection, if such supplemental ap-
20 plication complies with the requirements of subparagraph
21 (B) of section 505(c)(5) of the Federal Food, Drug, and
22 Cosmetic Act.

23 “(ii) In this subparagraph, the terms ‘qualified indi-
24 cation’ and ‘qualified data summary’ have the meanings

1 given such terms in section 505(c)(5) of the Federal Food,
2 Drug, and Cosmetic Act.”.

3 **SEC. 3032. EXPANDED ACCESS POLICY.**

4 Chapter V of the Federal Food, Drug, and Cosmetic
5 Act is amended by inserting after section 561 (21 U.S.C.
6 360bbb) the following:

7 **“SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR IN-**
8 **VESTIGATIONAL DRUGS.**

9 “(a) IN GENERAL.—The manufacturer or distributor
10 of one or more investigational drugs for the diagnosis,
11 monitoring, or treatment of one or more serious diseases
12 or conditions shall make available the policy of the manu-
13 facturer or distributor on evaluating and responding to re-
14 quests submitted under section 561(b) for provision of
15 such a drug.

16 “(b) PUBLIC AVAILABILITY OF EXPANDED ACCESS
17 POLICY.—The policies under subsection (a) shall be made
18 public and readily available, such as by posting such poli-
19 cies on a publicly available Internet website. Such policies
20 may be generally applicable to all investigational drugs of
21 such manufacturer or distributor.

22 “(c) CONTENT OF POLICY.—A policy described in
23 subsection (a) shall include—

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

4 “(2) procedures for making such requests;

5 “(3) the general criteria the manufacturer or
6 distributor will use to evaluate such requests for in-
7 dividual patients, and for responses to such requests;

8 “(4) the length of time the manufacturer or dis-
9 tributor anticipates will be necessary to acknowledge
10 receipt of such requests; and

11 “(5) a hyperlink or other reference to the clin-
12 ical trial record containing information about the ex-
13 panded access for such drug that is required under
14 section 402(j)(2)(A)(ii)(II)(gg) of the Public Health
15 Service Act.

16 “(d) NO GUARANTEE OF ACCESS.—The posting of
17 policies by manufacturers and distributors under sub-
18 section (a) shall not serve as a guarantee of access to any
19 specific investigational drug by any individual patient.

20 “(e) REVISED POLICY.—Nothing in this section shall
21 prevent a manufacturer or distributor from revising a pol-
22 icy required under this section at any time.

23 “(f) APPLICATION.—This section shall apply to a
24 manufacturer or distributor with respect to an investiga-
25 tional drug beginning on the later of—

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

3 “(2) the first initiation of a phase 2 or phase
4 3 study (as such terms are defined in section
5 312.21(b) and (c) of title 21, Code of Federal Regu-
6 lations (or any successor regulations)) with respect
7 to such investigational drug.”.

8 **SEC. 3033. ACCELERATED APPROVAL FOR REGENERATIVE**
9 **ADVANCED THERAPIES.**

10 (a) IN GENERAL.—Section 506 of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

12 (1) by transferring subsection (e) (relating to
13 construction) so that it appears before subsection (f)
14 (relating to awareness efforts); and

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

16 “(g) REGENERATIVE ADVANCED THERAPY.—

17 “(1) IN GENERAL.—The Secretary, at the re-
18 quest of the sponsor of a drug, shall facilitate an ef-
19 ficient development program for, and expedite review
20 of, such drug if the drug qualifies as a regenerative
21 advanced therapy under the criteria described in
22 paragraph (2).

23 “(2) CRITERIA.—A drug is eligible for designa-
24 tion as a regenerative advanced therapy under this
25 subsection if—

1 “(A) the drug is a regenerative medicine
2 therapy (as defined in paragraph (8));

3 “(B) the drug is intended to treat, modify,
4 reverse, or cure a serious or life-threatening dis-
5 ease or condition; and

6 “(C) preliminary clinical evidence indicates
7 that the drug has the potential to address
8 unmet medical needs for such a disease or con-
9 dition.

10 “(3) REQUEST FOR DESIGNATION.—The spon-
11 sor of a drug may request the Secretary to designate
12 the drug as a regenerative advanced therapy concu-
13 rently with, or at any time after, submission of an
14 application for the investigation of the drug under
15 section 505(i) of this Act or section 351(a)(3) of the
16 Public Health Service Act.

17 “(4) DESIGNATION.—Not later than 60 cal-
18 endar days after the receipt of a request under para-
19 graph (3), the Secretary shall determine whether the
20 drug that is the subject of the request meets the cri-
21 teria described in paragraph (2). If the Secretary de-
22 termines that the drug meets the criteria, the Sec-
23 retary shall designate the drug as a regenerative ad-
24 vanced therapy and shall take such actions as are
25 appropriate under paragraph (1). If the Secretary

1 determines that a drug does not meet the criteria for
2 such designation, the Secretary shall include with
3 the determination a written description of the ra-
4 tionale for such determination.

5 “(5) ACTIONS.—The sponsor of a regenerative
6 advanced therapy shall be eligible for the actions to
7 expedite development and review of such therapy
8 under subsection (a)(3)(B), including early inter-
9 actions to discuss any potential surrogate or inter-
10 mediate endpoint to be used to support the acceler-
11 ated approval of an application for the product
12 under subsection (c).

13 “(6) ACCESS TO EXPEDITED APPROVAL PATH-
14 WAYS.—An application for a regenerative advanced
15 therapy under section 505(b)(1) of this Act or sec-
16 tion 351(a) of the Public Health Service Act may
17 be—

18 “(A) eligible for priority review, as de-
19 scribed in the Manual of Policies and Proce-
20 dures of the Food and Drug Administration
21 and goals identified in the letters described in
22 section 101(b) of the Prescription Drug User
23 Fee Amendments of 2012; and

24 “(B) eligible for accelerated approval
25 under subsection (c), as agreed upon pursuant

1 to subsection (a)(3)(B), through, as appro-
2 priate—

3 “(i) surrogate or intermediate
4 endpoints reasonably likely to predict long-
5 term clinical benefit; or

6 “(ii) reliance upon data obtained from
7 a meaningful number of sites, including
8 through expansion to additional sites, as
9 appropriate.

10 “(7) POSTAPPROVAL REQUIREMENTS.—The
11 sponsor of a regenerative advanced therapy that is
12 granted accelerated approval and is subject to the
13 postapproval requirements under subsection (c) may,
14 as appropriate, fulfill such requirements, as the Sec-
15 retary may require, through—

16 “(A) the submission of clinical evidence,
17 clinical studies, patient registries, or other
18 sources of real world evidence, such as elec-
19 tronic health records;

20 “(B) the collection of larger confirmatory
21 data sets, as agreed upon pursuant to sub-
22 section (a)(3)(B); or

23 “(C) postapproval monitoring of all pa-
24 tients treated with such therapy prior to ap-
25 proval of the therapy.

1 “(8) DEFINITION.—For purposes of this sec-
2 tion, the term ‘regenerative medicine therapy’ in-
3 cludes cell therapy, therapeutic tissue engineering
4 products, human cell and tissue products, and com-
5 bination products using any such therapies or prod-
6 ucts, except for those regulated solely under section
7 361 of the Public Health Service Act and part 1271
8 of title 21, Code of Federal Regulations.”.

9 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
10 tion and the amendments made by this section shall be
11 construed to alter the authority of the Secretary of Health
12 and Human Services—

13 (1) to approve drugs pursuant to the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
15 seq.) and section 351 of the Public Health Service
16 Act (42 U.S.C. 262) as authorized prior to the date
17 of enactment of the 21st Century Cures Act, includ-
18 ing the standards of evidence, and applicable condi-
19 tions, for approval under such Acts; or

20 (2) to alter the authority of the Secretary to re-
21 quire postapproval studies pursuant to such Acts, as
22 authorized prior to the date of enactment of the 21st
23 Century Cures Act.

24 (c) CONFORMING AMENDMENT.—Section 506(e)(1)
25 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 356(e)(1)) is amended by inserting “and the 21st Century
2 Cures Act” after “Food and Drug Administration Safety
3 and Innovation Act”.

4 **SEC. 3034. GUIDANCE REGARDING DEVICES USED IN THE**
5 **RECOVERY, ISOLATION, OR DELIVERY OF RE-**
6 **GENERATIVE ADVANCED THERAPIES.**

7 (a) DRAFT GUIDANCE.—Not later than 1 year after
8 the date of enactment of the 21st Century Cures Act, the
9 Secretary of Health and Human Services, acting through
10 the Commissioner of Food and Drugs, shall issue draft
11 guidance clarifying how, in the context of regenerative ad-
12 vanced therapies, the Secretary will evaluate devices used
13 in the recovery, isolation, or delivery of regenerative ad-
14 vanced therapies. In doing so, the Secretary shall specifi-
15 cally address—

16 (1) how the Food and Drug Administration in-
17 tends to simplify and streamline regulatory require-
18 ments for combination device and cell or tissue prod-
19 ucts;

20 (2) what, if any, intended uses or specific at-
21 tributes would result in a device used with a regen-
22 erative therapy product to be classified as a class III
23 device;

24 (3) when the Food and Drug Administration
25 considers it is necessary, if ever, for the intended use

1 of a device to be limited to a specific intended use
2 with only one particular type of cell; and

3 (4) application of the least burdensome ap-
4 proach to demonstrate how a device may be used
5 with more than one cell type.

6 (b) FINAL GUIDANCE.—Not later than 12 months
7 after the close of the period for public comment on the
8 draft guidance under subsection (a), the Secretary of
9 Health and Human Services shall finalize such guidance.

10 **SEC. 3035. REPORT ON REGENERATIVE ADVANCED THERA-**
11 **PIES.**

12 (a) REPORT TO CONGRESS.—Before March 1 of each
13 calendar year, the Secretary of Health and Human Serv-
14 ices shall, with respect to the previous calendar year, sub-
15 mit a report to the Committee on Health, Education,
16 Labor, and Pensions of the Senate and the Committee on
17 Energy and Commerce of the House of Representatives
18 on—

19 (1) the number and type of applications for ap-
20 proval of regenerative advanced therapies filed, ap-
21 proved or licensed as applicable, withdrawn, or de-
22 nied; and

23 (2) how many of such applications or therapies,
24 as applicable, were granted accelerated approval or
25 priority review.

1 (b) REGENERATIVE ADVANCED THERAPY.—In this
2 section, the term “regenerative advanced therapy” has the
3 meaning given such term in section 506(g) of the Federal
4 Food, Drug, and Cosmetic Act, as added by section 3033
5 of this Act.

6 **SEC. 3036. STANDARDS FOR REGENERATIVE MEDICINE AND**
7 **REGENERATIVE ADVANCED THERAPIES.**

8 Subchapter A of chapter V of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
10 ed by inserting after section 506F the following:

11 **“SEC. 506G. STANDARDS FOR REGENERATIVE MEDICINE**
12 **AND REGENERATIVE ADVANCED THERAPIES.**

13 “(a) IN GENERAL.—Not later than 2 years after the
14 date of enactment of the 21st Century Cures Act, the Sec-
15 retary, in consultation with the National Institute of
16 Standards and Technology and stakeholders (including re-
17 generative medicine and advanced therapies manufactur-
18 ers and clinical trial sponsors, contract manufacturers,
19 academic institutions, practicing clinicians, regenerative
20 medicine and advanced therapies industry organizations,
21 and standard setting organizations), shall facilitate an ef-
22 fort to coordinate and prioritize the development of stand-
23 ards and consensus definition of terms, through a public
24 process, to support, through regulatory predictability, the
25 development, evaluation, and review of regenerative medi-

1 cine therapies and regenerative advanced therapies, in-
2 cluding with respect to the manufacturing processes and
3 controls of such products.

4 “(b) ACTIVITIES.—

5 “(1) IN GENERAL.—In carrying out this sec-
6 tion, the Secretary shall continue to—

7 “(A) identify opportunities to help advance
8 the development of regenerative medicine thera-
9 pies and regenerative advanced therapies;

10 “(B) identify opportunities for the develop-
11 ment of laboratory regulatory science research
12 and documentary standards that the Secretary
13 determines would help support the development,
14 evaluation, and review of regenerative medicine
15 therapies and regenerative advanced therapies
16 through regulatory predictability; and

17 “(C) work with stakeholders, such as those
18 described in subsection (a), as appropriate, in
19 the development of such standards.

20 “(2) REGULATIONS AND GUIDANCE.—Not later
21 than 1 year after the development of standards as
22 described in subsection (a), the Secretary shall re-
23 view relevant regulations and guidance and, through
24 a public process, update such regulations and guid-
25 ance as the Secretary determines appropriate.

1 “(c) DEFINITIONS.—For purposes of this section, the
2 terms ‘regenerative medicine therapy’ and ‘regenerative
3 advanced therapy’ have the meanings given such terms in
4 section 506(g).”.

5 **SEC. 3037. HEALTH CARE ECONOMIC INFORMATION.**

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

8 (1) by striking “(a) If its” and inserting
9 “(a)(1) If its”;

10 (2) by striking “a formulary committee, or
11 other similar entity, in the course of the committee
12 or the entity carrying out its responsibilities for the
13 selection of drugs for managed care or other similar
14 organizations” and inserting “a payor, formulary
15 committee, or other similar entity with knowledge
16 and expertise in the area of health care economic
17 analysis, carrying out its responsibilities for the se-
18 lection of drugs for coverage or reimbursement”;

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

21 (4) by striking “and is based on competent and
22 reliable scientific evidence. The requirements set
23 forth in section 505(a) or in section 351(a) of the
24 Public Health Service Act shall not apply to health
25 care economic information provided to such a com-

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

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

16 “(2)(A) For purposes of this paragraph, the term
17 ‘health care economic information’ means any analysis (in-
18 cluding the clinical data, inputs, clinical or other assump-
19 tions, methods, results, and other components underlying
20 or comprising the analysis) that identifies, measures, or
21 describes the economic consequences, which may be based
22 on the separate or aggregated clinical consequences of the
23 represented health outcomes, of the use of a drug. Such
24 analysis may be comparative to the use of another drug,
25 to another health care intervention, or to no intervention.

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

5 **SEC. 3038. COMBINATION PRODUCT INNOVATION.**

6 (a) IN GENERAL.—Section 503(g) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is
8 amended—

9 (1) by striking paragraph (3);

10 (2) by redesignating paragraph (2) as para-
11 graph (7);

12 (3) by redesignating paragraphs (4) and (5) as
13 paragraphs (8) and (9), respectively;

14 (4) by striking “(g)(1)” and all that follows
15 through the end of paragraph (1) and inserting the
16 following:

17 “(g)(1)(A) The Secretary shall, in accordance with
18 this subsection, assign a primary agency center to regulate
19 products that constitute a combination of a drug, device,
20 or biological product.

21 “(B) The Secretary shall conduct the premarket re-
22 view of any combination product under a single applica-
23 tion, whenever appropriate.

24 “(C) For purposes of this subsection, the term ‘pri-
25 mary mode of action’ means the single mode of action of

1 a combination product expected to make the greatest con-
2 tribution to the overall intended therapeutic effects of the
3 combination product.

4 “(D) The Secretary shall determine the primary
5 mode of action of the combination product. If the Sec-
6 retary determines that the primary mode of action is that
7 of—

8 “(i) a drug (other than a biological product),
9 the agency center charged with premarket review of
10 drugs shall have primary jurisdiction;

11 “(ii) a device, the agency center charged with
12 premarket review of devices shall have primary juris-
13 diction; or

14 “(iii) a biological product, the agency center
15 charged with premarket review of biological products
16 shall have primary jurisdiction.

17 “(E) In determining the primary mode of action of
18 a combination product, the Secretary shall not determine
19 that the primary mode of action is that of a drug or bio-
20 logical product solely because the combination product has
21 any chemical action within or on the human body.

22 “(F) If a sponsor of a combination product disagrees
23 with the determination under subparagraph (D)—

24 “(i) such sponsor may request, and the Sec-
25 retary shall provide, a substantive rationale to such

1 sponsor that references scientific evidence provided
2 by the sponsor and any other scientific evidence re-
3 lied upon by the Secretary to support such deter-
4 mination; and

5 “(ii)(I) the sponsor of the combination product
6 may propose one or more studies (which may be
7 nonclinical, clinical, or both) to establish the rel-
8 evance, if any, of the chemical action in achieving
9 the primary mode of action of such product;

10 “(II) if the sponsor proposes any such studies,
11 the Secretary and the sponsor of such product shall
12 collaborate and seek to reach agreement, within a
13 reasonable time of such proposal, not to exceed 90
14 calendar days, on the design of such studies; and

15 “(III) if an agreement is reached under sub-
16 clause (II) and the sponsor conducts one or more of
17 such studies, the Secretary shall consider the data
18 resulting from any such study when reevaluating the
19 determination of the primary mode of action of such
20 product, and unless and until such reevaluation has
21 occurred and the Secretary issues a new determina-
22 tion, the determination of the Secretary under sub-
23 paragraph (D) shall remain in effect.

24 “(2)(A)(i) To establish clarity and certainty for the
25 sponsor, the sponsor of a combination product may re-

1 quest a meeting on such combination product. If the Sec-
2 retary concludes that a determination of the primary mode
3 of action pursuant to paragraph (1)(D) is necessary, the
4 sponsor may request such meeting only after the Secretary
5 makes such determination. If the sponsor submits a writ-
6 ten meeting request, the Secretary shall, not later than
7 75 calendar days after receiving such request, meet with
8 the sponsor of such combination product.

9 “(ii) A meeting under clause (i) may—

10 “(I) address the standards and requirements
11 for market approval or clearance of the combination
12 product;

13 “(II) address other issues relevant to such com-
14 bination product, such as requirements related to
15 postmarket modification of such combination prod-
16 uct and good manufacturing practices applicable to
17 such combination product; and

18 “(III) identify elements under subclauses (I)
19 and (II) that may be more appropriate for discus-
20 sion and agreement with the Secretary at a later
21 date given that scientific or other information is not
22 available, or agreement is otherwise not feasible re-
23 garding such elements, at the time a request for
24 such meeting is made.

1 “(iii) Any agreement under this subparagraph shall
2 be in writing and made part of the administrative record
3 by the Secretary.

4 “(iv) Any such agreement shall remain in effect, ex-
5 cept—

6 “(I) upon the written agreement of the Sec-
7 retary and the sponsor or applicant; or

8 “(II) pursuant to a decision by the director of
9 the reviewing division of the primary agency center,
10 or a person more senior than such director, in con-
11 sultation with consulting centers and the Office, as
12 appropriate, that an issue essential to determining
13 whether the standard for market clearance or other
14 applicable standard under this Act or the Public
15 Health Service Act applicable to the combination
16 product has been identified since the agreement was
17 reached, or that deviating from the agreement is
18 otherwise justifiable based on scientific evidence, for
19 public health reasons.

20 “(3) For purposes of conducting the premarket re-
21 view of a combination product that contains an approved
22 constituent part described in paragraph (4), the Secretary
23 may require that the sponsor of such combination product
24 submit to the Secretary only data or information that the
25 Secretary determines is necessary to meet the standard

1 for clearance or approval, as applicable, under this Act
2 or the Public Health Service Act, including any incre-
3 mental risks and benefits posed by such combination prod-
4 uct, using a risk-based approach and taking into account
5 any prior finding of safety and effectiveness or substantial
6 equivalence for the approved constituent part relied upon
7 by the applicant in accordance with paragraph (5).

8 “(4) For purposes of paragraph (3), an approved con-
9 stituent part is—

10 “(A) a drug constituent part of a combination
11 product being reviewed in a single application or re-
12 quest under section 515, 510(k), or 513(f)(2) (sub-
13 mitted in accordance with paragraph (5)), that is an
14 approved drug, provided such application or request
15 complies with paragraph (5);

16 “(B) a device constituent part approved under
17 section 515 that is referenced by the sponsor and
18 that is available for use by the Secretary under sec-
19 tion 520(h)(4); or

20 “(C) any constituent part that was previously
21 approved, cleared, or classified under section 505,
22 510(k), 513(f)(2), or 515 of this Act for which the
23 sponsor has a right of reference or any constituent
24 part that is a nonprescription drug, as defined in
25 section 760(a)(2).

1 “(5)(A) If an application is submitted under section
2 515 or 510(k) or a request is submitted under section
3 513(f)(2), consistent with any determination made under
4 paragraph (1)(D), for a combination product containing
5 as a constituent part an approved drug—

6 “(i) the application or request shall include the
7 certification or statement described in section
8 505(b)(2); and

9 “(ii) the applicant or requester shall provide no-
10 tice as described in section 505(b)(3).

11 “(B) For purposes of this paragraph and paragraph
12 (4), the term ‘approved drug’ means an active ingre-
13 dient—

14 “(i) that was in an application previously ap-
15 proved under section 505(c);

16 “(ii) where such application is relied upon by
17 the applicant submitting the application or request
18 described in subparagraph (A);

19 “(iii) for which full reports of investigations
20 that have been made to show whether such drug is
21 safe for use and whether such drug is effective in
22 use were not conducted by or for the applicant sub-
23 mitting the application or request described in sub-
24 paragraph (A); and

1 “(iv) for which the applicant submitting the ap-
2 plication or request described in subparagraph (A)
3 has not obtained a right of reference or use from the
4 person by or for whom the investigations described
5 in clause (iii) were conducted.

6 “(C) The following provisions shall apply with respect
7 to an application or request described in subparagraph (A)
8 to the same extent and in the same manner as if such
9 application or request were an application described in sec-
10 tion 505(b)(2) that referenced the approved drug:

11 “(i) Subparagraphs (A), (B), (C), and (D) of
12 section 505(c)(3).

13 “(ii) Clauses (ii), (iii), and (iv) of section
14 505(c)(3)(E).

15 “(iii) Subsections (b) and (c) of section 505A.

16 “(iv) Section 505E(a).

17 “(v) Section 527(a).

18 “(D) Notwithstanding any other provision of this
19 subsection, an application or request for classification for
20 a combination product described in subparagraph (A)
21 shall be considered an application submitted under section
22 505(b)(2) for purposes of section 271(e)(2)(A) of title 35,
23 United States Code.

24 “(6) Nothing in this subsection shall be construed as
25 prohibiting a sponsor from submitting separate applica-

1 tions for the constituent parts of a combination product,
2 unless the Secretary determines that a single application
3 is necessary.”;

4 (5) in paragraph (8) (as redesignated by para-
5 graph (3))—

6 (A) in subparagraph (C)—

7 (i) by amending clause (i) to read as
8 follows:

9 “(i) In carrying out this subsection, the Office shall
10 help to ensure timely and effective premarket review that
11 involves more than one agency center by coordinating such
12 reviews, overseeing the timeliness of such reviews, and
13 overseeing the alignment of feedback regarding such re-
14 views.”;

15 (ii) in clause (ii), by inserting “and
16 alignment” after “the timeliness” each
17 place it appears; and

18 (iii) by adding at the end the fol-
19 lowing new clauses:

20 “(iii) The Office shall ensure that, with respect to a
21 combination product, a designated person or persons in
22 the primary agency center is the primary point or points
23 of contact for the sponsor of such combination product.
24 The Office shall also coordinate communications to and
25 from any consulting center involved in such premarket re-

1 view, if requested by such primary agency center or any
2 such consulting center. Agency communications and com-
3 mitments, to the extent consistent with other provisions
4 of law and the requirements of all affected agency centers,
5 from the primary agency center shall be considered as
6 communication from the Secretary on behalf of all agency
7 centers involved in the review.

8 “(iv) The Office shall, with respect to the premarket
9 review of a combination product—

10 “(I) ensure that any meeting between the Sec-
11 retary and the sponsor of such product is attended
12 by each agency center involved in the review, as ap-
13 propriate;

14 “(II) ensure that each consulting agency center
15 has completed its premarket review and provided the
16 results of such review to the primary agency center
17 in a timely manner; and

18 “(III) ensure that each consulting center fol-
19 lows the guidance described in clause (vi) and ad-
20 vises, as appropriate, on other relevant regulations,
21 guidances, and policies.

22 “(v) In seeking agency action with respect to a com-
23 bination product, the sponsor of such product—

24 “(I) shall identify the product as a combination
25 product; and

1 “(II) may request in writing the participation of
2 representatives of the Office in meetings related to
3 such combination product, or to have the Office oth-
4 erwise engage on such regulatory matters concerning
5 the combination product.

6 “(vi) Not later than 4 years after the date of enact-
7 ment of the 21st Century Cures Act, and after a public
8 comment period of not less than 60 calendar days, the
9 Secretary shall issue a final guidance that describes—

10 “(I) the structured process for managing pre-
11 submission interactions with sponsors developing
12 combination products;

13 “(II) the best practices for ensuring that the
14 feedback in such pre-submission interactions rep-
15 resents the Agency’s best advice based on the infor-
16 mation provided during such pre-submission inter-
17 actions;

18 “(III) the information that is required to be
19 submitted with a meeting request under paragraph
20 (2), how such meetings relate to other types of meet-
21 ings in the Food and Drug Administration, and the
22 form and content of any agreement reached through
23 a meeting under such paragraph (2);”;

24 (B) in subparagraph (G)—

1 (i) in the matter preceding clause (i),
2 by inserting “(except with respect to clause
3 (iv), beginning not later than one year
4 after the date of the enactment of the 21st
5 Century Cures Act)” after “enactment of
6 this paragraph”;

7 (ii) in clause (ii), by striking “and” at
8 the end;

9 (iii) in clause (iii), by striking the pe-
10 riod at the end and inserting “; and”; and

11 (iv) by adding at the end the following
12 new clause:

13 “(iv) identifying the percentage of combination
14 products for which a dispute resolution, with respect
15 to premarket review, was requested by the combina-
16 tion product’s sponsor.”; and

17 (6) in paragraph (9) (as redesignated by para-
18 graph (3))—

19 (A) in subparagraph (C)—

20 (i) in clause (i), by striking the
21 comma at the end and inserting a semi-
22 colon;

23 (ii) in clause (ii), by striking “, and”
24 at the end and inserting a semicolon;

1 (iii) in clause (iii), by striking the pe-
2 riod at the end and inserting “; and”;

3 (iv) by adding at the end the fol-
4 lowing:

5 “(iv) de novo classification under sec-
6 tion 513(a)(1).”; and

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

8 “(D) The terms ‘premarket review’ and ‘re-
9 views’ include all activities of the Food and Drug
10 Administration conducted prior to approval or clear-
11 ance of an application, notification, or request for
12 classification submitted under section 505, 510(k),
13 513(f)(2), 515, or 520 of this Act or under section
14 351 of the Public Health Service Act, including with
15 respect to investigational use of the product.”.

16 (b) INFORMATION FOR APPROVAL OF COMBINATION
17 PRODUCTS.—Section 520(h)(4) of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 360j(h)(4)) is amend-
19 ed—

20 (1) in subparagraph (A), by striking “Any in-
21 formation” and inserting “Subject to subparagraph
22 (C), any information”; and

23 (2) by adding at the end the following new sub-
24 paragraph:

1 “(C) No information contained in an application for
2 premarket approval filed with the Secretary pursuant to
3 section 515(c) may be used to approve or clear any appli-
4 cation submitted under section 515 or 510(k) or to classify
5 a product under section 513(f)(2) for a combination prod-
6 uct containing as a constituent part an approved drug (as
7 defined in section 503(g)(5)(B)) unless—

8 “(i) the application includes the certification or
9 statement referenced in section 503(g)(5)(A);

10 “(ii) the applicant provides notice as described
11 in section 503(g)(5)(A); and

12 “(iii) the Secretary’s approval of such applica-
13 tion is subject to the provisions in section
14 503(g)(5)(C).”.

15 (c) VARIATIONS FROM CGMP STREAMLINED AP-
16 PROACH.—Not later than 18 months after the date of en-
17 actment of this Act, the Secretary of Health and Human
18 Services (referred to in this subsection as the “Secretary”)
19 shall identify types of combination products and manufac-
20 turing processes with respect to which the Secretary pro-
21 poses that good manufacturing processes may be adopted
22 that vary from the requirements set forth in section 4.4
23 of title 21, Code of Federal Regulations (or any successor
24 regulations) or that the Secretary proposes can satisfy the
25 requirements in section 4.4 through alternative or stream-

1 lined mechanisms. The Secretary shall identify such types,
2 variations from such requirements, and such mechanisms,
3 in a proposed list published in the Federal Register. After
4 a public comment period regarding the appropriate good
5 manufacturing practices for such types, the Secretary
6 shall publish a final list in the Federal Register, notwith-
7 standing section 553 of title 5, United States Code. The
8 Secretary shall evaluate such types, variations, and mech-
9 anisms using a risk-based approach. The Secretary shall
10 periodically review such final list.

11 **Subtitle E—Antimicrobial**
12 **Innovation and Stewardship**

13 **SEC. 3041. ANTIMICROBIAL RESISTANCE MONITORING.**

14 (a) IN GENERAL.—Section 319E of the Public
15 Health Service Act (42 U.S.C. 247d–5) is amended—

16 (1) by redesignating subsections (f) and (g) as
17 subsections (l) and (m), respectively; and

18 (2) by inserting after subsection (e), the fol-
19 lowing:

20 “(f) MONITORING AT FEDERAL HEALTH CARE FA-
21 CILITIES.—The Secretary shall encourage reporting on ag-
22 gregate antimicrobial drug use and antimicrobial resist-
23 ance to antimicrobial drugs and the implementation of
24 antimicrobial stewardship programs by health care facili-
25 ties of the Department of Defense, the Department of Vet-

1 erans Affairs, and the Indian Health Service and shall
2 provide technical assistance to the Secretary of Defense
3 and the Secretary of Veterans Affairs, as appropriate and
4 upon request.

5 “(g) REPORT ON ANTIMICROBIAL RESISTANCE IN
6 HUMANS AND USE OF ANTIMICROBIAL DRUGS.—Not
7 later than 1 year after the date of enactment of the 21st
8 Century Cures Act, and annually thereafter, the Secretary
9 shall prepare and make publicly available data and infor-
10 mation concerning—

11 “(1) aggregate national and regional trends of
12 antimicrobial resistance in humans to antimicrobial
13 drugs, including such drugs approved under section
14 506(h) of the Federal Food, Drug, and Cosmetic
15 Act;

16 “(2) antimicrobial stewardship, which may in-
17 clude summaries of State efforts to address anti-
18 microbial resistance in humans to antimicrobial
19 drugs and antimicrobial stewardship; and

20 “(3) coordination between the Director of the
21 Centers for Disease Control and Prevention and the
22 Commissioner of Food and Drugs with respect to
23 the monitoring of—

24 “(A) any applicable resistance under para-
25 graph (1); and

1 “(B) drugs approved under section 506(h)
2 of the Federal Food, Drug, and Cosmetic Act.

3 “(h) INFORMATION RELATED TO ANTIMICROBIAL
4 STEWARDSHIP PROGRAMS.—The Secretary shall, as ap-
5 propriate, disseminate guidance, educational materials, or
6 other appropriate materials related to the development
7 and implementation of evidence-based antimicrobial stew-
8 ardsHIP programs or practices at health care facilities,
9 such as nursing homes and other long-term care facilities,
10 ambulatory surgical centers, dialysis centers, outpatient
11 clinics, and hospitals, including community and rural hos-
12 pitals.

13 “(i) SUPPORTING STATE-BASED ACTIVITIES TO
14 COMBAT ANTIMICROBIAL RESISTANCE.—The Secretary
15 shall continue to work with State and local public health
16 departments on statewide or regional programs related to
17 antimicrobial resistance. Such efforts may include activi-
18 ties to related to—

19 “(1) identifying patterns of bacterial and fungal
20 resistance in humans to antimicrobial drugs;

21 “(2) preventing the spread of bacterial and
22 fungal infections that are resistant to antimicrobial
23 drugs; and

24 “(3) promoting antimicrobial stewardship.

1 “(j) ANTIMICROBIAL RESISTANCE AND STEWARD-
2 SHIP ACTIVITIES.—

3 “(1) IN GENERAL.—For the purposes of sup-
4 porting stewardship activities, examining changes in
5 antimicrobial resistance, and evaluating the effec-
6 tiveness of section 506(h) of the Federal Food,
7 Drug, and Cosmetic Act, the Secretary shall—

8 “(A) provide a mechanism for facilities to
9 report data related to their antimicrobial stew-
10 ardship activities (including analyzing the out-
11 comes of such activities); and

12 “(B) evaluate—

13 “(i) antimicrobial resistance data
14 using a standardized approach; and

15 “(ii) trends in the utilization of drugs
16 approved under such section 506(h) with
17 respect to patient populations.

18 “(2) USE OF SYSTEMS.—The Secretary shall
19 use available systems, including the National
20 Healthcare Safety Network or other systems identi-
21 fied by the Secretary, to fulfill the requirements or
22 conduct activities under this section.

23 “(k) ANTIMICROBIAL.—For purposes of subsections
24 (f) through (j), the term ‘antimicrobial’ includes any anti-
25 bacterial or antifungal drugs, and may include drugs that

1 eliminate or inhibit the growth of other microorganisms,
2 as appropriate.”.

3 (b) AVAILABILITY OF DATA.—The Secretary shall
4 make the data collected pursuant to this subsection public.
5 Nothing in this subsection shall be construed as author-
6 izing the Secretary to disclose any information that is a
7 trade secret or confidential information subject to section
8 552(b)(4) of title 5, United States Code, or section 1905
9 of title 18, United States Code.

10 **SEC. 3042. LIMITED POPULATION PATHWAY.**

11 Section 506 of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 356), as amended by section 3033, is fur-
13 ther amended by adding at the end the following:

14 “(h) LIMITED POPULATION PATHWAY FOR ANTI-
15 BACTERIAL AND ANTIFUNGAL DRUGS.—

16 “(1) IN GENERAL.—The Secretary may approve
17 an antibacterial or antifungal drug, alone or in com-
18 bination with one or more other drugs, as a limited
19 population drug pursuant to this subsection only
20 if—

21 “(A) the drug is intended to treat a serious
22 or life-threatening infection in a limited popu-
23 lation of patients with unmet needs;

24 “(B) the standards for approval under sec-
25 tion 505(c) and (d), or the standards for licen-

1 sure under section 351 of the Public Health
2 Service Act, as applicable, are met; and

3 “(C) the Secretary receives a written re-
4 quest from the sponsor to approve the drug as
5 a limited population drug pursuant to this sub-
6 section.

7 “(2) BENEFIT-RISK CONSIDERATION.—The Sec-
8 retary’s determination of safety and effectiveness of
9 an antibacterial or antifungal drug shall reflect the
10 benefit-risk profile of such drug in the intended lim-
11 ited population, taking into account the severity, rar-
12 ity, or prevalence of the infection the drug is in-
13 tended to treat and the availability or lack of alter-
14 native treatment in such limited population. Such
15 drug may be approved under this subsection not-
16 withstanding a lack of evidence to fully establish a
17 favorable benefit-risk profile in a population that is
18 broader than the intended limited population.

19 “(3) ADDITIONAL REQUIREMENTS.—A drug ap-
20 proved under this subsection shall be subject to the
21 following requirements, in addition to any other ap-
22 plicable requirements of this Act:

23 “(A) LABELING.—To indicate that the
24 safety and effectiveness of a drug approved

1 under this subsection has been demonstrated
2 only with respect to a limited population—

3 “(i) all labeling and advertising of an
4 antibacterial or antifungal drug approved
5 under this subsection shall contain the
6 statement ‘Limited Population’ in a promi-
7 nent manner and adjacent to, and not
8 more prominent than—

9 “(I) the proprietary name of such
10 drug, if any; or

11 “(II) if there is no proprietary
12 name, the established name of the
13 drug, if any, as defined in section
14 503(e)(3), or, in the case of a drug
15 that is a biological product, the proper
16 name, as defined by regulation; and

17 “(ii) the prescribing information for
18 the drug required by section 201.57 of title
19 21, Code of Federal Regulations (or any
20 successor regulation) shall also include the
21 following statement: ‘This drug is indicated
22 for use in a limited and specific population
23 of patients.’.

24 “(B) PROMOTIONAL MATERIAL.—The
25 sponsor of an antibacterial or antifungal drug

1 subject to this subsection shall submit to the
2 Secretary copies of all promotional materials re-
3 lated to such drug at least 30 calendar days
4 prior to dissemination of the materials.

5 “(4) OTHER PROGRAMS.—A sponsor of a drug
6 that seeks approval of a drug under this subsection
7 may also seek designation or approval, as applicable,
8 of such drug under other applicable sections or sub-
9 sections of this Act of the Public Health Service Act.

10 “(5) GUIDANCE.—Not later than 18 months
11 after the date of enactment of the 21st Century
12 Cures Act, the Secretary shall issue draft guidance
13 describing criteria, processes, and other general con-
14 siderations for demonstrating the safety and effec-
15 tiveness of limited population antibacterial and
16 antifungal drugs. The Secretary shall publish final
17 guidance within 18 months of the close of the public
18 comment period on such draft guidance. The Sec-
19 retary may approve antibacterial and antifungal
20 drugs under this subsection prior to issuing guid-
21 ance under this paragraph.

22 “(6) ADVICE.—The Secretary shall provide
23 prompt advice to the sponsor of a drug for which the
24 sponsor seeks approval under this subsection to en-
25 able the sponsor to plan a development program to

1 obtain the necessary data for such approval, and to
2 conduct any additional studies that would be re-
3 quired to gain approval of such drug for use in a
4 broader population.

5 “(7) TERMINATION OF LIMITATIONS.—If, after
6 approval of a drug under this subsection, the Sec-
7 retary approves a broader indication for such drug
8 under section 505(b) or section 351(a) of the Public
9 Health Service Act, the Secretary may remove any
10 postmarketing conditions, including requirements
11 with respect to labeling and review of promotional
12 materials under paragraph (3), applicable to the ap-
13 proval of the drug under this subsection.

14 “(8) RULES OF CONSTRUCTION.—Nothing in
15 this subsection shall be construed to alter the au-
16 thority of the Secretary to approve drugs pursuant
17 to this Act or section 351 of the Public Health Serv-
18 ice Act, including the standards of evidence and ap-
19 plicable conditions for approval under such Acts, the
20 standards of approval of a drug under such Acts, or
21 to alter the authority of the Secretary to monitor
22 drugs pursuant to such Acts.

23 “(9) REPORTING AND ACCOUNTABILITY.—

24 “(A) BIENNIAL REPORTING.—The Sec-
25 retary shall report to Congress not less often

1 than once every 2 years on the number of re-
2 quests for approval, and the number of approv-
3 als, of an antibacterial or antifungal drug under
4 this subsection.

5 “(B) GAO REPORT.—Not later than De-
6 cember 2021, the Comptroller General of the
7 United States shall submit to the Committee on
8 Energy and Commerce of the House of Rep-
9 resentatives and the Committee on Health,
10 Education, Labor and Pensions of the Senate a
11 report on the coordination of activities required
12 under section 319E of the Public Health Serv-
13 ice Act. Such report shall include a review of
14 such activities, and the extent to which the use
15 of the pathway established under this sub-
16 section has streamlined premarket approval for
17 antibacterial or antifungal drugs for limited
18 populations, if such pathway has functioned as
19 intended, if such pathway has helped provide
20 for safe and effective treatment for patients, if
21 such premarket approval would be appropriate
22 for other categories of drugs, and if the au-
23 thorities under this subsection have affected
24 antibacterial or antifungal resistance.”.

1 **SEC. 3043. PRESCRIBING AUTHORITY.**

2 Nothing in this subtitle, or an amendment made by
3 this subtitle, shall be construed to restrict the prescribing
4 of antimicrobial drugs or other products, including drugs
5 approved under subsection (h) of section 506 of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 356) (as
7 added by section 3042), by health care professionals, or
8 to limit the practice of health care.

9 **SEC. 3044. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**
10 **FOR MICROORGANISMS; ANTIMICROBIAL**
11 **SUSCEPTIBILITY TESTING DEVICES.**

12 (a) IN GENERAL.—Subchapter A of chapter V of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
14 et seq.) is amended by inserting after section 511 the fol-
15 lowing:

16 **“SEC. 511A. SUSCEPTIBILITY TEST INTERPRETIVE CRI-**
17 **TERIA FOR MICROORGANISMS.**

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

19 “(1) PURPOSE.—The purpose of this section is
20 to clarify the Secretary’s authority to—

21 “(A) efficiently update susceptibility test
22 interpretive criteria for antimicrobial drugs
23 when necessary for public health, due to, among
24 other things, the constant evolution of micro-
25 organisms that leads to the development of re-
26 sistance to drugs that have been effective in de-

1 creasing morbidity and mortality for patients,
2 which warrants unique management of anti-
3 microbial drugs that is inappropriate for most
4 other drugs in order to delay or prevent the de-
5 velopment of further resistance to existing
6 therapies;

7 “(B) provide for public notice of the avail-
8 ability of recognized interpretive criteria and in-
9 terpretive criteria standards; and

10 “(C) clear under section 510(k), classify
11 under section 513(f)(2), or approve under sec-
12 tion 515, antimicrobial susceptibility testing de-
13 vices utilizing updated, recognized susceptibility
14 test interpretive criteria to characterize the in
15 vitro susceptibility of particular bacteria, fungi,
16 or other microorganisms, as applicable, to anti-
17 microbial drugs.

18 “(2) IDENTIFICATION OF CRITERIA.—The Sec-
19 retary shall identify appropriate susceptibility test
20 interpretive criteria with respect to antimicrobial
21 drugs—

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

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

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

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

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

14 “(B) the relationship of susceptibility test
15 interpretive criteria to morbidity and mortality
16 associated with the disease or condition for
17 which such drug is used; and

18 “(C) such other evidence and information
19 as the Secretary considers appropriate.

20 “(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA
21 WEBSITE.—

22 “(1) IN GENERAL.—Not later than 1 year after
23 the date of the enactment of the 21st Century Cures
24 Act, the Secretary shall establish, and maintain
25 thereafter, on the website of the Food and Drug Ad-

1 ministration, a dedicated website that contains a list
2 of any appropriate new or updated susceptibility test
3 interpretive criteria standards and interpretive cri-
4 teria in accordance with paragraph (2) (referred to
5 in this section as the ‘Interpretive Criteria Website’).

6 “(2) LISTING OF SUSCEPTIBILITY TEST INTER-
7 PRETIVE CRITERIA STANDARDS AND INTERPRETIVE
8 CRITERIA.—

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

13 “(i) established by a nationally or
14 internationally recognized standard devel-
15 opment organization that—

16 “(I) establishes and maintains
17 procedures to address potential con-
18 flicts of interest and ensure trans-
19 parent decisionmaking;

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

1 “(III) permits its standards to be
2 made publicly available, through the
3 National Library of Medicine or an-
4 other similar source acceptable to the
5 Secretary; and

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

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

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

19 “(ii) the Secretary withdraws under
20 subsection (c)(1)(A) recognition of a stand-
21 ard, in whole or in part, otherwise applica-
22 ble to such a drug;

23 “(iii) the Secretary approves an appli-
24 cation under section 505 of this Act or sec-
25 tion 351 of the Public Health Service Act,

1 as applicable, with respect to marketing of
2 such a drug for which there are no rel-
3 evant interpretive criteria included in a
4 standard recognized by the Secretary
5 under subsection (c); or

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

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

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

17 “(C) REQUIRED STATEMENTS.—The Inter-
18 pretive Criteria Website shall include state-
19 ments conveying—

20 “(i) that the website provides informa-
21 tion about the in vitro susceptibility of bac-
22 teria, fungi, or other microorganisms, as
23 applicable to a certain drug (or drugs);

24 “(ii) that—

1 “(I) the safety and efficacy of
2 such drugs in treating clinical infec-
3 tions due to such bacteria, fungi, or
4 other microorganisms, as applicable,
5 may or may not have been established
6 in adequate and well-controlled clin-
7 ical trials in order for the suscepti-
8 bility information described in clause
9 (i) to be included on the website; and

10 “(II) the clinical significance of
11 such susceptibility information in such
12 instances is unknown;

13 “(iii) that the approved product label-
14 ing for specific drugs provides the uses for
15 which the Secretary has approved the
16 product; and

17 “(iv) any other information that the
18 Secretary determines appropriate to ade-
19 quately convey the meaning of the data
20 supporting the recognition or listing of sus-
21 ceptibility test interpretive criteria stand-
22 ards or susceptibility test interpretive cri-
23 teria included on the website.

24 “(3) NOTICE.—Not later than the date on
25 which the Interpretive Criteria Website is estab-

1 lished, the Secretary shall publish a notice of that
2 establishment in the Federal Register.

3 “(4) INAPPLICABILITY OF MISBRANDING PROVI-
4 SION.—The inclusion in the approved labeling of an
5 antimicrobial drug of a reference or hyperlink to the
6 Interpretive Criteria Website, in and of itself, shall
7 not cause the drug to be misbranded in violation of
8 section 502.

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

15 “(c) RECOGNITION OF SUSCEPTIBILITY TEST INTER-
16 PRETIVE CRITERIA.—

17 “(1) EVALUATION AND PUBLICATION.—

18 “(A) IN GENERAL.—Beginning on the date
19 of the establishment of the Interpretive Criteria
20 Website, and at least every 6 months thereafter,
21 the Secretary shall—

22 “(i) evaluate any appropriate new or
23 updated susceptibility test interpretive cri-
24 teria standards established by a nationally
25 or internationally recognized standard de-

1 velopment organization described in sub-
2 section (b)(2)(A)(i); and

3 “ (ii) publish on the public website of
4 the Food and Drug Administration a no-
5 tice—

6 “ (I) withdrawing recognition of
7 any different susceptibility test inter-
8 pretive criteria standard, in whole or
9 in part;

10 “ (II) recognizing the new or up-
11 dated standards;

12 “ (III) recognizing one or more
13 parts of the new or updated interpre-
14 tive criteria specified in such a stand-
15 ard and declining to recognize the re-
16 mainder of such standard; and

17 “ (IV) making any necessary up-
18 dates to the lists under subsection
19 (b)(2).

20 “ (B) UPON APPROVAL OF A DRUG.—Upon
21 the approval of an initial or supplemental appli-
22 cation for an antimicrobial drug under section
23 505 of this Act or section 351 of the Public
24 Health Service Act, as applicable, where such
25 approval is based on susceptibility test interpre-

1 tive criteria which differ from those contained
2 in a standard recognized, or from those other-
3 wise listed, by the Secretary pursuant to this
4 subsection, or for which there are no relevant
5 interpretive criteria standards recognized, or in-
6 terpretive criteria otherwise listed, by the Sec-
7 retary pursuant to this subsection, the Sec-
8 retary shall update the lists under subpara-
9 graphs (A) and (B) of subsection (b)(2) to in-
10 clude the susceptibility test interpretive criteria
11 upon which such approval was based.

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

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

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

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

4 “(D) such other information or factors as
5 the Secretary determines appropriate.

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

15 “(A) recognized by the Secretary under
16 this subsection; or

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

19 “(4) RELATION TO SECTION 514(c).—Any sus-
20 ceptibility test interpretive standard recognized
21 under this subsection or any criteria otherwise listed
22 under subsection (b)(2)(B) shall be deemed to be
23 recognized as a standard by the Secretary under sec-
24 tion 514(c)(1).

1 “(5) VOLUNTARY USE OF INTERPRETIVE CRI-
2 TERIA.—Nothing in this section prohibits a person
3 from seeking approval or clearance of a drug or de-
4 vice, or changes to the drug or the device, on the
5 basis of susceptibility test interpretive criteria which
6 differ from those contained in a standard recognized,
7 or from those otherwise listed, by the Secretary pur-
8 suant to subsection (b)(2).

9 “(d) ANTIMICROBIAL DRUG LABELING.—

10 “(1) DRUGS MARKETED PRIOR TO ESTABLISH-
11 MENT OF INTERPRETIVE CRITERIA WEBSITE.—

12 “(A) IN GENERAL.—With respect to an
13 antimicrobial drug lawfully introduced or deliv-
14 ered for introduction into interstate commerce
15 for commercial distribution before the establish-
16 ment of the Interpretive Criteria Website, a
17 holder of an approved application under section
18 505 of this Act or section 351 of the Public
19 Health Service Act, as applicable, for each such
20 drug, not later than 1 year after establishment
21 of the Interpretive Criteria Website described in
22 subsection (b)(1), shall remove susceptibility
23 test interpretive criteria, if any, and related in-
24 formation from the approved drug labeling and

1 replace it with a reference to the Interpretive
2 Criteria Website.

3 “(B) LABELING CHANGES.—The labeling
4 changes required by this section shall be consid-
5 ered a minor change under section 314.70 of
6 title 21, Code of Federal Regulations (or any
7 successor regulations) that may be implemented
8 through documentation in the next applicable
9 annual report.

10 “(2) DRUGS MARKETED SUBSEQUENT TO ES-
11 TABLISHMENT OF INTERPRETIVE CRITERIA
12 WEBSITE.—With respect to antimicrobial drugs ap-
13 proved on or after the date of the establishment of
14 the Interpretive Criteria Website described in sub-
15 section (b)(1), the labeling for such a drug shall in-
16 clude, in lieu of susceptibility test interpretive cri-
17 teria and related information, a reference to such
18 Website.

19 “(e) SPECIAL CONDITION FOR MARKETING OF ANTI-
20 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

21 “(1) IN GENERAL.—Notwithstanding sections
22 501, 502, 505, 510, 513, and 515, if the conditions
23 specified in paragraph (2) are met (in addition to
24 other applicable provisions under this chapter) with
25 respect to an antimicrobial susceptibility testing de-

1 vice described in subsection (f)(1), the Secretary
2 may authorize the marketing of such device for a
3 use described in such subsection.

4 “(2) CONDITIONS APPLICABLE TO ANTI-
5 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

6 The conditions specified in this paragraph are the
7 following:

8 “(A) The device is used to make a deter-
9 mination of susceptibility using susceptibility
10 test interpretive criteria that are—

11 “(i) included in a standard recognized
12 by the Secretary under subsection (c); or

13 “(ii) otherwise listed on the Interpre-
14 tive Criteria Website under subsection
15 (b)(2).

16 “(B) The labeling of such device includes
17 statements conveying—

18 “(i) that the device provides informa-
19 tion about the in vitro susceptibility of bac-
20 teria, fungi, or other microorganisms, as
21 applicable to antimicrobial drugs;

22 “(ii) that—

23 “(I) the safety and efficacy of
24 such drugs in treating clinical infec-
25 tions due to such bacteria, fungi, or

1 other microorganisms, as applicable,
2 may or may not have been established
3 in adequate and well-controlled clin-
4 ical trials in order for the device to re-
5 port the susceptibility of such bac-
6 teria, fungi, or other microorganisms,
7 as applicable, to such drugs; and

8 “(II) the clinical significance of
9 such susceptibility information in
10 those instances is unknown;

11 “(iii) that the approved labeling for
12 drugs tested using such a device provides
13 the uses for which the Secretary has ap-
14 proved such drugs; and

15 “(iv) any other information the Sec-
16 retary determines appropriate to ade-
17 quately convey the meaning of the data
18 supporting the recognition or listing of sus-
19 ceptibility test interpretive criteria stand-
20 ards or susceptibility test interpretive cri-
21 teria described in subparagraph (A).

22 “(C) The antimicrobial susceptibility test-
23 ing device meets all other requirements to be
24 cleared under section 510(k), classified under

1 section 513(f)(2), or approved under section
2 515.

3 “(f) DEFINITIONS.—In this section:

4 “(1) The term ‘antimicrobial susceptibility test-
5 ing device’ means a device that utilizes susceptibility
6 test interpretive criteria to determine and report the
7 in vitro susceptibility of certain microorganisms to a
8 drug (or drugs).

9 “(2) The term ‘qualified infectious disease
10 product’ means a qualified infectious disease product
11 designated under section 505E(d).

12 “(3) The term ‘susceptibility test interpretive
13 criteria’ means—

14 “(A) one or more specific numerical values
15 which characterize the susceptibility of bacteria
16 or other microorganisms to the drug tested; and

17 “(B) related categorizations of such sus-
18 ceptibility, including categorization of the drug
19 as susceptible, intermediate, resistant, or such
20 other term as the Secretary determines appro-
21 priate.

22 “(4)(A) The term ‘antimicrobial drug’ means,
23 subject to subparagraph (B), a systemic anti-
24 bacterial or antifungal drug that—

1 “(i) is intended for human use in the treat-
2 ment of a disease or condition caused by a bac-
3 terium or fungus;

4 “(ii) may include a qualified infectious dis-
5 ease product designated under section 505E(d);
6 and

7 “(iii) is subject to section 503(b)(1).

8 “(B) If provided by the Secretary through regu-
9 lations, such term may include—

10 “(i) drugs other than systemic anti-
11 bacterial and antifungal drugs; and

12 “(ii) biological products (as such term is
13 defined in section 351 of the Public Health
14 Service Act) to the extent such products exhibit
15 antimicrobial activity.

16 “(5) The term ‘interpretive criteria standard’
17 means a compilation of susceptibility test interpre-
18 tive criteria developed by a standard development or-
19 ganization that meets the criteria set forth in sub-
20 section (b)(2)(A)(i).

21 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
22 tion shall be construed to—

23 “(1) alter the standards of evidence under sub-
24 section (c) or (d) of section 505 (including the sub-
25 stantial evidence standard under section 505(d)) or

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

3 “(2) with respect to clearing devices under sec-
4 tion 510(k), classifying devices under section
5 513(f)(2), or approving devices under section 515—

6 “(A) apply with respect to any drug, de-
7 vice, or biological product, in any context other
8 than an antimicrobial drug and an anti-
9 microbial susceptibility testing device that uses
10 susceptibility test interpretive criteria to charac-
11 terize and report the susceptibility of certain
12 bacteria, fungi, or other microorganisms, as ap-
13 plicable, to such drug to reflect patient mor-
14 bidity and mortality in accordance with this sec-
15 tion; or

16 “(B) unless specifically stated, have any ef-
17 fect on authorities provided under other sec-
18 tions of this Act, including any regulations
19 issued under such sections.”.

20 (b) CONFORMING AMENDMENTS.—

21 (1) REPEAL OF PRIOR RELATED AUTHORITY.—

22 Section 1111 of the Food and Drug Administration
23 Amendments Act of 2007 (42 U.S.C. 247d–5a), re-
24 lating to identification of clinically susceptible con-
25 centrations of antimicrobials, is repealed.

1 (2) ADDITION TO CATEGORIES OF MISBRANDED
2 DRUGS.—Section 502 of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 352) is amended by
4 adding at the end the following:

5 “(dd) If it is an antimicrobial drug, as defined in sec-
6 tion 511A(f), and its labeling fails to conform with the
7 requirements under section 511A(d).”.

8 (3) RECOGNITION OF INTERPRETIVE CRITERIA
9 STANDARD AS DEVICE STANDARD.—Section
10 514(c)(1)(A) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 360d(c)(1)(A)) is amended by
12 inserting after “the Secretary shall, by publication in
13 the Federal Register” the following: “(or, with re-
14 spect to a susceptibility test interpretive criteria
15 standard under section 511A, by posting on the In-
16 terpretive Criteria Website in accordance with such
17 section)”.

18 (c) REPORT TO CONGRESS.—Not later than 2 years
19 after the date of enactment of this Act, the Secretary of
20 Health and Human Services shall submit to the Com-
21 mittee on Health, Education, Labor, and Pensions of the
22 Senate and the Committee on Energy and Commerce of
23 the House of Representatives a report on the progress
24 made in implementing section 511A of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 360a), as added by
2 subsection (a).

3 (d) REQUESTS FOR UPDATES TO INTERPRETIVE CRI-
4 TERIA WEBSITE.—Chapter 35 of title 44, United States
5 Code, shall not apply to the collection of information from
6 interested parties regarding updating the lists established
7 under section 511A(b) of the Federal Food, Drug, and
8 Cosmetic Act and posted on the Interpretive Criteria
9 Website established under section 511A(c) of such Act.

10 **Subtitle F—Medical Device** 11 **Innovations**

12 **SEC. 3051. BREAKTHROUGH DEVICES.**

13 (a) IN GENERAL.—Chapter V of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
15 ed by inserting after section 515B, as added by section
16 3034(b), the following:

17 **“SEC. 515C. BREAKTHROUGH DEVICES.**

18 “(a) PURPOSE.—The purpose of this section is to en-
19 courage the Secretary, and provide the Secretary with suf-
20 ficient authority, to apply efficient and flexible approaches
21 to expedite the development of, and prioritize the Food
22 and Drug Administration’s review of, devices that rep-
23 resent breakthrough technologies.

24 “(b) ESTABLISHMENT OF PROGRAM.—The Secretary
25 shall establish a program to expedite the development of,

1 and provide for the priority review for, devices, as deter-
2 mined by the Secretary—

3 “(1) that provide for more effective treatment
4 or diagnosis of life-threatening or irreversibly debili-
5 tating human disease or conditions; and

6 “(2)(A) that represent breakthrough tech-
7 nologies;

8 “(B) for which no approved or cleared alter-
9 natives exist;

10 “(C) that offer significant advantages over ex-
11 isting approved or cleared alternatives, including the
12 potential, compared to existing approved alter-
13 natives, to reduce or eliminate the need for hos-
14 pitalization, improve patient quality of life, facilitate
15 patients’ ability to manage their own care (such as
16 through self-directed personal assistance), or estab-
17 lish long-term clinical efficiencies; or

18 “(D) the availability of which is in the best in-
19 terest of patients.

20 “(c) REQUEST FOR DESIGNATION.—A sponsor of a
21 device may request that the Secretary designate such de-
22 vice for expedited development and priority review under
23 this section. Any such request for designation may be
24 made at any time prior to the submission of an application

1 under section 515(c), a notification under section 510(k),
2 or a petition for classification under section 513(f)(2).

3 “(d) DESIGNATION PROCESS.—

4 “(1) IN GENERAL.—Not later than 60 calendar
5 days after the receipt of a request under subsection
6 (c), the Secretary shall determine whether the device
7 that is the subject of the request meets the criteria
8 described in subsection (b). If the Secretary deter-
9 mines that the device meets the criteria, the Sec-
10 retary shall designate the device for expedited devel-
11 opment and priority review.

12 “(2) REVIEW.—Review of a request under sub-
13 section (c) shall be undertaken by a team that is
14 composed of experienced staff and senior managers
15 of the Food and Drug Administration.

16 “(3) WITHDRAWAL.—The Secretary may not
17 withdraw a designation granted under this section
18 on the basis of the criteria under subsection (b) no
19 longer applying because of the subsequent clearance
20 or approval of another device that—

21 “(A) was designated under this section; or

22 “(B) was given priority review under sec-
23 tion 515(d)(5), as in effect prior to the date of
24 enactment of the 21st Century Cures Act.

1 “(e) EXPEDITED DEVELOPMENT AND PRIORITY RE-
2 VIEW.—

3 “(1) ACTIONS.—For purposes of expediting the
4 development and review of devices designated under
5 subsection (d) the Secretary shall—

6 “(A) assign a team of staff, including a
7 team leader with appropriate subject matter ex-
8 pertise and experience, for each device for
9 which a request is submitted under subsection
10 (c);

11 “(B) provide for oversight of the team by
12 senior agency personnel to facilitate the effi-
13 cient development of the device and the efficient
14 review of any submission described in sub-
15 section (c) for the device;

16 “(C) adopt an efficient process for timely
17 dispute resolution;

18 “(D) provide for interactive and timely
19 communication with the sponsor of the device
20 during the development program and review
21 process;

22 “(E) expedite the Secretary’s review of
23 manufacturing and quality systems compliance,
24 as applicable;

1 “(F) disclose to the sponsor, not less than
2 5 business days in advance, the topics of any
3 consultation the Secretary intends to undertake
4 with external experts or an advisory committee
5 concerning the sponsor’s device and provide the
6 sponsor the opportunity to recommend such ex-
7 ternal experts;

8 “(G) provide for advisory committee input,
9 as the Secretary determines appropriate (in-
10 cluding in response to the request of the spon-
11 sor) for applications submitted under section
12 515(c); and

13 “(H) assign staff to be available within a
14 reasonable time to address questions by institu-
15 tional review committees concerning the condi-
16 tions and clinical testing requirements applica-
17 ble to the investigational use of the device pur-
18 suant to an exemption under section 520(g).

19 “(2) ADDITIONAL ACTIONS.—In addition to the
20 actions described in paragraph (1), for purposes of
21 expediting the development and review of devices
22 designated under subsection (d), the Secretary, in
23 collaboration with the device sponsor, may, as appro-
24 priate—

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

3 “(B) take steps to ensure that the design
4 of clinical trials is as efficient and flexible as
5 practicable, when scientifically appropriate;

6 “(C) facilitate, when scientifically appro-
7 priate, expedited and efficient development and
8 review of the device through utilization of time-
9 ly postmarket data collection with regard to ap-
10 plication for approval under section 515(c); and

11 “(D) agree in writing to clinical protocols
12 that the Secretary will consider binding on the
13 Secretary and the sponsor, subject to—

14 “(i) changes to such protocols agreed
15 to in writing by the sponsor and the Sec-
16 retary; or

17 “(ii) a decision, made by the director
18 of the office responsible for reviewing the
19 device submission, that a substantial sci-
20 entific issue essential to determining the
21 safety or effectiveness of such device exists,
22 provided that such decision is in writing,
23 and is made only after the Secretary pro-
24 vides to the device sponsor or applicant an
25 opportunity for a meeting at which the di-

1 rector and the sponsor or applicant are
2 present and at which the director docu-
3 ments the substantial scientific issue.

4 “(f) PRIORITY REVIEW GUIDANCE.—

5 “(1) CONTENT.—Not later than 1 year after
6 the date of enactment of the 21st Century Cures
7 Act, the Secretary shall issue guidance on the imple-
8 mentation of this section. Such guidance shall—

9 “(A) set forth the process by which a per-
10 son may seek a designation under subsection
11 (d);

12 “(B) provide a template for requests under
13 subsection (c);

14 “(C) identify the criteria the Secretary will
15 use in evaluating a request for designation
16 under this section; and

17 “(D) identify the criteria and processes the
18 Secretary will use to assign a team of staff, in-
19 cluding team leaders, to review devices des-
20 ignated for expedited development and priority
21 review, including any training required for such
22 personnel to ensure effective and efficient re-
23 view.

1 “(2) PROCESS.—Prior to finalizing the guid-
2 ance under paragraph (1), the Secretary shall seek
3 public comment on a proposed guidance.

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

6 “(1) the criteria and standards for evaluating
7 an application pursuant to section 515(c), a report
8 and request for classification under section
9 513(f)(2), or a report under section 510(k), includ-
10 ing the recognition of valid scientific evidence as de-
11 scribed in section 513(a)(3)(B) and consideration
12 and application of the least burdensome means of
13 evaluating device effectiveness or demonstrating sub-
14 stantial equivalence between devices with differing
15 technological characteristics, as applicable;

16 “(2) the authority of the Secretary with respect
17 to clinical holds under section 520(g)(8)(A);

18 “(3) the authority of the Secretary to act on an
19 application pursuant to section 515(d) before com-
20 pletion of an establishment inspection, as the Sec-
21 retary determines appropriate; or

22 “(4) the authority of the Secretary with respect
23 to postmarket surveillance under sections 519(h)
24 and 522.”.

1 (b) DOCUMENTATION AND REVIEW OF SIGNIFICANT
2 DECISIONS.—Section 517A(a)(1) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)(1)) is
4 amended by inserting “a request for designation under
5 section 515C,” after “application under section 515,”.

6 (c) TERMINATION OF PREVIOUS PROGRAM.—

7 (1) IN GENERAL.—Section 515(d) of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C.
9 360e(d)) is amended—

10 (A) by striking paragraph (5); and

11 (B) by redesignating paragraph (6) as
12 paragraph (5).

13 (2) CONFORMING AMENDMENT.—Section
14 737(5) of the Federal Food, Drug, and Cosmetics
15 Act (21 U.S.C. 379i(5)) is amended by striking
16 “515(d)(6)” and inserting “515(d)(5)”.

17 (d) REPORT.—On January 1, 2019, the Secretary of
18 Health and Human Services shall issue a report to the
19 Committee on Health, Education, Labor, and Pensions of
20 the Senate and the Committee on Energy and Commerce
21 of the House of Representatives—

22 (1) on the program under section 515C of the
23 Federal Food, Drug, and Cosmetic Act, as added by
24 subsection (a), in bringing safe and effective devices

1 included in such program to patients as soon as possible;
2 and

3 (2) that includes recommendations, if any, to
4 strengthen the program to better meet patient device
5 needs in a manner as timely as possible.

6 **SEC. 3052. HUMANITARIAN DEVICE EXEMPTION.**

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

10 (1) in paragraph (1) by striking “fewer than
11 4,000” and inserting “not more than 8,000”;

12 (2) in paragraph (2)(A) by striking “fewer than
13 4,000” and inserting “not more than 8,000”; and

14 (3) in paragraph (6)(A)(ii), by striking “4,000”
15 and inserting “8,000”.

16 (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
17 Services, acting through the Commissioner of Food and
18 Drugs, shall publish a draft guidance that defines the criteria for establishing “probable benefit” as that term is
19 used in section 520(m)(2)(C) of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).
21
22
23

1 **SEC. 3053. RECOGNITION OF STANDARDS.**

2 (a) IN GENERAL.—Section 514(c) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) is
4 amended—

5 (1) in paragraph (1), by inserting after sub-
6 paragraph (B) the following new subparagraphs:

7 “(C)(i) Any person may submit a request for recogni-
8 tion under subparagraph (A) of all or part of an appro-
9 priate standard established by a nationally or internation-
10 ally recognized standard organization.

11 “(ii) Not later than 60 calendar days after the Sec-
12 retary receives such a request, the Secretary shall—

13 “(I) make a determination to recognize all,
14 part, or none of the standard that is the subject of
15 the request; and

16 “(II) issue to the person who submitted such
17 request a response in writing that states the Sec-
18 retary’s rationale for that determination, including
19 the scientific, technical, regulatory, or other basis for
20 such determination.

21 “(iii) The Secretary shall make a response issued
22 under clause (ii)(II) publicly available, in such a manner
23 as the Secretary determines appropriate.

24 “(iv) The Secretary shall take such actions as may
25 be necessary to implement all or part of a standard recog-

1 nized under clause (ii)(I), in accordance with subpara-
2 graph (A).

3 “(D) The Secretary shall make publicly available, in
4 such manner as the Secretary determines appropriate, the
5 rationale for recognition under subparagraph (A) of all,
6 part, or none of a standard, including the scientific, tech-
7 nical, regulatory, or other basis for the decision regarding
8 such recognition.”; and

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

10 “(4) The Secretary shall provide to all employees of
11 the Food and Drug Administration who review premarket
12 submissions for devices periodic training on the concept
13 and use of recognized standards for purposes of meeting
14 a premarket submission requirement or other applicable
15 requirement under this Act, including standards relevant
16 to an employee’s area of device review.”.

17 (b) GUIDANCE.—The Secretary of Health and
18 Human Services, acting through the Commissioner of
19 Food and Drugs, shall review and update, if necessary,
20 previously published guidance and standard operating pro-
21 cedures identifying the principles for recognizing stand-
22 ards, and for withdrawing the recognition of standards,
23 under section 514(c) of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 360d(c)), taking into account the
25 experience with and reliance on a standard by foreign reg-

1 ulatory authorities and the device industry, and whether
2 recognition of a standard will promote harmonization
3 among regulatory authorities in the regulation of devices.

4 **SEC. 3054. CERTAIN CLASS I AND CLASS II DEVICES.**

5 (a) CLASS I DEVICES.—Section 510(l) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is
7 amended—

8 (1) by striking “A report under subsection (k)”
9 and inserting “(1) A report under subsection (k)”;
10 and

11 (2) by adding at the end the following new
12 paragraph:

13 “(2) Not later than 120 calendar days after the date
14 of enactment of the 21st Century Cures Act and at least
15 once every 5 years thereafter, as the Secretary determines
16 appropriate, the Secretary shall identify, through publica-
17 tion in the Federal Register, any type of class I device
18 that the Secretary determines no longer requires a report
19 under subsection (k) to provide reasonable assurance of
20 safety and effectiveness. Upon such publication—

21 “(A) each type of class I device so identified
22 shall be exempt from the requirement for a report
23 under subsection (k); and

1 “(B) the classification regulation applicable to
2 each such type of device shall be deemed amended
3 to incorporate such exemption.”.

4 (b) CLASS II DEVICES.—Section 510(m) of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360(m))
6 is amended—

7 (1) by striking “(m)(1)” and all that follows
8 through “by the Secretary.” and inserting the fol-
9 lowing:

10 “(m)(1) The Secretary shall—

11 “(A) not later than 90 days after the date of
12 enactment of the 21st Century Cures Act and at
13 least once every 5 years thereafter, as the Secretary
14 determines appropriate—

15 “(i) publish in the Federal Register a no-
16 tice that contains a list of each type of class II
17 device that the Secretary determines no longer
18 requires a report under subsection (k) to pro-
19 vide reasonable assurance of safety and effec-
20 tiveness; and

21 “(ii) provide for a period of not less than
22 60 calendar days for public comment beginning
23 on the date of the publication of such notice;
24 and

1 “(B) not later than 210 calendar days after the
2 date of enactment of the 21st Century Cures Act,
3 publish in the Federal Register a list representing
4 the Secretary’s final determination with respect to
5 the devices contained in the list published under sub-
6 paragraph (A).”; and

7 (2) in paragraph (2)—

8 (A) by striking “1 day after the date of
9 publication of a list under this subsection,” and
10 inserting “1 calendar day after the date of pub-
11 lication of the final list under paragraph
12 (1)(B),”; and

13 (B) by striking “30-day period” and in-
14 serting “60-calendar-day period”; and

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

17 “(3) Upon the publication of the final list under para-
18 graph (1)(B)—

19 “(A) each type of class II device so listed shall
20 be exempt from the requirement for a report under
21 subsection (k); and

22 “(B) the classification regulation applicable to
23 each such type of device shall be deemed amended
24 to incorporate such exemption.”.

1 **SEC. 3055. CLASSIFICATION PANELS.**

2 (a) CLASSIFICATION PANELS.—Paragraph (5) of sec-
3 tion 513(b) of the Federal Food, Drug, and Cosmetic Act
4 (21 U.S.C. 360c(b)) is amended—

5 (1) by striking “(5)” and inserting “(5)(A)”;
6 and

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

8 “(B) When a device is specifically the subject of re-
9 view by a classification panel, the Secretary shall—

10 “(i) ensure that adequate expertise is rep-
11 resented on the classification panel to assess—

12 “(I) the disease or condition which the de-
13 vice is intended to cure, treat, mitigate, prevent,
14 or diagnose; and

15 “(II) the technology of the device; and

16 “(ii) provide an opportunity for the person
17 whose device is specifically the subject of panel re-
18 view to provide recommendations on the expertise
19 needed among the voting members of the panel.

20 “(C) For purposes of subparagraph (B)(i), the term
21 ‘adequate expertise’ means that the membership of the
22 classification panel includes—

23 “(i) two or more voting members, with a spe-
24 cialty or other expertise clinically relevant to the de-
25 vice under review; and

1 “(ii) at least one voting member who is knowl-
2 edgeable about the technology of the device.

3 “(D) The Secretary shall provide an annual oppor-
4 tunity for patients, representatives of patients, and spon-
5 sors of medical device submissions to provide rec-
6 ommendations for individuals with appropriate expertise
7 to fill voting member positions on classification panels.”.

8 (b) PANEL REVIEW PROCESS.—Section 513(b)(6) of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 360c(b)(6)) is amended—

11 (1) in subparagraph (A)(iii), by inserting before
12 the period at the end “, including, subject to the dis-
13 cretion of the panel chairperson, by designating a
14 representative who will be provided a time during
15 the panel meeting to address the panel for the pur-
16 pose of correcting misstatements of fact or providing
17 clarifying information, and permitting the person or
18 representative to call on experts within the person’s
19 organization to address such specific issues in the
20 time provided”; and

21 (2) by striking subparagraph (B) and inserting
22 the following new subparagraph:

23 “(B)(i) Any meeting of a classification panel with re-
24 spect to the review of a device shall—

1 “(I) provide adequate time for initial presen-
2 tations by the person whose device is specifically the
3 subject of such review and by the Secretary; and

4 “(II) encourage free and open participation by
5 all interested persons.

6 “(ii) Following the initial presentations described in
7 clause (i), the panel may—

8 “(I) pose questions to a designated representa-
9 tive described in subparagraph (A)(iii); and

10 “(II) consider the responses to such questions
11 in the panel’s review of the device.”.

12 **SEC. 3056. INSTITUTIONAL REVIEW BOARD FLEXIBILITY.**

13 Section 520 of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 360j) is amended—

15 (1) in subsection (g)(3)—

16 (A) in subparagraph (A)(i)—

17 (i) by striking “local”; and

18 (ii) by striking “which has been”; and

19 (B) in subparagraph (B), by striking “a
20 local institutional” and inserting “an institu-
21 tional”; and

22 (2) in subsection (m)(4)—

23 (A) by striking subparagraph (A) and in-
24 serting the following:

1 “(A) in facilities in which clinical testing of de-
2 vices is supervised by an institutional review com-
3 mittee established in accordance with the regulations
4 of the Secretary; and”;

5 (B) in subparagraph (B), by striking “a
6 local institutional” and inserting “an institu-
7 tional”; and

8 (C) in the matter following subparagraph
9 (B), by striking “local”.

10 **SEC. 3057. CLIA WAIVER IMPROVEMENTS.**

11 (a) DRAFT REVISED GUIDANCE.—Not later than 1
12 year after the date of the enactment of this Act, the Sec-
13 retary of Health and Human Services, acting through the
14 Commissioner of Food and Drugs, shall publish a draft
15 guidance that—

16 (1) revises “Section V. Demonstrating Insignifi-
17 cant Risk of an Erroneous Result – Accuracy” of
18 the guidance entitled “Recommendations for Clinical
19 Laboratory Improvement Amendments of 1988
20 (CLLA) Waiver Applications for Manufacturers of In
21 Vitro Diagnostic Devices” and dated January 30,
22 2008; and

23 (2) includes the appropriate use of comparable
24 performance between a waived user and a mod-

1 erately complex laboratory user to demonstrate accu-
2 racy.

3 (b) FINAL REVISED GUIDANCE.—The Secretary of
4 Health and Human Services, acting through the Commis-
5 sioner of Food and Drugs, shall finalize the draft guidance
6 published under subsection (a) not later than 1 year after
7 the comment period for such draft guidance closes.

8 **SEC. 3058. LEAST BURDENSOME DEVICE REVIEW.**

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

12 “(j) TRAINING AND OVERSIGHT OF LEAST BURDEN-
13 SOME REQUIREMENTS.—

14 “(1) The Secretary shall—

15 “(A) ensure that each employee of the
16 Food and Drug Administration who is involved
17 in the review of premarket submissions, includ-
18 ing supervisors, receives training regarding the
19 meaning and implementation of the least bur-
20 densome requirements under subsections
21 (a)(3)(D) and (i)(1)(D) of this section and sec-
22 tion 515(c)(5); and

23 “(B) periodically assess the implementa-
24 tion of the least burdensome requirements, in-
25 cluding the employee training under subpara-

1 graph (A), to ensure that the least burdensome
2 requirements are fully and consistently applied.

3 “(2) Not later than 18 months after the date
4 of enactment of the 21st Century Cures Act, the om-
5 budsman for any organizational unit of the Food
6 and Drug Administration responsible for the pre-
7 market review of devices shall—

8 “(A) conduct an audit of the training de-
9 scribed in paragraph (1)(A), including the effec-
10 tiveness of such training in implementing the
11 least burdensome requirements;

12 “(B) include in such audit interviews of
13 persons who are representatives of the device
14 industry regarding their experiences in the de-
15 vice premarket review process, including with
16 respect to the application of least burdensome
17 concepts to premarket review and decision-
18 making;

19 “(C) include in such audit a list of the
20 measurement tools the Secretary uses to assess
21 the implementation of the least burdensome re-
22 quirements, including under paragraph (1)(B)
23 and section 517A(a)(3), and may also provide
24 feedback on the effectiveness of such tools in

1 the implementation of the least burdensome re-
2 quirements;

3 “(D) summarize the findings of such audit
4 in a final audit report; and

5 “(E) within 30 calendar days of completion
6 of such final audit report, make such final audit
7 report available—

8 “(i) to the Committee on Health,
9 Education, Labor, and Pensions of the
10 Senate and the Committee on Energy and
11 Commerce of the House of Representa-
12 tives; and

13 “(ii) on the Internet website of the
14 Food and Drug Administration.”.

15 (b) **PREMARKET APPLICATIONS.**—Section 515(c) of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 360e(c)) is amended by adding at the end the following:

18 “(5)(A) In requesting additional information with re-
19 spect to an application under this section, the Secretary
20 shall consider the least burdensome appropriate means
21 necessary to demonstrate a reasonable assurance of device
22 safety and effectiveness.

23 “(B) For purposes of subparagraph (A), the term
24 ‘necessary’ means the minimum required information that
25 would support a determination by the Secretary that an

1 application provides a reasonable assurance of the safety
2 and effectiveness of the device.

3 “(C) For purposes of this paragraph, the Secretary
4 shall consider the role of postmarket information in deter-
5 mining the least burdensome means of demonstrating a
6 reasonable assurance of device safety and effectiveness.

7 “(D) Nothing in this paragraph alters the standards
8 for premarket approval of a device.”.

9 (c) RATIONALE FOR SIGNIFICANT DECISIONS RE-
10 GARDING DEVICES.—Section 517A(a) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)) is
12 amended by adding at the end the following:

13 “(3) APPLICATION OF LEAST BURDENSOME RE-
14 QUIREMENTS.—The substantive summary required
15 under this subsection shall include a brief statement
16 regarding how the least burdensome requirements
17 were considered and applied consistent with section
18 513(i)(1)(D), section 513(a)(3)(D), and section
19 515(c)(5), as applicable.”.

20 **SEC. 3059. CLEANING INSTRUCTIONS AND VALIDATION**
21 **DATA REQUIREMENT.**

22 (a) IN GENERAL.—Section 510 of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 360) is amended by
24 adding at the end the following:

25 “(q) REUSABLE MEDICAL DEVICES.—

1 “(1) IN GENERAL.—Not later than 180 days
2 after the date of enactment of the 21st Century
3 Cures Act, the Secretary shall identify and publish
4 a list of reusable device types for which reports
5 under subsection (k) are required to include—

6 “(A) instructions for use, which have been
7 validated in a manner specified by the Sec-
8 retary; and

9 “(B) validation data, the types of which
10 shall be specified by the Secretary;
11 regarding cleaning, disinfection, and sterilization,
12 and for which a substantial equivalence determina-
13 tion may be based.

14 “(2) REVISION OF LIST.—The Secretary shall
15 revise the list under paragraph (2), as the Secretary
16 determines appropriate, with notice in the Federal
17 Register.

18 “(3) CONTENT OF REPORTS.—Reports under
19 subsection (k) that are submitted after the publica-
20 tion of the list described in paragraph (1), for de-
21 vices or types of devices included on such list, shall
22 include such instructions for use and validation
23 data.”.

24 (b) DEVICE MODIFICATIONS.—The Secretary of
25 Health and Human Services, acting through the Commis-

1 sioner of Food and Drugs, shall issue final guidance re-
2 garding when a premarket notification under section
3 510(k) of the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 360(k)) is required to be submitted for a modifica-
5 tion or change to a legally marketed device. Such final
6 guidance shall be issued not later than 1 year after the
7 date on which the comment period closes for the draft
8 guidance on such subject.

9 **SEC. 3060. CLARIFYING MEDICAL SOFTWARE REGULATION.**

10 (a) IN GENERAL.—Section 520 of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by
12 adding at the end the following:

13 “(o) REGULATION OF MEDICAL AND CERTAIN DECI-
14 SIONS SUPPORT SOFTWARE.—

15 “(1) The term device, as defined in section
16 201(h), shall not include a software function that is
17 intended—

18 “(A) for administrative support of a health
19 care facility, including the processing and main-
20 tenance of financial records, claims or billing
21 information, appointment schedules, business
22 analytics, information about patient popu-
23 lations, admissions, practice and inventory man-
24 agement, analysis of historical claims data to
25 predict future utilization or cost-effectiveness,

1 determination of health benefit eligibility, popu-
2 lation health management, and laboratory
3 workflow;

4 “(B) for maintaining or encouraging a
5 healthy lifestyle and is unrelated to the diag-
6 nosis, cure, mitigation, prevention, or treatment
7 of a disease or condition;

8 “(C) to serve as electronic patient records,
9 including patient-provided information, to the
10 extent that such records are intended to trans-
11 fer, store, convert formats, or display the equiv-
12 alent of a paper medical chart, so long as—

13 “(i) such records were created, stored,
14 transferred, or reviewed by health care
15 professionals, or by individuals working
16 under supervision of such professionals;

17 “(ii) such records are part of health
18 information technology that is certified
19 under section 3001(c)(5) of the Public
20 Health Service Act; and

21 “(iii) such function is not intended to
22 interpret or analyze patient records, in-
23 cluding medical image data, for the pur-
24 pose of the diagnosis, cure, mitigation, pre-

1 vention, or treatment of a disease or condi-
2 tion;

3 “(D) for transferring, storing, converting
4 formats, or displaying clinical laboratory test or
5 other device data and results, findings by a
6 health care professional with respect to such
7 data and results, general information about
8 such findings, and general background informa-
9 tion about such laboratory test or other device,
10 unless such function is intended to interpret or
11 analyze clinical laboratory test or other device
12 data, results, and findings; or

13 “(E) unless the function is intended to ac-
14 quire, process, or analyze a medical image or a
15 signal from an in vitro diagnostic device or a
16 pattern or signal from a signal acquisition sys-
17 tem, for the purpose of—

18 “(i) displaying, analyzing, or printing
19 medical information about a patient or
20 other medical information (such as peer-re-
21 viewed clinical studies and clinical practice
22 guidelines);

23 “(ii) supporting or providing rec-
24 ommendations to a health care professional

1 about prevention, diagnosis, or treatment
2 of a disease or condition; and

3 “(iii) enabling such health care profes-
4 sional to independently review the basis for
5 such recommendations that such software
6 presents so that it is not the intent that
7 such health care professional rely primarily
8 on any of such recommendations to make
9 a clinical diagnosis or treatment decision
10 regarding an individual patient.

11 “(2) In the case of a product with multiple
12 functions that contains—

13 “(A) at least one software function that
14 meets the criteria under paragraph (1) or that
15 otherwise does not meet the definition of device
16 under section 201(h); and

17 “(B) at least one function that does not
18 meet the criteria under paragraph (1) and that
19 otherwise meets the definition of a device under
20 section 201(h),

21 the Secretary shall not regulate the software func-
22 tion of such product described in subparagraph (A)
23 as a device. Notwithstanding the preceding sentence,
24 when assessing the safety and effectiveness of the
25 device function or functions of such product de-

1 scribed in subparagraph (B), the Secretary may as-
2 sess the impact that the software function or func-
3 tions described in subparagraph (A) have on such
4 device function or functions.

5 “(3)(A) Notwithstanding paragraph (1), a soft-
6 ware function described in subparagraph (C), (D),
7 or (E) of paragraph (1) shall not be excluded from
8 the definition of device under section 201(h) if—

9 “(i) the Secretary makes a finding that use
10 of such software function would be reasonably
11 likely to have serious adverse health con-
12 sequences; and

13 “(ii) the software function has been identi-
14 fied in a final order issued by the Secretary
15 under subparagraph (B).

16 “(B) Subparagraph (A) shall apply only if the
17 Secretary—

18 “(i) publishes a notification and proposed
19 order in the Federal Register;

20 “(ii) includes in such notification the Sec-
21 retary’s finding, including the rationale and
22 identification of the evidence on which such
23 finding was based, as described in subpara-
24 graph (A)(i); and

1 “(iii) provides for a period of not less than
2 30 calendar days for public comment before
3 issuing a final order or withdrawing such pro-
4 posed order.

5 “(C) In making a finding under subparagraph
6 (A)(i) with respect to a software function, the Sec-
7 retary shall consider—

8 “(i) the likelihood and severity of patient
9 harm if the software function were to not per-
10 form as intended;

11 “(ii) the extent to which the software func-
12 tion is intended to support the clinical judgment
13 of a health care professional;

14 “(iii) whether there is a reasonable oppor-
15 tunity for a health care professional to review
16 the basis of the information or treatment rec-
17 ommendation provided by the software function;
18 and

19 “(iv) the intended user and user environ-
20 ment, such as whether a health care profes-
21 sional will use a software function of a type de-
22 scribed in subparagraph (E) of paragraph (1).

23 “(4) Nothing in this subsection shall be con-
24 strued as limiting the authority of the Secretary
25 to—

1 “(A) exercise enforcement discretion as to
2 any device subject to regulation under this Act;

3 “(B) regulate software used in the manu-
4 facture and transfusion of blood and blood com-
5 ponents to assist in the prevention of disease in
6 humans; or

7 “(C) regulate software as a device under
8 this Act if such software meets the criteria
9 under section 513(a)(1)(C).”.

10 (b) REPORTS.—The Secretary of Health and Human
11 Services (referred to in this subsection as the “Sec-
12 retary”), after consultation with agencies and offices of
13 the Department of Health and Human Services involved
14 in health information technology, shall publish a report,
15 not later than 2 years after the date of enactment of this
16 Act and every 2 years thereafter, that—

17 (1) includes input from outside experts, such as
18 representatives of patients, consumers, health care
19 providers, startup companies, health plans or other
20 third-party payers, venture capital investors, infor-
21 mation technology vendors, health information tech-
22 nology vendors, small businesses, purchasers, em-
23 ployers, and other stakeholders with relevant exper-
24 tise, as determined by the Secretary;

1 (2) examines information available to the Sec-
2 retary on any risks and benefits to health associated
3 with software functions described in section
4 520(o)(1) of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 360j) (as amended by subsection
6 (a)); and

7 (3) summarizes findings regarding the impact
8 of such software functions on patient safety, includ-
9 ing best practices to promote safety, education, and
10 competency related to such functions.

11 (c) CLASSIFICATION OF ACCESSORIES.—Section
12 513(b) of the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 360c(b)) is amended by adding at the end the fol-
14 lowing:

15 “(9) The Secretary shall classify an accessory under
16 this section based on the intended use of the accessory,
17 notwithstanding the classification of any other device with
18 which such accessory is intended to be used.”.

19 (d) CONFORMING AMENDMENT.—Section 201(h) of
20 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
21 321(h)) is amended by adding at the end the following:
22 “The term ‘device’ does not include software functions ex-
23 cluded pursuant to section 520(o).”.

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

3 **SEC. 3071. SILVIO O. CONTE SENIOR BIOMEDICAL RE-**
4 **SEARCH AND BIOMEDICAL PRODUCT ASSESS-**
5 **MENT SERVICE.**

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

9 (1) in the section heading, by inserting “**AND**
10 **BIOMEDICAL PRODUCT ASSESSMENT**” after
11 “**RESEARCH**”;

12 (2) in subsection (a)—

13 (A) in paragraph (1), by striking “Silvio
14 O. Conte Senior Biomedical Research Service,
15 not to exceed 500 members” and inserting
16 “Silvio O. Conte Senior Biomedical Research
17 and Biomedical Product Assessment Service (in
18 this section referred to as the ‘Service’), not to
19 exceed 2,000 members, the purpose of which is
20 to recruit and retain outstanding and qualified
21 scientific and technical experts in the fields of
22 biomedical research, clinical research evalua-
23 tion, and biomedical product assessment”;

24 (B) by amending paragraph (2) to read as
25 follows:

1 “(2) The authority established in paragraph (1) may
2 not be construed to require the Secretary to reduce the
3 number of employees serving under any other employment
4 system in order to offset the number of members serving
5 in the Service.”; and

6 (C) by adding at the end the following:

7 “(3) The Secretary shall assign experts under this
8 section to agencies within the Department of Health and
9 Human Services taking into account the need for the ex-
10 pertise of such expert.”;

11 (3) in subsection (b)—

12 (A) in the matter preceding paragraph (1),
13 by striking “or clinical research evaluation” and
14 inserting “, clinical research evaluation, or bio-
15 medical product assessment”; and

16 (B) in paragraph (1), by inserting “or a
17 doctoral or master’s level degree in engineering,
18 bioinformatics, or a related or emerging field,”
19 after the comma;

20 (4) in subsection (d)(2), by striking “and shall
21 not exceed the rate payable for level I of the Execu-
22 tive Schedule unless approved by the President
23 under section 5377(d)(2) of title 5, United States
24 Code” and inserting “and shall not exceed the
25 amount of annual compensation (excluding expenses)

1 specified in section 102 of title 3, United States
2 Code”;

3 (5) by striking subsection (e); and

4 (6) by redesignating subsections (f) and (g) as
5 subsections (e) and (f), respectively.

6 (b) GAO STUDY.—

7 (1) IN GENERAL.—The Comptroller General of
8 the United States shall conduct a study of the effec-
9 tiveness of the amendments to section 228 of the
10 Public Health Service Act (42 U.S.C. 237) made by
11 subsection (a) and the impact of such amendments,
12 if any, on all agencies or departments of the Depart-
13 ment of Health and Human Services, and, not later
14 than 4 years after the date of enactment of this Act,
15 shall submit a report based on such study to the
16 Committee on Health, Education, Labor, and Pen-
17 sions of the Senate and the Committee on Energy
18 and Commerce of the House of Representatives.

19 (2) CONTENT OF STUDY AND REPORT.—The
20 study and report under paragraph (1) shall include
21 an examination of the extent to which recruitment
22 and retention of outstanding and qualified scientific,
23 medical, or technical experts in the fields of bio-
24 medical research, clinical research evaluation, and
25 biomedical product assessment have improved or

1 otherwise have been affected by the amendments to
2 section 228 of the Public Health Service Act (42
3 U.S.C. 237) made by subsection (a), including by
4 determining, during the period between the date of
5 enactment of this Act and the completion of the
6 study—

7 (A) the total number of members recruited
8 and retained under the Senior Biomedical Re-
9 search and Biomedical Product Assessment
10 Service under such section 228, and the effect
11 of increasing the number of members eligible
12 for such Service;

13 (B) the number of members of such Senior
14 Biomedical Research and Biomedical Product
15 Assessment Service hired with a doctoral level
16 degree in biomedicine or a related field, and the
17 number of such members hired with a doctoral
18 or master's level degree in engineering,
19 bioinformatics, or a related or emerging field;
20 and

21 (C) the number of Senior Biomedical Re-
22 search and Biomedical Product Assessment
23 Service members that have been hired by each
24 agency or department of the Department of
25 Health and Human Services, and how such De-

1 partment assigns such members to each agency
2 or department.

3 **SEC. 3072. HIRING AUTHORITY FOR SCIENTIFIC, TECH-**
4 **NICAL, AND PROFESSIONAL PERSONNEL.**

5 (a) IN GENERAL.—The Federal Food, Drug, and
6 Cosmetic Act is amended by inserting after section 714
7 (21 U.S.C. 379d–3) the following:

8 **“SEC. 714A. HIRING AUTHORITY FOR SCIENTIFIC, TECH-**
9 **NICAL, AND PROFESSIONAL PERSONNEL.**

10 “(a) IN GENERAL.—The Secretary may, notwith-
11 standing title 5, United States Code, governing appoint-
12 ments in the competitive service, appoint outstanding and
13 qualified candidates to scientific, technical, or professional
14 positions that support the development, review, and regu-
15 lation of medical products. Such positions shall be within
16 the competitive service.

17 “(b) COMPENSATION.—

18 “(1) IN GENERAL.—Notwithstanding any other
19 provision of law, including any requirement with re-
20 spect to General Schedule pay rates under sub-
21 chapter III of chapter 53 of title 5, United States
22 Code, and consistent with the requirements of para-
23 graph (2), the Commissioner of Food and Drugs
24 may determine and fix—

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

3 “(B) for purposes of retaining qualified
4 employees, the annual rate of pay for any quali-
5 fied scientific, technical, or professional per-
6 sonnel appointed to a position described in sub-
7 section (a) before the date of enactment of the
8 21st Century Cures Act.

9 “(2) LIMITATION.—The annual rate of pay es-
10 tablished pursuant to paragraph (1) may not exceed
11 the amount of annual compensation (excluding ex-
12 penses) specified in section 102 of title 3, United
13 States Code.

14 “(3) PUBLIC AVAILABILITY.—The annual rate
15 of pay provided to an individual in accordance with
16 this section shall be publicly available information.

17 “(c) RULE OF CONSTRUCTION.—The authorities
18 under this section shall not be construed to affect the au-
19 thority provided under section 714.

20 “(d) REPORT ON WORKFORCE PLANNING.—

21 “(1) IN GENERAL.—Not later than 18 months
22 after the date of enactment of the 21st Century
23 Cures Act, the Secretary shall submit a report on
24 workforce planning to the Committee on Health,
25 Education, Labor, and Pensions of the Senate and

1 the Committee on Energy and Commerce of the
2 House of Representatives that examines the extent
3 to which the Food and Drug Administration has a
4 critical need for qualified individuals for scientific,
5 technical, or professional positions, including—

6 “(A) an analysis of the workforce needs at
7 the Food and Drug Administration and the
8 Secretary’s strategic plan for addressing such
9 needs, including through use of the authority
10 under this section; and

11 “(B) a recruitment and retention plan for
12 hiring qualified scientific, technical, and profes-
13 sional candidates, which may include the use
14 of—

15 “(i) recruitment through nongovern-
16 mental recruitment or placement agencies;

17 “(ii) recruitment through academic in-
18 stitutions;

19 “(iii) recruitment or hiring bonuses, if
20 applicable;

21 “(iv) recruitment using targeted direct
22 hiring authorities; and

23 “(v) retention of qualified scientific,
24 technical, and professional employees using

1 the authority under this section, or other
2 applicable authorities of the Secretary.

3 “(2) RECOMMENDATIONS.—The report under
4 paragraph (1) may include the recommendations of
5 the Commissioner of Food and Drugs that would
6 help the Food and Drug Administration to better re-
7 cruit and retain qualified individuals for scientific,
8 technical, or professional positions at the agency.”.

9 (b) GAO STUDY AND REPORT.—

10 (1) IN GENERAL.—The Comptroller General of
11 the United States shall conduct a study of the abil-
12 ity of the Food and Drug Administration to hire,
13 train, and retain qualified scientific, technical, and
14 professional staff, not including contractors, nec-
15 essary to fulfill the mission of the Food and Drug
16 Administration to protect and promote public health.
17 Not later than January 1, 2022, the Comptroller
18 General shall submit a report on such study to the
19 Committee on Health, Education, Labor, and Pen-
20 sions of the Senate and the Committee on Energy
21 and Commerce of the House of Representatives.

22 (2) CONTENTS OF STUDY.—The Comptroller
23 General shall include in the study and report under
24 paragraph (1)—

1 (A) information about the progress of the
2 Food and Drug Administration in recruiting
3 and retaining qualified scientific, technical, and
4 professional staff outstanding in the field of
5 biomedical research, clinical research evalua-
6 tion, and biomedical product assessment;

7 (B) the extent to which critical staffing
8 needs exist at the Food and Drug Administra-
9 tion, and barriers to hiring, training, and re-
10 taining qualified staff, if any;

11 (C) an examination of the recruitment and
12 retention strategies of the Food and Drug Ad-
13 ministration, including examining any strategic
14 workforce plan, focused on improving scientific,
15 technical, and professional staff recruitment
16 and retention; and

17 (D) recommendations for potential im-
18 provements that would address staffing needs
19 of the Food and Drug Administration.

20 **SEC. 3073. ESTABLISHMENT OF FOOD AND DRUG ADMINIS-**
21 **TRATION INTERCENTER INSTITUTES.**

22 (a) IN GENERAL.—Chapter X of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-
24 ed by adding at the end the following:

1 **“SEC. 1014. FOOD AND DRUG ADMINISTRATION INTER-**
2 **CENTER INSTITUTES.**

3 “(a) IN GENERAL.—The Secretary shall establish one
4 or more Intercenter Institutes within the Food and Drug
5 Administration (referred to in this section as an ‘Insti-
6 tute’) for a major disease area or areas. With respect to
7 the major disease area of focus of an Institute, such Insti-
8 tute shall develop and implement processes for coordina-
9 tion of activities, as applicable to such major disease area
10 or areas, among the Center for Drug Evaluation and Re-
11 search, the Center for Biologics Evaluation and Research,
12 and the Center for Devices and Radiological Health (for
13 the purposes of this section, referred to as the ‘Centers’).
14 Such activities may include—

15 “(1) coordination of staff from the Centers with
16 diverse product expertise in the diagnosis, cure, miti-
17 gation, treatment, or prevention of the specific dis-
18 eases relevant to the major disease area of focus of
19 the Institute;

20 “(2) streamlining, where appropriate, the re-
21 view of medical products to diagnose, cure, mitigate,
22 treat, or prevent the specific diseases relevant to the
23 major disease area of focus of the Institute, applying
24 relevant standards under sections 505, 510(k),
25 513(f)(2), and 515 of this Act and section 351 of

1 the Public Health Service Act, and other applicable
2 authorities;

3 “(3) promotion of scientific programs within
4 the Centers related to the major disease area of
5 focus of the Institute;

6 “(4) development of programs and enhancement
7 of strategies to recruit, train, and provide continuing
8 education opportunities for the personnel of the Cen-
9 ters with expertise related to the major disease area
10 of focus of the Institute;

11 “(5) enhancement of the interactions of the
12 Centers with patients, sponsors, and the external
13 biomedical community regarding the major disease
14 area of focus of the Institute; and

15 “(6) facilitation of the collaborative relation-
16 ships of the Centers with other agencies within the
17 Department of Health and Human Services regard-
18 ing the major disease area of focus of the Institute.

19 “(b) PUBLIC PROCESS.—The Secretary shall provide
20 a period for public comment during the time that each
21 Institute is being implemented.

22 “(c) TIMING.—The Secretary shall establish at least
23 one Institute under subsection (a) before the date that is
24 1 year after the date of enactment of the 21st Century
25 Cures Act.

1 “(d) **TERMINATION OF INSTITUTES.**—The Secretary
2 may terminate any Institute established pursuant to this
3 section if the Secretary determines such Institute is no
4 longer benefitting the public health. Not less than 60 days
5 prior to so terminating an Institute, the Secretary shall
6 provide public notice, including the rationale for such ter-
7 mination.”.

8 (b) **TECHNICAL AMENDMENTS.**—Chapter X of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391
10 et seq.) is amended—

11 (1) by redesignating section 1012 as section
12 1013; and

13 (2) by redesignating the second section 1011
14 (with respect to improving the training of State,
15 local, territorial, and tribal food safety officials), as
16 added by section 209(a) of the FDA Food Safety
17 Modernization Act (Public Law 111–353), as section
18 1012.

19 **SEC. 3074. SCIENTIFIC ENGAGEMENT.**

20 (a) **IN GENERAL.**—Scientific meetings that are at-
21 tended by scientific or medical personnel, or other profes-
22 sionals, of the Department of Health and Human Services
23 for whom attendance at such meeting is directly related
24 to their professional duties and the mission of the Depart-
25 ment—

1 (1) shall not be considered conferences for the
2 purposes of complying with Federal reporting re-
3 quirements contained in annual appropriations Acts
4 or in this section; and

5 (2) shall not be considered conferences for pur-
6 poses of a restriction contained in an annual appro-
7 priations Act, based on Office of Management and
8 Budget Memorandum M-12-12 or any other regula-
9 tion restricting travel to such meeting.

10 (b) LIMITATION.—Nothing in this section shall be
11 construed to exempt travel for scientific meetings from
12 Federal regulations relating to travel.

13 (c) REPORTS.—Not later than 90 days after the end
14 of the fiscal year, each operating division of the Depart-
15 ment of Health and Human Services shall prepare, and
16 post on an Internet website of the operating division, an
17 annual report on scientific meeting attendance and related
18 travel spending for each fiscal year. Such report shall in-
19 clude—

20 (1) general information concerning the scientific
21 meeting activities involved;

22 (2) information concerning the total amount ex-
23 pended for such meetings;

24 (3) a description of all such meetings that were
25 attended by scientific or medical personnel, or other

1 professionals, of each such operating division where
2 the total amount expended by the operating division
3 associated with each such meeting were in excess of
4 \$30,000, including—

5 (A) the total amount of meeting expenses
6 incurred by the operating division for such
7 meeting;

8 (B) the location of such meeting;

9 (C) the date of such meeting;

10 (D) a brief explanation on how such meet-
11 ing advanced the mission of the operating divi-
12 sion; and

13 (E) the total number of individuals whose
14 travel expenses or other scientific meeting ex-
15 penses were paid by the operating division; and

16 (4) with respect to any such meeting where the
17 total expenses to the operating division exceeded
18 \$150,000, a description of the exceptional cir-
19 cumstances that necessitated the expenditure of such
20 amounts.

21 **SEC. 3075. DRUG SURVEILLANCE.**

22 (a) NEW DRUGS.—Section 505(k)(5) of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)(5)), as
24 amended by section 2074, is further amended—

1 (1) in subparagraph (A), by striking “, bi-week-
2 ly screening” and inserting “screenings”;

3 (2) in subparagraph (B), as redesignated by
4 section 2074(1)(C), by striking the period at the end
5 and inserting “; and”; and

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

7 “(C) make available on the Internet website of
8 the Food and Drug Administration—

9 “(i) guidelines, developed with input from
10 experts qualified by scientific training and expe-
11 rience to evaluate the safety and effectiveness of
12 drugs, that detail best practices for drug safety
13 surveillance using the Adverse Event Reporting
14 System; and

15 “(ii) criteria for public posting of adverse
16 event signals.”.

17 (b) FAERS REVISION.—Section 505(r)(2)(D) of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 355(r)(2)(D)) is amended by striking “, by 18 months”
20 and all that follows through the semicolon at the end of
21 the subparagraph and inserting “and making publicly
22 available on the Internet website established under para-
23 graph (1) best practices for drug safety surveillance activi-
24 ties for drugs approved under this section or section 351
25 of the Public Health Service Act;”.

1 (c) RISK EVALUATION AND MITIGATION STRATE-
2 GIES.—Section 505–1(f)(5) of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 355–1(f)(5)) is amended—

4 (1) in the matter preceding subparagraph (A),
5 by inserting “or other advisory committee” after
6 “(or successor committee)”; and

7 (2) in subparagraph (B), by striking “at least
8 annually,” and inserting “periodically”.

9 **SEC. 3076. REAGAN-UDALL FOUNDATION FOR THE FOOD**
10 **AND DRUG ADMINISTRATION.**

11 (a) BOARD OF DIRECTORS.—

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

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

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

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

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

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

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

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

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

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

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

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

1 tablishing such positions, are members of
2 the Board.”.

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

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

15 **Subtitle H—Medical** 16 **Countermeasures Innovation**

17 **SEC. 3081. MEDICAL COUNTERMEASURE GUIDELINES.**

18 Section 319F–2 of the Public Health Service Act (42
19 U.S.C. 247d–6b) is amended—

20 (1) in subsection (a), by adding at the end the
21 following:

22 “(3) UTILIZATION GUIDELINES.—The Secretary
23 shall ensure timely and accurate recommended utili-
24 zation guidelines for qualified countermeasures (as
25 defined in section 319F–1), qualified pandemic and

1 epidemic products (as defined in section 319F–3),
2 and security countermeasures (as defined in sub-
3 section (c)), including for such products in the
4 stockpile.”; and

5 (2) in subsection (g)—

6 (A) by amending paragraph (4) to read as
7 follows:

8 “(4) REPORT ON SECURITY COUNTERMEASURE
9 PROCUREMENT.—Not later than March 1 of each
10 year in which the Secretary determines that the
11 amount of funds available for procurement of secu-
12 rity countermeasures is less than \$1,500,000,000,
13 the Secretary shall submit to the Committee on Ap-
14 propriations and the Committee on Health, Edu-
15 cation, Labor, and Pensions of the Senate and the
16 Committee on Appropriations and the Committee on
17 Energy and Commerce of the House of Representa-
18 tives a report detailing the amount of such funds
19 available for procurement and the impact such
20 amount of funding will have—

21 “(A) in meeting the security counter-
22 measure needs identified under this section; and

23 “(B) on the annual Public Health Emer-
24 gency Medical Countermeasures Enterprise and

1 Strategy Implementation Plan (pursuant to sec-
2 tion 2811(d)).”.

3 **SEC. 3082. CLARIFYING BARDA CONTRACTING AUTHORITY.**

4 (a) IN GENERAL.—Section 319F–2(g) of the Public
5 Health Service Act (42 U.S.C. 247d–6b(g)) is amended
6 by adding at the end the following:

7 “(5) CLARIFICATION ON CONTRACTING AU-
8 THORITY.—The Secretary, acting through the Direc-
9 tor of the Biomedical Advanced Research and Devel-
10 opment Authority, shall carry out the programs
11 funded by the special reserve fund (for the procure-
12 ment of security countermeasures under subsection
13 (c) and for carrying out section 319L), including the
14 execution of procurement contracts, grants, and co-
15 operative agreements pursuant to this section and
16 section 319L.”.

17 (b) BARDA CONTRACTING AUTHORITY.—Section
18 319L(c)(3) of the Public Health Service Act (42 U.S.C.
19 247d–7c) is amended by inserting “, including the execu-
20 tion of procurement contracts, grants, and cooperative
21 agreements pursuant to this section” before the period.

22 **SEC. 3083. COUNTERMEASURE BUDGET PLAN.**

23 Section 2811(b)(7) of the Public Health Service Act
24 (42 U.S.C. 300hh–10(b)(7)) is amended—

1 (1) in the matter preceding subparagraph (A),
2 by striking the first sentence and inserting “De-
3 velop, and update not later than March 1 of each
4 year, a coordinated 5-year budget plan based on the
5 medical countermeasure priorities described in sub-
6 section (d), including with respect to chemical, bio-
7 logical, radiological, and nuclear agent or agents
8 that may present a threat to the Nation, including
9 such agents that are novel or emerging infectious
10 diseases, and the corresponding efforts to develop
11 qualified countermeasures (as defined in section
12 319F–1), security countermeasures (as defined in
13 section 319F–2), and qualified pandemic or epidemic
14 products (as defined in section 319F–3) for each
15 such threat.”;

16 (2) in subparagraph (C), by striking “; and”
17 and inserting a semicolon;

18 (3) in subparagraph (D), by striking “to the
19 appropriate committees of Congress upon request.”
20 and inserting “, not later than March 15 of each
21 year, to the Committee on Appropriations and the
22 Committee on Health, Education, Labor, and Pen-
23 sions of the Senate and the Committee on Appro-
24 priations and the Committee on Energy and Com-
25 merce of the House of Representatives; and”;

1 (4) by adding at the end the following:

2 “(E) not later than March 15 of each year,
3 be made publicly available in a manner that
4 does not compromise national security.”.

5 **SEC. 3084. MEDICAL COUNTERMEASURES INNOVATION.**

6 Section 319L(c)(4) of the Public Health Service Act
7 (42 U.S.C. 247d–7e(c)(4)) is amended by adding at the
8 end the following:

9 “(E) MEDICAL COUNTERMEASURES INNO-
10 VATION PARTNER.—

11 “(i) IN GENERAL.—To support the
12 purposes described in paragraph (2), the
13 Secretary, acting through the Director of
14 BARDA, may enter into an agreement (in-
15 cluding through the use of grants, con-
16 tracts, cooperative agreements, or other
17 transactions as described in paragraph (5))
18 with an independent, nonprofit entity to—

19 “(I) foster and accelerate the de-
20 velopment and innovation of medical
21 countermeasures and technologies
22 that may assist advanced research
23 and the development of qualified
24 countermeasures and qualified pan-
25 demic or epidemic products, including

1 through the use of strategic venture
2 capital practices and methods;

3 “(II) promote the development of
4 new and promising technologies that
5 address urgent medical counter-
6 measure needs, as identified by the
7 Secretary;

8 “(III) address unmet public
9 health needs that are directly related
10 to medical countermeasure require-
11 ments, such as novel antimicrobials
12 for multidrug resistant organisms and
13 multiuse platform technologies for
14 diagnostics, prophylaxis, vaccines, and
15 therapeutics; and

16 “(IV) provide expert consultation
17 and advice to foster viable medical
18 countermeasure innovators, including
19 helping qualified countermeasure
20 innovators navigate unique industry
21 challenges with respect to developing
22 chemical, biological, radiological, and
23 nuclear countermeasure products.

24 “(ii) ELIGIBILITY.—

1 “(I) IN GENERAL.—To be eligible
2 to enter into an agreement under
3 clause (i) an entity shall—

4 “(aa) be an independent,
5 nonprofit entity;

6 “(bb) have a demonstrated
7 record of being able to create
8 linkages between innovators and
9 investors and leverage such part-
10 nerships and resources for the
11 purpose of addressing identified
12 strategic needs of the Federal
13 Government;

14 “(cc) have experience in pro-
15 moting novel technology innova-
16 tion;

17 “(dd) be problem-driven and
18 solution-focused based on the
19 needs, requirements, and prob-
20 lems identified by the Secretary
21 under clause (iv);

22 “(ee) demonstrate the abil-
23 ity, or the potential ability, to
24 promote the development of med-
25 ical countermeasure products;

1 “(ff) demonstrate expertise,
2 or the capacity to develop or ac-
3 quire expertise, related to tech-
4 nical and regulatory consider-
5 ations with respect to medical
6 countermeasures; and

7 “(gg) not be within the De-
8 partment of Health and Human
9 Services.

10 “(II) PARTNERING EXPERI-
11 ENCE.—In selecting an entity with
12 which to enter into an agreement
13 under clause (i), the Secretary shall
14 place a high value on the dem-
15 onstrated experience of the entity in
16 partnering with the Federal Govern-
17 ment to meet identified strategic
18 needs.

19 “(iii) NOT AGENCY.—An entity that
20 enters into an agreement under clause (i)
21 shall not be deemed to be a Federal agency
22 for any purpose, including for any purpose
23 under title 5, United States Code.

24 “(iv) DIRECTION.—Pursuant to an
25 agreement entered into under this subpara-

1 graph, the Secretary, acting through the
2 Director of BARDA, shall provide direc-
3 tion to the entity that enters into an agree-
4 ment under clause (i). As part of this
5 agreement the Director of BARDA shall—

6 “(I) communicate the medical
7 countermeasure needs, requirements,
8 and problems to be addressed by the
9 entity under the agreement;

10 “(II) develop a description of
11 work to be performed by the entity
12 under the agreement;

13 “(III) provide technical feedback
14 and appropriate oversight over work
15 carried out by the entity under the
16 agreement, including subsequent de-
17 velopment and partnerships consistent
18 with the needs and requirements set
19 forth in this subparagraph;

20 “(IV) ensure fair consideration of
21 products developed under the agree-
22 ment in order to maintain competition
23 to the maximum practical extent, as
24 applicable and appropriate under ap-
25 plicable provisions of this section; and

1 “(V) ensure, as a condition of the
2 agreement that the entity—

3 “(aa) has in place a com-
4 prehensive set of policies that
5 demonstrate a commitment to
6 transparency and accountability;

7 “(bb) protects against con-
8 flicts of interest through a com-
9 prehensive set of policies that ad-
10 dress potential conflicts of inter-
11 est, ethics, disclosure, and report-
12 ing requirements;

13 “(cc) provides monthly ac-
14 counting on the use of funds pro-
15 vided under such agreement; and

16 “(dd) provides on a quar-
17 terly basis, reports regarding the
18 progress made toward meeting
19 the identified needs set forth in
20 the agreement.

21 “(v) SUPPLEMENT NOT SUPPLANT.—
22 Activities carried out under this subpara-
23 graph shall supplement, and not supplant,
24 other activities carried out under this sec-
25 tion.

1 “(vi) NO ESTABLISHMENT OF ENTI-
2 TY.—To prevent unnecessary duplication
3 and target resources effectively, nothing in
4 this subparagraph shall be construed to
5 authorize the Secretary to establish within
6 the Department of Health and Human
7 Services an entity for the purposes of car-
8 rying out this subparagraph.

9 “(vii) TRANSPARENCY AND OVER-
10 SIGHT.—Upon request, the Secretary shall
11 provide to Congress the information pro-
12 vided to the Secretary under clause
13 (iv)(V)(dd).

14 “(viii) INDEPENDENT EVALUATION.—
15 Not later than 4 years after the date of en-
16 actment of the 21st Century Cures Act,
17 the Comptroller General of the United
18 States shall conduct an independent eval-
19 uation, and submit to the Secretary and
20 the appropriate committees of Congress a
21 report, concerning the activities conducted
22 under this subparagraph. Such report shall
23 include recommendations with respect to
24 any agreement or activities carried out
25 pursuant to this subparagraph.

1 “(ix) SUNSET.—This subparagraph
2 shall have no force or effect after Sep-
3 tember 30, 2022.”.

4 **SEC. 3085. STREAMLINING PROJECT BIOSHIELD PROCURE-**
5 **MENT.**

6 Section 319F–2(c) of the Public Health Service Act
7 (42 U.S.C. 247d–6b(c)) is amended—

8 (1) in paragraph (4)(A)(ii), by striking “make
9 a recommendation under paragraph (6) that the spe-
10 cial reserve fund as defined in subsection (h) be
11 made available for the procurement of such counter-
12 measure” and inserting “and subject to the avail-
13 ability of appropriations, make available the special
14 reserve fund as defined in subsection (h) for pro-
15 curement of such countermeasure, as applicable”;

16 (2) in paragraph (6)—

17 (A) by striking subparagraphs (A), (B),
18 and (E);

19 (B) by redesignating subparagraphs (C)
20 and (D) as subparagraphs (A) and (B), respec-
21 tively;

22 (C) by amending subparagraph (A), as so
23 redesignated, to read as follows:

24 “(A) NOTICE TO APPROPRIATE CONGRES-
25 SIONAL COMMITTEES.—The Secretary shall no-

1 tify the Committee on Appropriations and the
2 Committee on Health, Education, Labor, and
3 Pensions of the Senate and the Committee on
4 Appropriations and the Committee on Energy
5 and Commerce of the House of Representatives
6 of each decision to make available the special
7 reserve fund as defined in subsection (h) for
8 procurement of a security countermeasure, in-
9 cluding, where available, the number of, the na-
10 ture of, and other information concerning po-
11 tential suppliers of such countermeasure, and
12 whether other potential suppliers of the same or
13 similar countermeasures were considered and
14 rejected for procurement under this section and
15 the reasons for each such rejection.”; and

16 (D) in the heading, by striking “REC-
17 COMMENDATION FOR PRESIDENT’S APPROVAL”
18 and inserting “RECOMMENDATIONS FOR PRO-
19 CUREMENT”; and

20 (3) in paragraph (7)—

21 (A) by striking subparagraphs (A) and (B)
22 and inserting the following:

23 “(A) PAYMENTS FROM SPECIAL RESERVE
24 FUND.—The special reserve fund as defined in
25 subsection (h) shall be available for payments

1 made by the Secretary to a vendor for procure-
2 ment of a security countermeasure in accord-
3 ance with the provisions of this paragraph.”;
4 and

5 (B) by redesignating subparagraph (C) as
6 subparagraph (B).

7 **SEC. 3086. ENCOURAGING TREATMENTS FOR AGENTS THAT**
8 **PRESENT A NATIONAL SECURITY THREAT.**

9 Subchapter E of chapter V of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
11 amended by inserting after section 565 the following:

12 **“SEC. 565A. PRIORITY REVIEW TO ENCOURAGE TREAT-**
13 **MENTS FOR AGENTS THAT PRESENT NA-**
14 **TIONAL SECURITY THREATS.**

15 “(a) DEFINITIONS.—In this section:

16 “(1) HUMAN DRUG APPLICATION.—The term
17 ‘human drug application’ has the meaning given
18 such term in section 735(1).

19 “(2) PRIORITY REVIEW.—The term ‘priority re-
20 view’, with respect to a human drug application,
21 means review and action by the Secretary on such
22 application not later than 6 months after receipt by
23 the Secretary of such application, as described in the
24 Manual of Policies and Procedures in the Food and
25 Drug Administration and goals identified in the let-

1 ters described in section 101(b) of the Food and
2 Drug Administration Safety and Innovation Act.

3 “(3) PRIORITY REVIEW VOUCHER.—The term
4 ‘priority review voucher’ means a voucher issued by
5 the Secretary to the sponsor of a material threat
6 medical countermeasure application that entitles the
7 holder of such voucher to priority review of a single
8 human drug application submitted under section
9 505(b)(1) or section 351(a) of the Public Health
10 Service Act after the date of approval of the mate-
11 rial threat medical countermeasure application.

12 “(4) MATERIAL THREAT MEDICAL COUNTER-
13 MEASURE APPLICATION.—The term ‘material threat
14 medical countermeasure application’ means an appli-
15 cation that—

16 “(A) is a human drug application for a
17 drug intended for use—

18 “(i) to prevent, or treat harm from a
19 biological, chemical, radiological, or nuclear
20 agent identified as a material threat under
21 section 319F–2(c)(2)(A)(ii) of the Public
22 Health Service Act; or

23 “(ii) to mitigate, prevent, or treat
24 harm from a condition that may result in
25 adverse health consequences or death and

1 may be caused by administering a drug, or
2 biological product against such agent; and

3 “(B) the Secretary determines eligible for
4 priority review;

5 “(C) is approved after the date of enact-
6 ment of the 21st Century Cures Act; and

7 “(D) is for a human drug, no active ingre-
8 dient (including any ester or salt of the active
9 ingredient) of which has been approved in any
10 other application under section 505(b)(1) or
11 section 351(a) of the Public Health Service Act.

12 “(b) PRIORITY REVIEW VOUCHER.—

13 “(1) IN GENERAL.—The Secretary shall award
14 a priority review voucher to the sponsor of a mate-
15 rial threat medical countermeasure application upon
16 approval by the Secretary of such material threat
17 medical countermeasure application.

18 “(2) TRANSFERABILITY.—The sponsor of a ma-
19 terial threat medical countermeasure application
20 that receives a priority review voucher under this
21 section may transfer (including by sale) the entitle-
22 ment to such voucher to a sponsor of a human drug
23 for which an application under section 505(b)(1) or
24 section 351(a) of the Public Health Service Act will
25 be submitted after the date of the approval of the

1 material threat medical countermeasure application.
2 There is no limit on the number of times a priority
3 review voucher may be transferred before such
4 voucher is used.

5 “(3) NOTIFICATION.—

6 “(A) IN GENERAL.—The sponsor of a
7 human drug application shall notify the Sec-
8 retary not later than 90 calendar days prior to
9 submission of the human drug application that
10 is the subject of a priority review voucher of an
11 intent to submit the human drug application,
12 including the date on which the sponsor intends
13 to submit the application. Such notification
14 shall be a legally binding commitment to pay
15 for the user fee to be assessed in accordance
16 with this section.

17 “(B) TRANSFER AFTER NOTICE.—The
18 sponsor of a human drug application that pro-
19 vides notification of the intent of such sponsor
20 to use the voucher for the human drug applica-
21 tion under subparagraph (A) may transfer the
22 voucher after such notification is provided, if
23 such sponsor has not yet submitted the human
24 drug application described in the notification.

25 “(c) PRIORITY REVIEW USER FEE.—

1 “(1) IN GENERAL.—The Secretary shall estab-
2 lish a user fee program under which a sponsor of a
3 human drug application that is the subject of a pri-
4 ority review voucher shall pay to the Secretary a fee
5 determined under paragraph (2). Such fee shall be
6 in addition to any fee required to be submitted by
7 the sponsor under chapter VII.

8 “(2) FEE AMOUNT.—The amount of the pri-
9 ority review user fee shall be determined each fiscal
10 year by the Secretary and based on the average cost
11 incurred by the agency in the review of a human
12 drug application subject to priority review in the
13 previous fiscal year.

14 “(3) ANNUAL FEE SETTING.—The Secretary
15 shall establish, before the beginning of each fiscal
16 year beginning after September 30, 2016, for that
17 fiscal year, the amount of the priority review user
18 fee.

19 “(4) PAYMENT.—

20 “(A) IN GENERAL.—The priority review
21 user fee required by this subsection shall be due
22 upon the submission of a human drug applica-
23 tion under section 505(b)(1) or section 351(a)
24 of the Public Health Service Act for which the
25 priority review voucher is used.

1 “(B) COMPLETE APPLICATION.—An appli-
2 cation described under subparagraph (A) for
3 which the sponsor requests the use of a priority
4 review voucher shall be considered incomplete if
5 the fee required by this subsection and all other
6 applicable user fees are not paid in accordance
7 with the Secretary’s procedures for paying such
8 fees.

9 “(C) NO WAIVERS, EXEMPTIONS, REDUC-
10 TIONS, OR REFUNDS.—The Secretary may not
11 grant a waiver, exemption, reduction, or refund
12 of any fees due and payable under this section.

13 “(5) OFFSETTING COLLECTIONS.—Fees col-
14 lected pursuant to this subsection for any fiscal
15 year—

16 “(A) shall be deposited and credited as off-
17 setting collections to the account providing ap-
18 propriations to the Food and Drug Administra-
19 tion; and

20 “(6) shall not be collected for any fiscal year
21 except to the extent provided in advance in appro-
22 priation Acts.

23 “(d) NOTICE OF ISSUANCE OF VOUCHER AND AP-
24 PROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary
25 shall publish a notice in the Federal Register and on the

1 Internet website of the Food and Drug Administration not
2 later than 30 calendar days after the occurrence of each
3 of the following:

4 “(1) The Secretary issues a priority review
5 voucher under this section.

6 “(2) The Secretary approves a drug pursuant
7 to an application submitted under section 505(b) of
8 this Act or section 351(a) of the Public Health Serv-
9 ice Act for which the sponsor of the application used
10 a priority review voucher issued under this section.

11 “(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing
12 in this section precludes a sponsor who seeks a priority
13 review voucher under this section from participating in
14 any other incentive program, including under this Act, ex-
15 cept that no sponsor of a material threat medical counter-
16 measure application may receive more than one priority
17 review voucher issued under any section of this Act with
18 respect to such drug.

19 “(f) RELATION TO OTHER PROVISIONS.—The provi-
20 sions of this section shall supplement, not supplant, any
21 other provisions of this Act or the Public Health Service
22 Act that encourage the development of medical counter-
23 measures.

1 “(g) SUNSET.—The Secretary may not award any
2 priority review vouchers under subsection (b) after Octo-
3 ber 1, 2023.”.

4 **SEC. 3087. PAPERWORK REDUCTION ACT WAIVER DURING**
5 **A PUBLIC HEALTH EMERGENCY.**

6 Section 319 of the Public Health Service Act (42
7 U.S.C. 247d) is amended by adding at the end the fol-
8 lowing:

9 “(f) DETERMINATION WITH RESPECT TO PAPER-
10 WORK REDUCTION ACT WAIVER DURING A PUBLIC
11 HEALTH EMERGENCY.—

12 “(1) DETERMINATION.—If the Secretary deter-
13 mines, after consultation with such public health of-
14 ficials as may be necessary, that—

15 “(A)(i) the criteria set forth for a public
16 health emergency under paragraph (1) or (2) of
17 subsection (a) has been met; or

18 “(ii) a disease or disorder, including a
19 novel and emerging public health threat, is sig-
20 nificantly likely to become a public health emer-
21 gency; and

22 “(B) the circumstances of such public
23 health emergency, or potential for such signifi-
24 cantly likely public health emergency, including
25 the specific preparation for and response to

1 such public health emergency or threat, neces-
2 sitate a waiver from the requirements of sub-
3 chapter I of chapter 35 of title 44, United
4 States Code (commonly referred to as the Pa-
5 perwork Reduction Act),
6 then the requirements of such subchapter I with re-
7 spect to voluntary collection of information shall not
8 be applicable during the immediate investigation of,
9 and response to, such public health emergency dur-
10 ing the period of such public health emergency or
11 the period of time necessary to determine if a dis-
12 ease or disorder, including a novel and emerging
13 public health threat, will become a public health
14 emergency as provided for in this paragraph. The re-
15 quirements of such subchapter I with respect to vol-
16 untary collection of information shall not be applica-
17 ble during the immediate postresponse review re-
18 garding such public health emergency if such imme-
19 diate postresponse review does not exceed a reason-
20 able length of time.

21 “(2) **TRANSPARENCY.**—If the Secretary deter-
22 mines that a waiver is necessary under paragraph
23 (1), the Secretary shall promptly post on the Inter-
24 net website of the Department of Health and
25 Human Services a brief justification for such waiver,

1 the anticipated period of time such waiver will be in
2 effect, and the agencies and offices within the De-
3 partment of Health and Human Services to which
4 such waiver shall apply, and update such informa-
5 tion posted on the Internet website of the Depart-
6 ment of Health and Human Services, as applicable.

7 “(3) EFFECTIVENESS OF WAIVER.—Any waiver
8 under this subsection shall take effect on the date on
9 which the Secretary posts information on the Inter-
10 net website as provided for in this subsection.

11 “(4) TERMINATION OF WAIVER.—Upon deter-
12 mining that the circumstances necessitating a waiver
13 under paragraph (1) no longer exist, the Secretary
14 shall promptly update the Internet website of the
15 Department of Health and Human Services to re-
16 flect the termination of such waiver.

17 “(5) LIMITATIONS.—

18 “(A) PERIOD OF WAIVER.—The period of
19 a waiver under paragraph (1) shall not exceed
20 the period of time for the related public health
21 emergency, including a public health emergency
22 declared pursuant to subsection (a), and any
23 immediate postresponse review regarding the
24 public health emergency consistent with the re-
25 quirements of this subsection.

1 “(B) SUBSEQUENT COMPLIANCE.—An ini-
2 tiative subject to a waiver under paragraph (1)
3 that is ongoing after the date on which the
4 waiver expires, shall be subject to the require-
5 ments of subchapter I of chapter 35 of title 44,
6 United States Code, and the Secretary shall en-
7 sure that compliance with such requirements
8 occurs in as timely a manner as possible based
9 on the applicable circumstances, but not to ex-
10 ceed 30 calendar days after the expiration of
11 the applicable waiver.”.

12 **SEC. 3088. CLARIFYING FOOD AND DRUG ADMINISTRATION**
13 **EMERGENCY USE AUTHORIZATION.**

14 (a) AUTHORIZATION FOR MEDICAL PRODUCTS FOR
15 USE IN EMERGENCIES.—Section 564 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 360bbb-3) is amend-
17 ed—

18 (1) in subsection (a)(2)—

19 (A) in subparagraph (A)—

20 (i) by striking “or 515” and inserting
21 “512, or 515”; and

22 (ii) by inserting “or conditionally ap-
23 proved under section 571 of this Act” after
24 “Public Health Service Act”; and

1 (B) in subparagraph (B), by inserting
2 “conditionally approved under section 571,”
3 after “approved,” each place the term appears;

4 (2) in subsection (b)(4), by striking the second
5 comma after “determination”;

6 (3) in subsection (e)(3)(B), by striking “section
7 503(b)” and inserting “subsection (b) or (f) of sec-
8 tion 503 or under section 504”;

9 (4) in subsection (f)(2)—

10 (A) by inserting “, or an animal to which,”
11 after “to a patient to whom”; and

12 (B) by inserting “or by the veterinarian
13 caring for such animal, as applicable” after “at-
14 tending physician”;

15 (5) in subsection (g)(1), by inserting “condi-
16 tional approval under section 571,” after “ap-
17 proval,”;

18 (6) in subsection (h)(1), by striking “or section
19 520(g)” and inserting “512(j), or 520(g)”; and

20 (7) in subsection (k), by striking “section
21 520(g),” and inserting “512(j), or 520(g)”.

22 (b) NEW ANIMAL DRUGS.—Section 512(a)(1) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 360b(a)(1)) is amended—

1 (1) in subparagraph (B), by striking “or” at
2 the end;

3 (2) in subparagraph (C), by striking the period
4 and inserting “; or”; and

5 (3) by inserting after subparagraph (C) the fol-
6 lowing:

7 “(D) there is in effect an authorization pursu-
8 ant to section 564 with respect to such use or in-
9 tended use of such drug, and such drug, its labeling,
10 and such use conform to any conditions of such au-
11 thorization.”.

12 (c) EMERGENCY USE OF MEDICAL PRODUCTS.—Sec-
13 tion 564A of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 360bbb–3a) is amended—

15 (1) in subsection (a)(1)(A), by inserting “, con-
16 ditionally approved under section 571,” after “chap-
17 ter”; and

18 (2) in subsection (d), by striking “sections
19 503(b) and 520(e)” and inserting “subsections (b)
20 and (f) of section 503, section 504, and section
21 520(e)”.

22 (d) PRODUCTS HELD FOR EMERGENCY USE.—Sec-
23 tion 564B(2) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 360bbb–3b(2)) is amended—

25 (1) in subparagraph (A)—

1 (A) by inserting “or conditionally approved
2 under section 571 of this Act” after “Public
3 Health Service Act”; and

4 (B) by striking “or 515” and inserting
5 “512, or 515”; and

6 (2) in subparagraph (B), by striking “or 520”
7 and inserting “512, or 520”.

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

10 **SEC. 3091. PREDICTABLE REVIEW TIMELINES OF VACCINES**

11 **BY THE ADVISORY COMMITTEE ON IMMUNI-**
12 **ZATION PRACTICES.**

13 (a) CONSIDERATION OF NEW VACCINES.—Upon the
14 licensure of any vaccine or any new indication for a vac-
15 cine, the Advisory Committee on Immunization Practices
16 (in this section referred to as the “Advisory Committee”)
17 shall, as appropriate, consider the use of the vaccine at
18 its next regularly scheduled meeting.

19 (b) ADDITIONAL INFORMATION.—If the Advisory
20 Committee does not make a recommendation with respect
21 to the use of a vaccine at the Advisory Committee’s first
22 regularly scheduled meeting after the licensure of the vac-
23 cine or any new indication for the vaccine, the Advisory
24 Committee shall provide an update on the status of such
25 committee’s review.

1 (c) CONSIDERATION FOR BREAKTHROUGH THERA-
2 PIES AND FOR POTENTIAL USE DURING PUBLIC HEALTH
3 EMERGENCY.—The Advisory Committee shall make rec-
4 ommendations with respect to the use of certain vaccines
5 in a timely manner, as appropriate, including vaccines
6 that—

7 (1) are designated as a breakthrough therapy
8 under section 506 of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 356) and licensed under
10 section 351 of the Public Health Service Act (42
11 U.S.C. 262); or

12 (2) could be used in a public health emergency.

13 (d) DEFINITION.—In this section, the terms “Advi-
14 sory Committee on Immunization Practices” and “Advi-
15 sory Committee” mean the Advisory Committee on Immu-
16 nization Practices established by the Secretary pursuant
17 to section 222 of the Public Health Service Act (42 U.S.C.
18 217a), acting through the Director of the Centers for Dis-
19 ease Control and Prevention.”.

20 **SEC. 3092. REVIEW OF PROCESSES AND CONSISTENCY OF**
21 **ADVISORY COMMITTEE ON IMMUNIZATION**
22 **PRACTICES RECOMMENDATIONS.**

23 (a) REVIEW.—The Director of the Centers for Dis-
24 ease Control and Prevention shall conduct a review of the
25 processes used by the Advisory Committee on Immuniza-

1 tion Practices in formulating and issuing recommenda-
2 tions pertaining to vaccines, including with respect to con-
3 sistency.

4 (b) CONSIDERATIONS.—The review under subsection
5 (a) shall include an assessment of—

6 (1) the criteria used to evaluate new and exist-
7 ing vaccines, including the identification of any
8 areas for which flexibility in evaluating such criteria
9 is necessary and the reason for such flexibility;

10 (2) the Grading of Recommendations, Assess-
11 ment, Development, and Evaluation (GRADE) ap-
12 proach to the review and analysis of scientific and
13 economic data, including the scientific basis for such
14 approach; and

15 (3) the extent to which the processes used by
16 the work groups of the Advisory Committee on Im-
17 munization Practices are consistent among such
18 groups, including the identification of reasons for
19 any variation.

20 (c) STAKEHOLDERS.—In carrying out the review
21 under subsection (a), the Director of the Centers for Dis-
22 ease Control and Prevention shall solicit input from vac-
23 cine stakeholders.

24 (d) REPORT.—Not later than 18 months after the
25 date of enactment of this Act, the Director of the Centers

1 for Disease Control and Prevention shall submit to the
2 appropriate committees of the Congress, and make pub-
3 licly available, a report on the results of the review under
4 subsection (a), including any recommendations on improv-
5 ing the consistency of the processes described in such sub-
6 section.

7 (e) DEFINITION.—In this section, the term “Advisory
8 Committee on Immunization Practices” means the Advi-
9 sory Committee on Immunization Practices established by
10 the Secretary of Health and Human Services pursuant to
11 section 222 of the Public Health Service Act (42 U.S.C.
12 217a), acting through the Director of the Centers for Dis-
13 ease Control and Prevention.

14 **SEC. 3093. ENCOURAGING VACCINE INNOVATION.**

15 (a) VACCINE MEETINGS.—The Director of the Cen-
16 ters for Disease Control and Prevention shall ensure that
17 appropriate staff within the relevant centers and divisions
18 of the Office of Infectious Diseases, and others, as appro-
19 priate, coordinate with respect to the public health needs,
20 epidemiology, and program planning and implementation
21 considerations related to immunization, including with re-
22 gard to meetings with stakeholders related to such topics.

23 (b) REPORT ON VACCINE INNOVATION.—

24 (1) IN GENERAL.—Not later than 1 year after
25 the date of enactment of this Act, the Secretary of

1 Health and Human Services (referred to in this sec-
2 tion as the “Secretary”), in collaboration with ap-
3 propriate agencies or offices within the Department
4 of Health and Human Services, including the Na-
5 tional Institutes of Health, the Centers for Disease
6 Control and Prevention, the Food and Drug Admin-
7 istration, and the Biomedical Advanced Research
8 and Development Authority, shall submit to the
9 Committee on Health, Education, Labor, and Pen-
10 sions of the Senate and the Committee on Energy
11 and Commerce of the House of Representatives, and
12 post publicly on the Internet website of the Depart-
13 ment of Health and Human Services, a report on
14 ways to promote innovation in the development of
15 vaccines that minimize the burden of infectious dis-
16 ease.

17 (2) CONTENTS.—The report described in para-
18 graph (1) shall review the current status of vaccine
19 development and, as appropriate—

20 (A) consider the optimal process to deter-
21 mine which vaccines would be beneficial to pub-
22 lic health and how information on such vaccines
23 is disseminated to key stakeholders;

1 (B) examine and identify whether obstacles
2 exist that inhibit the development of beneficial
3 vaccines; and

4 (C) make recommendations about how best
5 to remove any obstacles identified under sub-
6 paragraph (B) in order to promote and
7 incentivize vaccine innovation and development.

8 (3) CONSULTATION.—In preparing the report
9 under this subsection, the Secretary may consult
10 with—

11 (A) representatives of relevant Federal
12 agencies and departments, including the De-
13 partment of Defense and the Department of
14 Veterans Affairs;

15 (B) academic researchers;

16 (C) developers and manufacturers of vac-
17 cines;

18 (D) medical and public health practi-
19 tioners;

20 (E) representatives of patient, policy, and
21 advocacy organizations; and

22 (F) representatives of other entities, as the
23 Secretary determines appropriate.

24 (c) UPDATES RELATED TO MATERNAL IMMUNIZA-
25 TION.—

1 (1) ADDITIONAL VACCINES.—Section 2114(e)
2 of the Public Health Service Act (42 U.S.C. 300aa–
3 14(e)) is amended by adding at the end the fol-
4 lowing:

5 “(3) VACCINES RECOMMENDED FOR USE IN
6 PREGNANT WOMEN.—The Secretary shall revise the
7 Vaccine Injury Table included in subsection (a),
8 through the process described in subsection (c), to
9 include vaccines recommended by the Centers for
10 Disease Control and Prevention for routine adminis-
11 tration in pregnant women and the information de-
12 scribed in subparagraphs (B) and (C) of paragraph
13 (2) with respect to such vaccines.”.

14 (2) PETITION CONTENT.—Section 2111 of the
15 Public Health Service Act (42 U.S.C. 300aa–11) is
16 amended by adding at the end the following:

17 “(f) MATERNAL IMMUNIZATION.—

18 “(1) IN GENERAL.—Notwithstanding any other
19 provision of law, for purposes of this subtitle, both
20 a woman who received a covered vaccine while preg-
21 nant and any child who was in utero at the time
22 such woman received the vaccine shall be considered
23 persons to whom the covered vaccine was adminis-
24 tered and persons who received the covered vaccine.

1 “(2) DEFINITION.—As used in this subsection,
2 the term ‘child’ shall have the meaning given that
3 term by subsections (a) and (b) of section 8 of title
4 1, United States Code, except that, for purposes of
5 this subsection, such section 8 shall be applied as if
6 the term ‘include’ in subsection (a) of such section
7 were replaced with the term ‘mean’.”

8 (3) PETITIONERS.—Section 2111(b)(2) of the
9 Public Health Service Act (42 U.S.C. 300aa–
10 11(b)(2)) is amended by adding “A covered vaccine
11 administered to a pregnant woman shall constitute
12 more than one administration, one to the mother
13 and one to each child (as such term is defined in
14 subsection (f)(2)) who was in utero at the time such
15 woman was administered the vaccine.” at the end.

16 **Subtitle J—Technical Corrections**

17 **SEC. 3101. TECHNICAL CORRECTIONS.**

18 (a) FFDCA.—

19 (1) REFERENCES.—Except as otherwise ex-
20 pressly provided, whenever in this subsection an
21 amendment is expressed in terms of an amendment
22 to a section or other provision, the reference shall be
23 considered to be made to that section or other provi-
24 sion of the Federal Food, Drug, and Cosmetic Act
25 (21 U.S.C. 301 et seq.).

1 (2) AMENDMENTS.—

2 (A) PROHIBITED ACTS.—Section 301(r)
3 (21 U.S.C. 331(r)) is amended by inserting “,
4 drug,” after “device” each place the term ap-
5 pears.

6 (B) NEW DRUGS.—Section 505 (21 U.S.C.
7 355) is amended—

8 (i) in subsection (d), in the last sen-
9 tence, by striking “premarket approval”
10 and inserting “marketing approval”; and

11 (ii) in subsection (q)(5)(A), by strik-
12 ing “subsection (b)(2) or (j) of the Act or
13 351(k)” and inserting “subsection (b)(2)
14 or (j) of this section or section 351(k)”.

15 (C) RISK EVALUATION AND MITIGATION
16 STRATEGIES.—Section 505–1(h)(21 U.S.C.
17 355–1(h)) is amended—

18 (i) in paragraph (2)(A)(iii)—

19 (I) in the clause heading, by
20 striking “LABEL” and inserting “LA-
21 BELING”;

22 (II) by striking “label” each
23 place the term appears and inserting
24 “labeling”; and

1 (III) by striking “sponsor” and
2 inserting “responsible person”; and
3 (ii) in paragraph (8), by striking “and
4 (7).” and inserting “and (7)”.

5 (D) PEDIATRIC STUDY PLANS.—Section
6 505B (21 U.S.C. 355c) is amended—

7 (i) in subsection (e)—

8 (I) in paragraph (2)—

9 (aa) in subparagraph (A),
10 by inserting “study” after “ini-
11 tial pediatric” each place the
12 term appears; and

13 (bb) in subparagraph (B), in
14 the subparagraph heading, by
15 striking “INITIAL PLAN” and in-
16 serting “INITIAL PEDIATRIC
17 STUDY PLAN”;

18 (II) in paragraph (5), in the
19 paragraph heading, by inserting
20 “AGREED INITIAL PEDIATRIC STUDY”
21 before “PLAN”; and

22 (III) in paragraph (6), by strik-
23 ing “agreed initial pediatric plan” and
24 inserting “agreed initial pediatric
25 study plan”; and

1 (ii) in subsection (f)(1), by inserting
2 “and any significant amendments to such
3 plans,” after “agreed initial pediatric study
4 plans,”.

5 (E) DISCONTINUANCE OR INTERRUPTION
6 IN THE PRODUCTION OF LIVE-SAVING DRUGS.—
7 Section 506C (21 U.S.C. 356c) is amended—

8 (i) in subsection (e), by striking “dis-
9 continuation” and inserting “discontinu-
10 ance”; and

11 (ii) in subsection (g)(1), by striking
12 “section 505(j) that could help” and in-
13 serting “section 505(j), that could help”.

14 (F) ANNUAL REPORTING ON DRUG SHORT-
15 AGES.—Section 506C–1(a) (21 U.S.C. 331(a))
16 is amended, in the matter before paragraph
17 (1)—

18 (i) by striking “Not later than the end
19 of calendar year 2013, and not later than
20 the end of each calendar year thereafter,”
21 and inserting “Not later than March 31 of
22 each calendar year,”; and

23 (ii) by inserting “, with respect to the
24 preceding calendar year,” after “a report”.

1 (G) DRUG SHORTAGE LIST.—Section
2 506E(b)(3)(E) (21 U.S.C. 356e(b)(3)(E)) is
3 amended by striking “discontinuation” and in-
4 sserting “discontinuance”.

5 (H) INSPECTIONS OF ESTABLISHMENTS.—
6 Section 510(h) (21 U.S.C. 360(h)) is amend-
7 ed—

8 (i) in paragraph (4), in the matter
9 preceding subparagraph (A), by striking
10 “establishing the risk-based scheduled”
11 and inserting “establishing a risk-based
12 schedule”; and

13 (ii) in paragraph (6)—

14 (I) in subparagraph (A), by strik-
15 ing “fiscal” and inserting “calendar”
16 each place the term appears; and

17 (II) in subparagraph (B), by
18 striking “an active ingredient of a
19 drug, a finished drug product, or an
20 excipient of a drug” and inserting “an
21 active ingredient of a drug or a fin-
22 ished drug product”.

23 (I) CLASSIFICATION OF DEVICES IN-
24 TENDED FOR HUMAN USE.—Section

1 513(f)(2)(A) (21 U.S.C. 360c(f)(2)(A)) is
2 amended—

3 (i) in clause (i), by striking “within
4 30 days”; and

5 (ii) in clause (iv), by striking “low-
6 moderate” and inserting “low to mod-
7 erate”.

8 (J) PREMARKET APPROVAL.—Section
9 515(a)(1) (21 U.S.C. 360e(a)(1)) is amended
10 by striking “subject to a an order” and insert-
11 ing “subject to an order”.

12 (K) PROGRAM TO IMPROVE THE DEVICE
13 RECALL SYSTEM.—Section 518A (21 U.S.C.
14 360h–1) is amended—

15 (i) by striking subsection (c); and

16 (ii) by redesignating subsection (d) as
17 subsection (c).

18 (L) UNIQUE DEVICE IDENTIFIER.—Section
19 519(f) (21 U.S.C. 360i(f)) is amended by strik-
20 ing “and life sustaining” and inserting “or life
21 sustaining”.

22 (M) PRIORITY REVIEW TO ENCOURAGE
23 TREATMENTS FOR TROPICAL DISEASES.—Sec-
24 tion 524(c)(4)(A) of the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 360n(c)(4)(A)) is

1 amended by striking “Services Act” and insert-
2 ing “Service Act”.

3 (N) PRIORITY REVIEW FOR QUALIFIED IN-
4 FECTIOUS DISEASE PRODUCTS.—Section 524A
5 (21 U.S.C. 360n–1) is amended—

6 (i) by striking “If the Secretary” and
7 inserting the following:

8 “(a) IN GENERAL.—If the Secretary”;

9 (ii) by striking “any” and inserting
10 “the first”; and

11 (iii) by adding at the end the fol-
12 lowing:

13 “(b) CONSTRUCTION.—Nothing in this section shall
14 prohibit the Secretary from giving priority review to a
15 human drug application or efficacy supplement submitted
16 for approval under section 505(b) that otherwise meets the
17 criteria for the Secretary to grant priority review.”.

18 (O) CONSULTATION WITH EXTERNAL EX-
19 PERTS ON RARE DISEASES, TARGETED THERA-
20 PIES, AND GENETIC TARGETING OF TREAT-
21 MENTS.—Section 569(a)(2)(A) (21 U.S.C.
22 360bbb–8(a)(2)(A)) is amended, in the first
23 sentence, by striking “subsection (c)” and in-
24 serting “subsection (b)”.

1 (P) OPTIMIZING GLOBAL CLINICAL
2 TRIALS.—Section 569A(c) (21 U.S.C. 360bbb–
3 8a(c)) is amended by inserting “or under the
4 Public Health Service Act” after “this Act”.

5 (Q) USE OF CLINICAL INVESTIGATION
6 DATA FROM OUTSIDE THE UNITED STATES.—
7 Section 569B (21 U.S.C. 360bbb–8b) is amend-
8 ed by striking “drug or device” and inserting
9 “drug, biological product, or device” each place
10 the term appears.

11 (R) MEDICAL GASES DEFINITIONS.—Sec-
12 tion 575(1)(H) (21 U.S.C. 360ddd(1)(H)) is
13 amended—

14 (i) by inserting “for a new drug” after
15 “any period of exclusivity”; and

16 (ii) by inserting “or any period of ex-
17 clusivity for a new animal drug under sec-
18 tion 512(c)(2)(F),” after “section 505A,”.

19 (S) REGULATION OF MEDICAL GASES.—
20 Section 576(a) (21 U.S.C. 360ddd–1(a)) is
21 amended—

22 (i) in the matter preceding subpara-
23 graph (A) of paragraph (1), by inserting
24 “who seeks to initially introduce or deliver
25 for introduction a designated medical gas

1 into interstate commerce” after “any per-
2 son”; and

3 (ii) in paragraph (3)—

4 (I) in subparagraph (A)—

5 (aa) in clause (i)(VIII), by
6 inserting “for a new drug” after
7 “any period of exclusivity”; and

8 (bb) in clause (ii), in the
9 matter preceding subclause (I),
10 by inserting “the” before “final
11 use”; and

12 (II) in subparagraph (B)—

13 (aa) in clause (i), by insert-
14 ing “for a new drug” after “any
15 period of exclusivity”; and

16 (bb) in clause (ii), by insert-
17 ing a comma after “drug prod-
18 uct”.

19 (T) INAPPLICABILITY OF DRUG FEES TO
20 DESIGNATED MEDICAL GASES.—Section 577
21 (21 U.S.C. 360ddd–2) is amended by inserting
22 “or 740(a)” after “section 736(a)”.

23 (U) CONFLICTS OF INTEREST.—Section
24 712(e)(1)(B) (21 U.S.C. 379d–1(e)(1)(B)) is

1 amended by striking “services” and inserting
2 “service”.

3 (V) AUTHORITY TO ASSESS AND USE BIO-
4 SIMILAR BIOLOGICAL PRODUCT FEES.—Section
5 744H(a) (21 U.S.C. 379j–52(a)) is amended—

6 (i) in paragraph (1)(A)(v), by striking
7 “Biosimilars User Fee Act of 2012” and
8 inserting “Biosimilar User Fee Act of
9 2012”; and

10 (ii) in paragraph (2)(B), by striking
11 “Biosimilars User Fee Act of 2012” and
12 inserting “Biosimilar User Fee Act of
13 2012”.

14 (W) REGISTRATION OF COMMERCIAL IM-
15 PORTERS.—

16 (i) AMENDMENT.—Section 801(s)(2)
17 (21 U.S.C. 381(s)(2)) is amended by add-
18 ing at the end the following:

19 “(D) EFFECTIVE DATE.—In establishing
20 the effective date of the regulations under sub-
21 paragraph (A), the Secretary shall, in consulta-
22 tion with the Secretary of Homeland Security
23 acting through U.S. Customs and Border Pro-
24 tection, as determined appropriate by the Sec-
25 retary of Health and Human Services, provide

1 a reasonable period of time for an importer of
2 a drug to comply with good importer practices,
3 taking into account differences among import-
4 ers and types of imports, including based on the
5 level of risk posed by the imported product.”.

6 (ii) CONFORMING AMENDMENT.—Sec-
7 tion 714 of the Food and Drug Adminis-
8 tration Safety and Innovation Act (Public
9 Law 112–144; 126 Stat. 1074) is amended
10 by striking subsection (d).

11 (X) RECOGNITION OF FOREIGN GOVERN-
12 MENT INSPECTIONS.—Section 809(a)(2) (21
13 U.S.C. 384e(a)(2)) is amended by striking
14 “conduction” and inserting “conducting”.

15 (b) FDASIA.—

16 (1) FINDINGS RELATING TO DRUG AP-
17 PROVAL.—Section 901(a)(1)(A) of the Food and
18 Drug Administration Safety and Innovation Act
19 (Public Law 112–144; 21 U.S.C. 356 note) is
20 amended by striking “serious and life-threatening
21 diseases” and inserting “serious or life-threatening
22 diseases”.

23 (2) REPORTING OF INCLUSION OF DEMO-
24 GRAPHIC SUBGROUPS.—Section 907 of the Food and
25 Drug Administration Safety and Innovation Act

1 (Public Law 112–144; 126 Stat. 1092, 1093) is
2 amended—

3 (A) in the section heading, by striking
4 “**BIOLOGICS**” in the heading and inserting
5 “**BIOLOGICAL PRODUCTS**”; and

6 (B) in subsection (a)(2)(B), by striking
7 “applications for new drug applications” and
8 inserting “new drug applications”.

9 (3) **COMBATING PRESCRIPTION DRUG ABUSE.**—
10 Section 1122 of the Food and Drug Administration
11 Safety and Innovation Act (Public Law 112–144;
12 126 Stat. 1112, 1113) is amended—

13 (A) in subsection (a)(2), by striking
14 “dependance” and inserting “dependence”; and

15 (B) in subsection (c), by striking “promul-
16 gate” and inserting “issue”.

17 **SEC. 3102. COMPLETED STUDIES.**

18 The Federal Food, Drug, and Cosmetic Act is amend-
19 ed—

20 (1) in section 505(k)(5) (21 U.S.C.
21 355(k)(5))—

22 (A) in subparagraph (A), by inserting
23 “and” after the semicolon;

24 (B) by striking subparagraph (B); and

1 (C) by redesignating subparagraph (C) as
2 subparagraph (B);
3 (2) in section 505A (21 U.S.C. 355a), by strik-
4 ing subsection (p);
5 (3) in section 505B (21 U.S.C. 355c)—
6 (A) by striking subsection (l); and
7 (B) by redesignating subsection (m) as
8 subsection (l); and
9 (4) in section 523 (21 U.S.C. 360m), by strik-
10 ing subsection (d).

11 **TITLE IV—DELIVERY**

12 **SEC. 4001. ASSISTING DOCTORS AND HOSPITALS IN IM-** 13 **PROVING QUALITY OF CARE FOR PATIENTS.**

14 (a) IN GENERAL.—The Health Information Tech-
15 nology for Economic and Clinical Health Act (title XIII
16 of division A of Public Law 111–5) is amended—

17 (1) by adding at the end of part 1 of subtitle
18 A the following:

19 **“SEC. 13103. ASSISTING DOCTORS AND HOSPITALS IN IM-** 20 **PROVING QUALITY OF CARE FOR PATIENTS.**

21 “(a) REDUCTION IN BURDENS GOAL.—The Sec-
22 retary of Health and Human Services (referred to in this
23 section as the ‘Secretary’), in consultation with providers
24 of health services, health care suppliers of services, health
25 care payers, health professional societies, health informa-

1 tion technology developers, health care quality organiza-
2 tions, health care accreditation organizations, public
3 health entities, States, and other appropriate entities,
4 shall, in accordance with subsection (b)—

5 “(1) establish a goal with respect to the reduc-
6 tion of regulatory or administrative burdens (such as
7 documentation requirements) relating to the use of
8 electronic health records;

9 “(2) develop a strategy for meeting the goal es-
10 tablished under paragraph (1); and

11 “(3) develop recommendations for meeting the
12 goal established under paragraph (1).

13 “(b) STRATEGY AND RECOMMENDATIONS.—

14 “(1) IN GENERAL.—To achieve the goal estab-
15 lished under subsection (a)(1), the Secretary, in con-
16 sultation with the entities described in such sub-
17 section, shall, not later than 1 year after the date
18 of enactment of the 21st Century Cures Act, develop
19 a strategy and recommendations to meet the goal in
20 accordance with this subsection.

21 “(2) STRATEGY.—The strategy developed under
22 paragraph (1) shall address the regulatory and ad-
23 ministrative burdens (such as documentation re-
24 quirements) relating to the use of electronic health

1 records. Such strategy shall include broad public
2 comment and shall prioritize—

3 “(A)(i) incentives for meaningful use of
4 certified EHR technology for eligible profes-
5 sionals and hospitals under sections 1848(a)(7)
6 and 1886(b)(3)(B)(ix), respectively, of the So-
7 cial Security Act (42 U.S.C. 1395w–4(a)(7),
8 1395ww(b)(3)(B)(ix));

9 “(ii) the program for making payments
10 under section 1903(a)(3)(F) of the Social Secu-
11 rity Act (42 U.S.C. 1396b(a)(3)(F)) to encour-
12 age the adoption and use of certified EHR
13 technology by Medicaid providers;

14 “(iii) the Merit-based Incentive Payment
15 System under section 1848(q) of the Social Se-
16 curity Act (42 U.S.C. 1395w–4(q));

17 “(iv) alternative payment models (as de-
18 fined in section 1833(z)(3)(C) of the Social Se-
19 curity Act (42 U.S.C. 1395l(z)(3)(C));

20 “(v) the Hospital Value-Based Purchasing
21 Program under section 1886(o) of the Social
22 Security Act (42 U.S.C. 1395ww(o)); and

23 “(vi) other value-based payment programs,
24 as the Secretary determines appropriate;

1 “(B) health information technology certifi-
2 cation;

3 “(C) standards and implementation speci-
4 fications, as appropriate;

5 “(D) activities that provide individuals ac-
6 cess to their electronic health information;

7 “(E) activities related to protecting the
8 privacy of electronic health information;

9 “(F) activities related to protecting the se-
10 curity of electronic health information;

11 “(G) activities related to facilitating health
12 and clinical research;

13 “(H) activities related to public health;

14 “(I) activities related to aligning and sim-
15 plifying quality measures across Federal pro-
16 grams and other payers;

17 “(J) activities related to reporting clinical
18 data for administrative purposes; and

19 “(K) other areas, as the Secretary deter-
20 mines appropriate.

21 “(3) RECOMMENDATIONS.—The recommenda-
22 tions developed under paragraph (1) shall address—

23 “(A) actions that improve the clinical doc-
24 umentation experience;

25 “(B) actions that improve patient care;

1 “(C) actions to be taken by the Secretary
2 and by other entities; and

3 “(D) other areas, as the Secretary deter-
4 mines appropriate, to reduce the reporting bur-
5 den required of health care providers.

6 “(4) FACA.—The Federal Advisory Committee
7 Act (5 U.S.C. App.) shall not apply to the develop-
8 ment of the goal, strategies, or recommendations de-
9 scribed in this section.

10 “(c) APPLICATION OF CERTAIN REGULATORY RE-
11 QUIREMENTS.—A physician (as defined in section
12 1861(r)(1) of the Social Security Act), to the extent con-
13 sistent with applicable State law, may delegate electronic
14 medical record documentation requirements specified in
15 regulations promulgated by the Centers for Medicare &
16 Medicaid Services to a person performing a scribe function
17 who is not such physician if such physician has signed and
18 verified the documentation.”; and

19 (2) in the table of contents in section 13001(b),
20 by inserting after the item relating to section 13102
21 the following:

 “13103. Assisting doctors and hospitals in improving the quality and care for
 patients.”.

22 (b) CERTIFICATION OF HEALTH INFORMATION
23 TECHNOLOGY FOR MEDICAL SPECIALTIES AND SITES OF
24 SERVICE.—Section 3001(c)(5) of the Public Health Serv-

1 ice Act (42 U.S.C. 300jj–11(e)(5)) is amended by adding
2 at the end the following:

3 “(C) HEALTH INFORMATION TECHNOLOGY
4 FOR MEDICAL SPECIALTIES AND SITES OF
5 SERVICE.—

6 “(i) IN GENERAL.—The National Co-
7 ordinator shall encourage, keep, or recog-
8 nize, through existing authorities, the vol-
9 untary certification of health information
10 technology under the program developed
11 under subparagraph (A) for use in medical
12 specialties and sites of service for which no
13 such technology is available or where more
14 technological advancement or integration is
15 needed.

16 “(ii) SPECIFIC MEDICAL SPECIAL-
17 TIES.—The Secretary shall accept public
18 comment on specific medical specialties
19 and sites of service, in addition to those
20 described in clause (i), for the purpose of
21 selecting additional specialties and sites of
22 service as necessary.

23 “(iii) HEALTH INFORMATION TECH-
24 NOLOGY FOR PEDIATRICS.—Not later than
25 18 months after the date of enactment of

1 the 21st Century Cures Act, the Secretary,
2 in consultation with relevant stakeholders,
3 shall make recommendations for the vol-
4 untary certification of health information
5 technology for use by pediatric health pro-
6 viders to support the health care of chil-
7 dren. Not later than 2 years after the date
8 of enactment of the 21st Century Cures
9 Act, the Secretary shall adopt certification
10 criteria under section 3004 to support the
11 voluntary certification of health informa-
12 tion technology for use by pediatric health
13 providers to support the health care of
14 children.”.

15 (c) MEANINGFUL USE STATISTICS.—

16 (1) IN GENERAL.—Not later than 6 months
17 after the date of enactment of this Act, the Sec-
18 retary of Health and Human Services shall submit
19 to the HIT Advisory Committee of the Office of the
20 National Coordinator for Health Information Tech-
21 nology, a report concerning attestation statistics for
22 the Medicare and Medicaid EHR Meaningful Use
23 Incentive programs to assist in informing standards
24 adoption and related practices. Such statistics shall
25 include attestation information delineated by State,

1 including, to the extent practicable, the number of
2 providers who did not meet the minimum criteria
3 necessary to attest for the Medicare and Medicaid
4 EHR Meaningful Use Incentive programs for a cal-
5 endar year, and shall be made publicly available on
6 the Internet website of the Secretary on at least a
7 quarterly basis.

8 (2) **AUTHORITY TO ALTER FORMAT.**—The Sec-
9 retary of Health and Human Services may alter the
10 format of the reports on the attestation of eligible
11 health care professionals following the first perform-
12 ance year of the Merit-based Incentive Payment Sys-
13 tem to account for changes arising from the imple-
14 mentation of such payment system.

15 **SEC. 4002. TRANSPARENT REPORTING ON USABILITY, SE-**
16 **CURITY, AND FUNCTIONALITY.**

17 (a) **ENHANCEMENTS TO CERTIFICATION.**—Section
18 3001(c)(5) of the Public Health Service Act (42 U.S.C.
19 300jj–11), as amended by section 4001(b), is further
20 amended by adding at the end the following:

21 “(D) **CONDITIONS OF CERTIFICATION.**—
22 Not later than 1 year after the date of enact-
23 ment of the 21st Century Cures Act, the Sec-
24 retary, through notice and comment rule-
25 making, shall require, as a condition of certifi-

1 cation and maintenance of certification for pro-
2 grams maintained or recognized under this
3 paragraph, consistent with other conditions and
4 requirements under this title, that the health
5 information technology developer or entity—

6 “(i) does not take any action that con-
7 stitutes information blocking as defined in
8 section 3022(a);

9 “(ii) provides assurances satisfactory
10 to the Secretary that such developer or en-
11 tity, unless for legitimate purposes speci-
12 fied by the Secretary, will not take any ac-
13 tion described in clause (i) or any other ac-
14 tion that may inhibit the appropriate ex-
15 change, access, and use of electronic health
16 information;

17 “(iii) does not prohibit or restrict
18 communication regarding—

19 “(I) the usability of the health
20 information technology;

21 “(II) the interoperability of the
22 health information technology;

23 “(III) the security of the health
24 information technology;

1 “(IV) relevant information re-
2 garding users’ experiences when using
3 the health information technology;

4 “(V) the business practices of de-
5 velopers of health information tech-
6 nology related to exchanging elec-
7 tronic health information; and

8 “(VI) the manner in which a user
9 of the health information technology
10 has used such technology;

11 “(iv) has published application pro-
12 gramming interfaces and allows health in-
13 formation from such technology to be
14 accessed, exchanged, and used without spe-
15 cial effort through the use of application
16 programming interfaces or successor tech-
17 nology or standards, as provided for under
18 applicable law, including providing access
19 to all data elements of a patient’s elec-
20 tronic health record to the extent permis-
21 sible under applicable privacy laws;

22 “(v) has successfully tested the real
23 world use of the technology for interoper-
24 ability (as defined in section 3000) in the

1 type of setting in which such technology
2 would be marketed;

3 “(vi) provides to the Secretary an at-
4 testation that the developer or entity—

5 “(I) has not engaged in any of
6 the conduct described in clause (i);

7 “(II) has provided assurances
8 satisfactory to the Secretary in ac-
9 cordance with clause (ii);

10 “(III) does not prohibit or re-
11 strict communication as described in
12 clause (iii);

13 “(IV) has published information
14 in accordance with clause (iv);

15 “(V) ensures that its technology
16 allows for health information to be ex-
17 changed, accessed, and used, in the
18 manner described in clause (iv); and

19 “(VI) has undertaken real world
20 testing as described in clause (v); and

21 “(vii) submits reporting criteria in ac-
22 cordance with section 3009A(b).”.

23 “(E) COMPLIANCE WITH CONDITIONS OF
24 CERTIFICATION.—The Secretary may encourage
25 compliance with the conditions of certification

1 described in subparagraph (D) and take action
2 to discourage noncompliance, as appropriate.”.

3 (b) EHR SIGNIFICANT HARDSHIP EXCEPTION.—

4 (1) APPLICATION TO ELIGIBLE PROFES-
5 SIONALS.—

6 (A) IN CASE OF DECERTIFICATION.—Sec-
7 tion 1848(a)(7)(B) of the Social Security Act
8 (42 U.S.C. 1395w-4(a)(7)(B)) is amended by
9 inserting after the first sentence the following
10 new sentence: “The Secretary shall exempt an
11 eligible professional from the application of the
12 payment adjustment under subparagraph (A)
13 with respect to a year, subject to annual re-
14 newal, if the Secretary determines that compli-
15 ance with the requirement for being a meaning-
16 ful EHR user is not possible because the cer-
17 tified EHR technology used by such profes-
18 sional has been decertified under a program
19 kept or recognized pursuant to section
20 3001(c)(5) of the Public Health Service Act.”.

21 (B) CONTINUED APPLICATION UNDER
22 MIPS.—Section 1848(o)(2)(D) of the Social Se-
23 curity Act (42 U.S.C. 1395w-4(o)(2)(D)) is
24 amended by adding at the end the following
25 new sentence: “The provisions of subparagraphs

1 (B) and (D) of subsection (a)(7), shall apply to
2 assessments of MIPS eligible professionals
3 under subsection (q) with respect to the per-
4 formance category described in subsection
5 (q)(2)(A)(iv) in an appropriate manner which
6 may be similar to the manner in which such
7 provisions apply with respect to payment ad-
8 justments made under subsection (a)(7)(A).”.

9 (2) APPLICATION TO ELIGIBLE HOSPITALS.—
10 Section 1886(b)(3)(B)(ix)(II) of the Social Security
11 Act (42 U.S.C. 1395ww(b)(3)(B)(ix)(II)) is amended
12 by inserting after the first sentence the following
13 new sentence: “The Secretary shall exempt an eligi-
14 ble hospital from the application of the payment ad-
15 justment under subclause (I) with respect to a fiscal
16 year, subject to annual renewal, if the Secretary de-
17 termines that compliance with the requirement for
18 being a meaningful EHR user is not possible be-
19 cause the certified EHR technology used by such
20 hospital is decertified under a program kept or rec-
21 ognized pursuant to section 3001(c)(5) of the Public
22 Health Service Act.”.

23 (c) ELECTRONIC HEALTH RECORD REPORTING PRO-
24 GRAM.—Subtitle A of title XXX of the Public Health

1 Service Act (42 U.S.C. 300jj–11 et seq.) is amended by
2 adding at the end the following:

3 **“SEC. 3009A. ELECTRONIC HEALTH RECORD REPORTING**
4 **PROGRAM.**

5 “(a) REPORTING CRITERIA.—

6 “(1) CONVENING OF STAKEHOLDERS.—Not
7 later than 1 year after the date of enactment of the
8 21st Century Cures Act, the Secretary shall convene
9 stakeholders, as described in paragraph (2), for the
10 purpose of developing the reporting criteria in ac-
11 cordance with paragraph (3).

12 “(2) DEVELOPMENT OF REPORTING CRI-
13 TERIA.—The reporting criteria under this subsection
14 shall be developed through a public, transparent
15 process that reflects input from relevant stake-
16 holders, including—

17 “(A) health care providers, including pri-
18 mary care and specialty care health care profes-
19 sionals;

20 “(B) hospitals and hospital systems;

21 “(C) health information technology devel-
22 opers;

23 “(D) patients, consumers, and their advo-
24 cates;

1 “(E) data sharing networks, such as health
2 information exchanges;

3 “(F) authorized certification bodies and
4 testing laboratories;

5 “(G) security experts;

6 “(H) relevant manufacturers of medical
7 devices;

8 “(I) experts in health information tech-
9 nology market economics;

10 “(J) public and private entities engaged in
11 the evaluation of health information technology
12 performance;

13 “(K) quality organizations, including the
14 consensus based entity described in section
15 1890 of the Social Security Act;

16 “(L) experts in human factors engineering
17 and the measurement of user-centered design;
18 and

19 “(M) other entities or individuals, as the
20 Secretary determines appropriate.

21 “(3) CONSIDERATIONS FOR REPORTING CRI-
22 TERIA.—The reporting criteria developed under this
23 subsection—

24 “(A) shall include measures that reflect
25 categories including—

1 “(i) security;

2 “(ii) usability and user-centered de-

3 sign;

4 “(iii) interoperability;

5 “(iv) conformance to certification test-

6 ing; and

7 “(v) other categories, as appropriate

8 to measure the performance of electronic

9 health record technology;

10 “(B) may include categories such as—

11 “(i) enabling the user to order and

12 view the results of laboratory tests, imag-

13 ing tests, and other diagnostic tests;

14 “(ii) submitting, editing, and retriev-

15 ing data from registries such as clinician-

16 led clinical data registries;

17 “(iii) accessing and exchanging infor-

18 mation and data from and through health

19 information exchanges;

20 “(iv) accessing and exchanging infor-

21 mation and data from medical devices;

22 “(v) accessing and exchanging infor-

23 mation and data held by Federal, State,

24 and local agencies and other applicable en-

25 tities useful to a health care provider or

1 other applicable user in the furtherance of
2 patient care;

3 “(vi) accessing and exchanging infor-
4 mation from other health care providers or
5 applicable users;

6 “(vii) accessing and exchanging pa-
7 tient generated information;

8 “(viii) providing the patient or an au-
9 thorized designee with a complete copy of
10 their health information from an electronic
11 record in a computable format;

12 “(ix) providing accurate patient infor-
13 mation for the correct patient, including
14 exchanging such information, and avoiding
15 the duplication of patients records; and

16 “(x) other categories regarding per-
17 formance, accessibility, as the Secretary
18 determines appropriate; and

19 “(C) shall be designed to ensure that small
20 and startup health information technology de-
21 velopers are not unduly disadvantaged by the
22 reporting criteria.

23 “(4) MODIFICATIONS.—After the reporting cri-
24 teria have been developed under paragraph (3), the
25 Secretary may convene stakeholders and conduct a

1 public comment period for the purpose of modifying
2 the reporting criteria developed under such para-
3 graph.

4 “(b) PARTICIPATION.—As a condition of maintaining
5 certification under section 3001(e)(5)(D), a developer of
6 certified electronic health records shall submit to an ap-
7 propriate recipient of a grant, contract, or agreement
8 under subsection (c)(1) responses to the criteria developed
9 under subsection (a), with respect to all certified tech-
10 nology offered by such developer.

11 “(c) REPORTING PROGRAM.—

12 “(1) IN GENERAL.—Not later than 1 year after
13 the date of enactment of the 21st Century Cures
14 Act, the Secretary shall award grants, contracts, or
15 agreements to independent entities on a competitive
16 basis to support the convening of stakeholders as de-
17 scribed in subsection (a)(2), collect the information
18 required to be reported in accordance with the cri-
19 teria established as described subsection (a)(3), and
20 develop and implement a process in accordance with
21 paragraph (5) and report such information to the
22 Secretary.

23 “(2) APPLICATIONS.—An independent entity
24 that seeks a grant, contract, or agreement under
25 this subsection shall submit an application to the

1 Secretary at such time, in such manner, and con-
2 taining such information as the Secretary may rea-
3 sonably require, including a description of—

4 “(A) the proposed method for reviewing
5 and summarizing information gathered based
6 on reporting criteria established under sub-
7 section (a);

8 “(B) if applicable, the intended focus on a
9 specific subset of certified electronic health
10 record technology users, such as health care
11 providers, including primary care, specialty
12 care, and care provided in rural settings; hos-
13 pitals and hospital systems; and patients, con-
14 sumers, and patients and consumer advocates;

15 “(C) the plan for widely distributing re-
16 ports described in paragraph (6);

17 “(D) the period for which the grant, con-
18 tract, or agreement is requested, which may be
19 up to 2 years; and

20 “(E) the budget for reporting program
21 participation, and whether the eligible inde-
22 pendent entity intends to continue participation
23 after the period of the grant, contract, or agree-
24 ment.

1 “(3) CONSIDERATIONS FOR INDEPENDENT EN-
2 TITIES.—In awarding grants, contracts, and agree-
3 ments under paragraph (1), the Secretary shall give
4 priority to independent entities with appropriate ex-
5 pertise in health information technology usability,
6 interoperability, and security (especially entities with
7 such expertise in electronic health records) with re-
8 spect to—

9 “(A) health care providers, including pri-
10 mary care, specialty care, and care provided in
11 rural settings;

12 “(B) hospitals and hospital systems; and

13 “(C) patients, consumers, and patient and
14 consumer advocates.

15 “(4) LIMITATIONS.—

16 “(A) ASSESSMENT AND REDETERMINA-
17 TION.—Not later than 4 years after the date of
18 enactment of the 21st Century Cures Act and
19 every 2 years thereafter, the Secretary, in con-
20 sultation with stakeholders, shall—

21 “(i) assess performance of the recipi-
22 ents of the grants, contracts, and agree-
23 ments under paragraph (1) based on qual-
24 ity and usability of reports described in
25 paragraph (6); and

1 “(ii) re-determine grants, contracts,
2 and agreements as necessary.

3 “(B) PROHIBITIONS ON PARTICIPATION.—

4 The Secretary may not award a grant, contract,
5 or cooperative agreement under paragraph (1)
6 to—

7 “(i) a proprietor of certified health in-
8 formation technology or a business affiliate
9 of such a proprietor;

10 “(ii) a developer of certified health in-
11 formation technology; or

12 “(iii) a State or local government
13 agency.

14 “(5) FEEDBACK.—Based on reporting criteria
15 established under subsection (a), the recipients of
16 grants, contracts, and agreements under paragraph
17 (1) shall develop and implement a process to collect
18 and verify confidential feedback on such criteria
19 from—

20 “(A) health care providers, patients, and
21 other users of certified electronic health record
22 technology; and

23 “(B) developers of certified electronic
24 health record technology.

25 “(6) REPORTS.—

1 “(A) DEVELOPMENT OF REPORTS.—Each
2 recipient of a grant, contract, or agreement
3 under paragraph (1) shall report on the infor-
4 mation reported to such recipient pursuant to
5 subsection (a) and the user feedback collected
6 under paragraph (5) by preparing summary re-
7 ports and detailed reports of such information.

8 “(B) DISTRIBUTION OF REPORTS.—Each
9 recipient of a grant, contract, or agreement
10 under paragraph (1) shall submit the reports
11 prepared under subparagraph (A) to the Sec-
12 retary for public distribution in accordance with
13 subsection (d).

14 “(d) PUBLICATION.—The Secretary shall distribute
15 widely, as appropriate, and publish, on the Internet
16 website of the Office of the National Coordinator—

17 “(1) the reporting criteria developed under sub-
18 section (a); and

19 “(2) the summary and detailed reports under
20 subsection (c)(6).

21 “(e) REVIEW.—Each recipient of a grant, contract,
22 or agreement under paragraph (1) shall develop and im-
23 plement a process through which participating electronic
24 health record technology developers may review and rec-
25 ommend changes to the reports created under subsection

1 (c)(6) for products developed by such developer prior to
2 the publication of such report under subsection (d).

3 “(f) **ADDITIONAL RESOURCES.**—The Secretary may
4 provide additional resources on the Internet website of the
5 Office of the National Coordinator to better inform con-
6 sumers of health information technology. Such reports
7 may be carried out through partnerships with private or-
8 ganizations with appropriate expertise.”.

9 (d) **AUTHORIZATION OF APPROPRIATIONS.**—There is
10 authorized to be appropriated \$15,000,000 for purposes
11 of carrying out subparagraph (D) of section 3001(c)(5)
12 of the Public Health Service Act (42 U.S.C. 300jj–11) (as
13 added by subsection (a)) and section 3009A of the Public
14 Health Service Act (as added by subsection (b)), including
15 for purposes of administering any contracts, grants, or
16 agreements, to remain available until expended.

17 **SEC. 4003. INTEROPERABILITY.**

18 (a) **DEFINITION.**—Section 3000 of the Public Health
19 Service Act (42 U.S.C. 300jj) is amended—

20 (1) by redesignating paragraphs (10) through
21 (14), as paragraphs (11) through (15), respectively;
22 and

23 (2) by inserting after paragraph (9) the fol-
24 lowing:

1 “(10) INTEROPERABILITY.—The term ‘inter-
2 operability’, with respect to health information tech-
3 nology, means such health information technology
4 that—

5 “(A) enables the secure exchange of elec-
6 tronic health information with, and use of elec-
7 tronic health information from, other health in-
8 formation technology without special effort on
9 the part of the user;

10 “(B) allows for complete access, exchange,
11 and use of all electronically accessible health in-
12 formation for authorized use under applicable
13 State or Federal law; and

14 “(C) does not constitute information block-
15 ing as defined in section 3022(a).”.

16 (b) SUPPORT FOR INTEROPERABLE NETWORK EX-
17 CHANGE.—Section 3001(c) of the Public Health Service
18 Act (42 U.S.C. 300jj–11(c)) is amended by adding at the
19 end the following:

20 “(9) SUPPORT FOR INTEROPERABLE NET-
21 WORKS EXCHANGE.—

22 “(A) IN GENERAL.—The National Coordi-
23 nator shall, in collaboration with the National
24 Institute of Standards and Technology and
25 other relevant agencies within the Department

1 of Health and Human Services, for the purpose
2 of ensuring full network-to-network exchange of
3 health information, convene public-private and
4 public-public partnerships to build consensus
5 and develop or support a trusted exchange
6 framework, including a common agreement
7 among health information networks nationally.
8 Such convention may occur at a frequency de-
9 termined appropriate by the Secretary.

10 “(B) ESTABLISHING A TRUSTED EX-
11 CHANGE FRAMEWORK.—

12 “(i) IN GENERAL.—Not later than 6
13 months after the date of enactment of the
14 21st Century Cures Act, the National Co-
15 ordinator shall convene appropriate public
16 and private stakeholders to develop or sup-
17 port a trusted exchange framework for
18 trust policies and practices and for a com-
19 mon agreement for exchange between
20 health information networks. The common
21 agreement may include—

22 “(I) a common method for au-
23 thenticating trusted health informa-
24 tion network participants;

1 “(II) a common set of rules for
2 trusted exchange;

3 “(III) organizational and oper-
4 ational policies to enable the exchange
5 of health information among net-
6 works, including minimum conditions
7 for such exchange to occur; and

8 “(IV) a process for filing and ad-
9 judicating noncompliance with the
10 terms of the common agreement.

11 “(ii) TECHNICAL ASSISTANCE.—The
12 National Coordinator, in collaboration with
13 the National Institute of Standards and
14 Technology, shall provide technical assist-
15 ance on how to implement the trusted ex-
16 change framework and common agreement
17 under this paragraph.

18 “(iii) PILOT TESTING.—The National
19 Coordinator, in consultation with the Na-
20 tional Institute of Standards and Tech-
21 nology, shall provide for the pilot testing of
22 the trusted exchange framework and com-
23 mon agreement established or supported
24 under this subsection (as authorized under
25 section 13201 of the Health Information

1 Technology for Economic and Clinical
2 Health Act). The National Coordinator, in
3 consultation with the National Institute of
4 Standards and Technology, may delegate
5 pilot testing activities under this clause to
6 independent entities with appropriate ex-
7 pertise.

8 “(C) PUBLICATION OF A TRUSTED EX-
9 CHANGE FRAMEWORK AND COMMON AGREE-
10 MENT.—Not later than 1 year after convening
11 stakeholders under subparagraph (A), the Na-
12 tional Coordinator shall publish on its public
13 Internet website, and in the Federal register,
14 the trusted exchange framework and common
15 agreement developed or supported under sub-
16 paragraph (B). Such trusted exchange frame-
17 work and common agreement shall be published
18 in a manner that protects proprietary and secu-
19 rity information, including trade secrets and
20 any other protected intellectual property.

21 “(D) DIRECTORY OF PARTICIPATING
22 HEALTH INFORMATION NETWORKS.—

23 “(i) IN GENERAL.—Not later than 2
24 years after convening stakeholders under
25 subparagraph (A), and annually thereafter,

1 the National Coordinator shall publish on
2 its public Internet website a list of the
3 health information networks that have
4 adopted the common agreement and are
5 capable of trusted exchange pursuant to
6 the common agreement developed or sup-
7 ported under paragraph (B).

8 “(ii) PROCESS.—The Secretary shall,
9 through notice and comment rulemaking,
10 establish a process for health information
11 networks that voluntarily elect to adopt the
12 trusted exchange framework and common
13 agreement to attest to such adoption of the
14 framework and agreement.

15 “(E) APPLICATION OF THE TRUSTED EX-
16 CHANGE FRAMEWORK AND COMMON AGREE-
17 MENT.—As appropriate, Federal agencies con-
18 tracting or entering into agreements with health
19 information exchange networks may require
20 that as each such network upgrades health in-
21 formation technology or trust and operational
22 practices, such network may adopt, where avail-
23 able, the trusted exchange framework and com-
24 mon agreement published under subparagraph
25 (C).

1 “(F) RULE OF CONSTRUCTION.—

2 “(i) GENERAL ADOPTION.—Nothing
3 in this paragraph shall be construed to re-
4 quire a health information network to
5 adopt the trusted exchange framework or
6 common agreement.

7 “(ii) ADOPTION WHEN EXCHANGE OF
8 INFORMATION IS WITHIN NETWORK.—
9 Nothing in this paragraph shall be con-
10 strued to require a health information net-
11 work to adopt the trusted exchange frame-
12 work or common agreement for the ex-
13 change of electronic health information be-
14 tween participants of the same network.

15 “(iii) EXISTING FRAMEWORKS AND
16 AGREEMENTS.—The trusted exchange
17 framework and common agreement pub-
18 lished under subparagraph (C) shall take
19 into account existing trusted exchange
20 frameworks and agreements used by health
21 information networks to avoid the disrup-
22 tion of existing exchanges between partici-
23 pants of health information networks.

24 “(iv) APPLICATION BY FEDERAL
25 AGENCIES.—Notwithstanding clauses (i),

1 (ii), and (iii), Federal agencies may require
2 the adoption of the trusted exchange
3 framework and common agreement pub-
4 lished under subparagraph (C) for health
5 information exchanges contracting with or
6 entering into agreements pursuant to sub-
7 paragraph (E).

8 “(v) CONSIDERATION OF ONGOING
9 WORK.—In carrying out this paragraph,
10 the Secretary shall ensure the consider-
11 ation of activities carried out by public and
12 private organizations related to exchange
13 between health information exchanges to
14 avoid duplication of efforts.”.

15 (c) PROVIDER DIGITAL CONTACT INFORMATION
16 INDEX.—

17 (1) IN GENERAL.—Not later than 3 years after
18 the date of enactment of this Act, the Secretary of
19 Health and Human Services (referred to in this sub-
20 section as the “Secretary”) shall, directly or through
21 a partnership with a private entity, establish a pro-
22 vider digital contact information index to provide
23 digital contact information for health professionals
24 and health facilities.

1 (2) USE OF EXISTING INDEX.—In establishing
2 the initial index under paragraph (1), the Secretary
3 may utilize an existing provider directory to make
4 such digital contact information available.

5 (3) CONTACT INFORMATION.—An index estab-
6 lished under this subsection shall ensure that con-
7 tact information is available at the individual health
8 care provider level and at the health facility or prac-
9 tice level.

10 (4) RULE OF CONSTRUCTION.—

11 (A) IN GENERAL.—The purpose of this
12 subsection is to encourage the exchange of elec-
13 tronic health information by providing the most
14 useful, reliable, and comprehensive index of pro-
15 viders possible. In furthering such purpose, the
16 Secretary shall include all health professionals
17 and health facilities applicable to provide a use-
18 ful, reliable, and comprehensive index for use in
19 the exchange of health information.

20 (B) LIMITATION.—In no case shall exclu-
21 sion from the index of providers be used as a
22 measure to achieve objectives other the objec-
23 tives described in subparagraph (A).

1 (d) STANDARDS DEVELOPMENT ORGANIZATIONS.—
2 Section 3004 of the Public Health Service Act (42 U.S.C.
3 300jj–14) is amended by adding at the end the following:

4 “(c) DEFERENCE TO STANDARDS DEVELOPMENT
5 ORGANIZATIONS.—In adopting and implementing stand-
6 ards under this section, the Secretary shall give deference
7 to standards published by standards development organi-
8 zations and voluntary consensus-based standards bodies.”.

9 (e) HEALTH INFORMATION TECHNOLOGY ADVISORY
10 COMMITTEE.—

11 (1) IN GENERAL.—Title XXX of the Public
12 Health Service Act (42 U.S.C. 300jj et seq.) is
13 amended by striking sections 3002 (42 U.S.C.
14 300jj–12) and 3003 (42 U.S.C. 300jj–13) and in-
15 serting the following:

16 **“SEC. 3002. HEALTH INFORMATION TECHNOLOGY ADVI-
17 SORY COMMITTEE.**

18 “(a) ESTABLISHMENT.—There is established a
19 Health Information Technology Advisory Committee (re-
20 ferred to in this section as the ‘HIT Advisory Committee’)
21 to recommend to the National Coordinator, consistent
22 with the implementation of the strategic plan described
23 in section 3001(c)(3), policies, and, for purposes of adop-
24 tion under section 3004, standards, implementation speci-
25 fications, and certification criteria, relating to the imple-

1 mentation of a health information technology infrastruc-
2 ture, nationally and locally, that advances the electronic
3 access, exchange, and use of health information. Such
4 Committee shall serve to unify the roles of, and replace,
5 the HIT Policy Committee and the HIT Standards Com-
6 mittee, as in existence before the date of the enactment
7 of the 21st Century Cures Act.

8 “(b) DUTIES.—

9 “(1) RECOMMENDATIONS ON POLICY FRAME-
10 WORK TO ADVANCE AN INTEROPERABLE HEALTH IN-
11 FORMATION TECHNOLOGY INFRASTRUCTURE.—

12 “(A) IN GENERAL.—The HIT Advisory
13 Committee shall recommend to the National
14 Coordinator a policy framework for adoption by
15 the Secretary consistent with the strategic plan
16 under section 3001(c)(3) for advancing the tar-
17 get areas described in this subsection. Such pol-
18 icy framework shall seek to prioritize achieving
19 advancements in the target areas specified in
20 subparagraph (B) of paragraph (2) and may, to
21 the extent consistent with this section, incor-
22 porate policy recommendations made by the
23 HIT Policy Committee, as in existence before
24 the date of the enactment of the 21st Century
25 Cures Act.

1 “(B) UPDATES.—The HIT Advisory Com-
2 mittee shall propose updates to such rec-
3 ommendations to the policy framework and
4 make new recommendations, as appropriate.

5 “(2) GENERAL DUTIES AND TARGET AREAS.—

6 “(A) IN GENERAL.—The HIT Advisory
7 Committee shall recommend to the National
8 Coordinator for purposes of adoption under sec-
9 tion 3004, standards, implementation specifica-
10 tions, and certification criteria and an order of
11 priority for the development, harmonization,
12 and recognition of such standards, specifica-
13 tions, and certification criteria. Such rec-
14 ommendations shall include recommended
15 standards, architectures, and software schemes
16 for access to electronic individually identifiable
17 health information across disparate systems in-
18 cluding user vetting, authentication, privilege
19 management, and access control.

20 “(B) PRIORITY TARGET AREAS.—For pur-
21 poses of this section, the HIT Advisory Com-
22 mittee shall make recommendations under sub-
23 paragraph (A) with respect to at least each of
24 the following target areas:

1 “(i) Achieving a health information
2 technology infrastructure, nationally and
3 locally, that allows for the electronic ac-
4 cess, exchange, and use of health informa-
5 tion, including through technology that
6 provides accurate patient information for
7 the correct patient, including exchanging
8 such information, and avoids the duplica-
9 tion of patient records.

10 “(ii) The promotion and protection of
11 privacy and security of health information
12 in health information technology, including
13 technologies that allow for an accounting
14 of disclosures and protections against dis-
15 closures of individually identifiable health
16 information made by a covered entity for
17 purposes of treatment, payment, and
18 health care operations (as such terms are
19 defined for purposes of the regulation pro-
20 mulgated under section 264(e) of the
21 Health Insurance Portability and Account-
22 ability Act of 1996), including for the seg-
23 mentation and protection from disclosure
24 of specific and sensitive individually identi-
25 fiable health information with the goal of

1 minimizing the reluctance of patients to
2 seek care.

3 “(iii) The facilitation of secure access
4 by an individual to such individual’s pro-
5 tected health information and access to
6 such information by a family member,
7 caregiver, or guardian acting on behalf of
8 a patient, including due to age-related and
9 other disability, cognitive impairment, or
10 dementia.

11 “(iv) Subject to subparagraph (D),
12 any other target area that the HIT Advi-
13 sory Committee identifies as an appro-
14 priate target area to be considered under
15 this subparagraph.

16 “(C) ADDITIONAL TARGET AREAS.—For
17 purposes of this section, the HIT Advisory
18 Committee may make recommendations under
19 subparagraph (A), in addition to areas de-
20 scribed in subparagraph (B), with respect to
21 any of the following areas:

22 “(i) The use of health information
23 technology to improve the quality of health
24 care, such as by promoting the coordina-
25 tion of health care and improving con-

1 tinuity of health care among health care
2 providers, reducing medical errors, improv-
3 ing population health, reducing chronic dis-
4 ease, and advancing research and edu-
5 cation.

6 “(ii) The use of technologies that ad-
7 dress the needs of children and other vul-
8 nerable populations.

9 “(iii) The use of electronic systems to
10 ensure the comprehensive collection of pa-
11 tient demographic data, including at a
12 minimum, race, ethnicity, primary lan-
13 guage, and gender information.

14 “(iv) The use of self-service, telemedi-
15 cine, home health care, and remote moni-
16 toring technologies.

17 “(v) The use of technologies that meet
18 the needs of diverse populations.

19 “(vi) The use of technologies that
20 support—

21 “(I) data for use in quality and
22 public reporting programs;

23 “(II) public health; or

24 “(III) drug safety.

1 “(vii) The use of technologies that
2 allow individually identifiable health infor-
3 mation to be rendered unusable,
4 unreadable, or indecipherable to unauthor-
5 ized individuals when such information is
6 transmitted in a health information net-
7 work or transported outside of the secure
8 facilities or systems where the disclosing
9 covered entity is responsible for security
10 conditions.

11 “(viii) The use of a certified health in-
12 formation technology for each individual in
13 the United States.

14 “(D) AUTHORITY FOR TEMPORARY ADDI-
15 TIONAL PRIORITY TARGET AREAS.—For pur-
16 poses of subparagraph (B)(iv), the HIT Advi-
17 sory Committee may identify an area to be con-
18 sidered for purposes of recommendations under
19 this subsection as a target area described in
20 subparagraph (B) if—

21 “(i) the area is so identified for pur-
22 poses of responding to new circumstances
23 that have arisen in the health information
24 technology community that affect the
25 interoperability, privacy, or security of

1 health information, or affect patient safety;
2 and

3 “(ii) at least 30 days prior to treating
4 such area as if it were a target area de-
5 scribed in subparagraph (B), the National
6 Coordinator provides adequate notice to
7 Congress of the intent to treat such area
8 as so described.

9 “(E) FOCUS OF COMMITTEE WORK.—It is
10 the sense of Congress that the HIT Advisory
11 Committee shall focus its work on the priority
12 areas described in subparagraph (B) before pro-
13 ceeding to other work under subparagraph (C).

14 “(3) RULES RELATING TO RECOMMENDATIONS
15 FOR STANDARDS, IMPLEMENTATION SPECIFICA-
16 TIONS, AND CERTIFICATION CRITERIA.—

17 “(A) IN GENERAL.—The HIT Advisory
18 Committee shall recommend to the National
19 Coordinator standards, implementation speci-
20 fications, and certification criteria described in
21 subsection (a), which may include standards,
22 implementation specifications, and certification
23 criteria that have been developed, harmonized,
24 or recognized by the HIT Advisory Committee
25 or predecessor committee. The HIT Advisory

1 Committee shall update such recommendations
2 and make new recommendations as appropriate,
3 including in response to a notification sent
4 under section 3004(a)(2)(B). Such rec-
5 ommendations shall be consistent with the lat-
6 est recommendations made by the Committee.

7 “(B) HARMONIZATION.—The HIT Advi-
8 sory Committee may recognize harmonized or
9 updated standards from an entity or entities for
10 the purpose of harmonizing or updating stand-
11 ards and implementation specifications in order
12 to achieve uniform and consistent implementa-
13 tion of the standards and implementation speci-
14 fication.

15 “(C) PILOT TESTING OF STANDARDS AND
16 IMPLEMENTATION SPECIFICATIONS.—In the de-
17 velopment, harmonization, or recognition of
18 standards and implementation specifications,
19 the HIT Advisory Committee for purposes of
20 recommendations under paragraph (2)(B),
21 shall, as appropriate, provide for the testing of
22 such standards and specifications by the Na-
23 tional Institute for Standards and Technology
24 under section 13201(a) of the Health Informa-

1 tion Technology for Economic and Clinical
2 Health Act.

3 “(D) CONSISTENCY.—The standards, im-
4 plementation specifications, and certification
5 criteria recommended under paragraph (2)(B)
6 shall be consistent with the standards for infor-
7 mation transactions and data elements adopted
8 pursuant to section 1173 of the Social Security
9 Act.

10 “(E) SPECIAL RULE RELATED TO INTER-
11 OPERABILITY.—Any recommendation made by
12 the HIT Advisory Committee after the date of
13 the enactment of this subparagraph with re-
14 spect to interoperability of health information
15 technology shall be consistent with interoper-
16 ability as described in section 3000.

17 “(4) FORUM.—The HIT Advisory Committee
18 shall serve as a forum for the participation of a
19 broad range of stakeholders with specific expertise in
20 policies, including technical expertise, relating to the
21 matters described in paragraphs (1), (2), and (3) to
22 provide input on the development, harmonization,
23 and recognition of standards, implementation speci-
24 fications, and certification criteria necessary for the
25 development and adoption of health information

1 technology infrastructure nationally and locally that
2 allows for the electronic access, exchange, and use of
3 health information.

4 “(5) SCHEDULE.—Not later than 30 days after
5 the date on which the HIT Advisory Committee first
6 meets, such HIT Advisory Committee shall develop
7 a schedule for the assessment of policy recommenda-
8 tions developed under paragraph (1). The HIT Advi-
9 sory Committee shall update such schedule annually.
10 The Secretary shall publish such schedule in the
11 Federal Register.

12 “(6) PUBLIC INPUT.—The HIT Advisory Com-
13 mittee shall conduct open public meetings and de-
14 velop a process to allow for public comment on the
15 schedule described in paragraph (5) and rec-
16 ommendations described in this subsection. Under
17 such process comments shall be submitted in a time-
18 ly manner after the date of publication of a rec-
19 ommendation under this subsection.

20 “(c) MEASURED PROGRESS IN ADVANCING PRIORITY
21 AREAS.—

22 “(1) IN GENERAL.—For purposes of this sec-
23 tion, the National Coordinator, in collaboration with
24 the Secretary, shall establish, and update as appro-
25 priate, objectives and benchmarks for advancing and

1 measuring the advancement of the priority target
2 areas described in subsection (b)(2)(B).

3 “(2) ANNUAL PROGRESS REPORTS ON ADVANC-
4 ING INTEROPERABILITY.—

5 “(A) IN GENERAL.—The HIT Advisory
6 Committee, in consultation with the National
7 Coordinator, shall annually submit to the Sec-
8 retary and Congress a report on the progress
9 made during the preceding fiscal year in—

10 “(i) achieving a health information
11 technology infrastructure, nationally and
12 locally, that allows for the electronic ac-
13 cess, exchange, and use of health informa-
14 tion; and

15 “(ii) meeting the objectives and
16 benchmarks described in paragraph (1).

17 “(B) CONTENT.—Each such report shall
18 include, for a fiscal year—

19 “(i) a description of the work con-
20 ducted by the HIT Advisory Committee
21 during the preceding fiscal year with re-
22 spect to the areas described in subsection
23 (b)(2)(B);

24 “(ii) an assessment of the status of
25 the infrastructure described in subpara-

1 graph (A), including the extent to which
2 electronic health information is appro-
3 priately and readily available to enhance
4 the access, exchange, and the use of elec-
5 tronic health information between users
6 and across technology offered by different
7 developers;

8 “(iii) the extent to which advance-
9 ments have been achieved with respect to
10 areas described in subsection (b)(2)(B);

11 “(iv) an analysis identifying existing
12 gaps in policies and resources for—

13 “(I) achieving the objectives and
14 benchmarks established under para-
15 graph (1); and

16 “(II) furthering interoperability
17 throughout the health information
18 technology infrastructure;

19 “(v) recommendations for addressing
20 the gaps identified in clause (iii); and

21 “(vi) a description of additional initia-
22 tives as the HIT Advisory Committee and
23 National Coordinator determine appro-
24 priate.

1 “(3) SIGNIFICANT ADVANCEMENT DETERMINA-
2 TION.—The Secretary shall periodically, based on
3 the reports submitted under this subsection, review
4 the target areas described in subsection (b)(2)(B),
5 and, based on the objectives and benchmarks estab-
6 lished under paragraph (1), the Secretary shall de-
7 termine if significant advancement has been achieved
8 with respect to such an area. Such determination
9 shall be taken into consideration by the HIT Advi-
10 sory Committee when determining to what extent
11 the Committee makes recommendations for an area
12 other than an area described in subsection
13 (b)(2)(B).

14 “(d) MEMBERSHIP AND OPERATIONS.—

15 “(1) IN GENERAL.—The National Coordinator
16 shall take a leading position in the establishment
17 and operations of the HIT Advisory Committee.

18 “(2) MEMBERSHIP.—The membership of the
19 HIT Advisory Committee shall—

20 “(A) include at least 25 members, of
21 which—

22 “(i) no fewer than 2 members are ad-
23 vocates for patients or consumers of health
24 information technology;

1 “(ii) 3 members are appointed by the
2 Secretary, 1 of whom shall be appointed to
3 represent the Department of Health and
4 Human Services and 1 of whom shall be a
5 public health official;

6 “(iii) 2 members are appointed by the
7 majority leader of the Senate;

8 “(iv) 2 members are appointed by the
9 minority leader of the Senate;

10 “(v) 2 members are appointed by the
11 Speaker of the House of Representatives;

12 “(vi) 2 members are appointed by the
13 minority leader of the House of Represent-
14 atives; and

15 “(vii) such other members are ap-
16 pointed by the Comptroller General of the
17 United States; and

18 “(B) at least reflect providers, ancillary
19 health care workers, consumers, purchasers,
20 health plans, health information technology de-
21 velopers, researchers, patients, relevant Federal
22 agencies, and individuals with technical exper-
23 tise on health care quality, system functions,
24 privacy, security, and on the electronic ex-

1 change and use of health information, including
2 the use standards for such activity.

3 “(3) PARTICIPATION.—The members of the
4 HIT Advisory Committee shall represent a balance
5 among various sectors of the health care system so
6 that no single sector unduly influences the rec-
7 ommendations of the Committee.

8 “(4) TERMS.—

9 “(A) IN GENERAL.—The terms of the
10 members of the HIT Advisory Committee shall
11 be for 3 years, except that the Secretary shall
12 designate staggered terms of the members first
13 appointed.

14 “(B) VACANCIES.—Any member appointed
15 to fill a vacancy in the membership of the HIT
16 Advisory Committee that occurs prior to the ex-
17 piration of the term for which the member’s
18 predecessor was appointed shall be appointed
19 only for the remainder of that term. A member
20 may serve after the expiration of that member’s
21 term until a successor has been appointed. A
22 vacancy in the HIT Advisory Committee shall
23 be filled in the manner in which the original ap-
24 pointment was made.

1 “(C) LIMITS.—Members of the HIT Advi-
2 sory Committee shall be limited to two 3-year
3 terms, for a total of not to exceed 6 years of
4 service on the Committee.

5 “(5) OUTSIDE INVOLVEMENT.—The HIT Advi-
6 sory Committee shall ensure an opportunity for the
7 participation in activities of the Committee of out-
8 side advisors, including individuals with expertise in
9 the development of policies and standards for the
10 electronic exchange and use of health information,
11 including in the areas of health information privacy
12 and security.

13 “(6) QUORUM.—A majority of the members of
14 the HIT Advisory Committee shall constitute a
15 quorum for purposes of voting, but a lesser number
16 of members may meet and hold hearings.

17 “(7) CONSIDERATION.—The National Coordi-
18 nator shall ensure that the relevant and available
19 recommendations and comments from the National
20 Committee on Vital and Health Statistics are con-
21 sidered in the development of policies.

22 “(8) ASSISTANCE.—For the purposes of car-
23 rying out this section, the Secretary may provide or
24 ensure that financial assistance is provided by the
25 HIT Advisory Committee to defray in whole or in

1 part any membership fees or dues charged by such
2 Committee to those consumer advocacy groups and
3 not-for-profit entities that work in the public interest
4 as a party of their mission.

5 “(e) APPLICATION OF FACA.—The Federal Advisory
6 Committee Act (5 U.S.C. App.), other than section 14 of
7 such Act, shall apply to the HIT Advisory Committee.

8 “(f) PUBLICATION.—The Secretary shall provide for
9 publication in the Federal Register and the posting on the
10 Internet website of the Office of the National Coordinator
11 for Health Information Technology of all policy rec-
12 ommendations made by the HIT Advisory Committee
13 under this section.”.

14 (2) TECHNICAL AND CONFORMING AMEND-
15 MENTS.—Title XXX of the Public Health Service
16 Act (42 U.S.C. 300jj et seq.) is amended—

17 (A) by striking—

18 (i) “HIT Policy Committee” and
19 “HIT Standards Committee” each place
20 that such terms appear (other than within
21 the term “HIT Policy Committee and the
22 HIT Standards Committee” or within the
23 term “HIT Policy Committee or the HIT
24 Standards Committee”) and inserting
25 “HIT Advisory Committee”;

1 (ii) “HIT Policy Committee and the
2 HIT Standards Committee” each place
3 that such term appears and inserting
4 “HIT Advisory Committee”; and

5 (iii) “HIT Policy Committee or the
6 HIT Standards Committee” each place
7 that such term appears and inserting
8 “HIT Advisory Committee”;

9 (B) in section 3000 (42 U.S.C. 300jj)—

10 (i) by striking paragraphs (7) and (8)
11 and redesignating paragraphs (9) through
12 (14) as paragraphs (8) through (13), re-
13 spectively; and

14 (ii) by inserting after paragraph (6)
15 the following paragraph:

16 “(7) HIT ADVISORY COMMITTEE.—The term
17 ‘HIT Advisory Committee’ means such Committee
18 established under section 3002(a).”;

19 (C) in section 3001(c) (42 U.S.C. 300jj–
20 11(c))—

21 (i) in paragraph (1)(A), by striking
22 “under section 3003” and inserting “under
23 section 3002”;

24 (ii) in paragraph (2), by striking sub-
25 paragraph (B) and inserting the following:

1 “(B) HIT ADVISORY COMMITTEE.—The
2 National Coordinator shall be a leading member
3 in the establishment and operations of the HIT
4 Advisory Committee and shall serve as a liaison
5 between that Committee and the Federal Gov-
6 ernment.”;

7 (D) in section 3004(b)(3) (42 U.S.C.
8 300jj-14(b)(3)), by striking “3003(b)(2)” and
9 inserting “3002(b)(4)”;

10 (E) in section 3007(b) (42 U.S.C. 300jj-
11 17(b)), by striking “3003(a)” and inserting
12 “3002(a)(2)”;

13 (F) in section 3008 (42 U.S.C. 300jj-
14 18)—

15 (i) in subsection (b), by striking “or
16 3003”; and

17 (ii) in subsection (c), by striking
18 “3003(b)(1)(A)” and inserting
19 “3002(b)(2)”.

20 (3) TRANSITION TO THE HIT ADVISORY COM-
21 MITTEE.—The Secretary of Health and Human
22 Services shall provide for an orderly and timely tran-
23 sition to the HIT Advisory Committee established
24 under amendments made by this section.

1 (f) PRIORITIES FOR ADOPTION OF STANDARDS, IM-
2 PLEMENTATION SPECIFICATIONS, AND CERTIFICATION
3 CRITERIA.—Title XXX of the Public Health Service Act
4 (42 U.S.C. 300jj et seq.), as amended by subsection (e),
5 is further amended by inserting after section 3002 the fol-
6 lowing:

7 **“SEC. 3003. SETTING PRIORITIES FOR STANDARDS ADOPTI-**
8 **ON.**

9 “(a) IDENTIFYING PRIORITIES.—

10 “(1) IN GENERAL.—Not later than 6 months
11 after the date on which the HIT Advisory Com-
12 mittee first meets, the National Coordinator shall
13 periodically convene the HIT Advisory Committee
14 to—

15 “(A) identify priority uses of health infor-
16 mation technology, focusing on priorities—

17 “(i) arising from the implementation
18 of the incentive programs for the meaning-
19 ful use of certified EHR technology, the
20 Merit-based Incentive Payment System, Al-
21 ternative Payment Models, the Hospital
22 Value-Based Purchasing Program, and any
23 other value-based payment program deter-
24 mined appropriate by the Secretary;

1 “(ii) related to the quality of patient
2 care;
3 “(iii) related to public health;
4 “(iv) related to clinical research;
5 “(v) related to the privacy and secu-
6 rity of electronic health information;
7 “(vi) related to innovation in the field
8 of health information technology;
9 “(vii) related to patient safety;
10 “(viii) related to the usability of
11 health information technology;
12 “(ix) related to individuals’ access to
13 electronic health information; and
14 “(x) other priorities determined ap-
15 propriate by the Secretary;
16 “(B) identify existing standards and imple-
17 mentation specifications that support the use
18 and exchange of electronic health information
19 needed to meet the priorities identified in sub-
20 paragraph (A); and
21 “(C) publish a report summarizing the
22 findings of the analysis conducted under sub-
23 paragraphs (A) and (B) and make appropriate
24 recommendations.

1 “(2) PRIORITIZATION.—In identifying such
2 standards and implementation specifications under
3 paragraph (1)(B), the HIT Advisory Committee
4 shall prioritize standards and implementation speci-
5 fications developed by consensus-based standards de-
6 velopment organizations.

7 “(3) GUIDELINES FOR REVIEW OF EXISTING
8 STANDARDS AND SPECIFICATIONS.—In consultation
9 with the consensus-based entity described in section
10 1890 of the Social Security Act and other appro-
11 priate Federal agencies, the analysis of existing
12 standards under paragraph (1)(B) shall include an
13 evaluation of the need for a core set of common data
14 elements and associated value sets to enhance the
15 ability of certified health information technology to
16 capture, use, and exchange structured electronic
17 health information.

18 “(b) REVIEW OF ADOPTED STANDARDS.—

19 “(1) IN GENERAL.—Beginning 5 years after the
20 date of enactment of the 21st Century Cures Act
21 and every 3 years thereafter, the National Coordi-
22 nator shall convene stakeholders to review the exist-
23 ing set of adopted standards and implementation
24 specifications and make recommendations with re-
25 spect to whether to—

1 “(A) maintain the use of such standards
2 and implementation specifications; or

3 “(B) phase out such standards and imple-
4 mentation specifications.

5 “(2) PRIORITIES.—The HIT Advisory Com-
6 mittee, in collaboration with the National Institute
7 for Standards and Technology, shall annually and
8 through the use of public input, review and publish
9 priorities for the use of health information tech-
10 nology, standards, and implementation specifications
11 to support those priorities.

12 “(c) RULE OF CONSTRUCTION.—Nothing in this sec-
13 tion shall be construed to prevent the use or adoption of
14 novel standards that improve upon the existing health in-
15 formation technology infrastructure and facilitate the se-
16 cure exchange of health information.”.

17 **SEC. 4004. INFORMATION BLOCKING.**

18 Subtitle C of title XXX of the Public Health Service
19 Act (42 U.S.C. 300jj–51 et seq.) is amended by adding
20 at the end the following:

21 **“SEC. 3022. INFORMATION BLOCKING.**

22 “(a) DEFINITION.—

23 “(1) IN GENERAL.—In this section, the term
24 ‘information blocking’ means a practice that—

1 “(A) except as required by law or specified
2 by the Secretary pursuant to rulemaking under
3 paragraph (3), is likely to interfere with, pre-
4 vent, or materially discourage access, exchange,
5 or use of electronic health information; and

6 “(B)(i) if conducted by a health informa-
7 tion technology developer, exchange, or network,
8 such developer, exchange, or network knows, or
9 should know, that such practice is likely to
10 interfere with, prevent, or materially discourage
11 the access, exchange, or use of electronic health
12 information; or

13 “(ii) if conducted by a health care pro-
14 vider, such provider knows that such practice is
15 unreasonable and is likely to interfere with, pre-
16 vent, or materially discourage access, exchange,
17 or use of electronic health information.

18 “(2) PRACTICES DESCRIBED.—The information
19 blocking practices described in paragraph (1) may
20 include—

21 “(A) practices that restrict authorized ac-
22 cess, exchange, or use under applicable State or
23 Federal law of such information for treatment
24 and other permitted purposes under such appli-

1 cable law, including transitions between cer-
2 tified health information technologies;

3 “(B) implementing health information
4 technology in nonstandard ways that are likely
5 to substantially increase the complexity or bur-
6 den of accessing, exchanging, or using elec-
7 tronic health information; and

8 “(C) implementing health information
9 technology in ways that are likely to—

10 “(i) restrict the access, exchange, or
11 use of electronic health information with
12 respect to exporting complete information
13 sets or in transitioning between health in-
14 formation technology systems; or

15 “(ii) lead to fraud, waste, or abuse, or
16 impede innovations and advancements in
17 health information access, exchange, and
18 use, including care delivery enabled by
19 health information technology.

20 “(3) RULEMAKING.—The Secretary, through
21 rulemaking, shall identify reasonable and necessary
22 activities that do not constitute information blocking
23 for purposes of paragraph (1).

24 “(4) NO ENFORCEMENT BEFORE EXCEPTION
25 IDENTIFIED.—The term ‘information blocking’ does

1 not include any practice or conduct occurring prior
2 to the date that is 30 days after the date of enact-
3 ment of the 21st Century Cures Act.

4 “(5) CONSULTATION.—The Secretary may con-
5 sult with the Federal Trade Commission in promul-
6 gating regulations under this subsection, to the ex-
7 tent that such regulations define practices that are
8 necessary to promote competition and consumer wel-
9 fare.

10 “(6) APPLICATION.—The term ‘information
11 blocking’, with respect to an individual or entity,
12 shall not include an act or practice other than an act
13 or practice committed by such individual or entity.

14 “(7) CLARIFICATION.—In carrying out this sec-
15 tion, the Secretary shall ensure that health care pro-
16 viders are not penalized for the failure of developers
17 of health information technology or other entities of-
18 fering health information technology to such pro-
19 viders to ensure that such technology meets the re-
20 quirements to be certified under this title.

21 “(b) INSPECTOR GENERAL AUTHORITY.—

22 “(1) IN GENERAL.—The inspector general of
23 the Department of Health and Human Services (re-
24 ferred to in this section as the ‘Inspector General’)
25 may investigate any claim that—

1 “(A) a health information technology de-
2 veloper of certified health information tech-
3 nology or other entity offering certified health
4 information technology—

5 “(i) submitted a false attestation
6 under section 3001(c)(5)(D)(vii); or

7 “(ii) engaged in information blocking;

8 “(B) a health care provider engaged in in-
9 formation blocking; or

10 “(C) a health information exchange or net-
11 work engaged in information blocking.

12 “(2) PENALTIES.—

13 “(A) DEVELOPERS, NETWORKS, AND EX-
14 CHANGES.—Any individual or entity described
15 in subparagraph (A) or (C) of paragraph (1)
16 that the Inspector General, following an inves-
17 tigation conducted under this subsection, deter-
18 mines to have committed information blocking
19 shall be subject to a civil monetary penalty de-
20 termined by the Secretary for all such violations
21 identified through such investigation, which
22 may not exceed \$1,000,000 per violation. Such
23 determination shall take into account factors
24 such as the nature and extent of the informa-
25 tion blocking and harm resulting from such in-

1 formation blocking, including, where applicable,
2 the number of patients affected, the number of
3 providers affected, and the number of days the
4 information blocking persisted.

5 “(B) PROVIDERS.—Any individual or enti-
6 ty described in subparagraph (B) of paragraph
7 (1) determined by the Inspector General to
8 have committed information blocking shall be
9 referred to the appropriate agency to be subject
10 to appropriate disincentives using authorities
11 under applicable Federal law, as the Secretary
12 sets forth through notice and comment rule-
13 making.

14 “(C) PROCEDURE.—The provisions of sec-
15 tion 1128A of the Social Security Act (other
16 than subsections (a) and (b) of such section)
17 shall apply to a civil money penalty applied
18 under this paragraph in the same manner as
19 such provisions apply to a civil money penalty
20 or proceeding under such section 1128A(a).

21 “(D) RECOVERED PENALTY FUNDS.—The
22 amounts recovered under this paragraph shall
23 be allocated as follows:

24 “(i) ANNUAL OPERATING EX-
25 PENSES.—Each year following the estab-

1 lishment of the authority under this sub-
2 section, the Office of the Inspector General
3 shall provide to the Secretary an estimate
4 of the costs to carry out investigations
5 under this section. Such estimate may in-
6 clude reasonable reserves to account for
7 variance in annual amounts recovered
8 under this paragraph. There is authorized
9 to be appropriated for purposes of carrying
10 out this section an amount equal to the
11 amount specified in such estimate for the
12 fiscal year.

13 “(ii) APPLICATION TO OTHER PRO-
14 GRAMS.—The amounts recovered under
15 this paragraph and remaining after
16 amounts are made available under clause
17 (i) shall be transferred to the Federal Hos-
18 pital Insurance Trust Fund under section
19 1817 of the Social Security Act and the
20 Federal Supplementary Medical Insurance
21 Trust Fund under section 1841 of such
22 Act, in such proportion as the Secretary
23 determines appropriate.

24 “(E) AUTHORIZATION OF APPROPRIA-
25 TIONS.—There is authorized to be appropriated

1 to the Office of the Inspector General to carry
2 out this section \$10,000,000, to remain avail-
3 able until expended.

4 “(3) RESOLUTION OF CLAIMS.—

5 “(A) IN GENERAL.—The Office of the In-
6 spector General, if such Office determines that
7 a consultation regarding the health privacy and
8 security rules promulgated under section 264(c)
9 of the Health Insurance Portability and Ac-
10 countability Act of 1996 (42 U.S.C. 1320d–2
11 note) will resolve an information blocking claim,
12 may refer such instances of information block-
13 ing to the Office for Civil Rights of the Depart-
14 ment of Health and Human Services for resolu-
15 tion.

16 “(B) LIMITATION ON LIABILITY.—If a
17 health care provider or health information tech-
18 nology developer makes information available
19 based on a good faith reliance on consultations
20 with the Office for Civil Rights of the Depart-
21 ment of Health and Human Services pursuant
22 to a referral under subparagraph (A), with re-
23 spect to such information, the health care pro-
24 vider or developer shall not be liable for such

1 disclosure or disclosures made pursuant to sub-
2 paragraph (A).

3 “(c) IDENTIFYING BARRIERS TO EXCHANGE OF
4 CERTIFIED HEALTH INFORMATION TECHNOLOGY.—

5 “(1) TRUSTED EXCHANGE DEFINED.—In this
6 section, the term ‘trusted exchange’ with respect to
7 certified electronic health records means that the
8 certified electronic health record technology has the
9 technical capability to enable secure health informa-
10 tion exchange between users and multiple certified
11 electronic health record technology systems.

12 “(2) GUIDANCE.—The National Coordinator, in
13 consultation with the Office for Civil Rights of the
14 Department of Health and Human Services, shall
15 issue guidance on common legal, governance, and se-
16 curity barriers that prevent the trusted exchange of
17 electronic health information.

18 “(3) REFERRAL.—The National Coordinator
19 and the Office for Civil Rights of the Department of
20 Health and Human Services may refer to the In-
21 spector General instances or patterns of refusal to
22 exchange health information with an individual or
23 entity using certified electronic health record tech-
24 nology that is technically capable of trusted ex-

1 change and under conditions when exchange is le-
2 gally permissible.

3 “(d) ADDITIONAL PROVISIONS.—

4 “(1) INFORMATION SHARING PROVISIONS.—The
5 National Coordinator may serve as a technical con-
6 sultant to the Inspector General and the Federal
7 Trade Commission for purposes of carrying out this
8 section. The National Coordinator may, notwith-
9 standing any other provision of law, share informa-
10 tion related to claims or investigations under sub-
11 section (b) with the Federal Trade Commission for
12 purposes of such investigations and shall share in-
13 formation with the Inspector General, as required by
14 law.

15 “(2) PROTECTION FROM DISCLOSURE OF IN-
16 FORMATION.—Any information that is received by
17 the National Coordinator in connection with a claim
18 or suggestion of possible information blocking and
19 that could reasonably be expected to facilitate identi-
20 fication of the source of the information—

21 “(A) shall not be disclosed by the National
22 Coordinator except as may be necessary to
23 carry out the purpose of this section;

24 “(B) shall be exempt from mandatory dis-
25 closure under section 552 of title 5, United

1 States Code, as provided by subsection (b)(3) of
2 such section; and

3 “(C) may be used by the Inspector General
4 or Federal Trade Commission for reporting
5 purposes to the extent that such information
6 could not reasonably be expected to facilitate
7 identification of the source of such information.

8 “(3) STANDARDIZED PROCESS.—

9 “(A) IN GENERAL.—The National Coordi-
10 nator shall implement a standardized process
11 for the public to submit reports on claims of—

12 “(i) health information technology
13 products or developers of such products (or
14 other entities offering such products to
15 health care providers) not being interoper-
16 able or resulting in information blocking;

17 “(ii) actions described in subsection
18 (b)(1) that result in information blocking
19 as described in subsection (a); and

20 “(iii) any other act described in sub-
21 section (a).

22 “(B) COLLECTION OF INFORMATION.—The
23 standardized process implemented under sub-
24 paragraph (A) shall provide for the collection of
25 such information as the originating institution,

1 location, type of transaction, system and
2 version, timestamp, terminating institution, lo-
3 cations, system and version, failure notice, and
4 other related information.

5 “(4) NONDUPLICATION OF PENALTY STRUC-
6 TURES.—In carrying out this subsection, the Sec-
7 retary shall, to the extent possible, ensure that pen-
8 alties do not duplicate penalty structures that would
9 otherwise apply with respect to information blocking
10 and the type of individual or entity involved as of
11 the day before the date of the enactment of this sec-
12 tion.”.

13 **SEC. 4005. LEVERAGING ELECTRONIC HEALTH RECORDS**
14 **TO IMPROVE PATIENT CARE.**

15 (a) REQUIREMENT RELATING TO REGISTRIES.—

16 (1) IN GENERAL.—To be certified in accordance
17 with title XXX of the Public Health Service Act (42
18 U.S.C. 300jj et seq.), electronic health records shall
19 be capable of transmitting to, and where applicable,
20 receiving and accepting data from, registries in ac-
21 cordance with standards recognized by the Office of
22 the National Coordinator for Health Information
23 Technology, including clinician-led clinical data reg-
24 istries, that are also certified to be technically capa-
25 ble of receiving and accepting from, and where appli-

1 cable, transmitting data to certified electronic health
2 record technology in accordance with such stand-
3 ards.

4 (2) RULE OF CONSTRUCTION.—Nothing in this
5 subsection shall be construed to require the certifi-
6 cation of registries beyond the technical capability to
7 exchange data in accordance with applicable recog-
8 nized standards.

9 (b) DEFINITION.—For purposes of this Act, the term
10 “clinician-led clinical data registry” means a clinical data
11 repository—

12 (1) that is established and operated by a clini-
13 cian-led or controlled, tax-exempt (pursuant to sec-
14 tion 501(c) of the Internal Revenue Code of 1986),
15 professional society or other similar clinician-led or
16 -controlled organization, or such organization’s con-
17 trolled affiliate, devoted to the care of a population
18 defined by a particular disease, condition, exposure
19 or therapy;

20 (2) that is designed to collect detailed, stand-
21 ardized data on an ongoing basis for medical proce-
22 dures, services, or therapies for particular diseases,
23 conditions, or exposures;

24 (3) that provides feedback to participants who
25 submit reports to the repository;

1 (4) that meets standards for data quality in-
2 cluding—

3 (A) systematically collecting clinical and
4 other health care data, using standardized data
5 elements and having procedures in place to
6 verify the completeness and validity of those
7 data; and

8 (B) being subject to regular data checks or
9 audits to verify completeness and validity; and

10 (5) that provides ongoing participant training
11 and support.

12 (c) TREATMENT OF HEALTH INFORMATION TECH-
13 NOLOGY DEVELOPERS WITH RESPECT TO PATIENT SAFE-
14 TY ORGANIZATIONS.—

15 (1) IN GENERAL.—In applying part C of title
16 IX of the Public Health Service Act (42 U.S.C.
17 299b–21 et seq.), a health information technology
18 developer shall be treated as a provider (as defined
19 in section 921 of such Act) for purposes of reporting
20 and conducting patient safety activities concerning
21 improving clinical care through the use of health in-
22 formation technology that could result in improved
23 patient safety, health care quality, or health care
24 outcomes.

1 (2) REPORT.—Not later than 4 years after the
2 date of enactment of this Act, the Secretary of
3 Health and Human Services shall submit to the
4 Committee on Health, Education, Labor, and Pen-
5 sions of the Senate and the Committee on Energy
6 and Commerce of the House of Representatives, a
7 report concerning best practices and current trends
8 voluntarily provided, without identifying individual
9 providers or disclosing or using protected health in-
10 formation or individually identifiable information, by
11 patient safety organizations to improve the integra-
12 tion of health information technology into clinical
13 practice.

14 **SEC. 4006. EMPOWERING PATIENTS AND IMPROVING PA-**
15 **TIENT ACCESS TO THEIR ELECTRONIC**
16 **HEALTH INFORMATION.**

17 (a) USE OF HEALTH INFORMATION EXCHANGES FOR
18 PATIENT ACCESS.—Section 3009 of the Public Health
19 Service Act (42 U.S.C. 300jj–19) is amended by adding
20 at the end the following:

21 “(c) PROMOTING PATIENT ACCESS TO ELECTRONIC
22 HEALTH INFORMATION THROUGH HEALTH INFORMA-
23 TION EXCHANGES .—

24 “(1) IN GENERAL.—The Secretary shall use ex-
25 isting authorities to encourage partnerships between

1 health information exchange organizations and net-
2 works and health care providers, health plans, and
3 other appropriate entities with the goal of offering
4 patients access to their electronic health information
5 in a single, longitudinal format that is easy to un-
6 derstand, secure, and may be updated automatically.

7 “(2) EDUCATION OF PROVIDERS.—The Sec-
8 retary, in coordination with the Office for Civil
9 Rights of the Department of Health and Human
10 Services, shall—

11 “(A) educate health care providers on ways
12 of leveraging the capabilities of health informa-
13 tion exchanges (or other relevant platforms) to
14 provide patients with access to their electronic
15 health information;

16 “(B) clarify misunderstandings by health
17 care providers about using health information
18 exchanges (or other relevant platforms) for pa-
19 tient access to electronic health information;
20 and

21 “(C) to the extent practicable, educate pro-
22 viders about health information exchanges (or
23 other relevant platforms) that employ some or
24 all of the capabilities described in paragraph
25 (1).

1 “(3) REQUIREMENTS.—In carrying out para-
2 graph (1), the Secretary, in coordination with the
3 Office for Civil Rights, shall issue guidance to health
4 information exchanges related to best practices to
5 ensure that the electronic health information pro-
6 vided to patients is—

7 “(A) private and secure;

8 “(B) accurate;

9 “(C) verifiable; and

10 “(D) where a patient’s authorization to ex-
11 change information is required by law, easily
12 exchanged pursuant to such authorization.

13 “(4) RULE OF CONSTRUCTION.—Nothing in
14 this subsection shall be construed to preempt State
15 laws applicable to patient consent for the access of
16 information through a health information exchange
17 (or other relevant platform) that provide protections
18 to patients that are greater than the protections oth-
19 erwise provided for under applicable Federal law.

20 “(d) EFFORTS TO PROMOTE ACCESS TO HEALTH IN-
21 FORMATION.—The National Coordinator and the Office
22 for Civil Rights of the Department of Health and Human
23 Services shall jointly promote patient access to health in-
24 formation in a manner that would ensure that such infor-
25 mation is available in a form convenient for the patient,

1 in a reasonable manner, without burdening the health care
2 provider involved.

3 “(e) ACCESSIBILITY OF PATIENT RECORDS.—

4 “(1) ACCESSIBILITY AND UPDATING OF INFOR-
5 MATION.—

6 “(A) IN GENERAL.—The Secretary, in con-
7 sultation with the National Coordinator, shall
8 promote policies that ensure that a patient’s
9 electronic health information is accessible to
10 that patient and the patient’s designees, in a
11 manner that facilitates communication with the
12 patient’s health care providers and other indi-
13 viduals, including researchers, consistent with
14 such patient’s consent.

15 “(B) UPDATING EDUCATION ON ACCESS-
16 ING AND EXCHANGING PERSONAL HEALTH IN-
17 FORMATION.—To promote awareness that an
18 individual has a right of access to inspect, ob-
19 tain a copy of, and transmit to a third party a
20 copy of such individual’s protected health infor-
21 mation pursuant to the Health Information
22 Portability and Accountability Act, Privacy
23 Rule (subpart E of part 164 of title 45, Code
24 of Federal Regulations), the Director of the Of-
25 fice for Civil Rights, in consultation with the

1 National Coordinator, shall assist individuals
2 and health care providers in understanding a
3 patient’s rights to access and protect personal
4 health information under the Health Insurance
5 Portability and Accountability Act of 1996
6 (Public Law 104–191), including providing best
7 practices for requesting personal health infor-
8 mation in a computable format, including using
9 patient portals or third-party applications and
10 common cases when a provider is permitted to
11 exchange and provide access to health informa-
12 tion.”.

13 “(2) CERTIFYING USABILITY FOR PATIENTS.—

14 In carrying out certification programs under section
15 3001(c)(5), the National Coordinator may require
16 that—

17 “(A) the certification criteria support—

18 “(i) patient access to their electronic
19 health information, including in a single
20 longitudinal format that is easy to under-
21 stand, secure, and may be updated auto-
22 matically;

23 “(ii) the patient’s ability to electroni-
24 cally communicate patient-reported infor-

1 mation (such as family history and medical
2 history); and

3 “(iii) patient access to their personal
4 electronic health information for research
5 at the option of the patient; and

6 “(B) the HIT Advisory Committee develop
7 and prioritize standards, implementation speci-
8 fications, and certification criteria required to
9 help support patient access to electronic health
10 information, patient usability, and support for
11 technologies that offer patients access to their
12 electronic health information in a single, longi-
13 tudinal format that is easy to understand, se-
14 cure, and may be updated automatically.”.

15 (b) ACCESS TO INFORMATION IN AN ELECTRONIC
16 FORMAT.—Section 13405(e) of the Health Information
17 Technology for Economic and Clinical Health Act (42
18 U.S.C. 17935) is amended—

19 (1) in paragraph (1), by striking “and” at the
20 end;

21 (2) by redesignating paragraph (2) as para-
22 graph (3); and

23 (3) by inserting after paragraph (1), the fol-
24 lowing:

1 “(2) if the individual makes a request to a busi-
2 ness associate for access to, or a copy of, protected
3 health information about the individual, or if an in-
4 dividual makes a request to a business associate to
5 grant such access to, or transmit such copy directly
6 to, a person or entity designated by the individual,
7 a business associate may provide the individual with
8 such access or copy, which may be in an electronic
9 form, or grant or transmit such access or copy to
10 such person or entity designated by the individual;
11 and”.

12 **SEC. 4007. GAO STUDY ON PATIENT MATCHING.**

13 (a) IN GENERAL.—Not later than 1 year after the
14 date of enactment of this Act, the Comptroller General
15 of the United States shall conduct a study to—

16 (1) review the policies and activities of the Of-
17 fice of the National Coordinator for Health Informa-
18 tion Technology and other relevant stakeholders,
19 which may include standards development organiza-
20 tions, experts in the technical aspects of health in-
21 formation technology, health information technology
22 developers, providers of health services, health care
23 suppliers, health care payers, health care quality or-
24 ganizations, States, health information technology
25 policy experts, and other appropriate entities, to en-

1 sure appropriate patient matching to protect patient
2 privacy and security with respect to electronic health
3 records and the exchange of electronic health infor-
4 mation; and

5 (2) survey ongoing efforts related to the policies
6 and activities described in paragraph (1) and the ef-
7 fectiveness of such efforts occurring in the private
8 sector.

9 (b) AREAS OF CONCENTRATION.—In conducting the
10 study under subsection (a), the Comptroller General
11 shall—

12 (1) evaluate current methods used in certified
13 electronic health records for patient matching based
14 on performance related to factors such as—

- 15 (A) the privacy of patient information;
- 16 (B) the security of patient information;
- 17 (C) improving matching rates;
- 18 (D) reducing matching errors; and
- 19 (E) reducing duplicate records; and

20 (2) determine whether the Office of the Na-
21 tional Coordinator for Health Information Tech-
22 nology could improve patient matching by taking
23 steps including—

- 24 (A) defining additional data elements to
25 assist in patient data matching;

1 (B) agreeing on a required minimum set of
2 elements that need to be collected and ex-
3 changed;

4 (C) requiring electronic health records to
5 have the ability to make certain fields required
6 and use specific standards; and

7 (D) other options recommended by the rel-
8 evant stakeholders consulted pursuant to sub-
9 section (a).

10 (c) REPORT.—Not later than 2 years after the date
11 of enactment of this Act, the Comptroller General shall
12 submit to the appropriate committees of Congress a report
13 concerning the findings of the study conducted under sub-
14 section (a).

15 **SEC. 4008. GAO STUDY ON PATIENT ACCESS TO HEALTH IN-**
16 **FORMATION.**

17 (a) STUDY.—

18 (1) IN GENERAL.—The Comptroller General of
19 the United States (referred to in this section as the
20 “Comptroller General”) shall build on prior Govern-
21 ment Accountability Office studies and other lit-
22 erature review and conduct a study to review patient
23 access to their own protected health information, in-
24 cluding barriers to such patient access and complica-
25 tions or difficulties providers experience in providing

1 access to patients. In conducting such study, the
2 Comptroller General shall consider the increase in
3 adoption of health information technology and the
4 increasing prevalence of protected health information
5 that is maintained electronically.

6 (2) AREAS OF CONCENTRATION.—In conducting
7 the review under paragraph (1), the Comptroller
8 General shall consider—

9 (A) instances when covered entities charge
10 individuals, including patients, third parties,
11 and health care providers, for record requests,
12 including records that are requested in an elec-
13 tronic format;

14 (B) examples of the amounts and types of
15 fees charged to individuals for record requests,
16 including instances when the record is re-
17 quested to be transmitted to a third party;

18 (C) the extent to which covered entities are
19 unable to provide the access requested by indi-
20 viduals in the form and format requested by the
21 individual, including examples of such in-
22 stances;

23 (D) instances in which third parties may
24 request protected health information through
25 patients' individual right of access, including in-

1 stances where such requests may be used to cir-
2 cumvent appropriate fees that may be charged
3 to third parties;

4 (E) opportunities that permit covered enti-
5 ties to charge appropriate fees to third parties
6 for patient records while providing patients with
7 access to their protected health information at
8 low or no cost;

9 (F) the ability of providers to distinguish
10 between requests originating from an individual
11 that require limitation to a cost-based fee and
12 requests originating from third parties that
13 may not be limited to cost-based fees; and

14 (G) other circumstances that may inhibit
15 the ability of providers to provide patients with
16 access to their records, and the ability of pa-
17 tients to gain access to their records.

18 (b) REPORT.—Not later than 18 months after the
19 date of enactment of this Act, the Comptroller General
20 shall submit a report to Congress on the findings of the
21 study conducted under subsection (a).

1 **SEC. 4009. STREAMLINING TRANSFERS USED FOR EDU-**
2 **CATIONAL PURPOSES.**

3 (a) IN GENERAL.—Section 1128G(e)(10)(B) of the
4 Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)) is
5 amended—

6 (1) in clause (iii), by inserting “, including
7 peer-reviewed journals, journal reprints, journal sup-
8 plements, medical conference reports, and medical
9 textbooks” after “patient use”; and

10 (2) by adding at the end the following new
11 clause:

12 “(xiii) In the case of a covered recipi-
13 ent who is a physician, an indirect pay-
14 ment or transfer of value to the covered re-
15 cipient—

16 “(I) for speaking at, or preparing
17 educational materials for, an edu-
18 cational event for physicians or other
19 health care professionals that does not
20 commercially promote a covered drug,
21 device, biological, or medical supply;
22 or

23 “(II) that serves the sole purpose
24 of providing the covered recipient with
25 medical education, such as by pro-
26 viding the covered recipient with the

1 tuition required to attend an edu-
2 cational event or with materials pro-
3 vided to physicians at an educational
4 event.”.

5 (b) **EFFECTIVE DATE.**—The amendments made by
6 this section shall apply with respect to payments and
7 transfers of value made on or after the date of enactment
8 of this Act.

9 **SEC. 4010. IMPROVING MEDICARE LOCAL COVERAGE DE-**
10 **TERMINATIONS.**

11 (a) **IN GENERAL.**—Section 1862(l)(5) of the Social
12 Security Act (42 U.S.C. 1395y(l)(5)) is amended by add-
13 ing at the end the following new subparagraph:

14 “(D) **LOCAL COVERAGE DETERMINA-**
15 **TIONS.**—The Secretary shall require each Medi-
16 care administrative contractor that develops a
17 local coverage determination to make available
18 on the Internet website of such contractor and
19 on the Medicare Internet website, at least 45
20 days before the effective date of such deter-
21 mination, the following information:

22 “(i) Such determination in its en-
23 tirety.

24 “(ii) Where and when the proposed
25 determination was first made public.

1 “(iii) Hyperlinks to the proposed de-
2 termination and a response to comments
3 submitted to the contractor with respect to
4 such proposed determination.

5 “(iv) A summary of evidence that was
6 considered by the contractor during the de-
7 velopment of such determination and a list
8 of the sources of such evidence.

9 “(v) An explanation of the rationale
10 that supports such determination.”.

11 (b) **EFFECTIVE DATE.**—The amendment made by
12 subsection (a) shall apply with respect to local coverage
13 determinations that are proposed or revised on or after
14 the date that is 180 days after the date of enactment of
15 this Act.

16 **SEC. 4011. MEDICARE PHARMACEUTICAL AND TECH-**
17 **NOLOGY OMBUDSMAN.**

18 Section 1808 of the Social Security Act (42 U.S.C.
19 1395b–9) is amended by adding at the end the following
20 new subsection:

21 “(d) **PHARMACEUTICAL AND TECHNOLOGY OMBUDS-**
22 **MAN.**—

23 “(1) **IN GENERAL.**—Not later than 12 months
24 after the date of enactment of this paragraph, the
25 Secretary shall provide for a pharmaceutical and

1 technology ombudsman within the Centers for Medi-
2 care & Medicaid Services who shall receive and re-
3 spond to complaints, grievances, and requests that—

4 “(A) are from entities that manufacture
5 pharmaceutical, biotechnology, medical device,
6 or diagnostic products that are covered or for
7 which coverage is being sought under this title;
8 and

9 “(B) are with respect to coverage, coding,
10 or payment under this title for such products.

11 “(2) APPLICATION.—The second sentence of
12 subsection (c)(2) shall apply to the ombudsman
13 under subparagraph (A) in the same manner as such
14 sentence applies to the Medicare Beneficiary Om-
15 budsman under subsection (c).”.

16 **SEC. 4012. MEDICARE SITE-OF-SERVICE PRICE TRANS-**
17 **PARENCY.**

18 Section 1834 of the Social Security Act (42 U.S.C.
19 1395m) is amended by adding at the end the following
20 new subsection:

21 “(t) SITE-OF-SERVICE PRICE TRANSPARENCY.—

22 “(1) IN GENERAL.—In order to facilitate price
23 transparency with respect to items and services for
24 which payment may be made either to a hospital
25 outpatient department or to an ambulatory surgical

1 center under this title, the Secretary shall, for 2018
2 and each year thereafter, make available to the pub-
3 lic via a searchable Internet website, with respect to
4 an appropriate number of such items and services—

5 “(A) the estimated payment amount for
6 the item or service under the outpatient depart-
7 ment fee schedule under subsection (t) of sec-
8 tion 1833 and the ambulatory surgical center
9 payment system under subsection (i) of such
10 section; and

11 “(B) the estimated amount of beneficiary
12 liability applicable to the item or service.

13 “(2) CALCULATION OF ESTIMATED BENE-
14 FICIARY LIABILITY.—For purposes of paragraph
15 (1)(B), the estimated amount of beneficiary liability,
16 with respect to an item or service, is the amount for
17 such item or service for which an individual who
18 does not have coverage under a Medicare supple-
19 mental policy certified under section 1882 or any
20 other supplemental insurance coverage is respon-
21 sible.

22 “(3) IMPLEMENTATION.—In carrying out this
23 subsection, the Secretary—

24 “(A) shall include in the notice described
25 in section 1804(a) a notification of the avail-

1 ability of the estimated amounts made available
2 under paragraph (1); and

3 “(B) may utilize mechanisms in existence
4 on the date of enactment of this subsection,
5 such as the portion of the Internet website of
6 the Centers for Medicare & Medicaid Services
7 on which information comparing physician per-
8 formance is posted (commonly referred to as
9 the Physician Compare Internet website), to
10 make available such estimated amounts under
11 such paragraph.

12 “(4) FUNDING.—For purposes of implementing
13 this subsection, the Secretary shall provide for the
14 transfer, from the Federal Supplementary Medical
15 Insurance Trust Fund under section 1841 to the
16 Centers for Medicare & Medicaid Services Program
17 Management Account, of \$6,000,000 for fiscal year
18 2017, to remain available until expended.”.

19 **SEC. 4013. TELEHEALTH SERVICES IN MEDICARE.**

20 (a) PROVISION OF INFORMATION BY CENTERS FOR
21 MEDICARE & MEDICAID SERVICES.—Not later than 1
22 year after the date of enactment of this Act, the Adminis-
23 trator of the Centers for Medicare & Medicaid Services
24 shall provide to the committees of jurisdiction of the

1 House of Representatives and the Senate information on
2 the following:

3 (1) The populations of Medicare beneficiaries,
4 such as those who are dually eligible for the Medi-
5 care program under title XVIII of the Social Secu-
6 rity Act (42 U.S.C. 1395 et seq.) and the Medicaid
7 program under title XIX of such Act (42 U.S.C.
8 1396 et seq.) and those with chronic conditions,
9 whose care may be improved most in terms of qual-
10 ity and efficiency by the expansion, in a manner that
11 meets or exceeds the existing in-person standard of
12 care under the Medicare program under such title
13 XVIII, of telehealth services under section
14 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

15 (2) Activities by the Center for Medicare and
16 Medicaid Innovation which examine the use of tele-
17 health services in models, projects, or initiatives
18 funded through section 1115A of such Act (42
19 U.S.C. 1315a).

20 (3) The types of high-volume services (and re-
21 lated diagnoses) under such title XVIII which might
22 be suitable to be furnished using telehealth.

23 (4) Barriers that might prevent the expansion
24 of telehealth services under section 1834(m)(4) of
25 the Social Security Act (42 U.S.C. 1395m(m)(4))

1 beyond such services that are in effect as of the date
2 of enactment of this Act.

3 (b) PROVISION OF INFORMATION BY MEDPAC.—Not
4 later than March 15, 2018, the Medicare Payment Advi-
5 sory Commission established under section 1805 of the So-
6 cial Security Act (42 U.S.C. 1395b–6) shall, using quan-
7 titative and qualitative research methods, provide informa-
8 tion to the committees of jurisdiction of the House of Rep-
9 resentatives and the Senate that identifies—

10 (1) the telehealth services for which payment
11 can be made, as of the date of enactment of this
12 Act, under the fee-for-service program under parts A
13 and B of title XVIII of such Act;

14 (2) the telehealth services for which payment
15 can be made, as of such date, under private health
16 insurance plans; and

17 (3) with respect to services identified under
18 paragraph (2) but not under paragraph (1), ways in
19 which payment for such services might be incor-
20 porated into such fee-for-service program (including
21 any recommendations for ways to accomplish this in-
22 corporation).

23 (c) SENSE OF CONGRESS.—It is the sense of Con-
24 gress that—

1 (1) eligible originating sites should be expanded
2 beyond those originating sites described in section
3 1834(m)(4)(C) of the Social Security Act (42 U.S.C.
4 1395m(m)(4)(C)); and

5 (2) any expansion of telehealth services under
6 the Medicare program under title XVIII of such Act
7 should—

8 (A) recognize that telemedicine is the deliv-
9 ery of safe, effective, quality health care serv-
10 ices, by a health care provider, using technology
11 as the mode of care delivery;

12 (B) meet or exceed the conditions of cov-
13 erage and payment with respect to the Medicare
14 program if the service was furnished in person,
15 including standards of care, unless specifically
16 addressed in subsequent legislation; and

17 (C) involve clinically appropriate means to
18 furnish such services.

19 **TITLE V—SAVINGS**

20 **SEC. 5001. SAVINGS IN THE MEDICARE IMPROVEMENT** 21 **FUND.**

22 Section 1898(b)(1) of the Social Security Act (42
23 U.S.C. 1395iii(b)(1)), as amended by section 704(h) of the
24 Comprehensive Addiction and Recovery Act of 2016, is

1 amended by striking “\$140,000,000” and inserting
2 “\$270,000,000”.

3 **SEC. 5002. MEDICAID REIMBURSEMENT TO STATES FOR DU-**
4 **RABLE MEDICAL EQUIPMENT.**

5 Section 1903(i)(27) of the Social Security Act (42
6 U.S.C. 1396b(i)(27)) is amended by striking “January 1,
7 2019” and inserting “January 1, 2018”.

8 **SEC. 5003. PENALTIES FOR VIOLATIONS OF GRANTS, CON-**
9 **TRACTS, AND OTHER AGREEMENTS.**

10 (a) IN GENERAL.—Section 1128A of the Social Secu-
11 rity Act (42 U.S.C. 1320a–7a) is amended by adding at
12 the end the following new subsections:

13 “(o) Any person (including an organization, agency,
14 or other entity, but excluding a program beneficiary, as
15 defined in subsection (q)(4)) that, with respect to a grant,
16 contract, or other agreement for which the Secretary pro-
17 vides funding—

18 “(1) knowingly presents or causes to be pre-
19 sented a specified claim (as defined in subsection
20 (r)) under such grant, contract, or other agreement
21 that the person knows or should know is false or
22 fraudulent;

23 “(2) knowingly makes, uses, or causes to be
24 made or used any false statement, omission, or mis-
25 representation of a material fact in any application,

1 proposal, bid, progress report, or other document
2 that is required to be submitted in order to directly
3 or indirectly receive or retain funds provided in
4 whole or in part by such Secretary pursuant to such
5 grant, contract, or other agreement;

6 “(3) knowingly makes, uses, or causes to be
7 made or used, a false record or statement material
8 to a false or fraudulent specified claim under such
9 grant, contract, or other agreement;

10 “(4) knowingly makes, uses, or causes to be
11 made or used, a false record or statement material
12 to an obligation (as defined in subsection (s)) to pay
13 or transmit funds or property to such Secretary with
14 respect to such grant, contract, or other agreement,
15 or knowingly conceals or knowingly and improperly
16 avoids or decreases an obligation to pay or transmit
17 funds or property to such Secretary with respect to
18 such grant, contract, or other agreement; or

19 “(5) fails to grant timely access, upon reason-
20 able request (as defined by such Secretary in regula-
21 tions), to the Inspector General of the Department,
22 for the purpose of audits, investigations, evaluations,
23 or other statutory functions of such Inspector Gen-
24 eral in matters involving such grants, contracts, or
25 other agreements;

1 shall be subject, in addition to any other penalties that
2 may be prescribed by law, to a civil money penalty in cases
3 under paragraph (1), of not more than \$10,000 for each
4 specified claim; in cases under paragraph (2), not more
5 than \$50,000 for each false statement, omission, or mis-
6 representation of a material fact; in cases under para-
7 graph (3), not more than \$50,000 for each false record
8 or statement; in cases under paragraph (4), not more than
9 \$50,000 for each false record or statement or \$10,000 for
10 each day that the person knowingly conceals or knowingly
11 and improperly avoids or decreases an obligation to pay;
12 or in cases under paragraph (5), not more than \$15,000
13 for each day of the failure described in such paragraph.
14 In addition, in cases under paragraphs (1) and (3), such
15 a person shall be subject to an assessment of not more
16 than 3 times the amount claimed in the specified claim
17 described in such paragraph in lieu of damages sustained
18 by the United States or a specified State agency because
19 of such specified claim, and in cases under paragraphs (2)
20 and (4), such a person shall be subject to an assessment
21 of not more than 3 times the total amount of the funds
22 described in paragraph (2) or (4), respectively (or, in the
23 case of an obligation to transmit property to the Secretary
24 described in paragraph (4), of the value of the property
25 described in such paragraph) in lieu of damages sustained

1 by the United States or a specified State agency because
2 of such case. In addition, the Secretary may make a deter-
3 mination in the same proceeding to exclude the person
4 from participation in the Federal health care programs (as
5 defined in section 1128B(f)(1)) and to direct the appro-
6 priate State agency to exclude the person from participa-
7 tion in any State health care program.

8 “(p) The provisions of subsections (e), (d), (g), and
9 (h) shall apply to a civil money penalty or assessment
10 under subsection (o) in the same manner as such provi-
11 sions apply to a penalty, assessment, or proceeding under
12 subsection (a). In applying subsection (d), each reference
13 to a claim under such subsection shall be treated as in-
14 cluding a reference to a specified claim (as defined in sub-
15 section (r)).

16 “(q) For purposes of this subsection and subsections
17 (o) and (p):

18 “(1) The term ‘Department’ means the Depart-
19 ment of Health and Human Services.

20 “(2) The term ‘material’ means having a nat-
21 ural tendency to influence, or be capable of influ-
22 encing, the payment or receipt of money or property.

23 “(3) The term ‘other agreement’ includes a co-
24 operative agreement, scholarship, fellowship, loan,
25 subsidy, payment for a specified use, donation agree-

1 ment, award, or subaward (regardless of whether
2 one or more of the persons entering into the agree-
3 ment is a contractor or subcontractor).

4 “(4) The term ‘program beneficiary’ means, in
5 the case of a grant, contract, or other agreement de-
6 signed to accomplish the objective of awarding or
7 otherwise furnishing benefits or assistance to indi-
8 viduals and for which the Secretary provides fund-
9 ing, an individual who applies for, or who receives,
10 such benefits or assistance from such grant, con-
11 tract, or other agreement. Such term does not in-
12 clude, with respect to such grant, contract, or other
13 agreement, an officer, employee, or agent of a per-
14 son or entity that receives such grant or that enters
15 into such contract or other agreement.

16 “(5) The term ‘recipient’ includes a sub-
17 recipient or subcontractor.

18 “(6) The term ‘specified State agency’ means
19 an agency of a State government established or des-
20 ignated to administer or supervise the administra-
21 tion of a grant, contract, or other agreement funded
22 in whole or in part by the Secretary.

23 “(r) For purposes of this section, the term ‘specified
24 claim’ means any application, request, or demand under
25 a grant, contract, or other agreement for money or prop-

1 erty, whether or not the United States or a specified State
2 agency has title to the money or property, that is not a
3 claim (as defined in subsection (i)(2)) and that—

4 “(1) is presented or caused to be presented to
5 an officer, employee, or agent of the Department or
6 agency thereof, or of any specified State agency; or

7 “(2) is made to a contractor, grantee, or any
8 other recipient if the money or property is to be
9 spent or used on the Department’s behalf or to ad-
10 vance a Department program or interest, and if the
11 Department—

12 “(A) provides or has provided any portion
13 of the money or property requested or de-
14 manded; or

15 “(B) will reimburse such contractor, grant-
16 ee, or other recipient for any portion of the
17 money or property which is requested or de-
18 manded.

19 “(s) For purposes of subsection (o), the term ‘obliga-
20 tion’ means an established duty, whether or not fixed, aris-
21 ing from an express or implied contractual, grantor-grant-
22 ee, or licensor-licensee relationship, for a fee-based or
23 similar relationship, from statute or regulation, or from
24 the retention of any overpayment.”.

1 (b) CONFORMING AMENDMENTS.—Section 1128A of
2 the Social Security Act (42 U.S.C. 1320a–7a) is amend-
3 ed—

4 (1) in subsection (e), by inserting “or specified
5 claim” after “claim” in the first sentence; and

6 (2) in subsection (f)—

7 (A) in the matter preceding paragraph

8 (1)—

9 (i) by inserting “or specified claim (as
10 defined in subsection (r))” after “district
11 where the claim”; and

12 (ii) by inserting “(or, with respect to
13 a person described in subsection (o), the
14 person)” after “claimant”; and

15 (B) in the matter following paragraph (4),
16 by inserting “(or, in the case of a penalty or as-
17 sessment under subsection (o), by a specified
18 State agency (as defined in subsection (q)(6)),”
19 after “or a State agency”.

20 **SEC. 5004. REDUCING OVERPAYMENTS OF INFUSION**
21 **DRUGS.**

22 (a) TREATMENT OF INFUSION DRUGS FURNISHED
23 THROUGH DURABLE MEDICAL EQUIPMENT.—Section
24 1842(o)(1) of the Social Security Act (42 U.S.C.
25 1395u(o)(1)) is amended—

1 (1) in subparagraph (C), by inserting “(and in-
2 cluding a drug or biological described in subpara-
3 graph (D)(i) furnished on or after January 1,
4 2017)” after “2005”; and

5 (2) in subparagraph (D)—

6 (A) by striking “infusion drugs” and in-
7 serting “infusion drugs or biologicals” each
8 place it appears; and

9 (B) in clause (i)—

10 (i) by striking “2004” and inserting
11 “2004, and before January 1, 2017”; and

12 (ii) by striking “for such drug”.

13 (b) NONINCLUSION OF DME INFUSION DRUGS
14 UNDER DME COMPETITIVE ACQUISITION PROGRAMS.—

15 (1) IN GENERAL.—Section 1847(a)(2)(A) of the
16 Social Security Act (42 U.S.C. 1395w-3(a)(2)(A)) is
17 amended—

18 (A) by striking “and excluding” and in-
19 serting “, excluding”; and

20 (B) by inserting before the period at the
21 end the following: “, and excluding drugs and
22 biologicals described in section 1842(o)(1)(D)”.

23 (2) CONFORMING AMENDMENT.—Section
24 1842(o)(1)(D)(ii) of the Social Security Act (42
25 U.S.C. 1395u(o)(1)(D)(ii)) is amended by striking

1 “2007” and inserting “2007, and before the date of
2 the enactment of the 21st Century Cures Act.”.

3 **SEC. 5005. INCREASING OVERSIGHT OF TERMINATION OF**
4 **MEDICAID PROVIDERS.**

5 (a) INCREASED OVERSIGHT AND REPORTING.—

6 (1) STATE REPORTING REQUIREMENTS.—Sec-
7 tion 1902(kk) of the Social Security Act (42 U.S.C.
8 1396a(kk)) is amended—

9 (A) by redesignating paragraph (8) as
10 paragraph (9); and

11 (B) by inserting after paragraph (7) the
12 following new paragraph:

13 “(8) PROVIDER TERMINATIONS.—

14 “(A) IN GENERAL.—Beginning on July 1,
15 2018, in the case of a notification under sub-
16 section (a)(41) with respect to a termination for
17 a reason specified in section 455.101 of title 42,
18 Code of Federal Regulations (as in effect on
19 November 1, 2015) or for any other reason
20 specified by the Secretary, of the participation
21 of a provider of services or any other person
22 under the State plan (or under a waiver of the
23 plan), the State, consistent with subparagraph
24 (B), submits to the Secretary with respect to
25 any such provider or person, as appropriate—

1 “(i) the name of such provider or per-
2 son;

3 “(ii) the provider type of such pro-
4 vider or person;

5 “(iii) the specialty of such provider’s
6 or person’s practice;

7 “(iv) the date of birth, Social Security
8 number, national provider identifier (if ap-
9 plicable), Federal taxpayer identification
10 number, and the State license or certifi-
11 cation number of such provider or person
12 (if applicable);

13 “(v) the reason for the termination;

14 “(vi) a copy of the notice of termi-
15 nation sent to the provider or person;

16 “(vii) the date on which such termi-
17 nation is effective, as specified in the no-
18 tice; and

19 “(viii) any other information required
20 by the Secretary.

21 “(B) EFFECTIVE DATE DEFINED.—For
22 purposes of this paragraph, the term ‘effective
23 date’ means, with respect to a termination de-
24 scribed in subparagraph (A), the later of—

1 “(i) the date on which such termi-
2 nation is effective, as specified in the no-
3 tice of such termination; or

4 “(ii) the date on which all appeal
5 rights applicable to such termination have
6 been exhausted or the timeline for any
7 such appeal has expired.”.

8 (2) CONTRACT REQUIREMENT FOR MANAGED
9 CARE ENTITIES.—Section 1932(d) of the Social Se-
10 curity Act (42 U.S.C. 1396u–2(d)) is amended by
11 adding at the end the following new paragraph:

12 “(5) CONTRACT REQUIREMENT FOR MANAGED
13 CARE ENTITIES.—With respect to any contract with
14 a managed care entity under section 1903(m) or
15 1905(t)(3) (as applicable), no later than July 1,
16 2018, such contract shall include a provision that
17 providers of services or persons terminated (as de-
18 scribed in section 1902(kk)(8)) from participation
19 under this title, title XVIII, or title XXI shall be
20 terminated from participating under this title as a
21 provider in any network of such entity that serves
22 individuals eligible to receive medical assistance
23 under this title.”.

24 (3) TERMINATION NOTIFICATION DATABASE.—
25 Section 1902 of the Social Security Act (42 U.S.C.

1 1396a) is amended by adding at the end the fol-
2 lowing new subsection:

3 “(ll) TERMINATION NOTIFICATION DATABASE.—In
4 the case of a provider of services or any other person
5 whose participation under this title or title XXI is termi-
6 nated (as described in subsection (kk)(8)), the Secretary
7 shall, not later than 30 days after the date on which the
8 Secretary is notified of such termination under subsection
9 (a)(41) (as applicable), review such termination and, if the
10 Secretary determines appropriate, include such termi-
11 nation in any database or similar system developed pursu-
12 ant to section 6401(b)(2) of the Patient Protection and
13 Affordable Care Act (42 U.S.C. 1395cc note; Public Law
14 111–148).”.

15 (4) NO FEDERAL FUNDS FOR ITEMS AND SERV-
16 ICES FURNISHED BY TERMINATED PROVIDERS.—
17 Section 1903 of the Social Security Act (42 U.S.C.
18 1396b) is amended—

19 (A) in subsection (i)(2)—

20 (i) in subparagraph (A), by striking
21 the comma at the end and inserting a
22 semicolon;

23 (ii) in subparagraph (B), by striking
24 “or” at the end; and

1 (iii) by adding at the end the fol-
2 lowing new subparagraph:

3 “(D) beginning on July 1, 2018, under the
4 plan by any provider of services or person
5 whose participation in the State plan is termi-
6 nated (as described in section 1902(kk)(8))
7 after the date that is 60 days after the date on
8 which such termination is included in the data-
9 base or other system under section 1902(ll);
10 or”; and

11 (B) in subsection (m), by inserting after
12 paragraph (2) the following new paragraph:

13 “(3) No payment shall be made under this title to
14 a State with respect to expenditures incurred by the State
15 for payment for services provided by a managed care enti-
16 ty (as defined under section 1932(a)(1)) under the State
17 plan under this title (or under a waiver of the plan) unless
18 the State—

19 “(A) beginning on July 1, 2018, has a contract
20 with such entity that complies with the requirement
21 specified in section 1932(d)(5); and

22 “(B) beginning on January 1, 2018, complies
23 with the requirement specified in section
24 1932(d)(6)(A).”.

1 (5) DEVELOPMENT OF UNIFORM TERMINOLOGY
2 FOR REASONS FOR PROVIDER TERMINATION.—Not
3 later than July 1, 2017, the Secretary of Health and
4 Human Services shall, in consultation with the
5 heads of State agencies administering State Med-
6 icaid plans (or waivers of such plans), issue regula-
7 tions establishing uniform terminology to be used
8 with respect to specifying reasons under subpara-
9 graph (A)(v) of paragraph (8) of section 1902(kk)
10 of the Social Security Act (42 U.S.C. 1396a(kk)), as
11 added by paragraph (1), for the termination (as de-
12 scribed in such paragraph (8)) of the participation
13 of certain providers in the Medicaid program under
14 title XIX of such Act or the Children’s Health In-
15 surance Program under title XXI of such Act.

16 (6) CONFORMING AMENDMENT.—Section
17 1902(a)(41) of the Social Security Act (42 U.S.C.
18 1396a(a)(41)) is amended by striking “provide that
19 whenever” and inserting “provide, in accordance
20 with subsection (kk)(8) (as applicable), that when-
21 ever”.

22 (b) INCREASING AVAILABILITY OF MEDICAID PRO-
23 VIDER INFORMATION.—

24 (1) FFS PROVIDER ENROLLMENT.—Section
25 1902(a) of the Social Security Act (42 U.S.C.

1 1396a(a)) is amended by inserting after paragraph
2 (77) the following new paragraph:

3 “(78) provide that, not later than January 1,
4 2017, in the case of a State that pursuant to its
5 State plan or waiver of the plan for medical assist-
6 ance pays for medical assistance on a fee-for-service
7 basis, the State shall require each provider fur-
8 nishing items and services to, or ordering, pre-
9 scribing, referring, or certifying eligibility for, serv-
10 ices for individuals eligible to receive medical assist-
11 ance under such plan to enroll with the State agency
12 and provide to the State agency the provider’s iden-
13 tifying information, including the name, specialty,
14 date of birth, Social Security number, national pro-
15 vider identifier (if applicable), Federal taxpayer
16 identification number, and the State license or cer-
17 tification number of the provider (if applicable);”.

18 (2) MANAGED CARE PROVIDER ENROLLMENT.—
19 Section 1932(d) of the Social Security Act (42
20 U.S.C. 1396u–2(d)), as amended by subsection
21 (a)(2), is amended by adding at the end the fol-
22 lowing new paragraph:

23 “(6) ENROLLMENT OF PARTICIPATING PRO-
24 VIDERS.—

1 “(A) IN GENERAL.—Beginning not later
2 than January 1, 2018, a State shall require
3 that, in order to participate as a provider in the
4 network of a managed care entity that provides
5 services to, or orders, prescribes, refers, or cer-
6 tifies eligibility for services for, individuals who
7 are eligible for medical assistance under the
8 State plan under this title (or under a waiver
9 of the plan) and who are enrolled with the enti-
10 ty, the provider is enrolled consistent with sec-
11 tion 1902(kk) with the State agency admin-
12 istering the State plan under this title. Such
13 enrollment shall include providing to the State
14 agency the provider’s identifying information,
15 including the name, specialty, date of birth, So-
16 cial Security number, national provider identi-
17 fier, Federal taxpayer identification number,
18 and the State license or certification number of
19 the provider.

20 “(B) RULE OF CONSTRUCTION.—Nothing
21 in subparagraph (A) shall be construed as re-
22 quiring a provider described in such subpara-
23 graph to provide services to individuals who are
24 not enrolled with a managed care entity under
25 this title.”.

1 (c) COORDINATION WITH CHIP.—

2 (1) IN GENERAL.—Section 2107(e)(1) of the
3 Social Security Act (42 U.S.C. 1397gg(e)(1)) is
4 amended—

5 (A) by redesignating subparagraphs (B),
6 (C), (D), (E), (F), (G), (H), (I), (J), (K), (L),
7 (M), (N), and (O) as subparagraphs (D), (E),
8 (F), (G), (H), (I), (J), (K), (M), (N), (O), (P),
9 (Q), and (R), respectively;

10 (B) by inserting after subparagraph (A)
11 the following new subparagraphs:

12 “(B) Section 1902(a)(39) (relating to ter-
13 mination of participation of certain providers).

14 “(C) Section 1902(a)(78) (relating to en-
15 rollment of providers participating in State
16 plans providing medical assistance on a fee-for-
17 service basis).”;

18 (C) by inserting after subparagraph (K)
19 (as redesignated by subparagraph (A)) the fol-
20 lowing new subparagraph:

21 “(L) Section 1903(m)(3) (relating to limi-
22 tation on payment with respect to managed
23 care).”; and

24 (D) in subparagraph (P) (as redesignated
25 by subparagraph (A)), by striking “(a)(2)(C)

1 and (h)” and inserting “(a)(2)(C) (relating to
2 Indian enrollment), (d)(5) (relating to contract
3 requirement for managed care entities), (d)(6)
4 (relating to enrollment of providers partici-
5 pating with a managed care entity), and (h)
6 (relating to special rules with respect to Indian
7 enrollees, Indian health care providers, and In-
8 dian managed care entities)”.

9 (2) EXCLUDING FROM MEDICAID PROVIDERS
10 EXCLUDED FROM CHIP.—Section 1902(a)(39) of the
11 Social Security Act (42 U.S.C. 1396a(a)(39)) is
12 amended by striking “title XVIII or any other State
13 plan under this title” and inserting “title XVIII, any
14 other State plan under this title (or waiver of the
15 plan), or any State child health plan under title XXI
16 (or waiver of the plan) and such termination is in-
17 cluded by the Secretary in any database or similar
18 system developed pursuant to section 6401(b)(2) of
19 the Patient Protection and Affordable Care Act”.

20 (d) RULE OF CONSTRUCTION.—Nothing in this sec-
21 tion shall be construed as changing or limiting the appeal
22 rights of providers or the process for appeals of States
23 under the Social Security Act.

24 (e) OIG REPORT.—Not later than March 31, 2020,
25 the Inspector General of the Department of Health and

1 Human Services shall submit to Congress a report on the
2 implementation of the amendments made by this section.

3 Such report shall include the following:

4 (1) An assessment of the extent to which pro-
5 viders who are included under subsection (ll) of sec-
6 tion 1902 of the Social Security Act (42 U.S.C.
7 1396a) (as added by subsection (a)(3)) in the data-
8 base or similar system referred to in such subsection
9 are terminated (as described in paragraph (8) of
10 subsection (kk) of such section, as added by sub-
11 section (a)(1)) from participation in all State plans
12 under title XIX of such Act (or waivers of such
13 plans).

14 (2) Information on the amount of Federal fi-
15 nancial participation paid to States under section
16 1903 of such Act in violation of the limitation on
17 such payment specified in subparagraph (D) of sub-
18 section (i)(2) of such section and paragraph (3) of
19 subsection (m) of such section, as added by sub-
20 section (a)(4).

21 (3) An assessment of the extent to which con-
22 tracts with managed care entities under title XIX of
23 such Act comply with the requirement specified in
24 paragraph (5) of section 1932(d) of such Act, as
25 added by subsection (a)(2).

1 (4) An assessment of the extent to which pro-
2 viders have been enrolled under section 1902(a)(78)
3 or 1932(d)(6)(A) of such Act (42 U.S.C.
4 1396a(a)(78), 1396u-2(d)(6)(A)) with State agen-
5 cies administering State plans under title XIX of
6 such Act (or waivers of such plans).

7 **SEC. 5006. REQUIRING PUBLICATION OF FEE-FOR-SERVICE**
8 **PROVIDER DIRECTORY.**

9 (a) IN GENERAL.—Section 1902(a) of the Social Se-
10 curity Act (42 U.S.C. 1396a(a)) is amended—

11 (1) in paragraph (81), by striking “and” at the
12 end;

13 (2) in paragraph (82), by striking the period at
14 the end and inserting “; and”; and

15 (3) by inserting after paragraph (82) the fol-
16 lowing new paragraph:

17 “(83) provide that, not later than January 1,
18 2017, in the case of a State plan (or waiver of the
19 plan) that provides medical assistance on a fee-for-
20 service basis or through a primary care case-man-
21 agement system described in section 1915(b)(1)
22 (other than a primary care case management entity
23 (as defined by the Secretary)), the State shall pub-
24 lish (and update on at least an annual basis) on the
25 public website of the State agency administering the

1 State plan, a directory of the physicians described in
2 subsection (mm) and, at State option, other pro-
3 viders described in such subsection that—

4 “(A) includes—

5 “(i) with respect to each such physi-
6 cian or provider—

7 “(I) the name of the physician or
8 provider;

9 “(II) the specialty of the physi-
10 cian or provider;

11 “(III) the address at which the
12 physician or provider provides serv-
13 ices; and

14 “(IV) the telephone number of
15 the physician or provider; and

16 “(ii) with respect to any such physi-
17 cian or provider participating in such a
18 primary care case-management system, in-
19 formation regarding—

20 “(I) whether the physician or
21 provider is accepting as new patients
22 individuals who receive medical assist-
23 ance under this title; and

24 “(II) the physician’s or provider’s
25 cultural and linguistic capabilities, in-

1 including the languages spoken by the
2 physician or provider or by the skilled
3 medical interpreter providing interpre-
4 tation services at the physician's or
5 provider's office; and

6 “(B) may include, at State option, with re-
7 spect to each such physician or provider—

8 “(i) the Internet website of such phy-
9 sician or provider; or

10 “(ii) whether the physician or provider
11 is accepting as new patients individuals
12 who receive medical assistance under this
13 title.”.

14 (b) DIRECTORY PHYSICIAN OR PROVIDER DE-
15 SCRIBED.—Section 1902 of the Social Security Act (42
16 U.S.C. 1396a), as amended by section 5005(a)(3), is fur-
17 ther amended by adding at the end the following new sub-
18 section:

19 “(mm) DIRECTORY PHYSICIAN OR PROVIDER DE-
20 SCRIBED.—A physician or provider described in this sub-
21 section is—

22 “(1) in the case of a physician or provider of
23 a provider type for which the State agency, as a con-
24 dition on receiving payment for items and services
25 furnished by the physician or provider to individuals

1 eligible to receive medical assistance under the State
2 plan, requires the enrollment of the physician or pro-
3 vider with the State agency, a physician or a pro-
4 vider that—

5 “(A) is enrolled with the agency as of the
6 date on which the directory is published or up-
7 dated (as applicable) under subsection (a)(83);
8 and

9 “(B) received payment under the State
10 plan in the 12-month period preceding such
11 date; and

12 “(2) in the case of a physician or provider of
13 a provider type for which the State agency does not
14 require such enrollment, a physician or provider that
15 received payment under the State plan (or a waiver
16 of the plan) in the 12-month period preceding the
17 date on which the directory is published or updated
18 (as applicable) under subsection (a)(83).”.

19 (c) RULE OF CONSTRUCTION.—

20 (1) IN GENERAL.—The amendment made by
21 subsection (a) shall not be construed to apply in the
22 case of a State (as defined for purposes of title XIX
23 of the Social Security Act) in which all the individ-
24 uals enrolled in the State plan under such title (or
25 under a waiver of such plan), other than individuals

1 described in paragraph (2), are enrolled with a med-
2 icaid managed care organization (as defined in sec-
3 tion 1903(m)(1)(A) of such Act (42 U.S.C.
4 1396b(m)(1)(A))), including prepaid inpatient health
5 plans and prepaid ambulatory health plans (as de-
6 fined by the Secretary of Health and Human Serv-
7 ices).

8 (2) INDIVIDUALS DESCRIBED.—An individual
9 described in this paragraph is an individual who is
10 an Indian (as defined in section 4 of the Indian
11 Health Care Improvement Act (25 U.S.C. 1603)) or
12 an Alaska Native.

13 (d) EXCEPTION FOR STATE LEGISLATION.—In the
14 case of a State plan under title XIX of the Social Security
15 Act (42 U.S.C. 1396 et seq.), which the Secretary of
16 Health and Human Services determines requires State
17 legislation in order for the respective plan to meet one or
18 more additional requirements imposed by amendments
19 made by this section, the respective plan shall not be re-
20 garded as failing to comply with the requirements of such
21 title solely on the basis of its failure to meet such an addi-
22 tional requirement before the first day of the first calendar
23 quarter beginning after the close of the first regular ses-
24 sion of the State legislature that begins after the date of
25 enactment of this Act. For purposes of the previous sen-

1 tence, in the case of a State that has a 2-year legislative
2 session, each year of the session shall be considered to be
3 a separate regular session of the State legislature.

4 **SEC. 5007. FAIRNESS IN MEDICAID SUPPLEMENTAL NEEDS**
5 **TRUSTS.**

6 (a) IN GENERAL.—Section 1917(d)(4)(A) of the So-
7 cial Security Act (42 U.S.C. 1396p(d)(4)(A)) is amended
8 by inserting “the individual,” after “for the benefit of such
9 individual by”.

10 (b) EFFECTIVE DATE.—The amendment made by
11 subsection (a) shall apply to trusts established on or after
12 the date of the enactment of this Act.

13 **SEC. 5008. ELIMINATING FEDERAL FINANCIAL PARTICIPA-**
14 **TION WITH RESPECT TO EXPENDITURES**
15 **UNDER MEDICAID FOR AGENTS USED FOR**
16 **COSMETIC PURPOSES OR HAIR GROWTH.**

17 (a) IN GENERAL.—Section 1903(i)(21) of the Social
18 Security Act (42 U.S.C. 1396b(i)(21)) is amended by in-
19 serting “section 1927(d)(2)(C) (relating to drugs when
20 used for cosmetic purposes or hair growth), except where
21 medically necessary, and” after “drugs described in”.

22 (b) EFFECTIVE DATE.—The amendment made by
23 subsection (a) shall apply with respect to calendar quar-
24 ters beginning on or after the date of the enactment of
25 this Act.

1 **SEC. 5009. AMENDMENT TO THE PREVENTION AND PUBLIC**
2 **HEALTH FUND.**

3 Section 4002(b) of the Patient Protection and Af-
4 fordable Care Act (42 U.S.C. 300u-11(b)) is amended—

5 (1) in paragraph (3), by striking
6 “\$1,250,000,000” and inserting “\$900,000,000”;

7 (2) in paragraph (4), by striking
8 “\$1,500,000,000” and inserting “\$1,000,000,000”;

9 and

10 (3) by striking paragraph (5) and inserting the
11 following:

12 “(5) for fiscal year 2022, \$1,500,000,000;

13 “(6) for fiscal year 2023, \$1,000,000,000;

14 “(7) for fiscal year 2024, \$1,700,000,000; and

15 “(8) for fiscal year 2025 and each fiscal year
16 thereafter, \$2,000,000,000.”.

17 **SEC. 5010. STRATEGIC PETROLEUM RESERVE DRAWDOWN.**

18 (a) DRAWDOWN AND SALE.—

19 (1) IN GENERAL.—Notwithstanding section 161
20 of the Energy Policy and Conservation Act (42
21 U.S.C. 6241), except as provided in subsections (b)
22 and (c), the Secretary of Energy shall drawdown
23 and sell from the Strategic Petroleum Reserve—

24 (A) 10,000,000 barrels of crude oil during
25 fiscal year 2017;

1 (B) 9,000,000 barrels of crude oil during
2 fiscal year 2018; and

3 (C) 6,000,000 barrels of crude oil during
4 fiscal year 2019.

5 (2) DEPOSIT OF AMOUNTS RECEIVED FROM
6 SALE.—Amounts received from a sale under para-
7 graph (1) shall be deposited in the general fund of
8 the Treasury during the fiscal year in which the sale
9 occurs.

10 (b) EMERGENCY PROTECTION.—The Secretary shall
11 not draw down and sell crude oil under this section in
12 quantities that would limit the authority to sell petroleum
13 products under section 161(h) of the Energy Policy and
14 Conservation Act (42 U.S.C. 6241(h)) in the full quantity
15 authorized by that subsection.

16 (c) STRATEGIC PETROLEUM DRAWDOWN LIMITA-
17 TIONS.—Subparagraphs (C) and (D) of section 161(h)(2)
18 of the Energy Policy and Conservation Act (42 U.S.C.
19 6241(h)(2)(C) and (D)) are both amended by striking
20 “500,000,000” and inserting “450,000,000”.

21 **SEC. 5011. RESCISSION OF PORTION OF ACA TERRITORY**
22 **FUNDING.**

23 Of the unobligated amounts available under section
24 1323(c)(1) of the Patient Protection and Affordable Care

1 Act (42 U.S.C. 18043(c)(1)), \$464,000,000 is rescinded
2 immediately upon the date of the enactment of this Act.

3 **SEC. 5012. MEDICARE COVERAGE OF HOME INFUSION**
4 **THERAPY.**

5 (a) IN GENERAL.—Section 1861 of the Social Secu-
6 rity Act (42 U.S.C. 1395x) is amended—

7 (1) in subsection (s)(2)—

8 (A) by striking “and” at the end of sub-
9 paragraph (EE);

10 (B) by inserting “and” at the end of sub-
11 paragraph (FF); and

12 (C) by inserting at the end the following
13 new subparagraph:

14 “(GG) home infusion therapy (as defined in
15 subsection (iii)(1));”; and

16 (2) by adding at the end the following new sub-
17 section:

18 “(iii) HOME INFUSION THERAPY.—(1) The term
19 ‘home infusion therapy’ means the items and services de-
20 scribed in paragraph (2) furnished by a qualified home
21 infusion therapy supplier (as defined in paragraph (3)(D))
22 which are furnished in the individual’s home (as defined
23 in paragraph (3)(B)) to an individual—

24 “(A) who is under the care of an applicable pro-
25 vider (as defined in paragraph (3)(A)); and

1 “(B) with respect to whom a plan prescribing
2 the type, amount, and duration of infusion therapy
3 services that are to be furnished such individual has
4 been established by a physician (as defined in sub-
5 section (r)(1)) and is periodically reviewed by a phy-
6 sician (as so defined) in coordination with the fur-
7 nishing of home infusion drugs (as defined in para-
8 graph (3)(C)) under part B.

9 “(2) The items and services described in this para-
10 graph are the following:

11 “(A) Professional services, including nursing
12 services, furnished in accordance with the plan.

13 “(B) Training and education (not otherwise
14 paid for as durable medical equipment (as defined in
15 subsection (n)), remote monitoring, and monitoring
16 services for the provision of home infusion therapy
17 and home infusion drugs furnished by a qualified
18 home infusion therapy supplier.

19 “(3) For purposes of this subsection:

20 “(A) The term ‘applicable provider’ means—

21 “(i) a physician;

22 “(ii) a nurse practitioner; and

23 “(iii) a physician assistant.

1 “(B) The term ‘home’ means a place of resi-
2 dence used as the home of an individual (as defined
3 for purposes of subsection (n)).

4 “(C) The term ‘home infusion drug’ means a
5 parenteral drug or biological administered intra-
6 venously, or subcutaneously for an administration
7 period of 15 minutes or more, in the home of an in-
8 dividual through a pump that is an item of durable
9 medical equipment (as defined in subsection (n)).
10 Such term does not include the following:

11 “(i) Insulin pump systems.

12 “(ii) A self-administered drug or biological
13 on a self-administered drug exclusion list.

14 “(D)(i) The term ‘qualified home infusion ther-
15 apy supplier’ means a pharmacy, physician, or other
16 provider of services or supplier licensed by the State
17 in which the pharmacy, physician, or provider or
18 services or supplier furnishes items or services and
19 that—

20 “(I) furnishes infusion therapy to individ-
21 uals with acute or chronic conditions requiring
22 administration of home infusion drugs;

23 “(II) ensures the safe and effective provi-
24 sion and administration of home infusion ther-
25 apy on a 7-day-a-week, 24-hour-a-day basis;

1 “(III) is accredited by an organization des-
2 signed by the Secretary pursuant to section
3 1834(u)(5); and

4 “(IV) meets such other requirements as
5 the Secretary determines appropriate, taking
6 into account the standards of care for home in-
7 fusion therapy established by Medicare Advan-
8 tage plans under part C and in the private sec-
9 tor.

10 “(ii) A qualified home infusion therapy supplier
11 may subcontract with a pharmacy, physician, pro-
12 vider of services, or supplier to meet the require-
13 ments of this subparagraph.”.

14 (b) PAYMENT AND RELATED REQUIREMENTS FOR
15 HOME INFUSION THERAPY.—Section 1834 of the Social
16 Security Act (42 U.S.C. 1395m), as amended by section
17 4012, is further amended by adding at the end the fol-
18 lowing new subsection:

19 “(u) PAYMENT AND RELATED REQUIREMENTS FOR
20 HOME INFUSION THERAPY.—

21 “(1) PAYMENT.—

22 “(A) SINGLE PAYMENT.—

23 “(i) IN GENERAL.—Subject to clause
24 (iii) and subparagraphs (B) and (C), the
25 Secretary shall implement a payment sys-

1 tem under which a single payment is made
2 under this title to a qualified home infu-
3 sion therapy supplier for items and serv-
4 ices described in subparagraphs (A) and
5 (B) of section 1861(iii)(2)) furnished by a
6 qualified home infusion therapy supplier
7 (as defined in section 1861(iii)(3)(D)) in
8 coordination with the furnishing of home
9 infusion drugs (as defined in section
10 1861(iii)(3)(C)) under this part.

11 “(ii) UNIT OF SINGLE PAYMENT.—A
12 unit of single payment under the payment
13 system implemented under this subpara-
14 graph is for each infusion drug administra-
15 tion calendar day in the individual’s home.
16 The Secretary shall, as appropriate, estab-
17 lish single payment amounts for types of
18 infusion therapy, including to take into ac-
19 count variation in utilization of nursing
20 services by therapy type.

21 “(iii) LIMITATION.—The single pay-
22 ment amount determined under this sub-
23 paragraph after application of subpara-
24 graph (B) and paragraph (3) shall not ex-
25 ceed the amount determined under the fee

1 schedule under section 1848 for infusion
2 therapy services furnished in a calendar
3 day if furnished in a physician office set-
4 ting, except such single payment shall not
5 reflect more than 5 hours of infusion for a
6 particular therapy in a calendar day.

7 “(B) REQUIRED ADJUSTMENTS.—The Sec-
8 retary shall adjust the single payment amount
9 determined under subparagraph (A) for home
10 infusion therapy services under section
11 1861(iii)(1) to reflect other factors such as—

12 “(i) a geographic wage index and
13 other costs that may vary by region; and

14 “(ii) patient acuity and complexity of
15 drug administration.

16 “(C) DISCRETIONARY ADJUSTMENTS.—

17 “(i) IN GENERAL.—Subject to clause
18 (ii), the Secretary may adjust the single
19 payment amount determined under sub-
20 paragraph (A) (after application of sub-
21 paragraph (B)) to reflect outlier situations
22 and other factors as the Secretary deter-
23 mines appropriate.

24 “(ii) REQUIREMENT OF BUDGET NEU-
25 TRALITY.—Any adjustment under this sub-

1 paragraph shall be made in a budget neu-
2 tral manner.

3 “(2) CONSIDERATIONS.—In developing the pay-
4 ment system under this subsection, the Secretary
5 may consider the costs of furnishing infusion ther-
6 apy in the home, consult with home infusion therapy
7 suppliers, consider payment amounts for similar
8 items and services under this part and part A, and
9 consider payment amounts established by Medicare
10 Advantage plans under part C and in the private in-
11 surance market for home infusion therapy (including
12 average per treatment day payment amounts by type
13 of home infusion therapy).

14 “(3) ANNUAL UPDATES.—

15 “(A) IN GENERAL.—Subject to subpara-
16 graph (B), the Secretary shall update the single
17 payment amount under this subsection from
18 year to year beginning in 2022 by increasing
19 the single payment amount from the prior year
20 by the percentage increase in the Consumer
21 Price Index for all urban consumers (United
22 States city average) for the 12-month period
23 ending with June of the preceding year.

24 “(B) ADJUSTMENT.—For each year, the
25 Secretary shall reduce the percentage increase

1 described in subparagraph (A) by the produc-
2 tivity adjustment described in section
3 1886(b)(3)(B)(xi)(II). The application of the
4 preceding sentence may result in a percentage
5 being less than 0.0 for a year, and may result
6 in payment being less than such payment rates
7 for the preceding year.

8 “(4) AUTHORITY TO APPLY PRIOR AUTHORIZA-
9 TION.—The Secretary may, as determined appro-
10 priate by the Secretary, apply prior authorization for
11 home infusion therapy services under section
12 1861(iii)(1).

13 “(5) ACCREDITATION OF QUALIFIED HOME IN-
14 FUSION THERAPY SUPPLIERS.—

15 “(A) FACTORS FOR DESIGNATION OF AC-
16 CREDITATION ORGANIZATIONS.—The Secretary
17 shall consider the following factors in desig-
18 nating accreditation organizations under sub-
19 paragraph (B) and in reviewing and modifying
20 the list of accreditation organizations des-
21 ignated pursuant to subparagraph (C):

22 “(i) The ability of the organization to
23 conduct timely reviews of accreditation ap-
24 plications.

1 “(ii) The ability of the organization to
2 take into account the capacities of sup-
3 pliers located in a rural area (as defined in
4 section 1886(d)(2)(D)).

5 “(iii) Whether the organization has
6 established reasonable fees to be charged
7 to suppliers applying for accreditation.

8 “(iv) Such other factors as the Sec-
9 retary determines appropriate.

10 “(B) DESIGNATION.—Not later than Janu-
11 ary 1, 2021, the Secretary shall designate orga-
12 nizations to accredit suppliers furnishing home
13 infusion therapy. The list of accreditation orga-
14 nizations so designated may be modified pursu-
15 ant to subparagraph (C).

16 “(C) REVIEW AND MODIFICATION OF LIST
17 OF ACCREDITATION ORGANIZATIONS.—

18 “(i) IN GENERAL.—The Secretary
19 shall review the list of accreditation organi-
20 zations designated under subparagraph (B)
21 taking into account the factors under sub-
22 paragraph (A). Taking into account the re-
23 sults of such review, the Secretary may, by
24 regulation, modify the list of accreditation

1 organizations designated under subpara-
2 graph (B).

3 “(ii) SPECIAL RULE FOR ACCREDITA-
4 TIONS DONE PRIOR TO REMOVAL FROM
5 LIST OF DESIGNATED ACCREDITATION OR-
6 GANIZATIONS.—In the case where the Sec-
7 retary removes an organization from the
8 list of accreditation organizations des-
9 ignated under subparagraph (B), any sup-
10 plier that is accredited by the organization
11 during the period beginning on the date on
12 which the organization is designated as an
13 accreditation organization under subpara-
14 graph (B) and ending on the date on
15 which the organization is removed from
16 such list shall be considered to have been
17 accredited by an organization designated
18 by the Secretary under subparagraph (B)
19 for the remaining period such accreditation
20 is in effect.

21 “(D) RULE FOR ACCREDITATIONS MADE
22 PRIOR TO DESIGNATION.—In the case of a sup-
23 plier that is accredited before January 1, 2021,
24 by an accreditation organization designated by
25 the Secretary under subparagraph (B) as of

1 January 1, 2019, such supplier shall be consid-
2 ered to have been accredited by an organization
3 designated by the Secretary under such para-
4 graph as of January 1, 2023, for the remaining
5 period such accreditation is in effect.

6 “(6) NOTIFICATION OF INFUSION THERAPY OP-
7 TIONS AVAILABLE PRIOR TO FURNISHING HOME IN-
8 FUSION THERAPY.—Prior to the furnishing of home
9 infusion therapy to an individual, the physician who
10 establishes the plan described in section 1861(iii)(1)
11 for the individual shall provide notification (in a
12 form, manner, and frequency determined appro-
13 priate by the Secretary) of the options available
14 (such as home, physician’s office, hospital outpatient
15 department) for the furnishing of infusion therapy
16 under this part.”.

17 (c) CONFORMING AMENDMENTS.—

18 (1) PAYMENT REFERENCE.—Section
19 1833(a)(1) of the Social Security Act (42 U.S.C.
20 1395l(a)(1)) is amended—

21 (A) by striking “and” before “(AA)”; and

22 (B) by inserting before the semicolon at
23 the end the following: “, and (BB) with respect
24 to home infusion therapy, the amount paid shall
25 be an amount equal to 80 percent of the lesser

1 of the actual charge for the services or the
2 amount determined under section 1834(u)”.

3 (2) DIRECT PAYMENT.—The first sentence of
4 section 1842(b)(6) of the Social Security Act (42
5 U.S.C. 1395u(b)(6)) is amended—

6 (A) by striking “and” before “(H)”; and

7 (B) by inserting before the period at the
8 end the following: “, and (I) in the case of
9 home infusion therapy, payment shall be made
10 to the qualified home infusion therapy sup-
11 plier”.

12 (3) EXCLUSION FROM HOME HEALTH SERV-
13 ICES.—Section 1861(m) of the Social Security Act
14 (42 U.S.C. 1395x(m)) is amended, in the first sen-
15 tence, by inserting the following before the period at
16 the end: “and home infusion therapy (as defined in
17 subsection (iii)(i))”.

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

21 **DIVISION B—HELPING FAMILIES**
22 **IN MENTAL HEALTH CRISIS**

23 **SEC. 6000. SHORT TITLE.**

24 This division may be cited as the “Helping Families
25 in Mental Health Crisis Reform Act of 2016”.

1 **TITLE VI—STRENGTHENING**
2 **LEADERSHIP AND ACCOUNT-**
3 **ABILITY**

4 **Subtitle A—Leadership**

5 **SEC. 6001. ASSISTANT SECRETARY FOR MENTAL HEALTH**
6 **AND SUBSTANCE USE.**

7 (a) ASSISTANT SECRETARY.—Section 501(c) of the
8 Public Health Service Act (42 U.S.C. 290aa(c)) is amend-
9 ed to read as follows:

10 “(c) ASSISTANT SECRETARY AND DEPUTY ASSIST-
11 ANT SECRETARY.—

12 “(1) ASSISTANT SECRETARY.—The Administra-
13 tion shall be headed by an official to be known as
14 the Assistant Secretary for Mental Health and Sub-
15 stance Use (hereinafter in this title referred to as
16 the ‘Assistant Secretary’) who shall be appointed by
17 the President, by and with the advice and consent
18 of the Senate.

19 “(2) DEPUTY ASSISTANT SECRETARY.—The As-
20 sistant Secretary, with the approval of the Secretary,
21 may appoint a Deputy Assistant Secretary and may
22 employ and prescribe the functions of such officers
23 and employees, including attorneys, as are necessary
24 to administer the activities to be carried out through
25 the Administration.”.

1 (b) TRANSFER OF AUTHORITIES.—The Secretary of
2 Health and Human Services shall delegate to the Assist-
3 ant Secretary for Mental Health and Substance Use all
4 duties and authorities that—

5 (1) as of the day before the date of enactment
6 of this Act, were vested in the Administrator of the
7 Substance Abuse and Mental Health Services Ad-
8 ministration; and

9 (2) are not terminated by this Act.

10 (c) CONFORMING AMENDMENTS.—Title V of the
11 Public Health Service Act (42 U.S.C. 290aa et seq.), as
12 amended by the previous provisions of this section, is fur-
13 ther amended—

14 (1) by striking “Administrator of the Substance
15 Abuse and Mental Health Services Administration”
16 each place it appears and inserting “Assistant Sec-
17 retary for Mental Health and Substance Use”; and

18 (2) by striking “Administrator” or “ADMINIS-
19 TRATOR” each place it appears (including in any
20 headings) and inserting “Assistant Secretary” or
21 “ASSISTANT SECRETARY”, respectively, except where
22 the term “Administrator” appears—

23 (A) in each of subsections (e) and (f) of
24 section 501 of such Act (42 U.S.C. 290aa), in-

1 including the headings of such subsections, within
2 the term “Associate Administrator”;

3 (B) in section 507(b)(6) of such Act (42
4 U.S.C. 290bb(b)(6)), within the term “Adminis-
5 trator of the Health Resources and Services Ad-
6 ministration”;

7 (C) in section 507(b)(6) of such Act (42
8 U.S.C. 290bb(b)(6)), within the term “Adminis-
9 trator of the Centers for Medicare & Medicaid
10 Services”;

11 (D) in section 519B(c)(1)(B) of such Act
12 (42 U.S.C. 290bb–25b(c)(1)(B)), within the
13 term “Administrator of the National Highway
14 Traffic Safety Administration”; or

15 (E) in each of sections 519B(c)(1)(B),
16 520C(a), and 520D(a) of such Act (42 U.S.C.
17 290bb–25b(c)(1)(B), 290bb–34(a), 290bb–
18 35(a)), within the term “Administrator of the
19 Office of Juvenile Justice and Delinquency Pre-
20 vention”.

21 (d) REFERENCES.—After executing subsections (a),
22 (b), and (c), any reference in statute, regulation, or guid-
23 ance to the Administrator of the Substance Abuse and
24 Mental Health Services Administration shall be construed

1 to be a reference to the Assistant Secretary for Mental
2 Health and Substance Use.

3 **SEC. 6002. STRENGTHENING THE LEADERSHIP OF THE SUB-**
4 **STANCE ABUSE AND MENTAL HEALTH SERV-**
5 **ICES ADMINISTRATION.**

6 Section 501 of the Public Health Service Act (42
7 U.S.C. 290aa), as amended by section 6001, is further
8 amended—

9 (1) in subsection (b)—

10 (A) in the subsection heading, by striking
11 “AGENCIES” and inserting “CENTERS”; and

12 (B) in the matter preceding paragraph (1),
13 by striking “entities” and inserting “Centers”;

14 (2) in subsection (d)—

15 (A) in paragraph (1)—

16 (i) by striking “agencies” each place
17 the term appears and inserting “Centers”;
18 and

19 (ii) by striking “such agency” and in-
20 serting “such Center”;

21 (B) in paragraph (2)—

22 (i) by striking “agencies” and insert-
23 ing “Centers”;

1 (ii) by striking “with respect to sub-
2 stance abuse” and inserting “with respect
3 to substance use disorders”; and

4 (iii) by striking “and individuals who
5 are substance abusers” and inserting “and
6 individuals with substance use disorders”;

7 (C) in paragraph (5), by striking “sub-
8 stance abuse” and inserting “substance use dis-
9 order”;

10 (D) in paragraph (6)—

11 (i) by striking “the Centers for Dis-
12 ease Control” and inserting “the Centers
13 for Disease Control and Prevention,”;

14 (ii) by striking “Administration de-
15 velop” and inserting “Administration, de-
16 velop”;

17 (iii) by striking “HIV or tuberculosis
18 among substance abusers and individuals
19 with mental illness” and inserting “HIV,
20 hepatitis, tuberculosis, and other commu-
21 nicable diseases among individuals with
22 mental or substance use disorders,”; and

23 (iv) by striking “illnesses” at the end
24 and inserting “diseases or disorders”;

1 (E) in paragraph (7), by striking “abuse
2 utilizing anti-addiction medications, including
3 methadone” and inserting “use disorders, in-
4 cluding services that utilize drugs or devices ap-
5 proved or cleared by the Food and Drug Ad-
6 ministration for the treatment of substance use
7 disorders”;

8 (F) in paragraph (8)—

9 (i) by striking “Agency for Health
10 Care Policy Research” and inserting
11 “Agency for Healthcare Research and
12 Quality”; and

13 (ii) by striking “treatment and pre-
14 vention” and inserting “prevention and
15 treatment”;

16 (G) in paragraph (9)—

17 (i) by inserting “and maintenance”
18 after “development”;

19 (ii) by striking “Agency for Health
20 Care Policy Research” and inserting
21 “Agency for Healthcare Research and
22 Quality”; and

23 (iii) by striking “treatment and pre-
24 vention services” and inserting “preven-
25 tion, treatment, and recovery support serv-

1 ices and are appropriately incorporated
2 into programs carried out by the Adminis-
3 tration”;

4 (H) in paragraph (10), by striking “abuse”
5 and inserting “use disorder”;

6 (I) by striking paragraph (11) and insert-
7 ing the following:

8 “(11) work with relevant agencies of the De-
9 partment of Health and Human Services on inte-
10 grating mental health promotion and substance use
11 disorder prevention with general health promotion
12 and disease prevention and integrating mental and
13 substance use disorders treatment services with
14 physical health treatment services;”;

15 (J) in paragraph (13)—

16 (i) in the matter preceding subpara-
17 graph (A), by striking “this title, assure
18 that” and inserting “this title or part B of
19 title XIX, or grant programs otherwise
20 funded by the Administration”;

21 (ii) in subparagraph (A)—

22 (I) by inserting “require that”
23 before “all grants”; and

24 (II) by striking “and” at the end;

1 (iii) by redesignating subparagraph
2 (B) as subparagraph (C);

3 (iv) by inserting after subparagraph
4 (A) the following:

5 “(B) ensure that the director of each Cen-
6 ter of the Administration consistently docu-
7 ments the application of criteria when awarding
8 grants and the ongoing oversight of grantees
9 after such grants are awarded;”;

10 (v) in subparagraph (C), as so redес-
11 igned—

12 (I) by inserting “require that”
13 before “all grants”; and

14 (II) in clause (ii), by inserting
15 “and” after the semicolon at the end;
16 and

17 (vi) by adding at the end the fol-
18 lowing:

19 “(D) inform a State when any funds are
20 awarded through such a grant to any entity
21 within such State;”;

22 (K) in paragraph (16), by striking “abuse
23 and mental health information” and inserting
24 “use disorder information, including evidence-
25 based and promising best practices for preven-

1 tion, treatment, and recovery support services
2 for individuals with mental and substance use
3 disorders,”;

4 (L) in paragraph (17)—

5 (i) by striking “substance abuse” and
6 inserting “substance use disorder”; and

7 (ii) by striking “and” at the end;

8 (M) in paragraph (18), by striking the pe-
9 riod and inserting a semicolon; and

10 (N) by adding at the end the following:

11 “(19) consult with State, local, and tribal gov-
12 ernments, nongovernmental entities, and individuals
13 with mental illness, particularly adults with a serious
14 mental illness, children with a serious emotional dis-
15 turbance, and the family members of such adults
16 and children, with respect to improving community-
17 based and other mental health services;

18 “(20) collaborate with the Secretary of Defense
19 and the Secretary of Veterans Affairs to improve the
20 provision of mental and substance use disorder serv-
21 ices provided by the Department of Defense and the
22 Department of Veterans Affairs to members of the
23 Armed Forces, veterans, and the family members of
24 such members and veterans, including through the
25 provision of services using the telehealth capabilities

1 of the Department of Defense and the Department
2 of Veterans Affairs;

3 “(21) collaborate with the heads of relevant
4 Federal agencies and departments, States, commu-
5 nities, and nongovernmental experts to improve men-
6 tal and substance use disorders services for chron-
7 ically homeless individuals, including by designing
8 strategies to provide such services in supportive
9 housing;

10 “(22) work with States and other stakeholders
11 to develop and support activities to recruit and re-
12 tain a workforce addressing mental and substance
13 use disorders;

14 “(23) collaborate with the Attorney General
15 and representatives of the criminal justice system to
16 improve mental and substance use disorders services
17 for individuals who have been arrested or incarcer-
18 ated;

19 “(24) after providing an opportunity for public
20 input, set standards for grant programs under this
21 title for mental and substance use disorders services
22 and prevention programs, which standards may ad-
23 dress—

24 “(A) the capacity of the grantee to imple-
25 ment the award;

1 “(B) requirements for the description of
2 the program implementation approach;

3 “(C) the extent to which the grant plan
4 submitted by the grantee as part of its applica-
5 tion must explain how the grantee will reach
6 the population of focus and provide a statement
7 of need, which may include information on how
8 the grantee will increase access to services and
9 a description of measurable objectives for im-
10 proving outcomes;

11 “(D) the extent to which the grantee must
12 collect and report on required performance
13 measures; and

14 “(E) the extent to which the grantee is
15 proposing to use evidence-based practices; and

16 “(25) advance, through existing programs, the
17 use of performance metrics, including those based on
18 the recommendations on performance metrics from
19 the Assistant Secretary for Planning and Evaluation
20 under section 6021(d) of the Helping Families in
21 Mental Health Crisis Reform Act of 2016.”; and

22 (3) in subsection (m), by adding at the end the
23 following:

24 “(4) EMERGENCY RESPONSE.—Amounts made
25 available for carrying out this subsection shall re-

1 main available through the end of the fiscal year fol-
2 lowing the fiscal year for which such amounts are
3 appropriated.”.

4 **SEC. 6003. CHIEF MEDICAL OFFICER.**

5 Section 501 of the Public Health Service Act (42
6 U.S.C. 290aa), as amended by sections 6001 and 6002,
7 is further amended—

8 (1) by redesignating subsections (g) through (j)
9 and subsections (k) through (o) as subsections (h)
10 through (k) and subsections (m) through (q), respec-
11 tively;

12 (2) in subsection (e)(3)(C), by striking “sub-
13 section (k)” and inserting “subsection (m)”;

14 (3) in subsection (f)(2)(C)(iii), by striking “sub-
15 section (k)” and inserting “subsection (m)”;

16 (4) by inserting after subsection (f) the fol-
17 lowing:

18 “(g) CHIEF MEDICAL OFFICER.—

19 “(1) IN GENERAL.—The Assistant Secretary,
20 with the approval of the Secretary, shall appoint a
21 Chief Medical Officer to serve within the Adminis-
22 tration.

23 “(2) ELIGIBLE CANDIDATES.—The Assistant
24 Secretary shall select the Chief Medical Officer from
25 among individuals who—

1 “(A) have a doctoral degree in medicine or
2 osteopathic medicine;

3 “(B) have experience in the provision of
4 mental or substance use disorder services;

5 “(C) have experience working with mental
6 or substance use disorder programs;

7 “(D) have an understanding of biological,
8 psychosocial, and pharmaceutical treatments of
9 mental or substance use disorders; and

10 “(E) are licensed to practice medicine in
11 one or more States.

12 “(3) DUTIES.—The Chief Medical Officer
13 shall—

14 “(A) serve as a liaison between the Admin-
15 istration and providers of mental and substance
16 use disorders prevention, treatment, and recov-
17 ery services;

18 “(B) assist the Assistant Secretary in the
19 evaluation, organization, integration, and co-
20 ordination of programs operated by the Admin-
21 istration;

22 “(C) promote evidence-based and prom-
23 ising best practices, including culturally and lin-
24 guistically appropriate practices, as appropriate,
25 for the prevention and treatment of, and recov-

1 ery from, mental and substance use disorders,
2 including serious mental illness and serious
3 emotional disturbances;

4 “(D) participate in regular strategic plan-
5 ning with the Administration;

6 “(E) coordinate with the Assistant Sec-
7 retary for Planning and Evaluation to assess
8 the use of performance metrics to evaluate ac-
9 tivities within the Administration related to
10 mental and substance use disorders; and

11 “(F) coordinate with the Assistant Sec-
12 retary to ensure mental and substance use dis-
13 orders grant programs within the Administra-
14 tion consistently utilize appropriate perform-
15 ance metrics and evaluation designs.”.

16 **SEC. 6004. IMPROVING THE QUALITY OF BEHAVIORAL**
17 **HEALTH PROGRAMS.**

18 Section 505 of the Public Health Service Act (42
19 U.S.C. 290aa-4), as amended by section 6001(c), is
20 amended—

21 (1) by striking the section designation and
22 heading and inserting the following:

1 **“SEC. 505. CENTER FOR BEHAVIORAL HEALTH STATISTICS**
2 **AND QUALITY.”;**

3 (2) by redesignating subsections (a) through (d)
4 as subsections (b) through (e), respectively;

5 (3) before subsection (b), as redesignated by
6 paragraph (2), by inserting the following:

7 “(a) IN GENERAL.—The Assistant Secretary shall
8 maintain within the Administration a Center for Behav-
9 ioral Health Statistics and Quality (in this section referred
10 to as the ‘Center’). The Center shall be headed by a Direc-
11 tor (in this section referred to as the ‘Director’) appointed
12 by the Secretary from among individuals with extensive
13 experience and academic qualifications in research and
14 analysis in behavioral health care or related fields.”;

15 (4) in subsection (b), as redesignated by para-
16 graph (2)—

17 (A) by redesignating paragraphs (1) and
18 (2) as subparagraphs (A) and (B), respectively;

19 (B) by striking “The Secretary, acting”
20 and all that follows through “year on—” and
21 inserting “The Director shall—

22 “(1) coordinate the Administration’s integrated
23 data strategy, including by collecting data each year
24 on—”;

1 (C) in the subparagraph (B), as redesignig-
2 nated by subparagraph (A), by striking “Assist-
3 ant Secretary” and inserting “Director”; and

4 (D) by adding at the end the following new
5 paragraphs:

6 “(2) provide statistical and analytical support
7 for activities of the Administration;

8 “(3) recommend a core set of performance
9 metrics to evaluate activities supported by the Ad-
10 ministration; and

11 “(4) coordinate with the Assistant Secretary,
12 the Assistant Secretary for Planning and Evalua-
13 tion, and the Chief Medical Officer appointed under
14 section 501(g), as appropriate, to improve the qual-
15 ity of services provided by programs of the Adminis-
16 tration and the evaluation of activities carried out by
17 the Administration.”.

18 (5) in subsection (c), as so redesignated—

19 (A) by striking “With respect to the activi-
20 ties” and inserting “MENTAL HEALTH.—With
21 respect to the activities”;

22 (B) by striking “Assistant Secretary” each
23 place it appears and inserting “Director”; and

24 (C) by striking “subsection (a)” and in-
25 serting “subsection (b)(1)”;

1 (6) in subsection (d), as so redesignated—

2 (A) by striking the subsection designation
3 and all that follows through “With respect to
4 the activities” and inserting the following:

5 “(d) SUBSTANCE ABUSE.—

6 “(1) IN GENERAL.—With respect to the activi-
7 ties”;

8 (B) in paragraph (1)—

9 (i) in the matter before subparagraph

10 (A)—

11 (I) by striking “subsection (a)”
12 and inserting “subsection (b)(1)”; and

13 (II) by striking “Assistant Sec-
14 retary” each place it appears and in-
15 serting “Director”; and

16 (ii) in subparagraph (B), by inserting
17 “in coordination with the Centers for Dis-
18 ease Control and Prevention” before the
19 semicolon at the end; and

20 (C) in paragraph (2), by striking “ANNUAL
21 SURVEYS” and inserting “ANNUAL SURVEYS;
22 PUBLIC AVAILABILITY OF DATA.—Annual sur-
23 veys”; and

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

1 (A) by striking “After consultation” and
2 inserting “CONSULTATION.—After consulta-
3 tion”; and

4 (B) by striking “Assistant Secretary shall
5 develop” and inserting “Assistant Secretary
6 shall use existing standards and best practices
7 to develop”.

8 **SEC. 6005. STRATEGIC PLAN.**

9 Section 501 of the Public Health Service Act (42
10 U.S.C. 290aa), as amended by sections 6001 through
11 6003, is further amended by inserting after subsection (k),
12 as redesignated by section 6003, the following:

13 “(l) STRATEGIC PLAN.—

14 “(1) IN GENERAL.—Not later than September
15 30, 2018, and every 4 years thereafter, the Assistant
16 Secretary shall develop and carry out a strategic
17 plan in accordance with this subsection for the plan-
18 ning and operation of activities carried out by the
19 Administration, including evidence-based programs.

20 “(2) COORDINATION.—In developing and car-
21 rying out the strategic plan under this subsection,
22 the Assistant Secretary shall take into consideration
23 the findings and recommendations of the Assistant
24 Secretary for Planning and Evaluation under section
25 6021(d) of the Helping Families in Mental Health

1 Crisis Reform Act of 2016 and the report of the
2 Interdepartmental Serious Mental Illness Coordin-
3 ating Committee under section 6031 of such Act.

4 “(3) PUBLICATION OF PLAN.—Not later than
5 September 30, 2018, and every 4 years thereafter,
6 the Assistant Secretary shall—

7 “(A) submit the strategic plan developed
8 under paragraph (1) to the Committee on En-
9 ergy and Commerce and the Committee on Ap-
10 propriations of the House of Representatives
11 and the Committee on Health, Education,
12 Labor, and Pensions and the Committee on Ap-
13 propriations of the Senate; and

14 “(B) post such plan on the Internet
15 website of the Administration.

16 “(4) CONTENTS.—The strategic plan developed
17 under paragraph (1) shall—

18 “(A) identify strategic priorities, goals, and
19 measurable objectives for mental and substance
20 use disorders activities and programs operated
21 and supported by the Administration, including
22 priorities to prevent or eliminate the burden of
23 mental and substance use disorders;

24 “(B) identify ways to improve the quality
25 of services for individuals with mental and sub-

1 stance use disorders, and to reduce homeless-
2 ness, arrest, incarceration, violence, including
3 self-directed violence, and unnecessary hos-
4 pitalization of individuals with a mental or sub-
5 stance use disorder, including adults with a se-
6 rious mental illness or children with a serious
7 emotional disturbance;

8 “(C) ensure that programs provide, as ap-
9 propriate, access to effective and evidence-based
10 prevention, diagnosis, intervention, treatment,
11 and recovery services, including culturally and
12 linguistically appropriate services, as appro-
13 priate, for individuals with a mental or sub-
14 stance use disorder;

15 “(D) identify opportunities to collaborate
16 with the Health Resources and Services Admin-
17 istration to develop or improve—

18 “(i) initiatives to encourage individ-
19 uals to pursue careers (especially in rural
20 and underserved areas and with rural and
21 underserved populations) as psychiatrists,
22 including child and adolescent psychia-
23 trists, psychologists, psychiatric nurse
24 practitioners, physician assistants, clinical
25 social workers, certified peer support spe-

1 cialists, licensed professional counselors, or
2 other licensed or certified mental health or
3 substance use disorder professionals, in-
4 cluding such professionals specializing in
5 the diagnosis, evaluation, or treatment of
6 adults with a serious mental illness or chil-
7 dren with a serious emotional disturbance;
8 and

9 “(ii) a strategy to improve the recruit-
10 ment, training, and retention of a work-
11 force for the treatment of individuals with
12 mental or substance use disorders, or co-
13 occurring disorders;

14 “(E) identify opportunities to improve col-
15 laboration with States, local governments, com-
16 munities, and Indian tribes and tribal organiza-
17 tions (as such terms are defined in section 4 of
18 the Indian Self-Determination and Education
19 Assistance Act); and

20 “(F) specify a strategy to disseminate evi-
21 dence-based and promising best practices re-
22 lated to prevention, diagnosis, early interven-
23 tion, treatment, and recovery services related to
24 mental illness, particularly for adults with a se-
25 rious mental illness and children with a serious

1 emotional disturbance, and for individuals with
2 a substance use disorder.”.

3 **SEC. 6006. BIENNIAL REPORT CONCERNING ACTIVITIES**
4 **AND PROGRESS.**

5 (a) IN GENERAL.—Section 501 of the Public Health
6 Service Act (42 U.S.C. 290aa), as so amended, is further
7 amended by amending subsection (m), as redesignated by
8 section 6003, to read as follows:

9 “(m) BIENNIAL REPORT CONCERNING ACTIVITIES
10 AND PROGRESS.—Not later than September 30, 2020,
11 and every 2 years thereafter, the Assistant Secretary shall
12 prepare and submit to the Committee on Energy and
13 Commerce and the Committee on Appropriations of the
14 House of Representatives and the Committee on Health,
15 Education, Labor, and Pensions and the Committee on
16 Appropriations of the Senate, and post on the Internet
17 website of the Administration, a report containing at a
18 minimum—

19 “(1) a review of activities conducted or sup-
20 ported by the Administration, including progress to-
21 ward strategic priorities, goals, and objectives identi-
22 fied in the strategic plan developed under subsection
23 (1);

24 “(2) an assessment of programs and activities
25 carried out by the Assistant Secretary, including the

1 extent to which programs and activities under this
2 title and part B of title XIX meet identified goals
3 and performance measures developed for the respec-
4 tive programs and activities;

5 “(3) a description of the progress made in ad-
6 dressing gaps in mental and substance use disorders
7 prevention, treatment, and recovery services and im-
8 proving outcomes by the Administration, including
9 with respect to serious mental illnesses, serious emo-
10 tional disturbances, and co-occurring disorders;

11 “(4) a description of the manner in which the
12 Administration coordinates and partners with other
13 Federal agencies and departments related to mental
14 and substance use disorders, including activities re-
15 lated to—

16 “(A) the implementation and dissemination
17 of research findings into improved programs,
18 including with respect to how advances in seri-
19 ous mental illness and serious emotional dis-
20 turbance research have been incorporated into
21 programs;

22 “(B) the recruitment, training, and reten-
23 tion of a mental and substance use disorders
24 workforce;

1 “(C) the integration of mental disorder
2 services, substance use disorder services, and
3 physical health services;

4 “(D) homelessness; and

5 “(E) veterans;

6 “(5) a description of the manner in which the
7 Administration promotes coordination by grantees
8 under this title, and part B of title XIX, with State
9 or local agencies; and

10 “(6) a description of the activities carried out
11 under section 501A(e), with respect to mental and
12 substance use disorders, including—

13 “(A) the number and a description of
14 grants awarded;

15 “(B) the total amount of funding for
16 grants awarded;

17 “(C) a description of the activities sup-
18 ported through such grants, including outcomes
19 of programs supported; and

20 “(D) information on how the National
21 Mental Health and Substance Use Policy Lab-
22 oratory is consulting with the Assistant Sec-
23 retary for Planning and Evaluation and collabo-
24 rating with the Center for Substance Abuse
25 Treatment, the Center for Substance Abuse

1 Prevention, the Center for Behavioral Health
2 Statistics and Quality, and the Center for Men-
3 tal Health Services to carry out such activities;
4 and

5 “(7) recommendations made by the Assistant
6 Secretary for Planning and Evaluation under section
7 6021 of the Helping Families in Mental Health Cri-
8 sis Reform Act of 2016 to improve programs within
9 the Administration, and actions taken in response to
10 such recommendations to improve programs within
11 the Administration.

12 The Assistant Secretary may meet reporting requirements
13 established under this title by providing the contents of
14 such reports as an addendum to the biennial report estab-
15 lished under this subsection, notwithstanding the timeline
16 of other reporting requirements in this title. Nothing in
17 this subsection shall be construed to alter the content re-
18 quirements of such reports or authorize the Assistant Sec-
19 retary to alter the timeline of any such reports to be less
20 frequent than biennially, unless as specified in this title.”.

21 (b) CONFORMING AMENDMENT.—Section 508(p) of
22 the Public Health Service Act (42 U.S.C. 290bb–1(p)) is
23 amended by striking “section 501(k)” and inserting “sec-
24 tion 501(m)”.

1 **SEC. 6007. AUTHORITIES OF CENTERS FOR MENTAL**
2 **HEALTH SERVICES, SUBSTANCE ABUSE PRE-**
3 **VENTION, AND SUBSTANCE ABUSE TREAT-**
4 **MENT.**

5 (a) CENTER FOR MENTAL HEALTH SERVICES.—Sec-
6 tion 520(b) of the Public Health Service Act (42 U.S.C.
7 290bb–31(b)) is amended—

8 (1) by redesignating paragraphs (3) through
9 (15) as paragraphs (4) through (16), respectively;

10 (2) by inserting after paragraph (2) the fol-
11 lowing:

12 “(3) collaborate with the Director of the Na-
13 tional Institute of Mental Health and the Chief Med-
14 ical Officer, appointed under section 501(g), to en-
15 sure that, as appropriate, programs related to the
16 prevention and treatment of mental illness and the
17 promotion of mental health and recovery support are
18 carried out in a manner that reflects the best avail-
19 able science and evidence-based practices, including
20 culturally and linguistically appropriate services, as
21 appropriate;”;

22 (3) in paragraph (5), as so redesignated, by in-
23 serting “, including through programs that reduce
24 risk and promote resiliency” before the semicolon;

25 (4) in paragraph (6), as so redesignated, by in-
26 serting “in collaboration with the Director of the

1 National Institute of Mental Health,” before “de-
2 velop”;

3 (5) in paragraph (8), as so redesignated, by in-
4 serting “, increase meaningful participation of indi-
5 viduals with mental illness in programs and activi-
6 ties of the Administration,” before “and protect the
7 legal”;

8 (6) in paragraph (10), as so redesignated, by
9 striking “professional and paraprofessional per-
10 sonnel pursuant to section 303” and inserting
11 “health paraprofessional personnel and health pro-
12 fessionals”;

13 (7) in paragraph (11), as so redesignated, by
14 inserting “and tele-mental health” after “rural men-
15 tal health”;

16 (8) in paragraph (12), as so redesignated, by
17 striking “establish a clearinghouse for mental health
18 information to assure the widespread dissemination
19 of such information” and inserting “disseminate
20 mental health information, including evidence-based
21 practices,”;

22 (9) in paragraph (15), as so redesignated, by
23 striking “and” at the end;

24 (10) in paragraph (16), as so redesignated, by
25 striking the period and inserting “; and”; and

1 (11) by adding at the end the following:

2 “(17) ensure the consistent documentation of
3 the application of criteria when awarding grants and
4 the ongoing oversight of grantees after such grants
5 are awarded.”.

6 (b) DIRECTOR OF THE CENTER FOR SUBSTANCE
7 ABUSE PREVENTION.—Section 515 of the Public Health
8 Service Act (42 U.S.C. 290bb–21) is amended—

9 (1) in the section heading, by striking “OF-
10 FICE” and inserting “CENTER”;

11 (2) in subsection (a)—

12 (A) by striking “an Office” and inserting
13 “a Center”; and

14 (B) by striking “The Office” and inserting
15 “The Prevention Center”; and

16 (3) in subsection (b)—

17 (A) in paragraph (1), by inserting
18 “through the reduction of risk and the pro-
19 motion of resiliency” before the semicolon;

20 (B) by redesignating paragraphs (3)
21 through (11) as paragraphs (4) through (12),
22 respectively;

23 (C) by inserting after paragraph (2) the
24 following:

1 “(3) collaborate with the Director of the Na-
2 tional Institute on Drug Abuse, the Director of the
3 National Institute on Alcohol Abuse and Alcoholism,
4 and States to promote the study of substance abuse
5 prevention and the dissemination and implementa-
6 tion of research findings that will improve the deliv-
7 ery and effectiveness of substance abuse prevention
8 activities;”;

9 (D) in paragraph (4), as so redesignated,
10 by striking “literature on the adverse effects of
11 cocaine free base (known as crack)” and insert-
12 ing “educational information on the effects of
13 drugs abused by individuals, including drugs
14 that are emerging as abused drugs”;

15 (E) in paragraph (6), as so redesignated—

16 (i) by striking “substance abuse coun-
17 selors” and inserting “health professionals
18 who provide substance use and misuse pre-
19 vention and treatment services”; and

20 (ii) by striking “drug abuse education,
21 prevention,” and inserting “illicit drug use
22 education and prevention”;

23 (F) by amending paragraph (7), as so re-
24 designated, to read as follows:

1 “(7) in cooperation with the Director of the
2 Centers for Disease Control and Prevention, develop
3 and disseminate educational materials to increase
4 awareness for individuals at greatest risk for sub-
5 stance use disorders to prevent the transmission of
6 communicable diseases, such as HIV, hepatitis, tu-
7 berculosis, and other communicable diseases;”;

8 (G) in paragraph (9), as so redesignated—

9 (i) by striking “to discourage” and in-
10 serting “that reduce the risk of”; and

11 (ii) by inserting before the semicolon
12 “and promote resiliency”;

13 (H) in paragraph (11), as so redesignated,
14 by striking “and” after the semicolon;

15 (I) in paragraph (12), as so redesignated,
16 by striking the period and inserting a semi-
17 colon; and

18 (J) by adding at the end the following:

19 “(13) ensure the consistent documentation of
20 the application of criteria when awarding grants and
21 the ongoing oversight of grantees after such grants
22 are awarded; and

23 “(14) assist and support States in preventing il-
24 licit drug use, including emerging illicit drug use
25 issues.”.

1 (c) DIRECTOR OF THE CENTER FOR SUBSTANCE
2 ABUSE TREATMENT.—Section 507 of the Public Health
3 Service Act (42 U.S.C. 290bb) is amended—

4 (1) in subsection (a)—

5 (A) by striking “treatment of substance
6 abuse” and inserting “treatment of substance
7 use disorders”; and

8 (B) by striking “abuse treatment systems”
9 and inserting “use disorder treatment systems”;
10 and

11 (2) in subsection (b)—

12 (A) in paragraph (1), by striking “abuse”
13 and inserting “use disorder”;

14 (B) in paragraph (3), by striking “abuse”
15 and inserting “use disorder”;

16 (C) in paragraph (4), by striking “individ-
17 uals who abuse drugs” and inserting “individ-
18 uals who illicitly use drugs”;

19 (D) in paragraph (9), by striking “carried
20 out by the Director”;

21 (E) by striking paragraph (10);

22 (F) by redesignating paragraphs (11)
23 through (14) as paragraphs (10) through (13),
24 respectively;

1 (G) in paragraph (12), as so redesignated,
2 by striking “; and” and inserting a semicolon;
3 and

4 (H) by striking paragraph (13), as so re-
5 designated, and inserting the following:

6 “(13) ensure the consistent documentation of
7 the application of criteria when awarding grants and
8 the ongoing oversight of grantees after such grants
9 are awarded; and

10 “(14) work with States, providers, and individ-
11 uals in recovery, and their families, to promote the
12 expansion of recovery support services and systems
13 of care oriented toward recovery.”.

14 **SEC. 6008. ADVISORY COUNCILS.**

15 Section 502(b) of the Public Health Service Act (42
16 U.S.C. 290aa-1(b)) is amended—

17 (1) in paragraph (2)—

18 (A) in subparagraph (E), by striking
19 “and” after the semicolon;

20 (B) by redesignating subparagraph (F) as
21 subparagraph (J); and

22 (C) by inserting after subparagraph (E),
23 the following:

24 “(F) the Chief Medical Officer, appointed
25 under section 501(g);

1 “(G) the Director of the National Institute
2 of Mental Health for the advisory councils ap-
3 pointed under subsections (a)(1)(A) and
4 (a)(1)(D);

5 “(H) the Director of the National Institute
6 on Drug Abuse for the advisory councils ap-
7 pointed under subsections (a)(1)(A), (a)(1)(B),
8 and (a)(1)(C);

9 “(I) the Director of the National Institute
10 on Alcohol Abuse and Alcoholism for the advi-
11 sory councils appointed under subsections
12 (a)(1)(A), (a)(1)(B), and (a)(1)(C); and”;

13 (2) in paragraph (3), by adding at the end the
14 following:

15 “(C) Not less than half of the members of
16 the advisory council appointed under subsection
17 (a)(1)(D)—

18 “(i) shall—

19 “(I) have a medical degree;

20 “(II) have a doctoral degree in
21 psychology; or

22 “(III) have an advanced degree
23 in nursing or social work from an ac-
24 credited graduate school or be a cer-
25 tified physician assistant; and

1 “(ii) shall specialize in the mental
2 health field.

3 “(D) Not less than half of the members of
4 the advisory councils appointed under sub-
5 sections (a)(1)(B) and (a)(1)(C)—

6 “(i) shall—

7 “(I) have a medical degree;

8 “(II) have a doctoral degree; or

9 “(III) have an advanced degree
10 in nursing, public health, behavioral
11 or social sciences, or social work from
12 an accredited graduate school or be a
13 certified physician assistant; and

14 “(ii) shall have experience in the pro-
15 vision of substance use disorder services or
16 the development and implementation of
17 programs to prevent substance misuse.”.

18 **SEC. 6009. PEER REVIEW.**

19 Section 504(b) of the Public Health Service Act (42
20 U.S.C. 290aa–3(b)) is amended by adding at the end the
21 following: “In the case of any such peer review group that
22 is reviewing a grant, cooperative agreement, or contract
23 related to mental illness treatment, not less than half of
24 the members of such peer review group shall be licensed
25 and experienced professionals in the prevention, diagnosis,

1 or treatment of, or recovery from, mental illness or co-
2 occurring mental illness and substance use disorders and
3 have a medical degree, a doctoral degree in psychology,
4 or an advanced degree in nursing or social work from an
5 accredited program, and the Secretary, in consultation
6 with the Assistant Secretary, shall, to the extent possible,
7 ensure such peer review groups include broad geographic
8 representation, including both urban and rural representa-
9 tives.”.

10 **Subtitle B—Oversight and** 11 **Accountability**

12 **SEC. 6021. IMPROVING OVERSIGHT OF MENTAL AND SUB-** 13 **STANCE USE DISORDERS PROGRAMS** 14 **THROUGH THE ASSISTANT SECRETARY FOR** 15 **PLANNING AND EVALUATION.**

16 (a) IN GENERAL.—The Secretary of Health and
17 Human Services, acting through the Assistant Secretary
18 for Planning and Evaluation, shall ensure efficient and ef-
19 fective planning and evaluation of mental and substance
20 use disorders prevention and treatment programs and re-
21 lated activities.

22 (b) EVALUATION STRATEGY.—In carrying out sub-
23 section (a), the Assistant Secretary for Planning and
24 Evaluation shall, not later than 180 days after the date
25 of enactment of this Act, develop a strategy for conducting

1 ongoing evaluations that identifies priority programs to be
2 evaluated by the Assistant Secretary for Planning and
3 Evaluation and priority programs to be evaluated by other
4 relevant offices and agencies within the Department of
5 Health and Human Services. The strategy shall—

6 (1) include a plan for evaluating programs re-
7 lated to mental and substance use disorders, includ-
8 ing co-occurring disorders, across agencies, as appro-
9 priate, including programs related to—

10 (A) prevention, intervention, treatment,
11 and recovery support services, including such
12 services for adults with a serious mental illness
13 or children with a serious emotional disturb-
14 ance;

15 (B) the reduction of homelessness and in-
16 carceration among individuals with a mental or
17 substance use disorder; and

18 (C) public health and health services; and

19 (2) include a plan for assessing the use of per-
20 formance metrics to evaluate activities carried out by
21 entities receiving grants, contracts, or cooperative
22 agreements related to mental and substance use dis-
23 orders prevention and treatment services under title
24 V or title XIX of the Public Health Service Act (42
25 U.S.C. 290aa et seq.; 42 U.S.C. 300w et seq.).

1 (c) CONSULTATION.—In carrying out this section, the
2 Assistant Secretary for Planning and Evaluation shall
3 consult, as appropriate, with the Assistant Secretary for
4 Mental Health and Substance Use, the Chief Medical Offi-
5 cer of the Substance Abuse and Mental Health Services
6 Administration appointed under section 501(g) of the
7 Public Health Service Act (42 U.S.C. 290aa(g)), as
8 amended by section 6003, the Behavioral Health Coordi-
9 nating Council of the Department of Health and Human
10 Services, other agencies within the Department of Health
11 and Human Services, and other relevant Federal depart-
12 ments and agencies.

13 (d) RECOMMENDATIONS.—In carrying out this sec-
14 tion, the Assistant Secretary for Planning and Evaluation
15 shall provide recommendations to the Secretary of Health
16 and Human Services, the Assistant Secretary for Mental
17 Health and Substance Use, and the Congress on improv-
18 ing the quality of prevention and treatment programs and
19 activities related to mental and substance use disorders,
20 including recommendations for the use of performance
21 metrics. The Assistant Secretary for Mental Health and
22 Substance Use shall include such recommendations in the
23 biennial report required by subsection 501(m) of the Pub-
24 lic Health Service Act, as redesignated by section 6003
25 of this Act.

1 **SEC. 6022. REPORTING FOR PROTECTION AND ADVOCACY**
2 **ORGANIZATIONS.**

3 (a) PUBLIC AVAILABILITY OF REPORTS.—Section
4 105(a)(7) of the Protection and Advocacy for Individuals
5 with Mental Illness Act (42 U.S.C. 10805(a)(7)) is
6 amended by striking “is located a report” and inserting
7 “is located, and make publicly available, a report”.

8 (b) DETAILED ACCOUNTING.—Section 114(a) of the
9 Protection and Advocacy for Individuals with Mental Ill-
10 ness Act (42 U.S.C. 10824(a)) is amended—

11 (1) in paragraph (3), by striking “and” at the
12 end;

13 (2) in paragraph (4), by striking the period at
14 the end and inserting “; and”; and

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

16 “(5) using data from the existing required an-
17 nual program progress reports submitted by each
18 system funded under this title, a detailed accounting
19 for each such system of how funds are spent,
20 disaggregated according to whether the funds were
21 received from the Federal Government, the State
22 government, a local government, or a private enti-
23 ty.”.

24 **SEC. 6023. GAO STUDY.**

25 (a) IN GENERAL.—Not later than 18 months after
26 the date of enactment of this Act, the Comptroller General

1 of the United States, in consultation with the Secretary
2 of Health and Human Services and the Assistant Sec-
3 retary for Mental Health and Substance Use, shall con-
4 duct an independent evaluation, and submit a report, to
5 the Committee on Health, Education, Labor, and Pen-
6 sions of the Senate and the Committee on Energy and
7 Commerce of the House of Representatives, on programs
8 funded by allotments made under title I of the Protection
9 and Advocacy for Individuals with Mental Illness Act (42
10 U.S.C. 10801 et seq.).

11 (b) CONTENTS.—The report and evaluation required
12 under subsection (a) shall include—

13 (1) a review of the programs described in such
14 subsection that are carried out by State agencies
15 and such programs that are carried out by private,
16 nonprofit organizations; and

17 (2) a review of the compliance of the programs
18 described in subsection (a) with statutory and regu-
19 latory responsibilities, such as—

20 (A) responsibilities relating to family en-
21 gagement;

22 (B) responsibilities relating to the griev-
23 ance procedure for clients or prospective clients
24 of the system to assure that individuals with
25 mental illness have full access to the services of

1 the system, for individuals who have received or
2 are receiving mental health services, and for
3 family members of such individuals with mental
4 illness, or representatives of such individuals or
5 family members, to assure that the eligible sys-
6 tem is operating in compliance with the provi-
7 sions of the Protection and Advocacy for Indi-
8 viduals with Mental Illness Act, as required to
9 be established by section 105(a)(9) of such Act
10 (42 U.S.C. 10805(a)(9));

11 (C) investigation of alleged abuse and ne-
12 glect of persons with mental illness;

13 (D) availability of adequate medical and
14 behavioral health treatment;

15 (E) denial of rights for persons with men-
16 tal illness; and

17 (F) compliance with the Federal prohibi-
18 tion on lobbying.

19 **Subtitle C—Interdepartmental Se-**
20 **rious Mental Illness Coordi-**
21 **nating Committee**

22 **SEC. 6031. INTERDEPARTMENTAL SERIOUS MENTAL ILL-**
23 **NESS COORDINATING COMMITTEE.**

24 (a) ESTABLISHMENT.—

1 (1) IN GENERAL.—Not later than 3 months
2 after the date of enactment of this Act, the Sec-
3 retary of Health and Human Services, or the des-
4 ignee of the Secretary, shall establish a committee to
5 be known as the Interdepartmental Serious Mental
6 Illness Coordinating Committee (in this section re-
7 ferred to as the “Committee”).

8 (2) FEDERAL ADVISORY COMMITTEE ACT.—Ex-
9 cept as provided in this section, the provisions of the
10 Federal Advisory Committee Act (5 U.S.C. App.)
11 shall apply to the Committee.

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

14 (c) RESPONSIBILITIES.—Not later than 1 year after
15 the date of enactment of this Act, and 5 years after such
16 date of enactment, the Committee shall submit to Con-
17 gress and any other relevant Federal department or agen-
18 cy a report including—

19 (1) a summary of advances in serious mental
20 illness and serious emotional disturbance research
21 related to the prevention of, diagnosis of, interven-
22 tion in, and treatment and recovery of serious men-
23 tal illnesses, serious emotional disturbances, and ad-
24 vances in access to services and support for adults

1 with a serious mental illness or children with a seri-
2 ous emotional disturbance;

3 (2) an evaluation of the effect Federal pro-
4 grams related to serious mental illness have on pub-
5 lic health, including public health outcomes such
6 as—

7 (A) rates of suicide, suicide attempts, inci-
8 dence and prevalence of serious mental ill-
9 nesses, serious emotional disturbances, and sub-
10 stance use disorders, overdose, overdose deaths,
11 emergency hospitalizations, emergency room
12 boarding, preventable emergency room visits,
13 interaction with the criminal justice system,
14 homelessness, and unemployment;

15 (B) increased rates of employment and en-
16 rollment in educational and vocational pro-
17 grams;

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

20 (D) any other criteria as may be deter-
21 mined by the Secretary; and

22 (3) specific recommendations for actions that
23 agencies can take to better coordinate the adminis-
24 tration of mental health services for adults with a

1 serious mental illness or children with a serious emo-
2 tional disturbance.

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

7 (e) MEMBERSHIP.—

8 (1) FEDERAL MEMBERS.—The Committee shall
9 be composed of the following Federal representa-
10 tives, or the designees of such representatives—

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

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

16 (C) the Attorney General;

17 (D) the Secretary of Veterans Affairs;

18 (E) the Secretary of Defense;

19 (F) the Secretary of Housing and Urban
20 Development;

21 (G) the Secretary of Education;

22 (H) the Secretary of Labor;

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

25 (J) the Commissioner of Social Security.

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

5 (A) at least 2 members shall be an indi-
6 vidual who has received treatment for a diag-
7 nosis of a serious mental illness;

8 (B) at least 1 member shall be a parent or
9 legal guardian of an adult with a history of a
10 serious mental illness or a child with a history
11 of a serious emotional disturbance;

12 (C) at least 1 member shall be a represent-
13 ative of a leading research, advocacy, or service
14 organization for adults with a serious mental
15 illness;

16 (D) at least 2 members shall be—

17 (i) a licensed psychiatrist with experi-
18 ence in treating serious mental illnesses;

19 (ii) a licensed psychologist with experi-
20 ence in treating serious mental illnesses
21 or serious emotional disturbances;

22 (iii) a licensed clinical social worker
23 with experience treating serious mental ill-
24 nesses or serious emotional disturbances;

25 or

1 (iv) a licensed psychiatric nurse, nurse
2 practitioner, or physician assistant with ex-
3 perience in treating serious mental ill-
4 nesses or serious emotional disturbances;

5 (E) at least 1 member shall be a licensed
6 mental health professional with a specialty in
7 treating children and adolescents with a serious
8 emotional disturbance;

9 (F) at least 1 member shall be a mental
10 health professional who has research or clinical
11 mental health experience in working with mi-
12 norities;

13 (G) at least 1 member shall be a mental
14 health professional who has research or clinical
15 mental health experience in working with medi-
16 cally underserved populations;

17 (H) at least 1 member shall be a State cer-
18 tified mental health peer support specialist;

19 (I) at least 1 member shall be a judge with
20 experience in adjudicating cases related to
21 criminal justice or serious mental illness;

22 (J) at least 1 member shall be a law en-
23 forcement officer or corrections officer with ex-
24 tensive experience in interfacing with adults
25 with a serious mental illness, children with a se-

1 rious emotional disturbance, or individuals in a
2 mental health crisis; and

3 (K) at least 1 member shall have experi-
4 ence providing services for homeless individuals
5 and working with adults with a serious mental
6 illness, children with a serious emotional dis-
7 turbance, or individuals in a mental health cri-
8 sis.

9 (3) TERMS.—A member of the Committee ap-
10 pointed under subsection (e)(2) shall serve for a
11 term of 3 years, and may be reappointed for 1 or
12 more additional 3-year terms. Any member ap-
13 pointed to fill a vacancy for an unexpired term shall
14 be appointed for the remainder of such term. A
15 member may serve after the expiration of the mem-
16 ber's term until a successor has been appointed.

17 (f) WORKING GROUPS.—In carrying out its func-
18 tions, the Committee may establish working groups. Such
19 working groups shall be composed of Committee members,
20 or their designees, and may hold such meetings as are nec-
21 essary.

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

1 **TITLE VII—ENSURING MENTAL**
2 **AND SUBSTANCE USE DIS-**
3 **ORDERS PREVENTION,**
4 **TREATMENT, AND RECOVERY**
5 **PROGRAMS KEEP PACE WITH**
6 **SCIENCE AND TECHNOLOGY**

7 **SEC. 7001. ENCOURAGING INNOVATION AND EVIDENCE-**
8 **BASED PROGRAMS.**

9 Title V of the Public Health Service Act (42 U.S.C.
10 290aa et seq.) is amended by inserting after section 501
11 (42 U.S.C. 290aa) the following:

12 **“SEC. 501A. NATIONAL MENTAL HEALTH AND SUBSTANCE**
13 **USE POLICY LABORATORY.**

14 “(a) **IN GENERAL.**—There shall be established within
15 the Administration a National Mental Health and Sub-
16 stance Use Policy Laboratory (referred to in this section
17 as the ‘Laboratory’).

18 “(b) **RESPONSIBILITIES.**—The Laboratory shall—

19 “(1) continue to carry out the authorities and
20 activities that were in effect for the Office of Policy,
21 Planning, and Innovation as such Office existed
22 prior to the date of enactment of the Helping Fami-
23 lies in Mental Health Crisis Reform Act of 2016;

24 “(2) identify, coordinate, and facilitate the im-
25 plementation of policy changes likely to have a sig-

1 nificant effect on mental health, mental illness, re-
2 covery supports, and the prevention and treatment
3 of substance use disorder services;

4 “(3) work with the Center for Behavioral
5 Health Statistics and Quality to collect, as appro-
6 priate, information from grantees under programs
7 operated by the Administration in order to evaluate
8 and disseminate information on evidence-based prac-
9 tices, including culturally and linguistically appro-
10 priate services, as appropriate, and service delivery
11 models;

12 “(4) provide leadership in identifying and co-
13 ordinating policies and programs, including evidence-
14 based programs, related to mental and substance use
15 disorders;

16 “(5) periodically review programs and activities
17 operated by the Administration relating to the diag-
18 nosis or prevention of, treatment for, and recovery
19 from, mental and substance use disorders to—

20 “(A) identify any such programs or activi-
21 ties that are duplicative;

22 “(B) identify any such programs or activi-
23 ties that are not evidence-based, effective, or ef-
24 ficient; and

1 “(C) formulate recommendations for co-
2 ordinating, eliminating, or improving programs
3 or activities identified under subparagraph (A)
4 or (B) and merging such programs or activities
5 into other successful programs or activities; and

6 “(6) carry out other activities as deemed nec-
7 essary to continue to encourage innovation and dis-
8 seminate evidence-based programs and practices.

9 “(c) EVIDENCE-BASED PRACTICES AND SERVICE
10 DELIVERY MODELS.—

11 “(1) IN GENERAL.—In carrying out subsection
12 (b)(3), the Laboratory—

13 “(A) may give preference to models that
14 improve—

15 “(i) the coordination between mental
16 health and physical health providers;

17 “(ii) the coordination among such pro-
18 viders and the justice and corrections sys-
19 tem; and

20 “(iii) the cost effectiveness, quality,
21 effectiveness, and efficiency of health care
22 services furnished to adults with a serious
23 mental illness, children with a serious emo-
24 tional disturbance, or individuals in a men-
25 tal health crisis; and

1 “(B) may include clinical protocols and
2 practices that address the needs of individuals
3 with early serious mental illness.

4 “(2) CONSULTATION.—In carrying out this sec-
5 tion, the Laboratory shall consult with—

6 “(A) the Chief Medical Officer appointed
7 under section 501(g);

8 “(B) representatives of the National Insti-
9 tute of Mental Health, the National Institute
10 on Drug Abuse, and the National Institute on
11 Alcohol Abuse and Alcoholism, on an ongoing
12 basis;

13 “(C) other appropriate Federal agencies;

14 “(D) clinical and analytical experts with
15 expertise in psychiatric medical care and clinical
16 psychological care, health care management,
17 education, corrections health care, and mental
18 health court systems, as appropriate; and

19 “(E) other individuals and agencies as de-
20 termined appropriate by the Assistant Sec-
21 retary.

22 “(d) DEADLINE FOR BEGINNING IMPLEMENTA-
23 TION.—The Laboratory shall begin implementation of this
24 section not later than January 1, 2018.

25 “(e) PROMOTING INNOVATION.—

1 “(1) IN GENERAL.—The Assistant Secretary, in
2 coordination with the Laboratory, may award grants
3 to States, local governments, Indian tribes or tribal
4 organizations (as such terms are defined in section
5 4 of the Indian Self-Determination and Education
6 Assistance Act), educational institutions, and non-
7 profit organizations to develop evidence-based inter-
8 ventions, including culturally and linguistically ap-
9 propriate services, as appropriate, for—

10 “(A) evaluating a model that has been sci-
11 entifically demonstrated to show promise, but
12 would benefit from further applied development,
13 for—

14 “(i) enhancing the prevention, diag-
15 nosis, intervention, and treatment of, and
16 recovery from, mental illness, serious emo-
17 tional disturbances, substance use dis-
18 orders, and co-occurring illness or dis-
19 orders; or

20 “(ii) integrating or coordinating phys-
21 ical health services and mental and sub-
22 stance use disorders services; and

23 “(B) expanding, replicating, or scaling evi-
24 dence-based programs across a wider area to
25 enhance effective screening, early diagnosis,

1 intervention, and treatment with respect to
2 mental illness, serious mental illness, serious
3 emotional disturbances, and substance use dis-
4 orders, primarily by—

5 “(i) applying such evidence-based pro-
6 grams to the delivery of care, including by
7 training staff in effective evidence-based
8 treatments; or

9 “(ii) integrating such evidence-based
10 programs into models of care across spe-
11 cialties and jurisdictions.

12 “(2) CONSULTATION.—In awarding grants
13 under this subsection, the Assistant Secretary shall,
14 as appropriate, consult with the Chief Medical Offi-
15 cer, appointed under section 501(g), the advisory
16 councils described in section 502, the National Insti-
17 tute of Mental Health, the National Institute on
18 Drug Abuse, and the National Institute on Alcohol
19 Abuse and Alcoholism, as appropriate.

20 “(3) AUTHORIZATION OF APPROPRIATIONS.—
21 There are authorized to be appropriated—

22 “(A) to carry out paragraph (1)(A),
23 \$7,000,000 for the period of fiscal years 2018
24 through 2020; and

1 “(B) to carry out paragraph (1)(B),
2 \$7,000,000 for the period of fiscal years 2018
3 through 2020.”.

4 **SEC. 7002. PROMOTING ACCESS TO INFORMATION ON EVI-**
5 **DENCE-BASED PROGRAMS AND PRACTICES.**

6 Part D of title V of the Public Health Service Act
7 (42 U.S.C. 290dd et seq.) is amended by inserting after
8 section 543 of such Act (42 U.S.C. 290dd–2) the fol-
9 lowing:

10 **“SEC. 543A. PROMOTING ACCESS TO INFORMATION ON EVI-**
11 **DENCE-BASED PROGRAMS AND PRACTICES.**

12 “(a) IN GENERAL.—The Assistant Secretary shall, as
13 appropriate, improve access to reliable and valid informa-
14 tion on evidence-based programs and practices, including
15 information on the strength of evidence associated with
16 such programs and practices, related to mental and sub-
17 stance use disorders for States, local communities, non-
18 profit entities, and other stakeholders, by posting on the
19 Internet website of the Administration information on evi-
20 dence-based programs and practices that have been re-
21 viewed by the Assistant Secretary in accordance with the
22 requirements of this section.

23 “(b) APPLICATIONS.—

24 “(1) APPLICATION PERIOD.—In carrying out
25 subsection (a), the Assistant Secretary may establish

1 a period for the submission of applications for evi-
2 dence-based programs and practices to be posted
3 publicly in accordance with subsection (a).

4 “(2) NOTICE.—In establishing the application
5 period under paragraph (1), the Assistant Secretary
6 shall provide for the public notice of such application
7 period in the Federal Register. Such notice may so-
8 licit applications for evidence-based programs and
9 practices to address gaps in information identified
10 by the Assistant Secretary, the National Mental
11 Health and Substance Use Policy Laboratory estab-
12 lished under section 501A, or the Assistant Sec-
13 retary for Planning and Evaluation, including pursu-
14 ant to the evaluation and recommendations under
15 section 6021 of the Helping Families in Mental
16 Health Crisis Reform Act of 2016 or priorities iden-
17 tified in the strategic plan under section 501(l).

18 “(c) REQUIREMENTS.—The Assistant Secretary may
19 establish minimum requirements for the applications sub-
20 mitted under subsection (b), including applications related
21 to the submission of research and evaluation.

22 “(d) REVIEW AND RATING.—

23 “(1) IN GENERAL.—The Assistant Secretary
24 shall review applications prior to public posting in
25 accordance with subsection (a), and may prioritize

1 the review of applications for evidence-based pro-
2 grams and practices that are related to topics in-
3 cluded in the notice provided under subsection
4 (b)(2).

5 “(2) SYSTEM.—In carrying out paragraph (1),
6 the Assistant Secretary may utilize a rating and re-
7 view system, which may include information on the
8 strength of evidence associated with the evidence-
9 based programs and practices and a rating of the
10 methodological rigor of the research supporting the
11 applications.

12 “(3) PUBLIC ACCESS TO METRICS AND RAT-
13 ING.—The Assistant Secretary shall make the
14 metrics used to evaluate applications under this sec-
15 tion, and any resulting ratings of such applications,
16 publicly available.”

17 **SEC. 7003. PRIORITY MENTAL HEALTH NEEDS OF RE-**
18 **GIONAL AND NATIONAL SIGNIFICANCE.**

19 Section 520A of the Public Health Service Act (42
20 U.S.C. 290bb–32) is amended—

21 (1) in subsection (a)—

22 (A) in paragraph (4), by inserting before
23 the period “, which may include technical as-
24 sistance centers”; and

1 (B) in the flush sentence following para-
2 graph (4)—

3 (i) by inserting “, contracts,” before
4 “or cooperative agreements”; and

5 (ii) by striking “Indian tribes and
6 tribal organizations” and inserting “Indian
7 tribes or tribal organizations (as such
8 terms are defined in section 4 of the In-
9 dian Self-Determination and Education
10 Assistance Act), health facilities, or pro-
11 grams operated by or in accordance with a
12 contract or grant with the Indian Health
13 Service, or”; and

14 (2) by amending subsection (f) to read as fol-
15 lows:

16 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
17 are authorized to be appropriated to carry out this section
18 \$394,550,000 for each of fiscal years 2018 through
19 2022.”.

20 **SEC. 7004. PRIORITY SUBSTANCE USE DISORDER TREAT-**
21 **MENT NEEDS OF REGIONAL AND NATIONAL**
22 **SIGNIFICANCE.**

23 Section 509 of the Public Health Service Act (42
24 U.S.C. 290bb-2) is amended—

25 (1) in subsection (a)—

1 (A) in the matter preceding paragraph (1),
2 by striking “abuse” and inserting “use dis-
3 order”;

4 (B) in paragraph (3), by inserting before
5 the period “that permit States, local govern-
6 ments, communities, and Indian tribes and trib-
7 al organizations (as the terms ‘Indian tribes’
8 and ‘tribal organizations’ are defined in section
9 4 of the Indian Self-Determination and Edu-
10 cation Assistance Act) to focus on emerging
11 trends in substance abuse and co-occurrence of
12 substance use disorders with mental illness or
13 other conditions”; and

14 (C) in the flush sentence following para-
15 graph (3)—

16 (i) by inserting “, contracts,” before
17 “or cooperative agreements”; and

18 (ii) by striking “Indian tribes and
19 tribal organizations,” and inserting “In-
20 dian tribes or tribal organizations (as such
21 terms are defined in section 4 of the In-
22 dian Self-Determination and Education
23 Assistance Act), health facilities, or pro-
24 grams operated by or in accordance with a

1 contract or grant with the Indian Health
2 Service, or”;

3 (2) in subsection (b)—

4 (A) in paragraph (1), by striking “abuse”
5 and inserting “use disorder”; and

6 (B) in paragraph (2), by striking “abuse”
7 and inserting “use disorder”;

8 (3) in subsection (e), by striking “abuse” and
9 inserting “use disorder”; and

10 (4) in subsection (f), by striking
11 “\$300,000,000” and all that follows through the pe-
12 riod and inserting “\$333,806,000 for each of fiscal
13 years 2018 through 2022.”.

14 **SEC. 7005. PRIORITY SUBSTANCE USE DISORDER PREVEN-**
15 **TION NEEDS OF REGIONAL AND NATIONAL**
16 **SIGNIFICANCE.**

17 Section 516 of the Public Health Service Act (42
18 U.S.C. 290bb–22) is amended—

19 (1) in the section heading, by striking
20 “**ABUSE**” and inserting “**USE DISORDER**”;

21 (2) in subsection (a)—

22 (A) in the matter preceding paragraph (1),
23 by striking “abuse” and inserting “use dis-
24 order”;

1 (B) in paragraph (3), by inserting before
2 the period “, including such programs that
3 focus on emerging drug abuse issues”; and

4 (C) in the flush sentence following para-
5 graph (3)—

6 (i) by inserting “, contracts,” before
7 “or cooperative agreements”; and

8 (ii) by striking “Indian tribes and
9 tribal organizations,” and inserting “In-
10 dian tribes or tribal organizations (as such
11 terms are defined in section 4 of the In-
12 dian Self-Determination and Education
13 Assistance Act), health facilities, or pro-
14 grams operated by or in accordance with a
15 contract or grant with the Indian Health
16 Service,”;

17 (3) in subsection (b)—

18 (A) in paragraph (1), by striking “abuse”
19 and inserting “use disorder”; and

20 (B) in paragraph (2)—

21 (i) in subparagraph (A), by striking “;
22 and” at the end and inserting “;”;

23 (ii) in subparagraph (B)—

24 (I) by striking “abuse” and in-
25 serting “use disorder”; and

1 (II) by striking the period and
2 inserting “; and”; and

3 (iii) by adding at the end the fol-
4 lowing:

5 “(C) substance use disorder prevention
6 among high-risk groups.”;

7 (4) in subsection (e), by striking “abuse” and
8 inserting “use disorder”; and

9 (5) in subsection (f), by striking
10 “\$300,000,000” and all that follows through the pe-
11 riod and inserting “\$211,148,000 for each of fiscal
12 years 2018 through 2022.”.

13 **TITLE VIII—SUPPORTING STATE**
14 **PREVENTION ACTIVITIES AND**
15 **RESPONSES TO MENTAL**
16 **HEALTH AND SUBSTANCE**
17 **USE DISORDER NEEDS**

18 **SEC. 8001. COMMUNITY MENTAL HEALTH SERVICES BLOCK**
19 **GRANT.**

20 (a) FORMULA GRANTS.—Section 1911(b) of the Pub-
21 lic Health Service Act (42 U.S.C. 300x(b)) is amended—

22 (1) by redesignating paragraphs (1) through
23 (3) as paragraphs (2) through (4), respectively; and

24 (2) by inserting before paragraph (2) (as so re-
25 designated) the following:

1 “(1) providing community mental health serv-
2 ices for adults with a serious mental illness and chil-
3 dren with a serious emotional disturbance as defined
4 in accordance with section 1912(c);”.

5 (b) STATE PLAN.—Section 1912(b) of the Public
6 Health Service Act (42 U.S.C. 300x–1(b)) is amended—

7 (1) in paragraph (3), by redesignating subpara-
8 graphs (A) through (C) as clauses (i) through (iii),
9 respectively, and realigning the margins accordingly;

10 (2) by redesignating paragraphs (1) through
11 (5) as subparagraphs (A) through (E), respectively,
12 and realigning the margins accordingly;

13 (3) in the matter preceding subparagraph (A)
14 (as so redesignated), by striking “With respect to”
15 and all that follows through “are as follows:” and
16 inserting “In accordance with subsection (a), a State
17 shall submit to the Secretary a plan every two years
18 that, at a minimum, includes each of the following:”;

19 (4) by inserting before subparagraph (A) (as so
20 redesignated) the following:

21 “(1) SYSTEM OF CARE.—A description of the
22 State’s system of care that contains the following:”;

23 (5) by striking subparagraph (A) (as so redesign-
24 ated) and inserting the following:

1 “(A) COMPREHENSIVE COMMUNITY-BASED
2 HEALTH SYSTEMS.—The plan shall—

3 “(i) identify the single State agency to
4 be responsible for the administration of the
5 program under the grant, including any
6 third party who administers mental health
7 services and is responsible for complying
8 with the requirements of this part with re-
9 spect to the grant;

10 “(ii) provide for an organized commu-
11 nity-based system of care for individuals
12 with mental illness, and describe available
13 services and resources in a comprehensive
14 system of care, including services for indi-
15 viduals with co-occurring disorders;

16 “(iii) include a description of the
17 manner in which the State and local enti-
18 ties will coordinate services to maximize
19 the efficiency, effectiveness, quality, and
20 cost-effectiveness of services and programs
21 to produce the best possible outcomes (in-
22 cluding health services, rehabilitation serv-
23 ices, employment services, housing services,
24 educational services, substance use dis-
25 order services, legal services, law enforce-

1 ment services, social services, child welfare
2 services, medical and dental care services,
3 and other support services to be provided
4 with Federal, State, and local public and
5 private resources) with other agencies to
6 enable individuals receiving services to
7 function outside of inpatient or residential
8 institutions, to the maximum extent of
9 their capabilities, including services to be
10 provided by local school systems under the
11 Individuals with Disabilities Education
12 Act;

13 “(iv) include a description of how the
14 State promotes evidence-based practices,
15 including those evidence-based programs
16 that address the needs of individuals with
17 early serious mental illness regardless of
18 the age of the individual at onset, provide
19 comprehensive individualized treatment, or
20 integrate mental and physical health serv-
21 ices;

22 “(v) include a description of case
23 management services;

24 “(vi) include a description of activities
25 that seek to engage adults with a serious

1 mental illness or children with a serious
2 emotional disturbance and their caregivers
3 where appropriate in making health care
4 decisions, including activities that enhance
5 communication among individuals, fami-
6 lies, caregivers, and treatment providers;
7 and

8 “(vii) as appropriate to, and reflective
9 of, the uses the State proposes for the
10 block grant funds, include—

11 “(I) a description of the activities
12 intended to reduce hospitalizations
13 and hospital stays using the block
14 grant funds;

15 “(II) a description of the activi-
16 ties intended to reduce incidents of
17 suicide using the block grant funds;

18 “(III) a description of how the
19 State integrates mental health and
20 primary care using the block grant
21 funds, which may include providing,
22 in the case of individuals with co-oc-
23 curring mental and substance use dis-
24 orders, both mental and substance use
25 disorders services in primary care set-

1 tings or arrangements to provide pri-
2 mary and specialty care services in
3 community-based mental and sub-
4 stance use disorders settings; and

5 “(IV) a description of recovery
6 and recovery support services for
7 adults with a serious mental illness
8 and children with a serious emotional
9 disturbance.”;

10 (6) in subparagraph (B) (as so redesignated)—

11 (A) by striking “The plan contains” and
12 inserting “The plan shall contain”; and

13 (B) by striking “presents quantitative tar-
14 gets to be achieved in the implementation of the
15 system described in paragraph (1)” and insert-
16 ing “present quantitative targets and outcome
17 measures for programs and services provided
18 under this subpart”;

19 (7) in subparagraph (C) (as so redesignated)—

20 (A) by striking “serious emotional disturb-
21 ance” in the matter preceding clause (i) (as so
22 redesignated) and all that follows through “sub-
23 stance abuse services” in clause (i) (as so red-
24 esignated) and inserting the following: “a serious
25 emotional disturbance (as defined pursuant to

1 subsection (c)), the plan shall provide for a sys-
2 tem of integrated social services, educational
3 services, child welfare services, juvenile justice
4 services, law enforcement services, and sub-
5 stance use disorder services”;

6 (B) by striking “Education Act);” and in-
7 serting “Education Act).”; and

8 (C) by striking clauses (ii) and (iii) (as so
9 redesignated);

10 (8) in subparagraph (D) (as so redesignated),
11 by striking “plan describes” and inserting “plan
12 shall describe”;

13 (9) in subparagraph (E) (as so redesignated)—

14 (A) in the subparagraph heading by strik-
15 ing “SYSTEMS” and inserting “SERVICES”;

16 (B) in the first sentence, by striking “plan
17 describes” and all that follows through “and
18 provides for” and inserting “plan shall describe
19 the financial resources available, the existing
20 mental health workforce, and the workforce
21 trained in treating individuals with co-occurring
22 mental and substance use disorders, and shall
23 provide for”; and

24 (C) in the second sentence—

1 (i) by striking “further describes” and
2 inserting “shall further describe”; and

3 (ii) by striking “involved.” and insert-
4 ing “involved, and the manner in which the
5 State intends to comply with each of the
6 funding agreements in this subpart and
7 subpart III.”;

8 (10) by striking the flush matter at the end;
9 and

10 (11) by adding at the end the following:

11 “(2) GOALS AND OBJECTIVES.—The establish-
12 ment of goals and objectives for the period of the
13 plan, including targets and milestones that are in-
14 tended to be met, and the activities that will be un-
15 dertaken to achieve those targets.”.

16 (c) EARLY SERIOUS MENTAL ILLNESS.—Section
17 1920 of the Public Health Service Act (42 U.S.C. 300x-
18 9) is amended by adding at the end the following:

19 “(c) EARLY SERIOUS MENTAL ILLNESS.—

20 “(1) IN GENERAL.—Except as provided in para-
21 graph (2), a State shall expend not less than 10 per-
22 cent of the amount the State receives for carrying
23 out this section for each fiscal year to support evi-
24 dence-based programs that address the needs of in-
25 dividuals with early serious mental illness, including

1 psychotic disorders, regardless of the age of the indi-
2 vidual at onset.

3 “(2) STATE FLEXIBILITY.—In lieu of expending
4 10 percent of the amount the State receives under
5 this section for a fiscal year as required under para-
6 graph (1), a State may elect to expend not less than
7 20 percent of such amount by the end of such suc-
8 ceeding fiscal year.”.

9 (d) ADDITIONAL PROVISIONS.—Section 1915(b) of
10 the Public Health Service Act (42 U.S.C. 300x-4(b)) is
11 amended—

12 (1) in paragraph (3)—

13 (A) by striking “The Secretary” and in-
14 serting the following:

15 “(A) IN GENERAL.—The Secretary”;

16 (B) by striking “paragraph (1) if” and in-
17 serting “paragraph (1) in whole or in part if”;

18 (C) by striking “State justify the waiver.”
19 and inserting “State in the fiscal year involved
20 or in the previous fiscal year justify the wai-
21 ver”; and

22 (D) by adding at the end the following:

23 “(B) DATE CERTAIN FOR ACTION UPON
24 REQUEST.—The Secretary shall approve or
25 deny a request for a waiver under this para-

1 graph not later than 120 days after the date on
2 which the request is made.

3 “(C) APPLICABILITY OF WAIVER.—A waiv-
4 er provided by the Secretary under this para-
5 graph shall be applicable only to the fiscal year
6 involved.”; and

7 (2) in paragraph (4)—

8 (A) in subparagraph (A)—

9 (i) by inserting after the subpara-
10 graph designation the following: “IN GEN-
11 ERAL.—”;

12 (ii) by striking “In making a grant”
13 and inserting the following:

14 “(i) DETERMINATION.—In making a
15 grant”; and

16 (iii) by inserting at the end the fol-
17 lowing:

18 “(ii) ALTERNATIVE.—A State that
19 has failed to comply with paragraph (1)
20 and would otherwise be subject to a reduc-
21 tion in the State’s allotment under section
22 1911 may, upon request by the State, in
23 lieu of having the amount of the allotment
24 under section 1911 for the State reduced
25 for the fiscal year of the grant, agree to

1 comply with a negotiated agreement that is
2 approved by the Secretary and carried out
3 in accordance with guidelines issued by the
4 Secretary. If a State fails to enter into or
5 comply with a negotiated agreement, the
6 Secretary may take action under this para-
7 graph or the terms of the negotiated agree-
8 ment.”; and

9 (B) in subparagraph (B)—

10 (i) by inserting after the subpara-
11 graph designation the following: “SUBMIS-
12 SION OF INFORMATION TO THE SEC-
13 RETARY.—”; and

14 (ii) by striking “subparagraph (A)”
15 and inserting “subparagraph (A)(i)”.

16 (e) APPLICATION FOR GRANT.—Section 1917(a) of
17 the Public Health Service Act (42 U.S.C. 300x–6(a)) is
18 amended—

19 (1) in paragraph (1), by striking “1941” and
20 inserting “1942(a)”; and

21 (2) in paragraph (5), by striking
22 “1915(b)(3)(B)” and inserting “1915(b)”.

23 (f) FUNDING.—Section 1920 of the Public Health
24 Service Act (42 U.S.C. 300x–9) is amended—

25 (1) in subsection (a)—

1 (A) by striking “section 505” and insert-
2 ing “section 505(c)”; and

3 (B) by striking “\$450,000,000” and all
4 that follows through the period and inserting
5 “\$532,571,000 for each of fiscal years 2018
6 through 2022.”; and

7 (2) in subsection (b)(2) by striking “sections
8 505 and” and inserting “sections 505(c) and”.

9 **SEC. 8002. SUBSTANCE ABUSE PREVENTION AND TREAT-**
10 **MENT BLOCK GRANT.**

11 (a) **FORMULA GRANTS.**—Section 1921(b) of the Pub-
12 lic Health Service Act (42 U.S.C. 300x–21(b)) is amend-
13 ed—

14 (1) by inserting “carrying out the plan devel-
15 oped in accordance with section 1932(b) and for”
16 after “for the purpose of”; and

17 (2) by striking “abuse” and inserting “use dis-
18 orders”.

19 (b) **OUTREACH TO PERSONS WHO INJECT DRUGS.**—
20 Section 1923(b) of the Public Health Service Act (42
21 U.S.C. 300x–23(b)) is amended—

22 (1) in the subsection heading, by striking “RE-
23 GARDING INTRAVENOUS SUBSTANCE ABUSE” and
24 inserting “TO PERSONS WHO INJECT DRUGS”; and

1 (2) by striking “for intravenous drug abuse”
2 and inserting “for persons who inject drugs”.

3 (c) REQUIREMENTS REGARDING TUBERCULOSIS AND
4 HUMAN IMMUNODEFICIENCY VIRUS.—Section 1924 of the
5 Public Health Service Act (42 U.S.C. 300x–24) is amend-
6 ed—

7 (1) in subsection (a)(1)—

8 (A) in the matter preceding subparagraph
9 (A), by striking “substance abuse” and insert-
10 ing “substance use disorders”; and

11 (B) in subparagraph (A), by striking “such
12 abuse” and inserting “such disorders”;

13 (2) in subsection (b)—

14 (A) in paragraph (1)(A), by striking “sub-
15 stance abuse” and inserting “substance use dis-
16 orders”;

17 (B) in paragraph (2), by inserting “and
18 Prevention” after “Disease Control”;

19 (C) in paragraph (3)—

20 (i) in the paragraph heading, by strik-
21 ing “ABUSE” and inserting “USE DIS-
22 ORDERS”; and

23 (ii) by striking “substance abuse” and
24 inserting “substance use disorders”; and

1 (D) in paragraph (6)(B), by striking “sub-
2 stance abuse” and inserting “substance use dis-
3 orders”;

4 (3) by striking subsection (d); and

5 (4) by redesignating subsection (e) as sub-
6 section (d).

7 (d) GROUP HOMES.—Section 1925 of the Public
8 Health Service Act (42 U.S.C. 300x–25) is amended—

9 (1) in the section heading, by striking “**RE-**
10 **COVERING SUBSTANCE ABUSERS**” and inserting
11 “**PERSONS IN RECOVERY FROM SUBSTANCE**
12 **USE DISORDERS**”; and

13 (2) in subsection (a), in the matter preceding
14 paragraph (1), by striking “recovering substance
15 abusers” and inserting “persons in recovery from
16 substance use disorders”.

17 (e) ADDITIONAL AGREEMENTS.—Section 1928 of the
18 Public Health Service Act (42 U.S.C. 300x–28) is amend-
19 ed—

20 (1) in subsection (a), by striking “(relative to
21 fiscal year 1992)”;

22 (2) by striking subsection (b) and inserting the
23 following:

24 “(b) PROFESSIONAL DEVELOPMENT.—A funding
25 agreement for a grant under section 1921 is that the State

1 involved will ensure that prevention, treatment, and recov-
2 ery personnel operating in the State’s substance use dis-
3 order prevention, treatment, and recovery systems have an
4 opportunity to receive training, on an ongoing basis, con-
5 cerning—

6 “(1) recent trends in substance use disorders in
7 the State;

8 “(2) improved methods and evidence-based
9 practices for providing substance use disorder pre-
10 vention and treatment services;

11 “(3) performance-based accountability;

12 “(4) data collection and reporting requirements;

13 and

14 “(5) any other matters that would serve to fur-
15 ther improve the delivery of substance use disorder
16 prevention and treatment services within the State.”;

17 and

18 (3) in subsection (d)(1), by striking “substance
19 abuse” and inserting “substance use disorders”.

20 (f) REPEAL.—Section 1929 of the Public Health
21 Service Act (42 U.S.C. 300x–29) is repealed.

22 (g) MAINTENANCE OF EFFORT.—Section 1930 of the
23 Public Health Service Act (42 U.S.C. 300x–30) is amend-
24 ed—

1 (1) in subsection (c)(1), by striking “in the
2 State justify the waiver” and inserting “exist in the
3 State, or any part of the State, to justify the waiv-
4 er”; and

5 (2) in subsection (d), by inserting at the end
6 the following:

7 “(3) ALTERNATIVE.—A State that has failed to
8 comply with this section and would otherwise be sub-
9 ject to a reduction in the State’s allotment under
10 section 1921, may, upon request by the State, in lieu
11 of having the State’s allotment under section 1921
12 reduced, agree to comply with a negotiated agree-
13 ment that is approved by the Secretary and carried
14 out in accordance with guidelines issued by the Sec-
15 retary. If a State fails to enter into or comply with
16 a negotiated agreement, the Secretary may take ac-
17 tion under this paragraph or the terms of the nego-
18 tiated agreement.”.

19 (h) RESTRICTIONS ON EXPENDITURES.—Section
20 1931(b)(1) of the Public Health Service Act (42 U.S.C.
21 300x–31(b)(1)) is amended by striking “substance abuse”
22 and inserting “substance use disorders”.

23 (i) APPLICATION.—Section 1932 of the Public Health
24 Service Act (42 U.S.C. 300x–32) is amended—

25 (1) in subsection (a)—

1 (A) in the matter preceding paragraph (1),
2 by striking “subsections (c) and (d)(2)” and in-
3 serting “subsection (c)”; and

4 (B) in paragraph (5), by striking “the in-
5 formation required in section 1929, the infor-
6 mation required in section 1930(c)(2), and”;

7 (2) in subsection (b)—

8 (A) by striking paragraph (1) and insert-
9 ing the following:

10 “(1) IN GENERAL.—In order for a State to be
11 in compliance with subsection (a)(6), the State shall
12 submit to the Secretary a plan that, at a minimum,
13 includes the following:

14 “(A) A description of the State’s system of
15 care that—

16 “(i) identifies the single State agency
17 responsible for the administration of the
18 program, including any third party who
19 administers substance use disorder services
20 and is responsible for complying with the
21 requirements of the grant;

22 “(ii) provides information on the need
23 for substance use disorder prevention and
24 treatment services in the State, including
25 estimates on the number of individuals

1 who need treatment, who are pregnant
2 women, women with dependent children,
3 individuals with a co-occurring mental
4 health and substance use disorder, persons
5 who inject drugs, and persons who are ex-
6 periencing homelessness;

7 “(iii) provides aggregate information
8 on the number of individuals in treatment
9 within the State, including the number of
10 such individuals who are pregnant women,
11 women with dependent children, individ-
12 uals with a co-occurring mental health and
13 substance use disorder, persons who inject
14 drugs, and persons who are experiencing
15 homelessness;

16 “(iv) provides a description of the sys-
17 tem that is available to provide services by
18 modality, including the provision of recov-
19 ery support services;

20 “(v) provides a description of the
21 State’s comprehensive statewide prevention
22 efforts, including the number of individuals
23 being served in the system, target popu-
24 lations, and priority needs, and provides a
25 description of the amount of funds from

1 the prevention set-aside expended on pri-
2 mary prevention;

3 “(vi) provides a description of the fi-
4 nancial resources available;

5 “(vii) describes the existing substance
6 use disorders workforce and workforce
7 trained in treating co-occurring substance
8 use and mental disorders;

9 “(viii) includes a description of how
10 the State promotes evidence-based prac-
11 tices; and

12 “(ix) describes how the State inte-
13 grates substance use disorder services and
14 primary health care, which in the case of
15 those individuals with co-occurring mental
16 health and substance use disorders may in-
17 clude providing both mental health and
18 substance use disorder services in primary
19 care settings or providing primary and spe-
20 cialty care services in community-based
21 mental health and substance use disorder
22 service settings.

23 “(B) The establishment of goals and objec-
24 tives for the period of the plan, including tar-
25 gets and milestones that are intended to be

1 met, and the activities that will be undertaken
2 to achieve those targets.

3 “(C) A description of how the State will
4 comply with each funding agreement for a
5 grant under section 1921 that is applicable to
6 the State, including a description of the manner
7 in which the State intends to expend grant
8 funds.”; and

9 (B) in paragraph (2)—

10 (i) in the paragraph heading, by strik-
11 ing “AUTHORITY OF SECRETARY REGARD-
12 ING MODIFICATIONS” and inserting “MODI-
13 FICATIONS”;

14 (ii) by striking “As a condition” and
15 inserting the following:

16 “(A) AUTHORITY OF SECRETARY.—As a
17 condition;”; and

18 (iii) by adding at the end the fol-
19 lowing:

20 “(B) STATE REQUEST FOR MODIFICA-
21 TION.—If the State determines that a modifica-
22 tion to such plan is necessary, the State may
23 request the Secretary to approve the modifica-
24 tion. Any such modification shall be in accord-

1 ance with paragraph (1) and section 1941.”;
2 and

3 (C) in paragraph (3), by inserting, “, in-
4 cluding any modification under paragraph (2)”
5 after “subsection (a)(6)”;

6 (3) in subsection (e)(2), by striking “section
7 1922(e)” and inserting “section 1922(b)”.

8 (j) DEFINITIONS.—Section 1934 of the Public Health
9 Service Act (42 U.S.C. 300x–34) is amended—

10 (1) in paragraph (3), by striking “substance
11 abuse” and inserting “substance use disorders”; and

12 (2) in paragraph (7), by striking “substance
13 abuse” and inserting “substance use disorders”.

14 (k) FUNDING.—Section 1935 of the Public Health
15 Service Act (42 U.S.C. 300x–35) is amended—

16 (1) in subsection (a)—

17 (A) by striking “section 505” and insert-
18 ing “section 505(d)”;

19 (B) by striking “\$2,000,000,000 for fiscal
20 year 2001, and such sums as may be necessary
21 for each of the fiscal years 2002 and 2003” and
22 inserting “\$1,858,079,000 for each of fiscal
23 years 2018 through 2022.”;

24 (2) in subsection (b)(1)(B) by striking “sections
25 505 and” and inserting “sections 505(d) and”.

1 **SEC. 8003. ADDITIONAL PROVISIONS RELATED TO THE**
2 **BLOCK GRANTS.**

3 Subpart III of part B of title XIX of the Public
4 Health Service Act (42 U.S.C. 300x–51 et seq.) is amend-
5 ed—

6 (1) in section 1943(a)(3) (42 U.S.C. 300x–
7 53(a)(3)), by striking “section 505” and inserting
8 “subsections (c) and (d) of section 505”;

9 (2) in section 1953(b) (42 U.S.C. 300x–63(b)),
10 by striking “substance abuse” and inserting “sub-
11 stance use disorder”; and

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

13 **“SEC. 1957. PUBLIC HEALTH EMERGENCIES.**

14 “In the case of a public health emergency (as deter-
15 mined under section 319), the Secretary, on a State by
16 State basis, may, as the circumstances of the emergency
17 reasonably require and for the period of the emergency,
18 grant an extension, or waive application deadlines or com-
19 pliance with any other requirement, of a grant authorized
20 under section 521, 1911, or 1921 or an allotment author-
21 ized under Public Law 99–319 (42 U.S.C. 10801 et seq.).

22 **“SEC. 1958. JOINT APPLICATIONS.**

23 “The Secretary, acting through the Assistant Sec-
24 retary for Mental Health and Substance Use, shall permit
25 a joint application to be submitted for grants under sub-
26 part I and subpart II upon the request of a State. Such

1 application may be jointly reviewed and approved by the
2 Secretary with respect to such subparts, consistent with
3 the purposes and authorized activities of each such grant
4 program. A State submitting such a joint application shall
5 otherwise meet the requirements with respect to each such
6 subpart.”.

7 **SEC. 8004. STUDY OF DISTRIBUTION OF FUNDS UNDER THE**
8 **SUBSTANCE ABUSE PREVENTION AND TREAT-**
9 **MENT BLOCK GRANT AND THE COMMUNITY**
10 **MENTAL HEALTH SERVICES BLOCK GRANT.**

11 (a) IN GENERAL.—The Secretary of Health and
12 Human Services, acting through the Assistant Secretary
13 for Mental Health and Substance Use, shall through a
14 grant or contract, or through an agreement with a third
15 party, conduct a study on the formulas for distribution
16 of funds under the substance abuse prevention and treat-
17 ment block grant, and the community mental health serv-
18 ices block grant, under part B of title XIX of the Public
19 Health Service Act (42 U.S.C. 300x et seq.) and rec-
20 ommend changes if necessary. Such study shall include—

21 (1) an analysis of whether the distributions
22 under such block grants accurately reflect the need
23 for the services under the grants in the States;

24 (2) an examination of whether the indices used
25 under the formulas for distribution of funds under

1 such block grants are appropriate, and if not, alter-
2 natives recommended by the Secretary;

3 (3) where recommendations are included under
4 paragraph (2) for the use of different indices, a de-
5 scription of the variables and data sources that
6 should be used to determine the indices;

7 (4) an evaluation of the variables and data
8 sources that are being used for each of the indices
9 involved, and whether such variables and data
10 sources accurately represent the need for services,
11 the cost of providing services, and the ability of the
12 States to pay for such services;

13 (5) the effect that the minimum allotment re-
14 quirements for each such block grant have on each
15 State's final allotment and the effect of such re-
16 quirements, if any, on each State's formula-based al-
17 lotment;

18 (6) recommendations for modifications to the
19 minimum allotment provisions to ensure an appro-
20 priate distribution of funds; and

21 (7) any other information that the Secretary
22 determines appropriate.

23 (b) REPORT.—Not later than 2 years after the date
24 of enactment of this Act, the Secretary of Health and
25 Human Services shall submit to the Committee on Health,

1 Education, Labor, and Pensions of the Senate and the
2 Committee on Energy and Commerce of the House of
3 Representatives, a report containing the findings and rec-
4 ommendations of the study conducted under subsection
5 (a) and the study conducted under section 9004(g).

6 **TITLE IX—PROMOTING ACCESS**
7 **TO MENTAL HEALTH AND**
8 **SUBSTANCE USE DISORDER**
9 **CARE**

10 **Subtitle A—Helping Individuals**
11 **and Families**

12 **SEC. 9001. GRANTS FOR TREATMENT AND RECOVERY FOR**
13 **HOMELESS INDIVIDUALS.**

14 Section 506 of the Public Health Service Act (42
15 U.S.C. 290aa-5) is amended—

16 (1) in subsection (a), by striking “substance
17 abuse” and inserting “substance use disorder”;

18 (2) in subsection (b)—

19 (A) in paragraphs (1) and (3), by striking
20 “substance abuse” each place the term appears
21 and inserting “substance use disorder”; and

22 (B) in paragraph (4), by striking “sub-
23 stance abuse” and inserting “a substance use
24 disorder”;

25 (3) in subsection (c)—

1 (A) in paragraph (1), by striking “sub-
2 stance abuse disorder” and inserting “sub-
3 stance use disorder”; and

4 (B) in paragraph (2)—

5 (i) in subparagraph (A), by striking
6 “substance abuse” and inserting “a sub-
7 stance use disorder”; and

8 (ii) in subparagraph (B), by striking
9 “substance abuse” and inserting “sub-
10 stance use disorder”; and

11 (4) in subsection (e), by striking “,
12 \$50,000,000 for fiscal year 2001, and such sums as
13 may be necessary for each of the fiscal years 2002
14 and 2003” and inserting “\$41,304,000 for each of
15 fiscal years 2018 through 2022”.

16 **SEC. 9002. GRANTS FOR JAIL DIVERSION PROGRAMS.**

17 Section 520G of the Public Health Service Act (42
18 U.S.C. 290bb–38) is amended—

19 (1) by striking “substance abuse” each place
20 such term appears and inserting “substance use dis-
21 order”;

22 (2) in subsection (a)—

23 (A) by striking “Indian tribes, and tribal
24 organizations” and inserting “and Indian tribes
25 and tribal organizations (as the terms ‘Indian

1 tribes' and 'tribal organizations' are defined in
2 section 4 of the Indian Self-Determination and
3 Education Assistance Act)"; and

4 (B) by inserting "or a health facility or
5 program operated by or in accordance with a
6 contract or grant with the Indian Health Serv-
7 ice," after "entities,";

8 (3) in subsection (c)(2)(A)(i), by striking "the
9 best known" and inserting "evidence-based";

10 (4) by redesignating subsections (d) through (i)
11 as subsections (e) through (j), respectively;

12 (5) by inserting after subsection (c) the fol-
13 lowing:

14 "(d) SPECIAL CONSIDERATION REGARDING VET-
15 ERANS.—In awarding grants under subsection (a), the
16 Secretary shall, as appropriate, give special consideration
17 to entities proposing to use grant funding to support jail
18 diversion services for veterans.";

19 (6) in subsection (e), as so redesignated—

20 (A) in paragraph (3), by striking "; and"
21 and inserting a semicolon;

22 (B) in paragraph (4), by striking the pe-
23 riod and inserting "; and"; and

24 (C) by adding at the end the following:

1 “(5) develop programs to divert individuals
2 prior to booking or arrest.”; and

3 (7) in subsection (j), as so redesignated, by
4 striking “\$10,000,000 for fiscal year 2001, and such
5 sums as may be necessary for fiscal years 2002
6 through 2003” and inserting “\$4,269,000 for each
7 of fiscal years 2018 through 2022”.

8 **SEC. 9003. PROMOTING INTEGRATION OF PRIMARY AND BE-**
9 **HAVIORAL HEALTH CARE.**

10 Section 520K of the Public Health Service Act (42
11 U.S.C. 290bb–42) is amended to read as follows:

12 **“SEC. 520K. INTEGRATION INCENTIVE GRANTS AND COOP-**
13 **ERATIVE AGREEMENTS.**

14 “(a) DEFINITIONS.—In this section:

15 “(1) ELIGIBLE ENTITY.—The term ‘eligible en-
16 tity’ means a State, or other appropriate State agen-
17 cy, in collaboration with 1 or more qualified commu-
18 nity programs as described in section 1913(b)(1) or
19 1 or more community health centers as described in
20 section 330.

21 “(2) INTEGRATED CARE.—The term ‘integrated
22 care’ means collaborative models or practices offer-
23 ing mental and physical health services, which may
24 include practices that share the same space in the
25 same facility.

1 “(3) SPECIAL POPULATION.—The term ‘special
2 population’ means—

3 “(A) adults with a mental illness who have
4 co-occurring physical health conditions or
5 chronic diseases;

6 “(B) adults with a serious mental illness
7 who have co-occurring physical health condi-
8 tions or chronic diseases;

9 “(C) children and adolescents with a seri-
10 ous emotional disturbance with co-occurring
11 physical health conditions or chronic diseases;
12 or

13 “(D) individuals with a substance use dis-
14 order.

15 “(b) GRANTS AND COOPERATIVE AGREEMENTS.—

16 “(1) IN GENERAL.—The Secretary may award
17 grants and cooperative agreements to eligible entities
18 to support the improvement of integrated care for
19 primary care and behavioral health care in accord-
20 ance with paragraph (2).

21 “(2) PURPOSES.—A grant or cooperative agree-
22 ment awarded under this section shall be designed
23 to—

1 “(A) promote full integration and collabo-
2 ration in clinical practices between primary and
3 behavioral health care;

4 “(B) support the improvement of inte-
5 grated care models for primary care and behav-
6 ioral health care to improve the overall wellness
7 and physical health status of adults with a seri-
8 ous mental illness or children with a serious
9 emotional disturbance; and

10 “(C) promote integrated care services re-
11 lated to screening, diagnosis, prevention, and
12 treatment of mental and substance use dis-
13 orders, and co-occurring physical health condi-
14 tions and chronic diseases.

15 “(c) APPLICATIONS.—

16 “(1) IN GENERAL.—An eligible entity seeking a
17 grant or cooperative agreement under this section
18 shall submit an application to the Secretary at such
19 time, in such manner, and accompanied by such in-
20 formation as the Secretary may require, including
21 the contents described in paragraph (2).

22 “(2) CONTENTS.—The contents described in
23 this paragraph are—

1 “(A) a description of a plan to achieve
2 fully collaborative agreements to provide serv-
3 ices to special populations;

4 “(B) a document that summarizes the poli-
5 cies, if any, that serve as barriers to the provi-
6 sion of integrated care, and the specific steps,
7 if applicable, that will be taken to address such
8 barriers;

9 “(C) a description of partnerships or other
10 arrangements with local health care providers
11 to provide services to special populations;

12 “(D) an agreement and plan to report to
13 the Secretary performance measures necessary
14 to evaluate patient outcomes and facilitate eval-
15 uations across participating projects; and

16 “(E) a plan for sustainability beyond the
17 grant or cooperative agreement period under
18 subsection (e).

19 “(d) GRANT AND COOPERATIVE AGREEMENT
20 AMOUNTS.—

21 “(1) TARGET AMOUNT.—The target amount
22 that an eligible entity may receive for a year through
23 a grant or cooperative agreement under this section
24 shall be \$2,000,000.

1 “(2) ADJUSTMENT PERMITTED.—The Sec-
2 retary, taking into consideration the quality of the
3 application and the number of eligible entities that
4 received grants under this section prior to the date
5 of enactment of the Helping Families in Mental
6 Health Crisis Reform Act of 2016, may adjust the
7 target amount that an eligible entity may receive for
8 a year through a grant or cooperative agreement
9 under this section.

10 “(3) LIMITATION.—An eligible entity receiving
11 funding under this section may not allocate more
12 than 10 percent of funds awarded under this section
13 to administrative functions, and the remaining
14 amounts shall be allocated to health facilities that
15 provide integrated care.

16 “(e) DURATION.—A grant or cooperative agreement
17 under this section shall be for a period not to exceed 5
18 years.

19 “(f) REPORT ON PROGRAM OUTCOMES.—An eligible
20 entity receiving a grant or cooperative agreement under
21 this section shall submit an annual report to the Secretary
22 that includes—

23 “(1) the progress made to reduce barriers to in-
24 tegrated care as described in the entity’s application
25 under subsection (c); and

1 “(2) a description of functional outcomes of
2 special populations, including—

3 “(A) with respect to adults with a serious
4 mental illness, participation in supportive hous-
5 ing or independent living programs, attendance
6 in social and rehabilitative programs, participa-
7 tion in job training opportunities, satisfactory
8 performance in work settings, attendance at
9 scheduled medical and mental health appoint-
10 ments, and compliance with prescribed medica-
11 tion regimes;

12 “(B) with respect to individuals with co-oc-
13 ccurring mental illness and physical health con-
14 ditions and chronic diseases, attendance at
15 scheduled medical and mental health appoint-
16 ments, compliance with prescribed medication
17 regimes, and participation in learning opportu-
18 nities related to improved health and lifestyle
19 practices; and

20 “(C) with respect to children and adoles-
21 cents with a serious emotional disturbance who
22 have co-occurring physical health conditions and
23 chronic diseases, attendance at scheduled med-
24 ical and mental health appointments, compli-
25 ance with prescribed medication regimes, and

1 participation in learning opportunities at school
2 and extracurricular activities.

3 “(g) TECHNICAL ASSISTANCE FOR PRIMARY-BEHAV-
4 IORAL HEALTH CARE INTEGRATION.—

5 “(1) IN GENERAL.—The Secretary may provide
6 appropriate information, training, and technical as-
7 sistance to eligible entities that receive a grant or
8 cooperative agreement under this section, in order to
9 help such entities meet the requirements of this sec-
10 tion, including assistance with—

11 “(A) development and selection of inte-
12 grated care models;

13 “(B) dissemination of evidence-based inter-
14 ventions in integrated care;

15 “(C) establishment of organizational prac-
16 tices to support operational and administrative
17 success; and

18 “(D) other activities, as the Secretary de-
19 termines appropriate.

20 “(2) ADDITIONAL DISSEMINATION OF TECH-
21 NICAL INFORMATION.—The information and re-
22 sources provided by the Secretary under paragraph
23 (1) shall, as appropriate, be made available to
24 States, political subdivisions of States, Indian tribes
25 or tribal organizations (as defined in section 4 of the

1 Indian Self-Determination and Education Assistance
2 Act), outpatient mental health and addiction treat-
3 ment centers, community mental health centers that
4 meet the criteria under section 1913(e), certified
5 community behavioral health clinics described in sec-
6 tion 223 of the Protecting Access to Medicare Act
7 of 2014, primary care organizations such as Feder-
8 ally qualified health centers or rural health clinics as
9 defined in section 1861(aa) of the Social Security
10 Act, other community-based organizations, or other
11 entities engaging in integrated care activities, as the
12 Secretary determines appropriate.

13 “(h) AUTHORIZATION OF APPROPRIATIONS.—To
14 carry out this section, there are authorized to be appro-
15 priated \$51,878,000 for each of fiscal years 2018 through
16 2022.”.

17 **SEC. 9004. PROJECTS FOR ASSISTANCE IN TRANSITION**
18 **FROM HOMELESSNESS.**

19 (a) FORMULA GRANTS TO STATES.—Section 521 of
20 the Public Health Service Act (42 U.S.C. 290cc–21) is
21 amended by striking “1991 through 1994” and inserting
22 “2018 through 2022”.

23 (b) PURPOSE OF GRANTS.—Section 522 of the Public
24 Health Service Act (42 U.S.C. 290cc–22) is amended—

1 (1) in subsection (a)(1)(B), by striking “sub-
2 stance abuse” and inserting “a substance use dis-
3 order”;

4 (2) in subsection (b)(6), by striking “substance
5 abuse” and inserting “substance use disorder”;

6 (3) in subsection (c), by striking “substance
7 abuse” and inserting “a substance use disorder”;

8 (4) in subsection (e)—

9 (A) in paragraph (1), by striking “sub-
10 stance abuse” and inserting “a substance use
11 disorder”; and

12 (B) in paragraph (2), by striking “sub-
13 stance abuse” and inserting “substance use dis-
14 order”;

15 (5) by striking subsection (g) and redesignating
16 subsections (h) and (i) as (g) and (h), accordingly;
17 and

18 (6) in subsection (g), as redesignated by para-
19 graph (5), by striking “substance abuse” each place
20 such term appears and inserting “substance use dis-
21 order”.

22 (c) DESCRIPTION OF INTENDED EXPENDITURES OF
23 GRANT.—Section 527 of the Public Health Service Act
24 (42 U.S.C. 290cc–27) is amended by striking “substance

1 abuse” each place such term appears and inserting “sub-
2 stance use disorder”.

3 (d) TECHNICAL ASSISTANCE.—Section 530 of the
4 Public Health Service Act (42 U.S.C. 290cc–30) is amend-
5 ed by striking “through the National Institute of Mental
6 Health, the National Institute of Alcohol Abuse and Alco-
7 holism, and the National Institute on Drug Abuse” and
8 inserting “acting through the Assistant Secretary”.

9 (e) DEFINITIONS.—Section 534(4) of the Public
10 Health Service Act (42 U.S.C. 290cc–34(4)) is amended
11 to read as follows:

12 “(4) SUBSTANCE USE DISORDER SERVICES.—
13 The term ‘substance use disorder services’ has the
14 meaning given the term ‘substance abuse services’ in
15 section 330(h)(5)(C).”.

16 (f) FUNDING.—Section 535(a) of the Public Health
17 Service Act (42 U.S.C. 290cc–35(a)) is amended by strik-
18 ing “\$75,000,000 for each of the fiscal years 2001
19 through 2003” and inserting “\$64,635,000 for each of fis-
20 cal years 2018 through 2022”.

21 (g) STUDY CONCERNING FORMULA.—

22 (1) IN GENERAL.—Not later than 2 years after
23 the date of enactment of this Act, the Assistant Sec-
24 retary for Mental Health and Substance Use (re-
25 ferred to in this section as the “Assistant Sec-

1 tion as the ‘program’), authorized under section 520A and
2 in effect prior to the date of enactment of the Helping
3 Families in Mental Health Crisis Reform Act of 2016.

4 “(b) ACTIVITIES.—In maintaining the program, the
5 activities of the Secretary shall include—

6 “(1) coordinating a network of crisis centers
7 across the United States for providing suicide pre-
8 vention and crisis intervention services to individuals
9 seeking help at any time, day or night;

10 “(2) maintaining a suicide prevention hotline to
11 link callers to local emergency, mental health, and
12 social services resources; and

13 “(3) consulting with the Secretary of Veterans
14 Affairs to ensure that veterans calling the suicide
15 prevention hotline have access to a specialized vet-
16 erans’ suicide prevention hotline.

17 “(c) AUTHORIZATION OF APPROPRIATIONS.—To
18 carry out this section, there are authorized to be appro-
19 priated \$7,198,000 for each of fiscal years 2018 through
20 2022.”.

21 **SEC. 9006. CONNECTING INDIVIDUALS AND FAMILIES WITH**
22 **CARE.**

23 Subpart 3 of part B of title V of the Public Health
24 Service Act (42 U.S.C. 290bb–31 et seq.), as amended by

1 section 9005, is further amended by inserting after section
2 520E–3 the following:

3 **“SEC. 520E–4. TREATMENT REFERRAL ROUTING SERVICE.**

4 “(a) IN GENERAL.—The Secretary, acting through
5 the Assistant Secretary, shall maintain the National
6 Treatment Referral Routing Service (referred to in this
7 section as the ‘Routing Service’) to assist individuals and
8 families in locating mental and substance use disorders
9 treatment providers.

10 “(b) ACTIVITIES OF THE SECRETARY.—To maintain
11 the Routing Service, the activities of the Assistant Sec-
12 retary shall include administering—

13 “(1) a nationwide, telephone number providing
14 year-round access to information that is updated on
15 a regular basis regarding local behavioral health pro-
16 viders and community-based organizations in a man-
17 ner that is confidential, without requiring individuals
18 to identify themselves, is in languages that include
19 at least English and Spanish, and is at no cost to
20 the individual using the Routing Service; and

21 “(2) an Internet website to provide a search-
22 able, online treatment services locator of behavioral
23 health treatment providers and community-based or-
24 ganizations, which shall include information on the

1 name, location, contact information, and basic serv-
2 ices provided by such providers and organizations.

3 “(c) REMOVING PRACTITIONER CONTACT INFORMA-
4 TION.—In the event that the Internet website described
5 in subsection (b)(2) contains information on any qualified
6 practitioner that is certified to prescribe medication for
7 opioid dependency under section 303(g)(2)(B) of the Con-
8 trolled Substances Act, the Assistant Secretary—

9 “(1) shall provide an opportunity to such prac-
10 titioner to have the contact information of the prac-
11 titioner removed from the website at the request of
12 the practitioner; and

13 “(2) may evaluate other methods to periodically
14 update the information displayed on such website.

15 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
16 tion shall be construed to prevent the Assistant Secretary
17 from using any unobligated amounts otherwise made
18 available to the Administration to maintain the Routing
19 Service.”.

20 **SEC. 9007. STRENGTHENING COMMUNITY CRISIS RE-**
21 **SPONSE SYSTEMS.**

22 Section 520F of the Public Health Service Act (42
23 U.S.C. 290bb–37) is amended to read as follows:

1 **“SEC. 520F. STRENGTHENING COMMUNITY CRISIS RE-**
2 **SPONSE SYSTEMS.**

3 “(a) IN GENERAL.—The Secretary shall award com-
4 petitive grants to—

5 “(1) State and local governments and Indian
6 tribes and tribal organizations, to enhance commu-
7 nity-based crisis response systems; or

8 “(2) States to develop, maintain, or enhance a
9 database of beds at inpatient psychiatric facilities,
10 crisis stabilization units, and residential community
11 mental health and residential substance use disorder
12 treatment facilities, for adults with a serious mental
13 illness, children with a serious emotional disturb-
14 ance, or individuals with a substance use disorder.

15 “(b) APPLICATIONS.—

16 “(1) IN GENERAL.—To receive a grant under
17 subsection (a), an entity shall submit to the Sec-
18 retary an application, at such time, in such manner,
19 and containing such information as the Secretary
20 may require.

21 “(2) COMMUNITY-BASED CRISIS RESPONSE
22 PLAN.—An application for a grant under subsection
23 (a)(1) shall include a plan for—

24 “(A) promoting integration and coordina-
25 tion between local public and private entities
26 engaged in crisis response, including first re-

1 sponders, emergency health care providers, pri-
2 mary care providers, law enforcement, court
3 systems, health care payers, social service pro-
4 viders, and behavioral health providers;

5 “(B) developing memoranda of under-
6 standing with public and private entities to im-
7 plement crisis response services;

8 “(C) addressing gaps in community re-
9 sources for crisis intervention and prevention;
10 and

11 “(D) developing models for minimizing
12 hospital readmissions, including through appro-
13 priate discharge planning.

14 “(3) BEDS DATABASE PLAN.—An application
15 for a grant under subsection (a)(2) shall include a
16 plan for developing, maintaining, or enhancing a
17 real-time, Internet-based bed database to collect, ag-
18 gregate, and display information about beds in inpa-
19 tient psychiatric facilities and crisis stabilization
20 units, and residential community mental health and
21 residential substance use disorder treatment facili-
22 ties to facilitate the identification and designation of
23 facilities for the temporary treatment of individuals
24 in mental or substance use disorder crisis.

1 “(c) DATABASE REQUIREMENTS.—A bed database
2 described in this section is a database that—

3 “(1) includes information on inpatient psy-
4 chiatric facilities, crisis stabilization units, and resi-
5 dential community mental health and residential
6 substance use disorder facilities in the State in-
7 volved, including contact information for the facility
8 or unit;

9 “(2) provides real-time information about the
10 number of beds available at each facility or unit and,
11 for each available bed, the type of patient that may
12 be admitted, the level of security provided, and any
13 other information that may be necessary to allow for
14 the proper identification of appropriate facilities for
15 treatment of individuals in mental or substance use
16 disorder crisis; and

17 “(3) enables searches of the database to iden-
18 tify available beds that are appropriate for the treat-
19 ment of individuals in mental or substance use dis-
20 order crisis.

21 “(d) EVALUATION.—An entity receiving a grant
22 under subsection (a)(1) shall submit to the Secretary, at
23 such time, in such manner, and containing such informa-
24 tion as the Secretary may reasonably require, a report,
25 including an evaluation of the effect of such grant on—

1 period at the end of paragraph (2) and inserting
2 “acting through the Assistant Secretary, shall estab-
3 lish a research, training, and technical assistance re-
4 source center to provide appropriate information,
5 training, and technical assistance to States, political
6 subdivisions of States, federally recognized Indian
7 tribes, tribal organizations, institutions of higher
8 education, public organizations, or private nonprofit
9 organizations regarding the prevention of suicide
10 among all ages, particularly among groups that are
11 at a high risk for suicide.”;

12 (3) by striking subsections (b) and (c);

13 (4) by redesignating subsection (d) as sub-
14 section (b);

15 (5) in subsection (b), as so redesignated—

16 (A) in the subsection heading, by striking
17 “ADDITIONAL CENTER” and inserting “RE-
18 SPONSIBILITIES OF THE CENTER”;

19 (B) in the matter preceding paragraph (1),
20 by striking “The additional research” and all
21 that follows through “nonprofit organizations
22 for” and inserting “The center established
23 under subsection (a) shall conduct activities for
24 the purpose of”;

1 (C) by striking “youth suicide” each place
2 such term appears and inserting “suicide”;

3 (D) in paragraph (1)—

4 (i) by striking “the development or
5 continuation of” and inserting “developing
6 and continuing”; and

7 (ii) by inserting “for all ages, particu-
8 larly among groups that are at a high risk
9 for suicide” before the semicolon at the
10 end;

11 (E) in paragraph (2), by inserting “for all
12 ages, particularly among groups that are at a
13 high risk for suicide” before the semicolon at
14 the end;

15 (F) in paragraph (3), by inserting “and
16 tribal” after “statewide”;

17 (G) in paragraph (5), by inserting “and
18 prevention” after “intervention”;

19 (H) in paragraph (8), by striking “in
20 youth”;

21 (I) in paragraph (9), by striking “and be-
22 havioral health” and inserting “health and sub-
23 stance use disorder”; and

24 (J) in paragraph (10), by inserting “con-
25 ducting” before “other”; and

1 (6) by striking subsection (e) and inserting the
2 following:

3 “(c) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out this section, there are authorized
5 to be appropriated \$5,988,000 for each of fiscal years
6 2018 through 2022.

7 “(d) ANNUAL REPORT.—Not later than 2 years after
8 the date of enactment of this subsection, the Secretary
9 shall submit to Congress a report on the activities carried
10 out by the center established under subsection (a) during
11 the year involved, including the potential effects of such
12 activities, and the States, organizations, and institutions
13 that have worked with the center.”.

14 (b) YOUTH SUICIDE EARLY INTERVENTION AND
15 PREVENTION STRATEGIES.—Section 520E of the Public
16 Health Service Act (42 U.S.C. 290bb–36) is amended—

17 (1) in paragraph (1) of subsection (a) and in
18 subsection (c), by striking “substance abuse” each
19 place such term appears and inserting “substance
20 use disorder”;

21 (2) in subsection (b)—

22 (A) in paragraph (2)—

23 (i) by striking “ensure that each State
24 is awarded only 1 grant or cooperative
25 agreement under this section” and insert-

1 ing “ensure that a State does not receive
2 more than 1 grant or cooperative agree-
3 ment under this section at any 1 time”;
4 and

5 (ii) by striking “been awarded” and
6 inserting “received”; and

7 (B) by adding after paragraph (2) the fol-
8 lowing:

9 “(3) CONSIDERATION.—In awarding grants
10 under this section, the Secretary shall take into con-
11 sideration the extent of the need of the applicant, in-
12 cluding the incidence and prevalence of suicide in
13 the State and among the populations of focus, in-
14 cluding rates of suicide determined by the Centers
15 for Disease Control and Prevention for the State or
16 population of focus.”;

17 (3) in subsection (g)(2), by striking “2 years
18 after the date of enactment of this section,” and in-
19 sert “2 years after the date of enactment of Helping
20 Families in Mental Health Crisis Reform Act of
21 2016,”; and

22 (4) by striking subsection (m) and inserting the
23 following:

24 “(m) AUTHORIZATION OF APPROPRIATIONS.—For
25 the purpose of carrying out this section, there are author-

1 ized to be appropriated \$30,000,000 for each of fiscal
2 years 2018 through 2022.”.

3 **SEC. 9009. ADULT SUICIDE PREVENTION.**

4 Subpart 3 of part B of title V of the Public Health
5 Service Act (42 U.S.C. 290bb–31 et seq.) is amended by
6 adding at the end the following:

7 **“SEC. 520L. ADULT SUICIDE PREVENTION.**

8 “(a) GRANTS.—

9 “(1) IN GENERAL.—The Assistant Secretary
10 shall award grants to eligible entities described in
11 paragraph (2) to implement suicide prevention and
12 intervention programs, for individuals who are 25
13 years of age or older, that are designed to raise
14 awareness of suicide, establish referral processes,
15 and improve care and outcomes for such individuals
16 who are at risk of suicide.

17 “(2) ELIGIBLE ENTITIES.—To be eligible to re-
18 ceive a grant under this section, an entity shall be
19 a community-based primary care or behavioral
20 health care setting, an emergency department, a
21 State mental health agency (or State health agency
22 with mental or behavioral health functions), public
23 health agency, a territory of the United States, or
24 an Indian tribe or tribal organization (as the terms
25 ‘Indian tribe’ and ‘tribal organization’ are defined in

1 section 4 of the Indian Self-Determination and Edu-
2 cation Assistance Act).

3 “(3) USE OF FUNDS.—The grants awarded
4 under paragraph (1) shall be used to implement pro-
5 grams, in accordance with such paragraph, that in-
6 clude one or more of the following components:

7 “(A) Screening for suicide risk, suicide
8 intervention services, and services for referral
9 for treatment for individuals at risk for suicide.

10 “(B) Implementing evidence-based prac-
11 tices to provide treatment for individuals at risk
12 for suicide, including appropriate followup serv-
13 ices.

14 “(C) Raising awareness and reducing stig-
15 ma of suicide.

16 “(b) EVALUATIONS AND TECHNICAL ASSISTANCE.—
17 The Assistant Secretary shall—

18 “(1) evaluate the activities supported by grants
19 awarded under subsection (a), and disseminate, as
20 appropriate, the findings from the evaluation; and

21 “(2) provide appropriate information, training,
22 and technical assistance, as appropriate, to eligible
23 entities that receive a grant under this section, in
24 order to help such entities to meet the requirements
25 of this section, including assistance with selection

1 and implementation of evidence-based interventions
2 and frameworks to prevent suicide.

3 “(c) DURATION.—A grant under this section shall be
4 for a period of not more than 5 years.

5 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
6 are authorized to be appropriated to carry out this section
7 \$30,000,000 for the period of fiscal years 2018 through
8 2022.”.

9 **SEC. 9010. MENTAL HEALTH AWARENESS TRAINING**
10 **GRANTS.**

11 Section 520J of the Public Health Service Act (42
12 U.S.C. 290bb–41) is amended—

13 (1) in the section heading, by inserting “**MEN-**
14 **TAL HEALTH AWARENESS**” before “**TRAINING**”;
15 and

16 (2) in subsection (b)—

17 (A) in the subsection heading, by striking
18 “ILLNESS” and inserting “HEALTH”;

19 (B) in paragraph (1), by inserting “vet-
20 erans, law enforcement, and other categories of
21 individuals, as determined by the Secretary,”
22 after “emergency services personnel”;

23 (C) in paragraph (5)—

24 (i) in the matter preceding subpara-
25 graph (A), by striking “to” and inserting

1 “for evidence-based programs that provide
2 training and education in accordance with
3 paragraph (1) on matters including”; and

4 (ii) by striking subparagraphs (A)
5 through (C) and inserting the following:

6 “(A) recognizing the signs and symptoms
7 of mental illness; and

8 “(B)(i) resources available in the commu-
9 nity for individuals with a mental illness and
10 other relevant resources; or

11 “(ii) safely de-escalating crisis situations
12 involving individuals with a mental illness.”;
13 and

14 (D) in paragraph (7), by striking “,
15 \$25,000,000” and all that follows through the
16 period at the end and inserting “\$14,693,000
17 for each of fiscal years 2018 through 2022.”.

18 **SEC. 9011. SENSE OF CONGRESS ON PRIORITIZING AMER-**
19 **ICAN INDIANS AND ALASKA NATIVE YOUTH**
20 **WITHIN SUICIDE PREVENTION PROGRAMS.**

21 (a) FINDINGS.—The Congress finds as follows:

22 (1) Suicide is the eighth leading cause of death
23 among American Indians and Alaska Natives across
24 all ages.

1 (2) Among American Indians and Alaska Na-
2 tives who are 10 to 34 years of age, suicide is the
3 second leading cause of death.

4 (3) The suicide rate among American Indian
5 and Alaska Native adolescents and young adults
6 ages 15 to 34 (17.9 per 100,000) is approximately
7 1.3 times higher than the national average for that
8 age group (13.3 per 100,000).

9 (b) SENSE OF CONGRESS.—It is the sense of Con-
10 gress that the Secretary of Health and Human Services,
11 in carrying out suicide prevention and intervention pro-
12 grams, should prioritize programs and activities for popu-
13 lations with disproportionately high rates of suicide, such
14 as American Indians and Alaska Natives.

15 **SEC. 9012. EVIDENCE-BASED PRACTICES FOR OLDER**
16 **ADULTS.**

17 Section 520A(e) of the Public Health Service Act (42
18 U.S.C. 290bb–32(e)) is amended by adding at the end the
19 following:

20 “(3) GERIATRIC MENTAL DISORDERS.—The
21 Secretary shall, as appropriate, provide technical as-
22 sistance to grantees regarding evidence-based prac-
23 tices for the prevention and treatment of geriatric
24 mental disorders and co-occurring mental health and
25 substance use disorders among geriatric populations,

1 as well as disseminate information about such evi-
2 dence-based practices to States and nongrantees
3 throughout the United States.”.

4 **SEC. 9013. NATIONAL VIOLENT DEATH REPORTING SYSTEM.**

5 The Secretary of Health and Human Services, acting
6 through the Director of the Centers for Disease Control
7 and Prevention, is encouraged to improve, particularly
8 through the inclusion of additional States, the National
9 Violent Death Reporting System as authorized by title III
10 of the Public Health Service Act (42 U.S.C. 241 et seq.).
11 Participation in the system by the States shall be vol-
12 untary.

13 **SEC. 9014. ASSISTED OUTPATIENT TREATMENT.**

14 Section 224 of the Protecting Access to Medicare Act
15 of 2014 (42 U.S.C. 290aa note) is amended—

16 (1) in subsection (e), by striking “and 2018,”
17 and inserting “2018, 2019, 2020, 2021, and 2022,”;
18 and

19 (2) in subsection (g)—

20 (A) in paragraph (1), by striking “2018”
21 and inserting “2022”; and

22 (B) in paragraph (2), by striking “is au-
23 thorized to be appropriated to carry out this
24 section \$15,000,000 for each of fiscal years
25 2015 through 2018” and inserting “are author-

1 ized to be appropriated to carry out this section
2 \$15,000,000 for each of fiscal years 2015
3 through 2017, \$20,000,000 for fiscal year
4 2018, \$19,000,000 for each of fiscal years 2019
5 and 2020, and \$18,000,000 for each of fiscal
6 years 2021 and 2022”.

7 **SEC. 9015. ASSERTIVE COMMUNITY TREATMENT GRANT**
8 **PROGRAM.**

9 Part B of title V of the Public Health Service Act
10 (42 U.S.C. 290bb et seq.), as amended by section 9009,
11 is further amended by adding at the end the following:

12 **“SEC. 520M. ASSERTIVE COMMUNITY TREATMENT GRANT**
13 **PROGRAM.**

14 “(a) IN GENERAL.—The Assistant Secretary shall
15 award grants to eligible entities—

16 “(1) to establish assertive community treatment
17 programs for adults with a serious mental illness; or

18 “(2) to maintain or expand such programs.

19 “(b) ELIGIBLE ENTITIES.—To be eligible to receive
20 a grant under this section, an entity shall be a State, polit-
21 ical subdivision of a State, Indian tribe or tribal organiza-
22 tion (as such terms are defined in section 4 of the Indian
23 Self-Determination and Education Assistance Act), men-
24 tal health system, health care facility, or any other entity
25 the Assistant Secretary deems appropriate.

1 “(c) SPECIAL CONSIDERATION.—In selecting among
2 applicants for a grant under this section, the Assistant
3 Secretary may give special consideration to the potential
4 of the applicant’s program to reduce hospitalization,
5 homelessness, and involvement with the criminal justice
6 system while improving the health and social outcomes of
7 the patient.

8 “(d) ADDITIONAL ACTIVITIES.—The Assistant Sec-
9 retary shall—

10 “(1) not later than the end of fiscal year 2021,
11 submit a report to the appropriate congressional
12 committees on the grant program under this section,
13 including an evaluation of—

14 “(A) any cost savings and public health
15 outcomes such as mortality, suicide, substance
16 use disorders, hospitalization, and use of serv-
17 ices;

18 “(B) rates of involvement with the criminal
19 justice system of patients;

20 “(C) rates of homelessness among patients;
21 and

22 “(D) patient and family satisfaction with
23 program participation; and

24 “(2) provide appropriate information, training,
25 and technical assistance to grant recipients under

1 this section to help such recipients to establish,
2 maintain, or expand their assertive community treat-
3 ment programs.

4 “(e) AUTHORIZATION OF APPROPRIATIONS.—

5 “(1) IN GENERAL.—To carry out this section,
6 there is authorized to be appropriated \$5,000,000
7 for the period of fiscal years 2018 through 2022.

8 “(2) USE OF CERTAIN FUNDS.—Of the funds
9 appropriated to carry out this section in any fiscal
10 year, not more than 5 percent shall be available to
11 the Assistant Secretary for carrying out subsection
12 (d).”.

13 **SEC. 9016. SOBER TRUTH ON PREVENTING UNDERAGE**
14 **DRINKING REAUTHORIZATION.**

15 Section 519B of the Public Health Service Act (42
16 U.S.C. 290bb–25b) is amended—

17 (1) in subsection (e)(3), by striking “fiscal year
18 2007” and all that follows through the period at the
19 end and inserting “each of the fiscal years 2018
20 through 2022.”;

21 (2) in subsection (d)(4), by striking “fiscal year
22 2007” and all that follows through the period at the
23 end and inserting “each of the fiscal years 2018
24 through 2022.”;

1 (3) in subsection (e)(1)(I), by striking “fiscal
2 year 2007” and all that follows through the period
3 at the end and inserting “each of the fiscal years
4 2018 through 2022.”;

5 (4) in subsection (f)(2), by striking
6 “\$6,000,000 for fiscal year 2007” and all that fol-
7 lows through the period at the end and inserting
8 “\$3,000,000 for each of the fiscal years 2018
9 through 2022”; and

10 (5) by adding at the end the following new sub-
11 section:

12 “(g) REDUCING UNDERAGE DRINKING THROUGH
13 SCREENING AND BRIEF INTERVENTION.—

14 “(1) GRANTS TO PEDIATRIC HEALTH CARE
15 PROVIDERS TO REDUCE UNDERAGE DRINKING.—The
16 Assistant Secretary may make grants to eligible en-
17 tities to increase implementation of practices for re-
18 ducing the prevalence of alcohol use among individ-
19 uals under the age of 21, including college students.

20 “(2) PURPOSES.—Grants under this subsection
21 shall be made to improve—

22 “(A) screening children and adolescents for
23 alcohol use;

24 “(B) offering brief interventions to chil-
25 dren and adolescents to discourage such use;

1 “(C) educating parents about the dangers
2 of, and methods of discouraging, such use;

3 “(D) diagnosing and treating alcohol use
4 disorders; and

5 “(E) referring patients, when necessary, to
6 other appropriate care.

7 “(3) USE OF FUNDS.—An entity receiving a
8 grant under this subsection may use such funding
9 for the purposes identified in paragraph (2) by—

10 “(A) providing training to health care pro-
11 viders;

12 “(B) disseminating best practices, includ-
13 ing culturally and linguistically appropriate best
14 practices, as appropriate, and developing and
15 distributing materials; and

16 “(C) supporting other activities, as deter-
17 mined appropriate by the Assistant Secretary.

18 “(4) APPLICATION.—To be eligible to receive a
19 grant under this subsection, an entity shall submit
20 an application to the Assistant Secretary at such
21 time, and in such manner, and accompanied by such
22 information as the Assistant Secretary may require.
23 Each application shall include—

24 “(A) a description of the entity;

1 “(B) a description of activities to be com-
2 pleted;

3 “(C) a description of how the services spec-
4 ified in paragraphs (2) and (3) will be carried
5 out and the qualifications for providing such
6 services; and

7 “(D) a timeline for the completion of such
8 activities.

9 “(5) DEFINITIONS.—For the purpose of this
10 subsection:

11 “(A) BRIEF INTERVENTION.—The term
12 ‘brief intervention’ means, after screening a pa-
13 tient, providing the patient with brief advice
14 and other brief motivational enhancement tech-
15 niques designed to increase the insight of the
16 patient regarding the patient’s alcohol use, and
17 any realized or potential consequences of such
18 use, to effect the desired related behavioral
19 change.

20 “(B) CHILDREN AND ADOLESCENTS.—The
21 term ‘children and adolescents’ means any per-
22 son under 21 years of age.

23 “(C) ELIGIBLE ENTITY.—The term ‘eligi-
24 ble entity’ means an entity consisting of pedi-
25 atric health care providers and that is qualified

1 to support or provide the activities identified in
2 paragraph (2).

3 “(D) PEDIATRIC HEALTH CARE PRO-
4 VIDER.—The term ‘pediatric health care pro-
5 vider’ means a provider of primary health care
6 to individuals under the age of 21 years.

7 “(E) SCREENING.—The term ‘screening’
8 means using validated patient interview tech-
9 niques to identify and assess the existence and
10 extent of alcohol use in a patient.”.

11 **SEC. 9017. CENTER AND PROGRAM REPEALS.**

12 Part B of title V of the Public Health Service Act
13 (42 U.S.C. 290bb et seq.) is amended by striking section
14 506B (42 U.S.C. 290aa–5b), the second section 514 (42
15 U.S.C. 290bb–9) relating to methamphetamine and am-
16 phetamine treatment initiatives, and each of sections
17 514A, 517, 519A, 519C, 519E, 520B, 520D, and 520H
18 (42 U.S.C. 290bb–8, 290bb–23, 290bb–25a, 290bb–25c,
19 290bb–25e, 290bb–33, 290bb–35, and 290bb–39).

20 **Subtitle B—Strengthening the**
21 **Health Care Workforce**

22 **SEC. 9021. MENTAL AND BEHAVIORAL HEALTH EDUCATION**
23 **AND TRAINING GRANTS.**

24 Section 756 of the Public Health Service Act (42
25 U.S.C. 294e–1) is amended—

1 (1) in subsection (a)—

2 (A) in the matter preceding paragraph (1),
3 by striking “of higher education”; and

4 (B) by striking paragraphs (1) through (4)
5 and inserting the following:

6 “(1) accredited institutions of higher education
7 or accredited professional training programs that are
8 establishing or expanding internships or other field
9 placement programs in mental health in psychiatry,
10 psychology, school psychology, behavioral pediatrics,
11 psychiatric nursing (which may include master’s and
12 doctoral level programs), social work, school social
13 work, substance use disorder prevention and treat-
14 ment, marriage and family therapy, occupational
15 therapy, school counseling, or professional coun-
16 seling, including such programs with a focus on
17 child and adolescent mental health and transitional-
18 age youth;

19 “(2) accredited doctoral, internship, and post-
20 doctoral residency programs of health service psy-
21 chology (including clinical psychology, counseling,
22 and school psychology) for the development and im-
23 plementation of interdisciplinary training of psy-
24 chology graduate students for providing behavioral
25 health services, including substance use disorder pre-

1 vention and treatment services, as well as the devel-
2 opment of faculty in health service psychology;

3 “(3) accredited master’s and doctoral degree
4 programs of social work for the development and im-
5 plementation of interdisciplinary training of social
6 work graduate students for providing behavioral
7 health services, including substance use disorder pre-
8 vention and treatment services, and the development
9 of faculty in social work; and

10 “(4) State-licensed mental health nonprofit and
11 for-profit organizations to enable such organizations
12 to pay for programs for preservice or in-service
13 training in a behavioral health-related paraprofes-
14 sional field with preference for preservice or in-serv-
15 ice training of paraprofessional child and adolescent
16 mental health workers.”;

17 (2) in subsection (b)—

18 (A) by striking paragraph (5);

19 (B) by redesignating paragraphs (1)
20 through (4) as paragraphs (2) through (5), re-
21 spectively;

22 (C) by inserting before paragraph (2), as
23 so redesignated, the following:

1 “(1) an ability to recruit and place the students
2 described in subsection (a) in areas with a high need
3 and high demand population;”;

4 (D) in paragraph (3), as so redesignated,
5 by striking “subsection (a)” and inserting
6 “paragraph (2), especially individuals with men-
7 tal disorder symptoms or diagnoses, particularly
8 children and adolescents, and transitional-age
9 youth”;

10 (E) in paragraph (4), as so redesignated,
11 by striking “;” and inserting “; and”; and

12 (F) in paragraph (5), as so redesignated,
13 by striking “; and” and inserting a period;

14 (3) in subsection (c), by striking “authorized
15 under subsection (a)(1)” and inserting “awarded
16 under paragraphs (2) and (3) of subsection (a)”;

17 (4) by amending subsection (d) to read as fol-
18 lows:

19 “(d) PRIORITY.—In selecting grant recipients under
20 this section, the Secretary shall give priority to—

21 “(1) programs that have demonstrated the abil-
22 ity to train psychology, psychiatry, and social work
23 professionals to work in integrated care settings for
24 purposes of recipients under paragraphs (1), (2),
25 and (3) of subsection (a); and

1 “(2) programs for paraprofessionals that em-
2 phasize the role of the family and the lived experi-
3 ence of the consumer and family-paraprofessional
4 partnerships for purposes of recipients under sub-
5 section (a)(4).”; and

6 (5) by striking subsection (e) and inserting the
7 following:

8 “(e) REPORT TO CONGRESS.—Not later than 4 years
9 after the date of enactment of the Helping Families in
10 Mental Health Crisis Reform Act of 2016, the Secretary
11 shall include in the biennial report submitted to Congress
12 under section 501(m) an assessment on the effectiveness
13 of the grants under this section in—

14 “(1) providing graduate students support for
15 experiential training (internship or field placement);

16 “(2) recruiting students interested in behavioral
17 health practice;

18 “(3) recruiting students in accordance with sub-
19 section (b)(1);

20 “(4) developing and implementing interprofes-
21 sional training and integration within primary care;

22 “(5) developing and implementing accredited
23 field placements and internships; and

1 “(6) collecting data on the number of students
2 trained in behavioral health care and the number of
3 available accredited internships and field placements.

4 “(f) AUTHORIZATION OF APPROPRIATIONS.—For
5 each of fiscal years 2018 through 2022, there are author-
6 ized to be appropriated to carry out this section
7 \$50,000,000, to be allocated as follows:

8 “(1) For grants described in subsection (a)(1),
9 \$15,000,000.

10 “(2) For grants described in subsection (a)(2),
11 \$15,000,000.

12 “(3) For grants described in subsection (a)(3),
13 \$10,000,000.

14 “(4) For grants described in subsection (a)(4),
15 \$10,000,000.”.

16 **SEC. 9022. STRENGTHENING THE MENTAL AND SUBSTANCE**
17 **USE DISORDERS WORKFORCE.**

18 Part D of title VII of the Public Health Service Act
19 (42 U.S.C. 294 et seq.) is amended by adding at the end
20 the following:

21 **“SEC. 760. TRAINING DEMONSTRATION PROGRAM.**

22 “(a) IN GENERAL.—The Secretary shall establish a
23 training demonstration program to award grants to eligi-
24 ble entities to support—

1 “(1) training for medical residents and fellows
2 to practice psychiatry and addiction medicine in un-
3 derserved, community-based settings that integrate
4 primary care with mental and substance use dis-
5 orders prevention and treatment services;

6 “(2) training for nurse practitioners, physician
7 assistants, health service psychologists, and social
8 workers to provide mental and substance use dis-
9 orders services in underserved community-based set-
10 tings that integrate primary care and mental and
11 substance use disorders services; and

12 “(3) establishing, maintaining, or improving
13 academic units or programs that—

14 “(A) provide training for students or fac-
15 ulty, including through clinical experiences and
16 research, to improve the ability to be able to
17 recognize, diagnose, and treat mental and sub-
18 stance use disorders, with a special focus on ad-
19 diction; or

20 “(B) develop evidence-based practices or
21 recommendations for the design of the units or
22 programs described in subparagraph (A), in-
23 cluding curriculum content standards.

24 “(b) ACTIVITIES.—

1 “(1) TRAINING FOR RESIDENTS AND FEL-
2 LWS.—A recipient of a grant under subsection
3 (a)(1)—

4 “(A) shall use the grant funds—

5 “(i)(I) to plan, develop, and operate a
6 training program for medical psychiatry
7 residents and fellows in addiction medicine
8 practicing in eligible entities described in
9 subsection (c)(1); or

10 “(II) to train new psychiatric resi-
11 dents and fellows in addiction medicine to
12 provide and expand access to integrated
13 mental and substance use disorders serv-
14 ices; and

15 “(ii) to provide at least 1 training
16 track that is—

17 “(I) a virtual training track that
18 includes an in-person rotation at a
19 teaching health center or in a commu-
20 nity-based setting, followed by a vir-
21 tual rotation in which the resident or
22 fellow continues to support the care of
23 patients at the teaching health center
24 or in the community-based setting
25 through the use of health information

1 technology and, as appropriate, tele-
2 health services;

3 “(II) an in-person training track
4 that includes a rotation, during which
5 the resident or fellow practices at a
6 teaching health center or in a commu-
7 nity-based setting; or

8 “(III) an in-person training track
9 that includes a rotation during which
10 the resident practices in a community-
11 based setting that specializes in the
12 treatment of infants, children, adoles-
13 cents, or pregnant or postpartum
14 women; and

15 “(B) may use the grant funds to provide
16 additional support for the administration of the
17 program or to meet the costs of projects to es-
18 tablish, maintain, or improve faculty develop-
19 ment, or departments, divisions, or other units
20 necessary to implement such training.

21 “(2) TRAINING FOR OTHER PROVIDERS.—A re-
22 cipient of a grant under subsection (a)(2)—

23 “(A) shall use the grant funds to plan, de-
24 velop, or operate a training program to provide
25 mental and substance use disorders services in

1 underserved, community-based settings, as ap-
2 propriate, that integrate primary care and men-
3 tal and substance use disorders prevention and
4 treatment services; and

5 “(B) may use the grant funds to provide
6 additional support for the administration of the
7 program or to meet the costs of projects to es-
8 tablish, maintain, or improve faculty develop-
9 ment, or departments, divisions, or other units
10 necessary to implement such program.

11 “(3) ACADEMIC UNITS OR PROGRAMS.—A re-
12 cipient of a grant under subsection (a)(3) shall enter
13 into a partnership with organizations such as an
14 education accrediting organization (such as the Liai-
15 son Committee on Medical Education, the Accredita-
16 tion Council for Graduate Medical Education, the
17 Commission on Osteopathic College Accreditation,
18 the Accreditation Commission for Education in
19 Nursing, the Commission on Collegiate Nursing
20 Education, the Accreditation Council for Pharmacy
21 Education, the Council on Social Work Education,
22 American Psychological Association Commission on
23 Accreditation, or the Accreditation Review Commis-
24 sion on Education for the Physician Assistant) to
25 carry out activities under subsection (a)(3).

1 “(c) ELIGIBLE ENTITIES.—

2 “(1) TRAINING FOR RESIDENTS AND FEL-
3 LOWS.—To be eligible to receive a grant under sub-
4 section (a)(1), an entity shall—

5 “(A) be a consortium consisting of—

6 “(i) at least one teaching health cen-
7 ter; and

8 “(ii) the sponsoring institution (or
9 parent institution of the sponsoring insti-
10 tution) of—

11 “(I) a psychiatry residency pro-
12 gram that is accredited by the Accred-
13 itation Council of Graduate Medical
14 Education (or the parent institution
15 of such a program); or

16 “(II) a fellowship in addiction
17 medicine, as determined appropriate
18 by the Secretary; or

19 “(B) be an entity described in subpara-
20 graph (A)(ii) that provides opportunities for
21 residents or fellows to train in community-based
22 settings that integrate primary care with men-
23 tal and substance use disorders prevention and
24 treatment services.

1 “(2) TRAINING FOR OTHER PROVIDERS.—To be
2 eligible to receive a grant under subsection (a)(2),
3 an entity shall be—

4 “(A) a teaching health center (as defined
5 in section 749A(f));

6 “(B) a Federally qualified health center
7 (as defined in section 1905(l)(2)(B) of the So-
8 cial Security Act);

9 “(C) a community mental health center (as
10 defined in section 1861(ff)(3)(B) of the Social
11 Security Act);

12 “(D) a rural health clinic (as defined in
13 section 1861(aa) of the Social Security Act);

14 “(E) a health center operated by the In-
15 dian Health Service, an Indian tribe, a tribal
16 organization, or an urban Indian organization
17 (as defined in section 4 of the Indian Health
18 Care Improvement Act); or

19 “(F) an entity with a demonstrated record
20 of success in providing training for nurse prac-
21 titioners, physician assistants, health service
22 psychologists, and social workers.

23 “(3) ACADEMIC UNITS OR PROGRAMS.—To be
24 eligible to receive a grant under subsection (a)(3),
25 an entity shall be a school of medicine or osteopathic

1 medicine, a nursing school, a physician assistant
2 training program, a school of pharmacy, a school of
3 social work, an accredited public or nonprofit private
4 hospital, an accredited medical residency program,
5 or a public or private nonprofit entity which the Sec-
6 retary has determined is capable of carrying out
7 such grant.

8 “(d) PRIORITY.—

9 “(1) IN GENERAL.—In awarding grants under
10 subsection (a)(1) or (a)(2), the Secretary shall give
11 priority to eligible entities that—

12 “(A) demonstrate sufficient size, scope,
13 and capacity to undertake the requisite training
14 of an appropriate number of psychiatric resi-
15 dents, fellows, nurse practitioners, physician as-
16 sistants, or social workers in addiction medicine
17 per year to meet the needs of the area served;

18 “(B) demonstrate experience in training
19 providers to practice team-based care that inte-
20 grates mental and substance use disorder pre-
21 vention and treatment services with primary
22 care in community-based settings;

23 “(C) demonstrate experience in using
24 health information technology and, as appro-
25 priate, telehealth to support—

1 “(i) the delivery of mental and sub-
2 stance use disorders services at the eligible
3 entities described in subsections (c)(1) and
4 (c)(2); and

5 “(ii) community health centers in in-
6 tegrating primary care and mental and
7 substance use disorders treatment; or

8 “(D) have the capacity to expand access to
9 mental and substance use disorders services in
10 areas with demonstrated need, as determined by
11 the Secretary, such as tribal, rural, or other un-
12 derserved communities.

13 “(2) ACADEMIC UNITS OR PROGRAMS.—In
14 awarding grants under subsection (a)(3), the Sec-
15 retary shall give priority to eligible entities that—

16 “(A) have a record of training the greatest
17 percentage of mental and substance use dis-
18 orders providers who enter and remain in these
19 fields or who enter and remain in settings with
20 integrated primary care and mental and sub-
21 stance use disorder prevention and treatment
22 services;

23 “(B) have a record of training individuals
24 who are from underrepresented minority

1 groups, including native populations, or from a
2 rural or disadvantaged background;

3 “(C) provide training in the care of vulner-
4 able populations such as infants, children, ado-
5 lescents, pregnant and postpartum women,
6 older adults, homeless individuals, victims of
7 abuse or trauma, individuals with disabilities,
8 and other groups as defined by the Secretary;

9 “(D) teach trainees the skills to provide
10 interprofessional, integrated care through col-
11 laboration among health professionals; or

12 “(E) provide training in cultural com-
13 petency and health literacy.

14 “(e) DURATION.—Grants awarded under this section
15 shall be for a minimum of 5 years.

16 “(f) STUDY AND REPORT.—

17 “(1) STUDY.—

18 “(A) IN GENERAL.—The Secretary, acting
19 through the Administrator of the Health Re-
20 sources and Services Administration, shall con-
21 duct a study on the results of the demonstra-
22 tion program under this section.

23 “(B) DATA SUBMISSION.—Not later than
24 90 days after the completion of the first year
25 of the training program and each subsequent

1 year that the program is in effect, each recipi-
2 ent of a grant under subsection (a) shall submit
3 to the Secretary such data as the Secretary
4 may require for analysis for the report de-
5 scribed in paragraph (2).

6 “(2) REPORT TO CONGRESS.—Not later than 1
7 year after receipt of the data described in paragraph
8 (1)(B), the Secretary shall submit to Congress a re-
9 port that includes—

10 “(A) an analysis of the effect of the dem-
11 onstration program under this section on the
12 quality, quantity, and distribution of mental
13 and substance use disorders services;

14 “(B) an analysis of the effect of the dem-
15 onstration program on the prevalence of un-
16 treated mental and substance use disorders in
17 the surrounding communities of health centers
18 participating in the demonstration; and

19 “(C) recommendations on whether the
20 demonstration program should be expanded.

21 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
22 are authorized to be appropriated to carry out this section
23 \$10,000,000 for each of fiscal years 2018 through 2022.”.

1 **SEC. 9023. CLARIFICATION ON CURRENT ELIGIBILITY FOR**
2 **LOAN REPAYMENT PROGRAMS.**

3 The Administrator of the Health Resources and Serv-
4 ices Administration shall clarify the eligibility pursuant to
5 section 338B(b)(1)(B) of the Public Health Service Act
6 (42 U.S.C. 254l–1(b)(1)(B)) of child and adolescent psy-
7 chiatrists for the National Health Service Corps Loan Re-
8 payment Program under subpart III of part D of title III
9 of such Act (42 U.S.C. 254l et seq.).

10 **SEC. 9024. MINORITY FELLOWSHIP PROGRAM.**

11 Title V of the Public Health Service Act (42 U.S.C.
12 290aa et seq.) is amended by adding at the end the fol-
13 lowing:

14 **“PART K—MINORITY FELLOWSHIP PROGRAM**
15 **“SEC. 597. FELLOWSHIPS.**

16 “(a) IN GENERAL.—The Secretary shall maintain a
17 program, to be known as the Minority Fellowship Pro-
18 gram, under which the Secretary shall award fellowships,
19 which may include stipends, for the purposes of—

20 “(1) increasing the knowledge of mental and
21 substance use disorders practitioners on issues re-
22 lated to prevention, treatment, and recovery support
23 for individuals who are from racial and ethnic mi-
24 nority populations and who have a mental or sub-
25 stance use disorder;

1 “(2) improving the quality of mental and sub-
2 stance use disorder prevention and treatment serv-
3 ices delivered to racial and ethnic minority popu-
4 lations; and

5 “(3) increasing the number of culturally com-
6 petent mental and substance use disorders profes-
7 sionals who teach, administer services, conduct re-
8 search, and provide direct mental or substance use
9 disorder services to racial and ethnic minority popu-
10 lations.

11 “(b) TRAINING COVERED.—The fellowships awarded
12 under subsection (a) shall be for postbaccalaureate train-
13 ing (including for master’s and doctoral degrees) for men-
14 tal and substance use disorder treatment professionals, in-
15 cluding in the fields of psychiatry, nursing, social work,
16 psychology, marriage and family therapy, mental health
17 counseling, and substance use disorder and addiction
18 counseling.

19 “(c) AUTHORIZATION OF APPROPRIATIONS.—To
20 carry out this section, there are authorized to be appro-
21 priated \$12,669,000 for each of fiscal years 2018 through
22 2022.”.

1 **SEC. 9025. LIABILITY PROTECTIONS FOR HEALTH PROFES-**
2 **SIONAL VOLUNTEERS AT COMMUNITY**
3 **HEALTH CENTERS.**

4 Section 224 of the Public Health Service Act (42
5 U.S.C. 233) is amended by adding at the end the fol-
6 lowing:

7 “(q)(1) For purposes of this section, a health profes-
8 sional volunteer at a deemed entity described in subsection
9 (g)(4) shall, in providing a health professional service eli-
10 gible for funding under section 330 to an individual, be
11 deemed to be an employee of the Public Health Service
12 for a calendar year that begins during a fiscal year for
13 which a transfer was made under paragraph (4)(C). The
14 preceding sentence is subject to the provisions of this sub-
15 section.

16 “(2) In providing a health service to an individual,
17 a health care practitioner shall for purposes of this sub-
18 section be considered to be a health professional volunteer
19 at an entity described in subsection (g)(4) if the following
20 conditions are met:

21 “(A) The service is provided to the individual at
22 the facilities of an entity described in subsection
23 (g)(4), or through offsite programs or events carried
24 out by the entity.

25 “(B) The entity is sponsoring the health care
26 practitioner pursuant to paragraph (3)(B).

1 “(C) The health care practitioner does not re-
2 ceive any compensation for the service from the indi-
3 vidual, the entity described in subsection (g)(4), or
4 any third-party payer (including reimbursement
5 under any insurance policy or health plan, or under
6 any Federal or State health benefits program), ex-
7 cept that the health care practitioner may receive re-
8 payment from the entity described in subsection
9 (g)(4) for reasonable expenses incurred by the health
10 care practitioner in the provision of the service to
11 the individual, which may include travel expenses to
12 or from the site of services.

13 “(D) Before the service is provided, the health
14 care practitioner or the entity described in sub-
15 section (g)(4) posts a clear and conspicuous notice
16 at the site where the service is provided of the extent
17 to which the legal liability of the health care practi-
18 tioner is limited pursuant to this subsection.

19 “(E) At the time the service is provided, the
20 health care practitioner is licensed or certified in ac-
21 cordance with applicable Federal and State laws re-
22 garding the provision of the service.

23 “(F) At the time the service is provided, the en-
24 tity described in subsection (g)(4) maintains relevant

1 documentation certifying that the health care practi-
2 tioner meets the requirements of this subsection.

3 “(3) Subsection (g) (other than paragraphs (3) and
4 (5)) and subsections (h), (i), and (l) apply to a health care
5 practitioner for purposes of this subsection to the same
6 extent and in the same manner as such subsections apply
7 to an officer, governing board member, employee, or con-
8 tractor of an entity described in subsection (g)(4), subject
9 to paragraph (4), and subject to the following:

10 “(A) The first sentence of paragraph (1) ap-
11 plies in lieu of the first sentence of subsection
12 (g)(1)(A).

13 “(B) With respect to an entity described in sub-
14 section (g)(4), a health care practitioner is not a
15 health professional volunteer at such entity unless
16 the entity sponsors the health care practitioner. For
17 purposes of this subsection, the entity shall be con-
18 sidered to be sponsoring the health care practitioner
19 if—

20 “(i) with respect to the health care practi-
21 tioner, the entity submits to the Secretary an
22 application meeting the requirements of sub-
23 section (g)(1)(D); and

24 “(ii) the Secretary, pursuant to subsection
25 (g)(1)(E), determines that the health care prac-

1 titioner is deemed to be an employee of the
2 Public Health Service.

3 “(C) In the case of a health care practitioner
4 who is determined by the Secretary pursuant to sub-
5 section (g)(1)(E) to be a health professional volun-
6 teer at such entity, this subsection applies to the
7 health care practitioner (with respect to services per-
8 formed on behalf of the entity sponsoring the health
9 care practitioner pursuant to subparagraph (B)) for
10 any cause of action arising from an act or omission
11 of the health care practitioner occurring on or after
12 the date on which the Secretary makes such deter-
13 mination.

14 “(D) Subsection (g)(1)(F) applies to a health
15 care practitioner for purposes of this subsection only
16 to the extent that, in providing health services to an
17 individual, each of the conditions specified in para-
18 graph (2) is met.

19 “(4)(A) Amounts in the fund established under sub-
20 section (k)(2) shall be available for transfer under sub-
21 paragraph (C) for purposes of carrying out this sub-
22 section.

23 “(B)(i) Not later than May 1 of each fiscal year, the
24 Attorney General, in consultation with the Secretary, shall
25 submit to the Congress a report providing an estimate of

1 the amount of claims (together with related fees and ex-
2 penses of witnesses) that, by reason of the acts or omis-
3 sions of health professional volunteers, will be paid pursu-
4 ant to this section during the calendar year that begins
5 in the following fiscal year.

6 “(ii) Subsection (k)(1)(B) applies to the estimate
7 under clause (i) regarding health professional volunteers
8 to the same extent and in the same manner as such sub-
9 section applies to the estimate under such subsection re-
10 garding officers, governing board members, employees,
11 and contractors of entities described in subsection (g)(4).

12 “(iii) The report shall include a summary of the data
13 relied upon for the estimate in clause (i), including the
14 number of claims filed and paid from the previous cal-
15 endar year.

16 “(C) Not later than December 31 of each fiscal year,
17 the Secretary shall transfer from the fund under sub-
18 section (k)(2) to the appropriate accounts in the Treasury
19 an amount equal to the estimate made under subpara-
20 graph (B) for the calendar year beginning in such fiscal
21 year, subject to the extent of amounts in the fund.

22 “(5)(A) This subsection shall take effect on October
23 1, 2017, except as provided in subparagraph (B) and
24 paragraph (6).

1 “(B) Effective on the date of the enactment of this
2 subsection—

3 “(i) the Secretary may issue regulations for car-
4 rying out this subsection, and the Secretary may ac-
5 cept and consider applications submitted pursuant to
6 paragraph (3)(B); and

7 “(ii) reports under paragraph (4)(B) may be
8 submitted to Congress.

9 “(6) Beginning on October 1, 2022, this subsection
10 shall cease to have any force or effect.”.

11 **SEC. 9026. REPORTS.**

12 (a) WORKFORCE DEVELOPMENT REPORT.—

13 (1) IN GENERAL.—Not later than 2 years after
14 the date of enactment of this Act, the Administrator
15 of the Health Resources and Services Administra-
16 tion, in consultation with the Assistant Secretary for
17 Mental Health and Substance Use, shall conduct a
18 study and publicly post on the appropriate Internet
19 website of the Department of Health and Human
20 Services a report on the adult and pediatric mental
21 health and substance use disorder workforce in order
22 to inform Federal, State, and local efforts related to
23 workforce enhancement.

24 (2) CONTENTS.—The report under this sub-
25 section shall contain—

1 (A) national and State-level projections of
2 the supply and demand of the mental health
3 and substance use disorder health workforce,
4 disaggregated by profession;

5 (B) an assessment of the mental health
6 and substance use disorder workforce capacity,
7 strengths, and weaknesses as of the date of the
8 report, including the extent to which primary
9 care providers are preventing, screening, or re-
10 ferring for mental and substance use disorder
11 services;

12 (C) information on trends within the men-
13 tal health and substance use disorder provider
14 workforce, including the number of individuals
15 expected to enter the mental health workforce
16 over the next 5 years; and

17 (D) any additional information determined
18 by the Administrator of the Health Resources
19 and Services Administration, in consultation
20 with the Assistant Secretary for Mental Health
21 and Substance Use, to be relevant to the mental
22 health and substance use disorder provider
23 workforce.

24 (b) PEER-SUPPORT SPECIALIST PROGRAMS.—

1 (1) IN GENERAL.—The Comptroller General of
2 the United States shall conduct a study on peer-sup-
3 port specialist programs in up to 10 States that re-
4 ceive funding from the Substance Abuse and Mental
5 Health Services Administration.

6 (2) CONTENTS OF STUDY.—In conducting the
7 study under paragraph (1), the Comptroller General
8 of the United States shall examine and identify best
9 practices, in the States selected pursuant to such
10 paragraph, related to training and credential re-
11 quirements for peer-support specialist programs,
12 such as—

13 (A) hours of formal work or volunteer ex-
14 perience related to mental and substance use
15 disorders conducted through such programs;

16 (B) types of peer-support specialist exams
17 required for such programs in the selected
18 States;

19 (C) codes of ethics used by such programs
20 in the selected States;

21 (D) required or recommended skill sets for
22 such programs in the selected States; and

23 (E) requirements for continuing education.

24 (3) REPORT.—Not later than 2 years after the
25 date of enactment of this Act, the Comptroller Gen-

1 eral of the United States shall submit to the Com-
2 mittee on Health, Education, Labor, and Pensions
3 of the Senate and the Committee on Energy and
4 Commerce of the House of Representatives a report
5 on the study conducted under paragraph (1).

6 **Subtitle C—Mental Health on**
7 **Campus Improvement**

8 **SEC. 9031. MENTAL HEALTH AND SUBSTANCE USE DIS-**
9 **ORDER SERVICES ON CAMPUS.**

10 Section 520E–2 of the Public Health Service Act (42
11 U.S.C. 290bb–36b) is amended—

12 (1) in the section heading, by striking “**AND**
13 **BEHAVIORAL HEALTH**” and inserting “**HEALTH**
14 **AND SUBSTANCE USE DISORDER**”;

15 (2) in subsection (a)—

16 (A) by striking “Services,” and inserting
17 “Services and”;

18 (B) by striking “and behavioral health
19 problems” and inserting “health or substance
20 use disorders”;

21 (C) by striking “substance abuse” and in-
22 serting “substance use disorders”; and

23 (D) by adding after, “suicide attempts,”
24 the following: “prevent mental and substance
25 use disorders, reduce stigma, and improve the

1 identification and treatment for students at
2 risk,”;

3 (3) in subsection (b)—

4 (A) in the matter preceding paragraph (1),
5 by striking “for—” and inserting “for one or
6 more of the following:”; and

7 (B) by striking paragraphs (1) through (6)
8 and inserting the following:

9 “(1) Educating students, families, faculty, and
10 staff to increase awareness of mental and substance
11 use disorders.

12 “(2) The operation of hotlines.

13 “(3) Preparing informational material.

14 “(4) Providing outreach services to notify stu-
15 dents about available mental and substance use dis-
16 order services.

17 “(5) Administering voluntary mental and sub-
18 stance use disorder screenings and assessments.

19 “(6) Supporting the training of students, fac-
20 ulty, and staff to respond effectively to students with
21 mental and substance use disorders.

22 “(7) Creating a network infrastructure to link
23 institutions of higher education with health care pro-
24 viders who treat mental and substance use disorders.

1 “(8) Providing mental and substance use dis-
2 orders prevention and treatment services to stu-
3 dents, which may include early intervention, treat-
4 ment, and management, including through the use
5 of telehealth services.

6 “(9) Conducting research through a counseling
7 or health center at the institution of higher edu-
8 cation involved regarding improving the behavioral
9 health of students through clinical services, out-
10 reach, prevention, or academic success, in a manner
11 that is in compliance with all applicable personal pri-
12 vacy laws.

13 “(10) Supporting student groups on campus,
14 including athletic teams, that engage in activities to
15 educate students, including activities to reduce stig-
16 ma surrounding mental and behavioral disorders,
17 and promote mental health.

18 “(11) Employing appropriately trained staff.

19 “(12) Developing and supporting evidence-
20 based and emerging best practices, including a focus
21 on culturally and linguistically appropriate best
22 practices.”;

23 (4) in subsection (c)(5), by striking “substance
24 abuse” and inserting “substance use disorder”;

25 (5) in subsection (d)—

1 (A) in the matter preceding paragraph (1),
2 by striking “An institution of higher education
3 desiring a grant under this section” and insert-
4 ing “To be eligible to receive a grant under this
5 section, an institution of higher education”;

6 (B) by striking paragraph (1) and insert-
7 ing—

8 “(1) A description of the population to be tar-
9 geted by the program carried out under the grant,
10 including veterans whenever possible and appro-
11 priate, and of identified mental and substance use
12 disorder needs of students at the institution of high-
13 er education.”;

14 (C) in paragraph (2), by inserting “, which
15 may include, as appropriate and in accordance
16 with subsection (b)(7), a plan to seek input
17 from relevant stakeholders in the community,
18 including appropriate public and private enti-
19 ties, in order to carry out the program under
20 the grant” before the period at the end; and

21 (D) by adding after paragraph (5) the fol-
22 lowing new paragraphs:

23 “(6) An outline of the objectives of the program
24 carried out under the grant.

1 “(7) For an institution of higher education pro-
2 posing to use the grant for an activity described in
3 paragraph (8) or (9) of subsection (b), a description
4 of the policies and procedures of the institution of
5 higher education that are related to applicable laws
6 regarding access to, and sharing of, treatment
7 records of students at any campus-based mental
8 health center or partner organization, including the
9 policies and State laws governing when such records
10 can be accessed and shared for non-treatment pur-
11 poses and a description of the process used by the
12 institution of higher education to notify students of
13 these policies and procedures, including the extent to
14 which written consent is required.

15 “(8) An assurance that grant funds will be used
16 to supplement and not supplant any other Federal,
17 State, or local funds available to carry out activities
18 of the type carried out under the grant.”;

19 (6) in subsection (e)(1), by striking “and behav-
20 ioral health problems” and inserting “health and
21 substance use disorders”;

22 (7) in subsection (f)(2)—

23 (A) by striking “and behavioral health”
24 and inserting “health and substance use dis-
25 order”; and

1 (B) by striking “suicide and substance
2 abuse” and inserting “suicide and substance
3 use disorders”;

4 (8) by redesignating subsection (h) as sub-
5 section (i);

6 (9) by inserting after subsection (g) the fol-
7 lowing new subsection:

8 “(h) TECHNICAL ASSISTANCE.—The Secretary may
9 provide technical assistance to grantees in carrying out
10 this section.”; and

11 (10) in subsection (i), as redesignated by para-
12 graph (8), by striking “\$5,000,000 for fiscal year
13 2005” and all that follows through the period at the
14 end and inserting “\$7,000,000 for each of fiscal
15 years 2018 through 2022.”.

16 **SEC. 9032. INTERAGENCY WORKING GROUP ON COLLEGE**
17 **MENTAL HEALTH.**

18 (a) PURPOSE.—It is the purpose of this section to
19 provide for the establishment of a College Campus Task
20 Force to discuss mental and behavioral health concerns
21 on campuses of institutions of higher education.

22 (b) ESTABLISHMENT.—The Secretary of Health and
23 Human Services (referred to in this section as the “Sec-
24 retary”) shall establish a College Campus Task Force (re-
25 ferred to in this section as the “Task Force”) to discuss

1 mental and behavioral health concerns on campuses of in-
2 stitutions of higher education.

3 (c) MEMBERSHIP.—The Task Force shall be com-
4 posed of a representative from each Federal agency (as
5 appointed by the head of the agency) that has jurisdiction
6 over, or is affected by, mental health and education poli-
7 cies and projects, including—

8 (1) the Department of Education;

9 (2) the Department of Health and Human
10 Services;

11 (3) the Department of Veterans Affairs; and

12 (4) such other Federal agencies as the Assist-
13 ant Secretary for Mental Health and Substance Use,
14 in consultation with the Secretary, determines to be
15 appropriate.

16 (d) DUTIES.—The Task Force shall—

17 (1) serve as a centralized mechanism to coordi-
18 nate a national effort to—

19 (A) discuss and evaluate evidence and
20 knowledge on mental and behavioral health
21 services available to, and the prevalence of men-
22 tal illness among, the age population of stu-
23 dents attending institutions of higher education
24 in the United States;

1 (B) determine the range of effective, fea-
2 sible, and comprehensive actions to improve
3 mental and behavioral health on campuses of
4 institutions of higher education;

5 (C) examine and better address the needs
6 of the age population of students attending in-
7 stitutions of higher education dealing with men-
8 tal illness;

9 (D) survey Federal agencies to determine
10 which policies are effective in encouraging, and
11 how best to facilitate outreach without dupli-
12 cating, efforts relating to mental and behavioral
13 health promotion;

14 (E) establish specific goals within and
15 across Federal agencies for mental health pro-
16 motion, including determinations of account-
17 ability for reaching those goals;

18 (F) develop a strategy for allocating re-
19 sponsibilities and ensuring participation in men-
20 tal and behavioral health promotion, particu-
21 larly in the case of competing agency priorities;

22 (G) coordinate plans to communicate re-
23 search results relating to mental and behavioral
24 health amongst the age population of students
25 attending institutions of higher education to en-

1 able reporting and outreach activities to
2 produce more useful and timely information;

3 (H) provide a description of evidence-based
4 practices, model programs, effective guidelines,
5 and other strategies for promoting mental and
6 behavioral health on campuses of institutions of
7 higher education;

8 (I) make recommendations to improve
9 Federal efforts relating to mental and behav-
10 ioral health promotion on campuses of institu-
11 tions of higher education and to ensure Federal
12 efforts are consistent with available standards,
13 evidence, and other programs in existence as of
14 the date of enactment of this Act;

15 (J) monitor Federal progress in meeting
16 specific mental and behavioral health promotion
17 goals as they relate to settings of institutions of
18 higher education; and

19 (K) examine and disseminate best prac-
20 tices related to intracampus sharing of treat-
21 ment records;

22 (2) consult with national organizations with ex-
23 pertise in mental and behavioral health, especially
24 those organizations working with the age population

1 of students attending institutions of higher edu-
2 cation; and

3 (3) consult with and seek input from mental
4 health professionals working on campuses of institu-
5 tions of higher education as appropriate.

6 (e) MEETINGS.—

7 (1) IN GENERAL.—The Task Force shall meet
8 not fewer than three times each year.

9 (2) ANNUAL CONFERENCE.—The Secretary
10 shall sponsor an annual conference on mental and
11 behavioral health in settings of institutions of higher
12 education to enhance coordination, build partner-
13 ships, and share best practices in mental and behav-
14 ioral health promotion, data collection, analysis, and
15 services.

16 (f) DEFINITION.—In this section, the term “institu-
17 tion of higher education” has the meaning given such term
18 in section 101 of the Higher Education Act of 1965 (20
19 U.S.C. 1001).

20 (g) AUTHORIZATION OF APPROPRIATIONS.—To carry
21 out this section, there are authorized to be appropriated
22 \$1,000,000 for the period of fiscal years 2018 through
23 2022.

1 **SEC. 9033. IMPROVING MENTAL HEALTH ON COLLEGE CAM-**
2 **PUSES.**

3 Part D of title V of the Public Health Service Act
4 (42 U.S.C. 290dd et seq.) is amended by adding at the
5 end the following:

6 **“SEC. 549. MENTAL AND BEHAVIORAL HEALTH OUTREACH**
7 **AND EDUCATION ON COLLEGE CAMPUSES.**

8 “(a) **PURPOSE.**—It is the purpose of this section to
9 increase access to, and reduce the stigma associated with,
10 mental health services to ensure that students at institu-
11 tions of higher education have the support necessary to
12 successfully complete their studies.

13 “(b) **NATIONAL PUBLIC EDUCATION CAMPAIGN.**—
14 The Secretary, acting through the Assistant Secretary and
15 in collaboration with the Director of the Centers for Dis-
16 ease Control and Prevention, shall convene an interagency,
17 public-private sector working group to plan, establish, and
18 begin coordinating and evaluating a targeted public edu-
19 cation campaign that is designed to focus on mental and
20 behavioral health on the campuses of institutions of higher
21 education. Such campaign shall be designed to—

22 “(1) improve the general understanding of men-
23 tal health and mental disorders;

24 “(2) encourage help-seeking behaviors relating
25 to the promotion of mental health, prevention of
26 mental disorders, and treatment of such disorders;

1 “(3) make the connection between mental and
2 behavioral health and academic success; and

3 “(4) assist the general public in identifying the
4 early warning signs and reducing the stigma of men-
5 tal illness.

6 “(c) COMPOSITION.—The working group convened
7 under subsection (b) shall include—

8 “(1) mental health consumers, including stu-
9 dents and family members;

10 “(2) representatives of institutions of higher
11 education;

12 “(3) representatives of national mental and be-
13 havioral health associations and associations of insti-
14 tutions of higher education;

15 “(4) representatives of health promotion and
16 prevention organizations at institutions of higher
17 education;

18 “(5) representatives of mental health providers,
19 including community mental health centers; and

20 “(6) representatives of private-sector and pub-
21 lic-sector groups with experience in the development
22 of effective public health education campaigns.

23 “(d) PLAN.—The working group under subsection (b)
24 shall develop a plan that—

1 “(1) targets promotional and educational efforts
2 to the age population of students at institutions of
3 higher education and individuals who are employed
4 in settings of institutions of higher education, in-
5 cluding through the use of roundtables;

6 “(2) develops and proposes the implementation
7 of research-based public health messages and activi-
8 ties;

9 “(3) provides support for local efforts to reduce
10 stigma by using the National Health Information
11 Center as a primary point of contact for informa-
12 tion, publications, and service program referrals; and

13 “(4) develops and proposes the implementation
14 of a social marketing campaign that is targeted at
15 the population of students attending institutions of
16 higher education and individuals who are employed
17 in settings of institutions of higher education.

18 “(e) DEFINITION.—In this section, the term ‘institu-
19 tion of higher education’ has the meaning given such term
20 in section 101 of the Higher Education Act of 1965 (20
21 U.S.C. 1001).

22 “(f) AUTHORIZATION OF APPROPRIATIONS.—To
23 carry out this section, there are authorized to be appro-
24 priated \$1,000,000 for the period of fiscal years 2018
25 through 2022.”.

1 **TITLE X—STRENGTHENING MEN-**
2 **TAL AND SUBSTANCE USE**
3 **DISORDER CARE FOR CHIL-**
4 **DREN AND ADOLESCENTS**

5 **SEC. 10001. PROGRAMS FOR CHILDREN WITH A SERIOUS**
6 **EMOTIONAL DISTURBANCE.**

7 (a) **COMPREHENSIVE COMMUNITY MENTAL HEALTH**
8 **SERVICES FOR CHILDREN WITH A SERIOUS EMOTIONAL**
9 **DISTURBANCE.**—Section 561(a)(1) of the Public Health
10 Service Act (42 U.S.C. 290ff(a)(1)) is amended by insert-
11 ing “, which may include efforts to identify and serve chil-
12 dren at risk” before the period.

13 (b) **REQUIREMENTS WITH RESPECT TO CARRYING**
14 **OUT PURPOSE OF GRANTS.**—Section 562(b) of the Public
15 Health Service Act (42 U.S.C. 290ff–1(b)) is amended by
16 striking “will not provide an individual with access to the
17 system if the individual is more than 21 years of age”
18 and inserting “will provide an individual with access to
19 the system through the age of 21 years”.

20 (c) **ADDITIONAL PROVISIONS.**—Section 564(f) of the
21 Public Health Service Act (42 U.S.C. 290ff–3(f)) is
22 amended by inserting “(and provide a copy to the State
23 involved)” after “to the Secretary”.

24 (d) **GENERAL PROVISIONS.**—Section 565 of the Pub-
25 lic Health Service Act (42 U.S.C. 290ff–4) is amended—

1 (1) in subsection (b)(1)—

2 (A) in the matter preceding subparagraph
3 (A), by striking “receiving a grant under sec-
4 tion 561(a)” and inserting “, regardless of
5 whether such public entity is receiving a grant
6 under section 561(a)”; and

7 (B) in subparagraph (B), by striking “pur-
8 suant to” and inserting “described in”;

9 (2) in subsection (d)(1), by striking “not more
10 than 21 years of age” and inserting “through the
11 age of 21 years”; and

12 (3) in subsection (f)(1), by striking
13 “\$100,000,000 for fiscal year 2001, and such sums
14 as may be necessary for each of the fiscal years
15 2002 and 2003” and inserting “\$119,026,000 for
16 each of fiscal years 2018 through 2022”.

17 **SEC. 10002. INCREASING ACCESS TO PEDIATRIC MENTAL**
18 **HEALTH CARE.**

19 Title III of the Public Health Service Act is amended
20 by inserting after section 330L of such Act (42 U.S.C.
21 254c–18) the following new section:

22 **“SEC. 330M PEDIATRIC MENTAL HEALTH CARE ACCESS**
23 **GRANTS.**

24 “(a) IN GENERAL.—The Secretary, acting through
25 the Administrator of the Health Resources and Services

1 Administration and in coordination with other relevant
2 Federal agencies, shall award grants to States, political
3 subdivisions of States, and Indian tribes and tribal organi-
4 zations (for purposes of this section, as such terms are
5 defined in section 4 of the Indian Self-Determination and
6 Education Assistance Act (25 U.S.C. 450b)) to promote
7 behavioral health integration in pediatric primary care
8 by—

9 “(1) supporting the development of statewide or
10 regional pediatric mental health care telehealth ac-
11 cess programs; and

12 “(2) supporting the improvement of existing
13 statewide or regional pediatric mental health care
14 telehealth access programs.

15 “(b) PROGRAM REQUIREMENTS.—

16 “(1) IN GENERAL.—A pediatric mental health
17 care telehealth access program referred to in sub-
18 section (a), with respect to which a grant under such
19 subsection may be used, shall—

20 “(A) be a statewide or regional network of
21 pediatric mental health teams that provide sup-
22 port to pediatric primary care sites as an inte-
23 grated team;

24 “(B) support and further develop orga-
25 nized State or regional networks of pediatric

1 mental health teams to provide consultative
2 support to pediatric primary care sites;

3 “(C) conduct an assessment of critical be-
4 havioral consultation needs among pediatric
5 providers and such providers’ preferred mecha-
6 nisms for receiving consultation, training, and
7 technical assistance;

8 “(D) develop an online database and com-
9 munication mechanisms, including telehealth, to
10 facilitate consultation support to pediatric prac-
11 tices;

12 “(E) provide rapid statewide or regional
13 clinical telephone or telehealth consultations
14 when requested between the pediatric mental
15 health teams and pediatric primary care pro-
16 viders;

17 “(F) conduct training and provide tech-
18 nical assistance to pediatric primary care pro-
19 viders to support the early identification, diag-
20 nosis, treatment, and referral of children with
21 behavioral health conditions;

22 “(G) provide information to pediatric pro-
23 viders about, and assist pediatric providers in
24 accessing, pediatric mental health care pro-
25 viders, including child and adolescent psychia-

1 trists, and licensed mental health professionals,
2 such as psychologists, social workers, or mental
3 health counselors and in scheduling and con-
4 ducting technical assistance;

5 “(H) assist with referrals to specialty care
6 and community or behavioral health resources;
7 and

8 “(I) establish mechanisms for measuring
9 and monitoring increased access to pediatric
10 mental health care services by pediatric primary
11 care providers and expanded capacity of pedi-
12 atric primary care providers to identify, treat,
13 and refer children with mental health problems.

14 “(2) PEDIATRIC MENTAL HEALTH TEAMS.—In
15 this subsection, the term ‘pediatric mental health
16 team’ means a team consisting of at least one case
17 coordinator, at least one child and adolescent psy-
18 chiatrist, and at least one licensed clinical mental
19 health professional, such as a psychologist, social
20 worker, or mental health counselor. Such a team
21 may be regionally based.

22 “(c) APPLICATION.—A State, political subdivision of
23 a State, Indian tribe, or tribal organization seeking a
24 grant under this section shall submit an application to the
25 Secretary at such time, in such manner, and containing

1 such information as the Secretary may require, including
2 a plan for the comprehensive evaluation of activities that
3 are carried out with funds received under such grant.

4 “(d) EVALUATION.—A State, political subdivision of
5 a State, Indian tribe, or tribal organization that receives
6 a grant under this section shall prepare and submit an
7 evaluation of activities that are carried out with funds re-
8 ceived under such grant to the Secretary at such time,
9 in such manner, and containing such information as the
10 Secretary may reasonably require, including a process and
11 outcome evaluation.

12 “(e) ACCESS TO BROADBAND.—In administering
13 grants under this section, the Secretary may coordinate
14 with other agencies to ensure that funding opportunities
15 are available to support access to reliable, high-speed
16 Internet for providers.

17 “(f) MATCHING REQUIREMENT.—The Secretary may
18 not award a grant under this section unless the State, po-
19 litical subdivision of a State, Indian tribe, or tribal organi-
20 zation involved agrees, with respect to the costs to be in-
21 curred by the State, political subdivision of a State, Indian
22 tribe, or tribal organization in carrying out the purpose
23 described in this section, to make available non-Federal
24 contributions (in cash or in kind) toward such costs in

1 an amount that is not less than 20 percent of Federal
2 funds provided in the grant.

3 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
4 carry out this section, there are authorized to be appro-
5 priated, \$9,000,000 for the period of fiscal years 2018
6 through 2022.”.

7 **SEC. 10003. SUBSTANCE USE DISORDER TREATMENT AND**
8 **EARLY INTERVENTION SERVICES FOR CHIL-**
9 **DREN AND ADOLESCENTS.**

10 The first section 514 of the Public Health Service
11 Act (42 U.S.C. 290bb-7), relating to substance abuse
12 treatment services for children and adolescents, is amend-
13 ed—

14 (1) in the section heading, by striking “**ABUSE**
15 **TREATMENT**” and inserting “**USE DISORDER**
16 **TREATMENT AND EARLY INTERVENTION**”;

17 (2) by striking subsection (a) and inserting the
18 following:

19 “(a) IN GENERAL.—The Secretary shall award
20 grants, contracts, or cooperative agreements to public and
21 private nonprofit entities, including Indian tribes or tribal
22 organizations (as such terms are defined in section 4 of
23 the Indian Self-Determination and Education Assistance
24 Act), or health facilities or programs operated by or in

1 accordance with a contract or grant with the Indian
2 Health Service, for the purpose of—

3 “(1) providing early identification and services
4 to meet the needs of children and adolescents who
5 are at risk of substance use disorders;

6 “(2) providing substance use disorder treatment
7 services for children, including children and adoles-
8 cents with co-occurring mental illness and substance
9 use disorders; and

10 “(3) providing assistance to pregnant women,
11 and parenting women, with substance use disorders,
12 in obtaining treatment services, linking mothers to
13 community resources to support independent family
14 lives, and staying in recovery so that children are in
15 safe, stable home environments and receive appro-
16 priate health care services.”;

17 (3) in subsection (b)—

18 (A) by striking paragraph (1) and insert-
19 ing the following:

20 “(1) apply evidence-based and cost-effective
21 methods;”;

22 (B) in paragraph (2)—

23 (i) by striking “treatment”; and

24 (ii) by inserting “substance abuse,”
25 after “child welfare,”;

1 (C) in paragraph (3), by striking “sub-
2 stance abuse disorders” and inserting “sub-
3 stance use disorders, including children and
4 adolescents with co-occurring mental illness and
5 substance use disorders,”;

6 (D) in paragraph (5), by striking “treat-
7 ment;” and inserting “services; and”;

8 (E) in paragraph (6), by striking “sub-
9 stance abuse treatment; and” and inserting
10 “treatment.”; and

11 (F) by striking paragraph (7); and

12 (4) in subsection (f), by striking “\$40,000,000”
13 and all that follows through the period and inserting
14 “\$29,605,000 for each of fiscal years 2018 through
15 2022.”.

16 **SEC. 10004. CHILDREN’S RECOVERY FROM TRAUMA.**

17 The first section 582 of the Public Health Service
18 Act (42 U.S.C. 290hh–1; relating to grants to address the
19 problems of persons who experience violence related
20 stress) is amended—

21 (1) in subsection (a), by striking “developing
22 programs” and all that follows through the period at
23 the end and inserting the following: “developing and
24 maintaining programs that provide for—

1 “(1) the continued operation of the National
2 Child Traumatic Stress Initiative (referred to in this
3 section as the ‘NCTSI’), which includes a coopera-
4 tive agreement with a coordinating center, that fo-
5 cuses on the mental, behavioral, and biological as-
6 pects of psychological trauma response, prevention
7 of the long-term consequences of child trauma, and
8 early intervention services and treatment to address
9 the long-term consequences of child trauma; and

10 “(2) the development of knowledge with regard
11 to evidence-based practices for identifying and treat-
12 ing mental, behavioral, and biological disorders of
13 children and youth resulting from witnessing or ex-
14 periencing a traumatic event.”;

15 (2) in subsection (b)—

16 (A) by striking “subsection (a) related”
17 and inserting “subsection (a)(2) (related”;

18 (B) by striking “treating disorders associ-
19 ated with psychological trauma” and inserting
20 “treating mental, behavioral, and biological dis-
21 orders associated with psychological trauma)”;
22 and

23 (C) by striking “mental health agencies
24 and programs that have established clinical and
25 basic research” and inserting “universities, hos-

1 pitals, mental health agencies, and other pro-
2 grams that have established clinical expertise
3 and research”;

4 (3) by redesignating subsections (c) through (g)
5 as subsections (g) through (k), respectively;

6 (4) by inserting after subsection (b), the fol-
7 lowing:

8 “(c) CHILD OUTCOME DATA.—The NCTSI coordi-
9 nating center described in subsection (a)(1) shall collect,
10 analyze, report, and make publicly available, as appro-
11 priate, NCTSI-wide child treatment process and outcome
12 data regarding the early identification and delivery of evi-
13 dence-based treatment and services for children and fami-
14 lies served by the NCTSI grantees.

15 “(d) TRAINING.—The NCTSI coordinating center
16 shall facilitate the coordination of training initiatives in
17 evidence-based and trauma-informed treatments, interven-
18 tions, and practices offered to NCTSI grantees, providers,
19 and partners.

20 “(e) DISSEMINATION AND COLLABORATION.—The
21 NCTSI coordinating center shall, as appropriate, collabo-
22 rate with—

23 “(1) the Secretary, in the dissemination of evi-
24 dence-based and trauma-informed interventions,

1 treatments, products, and other resources to appro-
2 priate stakeholders; and

3 “(2) appropriate agencies that conduct or fund
4 research within the Department of Health and
5 Human Services, for purposes of sharing NCTSI ex-
6 pertise, evaluation data, and other activities, as ap-
7 propriate.

8 “(f) REVIEW.—The Secretary shall, consistent with
9 the peer-review process, ensure that NCTSI applications
10 are reviewed by appropriate experts in the field as part
11 of a consensus-review process. The Secretary shall include
12 review criteria related to expertise and experience in child
13 trauma and evidence-based practices.”;

14 (5) in subsection (g) (as so redesignated), by
15 striking “with respect to centers of excellence are
16 distributed equitably among the regions of the coun-
17 try” and inserting “are distributed equitably among
18 the regions of the United States”;

19 (6) in subsection (i) (as so redesignated), by
20 striking “recipient may not exceed 5 years” and in-
21 sserting “recipient shall not be less than 4 years, but
22 shall not exceed 5 years”; and

23 (7) in subsection (j) (as so redesignated), by
24 striking “\$50,000,000” and all that follows through

1 “2006” and inserting “\$46,887,000 for each of fis-
2 cal years 2018 through 2022”.

3 **SEC. 10005. SCREENING AND TREATMENT FOR MATERNAL**
4 **DEPRESSION.**

5 Part B of title III of the Public Health Service Act
6 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
7 tion 317L (42 U.S.C. 247b–13) the following:

8 **“SEC. 317L–1. SCREENING AND TREATMENT FOR MATER-**
9 **NAL DEPRESSION.**

10 “(a) GRANTS.—The Secretary shall make grants to
11 States to establish, improve, or maintain programs for
12 screening, assessment, and treatment services, including
13 culturally and linguistically appropriate services, as appro-
14 priate, for women who are pregnant, or who have given
15 birth within the preceding 12 months, for maternal de-
16 pression.

17 “(b) APPLICATION.—To seek a grant under this sec-
18 tion, a State shall submit an application to the Secretary
19 at such time, in such manner, and containing such infor-
20 mation as the Secretary may require. At a minimum, any
21 such application shall include explanations of—

22 “(1) how a program, or programs, will increase
23 the percentage of women screened and treated, as
24 appropriate, for maternal depression in 1 or more
25 communities; and

1 “(2) how a program, or programs, if expanded,
2 would increase access to screening and treatment
3 services for maternal depression.

4 “(c) PRIORITY.—In awarding grants under this sec-
5 tion, the Secretary may give priority to States proposing
6 to improve or enhance access to screening services for ma-
7 ternal depression in primary care settings.

8 “(d) USE OF FUNDS.—The activities eligible for
9 funding through a grant under subsection (a)—

10 “(1) shall include—

11 “(A) providing appropriate training to
12 health care providers; and

13 “(B) providing information to health care
14 providers, including information on maternal
15 depression screening, treatment, and followup
16 support services, and linkages to community-
17 based resources; and

18 “(2) may include—

19 “(A) enabling health care providers (in-
20 cluding obstetrician-gynecologists, pediatricians,
21 psychiatrists, mental health care providers, and
22 adult primary care clinicians) to provide or re-
23 ceive real-time psychiatric consultation (in-per-
24 son or remotely) to aid in the treatment of
25 pregnant and parenting women;

1 “(B) establishing linkages with and among
2 community-based resources, including mental
3 health resources, primary care resources, and
4 support groups; and

5 “(C) utilizing telehealth services for rural
6 areas and medically underserved areas (as de-
7 fined in section 330I(a)).

8 “(e) AUTHORIZATION OF APPROPRIATIONS.—To
9 carry out this section, there are authorized to be appro-
10 priated \$5,000,000 for each of fiscal years 2018 through
11 2022.”.

12 **SEC. 10006. INFANT AND EARLY CHILDHOOD MENTAL**
13 **HEALTH PROMOTION, INTERVENTION, AND**
14 **TREATMENT.**

15 Part Q of title III of the Public Health Service Act
16 (42 U.S.C. 280h et seq.) is amended by adding at the end
17 the following:

18 **“SEC. 399Z-2. INFANT AND EARLY CHILDHOOD MENTAL**
19 **HEALTH PROMOTION, INTERVENTION, AND**
20 **TREATMENT.**

21 “(a) GRANTS.—The Secretary shall—

22 “(1) award grants to eligible entities to develop,
23 maintain, or enhance infant and early childhood
24 mental health promotion, intervention, and treat-
25 ment programs, including—

1 “(A) programs for infants and children at
2 significant risk of developing, showing early
3 signs of, or having been diagnosed with mental
4 illness, including a serious emotional disturb-
5 ance; and

6 “(B) multigenerational therapy and other
7 services that support the caregiving relation-
8 ship; and

9 “(2) ensure that programs funded through
10 grants under this section are evidence-informed or
11 evidence-based models, practices, and methods that
12 are, as appropriate, culturally and linguistically ap-
13 propriate, and can be replicated in other appropriate
14 settings.

15 “(b) ELIGIBLE CHILDREN AND ENTITIES.—In this
16 section:

17 “(1) ELIGIBLE CHILD.—The term ‘eligible
18 child’ means a child from birth to not more than 12
19 years of age who—

20 “(A) is at risk for, shows early signs of, or
21 has been diagnosed with a mental illness, in-
22 cluding a serious emotional disturbance; and

23 “(B) may benefit from infant and early
24 childhood intervention or treatment programs
25 or specialized preschool or elementary school

1 programs that are evidence-based or that have
2 been scientifically demonstrated to show prom-
3 ise but would benefit from further applied de-
4 velopment.

5 “(2) ELIGIBLE ENTITY.—The term ‘eligible en-
6 tity’ means a human services agency or nonprofit in-
7 stitution that—

8 “(A) employs licensed mental health pro-
9 fessionals who have specialized training and ex-
10 perience in infant and early childhood mental
11 health assessment, diagnosis, and treatment, or
12 is accredited or approved by the appropriate
13 State agency, as applicable, to provide for chil-
14 dren from infancy to 12 years of age mental
15 health promotion, intervention, or treatment
16 services; and

17 “(B) provides services or programs de-
18 scribed in subsection (a) that are evidence-
19 based or that have been scientifically dem-
20 onstrated to show promise but would benefit
21 from further applied development.

22 “(c) APPLICATION.—An eligible entity seeking a
23 grant under subsection (a) shall submit to the Secretary
24 an application at such time, in such manner, and con-
25 taining such information as the Secretary may require.

1 “(d) USE OF FUNDS FOR EARLY INTERVENTION AND
2 TREATMENT PROGRAMS.—An eligible entity may use
3 amounts awarded under a grant under subsection (a)(1)
4 to carry out the following:

5 “(1) Provide age-appropriate mental health pro-
6 motion and early intervention services or mental ill-
7 ness treatment services, which may include special-
8 ized programs, for eligible children at significant
9 risk of developing, showing early signs of, or having
10 been diagnosed with a mental illness, including a se-
11 rious emotional disturbance. Such services may in-
12 clude social and behavioral services as well as
13 multigenerational therapy and other services that
14 support the caregiving relationship.

15 “(2) Provide training for health care profes-
16 sionals with expertise in infant and early childhood
17 mental health care with respect to appropriate and
18 relevant integration with other disciplines such as
19 primary care clinicians, early intervention specialists,
20 child welfare staff, home visitors, early care and edu-
21 cation providers, and others who work with young
22 children and families.

23 “(3) Provide mental health consultation to per-
24 sonnel of early care and education programs (includ-
25 ing licensed or regulated center-based and home-

1 based child care, home visiting, preschool special
2 education, and early intervention programs) who
3 work with children and families.

4 “(4) Provide training for mental health clini-
5 cians in infant and early childhood in promising and
6 evidence-based practices and models for infant and
7 early childhood mental health treatment and early
8 intervention, including with regard to practices for
9 identifying and treating mental illness and behav-
10 ioral disorders of infants and children resulting from
11 exposure or repeated exposure to adverse childhood
12 experiences or childhood trauma.

13 “(5) Provide age-appropriate assessment, diag-
14 nostic, and intervention services for eligible children,
15 including early mental health promotion, interven-
16 tion, and treatment services.

17 “(e) MATCHING FUNDS.—The Secretary may not
18 award a grant under this section to an eligible entity un-
19 less the eligible entity agrees, with respect to the costs to
20 be incurred by the eligible entity in carrying out the activi-
21 ties described in subsection (d), to make available non-
22 Federal contributions (in cash or in kind) toward such
23 costs in an amount that is not less than 10 percent of
24 the total amount of Federal funds provided in the grant.

1 “(f) AUTHORIZATION OF APPROPRIATIONS.—To
2 carry out this section, there are authorized to be appro-
3 priated \$20,000,000 for the period of fiscal years 2018
4 through 2022.”.

5 **TITLE XI—COMPASSIONATE**
6 **COMMUNICATION ON HIPAA**

7 **SEC. 11001. SENSE OF CONGRESS.**

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

9 (1) According to the National Survey on Drug
10 Use and Health, in 2015, there were approximately
11 9,800,000 adults in the United States with serious
12 mental illness.

13 (2) The Substance Abuse and Mental Health
14 Services Administration defines the term “serious
15 mental illness” as an illness affecting individuals 18
16 years of age or older as having, at any time in the
17 past year, a diagnosable mental, behavioral, or emo-
18 tional disorder that results in serious functional im-
19 pairment and substantially interferes with or limits
20 one or more major life activities.

21 (3) In reporting on the incidence of serious
22 mental illness, the Substance Abuse and Mental
23 Health Services Administration includes major de-
24 pression, schizophrenia, bipolar disorder, and other
25 mental disorders that cause serious impairment.

1 (4) Adults with a serious mental illness are at
2 a higher risk for chronic physical illnesses and pre-
3 mature death.

4 (5) According to the World Health Organiza-
5 tion, adults with a serious mental illness have life-
6 spans that are 10 to 25 years shorter than those
7 without serious mental illness. The vast majority of
8 these deaths are due to chronic physical medical con-
9 ditions, such as cardiovascular, respiratory, and in-
10 fectionous diseases, as well as diabetes and hyper-
11 tension.

12 (6) According to the World Health Organiza-
13 tion, the majority of deaths of adults with a serious
14 mental illness that are due to physical medical con-
15 ditions are preventable.

16 (7) Supported decision making can facilitate
17 care decisions in areas where serious mental illness
18 may impact the capacity of an individual to deter-
19 mine a course of treatment while still allowing the
20 individual to make decisions independently.

21 (8) Help should be provided to adults with a se-
22 rious mental illness to address their acute or chronic
23 physical illnesses, make informed choices about
24 treatment, and understand and follow through with
25 appropriate treatment.

1 (9) There is confusion in the health care com-
2 munity regarding permissible practices under the
3 regulations promulgated under the Health Insurance
4 Portability and Accountability Act of 1996 (com-
5 monly known as “HIPAA”). This confusion may
6 hinder appropriate communication of health care in-
7 formation or treatment preferences with appropriate
8 caregivers.

9 (b) SENSE OF CONGRESS.—It is the sense of Con-
10 gress that clarification is needed regarding the privacy
11 rule promulgated under section 264(c) of the Health In-
12 surance Portability and Accountability Act of 1996 (42
13 U.S.C. 1320d–2 note) regarding existing permitted uses
14 and disclosures of health information by health care pro-
15 fessionals to communicate with caregivers of adults with
16 a serious mental illness to facilitate treatment.

17 **SEC. 11002. CONFIDENTIALITY OF RECORDS.**

18 Not later than 1 year after the date on which the
19 Secretary of Health and Human Services (in this title re-
20 ferred to as the “Secretary”) first finalizes regulations up-
21 dating part 2 of title 42, Code of Federal Regulations,
22 relating to confidentiality of alcohol and drug abuse pa-
23 tient records, after the date of enactment of this Act, the
24 Secretary shall convene relevant stakeholders to determine

1 the effect of such regulations on patient care, health out-
2 comes, and patient privacy.

3 **SEC. 11003. CLARIFICATION ON PERMITTED USES AND DIS-**
4 **CLOSURES OF PROTECTED HEALTH INFOR-**
5 **MATION.**

6 (a) IN GENERAL.—The Secretary, acting through the
7 Director of the Office for Civil Rights, shall ensure that
8 health care providers, professionals, patients and their
9 families, and others involved in mental or substance use
10 disorder treatment have adequate, accessible, and easily
11 comprehensible resources relating to appropriate uses and
12 disclosures of protected health information under the reg-
13 ulations promulgated under section 264(c) of the Health
14 Insurance Portability and Accountability Act of 1996 (42
15 U.S.C. 1320d–2 note).

16 (b) GUIDANCE.—

17 (1) ISSUANCE.—In carrying out subsection (a),
18 not later than 1 year after the date of enactment of
19 this section, the Secretary shall issue guidance clari-
20 fying the circumstances under which, consistent with
21 regulations promulgated under section 264(c) of the
22 Health Insurance Portability and Accountability Act
23 of 1996, a health care provider or covered entity
24 may use or disclose protected health information.

1 (2) CIRCUMSTANCES ADDRESSED.—The guid-
2 ance issued under this section shall address cir-
3 cumstances including those that—

4 (A) require the consent of the patient;

5 (B) require providing the patient with an
6 opportunity to object;

7 (C) are based on the exercise of profes-
8 sional judgment regarding whether the patient
9 would object when the opportunity to object
10 cannot practicably be provided because of the
11 incapacity of the patient or an emergency treat-
12 ment circumstance; and

13 (D) are determined, based on the exercise
14 of professional judgment, to be in the best in-
15 terest of the patient when the patient is not
16 present or otherwise incapacitated.

17 (3) COMMUNICATION WITH FAMILY MEMBERS
18 AND CAREGIVERS.—In addressing the circumstances
19 described in paragraph (2), the guidance issued
20 under this section shall clarify permitted uses or dis-
21 closures of protected health information for purposes
22 of—

23 (A) communicating with a family member
24 of the patient, caregiver of the patient, or other
25 individual, to the extent that such family mem-

1 ber, caregiver, or individual is involved in the
2 care of the patient;

3 (B) in the case that the patient is an
4 adult, communicating with a family member of
5 the patient, caregiver of the patient, or other
6 individual involved in the care of the patient;

7 (C) in the case that the patient is a minor,
8 communicating with the parent or caregiver of
9 the patient;

10 (D) involving the family members or care-
11 givers of the patient, or others involved in the
12 patient's care or care plan, including facilitating
13 treatment and medication adherence;

14 (E) listening to the patient, or receiving in-
15 formation with respect to the patient from the
16 family or caregiver of the patient;

17 (F) communicating with family members
18 of the patient, caregivers of the patient, law en-
19 forcement, or others when the patient presents
20 a serious and imminent threat of harm to self
21 or others; and

22 (G) communicating to law enforcement and
23 family members or caregivers of the patient
24 about the admission of the patient to receive
25 care at, or the release of a patient from, a facil-

1 ity for an emergency psychiatric hold or invol-
2 untary treatment.

3 **SEC. 11004. DEVELOPMENT AND DISSEMINATION OF**
4 **MODEL TRAINING PROGRAMS.**

5 (a) INITIAL PROGRAMS AND MATERIALS.—Not later
6 than 1 year after the date of the enactment of this Act,
7 the Secretary, in consultation with appropriate experts,
8 shall identify the following model programs and materials,
9 or (in the case that no such programs or materials exist)
10 recognize private or public entities to develop and dissemi-
11 nate each of the following:

12 (1) Model programs and materials for training
13 health care providers (including physicians, emer-
14 gency medical personnel, psychiatrists, including
15 child and adolescent psychiatrists, psychologists,
16 counselors, therapists, nurse practitioners, physician
17 assistants, behavioral health facilities and clinics,
18 care managers, and hospitals, including individuals
19 such as general counsels or regulatory compliance
20 staff who are responsible for establishing provider
21 privacy policies) regarding the permitted uses and
22 disclosures, consistent with the standards governing
23 the privacy and security of individually identifiable
24 health information promulgated by the Secretary
25 under part C of title XI of the Social Security Act

1 (42 U.S.C. 1320d et seq.) and regulations promul-
2 gated under section 264(c) of the Health Insurance
3 Portability and Accountability Act of 1996 (42
4 U.S.C. 1320d–2 note) and such part C, of the pro-
5 tected health information of patients seeking or un-
6 dergoing mental or substance use disorder treat-
7 ment.

8 (2) A model program and materials for training
9 patients and their families regarding their rights to
10 protect and obtain information under the standards
11 and regulations specified in paragraph (1).

12 (b) PERIODIC UPDATES.—The Secretary shall—

13 (1) periodically review and update the model
14 programs and materials identified or developed
15 under subsection (a); and

16 (2) disseminate the updated model programs
17 and materials to the individuals described in sub-
18 section (a).

19 (c) COORDINATION.—The Secretary shall carry out
20 this section in coordination with the Director of the Office
21 for Civil Rights within the Department of Health and
22 Human Services, the Assistant Secretary for Mental
23 Health and Substance Use, the Administrator of the
24 Health Resources and Services Administration, and the

1 heads of other relevant agencies within the Department
2 of Health and Human Services.

3 (d) INPUT OF CERTAIN ENTITIES.—In identifying,
4 reviewing, or updating the model programs and materials
5 under subsections (a) and (b), the Secretary shall solicit
6 the input of relevant national, State, and local associa-
7 tions; medical societies; licensing boards; providers of men-
8 tal and substance use disorder treatment; organizations
9 with expertise on domestic violence, sexual assault, elder
10 abuse, and child abuse; and organizations representing pa-
11 tients and consumers and the families of patients and con-
12 sumers.

13 (e) FUNDING.—There are authorized to be appro-
14 priated to carry out this section—

15 (1) \$4,000,000 for fiscal year 2018;

16 (2) \$2,000,000 for each of fiscal years 2019
17 and 2020; and

18 (3) \$1,000,000 for each of fiscal years 2021
19 and 2022.

1 **TITLE XII—MEDICAID MENTAL**
2 **HEALTH COVERAGE**

3 **SEC. 12001. RULE OF CONSTRUCTION RELATED TO MED-**
4 **ICAID COVERAGE OF MENTAL HEALTH SERV-**
5 **ICES AND PRIMARY CARE SERVICES FUR-**
6 **NISHED ON THE SAME DAY.**

7 Nothing in title XIX of the Social Security Act (42
8 U.S.C. 1396 et seq.) shall be construed as prohibiting sep-
9 arate payment under the State plan under such title (or
10 under a waiver of the plan) for the provision of a mental
11 health service or primary care service under such plan,
12 with respect to an individual, because such service is—

13 (1) a primary care service furnished to the indi-
14 vidual by a provider at a facility on the same day
15 a mental health service is furnished to such indi-
16 vidual by such provider (or another provider) at the
17 facility; or

18 (2) a mental health service furnished to the in-
19 dividual by a provider at a facility on the same day
20 a primary care service is furnished to such individual
21 by such provider (or another provider) at the facil-
22 ity.

1 **SEC. 12002. STUDY AND REPORT RELATED TO MEDICAID**
2 **MANAGED CARE REGULATION.**

3 (a) STUDY.—The Secretary of Health and Human
4 Services, acting through the Administrator of the Centers
5 for Medicare & Medicaid Services, shall conduct a study
6 on coverage under the Medicaid program under title XIX
7 of the Social Security Act (42 U.S.C. 1396 et seq.) of serv-
8 ices provided through a medicaid managed care organiza-
9 tion (as defined in section 1903(m) of such Act (42 U.S.C.
10 1396b(m)) or a prepaid inpatient health plan (as defined
11 in section 438.2 of title 42, Code of Federal Regulations
12 (or any successor regulation)) with respect to individuals
13 over the age of 21 and under the age of 65 for the treat-
14 ment of a mental health disorder in institutions for mental
15 diseases (as defined in section 1905(i) of such Act (42
16 U.S.C. 1396d(i))). Such study shall include information
17 on the following:

18 (1) The extent to which States, including the
19 District of Columbia and each territory or possession
20 of the United States, are providing capitated pay-
21 ments to such organizations or plans for enrollees
22 who are receiving services in institutions for mental
23 diseases.

24 (2) The number of individuals receiving medical
25 assistance under a State plan under such title XIX,
26 or a waiver of such plan, who receive services in in-

1 stitutions for mental diseases through such organiza-
2 tions and plans.

3 (3) The range of and average number of
4 months, and the length of stay during such months,
5 that such individuals are receiving such services in
6 such institutions.

7 (4) How such organizations or plans determine
8 when to provide for the furnishing of such services
9 through an institution for mental diseases in lieu of
10 other benefits (including the full range of commu-
11 nity-based services) under their contract with the
12 State agency administering the State plan under
13 such title XIX, or a waiver of such plan, to address
14 psychiatric or substance use disorder treatment.

15 (5) The extent to which the provision of serv-
16 ices within such institutions has affected the
17 capitated payments for such organizations or plans.

18 (b) REPORT.—Not later than 3 years after the date
19 of the enactment of this Act, the Secretary shall submit
20 to Congress a report on the study conducted under sub-
21 section (a).

22 **SEC. 12003. GUIDANCE ON OPPORTUNITIES FOR INNOVA-**
23 **TION.**

24 Not later than 1 year after the date of the enactment
25 of this Act, the Administrator of the Centers for Medicare

1 & Medicaid Services shall issue a State Medicaid Director
2 letter regarding opportunities to design innovative service
3 delivery systems, including systems for providing commu-
4 nity-based services, for adults with a serious mental illness
5 or children with a serious emotional disturbance who are
6 receiving medical assistance under title XIX of the Social
7 Security Act (42 U.S.C. 1396 et seq.). The letter shall
8 include opportunities for demonstration projects under
9 section 1115 of such Act (42 U.S.C. 1315) to improve care
10 for such adults and children.

11 **SEC. 12004. STUDY AND REPORT ON MEDICAID EMERGENCY**
12 **PSYCHIATRIC DEMONSTRATION PROJECT.**

13 (a) COLLECTION OF INFORMATION.—The Secretary
14 of Health and Human Services, acting through the Ad-
15 ministrator of the Centers for Medicare & Medicaid Serv-
16 ices, shall, to the extent practical and data is available,
17 with respect to each State that has participated in the
18 demonstration project established under section 2707 of
19 the Patient Protection and Affordable Care Act (42
20 U.S.C. 1396a note), collect from each such State informa-
21 tion on the following:

22 (1) The number of institutions for mental dis-
23 eases (as defined in section 1905(i) of the Social Se-
24 curity Act (42 U.S.C. 1396d(i))) and beds in such
25 institutions that received payment for the provision

1 of services to individuals who receive medical assist-
2 ance under a State plan under the Medicaid pro-
3 gram under title XIX of the Social Security Act (42
4 U.S.C. 1396 et seq.) (or under a waiver of such
5 plan) through the demonstration project in each
6 such State as compared to the total number of insti-
7 tutions for mental diseases and beds in the State.

8 (2) The extent to which there is a reduction in
9 expenditures under the Medicaid program under title
10 XIX of the Social Security Act (42 U.S.C. 1396 et
11 seq.) or other spending on the full continuum of
12 physical or mental health care for individuals who
13 receive treatment in an institution for mental dis-
14 eases under the demonstration project, including
15 outpatient, inpatient, emergency, and ambulatory
16 care, that is attributable to such individuals receiv-
17 ing treatment in institutions for mental diseases
18 under the demonstration project.

19 (3) The number of forensic psychiatric hos-
20 pitals, the number of beds in such hospitals, and the
21 number of forensic psychiatric beds in other hos-
22 pitals in such State, based on the most recent data
23 available, to the extent practical, as determined by
24 such Administrator.

1 (4) The amount of any disproportionate share
2 hospital payments under section 1923 of the Social
3 Security Act (42 U.S.C. 1396r-4) that institutions
4 for mental diseases in the State received during the
5 period beginning on July 1, 2012, and ending on
6 June 30, 2015, and the extent to which the dem-
7 onstration project reduced the amount of such pay-
8 ments.

9 (5) The most recent data regarding all facilities
10 or sites in the State in which any adults with a seri-
11 ous mental illness who are receiving medical assist-
12 ance under a State plan under the Medicaid pro-
13 gram under title XIX of the Social Security Act (42
14 U.S.C. 1396 et seq.) (or under a waiver of such
15 plan) are treated during the period referred to in
16 paragraph (4), to the extent practical, as determined
17 by the Administrator, including—

18 (A) the types of such facilities or sites
19 (such as an institution for mental diseases, a
20 hospital emergency department, or other inpa-
21 tient hospital);

22 (B) the average length of stay in such a
23 facility or site by such an individual,
24 disaggregated by facility type; and

1 (C) the payment rate under the State plan
2 (or a waivers of such plan) for services fur-
3 nished to such an individual for that treatment,
4 disaggregated by facility type, during the period
5 in which the demonstration project is in oper-
6 ation.

7 (6) The extent to which the utilization of hos-
8 pital emergency departments during the period in
9 which the demonstration project was is in operation
10 differed, with respect to individuals who are receiv-
11 ing medical assistance under a State plan under the
12 Medicaid program under title XIX of the Social Se-
13 curity Act (42 U.S.C. 1396 et seq.) (or under a
14 waiver of such plan), between—

15 (A) those individuals who received treat-
16 ment in an institution for mental diseases
17 under the demonstration project;

18 (B) those individuals who met the eligi-
19 bility requirements for the demonstration
20 project but who did not receive treatment in an
21 institution for mental diseases under the dem-
22 onstration project; and

23 (C) those adults with a serious mental ill-
24 ness who did not meet such eligibility require-

1 ments and did not receive treatment for such
2 illness in an institution for mental diseases.

3 (b) REPORT.—Not later than 2 years after the date
4 of the enactment of this Act, the Secretary of Health and
5 Human Services shall submit to Congress a report that
6 summarizes and analyzes the information collected under
7 subsection (a). Such report may be submitted as part of
8 the report required under section 2707(f) of the Patient
9 Protection and Affordable Care Act (42 U.S.C. 1396a
10 note) or separately.

11 **SEC. 12005. PROVIDING EPSDT SERVICES TO CHILDREN IN**
12 **IMDS.**

13 (a) IN GENERAL.—Section 1905(a)(16) of the Social
14 Security Act (42 U.S.C. 1396d(a)(16)) is amended—

15 (1) by striking “effective January 1, 1973” and
16 inserting “(A) effective January 1, 1973”; and

17 (2) by inserting before the semicolon at the end
18 the following: “, and, (B) for individuals receiving
19 services described in subparagraph (A), early and
20 periodic screening, diagnostic, and treatment serv-
21 ices (as defined in subsection (r)), whether or not
22 such screening, diagnostic, and treatment services
23 are furnished by the provider of the services de-
24 scribed in such subparagraph”.

1 (b) EFFECTIVE DATE.—The amendments made by
2 subsection (a) shall apply with respect to items and serv-
3 ices furnished in calendar quarters beginning on or after
4 January 1, 2019.

5 **SEC. 12006. ELECTRONIC VISIT VERIFICATION SYSTEM RE-**
6 **QUIRED FOR PERSONAL CARE SERVICES AND**
7 **HOME HEALTH CARE SERVICES UNDER MED-**
8 **ICAID.**

9 (a) IN GENERAL.—Section 1903 of the Social Secu-
10 rity Act (42 U.S.C. 1396b) is amended by inserting after
11 subsection (k) the following new subsection:

12 “(l)(1) Subject to paragraphs (3) and (4), with re-
13 spect to any amount expended for personal care services
14 or home health care services requiring an in-home visit
15 by a provider that are provided under a State plan under
16 this title (or under a waiver of the plan) and furnished
17 in a calendar quarter beginning on or after January 1,
18 2019 (or, in the case of home health care services, on or
19 after January 1, 2023), unless a State requires the use
20 of an electronic visit verification system for such services
21 furnished in such quarter under the plan or such waiver,
22 the Federal medical assistance percentage shall be re-
23 duced—

24 “(A) in the case of personal care services—

1 “(i) for calendar quarters in 2019 and
2 2020, by .25 percentage points;

3 “(ii) for calendar quarters in 2021, by .5
4 percentage points;

5 “(iii) for calendar quarters in 2022, by .75
6 percentage points; and

7 “(iv) for calendar quarters in 2023 and
8 each year thereafter, by 1 percentage point; and

9 “(B) in the case of home health care services—

10 “(i) for calendar quarters in 2023 and
11 2024, by .25 percentage points;

12 “(ii) for calendar quarters in 2025, by .5
13 percentage points;

14 “(iii) for calendar quarters in 2026, by .75
15 percentage points; and

16 “(iv) for calendar quarters in 2027 and
17 each year thereafter, by 1 percentage point.

18 “(2) Subject to paragraphs (3) and (4), in imple-
19 menting the requirement for the use of an electronic visit
20 verification system under paragraph (1), a State shall—

21 “(A) consult with agencies and entities that
22 provide personal care services, home health care
23 services, or both under the State plan (or under a
24 waiver of the plan) to ensure that such system—

25 “(i) is minimally burdensome;

1 “(ii) takes into account existing best prac-
2 tices and electronic visit verification systems in
3 use in the State; and

4 “(iii) is conducted in accordance with the
5 requirements of HIPAA privacy and security
6 law (as defined in section 3009 of the Public
7 Health Service Act);

8 “(B) take into account a stakeholder process
9 that includes input from beneficiaries, family care-
10 givers, individuals who furnish personal care services
11 or home health care services, and other stakeholders,
12 as determined by the State in accordance with guid-
13 ance from the Secretary; and

14 “(C) ensure that individuals who furnish per-
15 sonal care services, home health care services, or
16 both under the State plan (or under a waiver of the
17 plan) are provided the opportunity for training on
18 the use of such system.

19 “(3) Paragraphs (1) and (2) shall not apply in the
20 case of a State that, as of the date of the enactment of
21 this subsection, requires the use of any system for the elec-
22 tronic verification of visits conducted as part of both per-
23 sonal care services and home health care services, so long
24 as the State continues to require the use of such system
25 with respect to the electronic verification of such visits.

1 “(4)(A) In the case of a State described in subpara-
2 graph (B), the reduction under paragraph (1) shall not
3 apply—

4 “(i) in the case of personal care services, for
5 calendar quarters in 2019; and

6 “(ii) in the case of home health care services,
7 for calendar quarters in 2023.

8 “(B) For purposes of subparagraph (A), a State de-
9 scribed in this subparagraph is a State that demonstrates
10 to the Secretary that the State—

11 “(i) has made a good faith effort to comply
12 with the requirements of paragraphs (1) and (2) (in-
13 cluding by taking steps to adopt the technology used
14 for an electronic visit verification system); and

15 “(ii) in implementing such a system, has en-
16 countered unavoidable system delays.

17 “(5) In this subsection:

18 “(A) The term ‘electronic visit verification sys-
19 tem’ means, with respect to personal care services or
20 home health care services, a system under which vis-
21 its conducted as part of such services are electroni-
22 cally verified with respect to—

23 “(i) the type of service performed;

24 “(ii) the individual receiving the service;

25 “(iii) the date of the service;

1 “(iv) the location of service delivery;

2 “(v) the individual providing the service;

3 and

4 “(vi) the time the service begins and ends.

5 “(B) The term ‘home health care services’
6 means services described in section 1905(a)(7) pro-
7 vided under a State plan under this title (or under
8 a waiver of the plan).

9 “(C) The term ‘personal care services’ means
10 personal care services provided under a State plan
11 under this title (or under a waiver of the plan), in-
12 cluding services provided under section 1905(a)(24),
13 1915(e), 1915(i), 1915(j), or 1915(k) or under a
14 wavier under section 1115.

15 “(6)(A) In the case in which a State requires personal
16 care service and home health care service providers to uti-
17 lize an electronic visit verification system operated by the
18 State or a contractor on behalf of the State, the Secretary
19 shall pay to the State, for each quarter, an amount equal
20 to 90 per centum of so much of the sums expended during
21 such quarter as are attributable to the design, develop-
22 ment, or installation of such system, and 75 per centum
23 of so much of the sums for the operation and maintenance
24 of such system.

1 “(B) Subparagraph (A) shall not apply in the case
2 in which a State requires personal care service and home
3 health care service providers to utilize an electronic visit
4 verification system that is not operated by the State or
5 a contractor on behalf of the State.”.

6 (b) COLLECTION AND DISSEMINATION OF BEST
7 PRACTICES.—Not later than January 1, 2018, the Sec-
8 retary of Health and Human Services shall, with respect
9 to electronic visit verification systems (as defined in sub-
10 section (l)(5) of section 1903 of the Social Security Act
11 (42 U.S.C. 1396b), as inserted by subsection (a)), collect
12 and disseminate best practices to State Medicaid Directors
13 with respect to—

14 (1) training individuals who furnish personal
15 care services, home health care services, or both
16 under the State plan under title XIX of such Act (or
17 under a waiver of the plan) on such systems and the
18 operation of such systems and the prevention of
19 fraud with respect to the provision of personal care
20 services or home health care services (as defined in
21 such subsection (l)(5)); and

22 (2) the provision of notice and educational ma-
23 terials to family caregivers and beneficiaries with re-
24 spect to the use of such electronic visit verification
25 systems and other means to prevent such fraud.

1 (c) RULES OF CONSTRUCTION.—

2 (1) NO EMPLOYER-EMPLOYEE RELATIONSHIP
3 ESTABLISHED.—Nothing in the amendment made by
4 this section may be construed as establishing an em-
5 ployer-employee relationship between the agency or
6 entity that provides for personal care services or
7 home health care services and the individuals who,
8 under a contract with such an agency or entity, fur-
9 nish such services for purposes of part 552 of title
10 29, Code of Federal Regulations (or any successor
11 regulations).

12 (2) NO PARTICULAR OR UNIFORM ELECTRONIC
13 VISIT VERIFICATION SYSTEM REQUIRED.—Nothing
14 in the amendment made by this section shall be con-
15 strued to require the use of a particular or uniform
16 electronic visit verification system (as defined in sub-
17 section (l)(5) of section 1903 of the Social Security
18 Act (42 U.S.C. 1396b), as inserted by subsection
19 (a)) by all agencies or entities that provide personal
20 care services or home health care under a State plan
21 under title XIX of the Social Security Act (or under
22 a waiver of the plan) (42 U.S.C. 1396 et seq.).

23 (3) NO LIMITS ON PROVISION OF CARE.—Noth-
24 ing in the amendment made by this section may be
25 construed to limit, with respect to personal care

1 services or home health care services provided under
2 a State plan under title XIX of the Social Security
3 Act (or under a waiver of the plan) (42 U.S.C. 1396
4 et seq.), provider selection, constrain beneficiaries'
5 selection of a caregiver, or impede the manner in
6 which care is delivered.

7 (4) NO PROHIBITION ON STATE QUALITY MEAS-
8 URES REQUIREMENTS.—Nothing in the amendment
9 made by this section shall be construed as prohib-
10 iting a State, in implementing an electronic visit
11 verification system (as defined in subsection (l)(5) of
12 section 1903 of the Social Security Act (42 U.S.C.
13 1396b), as inserted by subsection (a)), from estab-
14 lishing requirements related to quality measures for
15 such system.

16 **TITLE XIII—MENTAL HEALTH**
17 **PARITY**

18 **SEC. 13001. ENHANCED COMPLIANCE WITH MENTAL**
19 **HEALTH AND SUBSTANCE USE DISORDER**
20 **COVERAGE REQUIREMENTS.**

21 (a) COMPLIANCE PROGRAM GUIDANCE DOCU-
22 MENT.—Section 2726(a) of the Public Health Service Act
23 (42 U.S.C. 300gg–26(a)) is amended by adding at the end
24 the following:

1 “(6) COMPLIANCE PROGRAM GUIDANCE DOCU-
2 MENT.—

3 “(A) IN GENERAL.—Not later than 12
4 months after the date of enactment of the
5 Helping Families in Mental Health Crisis Re-
6 form Act of 2016, the Secretary, the Secretary
7 of Labor, and the Secretary of the Treasury, in
8 consultation with the Inspector General of the
9 Department of Health and Human Services, the
10 Inspector General of the Department of Labor,
11 and the Inspector General of the Department of
12 the Treasury, shall issue a compliance program
13 guidance document to help improve compliance
14 with this section, section 712 of the Employee
15 Retirement Income Security Act of 1974, and
16 section 9812 of the Internal Revenue Code of
17 1986, as applicable. In carrying out this para-
18 graph, the Secretaries may take into consider-
19 ation the 2016 publication of the Department
20 of Health and Human Services and the Depart-
21 ment of Labor, entitled ‘Warning Signs - Plan
22 or Policy Non-Quantitative Treatment Limita-
23 tions (NQTLs) that Require Additional Anal-
24 ysis to Determine Mental Health Parity Com-
25 pliance’.

1 “(B) EXAMPLES ILLUSTRATING COMPLI-
2 ANCE AND NONCOMPLIANCE.—

3 “(i) IN GENERAL.—The compliance
4 program guidance document required
5 under this paragraph shall provide illus-
6 trative, de-identified examples (that do not
7 disclose any protected health information
8 or individually identifiable information) of
9 previous findings of compliance and non-
10 compliance with this section, section 712 of
11 the Employee Retirement Income Security
12 Act of 1974, or section 9812 of the Inter-
13 nal Revenue Code of 1986, as applicable,
14 based on investigations of violations of
15 such sections, including—

16 “(I) examples illustrating re-
17 quirements for information disclosures
18 and nonquantitative treatment limita-
19 tions; and

20 “(II) descriptions of the viola-
21 tions uncovered during the course of
22 such investigations.

23 “(ii) NONQUANTITATIVE TREATMENT
24 LIMITATIONS.—To the extent that any ex-
25 ample described in clause (i) involves a

1 finding of compliance or noncompliance
2 with regard to any requirement for non-
3 quantitative treatment limitations, the ex-
4 ample shall provide sufficient detail to fully
5 explain such finding, including a full de-
6 scription of the criteria involved for ap-
7 proving medical and surgical benefits and
8 the criteria involved for approving mental
9 health and substance use disorder benefits.

10 “(iii) ACCESS TO ADDITIONAL INFOR-
11 MATION REGARDING COMPLIANCE.—In de-
12 veloping and issuing the compliance pro-
13 gram guidance document required under
14 this paragraph, the Secretaries specified in
15 subparagraph (A)—

16 “(I) shall enter into interagency
17 agreements with the Inspector Gen-
18 eral of the Department of Health and
19 Human Services, the Inspector Gen-
20 eral of the Department of Labor, and
21 the Inspector General of the Depart-
22 ment of the Treasury to share find-
23 ings of compliance and noncompliance
24 with this section, section 712 of the
25 Employee Retirement Income Security

1 Act of 1974, or section 9812 of the
2 Internal Revenue Code of 1986, as
3 applicable; and

4 “(II) shall seek to enter into an
5 agreement with a State to share infor-
6 mation on findings of compliance and
7 noncompliance with this section, sec-
8 tion 712 of the Employee Retirement
9 Income Security Act of 1974, or sec-
10 tion 9812 of the Internal Revenue
11 Code of 1986, as applicable.

12 “(C) RECOMMENDATIONS.—The compli-
13 ance program guidance document shall include
14 recommendations to advance compliance with
15 this section, section 712 of the Employee Re-
16 tirement Income Security Act of 1974, or sec-
17 tion 9812 of the Internal Revenue Code of
18 1986, as applicable, and encourage the develop-
19 ment and use of internal controls to monitor
20 adherence to applicable statutes, regulations,
21 and program requirements. Such internal con-
22 trols may include illustrative examples of non-
23 quantitative treatment limitations on mental
24 health and substance use disorder benefits,
25 which may fail to comply with this section, sec-

1 tion 712 of the Employee Retirement Income
2 Security Act of 1974, or section 9812 of the In-
3 ternal Revenue Code of 1986, as applicable, in
4 relation to nonquantitative treatment limita-
5 tions on medical and surgical benefits.

6 “(D) UPDATING THE COMPLIANCE PRO-
7 GRAM GUIDANCE DOCUMENT.—The Secretary,
8 the Secretary of Labor, and the Secretary of
9 the Treasury, in consultation with the Inspector
10 General of the Department of Health and
11 Human Services, the Inspector General of the
12 Department of Labor, and the Inspector Gen-
13 eral of the Department of the Treasury, shall
14 update the compliance program guidance docu-
15 ment every 2 years to include illustrative, de-
16 identified examples (that do not disclose any
17 protected health information or individually
18 identifiable information) of previous findings of
19 compliance and noncompliance with this sec-
20 tion, section 712 of the Employee Retirement
21 Income Security Act of 1974, or section 9812
22 of the Internal Revenue Code of 1986, as appli-
23 cable.”.

24 (b) ADDITIONAL GUIDANCE.—Section 2726(a) of the
25 Public Health Service Act (42 U.S.C. 300gg–26(a)), as

1 amended by subsection (a), is further amended by adding
2 at the end the following:

3 “(7) ADDITIONAL GUIDANCE.—

4 “(A) IN GENERAL.—Not later than 12
5 months after the date of enactment of the
6 Helping Families in Mental Health Crisis Re-
7 form Act of 2016, the Secretary, the Secretary
8 of Labor, and the Secretary of the Treasury
9 shall issue guidance to group health plans and
10 health insurance issuers offering group or indi-
11 vidual health insurance coverage to assist such
12 plans and issuers in satisfying the requirements
13 of this section, section 712 of the Employee Re-
14 tirement Income Security Act of 1974, or sec-
15 tion 9812 of the Internal Revenue Code of
16 1986, as applicable.

17 “(B) DISCLOSURE.—

18 “(i) GUIDANCE FOR PLANS AND
19 ISSUERS.—The guidance issued under this
20 paragraph shall include clarifying informa-
21 tion and illustrative examples of methods
22 that group health plans and health insur-
23 ance issuers offering group or individual
24 health insurance coverage may use for dis-
25 closing information to ensure compliance

1 with the requirements under this section,
2 section 712 of the Employee Retirement
3 Income Security Act of 1974, or section
4 9812 of the Internal Revenue Code of
5 1986, as applicable, (and any regulations
6 promulgated pursuant to such sections, as
7 applicable).

8 “(ii) DOCUMENTS FOR PARTICIPANTS,
9 BENEFICIARIES, CONTRACTING PROVIDERS,
10 OR AUTHORIZED REPRESENTATIVES.—The
11 guidance issued under this paragraph shall
12 include clarifying information and illus-
13 trative examples of methods that group
14 health plans and health insurance issuers
15 offering group or individual health insur-
16 ance coverage may use to provide any par-
17 ticipant, beneficiary, contracting provider,
18 or authorized representative, as applicable,
19 with documents containing information
20 that the health plans or issuers are re-
21 quired to disclose to participants, bene-
22 ficiaries, contracting providers, or author-
23 ized representatives to ensure compliance
24 with this section, section 712 of the Em-
25 ployee Retirement Income Security Act of

1 1974, or section 9812 of the Internal Rev-
2 enue Code of 1986, as applicable, compli-
3 ance with any regulation issued pursuant
4 to such respective section, or compliance
5 with any other applicable law or regula-
6 tion. Such guidance shall include informa-
7 tion that is comparative in nature with re-
8 spect to—

9 “(I) nonquantitative treatment
10 limitations for both medical and sur-
11 gical benefits and mental health and
12 substance use disorder benefits;

13 “(II) the processes, strategies,
14 evidentiary standards, and other fac-
15 tors used to apply the limitations de-
16 scribed in subclause (I); and

17 “(III) the application of the limi-
18 tations described in subclause (I) to
19 ensure that such limitations are ap-
20 plied in parity with respect to both
21 medical and surgical benefits and
22 mental health and substance use dis-
23 order benefits.

24 “(C) NONQUANTITATIVE TREATMENT LIM-
25 ITATIONS.—The guidance issued under this

1 paragraph shall include clarifying information
2 and illustrative examples of methods, processes,
3 strategies, evidentiary standards, and other fac-
4 tors that group health plans and health insur-
5 ance issuers offering group or individual health
6 insurance coverage may use regarding the de-
7 velopment and application of nonquantitative
8 treatment limitations to ensure compliance with
9 this section, section 712 of the Employee Re-
10 tirement Income Security Act of 1974, or sec-
11 tion 9812 of the Internal Revenue Code of
12 1986, as applicable, (and any regulations pro-
13 mulgated pursuant to such respective section),
14 including—

15 “(i) examples of methods of deter-
16 mining appropriate types of nonquantita-
17 tive treatment limitations with respect to
18 both medical and surgical benefits and
19 mental health and substance use disorder
20 benefits, including nonquantitative treat-
21 ment limitations pertaining to—

22 “(I) medical management stand-
23 ards based on medical necessity or ap-
24 propriateness, or whether a treatment
25 is experimental or investigative;

1 “(II) limitations with respect to
2 prescription drug formulary design;
3 and

4 “(III) use of fail-first or step
5 therapy protocols;

6 “(ii) examples of methods of deter-
7 mining—

8 “(I) network admission standards
9 (such as credentialing); and

10 “(II) factors used in provider re-
11 imbursement methodologies (such as
12 service type, geographic market, de-
13 mand for services, and provider sup-
14 ply, practice size, training, experience,
15 and licensure) as such factors apply to
16 network adequacy;

17 “(iii) examples of sources of informa-
18 tion that may serve as evidentiary stand-
19 ards for the purposes of making deter-
20 minations regarding the development and
21 application of nonquantitative treatment
22 limitations;

23 “(iv) examples of specific factors, and
24 the evidentiary standards used to evaluate
25 such factors, used by such plans or issuers

1 in performing a nonquantitative treatment
2 limitation analysis;

3 “(v) examples of how specific evi-
4 dentiary standards may be used to deter-
5 mine whether treatments are considered
6 experimental or investigative;

7 “(vi) examples of how specific evi-
8 dentiary standards may be applied to each
9 service category or classification of bene-
10 fits;

11 “(vii) examples of methods of reach-
12 ing appropriate coverage determinations
13 for new mental health or substance use
14 disorder treatments, such as evidence-
15 based early intervention programs for indi-
16 viduals with a serious mental illness and
17 types of medical management techniques;

18 “(viii) examples of methods of reach-
19 ing appropriate coverage determinations
20 for which there is an indirect relationship
21 between the covered mental health or sub-
22 stance use disorder benefit and a tradi-
23 tional covered medical and surgical benefit,
24 such as residential treatment or hos-

1 pitalizations involving voluntary or involun-
2 tary commitment; and

3 “(ix) additional illustrative examples
4 of methods, processes, strategies, evi-
5 dentiary standards, and other factors for
6 which the Secretary determines that addi-
7 tional guidance is necessary to improve
8 compliance with this section, section 712 of
9 the Employee Retirement Income Security
10 Act of 1974, or section 9812 of the Inter-
11 nal Revenue Code of 1986, as applicable.

12 “(D) PUBLIC COMMENT.—Prior to issuing
13 any final guidance under this paragraph, the
14 Secretary shall provide a public comment period
15 of not less than 60 days during which any
16 member of the public may provide comments on
17 a draft of the guidance.”.

18 (c) AVAILABILITY OF PLAN INFORMATION.—

19 (1) SOLICITATION OF PUBLIC FEEDBACK.—Not
20 later than 6 months after the date of enactment of
21 this Act, the Secretary of Health and Human Serv-
22 ices, the Secretary of Labor, and the Secretary of
23 the Treasury shall solicit feedback from the public
24 on how the disclosure request process for documents
25 containing information that health plans or health

1 insurance issuers are required under Federal or
2 State law to disclose to participants, beneficiaries,
3 contracting providers, or authorized representatives
4 to ensure compliance with existing mental health
5 parity and addiction equity requirements can be im-
6 proved while continuing to ensure consumers' rights
7 to access all information required by Federal or
8 State law to be disclosed.

9 (2) PUBLIC AVAILABILITY.—Not later than 12
10 months after the date of the enactment of this Act,
11 the Secretary of Health and Human Services, the
12 Secretary of Labor, and the Secretary of the Treas-
13 ury shall make such feedback publicly available.

14 (3) NAIC.—The Secretary of Health and
15 Human Services, the Secretary of Labor, and the
16 Secretary of the Treasury shall share feedback ob-
17 tained pursuant to paragraph (1) directly with the
18 National Association of Insurance Commissioners to
19 the extent such feedback includes recommendations
20 for the development of simplified information disclo-
21 sure tools to provide consistent information for con-
22 sumers. Such feedback may be taken into consider-
23 ation by the National Association of Insurance Com-
24 missioners and other appropriate entities for the vol-
25 untary development and voluntary use of common

1 templates and other sample standardized forms to
2 improve consumer access to plan information.

3 (d) IMPROVING COMPLIANCE.—

4 (1) IN GENERAL.—In the case that the Sec-
5 retary of Health and Human Services, the Secretary
6 of Labor, or the Secretary of the Treasury deter-
7 mines that a group health plan or health insurance
8 issuer offering group or individual health insurance
9 coverage has violated, at least 5 times, section 2726
10 of the Public Health Service Act (42 U.S.C. 300gg–
11 26), section 712 of the Employee Retirement Income
12 Security Act of 1974 (29 U.S.C. 1185a), or section
13 9812 of the Internal Revenue Code of 1986, respec-
14 tively, the appropriate Secretary shall audit plan
15 documents for such health plan or issuer in the plan
16 year following the Secretary’s determination in order
17 to help improve compliance with such section.

18 (2) RULE OF CONSTRUCTION.—Nothing in this
19 subsection shall be construed to limit the authority,
20 as in effect on the day before the date of enactment
21 of this Act, of the Secretary of Health and Human
22 Services, the Secretary of Labor, or the Secretary of
23 the Treasury to audit documents of health plans or
24 health insurance issuers.

1 **SEC. 13002. ACTION PLAN FOR ENHANCED ENFORCEMENT**
2 **OF MENTAL HEALTH AND SUBSTANCE USE**
3 **DISORDER COVERAGE.**

4 (a) PUBLIC MEETING.—

5 (1) IN GENERAL.—Not later than 6 months
6 after the date of enactment of this Act, the Sec-
7 retary of Health and Human Services shall convene
8 a public meeting of stakeholders described in para-
9 graph (2) to produce an action plan for improved
10 Federal and State coordination related to the en-
11 forcement of section 2726 of the Public Health Serv-
12 ice Act (42 U.S.C. 300gg–26), section 712 of the
13 Employee Retirement Income Security Act of 1974
14 (29 U.S.C. 1185a), and section 9812 of the Internal
15 Revenue Code of 1986, and any comparable provi-
16 sions of State law (in this section such sections and
17 provisions are collectively referred to as “mental
18 health parity and addiction equity requirements”).

19 (2) STAKEHOLDERS.—The stakeholders de-
20 scribed in this paragraph shall include each of the
21 following:

22 (A) The Federal Government, including
23 representatives from—

24 (i) the Department of Health and
25 Human Services;

26 (ii) the Department of the Treasury;

1 (iii) the Department of Labor; and

2 (iv) the Department of Justice.

3 (B) State governments, including—

4 (i) State health insurance commis-
5 sioners;

6 (ii) appropriate State agencies, includ-
7 ing agencies on public health or mental
8 health; and

9 (iii) State attorneys general or other
10 representatives of State entities involved in
11 the enforcement of mental health parity
12 and addiction equity requirements.

13 (C) Representatives from key stakeholder
14 groups, including—

15 (i) the National Association of Insur-
16 ance Commissioners;

17 (ii) health insurance issuers;

18 (iii) providers of mental health and
19 substance use disorder treatment;

20 (iv) employers; and

21 (v) patients or their advocates.

22 (b) ACTION PLAN.—Not later than 6 months after
23 the conclusion of the public meeting under subsection (a),
24 the Secretary of Health and Human Services shall finalize
25 the action plan described in such subsection and make it

1 plainly available on the Internet website of the Depart-
2 ment of Health and Human Services.

3 (c) CONTENT.—The action plan under this section
4 shall—

5 (1) take into consideration the recommenda-
6 tions of the Mental Health and Substance Use Dis-
7 order Parity Task Force in its final report issued in
8 October of 2016, and any subsequent Federal and
9 State actions in relation to such recommendations;

10 (2) reflect the input of the stakeholders partici-
11 pating in the public meeting under subsection (a);

12 (3) identify specific strategic objectives regard-
13 ing how the various Federal and State agencies
14 charged with enforcement of mental health parity
15 and addiction equity requirements will collaborate to
16 improve enforcement of such requirements;

17 (4) provide a timeline for implementing the ac-
18 tion plan; and

19 (5) provide specific examples of how such objec-
20 tives may be met, which may include—

21 (A) providing common educational infor-
22 mation and documents, such as the Consumer
23 Guide to Disclosure Rights, to patients about
24 their rights under mental health parity and ad-
25 diction equity requirements;

1 (B) facilitating the centralized collection
2 of, monitoring of, and response to patient com-
3 plaints or inquiries relating to mental health
4 parity and addiction equity requirements, which
5 may be through the development and adminis-
6 tration of—

7 (i) a single, toll-free telephone num-
8 ber; and

9 (ii) a new parity website—

10 (I) to help consumers find the
11 appropriate Federal or State agency
12 to assist with their parity complaints,
13 appeals, and other actions; and

14 (II) that takes into consideration,
15 but is not duplicative of, the parity
16 beta site being tested, and released for
17 public comment, by the Department
18 of Health and Human Services as of
19 the date of the enactment of this Act;

20 (C) Federal and State law enforcement
21 agencies entering into memoranda of under-
22 standing to better coordinate enforcement re-
23 sponsibilities and information sharing—

24 (i) including whether such agencies
25 should make the results of enforcement ac-

1 tions related to mental health parity and
2 addiction equity requirements publicly
3 available; and

4 (ii) which may include State Policy
5 Academies on Parity Implementation for
6 State Officials and other forums to bring
7 together national experts to provide tech-
8 nical assistance to teams of State officials
9 on strategies to advance compliance with
10 mental health parity and addiction equity
11 requirements in both the commercial mar-
12 ket, and in the Medicaid program under
13 title XIX of the Social Security Act and
14 the State Children's Health Insurance Pro-
15 gram under title XXI of such Act; and

16 (D) recommendations to the Congress re-
17 garding the need for additional legal authority
18 to improve enforcement of mental health parity
19 and addiction equity requirements, including
20 the need for additional legal authority to ensure
21 that nonquantitative treatment limitations are
22 applied, and the extent and frequency of the ap-
23 plications of such limitations, both to medical
24 and surgical benefits and to mental health and

1 substance use disorder benefits in a comparable
2 manner.

3 **SEC. 13003. REPORT ON INVESTIGATIONS REGARDING PAR-**
4 **ITY IN MENTAL HEALTH AND SUBSTANCE**
5 **USE DISORDER BENEFITS.**

6 (a) IN GENERAL.—Not later than 1 year after the
7 date of enactment of this Act, and annually thereafter for
8 the subsequent 5 years, the Assistant Secretary of Labor
9 of the Employee Benefits Security Administration, in col-
10 laboration with the Administrator of the Centers for Medi-
11 care & Medicaid Services and the Secretary of the Treas-
12 ury, shall submit to the Committee on Energy and Com-
13 merce of the House of Representatives and the Committee
14 on Health, Education, Labor, and Pensions of the Senate
15 a report summarizing the results of all closed Federal in-
16 vestigations completed during the preceding 12-month pe-
17 riod with findings of any serious violation regarding com-
18 pliance with mental health and substance use disorder cov-
19 erage requirements under section 2726 of the Public
20 Health Service Act (42 U.S.C. 300gg–26), section 712 of
21 the Employee Retirement Income Security Act of 1974
22 (29 U.S.C. 1185a), and section 9812 of the Internal Rev-
23 enue Code of 1986.

1 (b) CONTENTS.—Subject to subsection (c), a report
2 under subsection (a) shall, with respect to investigations
3 described in such subsection, include each of the following:

4 (1) The number of closed Federal investigations
5 conducted during the covered reporting period.

6 (2) Each benefit classification examined by any
7 such investigation conducted during the covered re-
8 porting period.

9 (3) Each subject matter, including compliance
10 with requirements for quantitative and nonquantita-
11 tive treatment limitations, of any such investigation
12 conducted during the covered reporting period.

13 (4) A summary of the basis of the final decision
14 rendered for each closed investigation conducted
15 during the covered reporting period that resulted in
16 a finding of a serious violation.

17 (c) LIMITATION.—Any individually identifiable infor-
18 mation shall be excluded from reports under subsection
19 (a) consistent with protections under the health privacy
20 and security rules promulgated under section 264(c) of the
21 Health Insurance Portability and Accountability Act of
22 1996 (42 U.S.C. 1320d–2 note).

1 **SEC. 13004. GAO STUDY ON PARITY IN MENTAL HEALTH**
2 **AND SUBSTANCE USE DISORDER BENEFITS.**

3 Not later than 3 years after the date of enactment
4 of this Act, the Comptroller General of the United States,
5 in consultation with the Secretary of Health and Human
6 Services, the Secretary of Labor, and the Secretary of the
7 Treasury, shall submit to the Committee on Energy and
8 Commerce of the House of Representatives and the Com-
9 mittee on Health, Education, Labor, and Pensions of the
10 Senate a report detailing the extent to which group health
11 plans or health insurance issuers offering group or indi-
12 vidual health insurance coverage that provides both med-
13 ical and surgical benefits and mental health or substance
14 use disorder benefits, medicaid managed care organiza-
15 tions with a contract under section 1903(m) of the Social
16 Security Act (42 U.S.C. 1396b(m)), and health plans pro-
17 vided under the State Children's Health Insurance Pro-
18 gram under title XXI of the Social Security Act (42
19 U.S.C. 1397aa et seq.) comply with section 2726 of the
20 Public Health Service Act (42 U.S.C. 300gg-26), section
21 712 of the Employee Retirement Income Security Act of
22 1974 (29 U.S.C. 1185a), and section 9812 of the Internal
23 Revenue Code of 1986, including—

24 (1) how nonquantitative treatment limitations,
25 including medical necessity criteria, of such plans or
26 issuers comply with such sections;

1 (2) how the responsible Federal departments
2 and agencies ensure that such plans or issuers com-
3 ply with such sections, including an assessment of
4 how the Secretary of Health and Human Services
5 has used its authority to conduct audits of such
6 plans to ensure compliance;

7 (3) a review of how the various Federal and
8 State agencies responsible for enforcing mental
9 health parity requirements have improved enforce-
10 ment of such requirements in accordance with the
11 objectives and timeline described in the action plan
12 under section 13002; and

13 (4) recommendations for how additional en-
14 forcement, education, and coordination activities by
15 responsible Federal and State departments and
16 agencies could better ensure compliance with such
17 sections, including recommendations regarding the
18 need for additional legal authority.

19 **SEC. 13005. INFORMATION AND AWARENESS ON EATING**
20 **DISORDERS.**

21 (a) INFORMATION.—The Secretary of Health and
22 Human Services, acting through the Director of the Office
23 on Women’s Health, may—

24 (1) update information, related fact sheets, and
25 resource lists related to eating disorders that are

1 available on the public Internet website of the Na-
2 tional Women's Health Information Center spon-
3 sored by the Office on Women's Health, to include—

4 (A) updated findings and current research
5 related to eating disorders, as appropriate; and

6 (B) information about eating disorders, in-
7 cluding information related to males and fe-
8 males;

9 (2) incorporate, as appropriate, and in coordi-
10 nation with the Secretary of Education, information
11 from publicly available resources into appropriate
12 obesity prevention programs developed by the Office
13 on Women's Health; and

14 (3) make publicly available (through a public
15 Internet website or other method) information, re-
16 lated fact sheets, and resource lists, as updated
17 under paragraph (1), and the information incor-
18 porated into appropriate obesity prevention pro-
19 grams under paragraph (2).

20 (b) AWARENESS.—The Secretary of Health and
21 Human Services may advance public awareness on—

22 (1) the types of eating disorders;

23 (2) the seriousness of eating disorders, includ-
24 ing prevalence, comorbidities, and physical and men-
25 tal health consequences;

1 (3) methods to identify, intervene, refer for
2 treatment, and prevent behaviors that may lead to
3 the development of eating disorders;

4 (4) discrimination and bullying based on body
5 size;

6 (5) the effects of media on self-esteem and body
7 image; and

8 (6) the signs and symptoms of eating disorders.

9 **SEC. 13006. EDUCATION AND TRAINING ON EATING DIS-**
10 **ORDERS.**

11 The Secretary of Health and Human Services may
12 facilitate the identification of model programs and mate-
13 rials for educating and training health professionals in ef-
14 fective strategies to—

15 (1) identify individuals with eating disorders;

16 (2) provide early intervention services for indi-
17 viduals with eating disorders;

18 (3) refer patients with eating disorders for ap-
19 propriate treatment;

20 (4) prevent the development of eating disorders;
21 and

22 (5) provide appropriate treatment services for
23 individuals with eating disorders.

1 **SEC. 13007. CLARIFICATION OF EXISTING PARITY RULES.**

2 If a group health plan or a health insurance issuer
3 offering group or individual health insurance coverage pro-
4 vides coverage for eating disorder benefits, including resi-
5 dential treatment, such group health plan or health insur-
6 ance issuer shall provide such benefits consistent with the
7 requirements of section 2726 of the Public Health Service
8 Act (42 U.S.C. 300gg-26), section 712 of the Employee
9 Retirement Income Security Act of 1974 (29 U.S.C.
10 1185a), and section 9812 of the Internal Revenue Code
11 of 1986.

12 **TITLE XIV—MENTAL HEALTH**
13 **AND SAFE COMMUNITIES**
14 **Subtitle A—Mental Health and Safe**
15 **Communities**

16 **SEC. 14001. LAW ENFORCEMENT GRANTS FOR CRISIS**
17 **INTERVENTION TEAMS, MENTAL HEALTH**
18 **PURPOSES.**

19 (a) EDWARD BYRNE MEMORIAL JUSTICE ASSIST-
20 ANCE GRANT PROGRAM.—Section 501(a)(1) of title I of
21 the Omnibus Crime Control and Safe Streets Act of 1968
22 (42 U.S.C. 3751(a)(1)) is amended by adding at the end
23 the following:

24 “(H) Mental health programs and related
25 law enforcement and corrections programs, in-

1 including behavioral programs and crisis interven-
2 tion teams.”.

3 (b) COMMUNITY ORIENTED POLICING SERVICES
4 PROGRAM.—Section 1701(b) of title I of the Omnibus
5 Crime Control and Safe Streets Act of 1968 (42 U.S.C.
6 3796dd(b)) is amended—

7 (1) in paragraph (17), by striking “and” at the
8 end;

9 (2) by redesignating paragraph (18) as para-
10 graph (22);

11 (3) by inserting after paragraph (17) the fol-
12 lowing:

13 “(18) to provide specialized training to law en-
14 forcement officers to—

15 “(A) recognize individuals who have a
16 mental illness; and

17 “(B) properly interact with individuals who
18 have a mental illness, including strategies for
19 verbal de-escalation of crises;

20 “(19) to establish collaborative programs that
21 enhance the ability of law enforcement agencies to
22 address the mental health, behavioral, and substance
23 abuse problems of individuals encountered by law
24 enforcement officers in the line of duty;

1 “(20) to provide specialized training to correc-
2 tions officers to recognize individuals who have a
3 mental illness;

4 “(21) to enhance the ability of corrections offi-
5 cers to address the mental health of individuals
6 under the care and custody of jails and prisons, in-
7 cluding specialized training and strategies for verbal
8 de-escalation of crises; and”;

9 (4) in paragraph (22), as redesignated, by
10 striking “through (17)” and inserting “through
11 (21)”.

12 (c) MODIFICATIONS TO THE STAFFING FOR ADE-
13 QUATE FIRE AND EMERGENCY RESPONSE GRANTS.—Sec-
14 tion 34(a)(1)(B) of the Federal Fire Prevention and Con-
15 trol Act of 1974 (15 U.S.C. 2229a(a)(1)(B)) is amended
16 by inserting before the period at the end the following:
17 “and to provide specialized training to paramedics, emer-
18 gency medical services workers, and other first responders
19 to recognize individuals who have mental illness and how
20 to properly intervene with individuals with mental illness,
21 including strategies for verbal de-escalation of crises”.

22 **SEC. 14002. ASSISTED OUTPATIENT TREATMENT PRO-**
23 **GRAMS.**

24 (a) IN GENERAL.—Section 2201 of title I of the Om-
25 nibus Crime Control and Safe Streets Act of 1968 (42

1 U.S.C. 3796ii) is amended in paragraph (2)(B), by insert-
2 ing before the semicolon the following: “, or court-ordered
3 assisted outpatient treatment when the court has deter-
4 mined such treatment to be necessary”.

5 (b) DEFINITIONS.—Section 2202 of title I of the Om-
6 nibus Crime Control and Safe Streets Act of 1968 (42
7 U.S.C. 3796ii—1) is amended—

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

10 (2) in paragraph (2), by striking the period at
11 the end and inserting a semicolon; and

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

13 “(3) the term ‘court-ordered assisted outpatient
14 treatment’ means a program through which a court
15 may order a treatment plan for an eligible patient
16 that—

17 “(A) requires such patient to obtain out-
18 patient mental health treatment while the pa-
19 tient is not currently residing in a correctional
20 facility or inpatient treatment facility; and

21 “(B) is designed to improve access and ad-
22 herence by such patient to intensive behavioral
23 health services in order to—

24 “(i) avert relapse, repeated hos-
25 pitalizations, arrest, incarceration, suicide,

1 property destruction, and violent behavior;

2 and

3 “(ii) provide such patient with the op-

4 portunity to live in a less restrictive alter-

5 native to incarceration or involuntary hos-

6 pitalization; and

7 “(4) the term ‘eligible patient’ means an adult,

8 mentally ill person who, as determined by a court—

9 “(A) has a history of violence, incarcer-
10 ation, or medically unnecessary hospitalizations;

11 “(B) without supervision and treatment,
12 may be a danger to self or others in the com-
13 munity;

14 “(C) is substantially unlikely to voluntarily
15 participate in treatment;

16 “(D) may be unable, for reasons other
17 than indigence, to provide for any of his or her
18 basic needs, such as food, clothing, shelter,
19 health, or safety;

20 “(E) has a history of mental illness or a
21 condition that is likely to substantially deterio-
22 rate if the person is not provided with timely
23 treatment; or

24 “(F) due to mental illness, lacks capacity
25 to fully understand or lacks judgment to make

1 informed decisions regarding his or her need for
2 treatment, care, or supervision.”.

3 **SEC. 14003. FEDERAL DRUG AND MENTAL HEALTH COURTS.**

4 (a) DEFINITIONS.—In this section—

5 (1) the term “eligible offender” means a person
6 who—

7 (A)(i) previously or currently has been di-
8 agnosed by a qualified mental health profes-
9 sional as having a mental illness, mental retar-
10 dation, or co-occurring mental illness and sub-
11 stance abuse disorders; or

12 (ii) manifests obvious signs of mental ill-
13 ness, mental retardation, or co-occurring mental
14 illness and substance abuse disorders during ar-
15 rest or confinement or before any court;

16 (B) comes into contact with the criminal
17 justice system or is arrested or charged with an
18 offense that is not—

19 (i) a crime of violence, as defined
20 under applicable State law or in section
21 3156 of title 18, United States Code; or

22 (ii) a serious drug offense, as defined
23 in section 924(e)(2)(A) of title 18, United
24 States Code; and

1 (C) is determined by a judge to be eligible;

2 and

3 (2) the term “mental illness” means a
4 diagnosable mental, behavioral, or emotional dis-
5 order—

6 (A) of sufficient duration to meet diag-
7 nostic criteria within the most recent edition of
8 the Diagnostic and Statistical Manual of Men-
9 tal Disorders published by the American Psy-
10 chiatric Association; and

11 (B) that has resulted in functional impair-
12 ment that substantially interferes with or limits
13 1 or more major life activities.

14 (b) ESTABLISHMENT OF PROGRAM.—Not later than
15 1 year after the date of enactment of this Act, the Attor-
16 ney General shall establish a pilot program to determine
17 the effectiveness of diverting eligible offenders from Fed-
18 eral prosecution, Federal probation, or a Bureau of Pris-
19 ons facility, and placing such eligible offenders in drug or
20 mental health courts.

21 (c) PROGRAM SPECIFICATIONS.—The pilot program
22 established under subsection (b) shall involve—

23 (1) continuing judicial supervision, including
24 periodic review, of program participants who have a
25 substance abuse problem or mental illness; and

1 (2) the integrated administration of services
2 and sanctions, which shall include—

3 (A) mandatory periodic testing, as appro-
4 priate, for the use of controlled substances or
5 other addictive substances during any period of
6 supervised release or probation for each pro-
7 gram participant;

8 (B) substance abuse treatment for each
9 program participant who requires such services;

10 (C) diversion, probation, or other super-
11 vised release with the possibility of prosecution,
12 confinement, or incarceration based on non-
13 compliance with program requirements or fail-
14 ure to show satisfactory progress toward com-
15 pleting program requirements;

16 (D) programmatic offender management,
17 including case management, and aftercare serv-
18 ices, such as relapse prevention, health care,
19 education, vocational training, job placement,
20 housing placement, and child care or other fam-
21 ily support services for each program partici-
22 pant who requires such services;

23 (E) outpatient or inpatient mental health
24 treatment, as ordered by the court, that carries
25 with it the possibility of dismissal of charges or

1 reduced sentencing upon successful completion
2 of such treatment;

3 (F) centralized case management, includ-
4 ing—

5 (i) the consolidation of all cases, in-
6 cluding violations of probations, of the pro-
7 gram participant; and

8 (ii) coordination of all mental health
9 treatment plans and social services, includ-
10 ing life skills and vocational training, hous-
11 ing and job placement, education, health
12 care, and relapse prevention for each pro-
13 gram participant who requires such serv-
14 ices; and

15 (G) continuing supervision of treatment
16 plan compliance by the program participant for
17 a term not to exceed the maximum allowable
18 sentence or probation period for the charged or
19 relevant offense and, to the extent practicable,
20 continuity of psychiatric care at the end of the
21 supervised period.

22 (d) IMPLEMENTATION; DURATION.—The pilot pro-
23 gram established under subsection (b) shall be con-
24 ducted—

1 (1) in not less than 1 United States judicial
2 district, designated by the Attorney General in con-
3 sultation with the Director of the Administrative Of-
4 fice of the United States Courts, as appropriate for
5 the pilot program; and

6 (2) during fiscal year 2017 through fiscal year
7 2021.

8 (e) CRITERIA FOR DESIGNATION.—Before making a
9 designation under subsection (d)(1), the Attorney General
10 shall—

11 (1) obtain the approval, in writing, of the
12 United States Attorney for the United States judi-
13 cial district being designated;

14 (2) obtain the approval, in writing, of the chief
15 judge for the United States judicial district being
16 designated; and

17 (3) determine that the United States judicial
18 district being designated has adequate behavioral
19 health systems for treatment, including substance
20 abuse and mental health treatment.

21 (f) ASSISTANCE FROM OTHER FEDERAL ENTI-
22 TIES.—The Administrative Office of the United States
23 Courts and the United States Probation Offices shall pro-
24 vide such assistance and carry out such functions as the
25 Attorney General may request in monitoring, supervising,

1 providing services to, and evaluating eligible offenders
2 placed in a drug or mental health court under this section.

3 (g) REPORTS.—The Attorney General, in consulta-
4 tion with the Director of the Administrative Office of the
5 United States Courts, shall monitor the drug and mental
6 health courts under this section, and shall submit a report
7 to Congress on the outcomes of the program at the end
8 of the period described in subsection (d)(2).

9 **SEC. 14004. MENTAL HEALTH IN THE JUDICIAL SYSTEM.**

10 Part V of title I of the Omnibus Crime Control and
11 Safe Streets Act of 1968 (42 U.S.C. 3796ii et seq.) is
12 amended by inserting at the end the following:

13 **“SEC. 2209. MENTAL HEALTH RESPONSES IN THE JUDICIAL**
14 **SYSTEM.**

15 “(a) PRETRIAL SCREENING AND SUPERVISION.—

16 “(1) IN GENERAL.—The Attorney General may
17 award grants to States, units of local government,
18 territories, Indian Tribes, nonprofit agencies, or any
19 combination thereof, to develop, implement, or ex-
20 pand pretrial services programs to improve the iden-
21 tification and outcomes of individuals with mental
22 illness.

23 “(2) ALLOWABLE USES.—Grants awarded
24 under this subsection may be may be used for—

1 “(A) behavioral health needs and risk
2 screening of defendants, including verification
3 of interview information, mental health evalua-
4 tion, and criminal history screening;

5 “(B) assessment of risk of pretrial mis-
6 conduct through objective, statistically validated
7 means, and presentation to the court of rec-
8 ommendations based on such assessment, in-
9 cluding services that will reduce the risk of pre-
10 trial misconduct;

11 “(C) followup review of defendants unable
12 to meet the conditions of pretrial release;

13 “(D) evaluation of process and results of
14 pre-trial service programs;

15 “(E) supervision of defendants who are on
16 pretrial release, including reminders to defend-
17 ants of scheduled court dates;

18 “(F) reporting on process and results of
19 pretrial services programs to relevant public
20 and private mental health stakeholders; and

21 “(G) data collection and analysis necessary
22 to make available information required for as-
23 sessment of risk.

24 “(b) BEHAVIORAL HEALTH ASSESSMENTS AND
25 INTERVENTION.—

1 “(1) IN GENERAL.—The Attorney General may
2 award grants to States, units of local government,
3 territories, Indian Tribes, nonprofit agencies, or any
4 combination thereof, to develop, implement, or ex-
5 pand a behavioral health screening and assessment
6 program framework for State or local criminal jus-
7 tice systems.

8 “(2) ALLOWABLE USES.—Grants awarded
9 under this subsection may be used for—

10 “(A) promotion of the use of validated as-
11 sessment tools to gauge the criminogenic risk,
12 substance abuse needs, and mental health needs
13 of individuals;

14 “(B) initiatives to match the risk factors
15 and needs of individuals to programs and prac-
16 tices associated with research-based, positive
17 outcomes;

18 “(C) implementing methods for identifying
19 and treating individuals who are most likely to
20 benefit from coordinated supervision and treat-
21 ment strategies, and identifying individuals who
22 can do well with fewer interventions; and

23 “(D) collaborative decision-making among
24 the heads of criminal justice agencies, mental
25 health systems, judicial systems, substance

1 abuse systems, and other relevant systems or
2 agencies for determining how treatment and in-
3 tensive supervision services should be allocated
4 in order to maximize benefits, and developing
5 and utilizing capacity accordingly.

6 “(c) USE OF GRANT FUNDS.—A State, unit of local
7 government, territory, Indian Tribe, or nonprofit agency
8 that receives a grant under this section shall, in accord-
9 ance with subsection (b)(2), use grant funds for the ex-
10 penses of a treatment program, including—

11 “(1) salaries, personnel costs, equipment costs,
12 and other costs directly related to the operation of
13 the program, including costs relating to enforcement;

14 “(2) payments for treatment providers that are
15 approved by the State or Indian Tribe and licensed,
16 if necessary, to provide needed treatment to program
17 participants, including aftercare supervision, voca-
18 tional training, education, and job placement; and

19 “(3) payments to public and nonprofit private
20 entities that are approved by the State or Indian
21 Tribe and licensed, if necessary, to provide alcohol
22 and drug addiction treatment to offenders partici-
23 pating in the program.

24 “(d) SUPPLEMENT OF NON-FEDERAL FUNDS.—

1 “(1) IN GENERAL.—Grants awarded under this
2 section shall be used to supplement, and not sup-
3 plant, non-Federal funds that would otherwise be
4 available for programs described in this section.

5 “(2) FEDERAL SHARE.—The Federal share of a
6 grant made under this section may not exceed 50
7 percent of the total costs of the program described
8 in an application under subsection (e).

9 “(e) APPLICATIONS.—To request a grant under this
10 section, a State, unit of local government, territory, Indian
11 Tribe, or nonprofit agency shall submit an application to
12 the Attorney General in such form and containing such
13 information as the Attorney General may reasonably re-
14 quire.

15 “(f) GEOGRAPHIC DISTRIBUTION.—The Attorney
16 General shall ensure that, to the extent practicable, the
17 distribution of grants under this section is equitable and
18 includes—

19 “(1) each State; and

20 “(2) a unit of local government, territory, In-
21 dian Tribe, or nonprofit agency—

22 “(A) in each State; and

23 “(B) in rural, suburban, Tribal, and urban
24 jurisdictions.

1 “(g) REPORTS AND EVALUATIONS.—For each fiscal
2 year, each grantee under this section during that fiscal
3 year shall submit to the Attorney General a report on the
4 effectiveness of activities carried out using such grant.
5 Each report shall include an evaluation in such form and
6 containing such information as the Attorney General may
7 reasonably require. The Attorney General shall specify the
8 dates on which such reports shall be submitted.

9 “(h) ACCOUNTABILITY.—Grants awarded under this
10 section shall be subject to the following accountability pro-
11 visions:

12 “(1) AUDIT REQUIREMENT.—

13 “(A) DEFINITION.—In this paragraph, the
14 term ‘unresolved audit finding’ means a finding
15 in the final audit report of the Inspector Gen-
16 eral of the Department of Justice under sub-
17 paragraph (C) that the audited grantee has
18 used grant funds for an unauthorized expendi-
19 ture or otherwise unallowable cost that is not
20 closed or resolved within 1 year after the date
21 on which final audit report is issued.

22 “(B) AUDITS.—Beginning in the first fis-
23 cal year beginning after the date of enactment
24 of this section, and in each fiscal year there-
25 after, the Inspector General of the Department

1 of Justice shall conduct audits of grantees
2 under this section to prevent waste, fraud, and
3 abuse of funds by grantees. The Inspector Gen-
4 eral shall determine the appropriate number of
5 grantees to be audited each year.

6 “(C) FINAL AUDIT REPORT.—The Inspec-
7 tor General of the Department of Justice shall
8 submit to the Attorney General a final report
9 on each audit conducted under subparagraph
10 (B).

11 “(D) MANDATORY EXCLUSION.—Grantees
12 under this section about which there is an unre-
13 solved audit finding shall not be eligible to re-
14 ceive a grant under this section during the 2
15 fiscal years beginning after the end of the 1-
16 year period described in subparagraph (A).

17 “(E) PRIORITY.—In making grants under
18 this section, the Attorney General shall give pri-
19 ority to applicants that did not have an unre-
20 solved audit finding during the 3 fiscal years
21 before submitting an application for a grant
22 under this section.

23 “(F) REIMBURSEMENT.—If an entity re-
24 ceives a grant under this section during the 2-
25 fiscal-year period during which the entity is

1 prohibited from receiving grants under subpara-
2 graph (D), the Attorney General shall—

3 “(i) deposit an amount equal to the
4 amount of the grant that was improperly
5 awarded to the grantee into the General
6 Fund of the Treasury; and

7 “(ii) seek to recoup the costs of the
8 repayment under clause (i) from the grant-
9 ee that was erroneously awarded grant
10 funds.

11 “(2) NONPROFIT AGENCY REQUIREMENTS.—

12 “(A) DEFINITION.—For purposes of this
13 paragraph and the grant program under this
14 section, the term ‘nonprofit agency’ means an
15 organization that is described in section
16 501(c)(3) of the Internal Revenue Code of 1986
17 (26 U.S.C. 501(c)(3)) and is exempt from tax-
18 ation under section 501(a) of the Internal Rev-
19 enue Code of 1986 (26 U.S.C. 501(a)).

20 “(B) PROHIBITION.—The Attorney Gen-
21 eral may not award a grant under this section
22 to a nonprofit agency that holds money in an
23 offshore account for the purpose of avoiding
24 paying the tax described in section 511(a) of

1 the Internal Revenue Code of 1986 (26 U.S.C.
2 511(a)).

3 “(C) DISCLOSURE.—Each nonprofit agen-
4 cy that is awarded a grant under this section
5 and uses the procedures prescribed in regula-
6 tions to create a rebuttable presumption of rea-
7 sonableness for the compensation of its officers,
8 directors, trustees, and key employees, shall dis-
9 close to the Attorney General, in the application
10 for the grant, the process for determining such
11 compensation, including the independent per-
12 sons involved in reviewing and approving such
13 compensation, the comparability data used, and
14 contemporaneous substantiation of the delibera-
15 tion and decision. Upon request, the Attorney
16 General shall make the information disclosed
17 under this subparagraph available for public in-
18 spection.

19 “(3) CONFERENCE EXPENDITURES.—

20 “(A) LIMITATION.—Not more than
21 \$20,000 of the amounts made available to the
22 Department of Justice to carry out this section
23 may be used by the Attorney General, or by any
24 individual or entity awarded a grant under this
25 section to host, or make any expenditures relat-

1 ing to, a conference unless the Deputy Attorney
2 General provides prior written authorization
3 that the funds may be expended to host the
4 conference or make such expenditure.

5 “(B) WRITTEN APPROVAL.—Written ap-
6 proval under subparagraph (A) shall include a
7 written estimate of all costs associated with the
8 conference, including the cost of all food, bev-
9 erages, audio-visual equipment, honoraria for
10 speakers, and entertainment.

11 “(C) REPORT.—The Deputy Attorney Gen-
12 eral shall submit an annual report to the Com-
13 mittee on the Judiciary of the Senate and the
14 Committee on the Judiciary of the House of
15 Representatives on all conference expenditures
16 approved under this paragraph.

17 “(4) ANNUAL CERTIFICATION.—Beginning in
18 the first fiscal year beginning after the date of en-
19 actment of this subsection, the Attorney General
20 shall submit to the Committee on the Judiciary and
21 the Committee on Appropriations of the Senate and
22 the Committee on the Judiciary and the Committee
23 on Appropriations of the House of Representatives
24 an annual certification—

25 “(A) indicating whether—

1 “(i) all final audit reports issued by
2 the Office of the Inspector General under
3 paragraph (1) have been completed and re-
4 viewed by the appropriate Assistant Attor-
5 ney General or Director;

6 “(ii) all mandatory exclusions required
7 under paragraph (1)(D) have been issued;
8 and

9 “(iii) any reimbursements required
10 under paragraph (1)(F) have been made;
11 and

12 “(B) that includes a list of any grantees
13 excluded under paragraph (1)(D) from the pre-
14 vious year.

15 “(i) PREVENTING DUPLICATIVE GRANTS.—

16 “(1) IN GENERAL.—Before the Attorney Gen-
17 eral awards a grant to an applicant under this sec-
18 tion, the Attorney General shall compare the pos-
19 sible grant with any other grants awarded to the ap-
20 plicant under this Act to determine whether the
21 grants are for the same purpose.

22 “(2) REPORT.—If the Attorney General awards
23 multiple grants to the same applicant for the same
24 purpose, the Attorney General shall submit to the
25 Committee on the Judiciary of the Senate and the

1 Committee on the Judiciary of the House of Rep-
2 resentatives a report that includes—

3 “(A) a list of all duplicate grants awarded,
4 including the total dollar amount of any such
5 grants awarded; and

6 “(B) the reason the Attorney General
7 awarded the duplicate grants.”.

8 **SEC. 14005. FORENSIC ASSERTIVE COMMUNITY TREAT-**
9 **MENT INITIATIVES.**

10 Section 2991 of the Omnibus Crime Control and Safe
11 Streets Act of 1968 (42 U.S.C. 3797aa) is amended by—

12 (1) redesignating subsection (j) as subsection
13 (o); and

14 (2) inserting after subsection (i) the following:

15 “(j) FORENSIC ASSERTIVE COMMUNITY TREATMENT
16 (FACT) INITIATIVE PROGRAM.—

17 “(1) IN GENERAL.—The Attorney General may
18 make grants to States, units of local government,
19 territories, Indian Tribes, nonprofit agencies, or any
20 combination thereof, to develop, implement, or ex-
21 pand Assertive Community Treatment initiatives to
22 develop forensic assertive community treatment (re-
23 ferred to in this subsection as ‘FACT’) programs
24 that provide high intensity services in the commu-
25 nity for individuals with mental illness with involve-

1 ment in the criminal justice system to prevent future
2 incarcerations.

3 “(2) ALLOWABLE USES.—Grant funds awarded
4 under this subsection may be used for—

5 “(A) multidisciplinary team initiatives for
6 individuals with mental illnesses with criminal
7 justice involvement that address criminal justice
8 involvement as part of treatment protocols;

9 “(B) FACT programs that involve mental
10 health professionals, criminal justice agencies,
11 chemical dependency specialists, nurses, psychi-
12 atrists, vocational specialists, forensic peer spe-
13 cialists, forensic specialists, and dedicated ad-
14 ministrative support staff who work together to
15 provide recovery oriented, 24/7 wraparound
16 services;

17 “(C) services such as integrated evidence-
18 based practices for the treatment of co-occur-
19 ring mental health and substance-related dis-
20 orders, assertive outreach and engagement,
21 community-based service provision at partici-
22 pants’ residence or in the community, psy-
23 chiatric rehabilitation, recovery oriented serv-
24 ices, services to address criminogenic risk fac-
25 tors, and community tenure;

1 “(D) payments for treatment providers
2 that are approved by the State or Indian Tribe
3 and licensed, if necessary, to provide needed
4 treatment to eligible offenders participating in
5 the program, including behavioral health serv-
6 ices and aftercare supervision; and

7 “(E) training for all FACT teams to pro-
8 mote high-fidelity practice principles and tech-
9 nical assistance to support effective and con-
10 tinuing integration with criminal justice agency
11 partners.

12 “(3) SUPPLEMENT AND NOT SUPPLANT.—
13 Grants made under this subsection shall be used to
14 supplement, and not supplant, non-Federal funds
15 that would otherwise be available for programs de-
16 scribed in this subsection.

17 “(4) APPLICATIONS.—To request a grant under
18 this subsection, a State, unit of local government,
19 territory, Indian Tribe, or nonprofit agency shall
20 submit an application to the Attorney General in
21 such form and containing such information as the
22 Attorney General may reasonably require.”.

1 **SEC. 14006. ASSISTANCE FOR INDIVIDUALS TRANSITIONING**
2 **OUT OF SYSTEMS.**

3 Section 2976(f) of title I of the Omnibus Crime Con-
4 trol and Safe Streets Act of 1968 (42 U.S.C. 3797w(f))
5 is amended—

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

8 (2) in paragraph (6), by striking the period at
9 the end and inserting a semicolon; and

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

11 “(7) provide mental health treatment and tran-
12 sitional services for those with mental illnesses or
13 with co-occurring disorders, including housing place-
14 ment or assistance; and”.

15 **SEC. 14007. CO-OCCURRING SUBSTANCE ABUSE AND MEN-**
16 **TAL HEALTH CHALLENGES IN DRUG COURTS.**

17 Part EE of title I of the Omnibus Crime Control and
18 Safe Streets Act of 1968 (42 U.S.C. 3797u et seq.) is
19 amended—

20 (1) in section 2951(a)(1) (42 U.S.C.
21 3797u(a)(1)), by inserting “, including co-occurring
22 substance abuse and mental health problems,” after
23 “problems”; and

24 (2) in section 2959(a) (42 U.S.C. 3797u–8(a)),
25 by inserting “, including training for drug court per-
26 sonnel and officials on identifying and addressing co-

1 occurring substance abuse and mental health prob-
2 lems” after “part”.

3 **SEC. 14008. MENTAL HEALTH TRAINING FOR FEDERAL UNI-**
4 **FORMED SERVICES.**

5 (a) IN GENERAL.—Not later than 180 days after the
6 date of enactment of this Act, the Secretary of Defense,
7 the Secretary of Homeland Security, the Secretary of
8 Health and Human Services, and the Secretary of Com-
9 merce shall provide the following to each of the uniformed
10 services (as that term is defined in section 101 of title
11 10, United States Code) under their direction:

12 (1) TRAINING PROGRAMS.—Programs that offer
13 specialized and comprehensive training in procedures
14 to identify and respond appropriately to incidents in
15 which the unique needs of individuals with mental
16 illnesses are involved.

17 (2) IMPROVED TECHNOLOGY.—Computerized
18 information systems or technological improvements
19 to provide timely information to Federal law enforce-
20 ment personnel, other branches of the uniformed
21 services, and criminal justice system personnel to
22 improve the Federal response to mentally ill individ-
23 uals.

24 (3) COOPERATIVE PROGRAMS.—The establish-
25 ment and expansion of cooperative efforts to pro-

1 mote public safety through the use of effective inter-
2 vention with respect to mentally ill individuals en-
3 countered by members of the uniformed services.

4 **SEC. 14009. ADVANCING MENTAL HEALTH AS PART OF OF-**
5 **FENDER REENTRY.**

6 (a) REENTRY DEMONSTRATION PROJECTS.—Section
7 2976(f) of title I of the Omnibus Crime Control and Safe
8 Streets Act of 1968 (42 U.S.C. 3797w(f)), as amended
9 by section 14006, is amended—

10 (1) in paragraph (3)(C), by inserting “mental
11 health services,” before “drug treatment”; and

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

13 “(8) target offenders with histories of homeless-
14 ness, substance abuse, or mental illness, including a
15 prerelease assessment of the housing status of the
16 offender and behavioral health needs of the offender
17 with clear coordination with mental health, sub-
18 stance abuse, and homelessness services systems to
19 achieve stable and permanent housing outcomes with
20 appropriate support service.”.

21 (b) MENTORING GRANTS.—Section 211(b)(2) of the
22 Second Chance Act of 2007 (42 U.S.C. 17531(b)(2)) is
23 amended by inserting “, including mental health care”
24 after “community”.

1 **SEC. 14010. SCHOOL MENTAL HEALTH CRISIS INTERVEN-**
2 **TION TEAMS.**

3 Section 2701(b) of title I of the Omnibus Crime Con-
4 trol and Safe Streets Act of 1968 (42 U.S.C. 3797a(b))
5 is amended—

6 (1) by redesignating paragraphs (4) and (5) as
7 paragraphs (5) and (6), respectively; and

8 (2) by inserting after paragraph (3) the fol-
9 lowing:

10 “(4) The development and operation of crisis
11 intervention teams that may include coordination
12 with law enforcement agencies and specialized train-
13 ing for school officials in responding to mental
14 health crises.”.

15 **SEC. 14011. ACTIVE-SHOOTER TRAINING FOR LAW EN-**
16 **FORCEMENT.**

17 The Attorney General, as part of the Preventing Vio-
18 lence Against Law Enforcement and Ensuring Officer Re-
19 silience and Survivability Initiative (VALOR) of the De-
20 partment of Justice, may provide safety training and tech-
21 nical assistance to local law enforcement agencies, includ-
22 ing active-shooter response training.

1 **SEC. 14012. CO-OCCURRING SUBSTANCE ABUSE AND MEN-**
2 **TAL HEALTH CHALLENGES IN RESIDENTIAL**
3 **SUBSTANCE ABUSE TREATMENT PROGRAMS.**

4 Section 1901(a) of title I of the Omnibus Crime Con-
5 trol and Safe Streets Act of 1968 (42 U.S.C. 3796ff(a))
6 is amended—

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

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

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

12 “(3) developing and implementing specialized
13 residential substance abuse treatment programs that
14 identify and provide appropriate treatment to in-
15 mates with co-occurring mental health and sub-
16 stance abuse disorders or challenges.”.

17 **SEC. 14013. MENTAL HEALTH AND DRUG TREATMENT AL-**
18 **TERNATIVES TO INCARCERATION PRO-**
19 **GRAMS.**

20 Title I of the Omnibus Crime Control and Safe
21 Streets Act of 1968 (42 U.S.C. 3711 et seq.) is amended
22 by striking part CC and inserting the following:

1 **“PART CC—MENTAL HEALTH AND DRUG TREAT-**
2 **MENT ALTERNATIVES TO INCARCERATION**
3 **PROGRAMS**

4 **“SEC. 2901. MENTAL HEALTH AND DRUG TREATMENT AL-**
5 **TERNATIVES TO INCARCERATION PRO-**
6 **GRAMS.**

7 “(a) DEFINITIONS.—In this section—

8 “(1) the term ‘eligible entity’ means a State,
9 unit of local government, Indian tribe, or nonprofit
10 organization; and

11 “(2) the term ‘eligible participant’ means an in-
12 dividual who—

13 “(A) comes into contact with the criminal
14 justice system or is arrested or charged with an
15 offense that is not—

16 “(i) a crime of violence, as defined
17 under applicable State law or in section
18 3156 of title 18, United States Code; or

19 “(ii) a serious drug offense, as defined
20 in section 924(e)(2)(A) of title 18, United
21 States Code;

22 “(B) has a history of, or a current—

23 “(i) substance use disorder;

24 “(ii) mental illness; or

25 “(iii) co-occurring mental illness and
26 substance use disorder; and

1 “(C) has been approved for participation in
2 a program funded under this section by the rel-
3 evant law enforcement agency, prosecuting at-
4 torney, defense attorney, probation official, cor-
5 rections official, judge, representative of a men-
6 tal health agency, or representative of a sub-
7 stance abuse agency, as required by law.

8 “(b) PROGRAM AUTHORIZED.—The Attorney General
9 may make grants to eligible entities to develop, implement,
10 or expand a treatment alternative to incarceration pro-
11 gram for eligible participants, including—

12 “(1) pre-booking treatment alternative to incar-
13 ceration programs, including—

14 “(A) law enforcement training on sub-
15 stance use disorders, mental illness, and co-oc-
16 curring mental illness and substance use dis-
17 orders;

18 “(B) receiving centers as alternatives to in-
19 carceration of eligible participants;

20 “(C) specialized response units for calls re-
21 lated to substance use disorders, mental illness,
22 or co-occurring mental illness and substance
23 use disorders; and

24 “(D) other arrest and pre-booking treat-
25 ment alternatives to incarceration models; or

1 “(2) post-booking treatment alternative to in-
2 carceration programs, including—

3 “(A) specialized clinical case management;

4 “(B) pre-trial services related to sub-
5 stances use disorders, mental illness, and co-oc-
6 curring mental illness and substance use dis-
7 orders;

8 “(C) prosecutor and defender based pro-
9 grams;

10 “(D) specialized probation;

11 “(E) treatment and rehabilitation pro-
12 grams; and

13 “(F) problem-solving courts, including
14 mental health courts, drug courts, co-occurring
15 mental health and substance abuse courts, DWI
16 courts, and veterans treatment courts.

17 “(c) APPLICATION.—

18 “(1) IN GENERAL.—An eligible entity desiring a
19 grant under this section shall submit an application
20 to the Attorney General—

21 “(A) that meets the criteria under para-
22 graph (2); and

23 “(B) at such time, in such manner, and
24 accompanied by such information as the Attor-
25 ney General may require.

1 “(2) CRITERIA.—An eligible entity, in submit-
2 ting an application under paragraph (1), shall—

3 “(A) provide extensive evidence of collabo-
4 ration with State and local government agencies
5 overseeing health, community corrections,
6 courts, prosecution, substance abuse, mental
7 health, victims services, and employment serv-
8 ices, and with local law enforcement agencies;

9 “(B) demonstrate consultation with the
10 Single State Authority for Substance Abuse of
11 the State (as that term is defined in section
12 201(e) of the Second Chance Act of 2007);

13 “(C) demonstrate that evidence-based
14 treatment practices will be utilized; and

15 “(D) demonstrate that evidence-based
16 screening and assessment tools will be used to
17 place participants in the treatment alternative
18 to incarceration program.

19 “(d) REQUIREMENTS.—Each eligible entity awarded
20 a grant for a treatment alternative to incarceration pro-
21 gram under this section shall—

22 “(1) determine the terms and conditions of par-
23 ticipation in the program by eligible participants,
24 taking into consideration the collateral consequences
25 of an arrest, prosecution or criminal conviction;

1 “(2) ensure that each substance abuse and
2 mental health treatment component is licensed and
3 qualified by the relevant jurisdiction;

4 “(3) for programs described in subsection
5 (b)(2), organize an enforcement unit comprised of
6 appropriately trained law enforcement professionals
7 under the supervision of the State, Tribal, or local
8 criminal justice agency involved, the duties of which
9 shall include—

10 “(A) the verification of addresses and
11 other contact information of each eligible par-
12 ticipant who participates or desires to partici-
13 pate in the program; and

14 “(B) if necessary, the location, apprehen-
15 sion, arrest, and return to custody of an eligible
16 participant in the program who has absconded
17 from the facility of a treatment provider or has
18 otherwise significantly violated the terms and
19 conditions of the program, consistent with Fed-
20 eral and State confidentiality requirements;

21 “(4) notify the relevant criminal justice entity if
22 any eligible participant in the program absconds
23 from the facility of the treatment provider or other-
24 wise violates the terms and conditions of the pro-

1 gram, consistent with Federal and State confiden-
2 tiality requirements;

3 “(5) submit periodic reports on the progress of
4 treatment or other measured outcomes from partici-
5 pation in the program of each eligible participant in
6 the program to the relevant State, Tribal, or local
7 criminal justice agency, including mental health
8 courts, drug courts, co-occurring mental health and
9 substance abuse courts, DWI courts, and veterans
10 treatment courts;

11 “(6) describe the evidence-based methodology
12 and outcome measurements that will be used to
13 evaluate the program, and specifically explain how
14 such measurements will provide valid measures of
15 the impact of the program; and

16 “(7) describe how the program could be broadly
17 replicated if demonstrated to be effective.

18 “(e) USE OF FUNDS.—An eligible entity shall use a
19 grant received under this section for expenses of a treat-
20 ment alternative to incarceration program, including—

21 “(1) salaries, personnel costs, equipment costs,
22 and other costs directly related to the operation of
23 the program, including the enforcement unit;

24 “(2) payments for treatment providers that are
25 approved by the relevant State or Tribal jurisdiction

1 and licensed, if necessary, to provide needed treat-
2 ment to eligible offenders participating in the pro-
3 gram, including aftercare supervision, vocational
4 training, education, and job placement; and

5 “(3) payments to public and nonprofit private
6 entities that are approved by the State or Tribal ju-
7 risdiction and licensed, if necessary, to provide alco-
8 hol and drug addiction treatment to eligible offend-
9 ers participating in the program.

10 “(f) SUPPLEMENT NOT SUPPLANT.—An eligible enti-
11 ty shall use Federal funds received under this section only
12 to supplement the funds that would, in the absence of
13 those Federal funds, be made available from other Federal
14 and non-Federal sources for the activities described in this
15 section, and not to supplant those funds. The Federal
16 share of a grant made under this section may not exceed
17 50 percent of the total costs of the program described in
18 an application under subsection (d).

19 “(g) GEOGRAPHIC DISTRIBUTION.—The Attorney
20 General shall ensure that, to the extent practicable, the
21 geographical distribution of grants under this section is
22 equitable and includes a grant to an eligible entity in—

23 “(1) each State;

24 “(2) rural, suburban, and urban areas; and

25 “(3) Tribal jurisdictions.

1 “(h) REPORTS AND EVALUATIONS.—Each fiscal
2 year, each recipient of a grant under this section during
3 that fiscal year shall submit to the Attorney General a
4 report on the outcomes of activities carried out using that
5 grant in such form, containing such information, and on
6 such dates as the Attorney General shall specify.

7 “(i) ACCOUNTABILITY.—All grants awarded by the
8 Attorney General under this section shall be subject to the
9 following accountability provisions:

10 “(1) AUDIT REQUIREMENT.—

11 “(A) DEFINITION.—In this paragraph, the
12 term ‘unresolved audit finding’ means a finding
13 in the final audit report of the Inspector Gen-
14 eral of the Department of Justice that the au-
15 dited grantee has utilized grant funds for an
16 unauthorized expenditure or otherwise unallow-
17 able cost that is not closed or resolved within
18 12 months from the date on which the final
19 audit report is issued.

20 “(B) AUDITS.—Beginning in the first fis-
21 cal year beginning after the date of enactment
22 of this subsection, and in each fiscal year there-
23 after, the Inspector General of the Department
24 of Justice shall conduct audits of recipients of
25 grants under this section to prevent waste,

1 fraud, and abuse of funds by grantees. The In-
2 spector General shall determine the appropriate
3 number of grantees to be audited each year.

4 “(C) MANDATORY EXCLUSION.—A recipi-
5 ent of grant funds under this section that is
6 found to have an unresolved audit finding shall
7 not be eligible to receive grant funds under this
8 section during the first 2 fiscal years beginning
9 after the end of the 12-month period described
10 in subparagraph (A).

11 “(D) PRIORITY.—In awarding grants
12 under this section, the Attorney General shall
13 give priority to eligible applicants that did not
14 have an unresolved audit finding during the 3
15 fiscal years before submitting an application for
16 a grant under this section.

17 “(E) REIMBURSEMENT.—If an entity is
18 awarded grant funds under this section during
19 the 2-fiscal-year period during which the entity
20 is barred from receiving grants under subpara-
21 graph (C), the Attorney General shall—

22 “(i) deposit an amount equal to the
23 amount of the grant funds that were im-
24 properly awarded to the grantee into the
25 General Fund of the Treasury; and

1 “(ii) seek to recoup the costs of the
2 repayment to the fund from the grant re-
3 cipient that was erroneously awarded grant
4 funds.

5 “(2) NONPROFIT ORGANIZATION REQUIRE-
6 MENTS.—

7 “(A) DEFINITION.—For purposes of this
8 paragraph and the grant programs under this
9 part, the term ‘nonprofit organization’ means
10 an organization that is described in section
11 501(c)(3) of the Internal Revenue Code of 1986
12 and is exempt from taxation under section
13 501(a) of such Code.

14 “(B) PROHIBITION.—The Attorney Gen-
15 eral may not award a grant under this part to
16 a nonprofit organization that holds money in
17 offshore accounts for the purpose of avoiding
18 paying the tax described in section 511(a) of
19 the Internal Revenue Code of 1986.

20 “(C) DISCLOSURE.—Each nonprofit orga-
21 nization that is awarded a grant under this sec-
22 tion and uses the procedures prescribed in regu-
23 lations to create a rebuttable presumption of
24 reasonableness for the compensation of its offi-
25 cers, directors, trustees, and key employees,

1 shall disclose to the Attorney General, in the
2 application for the grant, the process for deter-
3 mining such compensation, including the inde-
4 pendent persons involved in reviewing and ap-
5 proving such compensation, the comparability
6 data used, and contemporaneous substantiation
7 of the deliberation and decision. Upon request,
8 the Attorney General shall make the informa-
9 tion disclosed under this subparagraph available
10 for public inspection.

11 “(3) CONFERENCE EXPENDITURES.—

12 “(A) LIMITATION.—No amounts made
13 available to the Department of Justice under
14 this section may be used by the Attorney Gen-
15 eral, or by any individual or entity awarded dis-
16 cretionary funds through a cooperative agree-
17 ment under this section, to host or support any
18 expenditure for conferences that uses more than
19 \$20,000 in funds made available by the Depart-
20 ment of Justice, unless the head of the relevant
21 agency or department, provides prior written
22 authorization that the funds may be expended
23 to host the conference.

24 “(B) WRITTEN APPROVAL.—Written ap-
25 proval under subparagraph (A) shall include a

1 written estimate of all costs associated with the
2 conference, including the cost of all food, bev-
3 erages, audio-visual equipment, honoraria for
4 speakers, and entertainment.

5 “(C) REPORT.—The Deputy Attorney Gen-
6 eral shall submit an annual report to the Com-
7 mittee on the Judiciary of the Senate and the
8 Committee on the Judiciary of the House of
9 Representatives on all conference expenditures
10 approved under this paragraph.

11 “(4) ANNUAL CERTIFICATION.—Beginning in
12 the first fiscal year beginning after the date of en-
13 actment of this subsection, the Attorney General
14 shall submit, to the Committee on the Judiciary and
15 the Committee on Appropriations of the Senate and
16 the Committee on the Judiciary and the Committee
17 on Appropriations of the House of Representatives,
18 an annual certification—

19 “(A) indicating whether—

20 “(i) all audits issued by the Office of
21 the Inspector General under paragraph (1)
22 have been completed and reviewed by the
23 appropriate Assistant Attorney General or
24 Director;

1 “(ii) all mandatory exclusions required
2 under paragraph (1)(C) have been issued;
3 and

4 “(iii) all reimbursements required
5 under paragraph (1)(E) have been made;
6 and

7 “(B) that includes a list of any grant re-
8 cipients excluded under paragraph (1) from the
9 previous year.

10 “(5) PREVENTING DUPLICATIVE GRANTS.—

11 “(A) IN GENERAL.—Before the Attorney
12 General awards a grant to an applicant under
13 this section, the Attorney General shall compare
14 potential grant awards with other grants
15 awarded under this Act to determine if dupli-
16 cate grant awards are awarded for the same
17 purpose.

18 “(B) REPORT.—If the Attorney General
19 awards duplicate grants to the same applicant
20 for the same purpose the Attorney General shall
21 submit to the Committee on the Judiciary of
22 the Senate and the Committee on the Judiciary
23 of the House of Representatives a report that
24 includes—

1 “(i) a list of all duplicate grants
2 awarded, including the total dollar amount
3 of any duplicate grants awarded; and

4 “(ii) the reason the Attorney General
5 awarded the duplicate grants.”.

6 **SEC. 14014. NATIONAL CRIMINAL JUSTICE AND MENTAL**
7 **HEALTH TRAINING AND TECHNICAL ASSIST-**
8 **ANCE.**

9 Part HH of title I of the Omnibus Crime Control and
10 Safe Streets Act of 1968 (42 U.S.C. 3797aa et seq.) is
11 amended by adding at the end the following:

12 **“SEC. 2992. NATIONAL CRIMINAL JUSTICE AND MENTAL**
13 **HEALTH TRAINING AND TECHNICAL ASSIST-**
14 **ANCE.**

15 “(a) **AUTHORITY.**—The Attorney General may make
16 grants to eligible organizations to provide for the estab-
17 lishment of a National Criminal Justice and Mental
18 Health Training and Technical Assistance Center.

19 “(b) **ELIGIBLE ORGANIZATION.**—For purposes of
20 subsection (a), the term ‘eligible organization’ means a na-
21 tional nonprofit organization that provides technical as-
22 sistance and training to, and has special expertise and
23 broad, national-level experience in, mental health, crisis
24 intervention, criminal justice systems, law enforcement,
25 translating evidence into practice, training, and research,

1 and education and support of people with mental illness
2 and the families of such individuals.

3 “(c) USE OF FUNDS.—Any organization that receives
4 a grant under subsection (a) shall collaborate with other
5 grant recipients to establish and operate a National Crimi-
6 nal Justice and Mental Health Training and Technical As-
7 sistance Center to—

8 “(1) provide law enforcement officer training
9 regarding mental health and working with individ-
10 uals with mental illnesses, with an emphasis on de-
11 escalation of encounters between law enforcement of-
12 ficers and those with mental disorders or in crisis,
13 which shall include support the development of in-
14 person and technical information exchanges between
15 systems and the individuals working in those sys-
16 tems in support of the concepts identified in the
17 training;

18 “(2) provide education, training, and technical
19 assistance for States, Indian tribes, territories, units
20 of local government, service providers, nonprofit or-
21 ganizations, probation or parole officers, prosecu-
22 tors, defense attorneys, emergency response pro-
23 viders, and corrections institutions to advance prac-
24 tice and knowledge relating to mental health crisis

1 and approaches to mental health and criminal jus-
2 tice across systems;

3 “(3) provide training and best practices to men-
4 tal health providers and criminal justice agencies re-
5 lating to diversion initiatives, jail and prison strate-
6 gies, reentry of individuals with mental illnesses into
7 the community, and dispatch protocols and triage
8 capabilities, including the establishment of learning
9 sites;

10 “(4) develop suicide prevention and crisis inter-
11 vention training and technical assistance for criminal
12 justice agencies;

13 “(5) develop a receiving center system and pilot
14 strategy that provides, for a jurisdiction, a single
15 point of entry into the mental health and substance
16 abuse system for assessments and appropriate place-
17 ment of individuals experiencing a crisis;

18 “(6) collect data and best practices in mental
19 health and criminal health and criminal justice ini-
20 tiatives and policies from grantees under this part,
21 other recipients of grants under this section, Fed-
22 eral, State, and local agencies involved in the provi-
23 sion of mental health services, and nongovernmental
24 organizations involved in the provision of mental
25 health services;

1 “(7) develop and disseminate to mental health
2 providers and criminal justice agencies evaluation
3 tools, mechanisms, and measures to better assess
4 and document performance measures and outcomes
5 relating to the provision of mental health services;

6 “(8) disseminate information to States, units of
7 local government, criminal justice agencies, law en-
8 forcement agencies, and other relevant entities about
9 best practices, policy standards, and research find-
10 ings relating to the provision of mental health serv-
11 ices; and

12 “(9) provide education and support to individ-
13 uals with mental illness involved with, or at risk of
14 involvement with, the criminal justice system, includ-
15 ing the families of such individuals.

16 “(d) ACCOUNTABILITY.—Grants awarded under this
17 section shall be subject to the following accountability pro-
18 visions:

19 “(1) AUDIT REQUIREMENT.—

20 “(A) DEFINITION.—In this paragraph, the
21 term ‘unresolved audit finding’ means a finding
22 in the final audit report of the Inspector Gen-
23 eral of the Department of Justice under sub-
24 paragraph (C) that the audited grantee has
25 used grant funds for an unauthorized expendi-

1 ture or otherwise unallowable cost that is not
2 closed or resolved within 1 year after the date
3 on which the final audit report is issued.

4 “(B) AUDITS.—Beginning in the first fis-
5 cal year beginning after the date of enactment
6 of this section, and in each fiscal year there-
7 after, the Inspector General of the Department
8 of Justice shall conduct audits of grantees
9 under this section to prevent waste, fraud, and
10 abuse of funds by grantees. The Inspector Gen-
11 eral shall determine the appropriate number of
12 grantees to be audited each year.

13 “(C) FINAL AUDIT REPORT.—The Inspec-
14 tor General of the Department of Justice shall
15 submit to the Attorney General a final report
16 on each audit conducted under subparagraph
17 (B).

18 “(D) MANDATORY EXCLUSION.—Grantees
19 under this section about which there is an unre-
20 solved audit finding shall not be eligible to re-
21 ceive a grant under this section during the 2
22 fiscal years beginning after the end of the 1-
23 year period described in subparagraph (A).

24 “(E) PRIORITY.—In making grants under
25 this section, the Attorney General shall give pri-

1 ority to applicants that did not have an unre-
2 solved audit finding during the 3 fiscal years
3 before submitting an application for a grant
4 under this section.

5 “(F) REIMBURSEMENT.—If an entity re-
6 ceives a grant under this section during the 2-
7 fiscal-year period during which the entity is
8 prohibited from receiving grants under subpara-
9 graph (D), the Attorney General shall—

10 “(i) deposit an amount equal to the
11 amount of the grant that was improperly
12 awarded to the grantee into the General
13 Fund of the Treasury; and

14 “(ii) seek to recoup the costs of the
15 repayment under clause (i) from the grant-
16 ee that was erroneously awarded grant
17 funds.

18 “(2) NONPROFIT AGENCY REQUIREMENTS.—

19 “(A) DEFINITION.—For purposes of this
20 paragraph and the grant program under this
21 section, the term ‘nonprofit agency’ means an
22 organization that is described in section
23 501(c)(3) of the Internal Revenue Code of 1986
24 (26 U.S.C. 501(c)(3)) and is exempt from tax-

1 ation under section 501(a) of the Internal Rev-
2 enue Code of 1986 (26 U.S.C. 501(a)).

3 “(B) PROHIBITION.—The Attorney Gen-
4 eral may not award a grant under this section
5 to a nonprofit agency that holds money in an
6 offshore account for the purpose of avoiding
7 paying the tax described in section 511(a) of
8 the Internal Revenue Code of 1986 (26 U.S.C.
9 511(a)).

10 “(C) DISCLOSURE.—Each nonprofit agen-
11 cy that is awarded a grant under this section
12 and uses the procedures prescribed in regula-
13 tions to create a rebuttable presumption of rea-
14 sonableness for the compensation of its officers,
15 directors, trustees, and key employees, shall dis-
16 close to the Attorney General, in the application
17 for the grant, the process for determining such
18 compensation, including the independent per-
19 sons involved in reviewing and approving such
20 compensation, the comparability data used, and
21 contemporaneous substantiation of the delibera-
22 tion and decision. Upon request, the Attorney
23 General shall make the information disclosed
24 under this subparagraph available for public in-
25 spection.

1 “(3) CONFERENCE EXPENDITURES.—

2 “(A) LIMITATION.—No amounts made
3 available to the Department of Justice under
4 this section may be used by the Attorney Gen-
5 eral, or by any individual or entity awarded dis-
6 cretionary funds through a cooperative agree-
7 ment under this section, to host or support any
8 expenditure for conferences that uses more than
9 \$20,000 in funds made available by the Depart-
10 ment of Justice, unless the head of the relevant
11 agency or department, provides prior written
12 authorization that the funds may be expended
13 to host the conference.

14 “(B) WRITTEN APPROVAL.—Written ap-
15 proval under subparagraph (A) shall include a
16 written estimate of all costs associated with the
17 conference, including the cost of all food, bev-
18 erages, audio-visual equipment, honoraria for
19 speakers, and entertainment.

20 “(C) REPORT.—The Deputy Attorney Gen-
21 eral shall submit an annual report to the Com-
22 mittee on the Judiciary of the Senate and the
23 Committee on the Judiciary of the House of
24 Representatives on all conference expenditures
25 approved under this paragraph.

1 “(4) ANNUAL CERTIFICATION.—Beginning in
2 the first fiscal year beginning after the date of en-
3 actment of this subsection, the Attorney General
4 shall submit to the Committee on the Judiciary and
5 the Committee on Appropriations of the Senate and
6 the Committee on the Judiciary and the Committee
7 on Appropriations of the House of Representatives
8 an annual certification—

9 “(A) indicating whether—

10 “(i) all final audit reports issued by
11 the Office of the Inspector General under
12 paragraph (1) have been completed and re-
13 viewed by the appropriate Assistant Attor-
14 ney General or Director;

15 “(ii) all mandatory exclusions required
16 under paragraph (1)(D) have been issued;
17 and

18 “(iii) any reimbursements required
19 under paragraph (1)(F) have been made;
20 and

21 “(B) that includes a list of any grantees
22 excluded under paragraph (1)(D) from the pre-
23 vious year.

24 “(5) PREVENTING DUPLICATIVE GRANTS.—

1 “(A) IN GENERAL.—Before the Attorney
2 General awards a grant to an applicant under
3 this section, the Attorney General shall compare
4 potential grant awards with other grants
5 awarded under this Act to determine if dupli-
6 cate grant awards are awarded for the same
7 purpose.

8 “(B) REPORT.—If the Attorney General
9 awards duplicate grants to the same applicant
10 for the same purpose the Attorney General shall
11 submit to the Committee on the Judiciary of
12 the Senate and the Committee on the Judiciary
13 of the House of Representatives a report that
14 includes—

15 “(i) a list of all duplicate grants
16 awarded, including the total dollar amount
17 of any duplicate grants awarded; and

18 “(ii) the reason the Attorney General
19 awarded the duplicate grants.”.

20 **SEC. 14015. IMPROVING DEPARTMENT OF JUSTICE DATA**
21 **COLLECTION ON MENTAL ILLNESS INVOLVED**
22 **IN CRIME.**

23 (a) IN GENERAL.—Notwithstanding any other provi-
24 sion of law, on or after the date that is 90 days after the
25 date on which the Attorney General promulgates regula-

1 tions under subsection (b), any data prepared by, or sub-
2 mitted to, the Attorney General or the Director of the
3 Federal Bureau of Investigation with respect to the
4 incidences of homicides, law enforcement officers killed,
5 seriously injured, and assaulted, or individuals killed or
6 seriously injured by law enforcement officers shall include
7 data with respect to the involvement of mental illness in
8 such incidences, if any.

9 (b) REGULATIONS.—Not later than 90 days after the
10 date of the enactment of this Act, the Attorney General
11 shall promulgate or revise regulations as necessary to
12 carry out subsection (a).

13 **SEC. 14016. REPORTS ON THE NUMBER OF MENTALLY ILL**
14 **OFFENDERS IN PRISON.**

15 (a) REPORT ON THE COST OF TREATING THE MEN-
16 TALLY ILL IN THE CRIMINAL JUSTICE SYSTEM.—Not
17 later than 12 months after the date of enactment of this
18 Act, the Comptroller General of the United States shall
19 submit to Congress a report detailing the cost of imprison-
20 ment for individuals who have serious mental illness by
21 the Federal Government or a State or unit of local govern-
22 ment, which shall include—

23 (1) the number and type of crimes committed
24 by individuals with serious mental illness each year;
25 and

1 (2) detail strategies or ideas for preventing
2 crimes by those individuals with serious mental ill-
3 ness from occurring.

4 (b) DEFINITION.—For purposes of this section, the
5 Attorney General, in consultation with the Assistant Sec-
6 retary of Mental Health and Substance Use Disorders,
7 shall define “serious mental illness” based on the “Health
8 Care Reform for Americans with Severe Mental Illnesses:
9 Report” of the National Advisory Mental Health Council,
10 American Journal of Psychiatry 1993; 150:1447–1465.

11 **SEC. 14017. DEPARTMENT OF VETERANS AFFAIRS PA-**
12 **TIENTS’ RIGHTS.**

13 (a) IN GENERAL.—Chapter 55 of title 38, United
14 States Code, is amended by adding at the end the fol-
15 lowing new section:

16 **“§ 5511. Limitation on determinations regarding men-**
17 **tal competence of individuals**

18 “(a) IN GENERAL.—The Secretary may not make an
19 adjudicative determination concerning the mental capacity
20 of an individual unless such individual has been provided
21 all of the following:

22 “(1) Notice of the proposed determination.

23 “(2) An opportunity to request a hearing.

1 “(3) An opportunity to request the opinion or
2 presence of a medical professional at any such hear-
3 ing.

4 “(4) An opportunity to be represented (includ-
5 ing by counsel) at any such hearing.

6 “(b) APPEAL.—A determination of incompetency by
7 the Secretary under subsection (a) may be appealed in ac-
8 cordance with the provisions of chapters 71 and 72 of this
9 title.”.

10 (b) CLERICAL AMENDMENT.—The table of sections
11 at the beginning of chapter 55 of such title is amended
12 by adding at the end the following new item:

 “5511. Limitation on determinations regarding mental competence of individ-
 uals.”.

13 **SEC. 14018. REAUTHORIZATION OF APPROPRIATIONS.**

14 Subsection (o) of section 2991 of the Omnibus Crime
15 Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa),
16 as redesignated by section 14006, is amended—

17 (1) in paragraph (1)(C), by striking “2009
18 through 2014” and inserting “2017 through 2021”;
19 and

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

21 “(3) LIMITATION.—Not more than 20 percent of the
22 funds authorized to be appropriated under this section
23 may be used for purposes described in subsection (i) (re-
24 lating to veterans).”.

1 **Subtitle B—Comprehensive Justice**
2 **and Mental Health**

3 **SEC. 14021. SEQUENTIAL INTERCEPT MODEL.**

4 Section 2991 of title I of the Omnibus Crime Control
5 and Safe Streets Act of 1968 (42 U.S.C. 3797aa), as
6 amended by section 14005, is amended by inserting after
7 subsection (j), the following:

8 “(k) SEQUENTIAL INTERCEPT GRANTS.—

9 “(1) DEFINITION.—In this subsection, the term
10 ‘eligible entity’ means a State, unit of local govern-
11 ment, Indian tribe, or tribal organization.

12 “(2) AUTHORIZATION.—The Attorney General
13 may make grants under this subsection to an eligible
14 entity for sequential intercept mapping and imple-
15 mentation in accordance with paragraph (3).

16 “(3) SEQUENTIAL INTERCEPT MAPPING; IMPLE-
17 MENTATION.—An eligible entity that receives a
18 grant under this subsection may use funds for—

19 “(A) sequential intercept mapping,
20 which—

21 “(i) shall consist of—

22 “(I) convening mental health and
23 criminal justice stakeholders to—

24 “(aa) develop a shared un-
25 derstanding of the flow of justice-

1 involved individuals with mental
2 illnesses through the criminal
3 justice system; and

4 “(bb) identify opportunities
5 for improved collaborative re-
6 sponses to the risks and needs of
7 individuals described in item
8 (aa); and

9 “(II) developing strategies to ad-
10 dress gaps in services and bring inno-
11 vative and effective programs to scale
12 along multiple intercepts, including—

13 “(aa) emergency and crisis
14 services;

15 “(bb) specialized police-
16 based responses;

17 “(cc) court hearings and dis-
18 position alternatives;

19 “(dd) reentry from jails and
20 prisons; and

21 “(ee) community super-
22 vision, treatment and support
23 services; and

24 “(ii) may serve as a starting point for
25 the development of strategic plans to

1 achieve positive public health and safety
2 outcomes; and

3 “(B) implementation, which shall—

4 “(i) be derived from the strategic
5 plans described in subparagraph (A)(ii);
6 and

7 “(ii) consist of—

8 “(I) hiring and training per-
9 sonnel;

10 “(II) identifying the eligible enti-
11 ty’s target population;

12 “(III) providing services and sup-
13 ports to reduce unnecessary penetra-
14 tion into the criminal justice system;

15 “(IV) reducing recidivism;

16 “(V) evaluating the impact of the
17 eligible entity’s approach; and

18 “(VI) planning for the sustain-
19 ability of effective interventions.”.

20 **SEC. 14022. PRISON AND JAILS.**

21 Section 2991 of title I of the Omnibus Crime Control
22 and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is
23 amended by inserting after subsection (k), as added by
24 section 14021, the following:

25 “(l) CORRECTIONAL FACILITIES.—

1 “(1) DEFINITIONS.—

2 “(A) CORRECTIONAL FACILITY.—The term
3 ‘correctional facility’ means a jail, prison, or
4 other detention facility used to house people
5 who have been arrested, detained, held, or con-
6 victed by a criminal justice agency or a court.

7 “(B) ELIGIBLE INMATE.—The term ‘eligi-
8 ble inmate’ means an individual who—

9 “(i) is being held, detained, or incar-
10 cerated in a correctional facility; and

11 “(ii) manifests obvious signs of a
12 mental illness or has been diagnosed by a
13 qualified mental health professional as hav-
14 ing a mental illness.

15 “(2) CORRECTIONAL FACILITY GRANTS.—The
16 Attorney General may award grants to applicants to
17 enhance the capabilities of a correctional facility—

18 “(A) to identify and screen for eligible in-
19 mates;

20 “(B) to plan and provide—

21 “(i) initial and periodic assessments of
22 the clinical, medical, and social needs of in-
23 mates; and

1 “(ii) appropriate treatment and serv-
2 ices that address the mental health and
3 substance abuse needs of inmates;

4 “(C) to develop, implement, and enhance—

5 “(i) post-release transition plans for
6 eligible inmates that, in a comprehensive
7 manner, coordinate health, housing, med-
8 ical, employment, and other appropriate
9 services and public benefits;

10 “(ii) the availability of mental health
11 care services and substance abuse treat-
12 ment services; and

13 “(iii) alternatives to solitary confine-
14 ment and segregated housing and mental
15 health screening and treatment for inmates
16 placed in solitary confinement or seg-
17 regated housing; and

18 “(D) to train each employee of the correc-
19 tional facility to identify and appropriately re-
20 spond to incidents involving inmates with men-
21 tal health or co-occurring mental health and
22 substance abuse disorders.”.

23 **SEC. 14023. ALLOWABLE USES.**

24 Section 2991(b)(5)(I) of title I of the Omnibus Crime
25 Control and Safe Streets Act of 1968 (42 U.S.C.

1 3797aa(b)(5)(I) is amended by adding at the end the fol-
2 lowing:

3 “(v) TEAMS ADDRESSING FREQUENT
4 USERS OF CRISIS SERVICES.—Multidisci-
5 plinary teams that—

6 “(I) coordinate, implement, and
7 administer community-based crisis re-
8 sponses and long-term plans for fre-
9 quent users of crisis services;

10 “(II) provide training on how to
11 respond appropriately to the unique
12 issues involving frequent users of cri-
13 sis services for public service per-
14 sonnel, including criminal justice,
15 mental health, substance abuse, emer-
16 gency room, healthcare, law enforce-
17 ment, corrections, and housing per-
18 sonnel;

19 “(III) develop or support alter-
20 natives to hospital and jail admissions
21 for frequent users of crisis services
22 that provide treatment, stabilization,
23 and other appropriate supports in the
24 least restrictive, yet appropriate, envi-
25 ronment; and

1 “(IV) develop protocols and sys-
2 tems among law enforcement, mental
3 health, substance abuse, housing, cor-
4 rections, and emergency medical serv-
5 ice operations to provide coordinated
6 assistance to frequent users of crisis
7 services.”.

8 **SEC. 14024. LAW ENFORCEMENT TRAINING.**

9 Section 2991(h) of title I of the Omnibus Crime Con-
10 trol and Safe Streets Act of 1968 (42 U.S.C. 3797aa(h))
11 is amended—

12 (1) in paragraph (1), by adding at the end the
13 following:

14 “(F) **ACADEMY TRAINING.**—To provide
15 support for academy curricula, law enforcement
16 officer orientation programs, continuing edu-
17 cation training, and other programs that teach
18 law enforcement personnel how to identify and
19 respond to incidents involving persons with
20 mental health disorders or co-occurring mental
21 health and substance abuse disorders.”; and

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

23 “(4) **PRIORITY CONSIDERATION.**—The Attorney
24 General, in awarding grants under this subsection,
25 shall give priority to programs that law enforcement

1 personnel and members of the mental health and
2 substance abuse professions develop and administer
3 cooperatively.”.

4 **SEC. 14025. FEDERAL LAW ENFORCEMENT TRAINING.**

5 Not later than 1 year after the date of enactment
6 of this Act, the Attorney General shall provide direction
7 and guidance for the following:

8 (1) TRAINING PROGRAMS.—Programs that offer
9 specialized and comprehensive training, in proce-
10 dures to identify and appropriately respond to inci-
11 dents in which the unique needs of individuals who
12 have a mental illness are involved, to first respond-
13 ers and tactical units of—

14 (A) Federal law enforcement agencies; and

15 (B) other Federal criminal justice agencies
16 such as the Bureau of Prisons, the Administra-
17 tive Office of the United States Courts, and
18 other agencies that the Attorney General deter-
19 mines appropriate.

20 (2) IMPROVED TECHNOLOGY.—The establish-
21 ment of, or improvement of existing, computerized
22 information systems to provide timely information to
23 employees of Federal law enforcement agencies, and
24 Federal criminal justice agencies to improve the re-

1 sponse of such employees to situations involving in-
2 dividuals who have a mental illness.

3 **SEC. 14026. GAO REPORT.**

4 No later than 1 year after the date of enactment of
5 this Act, the Comptroller General of the United States,
6 in coordination with the Attorney General, shall submit
7 to Congress a report on—

8 (1) the practices that Federal first responders,
9 tactical units, and corrections officers are trained to
10 use in responding to individuals with mental illness;

11 (2) procedures to identify and appropriately re-
12 spond to incidents in which the unique needs of indi-
13 viduals who have a mental illness are involved, to
14 Federal first responders and tactical units;

15 (3) the application of evidence-based practices
16 in criminal justice settings to better address individ-
17 uals with mental illnesses; and

18 (4) recommendations on how the Department of
19 Justice can expand and improve information sharing
20 and dissemination of best practices.

21 **SEC. 14027. EVIDENCE BASED PRACTICES.**

22 Section 2991(c) of title I of the Omnibus Crime Con-
23 trol and Safe Streets Act of 1968 (42 U.S.C. 3797aa(e))
24 is amended—

1 (1) in paragraph (3), by striking “or” at the
2 end;

3 (2) by redesignating paragraph (4) as para-
4 graph (6); and

5 (3) by inserting after paragraph (3), the fol-
6 lowing:

7 “(4) propose interventions that have been
8 shown by empirical evidence to reduce recidivism;

9 “(5) when appropriate, use validated assess-
10 ment tools to target preliminarily qualified offenders
11 with a moderate or high risk of recidivism and a
12 need for treatment and services; or”.

13 **SEC. 14028. TRANSPARENCY, PROGRAM ACCOUNTABILITY,**
14 **AND ENHANCEMENT OF LOCAL AUTHORITY.**

15 (a) IN GENERAL.—Section 2991(a) of title I of the
16 Omnibus Crime Control and Safe Streets Act of 1968 (42
17 U.S.C. 3797aa(a)) is amended—

18 (1) in paragraph (7)—

19 (A) in the heading, by striking “MENTAL
20 ILLNESS” and inserting “MENTAL ILLNESS;
21 MENTAL HEALTH DISORDER”; and

22 (B) by striking “term ‘mental illness’
23 means” and inserting “terms ‘mental illness’
24 and ‘mental health disorder’ mean”; and

1 (2) by striking paragraph (9) and inserting the
2 following:

3 “(9) PRELIMINARILY QUALIFIED OFFENDER.—

4 “(A) IN GENERAL.—The term ‘prelimi-
5 narily qualified offender’ means an adult or ju-
6 venile accused of an offense who—

7 “(i)(I) previously or currently has
8 been diagnosed by a qualified mental
9 health professional as having a mental ill-
10 ness or co-occurring mental illness and
11 substance abuse disorders;

12 “(II) manifests obvious signs of men-
13 tal illness or co-occurring mental illness
14 and substance abuse disorders during ar-
15 rest or confinement or before any court; or

16 “(III) in the case of a veterans treat-
17 ment court provided under subsection (i),
18 has been diagnosed with, or manifests ob-
19 vious signs of, mental illness or a sub-
20 stance abuse disorder or co-occurring men-
21 tal illness and substance abuse disorder;

22 “(ii) has been unanimously approved
23 for participation in a program funded
24 under this section by, when appropriate—

25 “(I) the relevant—

1 “(aa) prosecuting attorney;
2 “(bb) defense attorney;
3 “(cc) probation or correc-
4 tions official; and
5 “(dd) judge; and
6 “(II) a representative from the
7 relevant mental health agency de-
8 scribed in subsection (b)(5)(B)(i);
9 “(iii) has been determined, by each
10 person described in clause (ii) who is in-
11 volved in approving the adult or juvenile
12 for participation in a program funded
13 under this section, to not pose a risk of vi-
14 olence to any person in the program, or
15 the public, if selected to participate in the
16 program; and
17 “(iv) has not been charged with or
18 convicted of—
19 “(I) any sex offense (as defined
20 in section 111 of the Sex Offender
21 Registration and Notification Act (42
22 U.S.C. 16911)) or any offense relat-
23 ing to the sexual exploitation of chil-
24 dren; or

1 “(II) murder or assault with in-
2 tent to commit murder.

3 “(B) DETERMINATION.—In determining
4 whether to designate a defendant as a prelimi-
5 narily qualified offender, the relevant pros-
6 ecuting attorney, defense attorney, probation or
7 corrections official, judge, and mental health or
8 substance abuse agency representative shall
9 take into account—

10 “(i) whether the participation of the
11 defendant in the program would pose a
12 substantial risk of violence to the commu-
13 nity;

14 “(ii) the criminal history of the de-
15 fendant and the nature and severity of the
16 offense for which the defendant is charged;

17 “(iii) the views of any relevant victims
18 to the offense;

19 “(iv) the extent to which the defend-
20 ant would benefit from participation in the
21 program;

22 “(v) the extent to which the commu-
23 nity would realize cost savings because of
24 the defendant’s participation in the pro-
25 gram; and

1 “(vi) whether the defendant satisfies
2 the eligibility criteria for program partici-
3 pation unanimously established by the rel-
4 evant prosecuting attorney, defense attor-
5 ney, probation or corrections official, judge
6 and mental health or substance abuse
7 agency representative.”.

8 (b) **TECHNICAL AND CONFORMING AMENDMENT.**—
9 Section 2927(2) of title I of the Omnibus Crime Control
10 and Safe Streets Act of 1968 (42 U.S.C. 3797s–6(2)) is
11 amended by striking “has the meaning given that term
12 in section 2991(a).” and inserting “means an offense
13 that—

14 “(A) does not have as an element the use,
15 attempted use, or threatened use of physical
16 force against the person or property of another;
17 or

18 “(B) is not a felony that by its nature in-
19 volves a substantial risk that physical force
20 against the person or property of another may
21 be used in the course of committing the of-
22 fense.”.

23 **SEC. 14029. GRANT ACCOUNTABILITY.**

24 Section 2991 of title I of the Omnibus Crime Control
25 and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is

1 amended by inserting after subsection (l), as added by sec-
2 tion 14022, the following:

3 “(m) ACCOUNTABILITY.—All grants awarded by the
4 Attorney General under this section shall be subject to the
5 following accountability provisions:

6 “(1) AUDIT REQUIREMENT.—

7 “(A) DEFINITION.—In this paragraph, the
8 term ‘unresolved audit finding’ means a finding
9 in the final audit report of the Inspector Gen-
10 eral of the Department of Justice that the au-
11 dited grantee has utilized grant funds for an
12 unauthorized expenditure or otherwise unallow-
13 able cost that is not closed or resolved within
14 12 months from the date when the final audit
15 report is issued.

16 “(B) AUDITS.—Beginning in the first fis-
17 cal year beginning after the date of enactment
18 of this subsection, and in each fiscal year there-
19 after, the Inspector General of the Department
20 of Justice shall conduct audits of recipients of
21 grants under this section to prevent waste,
22 fraud, and abuse of funds by grantees. The In-
23 spector General shall determine the appropriate
24 number of grantees to be audited each year.

1 “(C) MANDATORY EXCLUSION.—A recipi-
2 ent of grant funds under this section that is
3 found to have an unresolved audit finding shall
4 not be eligible to receive grant funds under this
5 section during the first 2 fiscal years beginning
6 after the end of the 12-month period described
7 in subparagraph (A).

8 “(D) PRIORITY.—In awarding grants
9 under this section, the Attorney General shall
10 give priority to eligible applicants that did not
11 have an unresolved audit finding during the 3
12 fiscal years before submitting an application for
13 a grant under this section.

14 “(E) REIMBURSEMENT.—If an entity is
15 awarded grant funds under this section during
16 the 2-fiscal-year period during which the entity
17 is barred from receiving grants under subpara-
18 graph (C), the Attorney General shall—

19 “(i) deposit an amount equal to the
20 amount of the grant funds that were im-
21 properly awarded to the grantee into the
22 General Fund of the Treasury; and

23 “(ii) seek to recoup the costs of the
24 repayment to the fund from the grant re-

1 cipient that was erroneously awarded grant
2 funds.

3 “(2) NONPROFIT ORGANIZATION REQUIRE-
4 MENTS.—

5 “(A) DEFINITION.—For purposes of this
6 paragraph and the grant programs under this
7 part, the term ‘nonprofit organization’ means
8 an organization that is described in section
9 501(c)(3) of the Internal Revenue Code of 1986
10 and is exempt from taxation under section
11 501(a) of such Code.

12 “(B) PROHIBITION.—The Attorney Gen-
13 eral may not award a grant under this part to
14 a nonprofit organization that holds money in
15 offshore accounts for the purpose of avoiding
16 paying the tax described in section 511(a) of
17 the Internal Revenue Code of 1986.

18 “(C) DISCLOSURE.—Each nonprofit orga-
19 nization that is awarded a grant under this sec-
20 tion and uses the procedures prescribed in regu-
21 lations to create a rebuttable presumption of
22 reasonableness for the compensation of its offi-
23 cers, directors, trustees, and key employees,
24 shall disclose to the Attorney General, in the
25 application for the grant, the process for deter-

1 mining such compensation, including the inde-
2 pendent persons involved in reviewing and ap-
3 proving such compensation, the comparability
4 data used, and contemporaneous substantiation
5 of the deliberation and decision. Upon request,
6 the Attorney General shall make the informa-
7 tion disclosed under this subparagraph available
8 for public inspection.

9 “(3) CONFERENCE EXPENDITURES.—

10 “(A) LIMITATION.—No amounts made
11 available to the Department of Justice under
12 this section may be used by the Attorney Gen-
13 eral, or by any individual or entity awarded dis-
14 cretionary funds through a cooperative agree-
15 ment under this section, to host or support any
16 expenditure for conferences that uses more than
17 \$20,000 in funds made available by the Depart-
18 ment of Justice, unless the head of the relevant
19 agency or department, provides prior written
20 authorization that the funds may be expended
21 to host the conference.

22 “(B) WRITTEN APPROVAL.—Written ap-
23 proval under subparagraph (A) shall include a
24 written estimate of all costs associated with the
25 conference, including the cost of all food, bev-

1 erages, audio-visual equipment, honoraria for
2 speakers, and entertainment.

3 “(C) REPORT.—The Deputy Attorney Gen-
4 eral shall submit an annual report to the Com-
5 mittee on the Judiciary of the Senate and the
6 Committee on the Judiciary of the House of
7 Representatives on all conference expenditures
8 approved under this paragraph.

9 “(4) ANNUAL CERTIFICATION.—Beginning in
10 the first fiscal year beginning after the date of en-
11 actment of this subsection, the Attorney General
12 shall submit, to the Committee on the Judiciary and
13 the Committee on Appropriations of the Senate and
14 the Committee on the Judiciary and the Committee
15 on Appropriations of the House of Representatives,
16 an annual certification—

17 “(A) indicating whether—

18 “(i) all audits issued by the Office of
19 the Inspector General under paragraph (1)
20 have been completed and reviewed by the
21 appropriate Assistant Attorney General or
22 Director;

23 “(ii) all mandatory exclusions required
24 under paragraph (1)(C) have been issued;
25 and

1 “(iii) all reimbursements required
2 under paragraph (1)(E) have been made;
3 and

4 “(B) that includes a list of any grant re-
5 cipients excluded under paragraph (1) from the
6 previous year.

7 “(n) PREVENTING DUPLICATIVE GRANTS.—

8 “(1) IN GENERAL.—Before the Attorney Gen-
9 eral awards a grant to an applicant under this sec-
10 tion, the Attorney General shall compare potential
11 grant awards with other grants awarded under this
12 Act to determine if duplicate grant awards are
13 awarded for the same purpose.

14 “(2) REPORT.—If the Attorney General awards
15 duplicate grants to the same applicant for the same
16 purpose the Attorney General shall submit to the
17 Committee on the Judiciary of the Senate and the
18 Committee on the Judiciary of the House of Rep-
19 resentatives a report that includes—

20 “(A) a list of all duplicate grants awarded,
21 including the total dollar amount of any dupli-
22 cate grants awarded; and

23 “(B) the reason the Attorney General
24 awarded the duplicate grants.”.

1 **DIVISION** **C—INCREASING**
2 **CHOICE, ACCESS, AND QUAL-**
3 **ITY IN HEALTH CARE FOR**
4 **AMERICANS**

5 **SEC. 15000. SHORT TITLE.**

6 This division may be cited as the “Increasing Choice,
7 Access, and Quality in Health Care for Americans Act”.

8 **TITLE XV—PROVISIONS RELAT-**
9 **ING TO MEDICARE PART A**

10 **SEC. 15001. DEVELOPMENT OF MEDICARE HCPCS VERSION**
11 **OF MS-DRG CODES FOR SIMILAR HOSPITAL**
12 **SERVICES.**

13 Section 1886 of the Social Security Act (42 U.S.C.
14 1395ww) is amended by adding at the end the following
15 new subsection:

16 “(t) RELATING SIMILAR INPATIENT AND OUT-
17 PATIENT HOSPITAL SERVICES.—

18 “(1) DEVELOPMENT OF HCPCS VERSION OF
19 MS-DRG CODES.—Not later than January 1, 2018,
20 the Secretary shall develop HCPCS versions for
21 MS-DRGs that are similar to the ICD-10-PCS for
22 such MS-DRGs such that, to the extent possible,
23 the MS-DRG assignment shall be similar for a
24 claim coded with the HCPCS version as an identical
25 claim coded with a ICD-10-PCS code.

1 “(2) COVERAGE OF SURGICAL MS-DRGS.—In
2 carrying out paragraph (1), the Secretary shall de-
3 velop HCPCS versions of MS-DRG codes for not
4 fewer than 10 surgical MS-DRGs.

5 “(3) PUBLICATION AND DISSEMINATION OF
6 THE HCPCS VERSIONS OF MS-DRGS.—

7 “(A) IN GENERAL.—The Secretary shall
8 develop a HCPCS MS-DRG definitions manual
9 and software that is similar to the definitions
10 manual and software for ICD-10-PCS codes
11 for such MS-DRGs. The Secretary shall post
12 the HCPCS MS-DRG definitions manual and
13 software on the Internet website of the Centers
14 for Medicare & Medicaid Services. The HCPCS
15 MS-DRG definitions manual and software shall
16 be in the public domain and available for use
17 and redistribution without charge.

18 “(B) USE OF PREVIOUS ANALYSIS DONE
19 BY MEDPAC.—In developing the HCPCS MS-
20 DRG definitions manual and software under
21 subparagraph (A), the Secretary shall consult
22 with the Medicare Payment Advisory Commis-
23 sion and shall consider the analysis done by
24 such Commission in translating outpatient sur-
25 gical claims into inpatient surgical MS-DRGs

1 in preparing chapter 7 (relating to hospital
2 short-stay policy issues) of its ‘Medicare and
3 the Health Care Delivery System’ report sub-
4 mitted to Congress in June 2015.

5 “(4) DEFINITION AND REFERENCE.—In this
6 subsection:

7 “(A) HCPCS.—The term ‘HCPCS’ means,
8 with respect to hospital items and services, the
9 code under the Healthcare Common Procedure
10 Coding System (HCPCS) (or a successor code)
11 for such items and services.

12 “(B) ICD–10–PCS.—The term ‘ICD–10–
13 PCS’ means the International Classification of
14 Diseases, 10th Revision, Procedure Coding Sys-
15 tem, and includes any subsequent revision of
16 such International Classification of Diseases,
17 Procedure Coding System.”.

18 **SEC. 15002. ESTABLISHING BENEFICIARY EQUITY IN THE**
19 **MEDICARE HOSPITAL READMISSION PRO-**
20 **GRAM.**

21 (a) TRANSITIONAL ADJUSTMENT FOR DUAL ELIGI-
22 BLE POPULATION.—Section 1886(q)(3) of the Social Se-
23 curity Act (42 U.S.C. 1395ww(q)(3)) is amended—

1 (1) in subparagraph (A), by inserting “subject
2 to subparagraph (D),” after “purposes of paragraph
3 (1),”; and

4 (2) by adding at the end the following new sub-
5 paragraph:

6 “(D) TRANSITIONAL ADJUSTMENT FOR
7 DUAL ELIGIBLES.—

8 “(i) IN GENERAL.—In determining a
9 hospital’s adjustment factor under this
10 paragraph for purposes of making pay-
11 ments for discharges occurring during and
12 after fiscal year 2019, and before the ap-
13 plication of clause (i) of subparagraph (E),
14 the Secretary shall assign hospitals to
15 groups (as defined by the Secretary under
16 clause (ii)) and apply the applicable provi-
17 sions of this subsection using a method-
18 ology in a manner that allows for separate
19 comparison of hospitals within each such
20 group, as determined by the Secretary.

21 “(ii) DEFINING GROUPS.—For pur-
22 poses of this subparagraph, the Secretary
23 shall define groups of hospitals, based on
24 their overall proportion, of the inpatients
25 who are entitled to, or enrolled for, bene-

1 fits under part A, and who are full-benefit
2 dual eligible individuals (as defined in sec-
3 tion 1935(c)(6)). In defining groups, the
4 Secretary shall consult the Medicare Pay-
5 ment Advisory Commission and may con-
6 sider the analysis done by such Commis-
7 sion in preparing the portion of its report
8 submitted to Congress in June 2013 relat-
9 ing to readmissions.

10 “(iii) MINIMIZING REPORTING BUR-
11 DEN ON HOSPITALS.—In carrying out this
12 subparagraph, the Secretary shall not im-
13 pose any additional reporting requirements
14 on hospitals.

15 “(iv) BUDGET NEUTRAL DESIGN
16 METHODOLOGY.—The Secretary shall de-
17 sign the methodology to implement this
18 subparagraph so that the estimated total
19 amount of reductions in payments under
20 this subsection equals the estimated total
21 amount of reductions in payments that
22 would otherwise occur under this sub-
23 section if this subparagraph did not
24 apply.”.

1 (b) CHANGES IN RISK ADJUSTMENT.—Section
2 1886(q)(3) of the Social Security Act (42 U.S.C.
3 1395ww(q)(3)), as amended by subsection (a), is further
4 amended by adding at the end the following new subpara-
5 graph:

6 “(E) CHANGES IN RISK ADJUSTMENT.—

7 “(i) CONSIDERATION OF REC-
8 OMMENDATIONS IN IMPACT REPORTS.—
9 The Secretary may take into account the
10 studies conducted and the recommenda-
11 tions made by the Secretary under section
12 2(d)(1) of the IMPACT Act of 2014 (Pub-
13 lic Law 113–185; 42 U.S.C. 1395lll note)
14 with respect to the application under this
15 subsection of risk adjustment methodolo-
16 gies. Nothing in this clause shall be con-
17 strued as precluding consideration of the
18 use of groupings of hospitals.

19 “(ii) CONSIDERATION OF EXCLUSION
20 OF PATIENT CASES BASED ON V OR OTHER
21 APPROPRIATE CODES.—In promulgating
22 regulations to carry out this subsection
23 with respect to discharges occurring after
24 fiscal year 2018, the Secretary may con-
25 sider the use of V or other ICD-related

1 codes for removal of a readmission. The
2 Secretary may consider modifying meas-
3 ures under this subsection to incorporate V
4 or other ICD-related codes at the same
5 time as other changes are being made
6 under this subparagraph.

7 “(iii) REMOVAL OF CERTAIN RE-
8 ADMISSIONS.—In promulgating regulations
9 to carry out this subsection, with respect
10 to discharges occurring after fiscal year
11 2018, the Secretary may consider removal
12 as a readmission of an admission that is
13 classified within one or more of the fol-
14 lowing: transplants, end-stage renal dis-
15 ease, burns, trauma, psychosis, or sub-
16 stance abuse. The Secretary may consider
17 modifying measures under this subsection
18 to remove readmissions at the same time
19 as other changes are being made under
20 this subparagraph.”.

21 (c) MEDPAC STUDY ON READMISSIONS PROGRAM.—
22 The Medicare Payment Advisory Commission shall con-
23 duct a study to review overall hospital readmissions de-
24 scribed in section 1886(q)(5)(E) of the Social Security Act
25 (42 U.S.C. 1395ww(q)(5)(E)) and whether such readmis-

1 sions are related to any changes in outpatient and emer-
2 gency services furnished. The Commission shall submit to
3 Congress a report on such study in its report to Congress
4 in June 2018.

5 **SEC. 15003. FIVE-YEAR EXTENSION OF THE RURAL COMMU-**
6 **NITY HOSPITAL DEMONSTRATION PROGRAM.**

7 (a) EXTENSION.—Section 410A of the Medicare Pre-
8 scription Drug, Improvement, and Modernization Act of
9 2003 (Public Law 108–173; 42 U.S.C. 1395ww note) is
10 amended—

11 (1) in subsection (a)(5), by striking “5-year ex-
12 tension period” and inserting “10-year extension pe-
13 riod”; and

14 (2) in subsection (g)—

15 (A) in the subsection heading, by striking
16 “FIVE-YEAR” and inserting “TEN-YEAR”;

17 (B) in paragraph (1), by striking “addi-
18 tional 5-year” and inserting “additional 10-
19 year”;

20 (C) by striking “5-year extension period”
21 and inserting “10-year extension period” each
22 place it appears;

23 (D) in paragraph (4)(B)—

1 (i) in the matter preceding clause (i),
2 by inserting “each 5-year period in” after
3 “hospital during”; and

4 (ii) in clause (i), by inserting “each
5 applicable 5-year period in” after “the first
6 day of”; and

7 (E) by adding at the end the following new
8 paragraphs:

9 “(5) OTHER HOSPITALS IN DEMONSTRATION
10 PROGRAM.—During the second 5 years of the 10-
11 year extension period, the Secretary shall apply the
12 provisions of paragraph (4) to rural community hos-
13 pitals that are not described in paragraph (4) but
14 are participating in the demonstration program
15 under this section as of December 30, 2014, in a
16 similar manner as such provisions apply to rural
17 community hospitals described in paragraph (4).

18 “(6) EXPANSION OF DEMONSTRATION PROGRAM
19 TO RURAL AREAS IN ANY STATE.—

20 “(A) IN GENERAL.—The Secretary shall,
21 notwithstanding subsection (a)(2) or paragraph
22 (2) of this subsection, not later than 120 days
23 after the date of the enactment of this para-
24 graph, issue a solicitation for applications to se-
25 lect up to the maximum number of additional

1 rural community hospitals located in any State
2 to participate in the demonstration program
3 under this section for the second 5 years of the
4 10-year extension period without exceeding the
5 limitation under paragraph (3) of this sub-
6 section.

7 “(B) PRIORITY.—In determining which
8 rural community hospitals that submitted an
9 application pursuant to the solicitation under
10 subparagraph (A) to select for participation in
11 the demonstration program, the Secretary—

12 “(i) shall give priority to rural com-
13 munity hospitals located in one of the 20
14 States with the lowest population densities
15 (as determined by the Secretary using the
16 2015 Statistical Abstract of the United
17 States); and

18 “(ii) may consider—

19 “(I) closures of hospitals located
20 in rural areas in the State in which
21 the rural community hospital is lo-
22 cated during the 5-year period imme-
23 diately preceding the date of the en-
24 actment of this paragraph; and

1 “(II) the population density of
2 the State in which the rural commu-
3 nity hospital is located.”.

4 (b) CHANGE IN TIMING FOR REPORT.—Subsection
5 (e) of such section 410A is amended—

6 (1) by striking “Not later than 6 months after
7 the completion of the demonstration program under
8 this section” and inserting “Not later than August
9 1, 2018”; and

10 (2) by striking “such program” and inserting
11 “the demonstration program under this section”.

12 **SEC. 15004. REGULATORY RELIEF FOR LTCHS.**

13 (a) TECHNICAL CHANGE TO THE MEDICARE LONG-
14 TERM CARE HOSPITAL MORATORIUM EXCEPTION.—

15 (1) IN GENERAL.—Section 114(d)(7) of the
16 Medicare, Medicaid, and SCHIP Extension Act of
17 2007 (42 U.S.C. 1395ww note), as amended by sec-
18 tions 3106(b) and 10312(b) of Public Law 111–148,
19 section 1206(b)(2) of the Pathway for SGR Reform
20 Act of 2013 (division B of Public Law 113–67), and
21 section 112 of the Protecting Access to Medicare Act
22 of 2014 (Public Law 113–93), is amended by strik-
23 ing “The moratorium under paragraph (1)(A)” and
24 inserting “Any moratorium under paragraph (1)”.

1 (2) EFFECTIVE DATE.—The amendment made
2 by paragraph (1) shall take effect as if included in
3 the enactment of section 112 of the Protecting Ac-
4 cess to Medicare Act of 2014.

5 (b) MODIFICATION TO MEDICARE LONG-TERM CARE
6 HOSPITAL HIGH COST OUTLIER PAYMENTS.—Section
7 1886(m) of the Social Security Act (42 U.S.C.
8 1395ww(m)) is amended by adding at the end the fol-
9 lowing new paragraph:

10 “(7) TREATMENT OF HIGH COST OUTLIER PAY-
11 MENTS.—

12 “(A) ADJUSTMENT TO THE STANDARD
13 FEDERAL PAYMENT RATE FOR ESTIMATED
14 HIGH COST OUTLIER PAYMENTS.—Under the
15 system described in paragraph (1), for fiscal
16 years beginning on or after October 1, 2017,
17 the Secretary shall reduce the standard Federal
18 payment rate as if the estimated aggregate
19 amount of high cost outlier payments for stand-
20 ard Federal payment rate discharges for each
21 such fiscal year would be equal to 8 percent of
22 estimated aggregate payments for standard
23 Federal payment rate discharges for each such
24 fiscal year.

1 “(B) LIMITATION ON HIGH COST OUTLIER
2 PAYMENT AMOUNTS.—Notwithstanding sub-
3 paragraph (A), the Secretary shall set the fixed
4 loss amount for high cost outlier payments such
5 that the estimated aggregate amount of high
6 cost outlier payments made for standard Fed-
7 eral payment rate discharges for fiscal years be-
8 ginning on or after October 1, 2017, shall be
9 equal to 99.6875 percent of 8 percent of esti-
10 mated aggregate payments for standard Fed-
11 eral payment rate discharges for each such fis-
12 cal year.

13 “(C) WAIVER OF BUDGET NEUTRALITY.—
14 Any reduction in payments resulting from the
15 application of subparagraph (B) shall not be
16 taken into account in applying any budget neu-
17 trality provision under such system.

18 “(D) NO EFFECT ON SITE NEUTRAL HIGH
19 COST OUTLIER PAYMENT RATE.—This para-
20 graph shall not apply with respect to the com-
21 putation of the applicable site neutral payment
22 rate under paragraph (6).”.

1 **SEC. 15005. SAVINGS FROM IPPS MACRA PAY-FOR**
2 **THROUGH NOT APPLYING DOCUMENTATION**
3 **AND CODING ADJUSTMENTS.**

4 Section 7(b)(1)(B)(iii) of the TMA, Abstinence Edu-
5 cation, and QI Programs Extension Act of 2007 (Public
6 Law 110–90), as amended by section 631(b) of the Amer-
7 ican Taxpayer Relief Act of 2012 (Public Law 122–240)
8 and section 414(1)(B)(iii) of the Medicare Access and
9 CHIP Reauthorization Act of 2015 (Public Law 114–10),
10 is amended by striking “an increase of 0.5 percentage
11 points for discharges occurring during each of fiscal years
12 2018 through 2023” and inserting “an increase of 0.4588
13 percentage points for discharges occurring during fiscal
14 year 2018 and 0.5 percentage points for discharges occur-
15 ring during each of fiscal years 2019 through 2023”.

16 **SEC. 15006. EXTENSION OF CERTAIN LTCH MEDICARE PAY-**
17 **MENT RULES.**

18 (a) 25–PERCENT PATIENT THRESHOLD PAYMENT
19 ADJUSTMENT.—Section 114(c)(1)(A) of the Medicare,
20 Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C.
21 1395ww note), as amended by section 4302(a) of division
22 B of the American Recovery and Reinvestment Act (Public
23 Law 111–5), sections 3106(a) and 10312(a) of Public
24 Law 111–148, and section 1206(b)(1)(B) of the Pathway
25 for SGR Reform Act of 2013 (division B of Public Law
26 113–67), is amended by striking “for a 9-year period” and

1 inserting “through June 30, 2016, and for discharges oc-
2 ccurring on or after October 1, 2016, and before October
3 1, 2017”.

4 (b) PAYMENT FOR HOSPITALS-WITHIN-HOS-
5 PITALS.—Section 114(c)(2) of the Medicare, Medicaid,
6 and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww
7 note), as amended by section 4302(a) of division B of the
8 American Recovery and Reinvestment Act (Public Law
9 111–5), sections 3106(a) and 10312(a) of Public Law
10 111–148, and section 1206(b)(1)(A) of the Pathway for
11 SGR Reform Act of 2013 (division B of Public Law 113–
12 67), is amended—

13 (1) in subparagraph (A), by inserting “or any
14 similar provision,” after “Regulations,”;

15 (2) in subparagraph (B)—

16 (A) in clause (i), by inserting “or any simi-
17 lar provision,” after “Regulations,”; and

18 (B) in clause (ii), by inserting “, or any
19 similar provision,” after “Regulations”; and

20 (3) in subparagraph (C), by striking “for a 9-
21 year period” and inserting “through June 30, 2016,
22 and for discharges occurring on or after October 1,
23 2016, and before October 1, 2017”.

1 **SEC. 15007. APPLICATION OF RULES ON THE CALCULATION**
2 **OF HOSPITAL LENGTH OF STAY TO ALL**
3 **LTCHS.**

4 (a) **IN GENERAL.**—Section 1206(a)(3) of the Path-
5 way for SGR Reform Act of 2013 (division B of Public
6 Law 113–67; 42 U.S.C. 1395ww note) is amended—

7 (1) by striking subparagraph (B);

8 (2) by striking “SITE NEUTRAL BASIS.—” and
9 all that follows through “For discharges occurring”
10 and inserting “SITE NEUTRAL BASIS.—For dis-
11 charges occurring”;

12 (3) by striking “subject to subparagraph (B),”;
13 and

14 (4) by redesignating clauses (i) and (ii) as sub-
15 paragraphs (A) and (B), respectively, and moving
16 each of such subparagraphs (as so redesignated) 2
17 ems to the left.

18 (b) **EFFECTIVE DATE.**—The amendments made by
19 subsection (a) shall be effective as if included in the enact-
20 ment of section 1206(a)(3) of the Pathway for SGR Re-
21 form Act of 2013 (division B of Public Law 113–67; 42
22 U.S.C. 1395ww note).

1 **SEC. 15008. CHANGE IN MEDICARE CLASSIFICATION FOR**
2 **CERTAIN HOSPITALS.**

3 (a) IN GENERAL.—Subsection (d)(1)(B)(iv) of sec-
4 tion 1886 of the Social Security Act (42 U.S.C. 1395ww)
5 is amended—

6 (1) in subclause (I), by striking “or” at the
7 end;

8 (2) in subclause (II)—

9 (A) by striking “, or” at the end and in-
10 serting a semicolon;

11 (B) by redesignating such subclause as
12 clause (vi) and by moving it to immediately fol-
13 low clause (v); and

14 (C) in clause (v), by striking the semicolon
15 at the end and inserting “, or”; and

16 (3) by striking “(iv)(I) a hospital” and insert-
17 ing “(iv) a hospital”.

18 (b) CONFORMING PAYMENT REFERENCES.—The sec-
19 ond sentence of subsection (d)(1)(B) of such section is
20 amended—

21 (1) by inserting “(as in effect as of such date)”
22 after “clause (iv)”; and

23 (2) by inserting “(or, in the case of a hospital
24 described in clause (iv)(II), as so in effect, shall be
25 classified under clause (vi) on and after the effective
26 date of such clause (vi) and for cost reporting peri-

1 ods beginning on or after January 1, 2015, shall not
2 be subject to subsection (m) as of the date of such
3 classification)” after “so classified”.

4 (c) APPLICATION.—

5 (1) IN GENERAL.—For cost reporting periods
6 beginning on or after January 1, 2015, in the case
7 of an applicable hospital (as defined in paragraph
8 (3)), the following shall apply:

9 (A) Payment for inpatient operating costs
10 shall be made on a reasonable cost basis in the
11 manner provided in section 412.526(c)(3) of
12 title 42, Code of Federal Regulations (as in ef-
13 fect on January 1, 2015) and in any subse-
14 quent modifications.

15 (B) Payment for capital costs shall be
16 made in the manner provided by section
17 412.526(c)(4) of title 42, Code of Federal Reg-
18 ulations (as in effect on such date).

19 (C) Claims for payment for Medicare bene-
20 ficiaries who are discharged on or after January
21 1, 2017, shall be processed as claims which are
22 paid on a reasonable cost basis as described in
23 section 412.526(c) of title 42, Code of Federal
24 Regulations (as in effect on such date).

1 (2) APPLICABLE HOSPITAL DEFINED.—In this
2 subsection, the term “applicable hospital” means a
3 hospital that is classified under clause (iv)(II) of sec-
4 tion 1886(d)(1)(B) of the Social Security Act (42
5 U.S.C. 1395ww(d)(1)(B)) on the day before the date
6 of the enactment of this Act and which is classified
7 under clause (vi) of such section, as redesignated
8 and moved by subsection (a), on or after such date
9 of enactment.

10 (d) CONFORMING TECHNICAL AMENDMENTS.—

11 (1) Section 1899B(a)(2)(A)(iv) of the Social
12 Security Act (42 U.S.C. 1395lll(a)(2)(A)(iv)) is
13 amended by striking “1886(d)(1)(B)(iv)(II)” and in-
14 serting “1886(d)(1)(B)(vi)”.

15 (2) Section 1886(m)(5)(F) of such Act (42
16 U.S.C. 1395ww(m)(5)(F)) is amended in each of
17 clauses (i) and (ii) by striking “(d)(1)(B)(iv)(II)”
18 and inserting “(d)(1)(B)(vi)”.

19 **SEC. 15009. TEMPORARY EXCEPTION TO THE APPLICATION**
20 **OF THE MEDICARE LTCH SITE NEUTRAL PRO-**
21 **VISIONS FOR CERTAIN SPINAL CORD SPE-**
22 **CIALTY HOSPITALS.**

23 (a) EXCEPTION.—Section 1886(m)(6) of the Social
24 Security Act (42 U.S.C. 1395ww(m)(6)) is amended—

1 (1) in subparagraph (A)(i), by striking “and
2 (E)” and inserting “, (E), and (F)”; and

3 (2) by adding at the end the following new sub-
4 paragraph:

5 “(F) TEMPORARY EXCEPTION FOR CER-
6 TAIN SPINAL CORD SPECIALTY HOSPITALS.—
7 For discharges in cost reporting periods begin-
8 ning during fiscal years 2018 and 2019, sub-
9 paragraph (A)(i) shall not apply (and payment
10 shall be made to a long-term care hospital with-
11 out regard to this paragraph) if such discharge
12 is from a long-term care hospital that meets
13 each of the following requirements:

14 “(i) NOT-FOR-PROFIT.—The long-
15 term care hospital was a not-for-profit
16 long-term care hospital on June 1, 2014,
17 as determined by cost report data.

18 “(ii) PRIMARILY PROVIDING TREAT-
19 MENT FOR CATASTROPHIC SPINAL CORD
20 OR ACQUIRED BRAIN INJURIES OR OTHER
21 PARALYZING NEUROMUSCULAR CONDI-
22 TIONS.—Of the discharges in calendar year
23 2013 from the long-term care hospital for
24 which payment was made under this sec-
25 tion, at least 50 percent were classified

1 under MS-LTCH-DRGs 28, 29, 52, 57,
2 551, 573, and 963.

3 “(iii) SIGNIFICANT OUT-OF-STATE AD-
4 MISSIONS.—

5 “(I) IN GENERAL.—The long-
6 term care hospital discharged inpa-
7 tients (including both individuals enti-
8 tled to, or enrolled for, benefits under
9 this title and individuals not so enti-
10 tled or enrolled) during fiscal year
11 2014 who had been admitted from at
12 least 20 of the 50 States, determined
13 by the States of residency of such in-
14 patients and based on such data sub-
15 mitted by the hospital to the Sec-
16 retary as the Secretary may require.

17 “(II) IMPLEMENTATION.—Not-
18 withstanding any other provision of
19 law, the Secretary may implement
20 subclause (I) by program instruction
21 or otherwise.

22 “(III) NON-APPLICATION OF PA-
23 PERWORK REDUCTION ACT.—Chapter
24 35 of title 44, United States Code,

1 shall not apply to data collected under
2 this clause.”.

3 (b) STUDY AND REPORT ON THE STATUS AND VIA-
4 BILITY OF CERTAIN SPINAL CORD SPECIALTY LONG-
5 TERM CARE HOSPITALS.—

6 (1) STUDY.—The Comptroller General of the
7 United States shall conduct a study on long-term
8 care hospitals described in section 1886(m)(6)(F) of
9 the Social Security Act, as added by subsection (a).
10 Such report shall include an analysis of the fol-
11 lowing:

12 (A) The impact on such hospitals of the
13 classification and facility licensure by State
14 agencies of such hospitals.

15 (B) The Medicare payment rates for such
16 hospitals.

17 (C) Data on the number and health care
18 needs of Medicare beneficiaries who have been
19 diagnosed with catastrophic spinal cord or ac-
20 quired brain injuries or other paralyzing neuro-
21 muscular conditions (as described within the
22 discharge classifications specified in clause (ii)
23 of such section) who are receiving services from
24 such hospitals.

1 (2) REPORT.—Not later than October 1, 2018,
2 the Comptroller General shall submit to Congress a
3 report on the study conducted under paragraph (1),
4 including recommendations for such legislation and
5 administrative action as the Comptroller General de-
6 termines appropriate.

7 **SEC. 15010. TEMPORARY EXTENSION TO THE APPLICATION**
8 **OF THE MEDICARE LTCH SITE NEUTRAL PRO-**
9 **VISIONS FOR CERTAIN DISCHARGES WITH SE-**
10 **VERE WOUNDS.**

11 (a) IN GENERAL.—Section 1886(m)(6) of the Social
12 Security Act (42 U.S.C. 1395ww(m)(6)), as amended by
13 section 15009, is further amended—

14 (1) in subparagraph (A)(i) by striking “and
15 (F)” and inserting “(F), and (G)”;

16 (2) in subparagraph (E)(i)(I)(aa), by striking
17 “the amendment made” and all that follows before
18 the semicolon and inserting “the last sentence of
19 subsection (d)(1)(B)”;

20 (3) by adding at the end the following new sub-
21 paragraph:

22 “(G) ADDITIONAL TEMPORARY EXCEPTION
23 FOR CERTAIN SEVERE WOUND DISCHARGES
24 FROM CERTAIN LONG-TERM CARE HOSPITALS.—

1 “(i) IN GENERAL.—For a discharge
2 occurring in a cost reporting period begin-
3 ning during fiscal year 2018, subpara-
4 graph (A)(i) shall not apply (and payment
5 shall be made to a long-term care hospital
6 without regard to this paragraph) if such
7 discharge—

8 “(I) is from a long-term care
9 hospital identified by the last sentence
10 of subsection (d)(1)(B);

11 “(II) is classified under MS-
12 LTCH-DRG 602, 603, 539, or 540;
13 and

14 “(III) is with respect to an indi-
15 vidual treated by a long-term care
16 hospital for a severe wound.

17 “(ii) SEVERE WOUND DEFINED.—In
18 this subparagraph, the term ‘severe wound’
19 means a wound which is a stage 3 wound,
20 stage 4 wound, unstageable wound, non-
21 healing surgical wound, or fistula as identi-
22 fied in the claim from the long-term care
23 hospital.

24 “(iii) WOUND DEFINED.—In this sub-
25 paragraph, the term ‘wound’ means an in-

1 jury involving division of tissue or rupture
2 of the integument or mucous membrane
3 with exposure to the external environ-
4 ment.”.

5 (c) STUDY AND REPORT TO CONGRESS.—

6 (1) STUDY.—The Comptroller General of the
7 United States shall, in consultation with relevant
8 stakeholders, conduct a study on the treatment
9 needs of individuals entitled to benefits under part
10 A of title XVIII of the Social Security Act or en-
11 rolled under part B of such title who require special-
12 ized wound care, and the cost, for such individuals
13 and the Medicare program under such title, of treat-
14 ing severe wounds in rural and urban areas. Such
15 study shall include an assessment of—

16 (A) access of such individuals to appro-
17 priate levels of care for such cases;

18 (B) the potential impact that section
19 1886(m)(6)(A)(i) of such Act (42 U.S.C.
20 1395ww(m)(6)(A)(i)) will have on the access,
21 quality, and cost of care for such individuals;
22 and

23 (C) how to appropriately pay for such care
24 under the Medicare program under such title.

1 (2) REPORT.—Not later than October 1, 2020,
2 the Comptroller General shall submit to Congress a
3 report on the study conducted under paragraph (1),
4 including recommendations for such legislation and
5 administrative action as the Comptroller General de-
6 termines appropriate.

7 **TITLE XVI—PROVISIONS RELAT-**
8 **ING TO MEDICARE PART B**

9 **SEC. 16001. CONTINUING MEDICARE PAYMENT UNDER**
10 **HOPD PROSPECTIVE PAYMENT SYSTEM FOR**
11 **SERVICES FURNISHED BY MID-BUILD OFF-**
12 **CAMPUS OUTPATIENT DEPARTMENTS OF**
13 **PROVIDERS.**

14 (a) IN GENERAL.—Section 1833(t)(21) of the Social
15 Security Act (42 U.S.C. 1395l(t)(21)) is amended—

16 (1) in subparagraph (B)—

17 (A) in clause (i), by striking “clause (ii)”
18 and inserting “the subsequent provisions of this
19 subparagraph”; and

20 (B) by adding at the end the following new
21 clauses:

22 “(iii) DEEMED TREATMENT FOR
23 2017.—For purposes of applying clause (ii)
24 with respect to applicable items and serv-
25 ices furnished during 2017, a department

1 of a provider (as so defined) not described
2 in such clause is deemed to be billing
3 under this subsection with respect to cov-
4 ered OPD services furnished prior to No-
5 vember 2, 2015, if the Secretary received
6 from the provider prior to December 2,
7 2015, an attestation (pursuant to section
8 413.65(b)(3) of title 42 of the Code of
9 Federal Regulations) that such department
10 was a department of a provider (as so de-
11 fined).

12 “(iv) ALTERNATIVE EXCEPTION BE-
13 GINNING WITH 2018.—For purposes of
14 paragraph (1)(B)(v) and this paragraph
15 with respect to applicable items and serv-
16 ices furnished during 2018 or a subsequent
17 year, the term ‘off-campus outpatient de-
18 partment of a provider’ also shall not in-
19 clude a department of a provider (as so de-
20 fined) that is not described in clause (ii)
21 if—

22 “(I) the Secretary receives from
23 the provider an attestation (pursuant
24 to such section 413.65(b)(3)) not later
25 than December 31, 2016 (or, if later,

1 60 days after the date of the enact-
2 ment of this clause), that such depart-
3 ment met the requirements of a de-
4 partment of a provider specified in
5 section 413.65 of title 42 of the Code
6 of Federal Regulations;

7 “(II) the provider includes such
8 department as part of the provider on
9 its enrollment form in accordance with
10 the enrollment process under section
11 1866(j); and

12 “(III) the department met the
13 mid-build requirement of clause (v)
14 and the Secretary receives, not later
15 than 60 days after the date of the en-
16 actment of this clause, from the chief
17 executive officer or chief operating of-
18 ficer of the provider a written certifi-
19 cation that the department met such
20 requirement.

21 “(v) MID-BUILD REQUIREMENT DE-
22 SCRIBED.—The mid-build requirement of
23 this clause is, with respect to a department
24 of a provider, that before November 2,
25 2015, the provider had a binding written

1 agreement with an outside unrelated party
2 for the actual construction of such depart-
3 ment.

4 “(vii) AUDIT.—Not later than Decem-
5 ber 31, 2018, the Secretary shall audit the
6 compliance with requirements of clause (iv)
7 with respect to each department of a pro-
8 vider to which such clause applies. If the
9 Secretary finds as a result of an audit
10 under this clause that the applicable re-
11 quirements were not met with respect to
12 such department, the department shall not
13 be excluded from the term ‘off-campus out-
14 patient department of a provider’ under
15 such clause.

16 “(viii) IMPLEMENTATION.—For pur-
17 poses of implementing clauses (iii) through
18 (vii):

19 “(I) Notwithstanding any other
20 provision of law, the Secretary may
21 implement such clauses by program
22 instruction or otherwise.

23 “(II) Subchapter I of chapter 35
24 of title 44, United States Code, shall
25 not apply.

1 “(III) For purposes of carrying
2 out this subparagraph with respect to
3 clauses (iii) and (iv) (and clause (vii)
4 insofar as it relates to clause (iv)),
5 \$10,000,000 shall be available from
6 the Federal Supplementary Medical
7 Insurance Trust Fund under section
8 1841, to remain available until De-
9 cember 31, 2018.”; and

10 (2) in subparagraph (E), by adding at the end
11 the following new clause:

12 “(iv) The determination of an audit
13 under subparagraph (B)(vii).”.

14 (b) **EFFECTIVE DATE.**—The amendments made by
15 this section shall be effective as if included in the enact-
16 ment of section 603 of the Bipartisan Budget Act of 2015
17 (Public Law 114–74).

18 **SEC. 16002. TREATMENT OF CANCER HOSPITALS IN OFF-**
19 **CAMPUS OUTPATIENT DEPARTMENT OF A**
20 **PROVIDER POLICY.**

21 (a) **IN GENERAL.**—Section 1833(t)(21)(B) of the So-
22 cial Security Act (42 U.S.C. 1395l(t)(21)(B)), as amended
23 by section 16001(a), is amended—

24 (1) by inserting after clause (v) the following
25 new clause:

1 “(vi) EXCLUSION FOR CERTAIN CAN-
2 CER HOSPITALS.—For purposes of para-
3 graph (1)(B)(v) and this paragraph with
4 respect to applicable items and services
5 furnished during 2017 or a subsequent
6 year, the term ‘off-campus outpatient de-
7 partment of a provider’ also shall not in-
8 clude a department of a provider (as so de-
9 fined) that is not described in clause (ii) if
10 the provider is a hospital described in sec-
11 tion 1886(d)(1)(B)(v) and—

12 “(I) in the case of a department
13 that met the requirements of section
14 413.65 of title 42 of the Code of Fed-
15 eral Regulations after November 1,
16 2015, and before the date of the en-
17 actment of this clause, the Secretary
18 receives from the provider an attesta-
19 tion that such department met such
20 requirements not later than 60 days
21 after such date of enactment; or

22 “(II) in the case of a department
23 that meets such requirements after
24 such date of enactment, the Secretary
25 receives from the provider an attesta-

1 tion that such department meets such
2 requirements not later than 60 days
3 after the date such requirements are
4 first met with respect to such depart-
5 ment.”;

6 (2) in clause (vii), by inserting after the first
7 sentence the following: “Not later than 2 years after
8 the date the Secretary receives an attestation under
9 clause (vi) relating to compliance of a department of
10 a provider with requirements referred to in such
11 clause, the Secretary shall audit the compliance with
12 such requirements with respect to the department.”;
13 and

14 (3) in clause (viii)(III), by adding at the end
15 the following: “For purposes of carrying out this
16 subparagraph with respect to clause (vi) (and clause
17 (vii) insofar as it relates to such clause), \$2,000,000
18 shall be available from the Federal Supplementary
19 Medical Insurance Trust Fund under section 1841,
20 to remain available until expended.”.

21 (b) OFFSETTING SAVINGS.—Section 1833(t)(18) of
22 the Social Security Act (42 U.S.C. 1395l(t)(18)) is
23 amended—

24 (1) in subparagraph (B), by inserting “, subject
25 to subparagraph (C),” after “shall”; and

1 (2) by adding at the end the following new sub-
2 paragraph:

3 “(C) TARGET PCR ADJUSTMENT.—In ap-
4 plying section 419.43(i) of title 42 of the Code
5 of Federal Regulations to implement the appro-
6 priate adjustment under this paragraph for
7 services furnished on or after January 1, 2018,
8 the Secretary shall use a target PCR that is 1.0
9 percentage points less than the target PCR that
10 would otherwise apply. In addition to the per-
11 centage point reduction under the previous sen-
12 tence, the Secretary may consider making an
13 additional percentage point reduction to such
14 target PCR that takes into account payment
15 rates for applicable items and services described
16 in paragraph (21)(C) other than for services
17 furnished by hospitals described in section
18 1886(d)(1)(B)(v). In making any budget neu-
19 trality adjustments under this subsection for
20 2018 or a subsequent year, the Secretary shall
21 not take into account the reduced expenditures
22 that result from the application of this subpara-
23 graph.”.

24 (c) EFFECTIVE DATE.—The amendments made by
25 this section shall be effective as if included in the enact-

1 ment of section 603 of the Bipartisan Budget Act of 2015
2 (Public Law 114–74).

3 **SEC. 16003. TREATMENT OF ELIGIBLE PROFESSIONALS IN**
4 **AMBULATORY SURGICAL CENTERS FOR**
5 **MEANINGFUL USE AND MIPS.**

6 Section 1848(a)(7)(D) of the Social Security Act (42
7 U.S.C. 1395w–4(a)(7)(D)) is amended—

8 (1) by striking “HOSPITAL-BASED ELIGIBLE
9 PROFESSIONALS” and all that follows through “No
10 payment” and inserting the following: “HOSPITAL-
11 BASED AND AMBULATORY SURGICAL CENTER-BASED
12 ELIGIBLE PROFESSIONALS.—

13 “(i) HOSPITAL-BASED.—No pay-
14 ment”; and

15 (2) by adding at the end the following new
16 clauses:

17 “(ii) AMBULATORY SURGICAL CEN-
18 TER-BASED.—Subject to clause (iv), no
19 payment adjustment may be made under
20 subparagraph (A) for 2017 and 2018 in
21 the case of an eligible professional with re-
22 spect to whom substantially all of the cov-
23 ered professional services furnished by
24 such professional are furnished in an am-
25 bulatory surgical center.

1 “(iii) DETERMINATION.—The deter-
2 mination of whether an eligible profes-
3 sional is an eligible professional described
4 in clause (ii) may be made on the basis
5 of—

6 “(I) the site of service (as de-
7 fined by the Secretary); or

8 “(II) an attestation submitted by
9 the eligible professional.

10 Determinations made under subclauses (I)
11 and (II) shall be made without regard to
12 any employment or billing arrangement be-
13 tween the eligible professional and any
14 other supplier or provider of services.

15 “(iv) SUNSET.—Clause (ii) shall no
16 longer apply as of the first year that be-
17 gins more than 3 years after the date on
18 which the Secretary determines, through
19 notice and comment rulemaking, that cer-
20 tified EHR technology applicable to the
21 ambulatory surgical center setting is avail-
22 able.”.

1 **SEC. 16004. CONTINUING ACCESS TO HOSPITALS ACT OF**
2 **2016.**

3 (a) EXTENSION OF ENFORCEMENT INSTRUCTION ON
4 SUPERVISION REQUIREMENTS FOR OUTPATIENT THERA-
5 PEUTIC SERVICES IN CRITICAL ACCESS AND SMALL
6 RURAL HOSPITALS THROUGH 2016.—Section 1 of Public
7 Law 113–198, as amended by section 1 of Public Law
8 114–112, is amended—

9 (1) in the heading, by striking “**2014 AND**
10 **2015**” and inserting “**2016**”; and

11 (2) by striking “and 2015” and inserting “,
12 2015, and 2016”.

13 (b) REPORT.—Not later than 1 year after the date
14 of the enactment of this Act, the Medicare Payment Advi-
15 sory Commission (established under section 1805 of the
16 Social Security Act (42 U.S.C. 1395b–6)) shall submit to
17 Congress a report analyzing the effect of the extension of
18 the enforcement instruction under section 1 of Public Law
19 113–198, as amended by section 1 of Public Law 114–
20 112 and subsection (a) of this section, on the access to
21 health care by Medicare beneficiaries, on the economic im-
22 pact and the impact upon hospital staffing needs, and on
23 the quality of health care furnished to such beneficiaries.

1 **SEC. 16005. DELAY OF IMPLEMENTATION OF MEDICARE**
2 **FEE SCHEDULE ADJUSTMENTS FOR WHEEL-**
3 **CHAIR ACCESSORIES AND SEATING SYSTEMS**
4 **WHEN USED IN CONJUNCTION WITH COM-**
5 **PLEX REHABILITATION TECHNOLOGY (CRT)**
6 **WHEELCHAIRS.**

7 Section 2(a) of the Patient Access and Medicare Pro-
8 tection Act (42 U.S.C. 1305 note) is amended by striking
9 “January 1, 2017” and inserting “July 1, 2017”.

10 **SEC. 16006. ALLOWING PHYSICAL THERAPISTS TO UTILIZE**
11 **LOCUM TENENS ARRANGEMENTS UNDER**
12 **MEDICARE.**

13 (a) IN GENERAL.—The first sentence of section
14 1842(b)(6) of the Social Security Act (42 U.S.C.
15 1395u(b)(6)), as amended by section 5012, is further
16 amended—

17 (1) by striking “and” before “(I)”; and

18 (2) by inserting before the period at the end the
19 following: “, and (J) in the case of outpatient phys-
20 ical therapy services furnished by physical therapists
21 in a health professional shortage area (as defined in
22 section 332(a)(1)(A) of the Public Health Service
23 Act), a medically underserved area (as designated
24 pursuant to section 330(b)(3)(A) of such Act), or a
25 rural area (as defined in section 1886(d)(2)(D)),
26 subparagraph (D) of this sentence shall apply to

1 such services and therapists in the same manner as
2 such subparagraph applies to physicians' services
3 furnished by physicians”.

4 (b) EFFECTIVE DATE; IMPLEMENTATION.—

5 (1) EFFECTIVE DATE.—The amendments made
6 by subsection (a) shall apply to services furnished
7 beginning not later than six months after the date
8 of the enactment of this Act.

9 (2) IMPLEMENTATION.—The Secretary of
10 Health and Human Services may implement sub-
11 paragraph (J) of section 1842(b)(6) of the Social
12 Security Act (42 U.S.C. 1395u(b)(6)), as added by
13 subsection (a)(2), by program instruction or other-
14 wise.

15 **SEC. 16007. EXTENSION OF THE TRANSITION TO NEW PAY-**
16 **MENT RATES FOR DURABLE MEDICAL EQUIP-**
17 **MENT UNDER THE MEDICARE PROGRAM.**

18 (a) IN GENERAL.—The Secretary of Health and
19 Human Services shall extend the transition period de-
20 scribed in clause (i) of section 414.210(g)(9) of title 42,
21 Code of Federal Regulations, from June 30, 2016, to De-
22 cember 31, 2016 (with the full implementation described
23 in clause (ii) of such section applying to items and services
24 furnished with dates of service on or after January 1,
25 2017).

1 (b) STUDY AND REPORT.—

2 (1) STUDY.—

3 (A) IN GENERAL.—The Secretary of
4 Health and Human Services shall conduct a
5 study that examines the impact of applicable
6 payment adjustments upon—

7 (i) the number of suppliers of durable
8 medical equipment that, on a date that is
9 not before January 1, 2016, and not later
10 than December 31, 2016, ceased to con-
11 duct business as such suppliers; and

12 (ii) the availability of durable medical
13 equipment, during the period beginning on
14 January 1, 2016, and ending on December
15 31, 2016, to individuals entitled to benefits
16 under part A of title XVIII of the Social
17 Security Act (42 U.S.C. 1395 et seq.) or
18 enrolled under part B of such title.

19 (B) DEFINITIONS.—For purposes of this
20 subsection, the following definitions apply:

21 (i) SUPPLIER; DURABLE MEDICAL
22 EQUIPMENT.—The terms “supplier” and
23 “durable medical equipment” have the
24 meanings given such terms by section 1861

1 of the Social Security Act (42 U.S.C.
2 1395x).

3 (ii) APPLICABLE PAYMENT ADJUST-
4 MENT.—The term “applicable payment ad-
5 justment” means a payment adjustment
6 described in section 414.210(g) of title 42,
7 Code of Federal Regulations, that is
8 phased in by paragraph (9)(i) of such sec-
9 tion. For purposes of the preceding sen-
10 tence, a payment adjustment that is
11 phased in pursuant to the extension under
12 subsection (a) shall be considered a pay-
13 ment adjustment that is phased in by such
14 paragraph (9)(i).

15 (2) REPORT.—The Secretary of Health and
16 Human Services shall, not later than January 12,
17 2017, submit to the Committees on Ways and
18 Means and on Energy and Commerce of the House
19 of Representatives, and to the Committee on Fi-
20 nance of the Senate, a report on the findings of the
21 study conducted under paragraph (1).

1 **SEC. 16008. REQUIREMENTS IN DETERMINING ADJUST-**
2 **MENTS USING INFORMATION FROM COM-**
3 **PETITIVE BIDDING PROGRAMS.**

4 (a) IN GENERAL.—Section 1834(a)(1)(G) of the So-
5 cial Security Act (42 U.S.C. 1395m(a)(1)(G)) is amended
6 by adding at the end the following new sentence: “In the
7 case of items and services furnished on or after January
8 1, 2019, in making any adjustments under clause (ii) or
9 (iii) of subparagraph (F), under subsection (h)(1)(H)(ii),
10 or under section 1842(s)(3)(B), the Secretary shall—

11 “(i) solicit and take into account
12 stakeholder input; and

13 “(ii) take into account the highest
14 amount bid by a winning supplier in a
15 competitive acquisition area and a com-
16 parison of each of the following with re-
17 spect to non-competitive acquisition areas
18 and competitive acquisition areas:

19 “(I) The average travel distance
20 and cost associated with furnishing
21 items and services in the area.

22 “(II) The average volume of
23 items and services furnished by sup-
24 pliers in the area.

25 “(III) The number of suppliers in
26 the area.”.

1 (b) CONFORMING AMENDMENTS.—(1) Section
2 1834(h)(1)(H)(ii) of the Social Security Act (42 U.S.C.
3 1395m(h)(1)(H)(ii)) is amended by striking “the Sec-
4 retary” and inserting “subject to subsection (a)(1)(G), the
5 Secretary”.

6 (2) Section 1842(s)(3)(B) of the Social Security Act
7 (42 U.S.C. 1395m(s)(3)(B)) is amended by striking “the
8 Secretary” and inserting “subject to section
9 1834(a)(1)(G), the Secretary”.

10 **TITLE XVII—OTHER MEDICARE** 11 **PROVISIONS**

12 **SEC. 17001. DELAY IN AUTHORITY TO TERMINATE CON-** 13 **TRACTS FOR MEDICARE ADVANTAGE PLANS** 14 **FAILING TO ACHIEVE MINIMUM QUALITY** 15 **RATINGS.**

16 (a) FINDINGS.—Consistent with the studies provided
17 under the IMPACT Act of 2014 (Public Law 113–185),
18 it is the intent of Congress—

19 (1) to continue to study and request input on
20 the effects of socioeconomic status and dual-eligible
21 populations on the Medicare Advantage STARS rat-
22 ing system before reforming such system with the
23 input of stakeholders; and

24 (2) pending the results of such studies and
25 input, to provide for a temporary delay in authority

1 of the Centers for Medicare & Medicaid Services
2 (CMS) to terminate Medicare Advantage plan con-
3 tracts solely on the basis of performance of plans
4 under the STARS rating system.

5 (b) DELAY IN MA CONTRACT TERMINATION AU-
6 THORITY FOR PLANS FAILING TO ACHIEVE MINIMUM
7 QUALITY RATINGS.—Section 1857(h) of the Social Secu-
8 rity Act (42 U.S.C. 1395w–27(h)) is amended by adding
9 at the end the following new paragraph:

10 “(3) DELAY IN CONTRACT TERMINATION AU-
11 THORITY FOR PLANS FAILING TO ACHIEVE MINIMUM
12 QUALITY RATING.—During the period beginning on
13 the date of the enactment of this paragraph and
14 through the end of plan year 2018, the Secretary
15 may not terminate a contract under this section with
16 respect to the offering of an MA plan by a Medicare
17 Advantage organization solely because the MA plan
18 has failed to achieve a minimum quality rating
19 under the 5-star rating system under section
20 1853(o)(4).”.

21 **SEC. 17002. REQUIREMENT FOR ENROLLMENT DATA RE-**
22 **PORTING FOR MEDICARE.**

23 Section 1874 of the Social Security Act (42 U.S.C.
24 1395kk) is amended by adding at the end the following
25 new subsection:

1 “(g) REQUIREMENT FOR ENROLLMENT DATA RE-
2 PORTING.—

3 “(1) IN GENERAL.—Each year (beginning with
4 2016), the Secretary shall submit to the Committees
5 on Ways and Means and Energy and Commerce of
6 the House of Representatives and the Committee on
7 Finance of the Senate a report on Medicare enroll-
8 ment data (and, in the case of part A, on data on
9 individuals receiving benefits under such part) as of
10 a date in such year specified by the Secretary. Such
11 data shall be presented—

12 “(A) by Congressional district and State;
13 and

14 “(B) in a manner that provides for such
15 data based on—

16 “(i) fee-for-service enrollment (as de-
17 fined in paragraph (2));

18 “(ii) enrollment under part C (includ-
19 ing separate for aggregate enrollment in
20 MA–PD plans and aggregate enrollment in
21 MA plans that are not MA–PD plans); and

22 “(iii) enrollment under part D.

23 “(2) FEE-FOR-SERVICE ENROLLMENT DE-
24 FINED.—For purpose of paragraph (1)(B)(i), the
25 term ‘fee-for-service enrollment’ means aggregate en-

1 rollment (including receipt of benefits other than
2 through enrollment) under—

3 “(A) part A only;

4 “(B) part B only; and

5 “(C) both part A and part B.”.

6 **SEC. 17003. UPDATING THE WELCOME TO MEDICARE PACK-**
7 **AGE.**

8 (a) IN GENERAL.—Not later than 12 months after
9 the last day of the period for the request of information
10 described in subsection (b), the Secretary of Health and
11 Human Services shall, taking into consideration informa-
12 tion collected pursuant to subsection (b), update the infor-
13 mation included in the Welcome to Medicare package to
14 include information, presented in a clear and simple man-
15 ner, about options for receiving benefits under the Medi-
16 care program under title XVIII of the Social Security Act
17 (42 U.S.C. 1395 et seq.), including through the original
18 medicare fee-for-service program under parts A and B of
19 such title (42 U.S.C. 1395c et seq., 42 U.S.C. 1395j et
20 seq.), Medicare Advantage plans under part C of such title
21 (42 U.S.C. 1395w–21 et seq.), and prescription drug plans
22 under part D of such title (42 U.S.C. 1395w–101 et
23 seq.)). The Secretary shall make subsequent updates to
24 the information included in the Welcome to Medicare
25 package as appropriate.

1 (b) REQUEST FOR INFORMATION.—Not later than 6
2 months after the date of the enactment of this Act, the
3 Secretary of Health and Human Services shall request in-
4 formation, including recommendations, from stakeholders
5 (including patient advocates, issuers, and employers) on
6 information included in the Welcome to Medicare package,
7 including pertinent data and information regarding enroll-
8 ment and coverage for Medicare eligible individuals.

9 **SEC. 17004. NO PAYMENT FOR ITEMS AND SERVICES FUR-**
10 **NISHED BY NEWLY ENROLLED PROVIDERS**
11 **OR SUPPLIERS WITHIN A TEMPORARY MORA-**
12 **TORIUM AREA.**

13 (a) MEDICARE.—Section 1866(j)(7) of the Social Se-
14 curity Act (42 U.S.C. 1395cc(j)(7)) is amended—

15 (1) in the paragraph heading, by inserting “;
16 NONPAYMENT” before the period; and

17 (2) by adding at the end the following new sub-
18 paragraph:

19 “(C) NONPAYMENT.—

20 “(i) IN GENERAL.—No payment may
21 be made under this title or under a pro-
22 gram described in subparagraph (A) with
23 respect to an item or service described in
24 clause (ii) furnished on or after October 1,
25 2017.

1 “(ii) ITEM OR SERVICE DESCRIBED.—

2 An item or service described in this clause
3 is an item or service furnished—

4 “(I) within a geographic area
5 with respect to which a temporary
6 moratorium imposed under subpara-
7 graph (A) is in effect; and

8 “(II) by a provider of services or
9 supplier that meets the requirements
10 of clause (iii).

11 “(iii) REQUIREMENTS.—For purposes
12 of clause (ii), the requirements of this
13 clause are that a provider of services or
14 supplier—

15 “(I) enrolls under this title on or
16 after the effective date of such tem-
17 porary moratorium; and

18 “(II) is within a category of pro-
19 viders of services and suppliers (as de-
20 scribed in subparagraph (A)) subject
21 to such temporary moratorium.

22 “(iv) PROHIBITION ON CHARGES FOR
23 SPECIFIED ITEMS OR SERVICES.—In no
24 case shall a provider of services or supplier
25 described in clause (ii)(II) charge an indi-

1 vidual or other person for an item or serv-
2 ice described in clause (ii) furnished on or
3 after October 1, 2017, to an individual en-
4 titled to benefits under part A or enrolled
5 under part B or an individual under a pro-
6 gram specified in subparagraph (A).”.

7 (b) CONFORMING AMENDMENTS.—

8 (1) MEDICAID.—

9 (A) IN GENERAL.—Section 1903(i)(2) of
10 the Social Security Act (42 U.S.C.
11 1396b(i)(2)), as amended by section
12 5005(a)(4), is further amended—

13 (i) in subparagraph (C), by striking
14 “or” at the end; and

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

17 “(E) with respect to any amount expended
18 for such an item or service furnished during
19 calendar quarters beginning on or after October
20 1, 2017, subject to section
21 1902(kk)(4)(A)(ii)(II), within a geographic area
22 that is subject to a moratorium imposed under
23 section 1866(j)(7) by a provider or supplier
24 that meets the requirements specified in sub-

1 paragraph (C)(iii) of such section, during the
2 period of such moratorium; or”.

3 (B) EXCEPTION WITH RESPECT TO AC-
4 CESS.—Section 1902(kk)(4)(A)(ii) of the Social
5 Security Act (42 U.S.C. 1396a(kk)(4)(A)(ii)) is
6 amended to read as follows:

7 “(ii) EXCEPTIONS.—

8 “(I) COMPLIANCE WITH MORATO-
9 RIUM.—A State shall not be required
10 to comply with a temporary morato-
11 rium described in clause (i) if the
12 State determines that the imposition
13 of such temporary moratorium would
14 adversely impact beneficiaries’ access
15 to medical assistance.

16 “(II) FFP AVAILABLE.—Not-
17 withstanding section 1903(i)(2)(D),
18 payment may be made to a State
19 under this title with respect to
20 amounts expended for items and serv-
21 ices described in such section if the
22 Secretary, in consultation with the
23 State agency administering the State
24 plan under this title (or a waiver of
25 the plan), determines that denying

1 payment to the State pursuant to
2 such section would adversely impact
3 beneficiaries' access to medical assist-
4 ance. ”.

5 (C) STATE PLAN REQUIREMENT WITH RE-
6 SPECT TO LIMITATION ON CHARGES TO BENE-
7 FICIARIES.—Section 1902(kk)(4)(A) of the So-
8 cial Security Act (42 U.S.C. 1396a(kk)(4)(A))
9 is amended by adding at the end the following
10 new clause:

11 “(iii) LIMITATION ON CHARGES TO
12 BENEFCIARIES.—With respect to any
13 amount expended for items or services fur-
14 nished during calendar quarters beginning
15 on or after October 1, 2017, the State pro-
16 hibits, during the period of a temporary
17 moratorium described in clause (i), a pro-
18 vider meeting the requirements specified in
19 subparagraph (C)(iii) of section 1866(j)(7)
20 from charging an individual or other per-
21 son eligible to receive medical assistance
22 under the State plan under this title (or a
23 waiver of the plan) for an item or service
24 described in section 1903(i)(2)(D) fur-
25 nished to such an individual.”.

1 (2) CORRECTING AMENDMENTS TO RELATED
2 PROVISIONS.—

3 (A) SECTION 1866(J).—Section 1866(j) of
4 the Social Security Act (42 U.S.C. 1395cc(j)) is
5 amended—

6 (i) in paragraph (1)(A)—

7 (I) by striking “paragraph (4)”
8 and inserting “paragraph (5)”;

9 (II) by striking “moratoria in ac-
10 cordance with paragraph (5)” and in-
11 sserting “moratoria in accordance with
12 paragraph (7)”;

13 (III) by striking “paragraph (6)”
14 and inserting “paragraph (9)”;

15 (ii) by redesignating the second para-
16 graph (8) (redesignated by section 1304(1)
17 of Public Law 111–152) as paragraph (9).

18 (B) SECTION 1902(KK).—Section 1902(kk)
19 of such Act (42 U.S.C. 1396a(kk)) is amend-
20 ed—

21 (i) in paragraph (1), by striking “sec-
22 tion 1886(j)(2)” and inserting “section
23 1866(j)(2)”;

1 (ii) in paragraph (2), by striking “sec-
2 tion 1886(j)(3)” and inserting “section
3 1866(j)(3)”;

4 (iii) in paragraph (3), by striking
5 “section 1886(j)(4)” and inserting “section
6 1866(j)(5)”;

7 (iv) in paragraph (4)(A), by striking
8 “section 1886(j)(6)” and inserting “section
9 1866(j)(7)”.

10 **SEC. 17005. PRESERVATION OF MEDICARE BENEFICIARY**
11 **CHOICE UNDER MEDICARE ADVANTAGE.**

12 Section 1851(e)(2) of the Social Security Act (42
13 U.S.C. 1395w-21(e)(2)) is amended—

14 (1) in subparagraph (C)—

15 (A) in the heading, by inserting “FROM
16 2011 THROUGH 2018” after “45-DAY PERIOD”;
17 and

18 (B) by inserting “and ending with 2018”
19 after “beginning with 2011”; and

20 (2) by adding at the end the following new sub-
21 paragraph:

22 “(G) CONTINUOUS OPEN ENROLLMENT
23 AND DISENROLLMENT FOR FIRST 3 MONTHS IN
24 2016 AND SUBSEQUENT YEARS.—

1 “(i) IN GENERAL.—Subject to clause
2 (ii) and subparagraph (D)—

3 “(I) in the case of an MA eligible
4 individual who is enrolled in an MA
5 plan, at any time during the first 3
6 months of a year (beginning with
7 2019); or

8 “(II) in the case of an individual
9 who first becomes an MA eligible indi-
10 vidual during a year (beginning with
11 2019) and enrolls in an MA plan, dur-
12 ing the first 3 months during such
13 year in which the individual is an MA
14 eligible individual;

15 such MA eligible individual may change the
16 election under subsection (a)(1).

17 “(ii) LIMITATION OF ONE CHANGE
18 DURING OPEN ENROLLMENT PERIOD EACH
19 YEAR.—An individual may change the elec-
20 tion pursuant to clause (i) only once dur-
21 ing the applicable 3-month period de-
22 scribed in such clause in each year. The
23 limitation under this clause shall not apply
24 to changes in elections effected during an
25 annual, coordinated election period under

1 paragraph (3) or during a special enroll-
2 ment period under paragraph (4).

3 “(iii) LIMITED APPLICATION TO PART
4 D.—Clauses (i) and (ii) of this subpara-
5 graph shall only apply with respect to
6 changes in enrollment in a prescription
7 drug plan under part D in the case of an
8 individual who, previous to such change in
9 enrollment, is enrolled in a Medicare Ad-
10 vantage plan.

11 “(iv) LIMITATIONS ON MARKETING.—
12 Pursuant to subsection (j), no unsolicited
13 marketing or marketing materials may be
14 sent to an individual described in clause (i)
15 during the continuous open enrollment and
16 disenrollment period established for the in-
17 dividual under such clause, notwith-
18 standing marketing guidelines established
19 by the Centers for Medicare & Medicaid
20 Services.”.

21 **SEC. 17006. ALLOWING END-STAGE RENAL DISEASE BENE-**
22 **FICIARIES TO CHOOSE A MEDICARE ADVAN-**
23 **TAGE PLAN.**

24 (a) REMOVING PROHIBITION.—

1 (1) IN GENERAL.—Section 1851(a)(3) of the
2 Social Security Act (42 U.S.C. 1395w–21(a)(3)) is
3 amended—

4 (A) by striking subparagraph (B); and

5 (B) by striking “ELIGIBLE INDIVIDUAL”
6 and all that follows through “In this title, sub-
7 ject to subparagraph (B),” and inserting “ELI-
8 GIBLE INDIVIDUAL.—In this title,”.

9 (2) CONFORMING AMENDMENTS.—

10 (A) Section 1852(b)(1) of the Social Secu-
11 rity Act (42 U.S.C. 1395w–22(b)(1)) is amend-
12 ed—

13 (i) by striking subparagraph (B); and

14 (ii) by striking “BENEFICIARIES” and
15 all that follows through “A
16 Medicare+Choice organization” and in-
17 serting “BENEFICIARIES.—A Medicare Ad-
18 vantage organization”.

19 (B) Section 1859(b)(6) of the Social Secu-
20 rity Act (42 U.S.C. 1395w–28(b)(6)) is amend-
21 ed, in the last sentence, by striking “may
22 waive” and all that follows through “subpara-
23 graph and”.

1 (3) EFFECTIVE DATE.—The amendments made
2 by this subsection shall apply with respect to plan
3 years beginning on or after January 1, 2021.

4 (b) EXCLUDING COSTS FOR KIDNEY ACQUISITIONS
5 FROM MA BENCHMARK.—Section 1853 of the Social Se-
6 curity Act (42 U.S.C. 1395w–23) is amended—

7 (1) in subsection (k)—

8 (A) in paragraph (1)—

9 (i) in the matter preceding subpara-
10 graph (A), by striking “paragraphs (2)
11 and (4)” and inserting “paragraphs (2),
12 (4), and (5)”; and

13 (ii) in subparagraph (B)(i), by strik-
14 ing “paragraphs (2) and (4)” and insert-
15 ing “paragraphs (2), (4), and (5)”; and

16 (B) by adding at the end the following new
17 paragraph:

18 “(5) EXCLUSION OF COSTS FOR KIDNEY ACQUI-
19 SITIONS FROM CAPITATION RATES.—After deter-
20 mining the applicable amount for an area for a year
21 under paragraph (1) (beginning with 2021), the Sec-
22 retary shall adjust such applicable amount to ex-
23 clude from such applicable amount the Secretary’s
24 estimate of the standardized costs for payments for
25 organ acquisitions for kidney transplants covered

1 under this title (including expenses covered under
2 section 1881(d)) in the area for the year.”; and

3 (2) in subsection (n)(2)—

4 (A) in subparagraph (A)(i), by inserting
5 “and, for 2021 and subsequent years, the exclu-
6 sion of payments for organ acquisitions for kid-
7 ney transplants from the capitation rate as de-
8 scribed in subsection (k)(5)” before the semi-
9 colon at the end;

10 (B) in subparagraph (E), in the matter
11 preceding clause (i), by striking “subparagraph
12 (F)” and inserting “subparagraphs (F) and
13 (G)”; and

14 (C) by adding at the end the following new
15 subparagraph:

16 “(G) APPLICATION OF KIDNEY ACQUISSI-
17 TIONS ADJUSTMENT.—The base payment
18 amount specified in subparagraph (E) for a
19 year (beginning with 2021) shall be adjusted in
20 the same manner under paragraph (5) of sub-
21 section (k) as the applicable amount is adjusted
22 under such subsection.”.

23 (c) FFS COVERAGE OF KIDNEY ACQUISITIONS.—

24 (1) IN GENERAL.—Section 1852(a)(1)(B)(i) of
25 the Social Security Act (42 U.S.C. 1395w-

1 22(a)(1)(B)(i) is amended by inserting “or coverage
2 for organ acquisitions for kidney transplants, includ-
3 ing as covered under section 1881(d)” after “hospice
4 care”.

5 (2) CONFORMING AMENDMENT.—Section
6 1851(i) of the Social Security Act (42 U.S.C.
7 1395w–21(i)) is amended by adding at the end the
8 following new paragraph:

9 “(3) FFS PAYMENT FOR EXPENSES FOR KID-
10 NEY ACQUISITIONS.—Paragraphs (1) and (2) shall
11 not apply with respect to expenses for organ acqui-
12 sitions for kidney transplants described in section
13 1852(a)(1)(B)(i).”.

14 (3) EFFECTIVE DATE.—The amendments made
15 by this subsection shall apply with respect to plan
16 years beginning on or after January 1, 2021.

17 (d) EVALUATION OF QUALITY.—

18 (1) IN GENERAL.—The Secretary of Health and
19 Human Services (in this subsection referred to as
20 the “Secretary”) shall conduct an evaluation of
21 whether the 5-star rating system based on the data
22 collected under section 1852(e) of the Social Secu-
23 rity Act (42 U.S.C. 1395w–22(e)) should include a
24 quality measure specifically related to care for en-
25 rollees in Medicare Advantage plans under part C of

1 title XVIII of such Act determined to have end-stage
2 renal disease.

3 (2) PUBLIC AVAILABILITY.—Not later than
4 April 1, 2020, the Secretary shall post on the Inter-
5 net website of the Centers for Medicare & Medicaid
6 Services the results of the evaluation under para-
7 graph (1).

8 (e) REPORT.—Not later than December 31, 2023, the
9 Secretary of Health and Human Services (in this sub-
10 section referred to as the “Secretary”) shall submit to
11 Congress a report on the impact of the provisions of, and
12 amendments made by, this section with respect to the fol-
13 lowing:

14 (1) Spending under—

15 (A) the original Medicare fee-for-service
16 program under parts A and B of title XVIII of
17 the Social Security Act; and

18 (B) the Medicare Advantage program
19 under part C of such title.

20 (2) The number of enrollees determined to have
21 end-stage renal disease—

22 (A) in the original Medicare fee-for-service
23 program; and

24 (B) in the Medicare Advantage program.

1 (3) The sufficiency of the amount of data under
2 the original Medicare fee-for-service program for in-
3 dividuals determined to have end-stage renal disease
4 for purposes of determining payment rates for end-
5 stage renal disease under the Medicare Advantage
6 program.

7 (f) IMPROVEMENTS TO RISK ADJUSTMENT UNDER
8 MEDICARE ADVANTAGE.—

9 (1) IN GENERAL.—Section 1853(a)(1) of the
10 Social Security Act (42 U.S.C. 1395w–23(a)(1)) is
11 amended—

12 (A) in subparagraph (C)(i), by striking
13 “The Secretary” and inserting “Subject to sub-
14 paragraph (I), the Secretary”; and

15 (B) by adding at the end the following new
16 subparagraph:

17 “(I) IMPROVEMENTS TO RISK ADJUSTMENT
18 FOR 2019 AND SUBSEQUENT YEARS.—

19 “(i) IN GENERAL.—In order to deter-
20 mine the appropriate adjustment for health
21 status under subparagraph (C)(i), the fol-
22 lowing shall apply:

23 “(I) TAKING INTO ACCOUNT
24 TOTAL NUMBER OF DISEASES OR CON-
25 DITIONS.—The Secretary shall take

1 into account the total number of dis-
2 eases or conditions of an individual
3 enrolled in an MA plan. The Secretary
4 shall make an additional adjustment
5 under such subparagraph as the num-
6 ber of diseases or conditions of an in-
7 dividual increases.

8 “(II) USING AT LEAST 2 YEARS
9 OF DIAGNOSTIC DATA.—The Secretary
10 may use at least 2 years of diagnosis
11 data.

12 “(III) PROVIDING SEPARATE AD-
13 JUSTMENTS FOR DUAL ELIGIBLE IN-
14 DIVIDUALS.—With respect to individ-
15 uals who are dually eligible for bene-
16 fits under this title and title XIX, the
17 Secretary shall make separate adjust-
18 ments for each of the following:

19 “(aa) Full-benefit dual eligi-
20 ble individuals (as defined in sec-
21 tion 1935(c)(6)).

22 “(bb) Such individuals not
23 described in item (aa).

24 “(IV) EVALUATION OF MENTAL
25 HEALTH AND SUBSTANCE USE DIS-

1 ORDERS.—The Secretary shall evalu-
2 ate the impact of including additional
3 diagnosis codes related to mental
4 health and substance use disorders in
5 the risk adjustment model.

6 “(V) EVALUATION OF CHRONIC
7 KIDNEY DISEASE.—The Secretary
8 shall evaluate the impact of including
9 the severity of chronic kidney disease
10 in the risk adjustment model.

11 “(VI) EVALUATION OF PAYMENT
12 RATES FOR END-STAGE RENAL DIS-
13 EASE.—The Secretary shall evaluate
14 whether other factors (in addition to
15 those described in subparagraph (H))
16 should be taken into consideration
17 when computing payment rates under
18 such subparagraph.

19 “(ii) PHASED-IN IMPLEMENTATION.—
20 The Secretary shall phase-in any changes
21 to risk adjustment payment amounts under
22 subparagraph (C)(i) under this subpara-
23 graph over a 3-year period, beginning with
24 2019, with such changes being fully imple-
25 mented for 2022 and subsequent years.

1 “(iii) OPPORTUNITY FOR REVIEW AND
2 PUBLIC COMMENT.—The Secretary shall
3 provide an opportunity for review of the
4 proposed changes to such risk adjustment
5 payment amounts under this subparagraph
6 and a public comment period of not less
7 than 60 days before implementing such
8 changes.”.

9 (2) STUDIES AND REPORTS.—

10 (A) REPORTS ON THE RISK ADJUSTMENT
11 SYSTEM.—

12 (i) MEDPAC EVALUATION AND RE-
13 PORT.—

14 (I) EVALUATION.—The Medicare
15 Payment Advisory Commission shall
16 conduct an evaluation of the impact of
17 the provisions of, and amendments
18 made by, this section on risk scores
19 for enrollees in Medicare Advantage
20 plans under part C of title XVIII of
21 the Social Security Act and payments
22 to Medicare Advantage plans under
23 such part, including the impact of
24 such provisions and amendments on
25 the overall accuracy of risk scores

1 under the Medicare Advantage pro-
2 gram.

3 (II) REPORT.—Not later than
4 July 1, 2020, the Medicare Payment
5 Advisory Commission shall submit to
6 Congress a report on the evaluation
7 under subclause (I), together with rec-
8 ommendations for such legislation and
9 administrative action as the Commis-
10 sion determines appropriate.

11 (ii) REPORTS BY SECRETARY OF
12 HEALTH AND HUMAN SERVICES.—Not
13 later than December 31, 2018, and every
14 3 years thereafter, the Secretary of Health
15 and Human Services shall submit to Con-
16 gress a report on the risk adjustment
17 model and the ESRD risk adjustment
18 model under the Medicare Advantage pro-
19 gram under part C of title XVIII of the
20 Social Security Act, including any revisions
21 to either such model since the previous re-
22 port. Such report shall include information
23 on how such revisions impact the predictive
24 ratios under either such model for groups
25 of enrollees in Medicare Advantage plans,

1 including very high and very low cost en-
2 rollees, and groups defined by the number
3 of chronic conditions of enrollees.

4 (B) STUDY AND REPORT ON FUNCTIONAL
5 STATUS.—

6 (i) STUDY.—The Comptroller General
7 of the United States (in this subparagraph
8 referred to as the “Comptroller General”)
9 shall conduct a study on how to most accu-
10 rately measure the functional status of en-
11 rollees in Medicare Advantage plans and
12 whether the use of such functional status
13 would improve the accuracy of risk adjust-
14 ment payments under the Medicare Advan-
15 tage program under part C of title XVIII
16 of the Social Security Act. Such study
17 shall include an analysis of the challenges
18 in collecting and reporting functional sta-
19 tus information for Medicare Advantage
20 plans under such part, providers of serv-
21 ices and suppliers under the Medicare pro-
22 gram, and the Centers for Medicare &
23 Medicaid Services.

24 (ii) REPORT.—Not later than June
25 30, 2018, the Comptroller General shall

1 submit to Congress a report containing the
2 results of the study under clause (i), to-
3 gether with recommendations for such leg-
4 islation and administrative action as the
5 Comptroller General determines appro-
6 priate.

7 **SEC. 17007. IMPROVEMENTS TO THE ASSIGNMENT OF**
8 **BENEFICIARIES UNDER THE MEDICARE**
9 **SHARED SAVINGS PROGRAM.**

10 Section 1899(c) of the Social Security Act (42 U.S.C.
11 1395jjj(c)) is amended—

12 (1) by striking “utilization of primary” and in-
13 serting “utilization of—

14 “(1) in the case of performance years beginning
15 on or after April 1, 2012, primary”;

16 (2) in paragraph (1), as added by paragraph
17 (1) of this section, by striking the period at the end
18 and inserting “; and”;

19 (3) by adding at the end the following new
20 paragraph:

21 “(2) in the case of performance years beginning
22 on or after January 1, 2019, services provided under
23 this title by a Federally qualified health center or
24 rural health clinic (as those terms are defined in sec-

1 tion 1861(aa)), as may be determined by the Sec-
2 retary.”.

3 **TITLE XVIII—OTHER**
4 **PROVISIONS**

5 **SEC. 18001. EXCEPTION FROM GROUP HEALTH PLAN RE-**
6 **QUIREMENTS FOR QUALIFIED SMALL EM-**
7 **PLOYER HEALTH REIMBURSEMENT AR-**
8 **RANGEMENTS.**

9 (a) AMENDMENTS TO THE INTERNAL REVENUE
10 CODE OF 1986 AND THE PATIENT PROTECTION AND AF-
11 FORDABLE CARE ACT.—

12 (1) IN GENERAL.—Section 9831 of the Internal
13 Revenue Code of 1986 is amended by adding at the
14 end the following new subsection:

15 “(d) EXCEPTION FOR QUALIFIED SMALL EMPLOYER
16 HEALTH REIMBURSEMENT ARRANGEMENTS.—

17 “(1) IN GENERAL.—For purposes of this title
18 (except as provided in section 4980I(f)(4) and not-
19 withstanding any other provision of this title), the
20 term ‘group health plan’ shall not include any quali-
21 fied small employer health reimbursement arrange-
22 ment.

23 “(2) QUALIFIED SMALL EMPLOYER HEALTH
24 REIMBURSEMENT ARRANGEMENT.—For purposes of
25 this subsection—

1 “(A) IN GENERAL.—The term ‘qualified
2 small employer health reimbursement arrange-
3 ment’ means an arrangement which—

4 “(i) is described in subparagraph (B),
5 and

6 “(ii) is provided on the same terms to
7 all eligible employees of the eligible em-
8 ployer.

9 “(B) ARRANGEMENT DESCRIBED.—An ar-
10 rangement is described in this subparagraph
11 if—

12 “(i) such arrangement is funded solely
13 by an eligible employer and no salary re-
14 duction contributions may be made under
15 such arrangement,

16 “(ii) such arrangement provides, after
17 the employee provides proof of coverage,
18 for the payment of, or reimbursement of,
19 an eligible employee for expenses for med-
20 ical care (as defined in section 213(d)) in-
21 curred by the eligible employee or the eligi-
22 ble employee’s family members (as deter-
23 mined under the terms of the arrange-
24 ment), and

1 “(iii) the amount of payments and re-
2 imbursements described in clause (ii) for
3 any year do not exceed \$4,950 (\$10,000 in
4 the case of an arrangement that also pro-
5 vides for payments or reimbursements for
6 family members of the employee).

7 “(C) CERTAIN VARIATION PERMITTED.—
8 For purposes of subparagraph (A)(ii), an ar-
9 rangement shall not fail to be treated as pro-
10 vided on the same terms to each eligible em-
11 ployee merely because the employee’s permitted
12 benefit under such arrangement varies in ac-
13 cordance with the variation in the price of an
14 insurance policy in the relevant individual
15 health insurance market based on—

16 “(i) the age of the eligible employee
17 (and, in the case of an arrangement which
18 covers medical expenses of the eligible em-
19 ployee’s family members, the age of such
20 family members), or

21 “(ii) the number of family members of
22 the eligible employee the medical expenses
23 of which are covered under such arrange-
24 ment.

1 The variation permitted under the preceding
2 sentence shall be determined by reference to the
3 same insurance policy with respect to all eligible
4 employees.

5 “(D) RULES RELATING TO MAXIMUM DOL-
6 LAR LIMITATION.—

7 “(i) AMOUNT PRORATED IN CERTAIN
8 CASES.—In the case of an individual who
9 is not covered by an arrangement for the
10 entire year, the limitation under subpara-
11 graph (B)(iii) for such year shall be an
12 amount which bears the same ratio to the
13 amount which would (but for this clause)
14 be in effect for such individual for such
15 year under subparagraph (B)(iii) as the
16 number of months for which such indi-
17 vidual is covered by the arrangement for
18 such year bears to 12.

19 “(ii) INFLATION ADJUSTMENT.—In
20 the case of any year beginning after 2016,
21 each of the dollar amounts in subpara-
22 graph (B)(iii) shall be increased by an
23 amount equal to—

24 “(I) such dollar amount, multi-
25 plied by

1 “(II) the cost-of-living adjust-
2 ment determined under section 1(f)(3)
3 for the calendar year in which the tax-
4 able year begins, determined by sub-
5 stituting ‘calendar year 2015’ for ‘cal-
6 endar year 1992’ in subparagraph (B)
7 thereof.

8 If any dollar amount increased under the
9 preceding sentence is not a multiple of
10 \$50, such dollar amount shall be rounded
11 to the next lowest multiple of \$50.

12 “(3) OTHER DEFINITIONS.—For purposes of
13 this subsection—

14 “(A) ELIGIBLE EMPLOYEE.—The term ‘eli-
15 gible employee’ means any employee of an eligi-
16 ble employer, except that the terms of the ar-
17 rangement may exclude from consideration em-
18 ployees described in any clause of section
19 105(h)(3)(B) (applied by substituting ‘90 days’
20 for ‘3 years’ in clause (i) thereof).

21 “(B) ELIGIBLE EMPLOYER.—The term ‘el-
22 igible employer’ means an employer that—

23 “(i) is not an applicable large em-
24 ployer as defined in section 4980H(c)(2),
25 and

1 “(ii) does not offer a group health
2 plan to any of its employees.

3 “(C) PERMITTED BENEFIT.—The term
4 ‘permitted benefit’ means, with respect to any
5 eligible employee, the maximum dollar amount
6 of payments and reimbursements which may be
7 made under the terms of the qualified small
8 employer health reimbursement arrangement
9 for the year with respect to such employee.

10 “(4) NOTICE.—

11 “(A) IN GENERAL.—An employer funding
12 a qualified small employer health reimburse-
13 ment arrangement for any year shall, not later
14 than 90 days before the beginning of such year
15 (or, in the case of an employee who is not eligi-
16 ble to participate in the arrangement as of the
17 beginning of such year, the date on which such
18 employee is first so eligible), provide a written
19 notice to each eligible employee which includes
20 the information described in subparagraph (B).

21 “(B) CONTENTS OF NOTICE.—The notice
22 required under subparagraph (A) shall include
23 each of the following:

24 “(i) A statement of the amount which
25 would be such eligible employee’s permitted

1 benefit under the arrangement for the
2 year.

3 “(ii) A statement that the eligible em-
4 ployee should provide the information de-
5 scribed in clause (i) to any health insur-
6 ance exchange to which the employee ap-
7 plies for advance payment of the premium
8 assistance tax credit.

9 “(iii) A statement that if the employee
10 is not covered under minimum essential
11 coverage for any month the employee may
12 be subject to tax under section 5000A for
13 such month and reimbursements under the
14 arrangement may be includible in gross in-
15 come.”.

16 (2) LIMITATION ON EXCLUSION FROM GROSS
17 INCOME.—Section 106 of such Code is amended by
18 adding at the end the following:

19 “(g) QUALIFIED SMALL EMPLOYER HEALTH REIM-
20 BURSEMENT ARRANGEMENT.—For purposes of this sec-
21 tion and section 105, payments or reimbursements from
22 a qualified small employer health reimbursement arrange-
23 ment (as defined in section 9831(d)) of an individual for
24 medical care (as defined in section 213(d)) shall not be
25 treated as paid or reimbursed under employer-provided

1 coverage for medical expenses under an accident or health
2 plan if for the month in which such medical care is pro-
3 vided the individual does not have minimum essential cov-
4 erage (within the meaning of section 5000A(f)).”.

5 (3) COORDINATION WITH HEALTH INSURANCE
6 PREMIUM CREDIT.—Section 36B(c) of such Code is
7 amended by adding at the end the following new
8 paragraph:

9 “(4) SPECIAL RULES FOR QUALIFIED SMALL
10 EMPLOYER HEALTH REIMBURSEMENT ARRANGE-
11 MENTS.—

12 “(A) IN GENERAL.—The term ‘coverage
13 month’ shall not include any month with re-
14 spect to an employee (or any spouse or depend-
15 ent of such employee) if for such month the em-
16 ployee is provided a qualified small employer
17 health reimbursement arrangement which con-
18 stitutes affordable coverage.

19 “(B) DENIAL OF DOUBLE BENEFIT.—In
20 the case of any employee who is provided a
21 qualified small employer health reimbursement
22 arrangement for any coverage month (deter-
23 mined without regard to subparagraph (A)), the
24 credit otherwise allowable under subsection (a)
25 to the taxpayer for such month shall be reduced

1 (but not below zero) by the amount described in
2 subparagraph (C)(i)(II) for such month.

3 “(C) AFFORDABLE COVERAGE.—For pur-
4 poses of subparagraph (A), a qualified small
5 employer health reimbursement arrangement
6 shall be treated as constituting affordable cov-
7 erage for a month if—

8 “(i) the excess of—

9 “(I) the amount that would be
10 paid by the employee as the premium
11 for such month for self-only coverage
12 under the second lowest cost silver
13 plan offered in the relevant individual
14 health insurance market, over

15 “(II) $\frac{1}{12}$ of the employee’s per-
16 mitted benefit (as defined in section
17 9831(d)(3)(C)) under such arrange-
18 ment, does not exceed—

19 “(ii) $\frac{1}{12}$ of 9.5 percent of the employ-
20 ee’s household income.

21 “(D) QUALIFIED SMALL EMPLOYER
22 HEALTH REIMBURSEMENT ARRANGEMENT.—
23 For purposes of this paragraph, the term
24 ‘qualified small employer health reimbursement

1 arrangement' has the meaning given such term
2 by section 9831(d)(2).

3 “(E) COVERAGE FOR LESS THAN ENTIRE
4 YEAR.—In the case of an employee who is pro-
5 vided a qualified small employer health reim-
6 bursement arrangement for less than an entire
7 year, subparagraph (C)(i)(II) shall be applied
8 by substituting ‘the number of months during
9 the year for which such arrangement was pro-
10 vided’ for ‘12’.

11 “(F) INDEXING.—In the case of plan years
12 beginning in any calendar year after 2014, the
13 Secretary shall adjust the 9.5 percent amount
14 under subparagraph (C)(ii) in the same manner
15 as the percentages are adjusted under sub-
16 section (b)(3)(A)(ii).”.

17 (4) APPLICATION OF EXCISE TAX ON HIGH
18 COST EMPLOYER-SPONSORED HEALTH COVERAGE.—

19 (A) IN GENERAL.—Section 4980I(f)(4) of
20 such Code is amended by adding at the end the
21 following: “Section 9831(d)(1) shall not apply
22 for purposes of this section.”.

23 (B) DETERMINATION OF COST OF COV-
24 ERAGE.—Section 4980I(d)(2) of such Code is
25 amended by redesignating subparagraph (D) as

1 subparagraph (E) and by inserting after sub-
2 paragraph (C) the following new subparagraph:

3 “(D) QUALIFIED SMALL EMPLOYER
4 HEALTH REIMBURSEMENT ARRANGEMENTS.—

5 In the case of applicable employer-sponsored
6 coverage consisting of coverage under any quali-
7 fied small employer health reimbursement ar-
8 rangement (as defined in section 9831(d)(2)),
9 the cost of coverage shall be equal to the
10 amount described in section 6051(a)(15).”.

11 (5) ENFORCEMENT OF NOTICE REQUIRE-
12 MENT.—Section 6652 of such Code is amended by
13 adding at the end the following new subsection:

14 “(o) FAILURE TO PROVIDE NOTICES WITH RESPECT
15 TO QUALIFIED SMALL EMPLOYER HEALTH REIMBURSE-
16 MENT ARRANGEMENTS.—In the case of each failure to
17 provide a written notice as required by section 9831(d)(4),
18 unless it is shown that such failure is due to reasonable
19 cause and not willful neglect, there shall be paid, on notice
20 and demand of the Secretary and in the same manner as
21 tax, by the person failing to provide such written notice,
22 an amount equal to \$50 per employee per incident of fail-
23 ure to provide such notice, but the total amount imposed
24 on such person for all such failures during any calendar
25 year shall not exceed \$2,500.”.

1 (6) REPORTING.—

2 (A) W-2 REPORTING.—Section 6051(a) of
3 such Code is amended by striking “and” at the
4 end of paragraph (13), by striking the period at
5 the end of paragraph (14) and inserting “,
6 and”, and by inserting after paragraph (14) the
7 following new paragraph:

8 “(15) the total amount of permitted benefit (as
9 defined in section 9831(d)(3)(C)) for the year under
10 a qualified small employer health reimbursement ar-
11 rangement (as defined in section 9831(d)(2)) with
12 respect to the employee.”.

13 (B) INFORMATION REQUIRED TO BE PRO-
14 VIDED BY EXCHANGE SUBSIDY APPLICANTS.—
15 Section 1411(b)(3) of the Patient Protection
16 and Affordable Care Act is amended by redesignig-
17 nating subparagraph (B) as subparagraph (C)
18 and by inserting after subparagraph (A) the fol-
19 lowing new subparagraph:

20 “(B) CERTAIN INDIVIDUAL HEALTH IN-
21 SURANCE POLICIES OBTAINED THROUGH SMALL
22 EMPLOYERS.—The amount of the enrollee’s
23 permitted benefit (as defined in section
24 9831(d)(3)(C) of the Internal Revenue Code of
25 1986) under a qualified small employer health

1 reimbursement arrangement (as defined in sec-
2 tion 9831(d)(2) of such Code).”.

3 (7) EFFECTIVE DATES.—

4 (A) IN GENERAL.—Except as otherwise
5 provided in this paragraph, the amendments
6 made by this subsection shall apply to years be-
7 ginning after December 31, 2016.

8 (B) TRANSITION RELIEF.—The relief
9 under Treasury Notice 2015–17 shall be treat-
10 ed as applying to any plan year beginning on or
11 before December 31, 2016.

12 (C) COORDINATION WITH HEALTH INSUR-
13 ANCE PREMIUM CREDIT.—The amendments
14 made by paragraph (3) shall apply to taxable
15 years beginning after December 31, 2016.

16 (D) EMPLOYEE NOTICE.—

17 (i) IN GENERAL.—The amendments
18 made by paragraph (5) shall apply to no-
19 tices with respect to years beginning after
20 December 31, 2016.

21 (ii) TRANSITION RELIEF.—For pur-
22 poses of section 6652(o) of the Internal
23 Revenue Code of 1986 (as added by this
24 Act), a person shall not be treated as fail-
25 ing to provide a written notice as required

1 by section 9831(d)(4) of such Code if such
2 notice is so provided not later than 90
3 days after the date of the enactment of
4 this Act.

5 (E) W-2 REPORTING.—The amendments
6 made by paragraph (6)(A) shall apply to cal-
7 endar years beginning after December 31,
8 2016.

9 (F) INFORMATION PROVIDED BY EX-
10 CHANGE SUBSIDY APPLICANTS.—

11 (i) IN GENERAL.—The amendments
12 made by paragraph (6)(B) shall apply to
13 applications for enrollment made after De-
14 cember 31, 2016.

15 (ii) VERIFICATION.—Verification
16 under section 1411 of the Patient Protec-
17 tion and Affordable Care Act of informa-
18 tion provided under section 1411(b)(3)(B)
19 of such Act shall apply with respect to
20 months beginning after October 2016.

21 (iii) TRANSITIONAL RELIEF.—In the
22 case of an application for enrollment under
23 section 1411(b) of the Patient Protection
24 and Affordable Care Act made before April
25 1, 2017, the requirement of section

1 1411(b)(3)(B) of such Act shall be treated
2 as met if the information described therein
3 is provided not later than 30 days after the
4 date on which the applicant receives the
5 notice described in section 9831(d)(4) of
6 the Internal Revenue Code of 1986.

7 (8) SUBSTANTIATION REQUIREMENTS.—The
8 Secretary of the Treasury (or his designee) may
9 issue substantiation requirements as necessary to
10 carry out this subsection.

11 (b) AMENDMENTS TO THE EMPLOYEE RETIREMENT
12 INCOME SECURITY ACT OF 1974.—

13 (1) IN GENERAL.—Section 733(a)(1) of the
14 Employee Retirement Income Security Act of 1974
15 (29 U.S.C. 1191b(a)(1)) is amended by adding at
16 the end the following: “Such term shall not include
17 any qualified small employer health reimbursement
18 arrangement (as defined in section 9831(d)(2) of the
19 Internal Revenue Code of 1986).”.

20 (2) EXCEPTION FROM CONTINUATION COV-
21 ERAGE REQUIREMENTS, ETC.—Section 607(1) of
22 such Act (29 U.S.C. 1167(1)) is amended by adding
23 at the end the following: “Such term shall not in-
24 clude any qualified small employer health reimburse-

1 ment arrangement (as defined in section 9831(d)(2)
2 of the Internal Revenue Code of 1986).”.

3 (3) EFFECTIVE DATE.—The amendments made
4 by this subsection shall apply to plan years begin-
5 ning after December 31, 2016.

6 (c) AMENDMENTS TO THE PUBLIC HEALTH SERVICE
7 ACT.—

8 (1) IN GENERAL.—Section 2791(a)(1) of the
9 Public Health Service Act (42 U.S.C. 300gg-
10 91(a)(1)) is amended by adding at the end the fol-
11 lowing: “Except for purposes of part C of title XI
12 of the Social Security Act (42 U.S.C. 1320d et seq.),
13 such term shall not include any qualified small em-
14 ployer health reimbursement arrangement (as de-
15 fined in section 9831(d)(2) of the Internal Revenue
16 Code of 1986).”.

17 (2) EXCEPTION FROM CONTINUATION COV-
18 ERAGE REQUIREMENTS.—Section 2208(1) of the
19 Public Health Service Act (42 U.S.C. 300bb-8(1)) is
20 amended by adding at the end the following: “Such
21 term shall not include any qualified small employer
22 health reimbursement arrangement (as defined in
23 section 9831(d)(2) of the Internal Revenue Code of
24 1986).”.

1 (3) EFFECTIVE DATE.—The amendments made
2 by this subsection shall apply to plan years begin-
3 ning after December 31, 2016.

4 **DIVISION D—CHILD AND FAMILY**
5 **SERVICES AND SUPPORT**

6 **SEC. 19000. SHORT TITLE.**

7 This division may be cited as the “Family First Pre-
8 vention Services Act of 2016”.

9 **TITLE XIX—INVESTING IN PRE-**
10 **VENTION AND FAMILY SERV-**
11 **ICES**

12 **SEC. 19001. PURPOSE.**

13 The purpose of this title is to enable States to use
14 Federal funds available under parts B and E of title IV
15 of the Social Security Act to provide enhanced support to
16 children and families and prevent foster care placements
17 through the provision of mental health and substance
18 abuse prevention and treatment services, in-home parent
19 skill-based programs, and kinship navigator services.

20 **Subtitle A—Prevention Activities**
21 **Under Title IV–E**

22 **SEC. 19011. FOSTER CARE PREVENTION SERVICES AND**
23 **PROGRAMS.**

24 (a) STATE OPTION.—Section 471 of the Social Secu-
25 rity Act (42 U.S.C. 671) is amended—

1 (1) in subsection (a)(1), by striking “and” and
2 all that follows through the semicolon and inserting
3 “, adoption assistance in accordance with section
4 473, and, at the option of the State, services or pro-
5 grams specified in subsection (e)(1) of this section
6 for children who are candidates for foster care or
7 who are pregnant or parenting foster youth and the
8 parents or kin caregivers of the children, in accord-
9 ance with the requirements of that subsection;”; and

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

11 “(e) PREVENTION AND FAMILY SERVICES AND PRO-
12 GRAMS.—

13 “(1) IN GENERAL.—Subject to the succeeding
14 provisions of this subsection, the Secretary may
15 make a payment to a State for providing the fol-
16 lowing services or programs for a child described in
17 paragraph (2) and the parents or kin caregivers of
18 the child when the need of the child, such a parent,
19 or such a caregiver for the services or programs are
20 directly related to the safety, permanence, or well-
21 being of the child or to preventing the child from en-
22 tering foster care:

23 “(A) MENTAL HEALTH AND SUBSTANCE
24 ABUSE PREVENTION AND TREATMENT SERV-
25 ICES.—Mental health and substance abuse pre-

1 vention and treatment services provided by a
2 qualified clinician for not more than a 12-
3 month period that begins on any date described
4 in paragraph (3) with respect to the child.

5 “(B) IN-HOME PARENT SKILL-BASED PRO-
6 GRAMS.—In-home parent skill-based programs
7 for not more than a 12-month period that be-
8 gins on any date described in paragraph (3)
9 with respect to the child and that include par-
10 enting skills training, parent education, and in-
11 dividual and family counseling.

12 “(2) CHILD DESCRIBED.—For purposes of
13 paragraph (1), a child described in this paragraph is
14 the following:

15 “(A) A child who is a candidate for foster
16 care (as defined in section 475(13)) but can re-
17 main safely at home or in a kinship placement
18 with receipt of services or programs specified in
19 paragraph (1).

20 “(B) A child in foster care who is a preg-
21 nant or parenting foster youth.

22 “(3) DATE DESCRIBED.—For purposes of para-
23 graph (1), the dates described in this paragraph are
24 the following:

1 “(A) The date on which a child is identi-
2 fied in a prevention plan maintained under
3 paragraph (4) as a child who is a candidate for
4 foster care (as defined in section 475(13)).

5 “(B) The date on which a child is identi-
6 fied in a prevention plan maintained under
7 paragraph (4) as a pregnant or parenting foster
8 youth in need of services or programs specified
9 in paragraph (1).

10 “(4) REQUIREMENTS RELATED TO PROVIDING
11 SERVICES AND PROGRAMS.—Services and programs
12 specified in paragraph (1) may be provided under
13 this subsection only if specified in advance in the
14 child’s prevention plan described in subparagraph
15 (A) and the requirements in subparagraphs (B)
16 through (E) are met:

17 “(A) PREVENTION PLAN.—The State
18 maintains a written prevention plan for the
19 child that meets the following requirements (as
20 applicable):

21 “(i) CANDIDATES.—In the case of a
22 child who is a candidate for foster care de-
23 scribed in paragraph (2)(A), the prevention
24 plan shall—

1 “(I) identify the foster care pre-
2 vention strategy for the child so that
3 the child may remain safely at home,
4 live temporarily with a kin caregiver
5 until reunification can be safely
6 achieved, or live permanently with a
7 kin caregiver;

8 “(II) list the services or pro-
9 grams to be provided to or on behalf
10 of the child to ensure the success of
11 that prevention strategy; and

12 “(III) comply with such other re-
13 quirements as the Secretary shall es-
14 tablish.

15 “(ii) PREGNANT OR PARENTING FOS-
16 TER YOUTH.—In the case of a child who is
17 a pregnant or parenting foster youth de-
18 scribed in paragraph (2)(B), the preven-
19 tion plan shall—

20 “(I) be included in the child’s
21 case plan required under section
22 475(1);

23 “(II) list the services or pro-
24 grams to be provided to or on behalf
25 of the youth to ensure that the youth

1 is prepared (in the case of a pregnant
2 foster youth) or able (in the case of a
3 parenting foster youth) to be a par-
4 ent;

5 “(III) describe the foster care
6 prevention strategy for any child born
7 to the youth; and

8 “(IV) comply with such other re-
9 quirements as the Secretary shall es-
10 tablish.

11 “(B) TRAUMA-INFORMED.—The services or
12 programs to be provided to or on behalf of a
13 child are provided under an organizational
14 structure and treatment framework that in-
15 volves understanding, recognizing, and respond-
16 ing to the effects of all types of trauma and in
17 accordance with recognized principles of a trau-
18 ma-informed approach and trauma-specific
19 interventions to address trauma’s consequences
20 and facilitate healing.

21 “(C) ONLY SERVICES AND PROGRAMS PRO-
22 VIDED IN ACCORDANCE WITH PROMISING, SUP-
23 PORTED, OR WELL-SUPPORTED PRACTICES PER-
24 MITTED.—

1 “(i) IN GENERAL.—Only State ex-
2 penditures for services or programs speci-
3 fied in subparagraph (A) or (B) of para-
4 graph (1) that are provided in accordance
5 with practices that meet the requirements
6 specified in clause (ii) of this subparagraph
7 and that meet the requirements specified
8 in clause (iii), (iv), or (v), respectively, for
9 being a promising, supported, or well-sup-
10 ported practice, shall be eligible for a Fed-
11 eral matching payment under section
12 474(a)(6)(A).

13 “(ii) GENERAL PRACTICE REQUIRE-
14 MENTS.—The general practice require-
15 ments specified in this clause are the fol-
16 lowing:

17 “(I) The practice has a book,
18 manual, or other available writings
19 that specify the components of the
20 practice protocol and describe how to
21 administer the practice.

22 “(II) There is no empirical basis
23 suggesting that, compared to its likely
24 benefits, the practice constitutes a
25 risk of harm to those receiving it.

1 “(III) If multiple outcome studies
2 have been conducted, the overall
3 weight of evidence supports the bene-
4 fits of the practice.

5 “(IV) Outcome measures are reli-
6 able and valid, and are administrated
7 consistently and accurately across all
8 those receiving the practice.

9 “(V) There is no case data sug-
10 gesting a risk of harm that was prob-
11 ably caused by the treatment and that
12 was severe or frequent.

13 “(iii) PROMISING PRACTICE.—A prac-
14 tice shall be considered to be a ‘promising
15 practice’ if the practice is superior to an
16 appropriate comparison practice using con-
17 ventional standards of statistical signifi-
18 cance (in terms of demonstrated meaning-
19 ful improvements in validated measures of
20 important child and parent outcomes, such
21 as mental health, substance abuse, and
22 child safety and well-being), as established
23 by the results or outcomes of at least one
24 study that—

1 “(I) was rated by an independent
2 systematic review for the quality of
3 the study design and execution and
4 determined to be well-designed and
5 well-executed; and

6 “(II) utilized some form of con-
7 trol (such as an untreated group, a
8 placebo group, or a wait list study).

9 “(iv) SUPPORTED PRACTICE.—A prac-
10 tice shall be considered to be a ‘supported
11 practice’ if—

12 “(I) the practice is superior to an
13 appropriate comparison practice using
14 conventional standards of statistical
15 significance (in terms of demonstrated
16 meaningful improvements in validated
17 measures of important child and par-
18 ent outcomes, such as mental health,
19 substance abuse, and child safety and
20 well-being), as established by the re-
21 sults or outcomes of at least one study
22 that—

23 “(aa) was rated by an inde-
24 pendent systematic review for the
25 quality of the study design and

1 execution and determined to be
2 well-designed and well-executed;

3 “(bb) was a rigorous ran-
4 dom-controlled trial (or, if not
5 available, a study using a rig-
6 orous quasi-experimental re-
7 search design); and

8 “(cc) was carried out in a
9 usual care or practice setting;
10 and

11 “(II) the study described in sub-
12 clause (I) established that the practice
13 has a sustained effect (when com-
14 pared to a control group) for at least
15 6 months beyond the end of the treat-
16 ment.

17 “(v) WELL-SUPPORTED PRACTICE.—A
18 practice shall be considered to be a ‘well-
19 supported practice’ if—

20 “(I) the practice is superior to an
21 appropriate comparison practice using
22 conventional standards of statistical
23 significance (in terms of demonstrated
24 meaningful improvements in validated
25 measures of important child and par-

1 ent outcomes, such as mental health,
2 substance abuse, and child safety and
3 well-being), as established by the re-
4 sults or outcomes of at least two stud-
5 ies that—

6 “(aa) were rated by an inde-
7 pendent systematic review for the
8 quality of the study design and
9 execution and determined to be
10 well-designed and well-executed;

11 “(bb) were rigorous random-
12 controlled trials (or, if not avail-
13 able, studies using a rigorous
14 quasi-experimental research de-
15 sign); and

16 “(cc) were carried out in a
17 usual care or practice setting;
18 and

19 “(II) at least one of the studies
20 described in subclause (I) established
21 that the practice has a sustained ef-
22 fect (when compared to a control
23 group) for at least 1 year beyond the
24 end of treatment.

1 “(D) GUIDANCE ON PRACTICES CRITERIA
2 AND PRE-APPROVED SERVICES AND PRO-
3 GRAMS.—

4 “(i) IN GENERAL.—Not later than Oc-
5 tober 1, 2018, the Secretary shall issue
6 guidance to States regarding the practices
7 criteria required for services or programs
8 to satisfy the requirements of subpara-
9 graph (C). The guidance shall include a
10 pre-approved list of services and programs
11 that satisfy the requirements.

12 “(ii) UPDATES.—The Secretary shall
13 issue updates to the guidance required by
14 clause (i) as often as the Secretary deter-
15 mines necessary.

16 “(E) OUTCOME ASSESSMENT AND REPORT-
17 ING.—The State shall collect and report to the
18 Secretary the following information with respect
19 to each child for whom, or on whose behalf
20 mental health and substance abuse prevention
21 and treatment services or in-home parent skill-
22 based programs are provided during a 12-
23 month period beginning on the date the child is
24 determined by the State to be a child described
25 in paragraph (2):

1 “(i) The specific services or programs
2 provided and the total expenditures for
3 each of the services or programs.

4 “(ii) The duration of the services or
5 programs provided.

6 “(iii) In the case of a child described
7 in paragraph (2)(A), the child’s placement
8 status at the beginning, and at the end, of
9 the 1-year period, respectively, and wheth-
10 er the child entered foster care within 2
11 years after being determined a candidate
12 for foster care.

13 “(5) STATE PLAN COMPONENT.—

14 “(A) IN GENERAL.—A State electing to
15 provide services or programs specified in para-
16 graph (1) shall submit as part of the State plan
17 required by subsection (a) a prevention services
18 and programs plan component that meets the
19 requirements of subparagraph (B).

20 “(B) PREVENTION SERVICES AND PRO-
21 GRAMS PLAN COMPONENT.—In order to meet
22 the requirements of this subparagraph, a pre-
23 vention services and programs plan component,
24 with respect to each 5-year period for which the

1 plan component is in operation in the State,
2 shall include the following:

3 “(i) How providing services and pro-
4 grams specified in paragraph (1) is ex-
5 pected to improve specific outcomes for
6 children and families.

7 “(ii) How the State will monitor and
8 oversee the safety of children who receive
9 services and programs specified in para-
10 graph (1), including through periodic risk
11 assessments throughout the period in
12 which the services and programs are pro-
13 vided on behalf of a child and reexamina-
14 tion of the prevention plan maintained for
15 the child under paragraph (4) for the pro-
16 vision of the services or programs if the
17 State determines the risk of the child en-
18 tering foster care remains high despite the
19 provision of the services or programs.

20 “(iii) With respect to the services and
21 programs specified in subparagraphs (A)
22 and (B) of paragraph (1), information on
23 the specific promising, supported, or well-
24 supported practices the State plans to use

1 to provide the services or programs, includ-
2 ing a description of—

3 “(I) the services or programs and
4 whether the practices used are prom-
5 ising, supported, or well-supported;

6 “(II) how the State plans to im-
7 plement the services or programs, in-
8 cluding how implementation of the
9 services or programs will be continu-
10 ously monitored to ensure fidelity to
11 the practice model and to determine
12 outcomes achieved and how informa-
13 tion learned from the monitoring will
14 be used to refine and improve prac-
15 tices;

16 “(III) how the State selected the
17 services or programs;

18 “(IV) the target population for
19 the services or programs; and

20 “(V) how each service or pro-
21 gram provided will be evaluated
22 through a well-designed and rigorous
23 process, which may consist of an on-
24 going, cross-site evaluation approved
25 by the Secretary.

1 “(iv) A description of the consultation
2 that the State agencies responsible for ad-
3 ministering the State plans under this part
4 and part B engage in with other State
5 agencies responsible for administering
6 health programs, including mental health
7 and substance abuse prevention and treat-
8 ment services, and with other public and
9 private agencies with experience in admin-
10 istering child and family services, including
11 community-based organizations, in order to
12 foster a continuum of care for children de-
13 scribed in paragraph (2) and their parents
14 or kin caregivers.

15 “(v) A description of how the State
16 shall assess children and their parents or
17 kin caregivers to determine eligibility for
18 services or programs specified in para-
19 graph (1).

20 “(vi) A description of how the services
21 or programs specified in paragraph (1)
22 that are provided for or on behalf of a
23 child and the parents or kin caregivers of
24 the child will be coordinated with other
25 child and family services provided to the

1 child and the parents or kin caregivers of
2 the child under the State plan under part
3 B.

4 “(vii) Descriptions of steps the State
5 is taking to support and enhance a com-
6 petent, skilled, and professional child wel-
7 fare workforce to deliver trauma-informed
8 and evidence-based services, including—

9 “(I) ensuring that staff is quali-
10 fied to provide services or programs
11 that are consistent with the prom-
12 ising, supported, or well-supported
13 practice models selected; and

14 “(II) developing appropriate pre-
15 vention plans, and conducting the risk
16 assessments required under clause
17 (iii).

18 “(viii) A description of how the State
19 will provide training and support for case-
20 workers in assessing what children and
21 their families need, connecting to the fami-
22 lies served, knowing how to access and de-
23 liver the needed trauma-informed and evi-
24 dence-based services, and overseeing and

1 evaluating the continuing appropriateness
2 of the services.

3 “(ix) A description of how caseload
4 size and type for prevention caseworkers
5 will be determined, managed, and overseen.

6 “(x) An assurance that the State will
7 report to the Secretary such information
8 and data as the Secretary may require
9 with respect to the provision of services
10 and programs specified in paragraph (1),
11 including information and data necessary
12 to determine the performance measures for
13 the State under paragraph (6) and compli-
14 ance with paragraph (7).

15 “(C) REIMBURSEMENT FOR SERVICES
16 UNDER THE PREVENTION PLAN COMPONENT.—

17 “(i) LIMITATION.—Except as provided
18 in subclause (ii), a State may not receive
19 a Federal payment under this part for a
20 given promising, supported, or well-sup-
21 ported practice unless (in accordance with
22 subparagraph (B)(iii)(V)) the plan includes
23 a well-designed and rigorous evaluation
24 strategy for that practice.

1 “(ii) WAIVER OF LIMITATION.—The
2 Secretary may waive the requirement for a
3 well-designed and rigorous evaluation of
4 any well-supported practice if the Sec-
5 retary deems the evidence of the effective-
6 ness of the practice to be compelling and
7 the State meets the continuous quality im-
8 provement requirements included in sub-
9 paragraph (B)(iii)(II) with regard to the
10 practice.

11 “(6) PREVENTION SERVICES MEASURES.—

12 “(A) ESTABLISHMENT; ANNUAL UP-
13 DATES.—Beginning with fiscal year 2021, and
14 annually thereafter, the Secretary shall estab-
15 lish the following prevention services measures
16 based on information and data reported by
17 States that elect to provide services and pro-
18 grams specified in paragraph (1):

19 “(i) PERCENTAGE OF CANDIDATES
20 FOR FOSTER CARE WHO DO NOT ENTER
21 FOSTER CARE.—The percentage of can-
22 didates for foster care for whom, or on
23 whose behalf, the services or programs are
24 provided who do not enter foster care, in-
25 cluding those placed with a kin caregiver

1 outside of foster care, during the 12-month
2 period in which the services or programs
3 are provided and through the end of the
4 succeeding 12-month-period.

5 “(ii) PER-CHILD SPENDING.—The
6 total amount of expenditures made for
7 mental health and substance abuse preven-
8 tion and treatment services or in-home
9 parent skill-based programs, respectively,
10 for, or on behalf of, each child described in
11 paragraph (2).

12 “(B) DATA.—The Secretary shall establish
13 and annually update the prevention services
14 measures—

15 “(i) based on the median State values
16 of the information reported under each
17 clause of subparagraph (A) for the 3 then
18 most recent years; and

19 “(ii) taking into account State dif-
20 ferences in the price levels of consumption
21 goods and services using the most recent
22 regional price parities published by the Bu-
23 reau of Economic Analysis of the Depart-
24 ment of Commerce or such other data as
25 the Secretary determines appropriate.

1 “(C) PUBLICATION OF STATE PREVENTION
2 SERVICES MEASURES.—The Secretary shall an-
3 nually make available to the public the preven-
4 tion services measures of each State.

5 “(7) MAINTENANCE OF EFFORT FOR STATE
6 FOSTER CARE PREVENTION EXPENDITURES.—

7 “(A) IN GENERAL.—If a State elects to
8 provide services and programs specified in para-
9 graph (1) for a fiscal year, the State foster care
10 prevention expenditures for the fiscal year shall
11 not be less than the amount of the expenditures
12 for fiscal year 2014 (or, at the option of a State
13 described in subparagraph (E), fiscal year 2015
14 or fiscal year 2016 (whichever the State
15 elects)).

16 “(B) STATE FOSTER CARE PREVENTION
17 EXPENDITURES.—The term ‘State foster care
18 prevention expenditures’ means the following:

19 “(i) TANF; IV-B; SSBG.—State ex-
20 penditures for foster care prevention serv-
21 ices and activities under the State program
22 funded under part A (including from
23 amounts made available by the Federal
24 Government), under the State plan devel-
25 oped under part B (including any such

1 amounts), or under the Social Services
2 Block Grant Programs under subtitle A of
3 title XX (including any such amounts).

4 “(ii) OTHER STATE PROGRAMS.—
5 State expenditures for foster care preven-
6 tion services and activities under any State
7 program that is not described in clause (i)
8 (other than any State expenditures for fos-
9 ter care prevention services and activities
10 under the State program under this part
11 (including under a waiver of the pro-
12 gram)).

13 “(C) STATE EXPENDITURES.—The term
14 ‘State expenditures’ means all State or local
15 funds that are expended by the State or a local
16 agency including State or local funds that are
17 matched or reimbursed by the Federal Govern-
18 ment and State or local funds that are not
19 matched or reimbursed by the Federal Govern-
20 ment.

21 “(D) DETERMINATION OF PREVENTION
22 SERVICES AND ACTIVITIES.—The Secretary
23 shall require each State that elects to provide
24 services and programs specified in paragraph
25 (1) to report the expenditures specified in sub-

1 paragraph (B) for fiscal year 2014 and for such
2 fiscal years thereafter as are necessary to deter-
3 mine whether the State is complying with the
4 maintenance of effort requirement in subpara-
5 graph (A). The Secretary shall specify the spe-
6 cific services and activities under each program
7 referred to in subparagraph (B) that are ‘pre-
8 vention services and activities’ for purposes of
9 the reports.

10 “(E) STATE DESCRIBED.—For purposes of
11 subparagraph (A), a State is described in this
12 subparagraph if the population of children in
13 the State in 2014 was less than 200,000 (as de-
14 termined by the Bureau of the Census).

15 “(8) PROHIBITION AGAINST USE OF STATE FOS-
16 TER CARE PREVENTION EXPENDITURES AND FED-
17 ERAL IV–E PREVENTION FUNDS FOR MATCHING OR
18 EXPENDITURE REQUIREMENT.—A State that elects
19 to provide services and programs specified in para-
20 graph (1) shall not use any State foster care preven-
21 tion expenditures for a fiscal year for the State
22 share of expenditures under section 474(a)(6) for a
23 fiscal year.

24 “(9) ADMINISTRATIVE COSTS.—Expenditures
25 described in section 474(a)(6)(B)—

1 “(A) shall not be eligible for payment
2 under subparagraph (A), (B), or (E) of section
3 474(a)(3); and

4 “(B) shall be eligible for payment under
5 section 474(a)(6)(B) without regard to whether
6 the expenditures are incurred on behalf of a
7 child who is, or is potentially, eligible for foster
8 care maintenance payments under this part.

9 “(10) APPLICATION.—

10 “(A) IN GENERAL.—The provision of serv-
11 ices or programs under this subsection to or on
12 behalf of a child described in paragraph (2)
13 shall not be considered to be receipt of aid or
14 assistance under the State plan under this part
15 for purposes of eligibility for any other program
16 established under this Act.

17 “(B) CANDIDATES IN KINSHIP CARE.—A
18 child described in paragraph (2) for whom such
19 services or programs under this subsection are
20 provided for more than 6 months while in the
21 home of a kin caregiver, and who would satisfy
22 the AFDC eligibility requirement of section
23 472(a)(3)(A)(ii)(II) but for residing in the
24 home of the caregiver for more than 6 months,
25 is deemed to satisfy that requirement for pur-

1 poses of determining whether the child is eligi-
2 ble for foster care maintenance payments under
3 section 472.”.

4 (b) DEFINITION.—Section 475 of such Act (42
5 U.S.C. 675) is amended by adding at the end the fol-
6 lowing:

7 “(13) The term ‘child who is a candidate for
8 foster care’ means, a child who is identified in a pre-
9 vention plan under section 471(e)(4)(A) as being at
10 imminent risk of entering foster care (without re-
11 gard to whether the child would be eligible for foster
12 care maintenance payments under section 472 or is
13 or would be eligible for adoption assistance or kin-
14 ship guardianship assistance payments under section
15 473) but who can remain safely in the child’s home
16 or in a kinship placement as long as services or pro-
17 grams specified in section 471(e)(1) that are nec-
18 essary to prevent the entry of the child into foster
19 care are provided. The term includes a child whose
20 adoption or guardianship arrangement is at risk of
21 a disruption or dissolution that would result in a
22 foster care placement.”.

23 (c) PAYMENTS UNDER TITLE IV–E.—Section 474(a)
24 of such Act (42 U.S.C. 674(a)) is amended—

1 (1) in paragraph (5), by striking the period at
2 the end and inserting “; plus”; and

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

4 “(6) subject to section 471(e)—

5 “(A) for each quarter—

6 “(i) subject to clause (ii)—

7 “(I) beginning after September
8 30, 2019, and before October 1, 2025,
9 an amount equal to 50 percent of the
10 total amount expended during the
11 quarter for the provision of services or
12 programs specified in subparagraph
13 (A) or (B) of section 471(e)(1) that
14 are provided in accordance with prom-
15 ising, supported, or well-supported
16 practices that meet the applicable cri-
17 teria specified for the practices in sec-
18 tion 471(e)(4)(C); and

19 “(II) beginning after September
20 30, 2025, an amount equal to the
21 Federal medical assistance percentage
22 (which shall be as defined in section
23 1905(b), in the case of a State other
24 than the District of Columbia, or 70
25 percent, in the case of the District of

1 Columbia) of the total amount ex-
2 pended during the quarter for the pro-
3 vision of services or programs speci-
4 fied in subparagraph (A) or (B) of
5 section 471(e)(1) that are provided in
6 accordance with promising, supported,
7 or well-supported practices that meet
8 the applicable criteria specified for the
9 practices in section 471(e)(4)(C) (or,
10 with respect to the payments made
11 during the quarter under a coopera-
12 tive agreement or contract entered
13 into by the State and an Indian tribe,
14 tribal organization, or tribal consor-
15 tium for the administration or pay-
16 ment of funds under this part, an
17 amount equal to the Federal medical
18 assistance percentage that would
19 apply under section 479B(d) (in this
20 paragraph referred to as the ‘tribal
21 FMAP’) if the Indian tribe, tribal or-
22 ganization, or tribal consortium made
23 the payments under a program oper-
24 ated under that section, unless the
25 tribal FMAP is less than the Federal

1 medical assistance percentage that ap-
2 plies to the State); except that

3 “(ii) not less than 50 percent of the
4 total amount payable to a State under
5 clause (i) for a fiscal year shall be for the
6 provision of services or programs specified
7 in subparagraph (A) or (B) of section
8 471(e)(1) that are provided in accordance
9 with well-supported practices; plus

10 “(B) for each quarter specified in subpara-
11 graph (A), an amount equal to the sum of the
12 following proportions of the total amount ex-
13 pended during the quarter:

14 “(i) 50 percent of so much of the ex-
15 penditures as are found necessary by the
16 Secretary for the proper and efficient ad-
17 ministration of the State plan for the pro-
18 vision of services or programs specified in
19 section 471(e)(1), including expenditures
20 for activities approved by the Secretary
21 that promote the development of necessary
22 processes and procedures to establish and
23 implement the provision of the services and
24 programs for individuals who are eligible
25 for the services and programs and expendi-

1 tures attributable to data collection and re-
2 porting; and

3 “(ii) 50 percent of so much of the ex-
4 penditures with respect to the provision of
5 services and programs specified in section
6 471(e)(1) as are for training of personnel
7 employed or preparing for employment by
8 the State agency or by the local agency ad-
9 ministering the plan in the political sub-
10 division and of the members of the staff of
11 State-licensed or State-approved child wel-
12 fare agencies providing services to children
13 described in section 471(e)(2) and their
14 parents or kin caregivers, including on how
15 to determine who are individuals eligible
16 for the services or programs, how to iden-
17 tify and provide appropriate services and
18 programs, and how to oversee and evaluate
19 the ongoing appropriateness of the services
20 and programs.”.

21 (d) TECHNICAL ASSISTANCE AND BEST PRACTICES,
22 CLEARINGHOUSE, AND DATA COLLECTION AND EVALUA-
23 TIONS.—Section 476 of such Act (42 U.S.C. 676) is
24 amended by adding at the end the following:

1 “(d) TECHNICAL ASSISTANCE AND BEST PRACTICES,
2 CLEARINGHOUSE, DATA COLLECTION, AND EVALUATIONS
3 RELATING TO PREVENTION SERVICES AND PROGRAMS.—

4 “(1) TECHNICAL ASSISTANCE AND BEST PRACTICES.—The Secretary shall provide to States and,
5 as applicable, to Indian tribes, tribal organizations,
6 and tribal consortia, technical assistance regarding
7 the provision of services and programs described in
8 section 471(e)(1) and shall disseminate best prac-
9 tices with respect to the provision of the services and
10 programs, including how to plan and implement a
11 well-designed and rigorous evaluation of a prom-
12 ising, supported, or well-supported practice.

13 “(2) CLEARINGHOUSE OF PROMISING, SUP-
14 PORTED, AND WELL-SUPPORTED PRACTICES.—The
15 Secretary shall, directly or through grants, con-
16 tracts, or interagency agreements, evaluate research
17 on the practices specified in clauses (iii), (iv), and
18 (v), respectively, of section 471(e)(4)(C), and pro-
19 grams that meet the requirements described in sec-
20 tion 427(a)(1), including culturally specific, or
21 location- or population-based adaptations of the
22 practices, to identify and establish a public clearing-
23 house of the practices that satisfy each category de-
24 scribed by such clauses. In addition, the clearing-
25

1 house shall include information on the specific out-
2 comes associated with each practice, including
3 whether the practice has been shown to prevent child
4 abuse and neglect and reduce the likelihood of foster
5 care placement by supporting birth families and kin-
6 ship families and improving targeted supports for
7 pregnant and parenting youth and their children.

8 “(3) DATA COLLECTION AND EVALUATIONS.—
9 The Secretary, directly or through grants, contracts,
10 or interagency agreements, may collect data and
11 conduct evaluations with respect to the provision of
12 services and programs described in section 471(e)(1)
13 for purposes of assessing the extent to which the
14 provision of the services and programs—

15 “(A) reduces the likelihood of foster care
16 placement;

17 “(B) increases use of kinship care arrange-
18 ments; or

19 “(C) improves child well-being.

20 “(4) REPORTS TO CONGRESS.—

21 “(A) IN GENERAL.—The Secretary shall
22 submit to the Committee on Finance of the
23 Senate and the Committee on Ways and Means
24 of the House of Representatives periodic reports
25 based on the provision of services and programs

1 described in section 471(e)(1) and the activities
2 carried out under this subsection.

3 “(B) PUBLIC AVAILABILITY.—The Sec-
4 retary shall make the reports to Congress sub-
5 mitted under this paragraph publicly available.

6 “(5) APPROPRIATION.—Out of any money in
7 the Treasury of the United States not otherwise ap-
8 propriated, there is appropriated to the Secretary
9 \$1,000,000 for fiscal year 2017 and each fiscal year
10 thereafter to carry out this subsection.”.

11 (e) APPLICATION TO PROGRAMS OPERATED BY IN-
12 DIAN TRIBAL ORGANIZATIONS.—

13 (1) IN GENERAL.—Section 479B of such Act
14 (42 U.S.C. 679e) is amended—

15 (A) in subsection (c)(1)—

16 (i) in subparagraph (C)(i)—

17 (I) in subclause (II), by striking
18 “and” after the semicolon;

19 (II) in subclause (III), by strik-
20 ing the period at the end and insert-
21 ing “; and”; and

22 (III) by adding at the end the
23 following:

24 “(IV) at the option of the tribe,
25 organization, or consortium, services

1 and programs specified in section
2 471(e)(1) to children described in sec-
3 tion 471(e)(2) and their parents or
4 kin caregivers, in accordance with sec-
5 tion 471(e) and subparagraph (E).”;
6 and

7 (ii) by adding at the end the fol-
8 lowing:

9 “(E) PREVENTION SERVICES AND PRO-
10 GRAMS FOR CHILDREN AND THEIR PARENTS
11 AND KIN CAREGIVERS.—

12 “(i) IN GENERAL.—In the case of a
13 tribe, organization, or consortium that
14 elects to provide services and programs
15 specified in section 471(e)(1) to children
16 described in section 471(e)(2) and their
17 parents or kin caregivers under the plan,
18 the Secretary shall specify the require-
19 ments applicable to the provision of the
20 services and programs. The requirements
21 shall, to the greatest extent practicable, be
22 consistent with the requirements applicable
23 to States under section 471(e) and shall
24 permit the provision of the services and
25 programs in the form of services and pro-

1 grams that are adapted to the culture and
2 context of the tribal communities served.

3 “(ii) PERFORMANCE MEASURES.—The
4 Secretary shall establish specific perform-
5 ance measures for each tribe, organization,
6 or consortium that elects to provide serv-
7 ices and programs specified in section
8 471(e)(1). The performance measures
9 shall, to the greatest extent practicable, be
10 consistent with the prevention services
11 measures required for States under section
12 471(e)(6) but shall allow for consideration
13 of factors unique to the provision of the
14 services by tribes, organizations, or con-
15 sortia.”; and

16 (B) in subsection (d)(1), by striking “and
17 (5)” and inserting “(5), and (6)(A)”.

18 (2) CONFORMING AMENDMENT.—The heading
19 for subsection (d) of section 479B of such Act (42
20 U.S.C. 679c) is amended by striking “FOR FOSTER
21 CARE MAINTENANCE AND ADOPTION ASSISTANCE
22 PAYMENTS”.

23 (f) APPLICATION TO PROGRAMS OPERATED BY TER-
24 RITORIES.—Section 1108(a)(2) of the Social Security Act

1 (42 U.S.C. 1308(a)(2)) is amended by striking “or
2 413(f)” and inserting “413(f), or 474(a)(6)”.

3 **SEC. 19012. FOSTER CARE MAINTENANCE PAYMENTS FOR**
4 **CHILDREN WITH PARENTS IN A LICENSED**
5 **RESIDENTIAL FAMILY-BASED TREATMENT**
6 **FACILITY FOR SUBSTANCE ABUSE.**

7 (a) IN GENERAL.—Section 472 of the Social Security
8 Act (42 U.S.C. 672) is amended—

9 (1) in subsection (a)(2)(C), by striking “or”
10 and inserting “, with a parent residing in a licensed
11 residential family-based treatment facility, but only
12 to the extent permitted under subsection (j), or in
13 a”; and

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

15 “(j) CHILDREN PLACED WITH A PARENT RESIDING
16 IN A LICENSED RESIDENTIAL FAMILY-BASED TREAT-
17 MENT FACILITY FOR SUBSTANCE ABUSE.—

18 “(1) IN GENERAL.—Notwithstanding the pre-
19 ceding provisions of this section, a child who is eligi-
20 ble for foster care maintenance payments under this
21 section, or who would be eligible for the payments if
22 the eligibility were determined without regard to
23 paragraphs (1)(B) and (3) of subsection (a), shall be
24 eligible for the payments for a period of not more
25 than 12 months during which the child is placed

1 with a parent who is in a licensed residential family-
2 based treatment facility for substance abuse, but
3 only if—

4 “(A) the recommendation for the place-
5 ment is specified in the child’s case plan before
6 the placement;

7 “(B) the treatment facility provides, as
8 part of the treatment for substance abuse, par-
9 enting skills training, parent education, and in-
10 dividual and family counseling; and

11 “(C) the substance abuse treatment, par-
12 enting skills training, parent education, and in-
13 dividual and family counseling is provided
14 under an organizational structure and treat-
15 ment framework that involves understanding,
16 recognizing, and responding to the effects of all
17 types of trauma and in accordance with recog-
18 nized principles of a trauma-informed approach
19 and trauma-specific interventions to address the
20 consequences of trauma and facilitate healing.

21 “(2) APPLICATION.—With respect to children
22 for whom foster care maintenance payments are
23 made under paragraph (1), only the children who
24 satisfy the requirements of paragraphs (1)(B) and
25 (3) of subsection (a) shall be considered to be chil-

1 children who are, or are potentially, eligible for fos-
2 ter care maintenance payments under this part.”.

3 **Subtitle B—Enhanced Support**
4 **Under Title IV-B**

5 **SEC. 19021. ELIMINATION OF TIME LIMIT FOR FAMILY RE-**
6 **UNIFICATION SERVICES WHILE IN FOSTER**
7 **CARE AND PERMITTING TIME-LIMITED FAM-**
8 **ILY REUNIFICATION SERVICES WHEN A**
9 **CHILD RETURNS HOME FROM FOSTER CARE.**

10 (a) IN GENERAL.—Section 431(a)(7) of the Social
11 Security Act (42 U.S.C. 629a(a)(7)) is amended—

12 (1) in the paragraph heading, by striking
13 “TIME-LIMITED FAMILY” and inserting “FAMILY”;
14 and

15 (2) in subparagraph (A)—

16 (A) by striking “time-limited family” and
17 inserting “family”;

18 (B) by inserting “or a child who has been
19 returned home” after “child care institution”;
20 and

21 (C) by striking “, but only during the 15-
22 month period that begins on the date that the
23 child, pursuant to section 475(5)(F), is consid-
24 ered to have entered foster care” and inserting
25 “and to ensure the strength and stability of the

1 reunification. In the case of a child who has
2 been returned home, the services and activities
3 shall only be provided during the 15-month pe-
4 riod that begins on the date that the child re-
5 turns home”.

6 (b) CONFORMING AMENDMENTS.—

7 (1) Section 430 of such Act (42 U.S.C. 629) is
8 amended in the matter preceding paragraph (1), by
9 striking “time-limited”.

10 (2) Subsections (a)(4), (a)(5)(A), and (b)(1) of
11 section 432 of such Act (42 U.S.C. 629b) are
12 amended by striking “time-limited” each place it ap-
13 pears.

14 **SEC. 19022. REDUCING BUREAUCRACY AND UNNECESSARY**
15 **DELAYS WHEN PLACING CHILDREN IN**
16 **HOMES ACROSS STATE LINES.**

17 (a) STATE PLAN REQUIREMENT.—Section
18 471(a)(25) of the Social Security Act (42 U.S.C.
19 671(a)(25)) is amended—

20 (1) by striking “provide” and insert “provides”;
21 and

22 (2) by inserting “, which, not later than Octo-
23 ber 1, 2026, shall include the use of an electronic
24 interstate case-processing system” before the first
25 semicolon.

1 (b) GRANTS FOR THE DEVELOPMENT OF AN ELEC-
2 TRONIC INTERSTATE CASE-PROCESSING SYSTEM TO EX-
3 PEDITE THE INTERSTATE PLACEMENT OF CHILDREN IN
4 FOSTER CARE OR GUARDIANSHIP, OR FOR ADOPTION.—
5 Section 437 of such Act (42 U.S.C. 629g) is amended by
6 adding at the end the following:

7 “(g) GRANTS FOR THE DEVELOPMENT OF AN ELEC-
8 TRONIC INTERSTATE CASE-PROCESSING SYSTEM TO EX-
9 PEDITE THE INTERSTATE PLACEMENT OF CHILDREN IN
10 FOSTER CARE OR GUARDIANSHIP, OR FOR ADOPTION.—

11 “(1) PURPOSE.—The purpose of this subsection
12 is to facilitate the development of an electronic inter-
13 state case-processing system for the exchange of
14 data and documents to expedite the placements of
15 children in foster, guardianship, or adoptive homes
16 across State lines.

17 “(2) APPLICATION REQUIREMENTS.—A State
18 that desires a grant under this subsection shall sub-
19 mit to the Secretary an application containing the
20 following:

21 “(A) A description of the goals and out-
22 comes to be achieved during the period for
23 which grant funds are sought, which goals and
24 outcomes must result in—

1 “(i) reducing the time it takes for a
2 child to be provided with a safe and appro-
3 priate permanent living arrangement
4 across State lines;

5 “(ii) improving administrative proc-
6 esses and reducing costs in the foster care
7 system; and

8 “(iii) the secure exchange of relevant
9 case files and other necessary materials in
10 real time, and timely communications and
11 placement decisions regarding interstate
12 placements of children.

13 “(B) A description of the activities to be
14 funded in whole or in part with the grant
15 funds, including the sequencing of the activities.

16 “(C) A description of the strategies for in-
17 tegrating programs and services for children
18 who are placed across State lines.

19 “(D) Such other information as the Sec-
20 retary may require.

21 “(3) GRANT AUTHORITY.—The Secretary may
22 make a grant to a State that complies with para-
23 graph (2).

24 “(4) USE OF FUNDS.—A State to which a grant
25 is made under this subsection shall use the grant to

1 support the State in connecting with the electronic
2 interstate case-processing system described in para-
3 graph (1).

4 “(5) EVALUATIONS.—Not later than 1 year
5 after the final year in which grants are awarded
6 under this subsection, the Secretary shall submit to
7 the Congress, and make available to the general
8 public by posting on a website, a report that con-
9 tains the following information:

10 “(A) How using the electronic interstate
11 case-processing system developed pursuant to
12 paragraph (4) has changed the time it takes for
13 children to be placed across State lines.

14 “(B) The number of cases subject to the
15 Interstate Compact on the Placement of Chil-
16 dren that were processed through the electronic
17 interstate case-processing system, and the num-
18 ber of interstate child placement cases that
19 were processed outside the electronic interstate
20 case-processing system, by each State in each
21 year.

22 “(C) The progress made by States in im-
23 plementing the electronic interstate case-proc-
24 essing system.

1 “(D) How using the electronic interstate
2 case-processing system has affected various
3 metrics related to child safety and well-being,
4 including the time it takes for children to be
5 placed across State lines.

6 “(E) How using the electronic interstate
7 case-processing system has affected administra-
8 tive costs and caseworker time spent on placing
9 children across State lines.

10 “(6) DATA INTEGRATION.—The Secretary, in
11 consultation with the Secretariat for the Interstate
12 Compact on the Placement of Children and the
13 States, shall assess how the electronic interstate
14 case-processing system developed pursuant to para-
15 graph (4) could be used to better serve and protect
16 children that come to the attention of the child wel-
17 fare system, by—

18 “(A) connecting the system with other
19 data systems (such as systems operated by
20 State law enforcement and judicial agencies,
21 systems operated by the Federal Bureau of In-
22 vestigation for the purposes of the Innocence
23 Lost National Initiative, and other systems);

24 “(B) simplifying and improving reporting
25 related to paragraphs (34) and (35) of section

1 471(a) regarding children or youth who have
2 been identified as being a sex trafficking victim
3 or children missing from foster care; and

4 “(C) improving the ability of States to
5 quickly comply with background check require-
6 ments of section 471(a)(20), including checks of
7 child abuse and neglect registries as required by
8 section 471(a)(20)(B).”.

9 (c) RESERVATION OF FUNDS TO IMPROVE THE
10 INTERSTATE PLACEMENT OF CHILDREN.—Section 437(b)
11 of such Act (42 U.S.C. 629g(b)) is amended by adding
12 at the end the following:

13 “(4) IMPROVING THE INTERSTATE PLACEMENT
14 OF CHILDREN.—The Secretary shall reserve
15 \$5,000,000 of the amount made available for fiscal
16 year 2017 for grants under subsection (g), and the
17 amount so reserved shall remain available through
18 fiscal year 2021.”.

19 **SEC. 19023. ENHANCEMENTS TO GRANTS TO IMPROVE**
20 **WELL-BEING OF FAMILIES AFFECTED BY**
21 **SUBSTANCE ABUSE.**

22 Section 437(f) of the Social Security Act (42 U.S.C.
23 629g(f)) is amended—

24 (1) in the subsection heading, by striking “IN-
25 CREASE THE WELL-BEING OF, AND TO IMPROVE

1 THE PERMANENCY OUTCOMES FOR, CHILDREN AF-
2 FECTED BY” and inserting “IMPLEMENT IV–E PRE-
3 VENTION SERVICES, AND IMPROVE THE WELL-
4 BEING OF, AND IMPROVE PERMANENCY OUTCOMES
5 FOR, CHILDREN AND FAMILIES AFFECTED BY HER-
6 OIN, OPIOIDS, AND OTHER”;

7 (2) by striking paragraph (2) and inserting the
8 following:

9 “(2) REGIONAL PARTNERSHIP DEFINED.—In
10 this subsection, the term ‘regional partnership’
11 means a collaborative agreement (which may be es-
12 tablished on an interstate, State, or intrastate basis)
13 entered into by the following:

14 “(A) MANDATORY PARTNERS FOR ALL
15 PARTNERSHIP GRANTS.—

16 “(i) The State child welfare agency
17 that is responsible for the administration
18 of the State plan under this part and part
19 E.

20 “(ii) The State agency responsible for
21 administering the substance abuse preven-
22 tion and treatment block grant provided
23 under subpart II of part B of title XIX of
24 the Public Health Service Act.

1 “(B) MANDATORY PARTNERS FOR PART-
2 NERSHIP GRANTS PROPOSING TO SERVE CHIL-
3 DREN IN OUT-OF-HOME PLACEMENTS.—If the
4 partnership proposes to serve children in out-of-
5 home placements, the Juvenile Court or Admin-
6 istrative Office of the Court that is most appro-
7 priate to oversee the administration of court
8 programs in the region to address the popu-
9 lation of families who come to the attention of
10 the court due to child abuse or neglect.

11 “(C) OPTIONAL PARTNERS.—At the option
12 of the partnership, any of the following:

13 “(i) An Indian tribe or tribal consor-
14 tium.

15 “(ii) Nonprofit child welfare service
16 providers.

17 “(iii) For-profit child welfare service
18 providers.

19 “(iv) Community health service pro-
20 viders, including substance abuse treat-
21 ment providers.

22 “(v) Community mental health pro-
23 viders.

24 “(vi) Local law enforcement agencies.

25 “(vii) School personnel.

1 “(viii) Tribal child welfare agencies
2 (or a consortia of the agencies).

3 “(ix) Any other providers, agencies,
4 personnel, officials, or entities that are re-
5 lated to the provision of child and family
6 services under a State plan approved under
7 this subpart.

8 “(D) EXCEPTION FOR REGIONAL PART-
9 NERSHIPS WHERE THE LEAD APPLICANT IS AN
10 INDIAN TRIBE OR TRIBAL CONSORTIA.—If an
11 Indian tribe or tribal consortium enters into a
12 regional partnership for purposes of this sub-
13 section, the Indian tribe or tribal consortium—

14 “(i) may (but is not required to) in-
15 clude the State child welfare agency as a
16 partner in the collaborative agreement;

17 “(ii) may not enter into a collabo-
18 rative agreement only with tribal child wel-
19 fare agencies (or a consortium of the agen-
20 cies); and

21 “(iii) if the condition described in
22 paragraph (2)(B) applies, may include
23 tribal court organizations in lieu of other
24 judicial partners.”;

25 (3) in paragraph (3)—

1 (A) in subparagraph (A)—

2 (i) by striking “2012 through 2016”
3 and inserting “2017 through 2021”; and

4 (ii) by striking “\$500,000 and not
5 more than \$1,000,000” and inserting
6 “\$250,000 and not more than
7 \$1,000,000”;

8 (B) in subparagraph (B)—

9 (i) in the subparagraph heading, by
10 inserting “; PLANNING” after “APPROVAL”;

11 (ii) in clause (i), by striking “clause
12 (ii)” and inserting “clauses (ii) and (iii)”;
13 and

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

16 “(iii) SUFFICIENT PLANNING.—A
17 grant awarded under this subsection shall
18 be disbursed in two phases: a planning
19 phase (not to exceed 2 years); and an im-
20 plementation phase. The total disburse-
21 ment to a grantee for the planning phase
22 may not exceed \$250,000, and may not ex-
23 ceed the total anticipated funding for the
24 implementation phase.”; and

25 (C) by adding at the end the following:

1 “(D) LIMITATION ON PAYMENT FOR A FIS-
2 CAL YEAR.—No payment shall be made under
3 subparagraph (A) or (C) for a fiscal year until
4 the Secretary determines that the eligible part-
5 nership has made sufficient progress in meeting
6 the goals of the grant and that the members of
7 the eligible partnership are coordinating to a
8 reasonable degree with the other members of
9 the eligible partnership.”;

10 (4) in paragraph (4)—

11 (A) in subparagraph (B)—

12 (i) in clause (i), by inserting “, par-
13 ents, and families” after “children”;

14 (ii) in clause (ii), by striking “safety
15 and permanence for such children; and”
16 and inserting “safe, permanent caregiving
17 relationships for the children;”;

18 (iii) in clause (iii), by striking “or”
19 and inserting “increase reunification rates
20 for children who have been placed in out of
21 home care, or decrease”; and

22 (iv) by redesignating clause (iii) as
23 clause (v) and inserting after clause (ii)
24 the following:

1 “(iii) improve the substance abuse
2 treatment outcomes for parents including
3 retention in treatment and successful com-
4 pletion of treatment;

5 “(iv) facilitate the implementation, de-
6 livery, and effectiveness of prevention serv-
7 ices and programs under section 471(e);
8 and”;

9 (B) in subparagraph (D), by striking
10 “where appropriate,”; and

11 (C) by striking subparagraphs (E) and (F)
12 and inserting the following:

13 “(E) A description of a plan for sustaining
14 the services provided by or activities funded
15 under the grant after the conclusion of the
16 grant period, including through the use of pre-
17 vention services and programs under section
18 471(e) and other funds provided to the State
19 for child welfare and substance abuse preven-
20 tion and treatment services.

21 “(F) Additional information needed by the
22 Secretary to determine that the proposed activi-
23 ties and implementation will be consistent with
24 research or evaluations showing which practices
25 and approaches are most effective.”;

1 (5) in paragraph (5)(A), by striking “abuse
2 treatment” and inserting “use disorder treatment in-
3 cluding medication assisted treatment and in-home
4 substance abuse disorder treatment and recovery”;

5 (6) in paragraph (7)—

6 (A) by striking “and” at the end of sub-
7 paragraph (C); and

8 (B) by redesignating subparagraph (D) as
9 subparagraph (E) and inserting after subpara-
10 graph (C) the following:

11 “(D) demonstrate a track record of suc-
12 cessful collaboration among child welfare, sub-
13 stance abuse disorder treatment and mental
14 health agencies; and”;

15 (7) in paragraph (8)—

16 (A) in subparagraph (A)—

17 (i) by striking “establish indicators
18 that will be” and inserting “review indica-
19 tors that are”; and

20 (ii) by striking “in using funds made
21 available under such grants to achieve the
22 purpose of this subsection” and inserting
23 “and establish a set of core indicators re-
24 lated to child safety, parental recovery,
25 parenting capacity, and family well-being.

1 In developing the core indicators, to the
2 extent possible, indicators shall be made
3 consistent with the outcome measures de-
4 scribed in section 471(e)(6)”; and

5 (B) in subparagraph (B)—

6 (i) in the matter preceding clause (i),
7 by inserting “base the performance meas-
8 ures on lessons learned from prior rounds
9 of regional partnership grants under this
10 subsection, and” before “consult”; and

11 (ii) by striking clauses (iii) and (iv)
12 and inserting the following:

13 “(iii) Other stakeholders or constitu-
14 encies as determined by the Secretary.”;

15 (8) in paragraph (9)(A), by striking clause (i)
16 and inserting the following:

17 “(i) SEMIANNUAL REPORTS.—Not
18 later than September 30 of each fiscal year
19 in which a recipient of a grant under this
20 subsection is paid funds under the grant,
21 and every 6 months thereafter, the grant
22 recipient shall submit to the Secretary a
23 report on the services provided and activi-
24 ties carried out during the reporting pe-
25 riod, progress made in achieving the goals

1 of the program, the number of children,
2 adults, and families receiving services, and
3 such additional information as the Sec-
4 retary determines is necessary. The report
5 due not later than September 30 of the
6 last such fiscal year shall include, at a
7 minimum, data on each of the performance
8 indicators included in the evaluation of the
9 regional partnership.”; and

10 (9) in paragraph (10), by striking “2012
11 through 2016” and inserting “2017 through 2021”.

12 **Subtitle C—Miscellaneous**

13 **SEC. 19031. REVIEWING AND IMPROVING LICENSING** 14 **STANDARDS FOR PLACEMENT IN A RELATIVE** 15 **FOSTER FAMILY HOME.**

16 (a) IDENTIFICATION OF REPUTABLE MODEL LI-
17 CENSING STANDARDS.—Not later than October 1, 2017,
18 the Secretary of Health and Human Services shall identify
19 reputable model licensing standards with respect to the li-
20 censing of foster family homes (as defined in section
21 472(c)(1) of the Social Security Act).

22 (b) STATE PLAN REQUIREMENT.—Section 471(a) of
23 the Social Security Act (42 U.S.C. 671(a)) is amended—

24 (1) in paragraph (34)(B), by striking “and”
25 after the semicolon;

1 (2) in paragraph (35)(B), by striking the period
2 at the end and inserting a semicolon; and

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

4 “(36) provides that, not later than April 1,
5 2018, the State shall submit to the Secretary infor-
6 mation addressing—

7 “(A) whether the State licensing standards
8 are in accord with model standards identified
9 by the Secretary, and if not, the reason for the
10 specific deviation and a description as to why
11 having a standard that is reasonably in accord
12 with the corresponding national model stand-
13 ards is not appropriate for the State;

14 “(B) whether the State has elected to
15 waive standards established in 471(a)(10)(A)
16 for relative foster family homes (pursuant to
17 waiver authority provided by 471(a)(10)(D)), a
18 description of which standards the State most
19 commonly waives, and if the State has not
20 elected to waive the standards, the reason for
21 not waiving these standards;

22 “(C) if the State has elected to waive
23 standards specified in subparagraph (B), how
24 caseworkers are trained to use the waiver au-
25 thority and whether the State has developed a

1 process or provided tools to assist caseworkers
2 in waiving nonsafety standards per the author-
3 ity provided in 471(a)(10)(D) to quickly place
4 children with relatives; and

5 “(D) a description of the steps the State is
6 taking to improve caseworker training or the
7 process, if any; and”.

8 **SEC. 19032. DEVELOPMENT OF A STATEWIDE PLAN TO PRE-**
9 **VENT CHILD ABUSE AND NEGLECT FATALI-**
10 **TIES.**

11 Section 422(b)(19) of the Social Security Act (42
12 U.S.C. 622(b)(19)) is amended to read as follows:

13 “(19) document steps taken to track and pre-
14 vent child maltreatment deaths by including—

15 “(A) a description of the steps the State is
16 taking to compile complete and accurate infor-
17 mation on the deaths required by Federal law
18 to be reported by the State agency referred to
19 in paragraph (1), including gathering relevant
20 information on the deaths from the relevant or-
21 ganizations in the State including entities such
22 as State vital statistics department, child death
23 review teams, law enforcement agencies, offices
24 of medical examiners or coroners; and

1 “(B) a description of the steps the state is
2 taking to develop and implement of a com-
3 prehensive, statewide plan to prevent the fatali-
4 ties that involves and engages relevant public
5 and private agency partners, including those in
6 public health, law enforcement, and the
7 courts.”.

8 **SEC. 19033. MODERNIZING THE TITLE AND PURPOSE OF**
9 **TITLE IV-E.**

10 (a) PART HEADING.—The heading for part E of title
11 IV of the Social Security Act (42 U.S.C. 670 et seq.) is
12 amended to read as follows:

13 **“PART E—FEDERAL PAYMENTS FOR FOSTER**
14 **CARE, PREVENTION, AND PERMANENCY”.**

15 (b) PURPOSE.—The first sentence of section 470 of
16 such Act (42 U.S.C. 670) is amended—

17 (1) by striking “1995) and” and inserting
18 “1995),”;

19 (2) by inserting “kinship guardianship assist-
20 ance, and prevention services or programs specified
21 in section 471(e)(1),” after “needs,”; and

22 (3) by striking “(commencing with the fiscal
23 year which begins October 1, 1980)”.

24 **SEC. 19034. EFFECTIVE DATES.**

25 (a) EFFECTIVE DATES.—

1 (1) IN GENERAL.—Except as provided in para-
2 graph (2), subject to subsection (b), the amend-
3 ments made by this title shall take effect on January
4 1, 2017.

5 (2) EXCEPTIONS.—The amendments made by
6 sections 19031 and 19033 shall take effect on the
7 date of enactment of this Act.

8 (b) TRANSITION RULE.—

9 (1) IN GENERAL.—In the case of a State plan
10 under part B or E of title IV of the Social Security
11 Act which the Secretary of Health and Human Serv-
12 ices determines requires State legislation (other than
13 legislation appropriating funds) in order for the plan
14 to meet the additional requirements imposed by the
15 amendments made by this title, the State plan shall
16 not be regarded as failing to comply with the re-
17 quirements of such part solely on the basis of the
18 failure of the plan to meet such additional require-
19 ments before the first day of the first calendar quar-
20 ter beginning after the close of the first regular ses-
21 sion of the State legislature that begins after the
22 date of enactment of this Act. For purposes of the
23 previous sentence, in the case of a State that has a
24 2-year legislative session, each year of the session

1 shall be deemed to be a separate regular session of
2 the State legislature.

3 (2) APPLICATION TO PROGRAMS OPERATED BY
4 INDIAN TRIBAL ORGANIZATIONS.—In the case of an
5 Indian tribe, tribal organization, or tribal consortium
6 which the Secretary of Health and Human Services
7 determines requires time to take action necessary to
8 comply with the additional requirements imposed by
9 the amendments made by this title (whether the
10 tribe, organization, or tribal consortium has a plan
11 under section 479B of the Social Security Act or a
12 cooperative agreement or contract entered into with
13 a State), the Secretary shall provide the tribe, orga-
14 nization, or tribal consortium with such additional
15 time as the Secretary determines is necessary for the
16 tribe, organization, or tribal consortium to take the
17 action to comply with the additional requirements
18 before being regarded as failing to comply with the
19 requirements.

1 **TITLE XX—ENSURING THE NE-**
2 **CESSITY OF A PLACEMENT**
3 **THAT IS NOT IN A FOSTER**
4 **FAMILY HOME**

5 **SEC. 20001. LIMITATION ON FEDERAL FINANCIAL PARTICI-**
6 **PATION FOR PLACEMENTS THAT ARE NOT IN**
7 **FOSTER FAMILY HOMES.**

8 (a) LIMITATION ON FEDERAL FINANCIAL PARTICIPA-
9 TION.—

10 (1) IN GENERAL.—Section 472 of the Social
11 Security Act (42 U.S.C. 672), as amended by sec-
12 tion 19012, is amended—

13 (A) in subsection (a)(2)(C), by inserting “,
14 but only to the extent permitted under sub-
15 section (k)” after “institution”; and

16 (B) by adding at the end the following:

17 “(k) LIMITATION ON FEDERAL FINANCIAL PARTICI-
18 PATION.—

19 “(1) IN GENERAL.—Beginning with the third
20 week for which foster care maintenance payments
21 are made under this section on behalf of a child
22 placed in a child-care institution, no Federal pay-
23 ment shall be made to the State under section
24 474(a)(1) for amounts expended for foster care

1 maintenance payments on behalf of the child un-
2 less—

3 “(A) the child is placed in a child-care in-
4 stitution that is a setting specified in paragraph
5 (2) (or is placed in a licensed residential family-
6 based treatment facility consistent with sub-
7 section (j)); and

8 “(B) in the case of a child placed in a
9 qualified residential treatment program (as de-
10 fined in paragraph (4)), the requirements speci-
11 fied in paragraph (3) and section 475A(c) are
12 met.

13 “(2) SPECIFIED SETTINGS FOR PLACEMENT.—
14 The settings for placement specified in this para-
15 graph are the following:

16 “(A) A qualified residential treatment pro-
17 gram (as defined in paragraph (4)).

18 “(B) A setting specializing in providing
19 prenatal, post-partum, or parenting supports
20 for youth.

21 “(C) In the case of a child who has at-
22 tained 18 years of age, a supervised setting in
23 which the child is living independently.

24 “(D) A setting providing high-quality resi-
25 dential care and supportive services to children

1 and youth who have been found to be, or are
2 at risk of becoming, sex trafficking victims, in
3 accordance with section 471(a)(9)(C).

4 “(3) ASSESSMENT TO DETERMINE APPRO-
5 PRIATENESS OF PLACEMENT IN A QUALIFIED RESI-
6 DENTIAL TREATMENT PROGRAM.—

7 “(A) DEADLINE FOR ASSESSMENT.—In
8 the case of a child who is placed in a qualified
9 residential treatment program, if the assess-
10 ment required under section 475A(c)(1) is not
11 completed within 30 days after the placement is
12 made, no Federal payment shall be made to the
13 State under section 474(a)(1) for any amounts
14 expended for foster care maintenance payments
15 on behalf of the child during the placement.

16 “(B) DEADLINE FOR TRANSITION OUT OF
17 PLACEMENT.—If the assessment required under
18 section 475A(c)(1) determines that the place-
19 ment of a child in a qualified residential treat-
20 ment program is not appropriate, a court dis-
21 approves such a placement under section
22 475A(c)(2), or a child who has been in an ap-
23 proved placement in a qualified residential
24 treatment program is going to return home or
25 be placed with a fit and willing relative, a legal

1 guardian, or an adoptive parent, or in a foster
2 family home, Federal payments shall be made
3 to the State under section 474(a)(1) for
4 amounts expended for foster care maintenance
5 payments on behalf of the child while the child
6 remains in the qualified residential treatment
7 program only during the period necessary for
8 the child to transition home or to such a place-
9 ment. In no event shall a State receive Federal
10 payments under section 474(a)(1) for amounts
11 expended for foster care maintenance payments
12 on behalf of a child who remains placed in a
13 qualified residential treatment program after
14 the end of the 30-day period that begins on the
15 date a determination is made that the place-
16 ment is no longer the recommended or approved
17 placement for the child.

18 “(4) QUALIFIED RESIDENTIAL TREATMENT
19 PROGRAM.—For purposes of this part, the term
20 ‘qualified residential treatment program’ means a
21 program that—

22 “(A) has a trauma-informed treatment
23 model that is designed to address the needs, in-
24 cluding clinical needs as appropriate, of chil-
25 dren with serious emotional or behavioral dis-

1 orders or disturbances and, with respect to a
2 child, is able to implement the treatment identi-
3 fied for the child by the assessment of the child
4 required under section 475A(c);

5 “(B) subject to paragraph (5), has reg-
6 istered or licensed nursing staff and other li-
7 censed clinical staff who—

8 “(i) provide care within the scope of
9 their practice as defined by State law;

10 “(ii) are on-site during business
11 hours; and

12 “(iii) are available 24 hours a day and
13 7 days a week;

14 “(C) to extent appropriate, and in accord-
15 ance with the child’s best interests, facilitates
16 participation of family members in the child’s
17 treatment program;

18 “(D) facilitates outreach to the family
19 members of the child, including siblings, docu-
20 ments how the outreach is made (including con-
21 tact information), and maintains contact infor-
22 mation for any known biological family and fic-
23 tive kin of the child;

24 “(E) documents how family members are
25 integrated into the treatment process for the

1 child, including post-discharge, and how sibling
2 connections are maintained;

3 “(F) provides discharge planning and fam-
4 ily-based aftercare support for at least 6
5 months post-discharge; and

6 “(G) is licensed in accordance with section
7 471(a)(10) and is accredited by any of the fol-
8 lowing independent, not-for-profit organizations:

9 “(i) The Commission on Accreditation
10 of Rehabilitation Facilities (CARF).

11 “(ii) The Joint Commission on Ac-
12 creditation of Healthcare Organizations
13 (JCAHO).

14 “(iii) The Council on Accreditation
15 (COA).

16 “(iv) Any other independent, not-for-
17 profit accrediting organization approved by
18 the Secretary.

19 “(5) FLEXIBILITY IN STAFFING REQUIREMENTS
20 FOR QUALIFIED RESIDENTIAL TREATMENT PRO-
21 GRAMS.—

22 “(A) IN GENERAL.—In the case of any
23 State that the Secretary determines is described
24 in subparagraph (B) and satisfies the require-
25 ments of subparagraphs (C) and (D), respec-

1 tively, the State may elect to satisfy the re-
2 quirement of paragraph (4)(B) that a qualified
3 residential treatment program have registered
4 or licensed nursing staff and other licensed clin-
5 ical staff with clinical staff which include staff
6 licensed to monitor medications and physical
7 and behavioral health staff with demonstrated
8 training in child development and trauma, in
9 lieu of with registered or licensed nursing staff
10 and other licensed clinical staff.

11 “(B) STATE DESCRIBED.—Subject to sub-
12 paragraph (E), a State is described in this sub-
13 paragraph if for the most recent fiscal year for
14 which data are available—

15 “(i) the percentage of children in fos-
16 ter care under the responsibility of the
17 State who have been placed in congregate
18 care settings—

19 “(I) is at or below 5 percent for
20 the fiscal year; or

21 “(II) has been reduced by at
22 least 20 percent from the preceding
23 fiscal year; and

24 “(ii) the average length of stay for
25 children in foster care under the responsi-

1 bility of the State in congregate care set-
2 tings is at or below 9 months.

3 “(C) DEMONSTRATION OF CAPACITY AND
4 NEED.—A State described in subparagraph (B)
5 shall be eligible to use the alternative staffing
6 model permitted under subparagraph (A) if the
7 State can demonstrate to the satisfaction of the
8 Secretary that the qualified residential treat-
9 ment programs utilizing the alternative staffing
10 models permitted under subparagraph (A) have
11 the capacity to serve children and youth whose
12 treatment plans—

13 “(i) indicate a need for increased su-
14 pervision based on behavioral history, his-
15 tory of juvenile delinquency, or history of
16 sexual offenses; and

17 “(ii) require a placement that con-
18 forms to the alternative staffing model per-
19 mitted under subparagraph (A).

20 “(D) EQUITABLE DISTRIBUTION OF CON-
21 GREGATE CARE POPULATION.—A State de-
22 scribed in subparagraph (B) shall be eligible to
23 use the alternative staffing model permitted
24 under subparagraph (A) if the State annually
25 demonstrates to the satisfaction of the Sec-

1 retary that the State is reducing the number of
2 children in foster care under the responsibility
3 of the State who are in congregate care place-
4 ments on a general statewide basis and without
5 wide disparities between rural, suburban, and
6 urban areas in the rates of such children in
7 congregate care placements.

8 “(E) ANNUAL DETERMINATION OF STATE
9 ELIGIBILITY BASED ON AFCARS AND OTHER
10 DATA.—The Secretary annually shall make the
11 determinations required under subparagraph
12 (B) with respect to a State and a fiscal year,
13 on the basis of data meeting the requirements
14 of the system established pursuant to section
15 479, as reported by the State and approved by
16 the Secretary, and, to the extent the Secretary
17 determines necessary, on the basis of such other
18 information reported to the Secretary as the
19 Secretary may require to determine that a
20 State is, or continues to be, a State described
21 in subparagraph (B).

22 “(F) CONGREGATE CARE SETTINGS.—In
23 this paragraph, the term ‘congregate care set-
24 tings’ includes any settings described as ‘group
25 homes’ or ‘institutions’ for purposes of data re-

1 ported in accordance with the requirements of
2 the system established pursuant to section 479
3 or any similar placement settings reported in
4 accordance with such requirements.

5 “(6) ADMINISTRATIVE COSTS.—The prohibition
6 in paragraph (1) on Federal payments under section
7 474(a)(1) shall not be construed as prohibiting Fed-
8 eral payments for administrative expenditures in-
9 curred on behalf of a child placed in a child-care in-
10 stitution and for which payment is available under
11 section 474(a)(3).”.

12 (2) CONFORMING AMENDMENT.—Section
13 474(a)(1) of the Social Security Act (42 U.S.C.
14 674(a)(1)), as amended by section 19012(b), is
15 amended by striking “section 472(j)” and inserting
16 “subsections (j) and (k) of section 472”.

17 (b) DEFINITION OF FOSTER FAMILY HOME, CHILD-
18 CARE INSTITUTION.—Section 472(c) of such Act (42
19 U.S.C. 672(c)(1)) is amended to read as follows:

20 “(c) DEFINITIONS.—For purposes of this part:

21 “(1) FOSTER FAMILY HOME.—

22 “(A) IN GENERAL.—The term ‘foster fam-
23 ily home’ means the home of an individual or
24 family—

1 “(i) that is licensed or approved by
2 the State in which it is situated as a foster
3 family home that meets the standards es-
4 tablished for the licensing or approval; and

5 “(ii) in which a child in foster care
6 has been placed in the care of an indi-
7 vidual, who resides with the child and who
8 has been licensed or approved by the State
9 to be a foster parent—

10 “(I) that the State deems capable
11 of adhering to the reasonable and pru-
12 dent parent standard;

13 “(II) that provides 24-hour sub-
14 stitute care for children placed away
15 from their parents or other care-
16 takers; and

17 “(III) that provides the care for
18 not more than six children in foster
19 care.

20 “(B) STATE FLEXIBILITY.—The number of
21 foster children that may be cared for in a home
22 under subparagraph (A) may exceed the numer-
23 ical limitation in subparagraph (A)(ii)(III), at
24 the option of the State, for any of the following
25 reasons:

1 “(i) To allow a parenting youth in fos-
2 ter care to remain with the child of the
3 parenting youth.

4 “(ii) To allow siblings to remain to-
5 gether.

6 “(iii) To allow a child with an estab-
7 lished meaningful relationship with the
8 family to remain with the family.

9 “(iv) To allow a family with special
10 training or skills to provide care to a child
11 who has a severe disability.

12 “(C) RULE OF CONSTRUCTION.—Subpara-
13 graph (A) shall not be construed as prohibiting
14 a foster parent from renting the home in which
15 the parent cares for a foster child placed in the
16 parent’s care.

17 “(2) CHILD-CARE INSTITUTION.—

18 “(A) IN GENERAL.—The term ‘child-care
19 institution’ means a private child-care institu-
20 tion, or a public child-care institution which ac-
21 commodates no more than 25 children, which is
22 licensed by the State in which it is situated or
23 has been approved by the agency of the State
24 responsible for licensing or approval of institu-

1 tions of this type as meeting the standards es-
2 tablished for the licensing.

3 “(B) SUPERVISED SETTINGS.—In the case
4 of a child who has attained 18 years of age, the
5 term shall include a supervised setting in which
6 the individual is living independently, in accord-
7 ance with such conditions as the Secretary shall
8 establish in regulations.

9 “(C) EXCLUSIONS.—The term shall not in-
10 clude detention facilities, forestry camps, train-
11 ing schools, or any other facility operated pri-
12 marily for the detention of children who are de-
13 termined to be delinquent.”.

14 (c) TRAINING FOR STATE JUDGES, ATTORNEYS, AND
15 OTHER LEGAL PERSONNEL IN CHILD WELFARE
16 CASES.—Section 438(b)(1) of such Act (42 U.S.C.
17 629h(b)(1)) is amended in the matter preceding subpara-
18 graph (A) by inserting “shall provide for the training of
19 judges, attorneys, and other legal personnel in child wel-
20 fare cases on Federal child welfare policies and payment
21 limitations with respect to children in foster care who are
22 placed in settings that are not a foster family home,” after
23 “with respect to the child,”.

24 (d) ASSURANCE OF NONIMPACT ON JUVENILE JUS-
25 TICE SYSTEM.—

1 (1) STATE PLAN REQUIREMENT.—Section
2 471(a) of such Act (42 U.S.C. 671(a)), as amended
3 by section 19031, is further amended by adding at
4 the end the following:

5 “(37) includes a certification that, in response
6 to the limitation imposed under section 472(k) with
7 respect to foster care maintenance payments made
8 on behalf of any child who is placed in a setting that
9 is not a foster family home, the State will not enact
10 or advance policies or practices that would result in
11 a significant increase in the population of youth in
12 the State’s juvenile justice system.”.

13 (2) GAO STUDY AND REPORT.—The Comp-
14 troller General of the United States shall evaluate
15 the impact, if any, on State juvenile justice systems
16 of the limitation imposed under section 472(k) of
17 the Social Security Act (as added by section
18 19001(a)(1)) on foster care maintenance payments
19 made on behalf of any child who is placed in a set-
20 ting that is not a foster family home, in accordance
21 with the amendments made by subsections (a) and
22 (b) of this section. In particular, the Comptroller
23 General shall evaluate the extent to which children
24 in foster care who also are subject to the juvenile
25 justice system of the State are placed in a facility

1 under the jurisdiction of the juvenile justice system
2 and whether the lack of available congregate care
3 placements under the jurisdiction of the child wel-
4 fare systems is a contributing factor to that result.
5 Not later than December 31, 2023, the Comptroller
6 General shall submit to Congress a report on the re-
7 sults of the evaluation.

8 **SEC. 20002. ASSESSMENT AND DOCUMENTATION OF THE**
9 **NEED FOR PLACEMENT IN A QUALIFIED RES-**
10 **IDENTIAL TREATMENT PROGRAM.**

11 Section 475A of the Social Security Act (42 U.S.C.
12 675a) is amended by adding at the end the following:

13 “(c) ASSESSMENT, DOCUMENTATION, AND JUDICIAL
14 DETERMINATION REQUIREMENTS FOR PLACEMENT IN A
15 QUALIFIED RESIDENTIAL TREATMENT PROGRAM.—In
16 the case of any child who is placed in a qualified residen-
17 tial treatment program (as defined in section 472(k)(4)),
18 the following requirements shall apply for purposes of ap-
19 proving the case plan for the child and the case system
20 review procedure for the child:

21 “(1)(A) Within 30 days of the start of each
22 placement in such a setting, a qualified individual
23 (as defined in subparagraph (D)) shall—

24 “(i) assess the strengths and needs of the
25 child using an age-appropriate, evidence-based,

1 validated, functional assessment tool approved
2 by the Secretary;

3 “(ii) determine whether the needs of the
4 child can be met with family members or
5 through placement in a foster family home or,
6 if not, which setting from among the settings
7 specified in section 472(k)(2) would provide the
8 most effective and appropriate level of care for
9 the child in the least restrictive environment
10 and be consistent with the short- and long-term
11 goals for the child, as specified in the perma-
12 nency plan for the child; and

13 “(iii) develop a list of child-specific short-
14 and long-term mental and behavioral health
15 goals.

16 “(B)(i) The State shall assemble a family and
17 permanency team for the child in accordance with
18 the requirements of clauses (ii) and (iii). The quali-
19 fied individual conducting the assessment required
20 under subparagraph (A) shall work in conjunction
21 with the family of, and permanency team for, the
22 child while conducting and making the assessment.

23 “(ii) The family and permanency team shall
24 consist of all appropriate biological family members,
25 relative, and fictive kin of the child, as well as, as

1 appropriate, professionals who are a resource to the
2 family of the child, such as teachers, medical or
3 mental health providers who have treated the child,
4 or clergy. In the case of a child who has attained
5 age 14, the family and permanency team shall in-
6 clude the members of the permanency planning team
7 for the child that are selected by the child in accord-
8 ance with section 475(5)(C)(iv).

9 “(iii) The State shall document in the child’s
10 case plan—

11 “(I) the reasonable and good faith effort of
12 the State to identify and include all such indi-
13 viduals on the family of, and permanency team
14 for, the child;

15 “(II) all contact information for members
16 of the family and permanency team, as well as
17 contact information for other family members
18 and fictive kin who are not part of the family
19 and permanency team;

20 “(III) evidence that meetings of the family
21 and permanency team, including meetings relat-
22 ing to the assessment required under subpara-
23 graph (A), are held at a time and place conven-
24 ient for family;

1 “(IV) if reunification is the goal, evidence
2 demonstrating that the parent from whom the
3 child was removed provided input on the mem-
4 bers of the family and permanency team;

5 “(V) evidence that the assessment required
6 under subparagraph (A) is determined in con-
7 junction with the family and permanency team;
8 and

9 “(VI) the placement preferences of the
10 family and permanency team relative to the as-
11 sessment and, if the placement preferences of
12 the family and permanency team and child are
13 not the placement setting recommended by the
14 qualified individual conducting the assessment
15 under subparagraph (A), the reasons why the
16 preferences of the team and of the child were
17 not recommended.

18 “(C) In the case of a child who the qualified in-
19 dividual conducting the assessment under subpara-
20 graph (A) determines should not be placed in a fos-
21 ter family home, the qualified individual shall specify
22 in writing the reasons why the needs of the child
23 cannot be met by the family of the child or in a fos-
24 ter family home. A shortage or lack of foster family
25 homes shall not be an acceptable reason for deter-

1 mining that a needs of the child cannot be met in
2 a foster family home. The qualified individual also
3 shall specify in writing why the recommended place-
4 ment in a qualified residential treatment program is
5 the setting that will provide the child with the most
6 effective and appropriate level of care in the least re-
7 strictive environment and how that placement is con-
8 sistent with the short- and long-term goals for the
9 child, as specified in the permanency plan for the
10 child.

11 “(D)(i) Subject to clause (ii), in this subsection,
12 the term ‘qualified individual’ means a trained pro-
13 fessional or licensed clinician who is not an employee
14 of the State agency and who is not connected to, or
15 affiliated with, any placement setting in which chil-
16 dren are placed by the State.

17 “(ii) The Secretary may approve a request of a
18 State to waive any requirement in clause (i) upon a
19 submission by the State, in accordance with criteria
20 established by the Secretary, that certifies that the
21 trained professionals or licensed clinicians with re-
22 sponsibility for performing the assessments de-
23 scribed in subparagraph (A) shall maintain objec-
24 tivity with respect to determining the most effective
25 and appropriate placement for a child.

1 “(2) Within 60 days of the start of each place-
2 ment in a qualified residential treatment program, a
3 family or juvenile court or another court (including
4 a tribal court) of competent jurisdiction, or an ad-
5 ministrative body appointed or approved by the
6 court, independently, shall—

7 “(A) consider the assessment, determina-
8 tion, and documentation made by the qualified
9 individual conducting the assessment under
10 paragraph (1);

11 “(B) determine whether the needs of the
12 child can be met through placement in a foster
13 family home or, if not, whether placement of
14 the child in a qualified residential treatment
15 program provides the most effective and appro-
16 priate level of care for the child in the least re-
17 strictive environment and whether that place-
18 ment is consistent with the short- and long-
19 term goals for the child, as specified in the per-
20 manency plan for the child; and

21 “(C) approve or disapprove the placement.

22 “(3) The written documentation made under
23 paragraph (1)(C) and documentation of the deter-
24 mination and approval or disapproval of the place-
25 ment in a qualified residential treatment program by

1 a court or administrative body under paragraph (2)
2 shall be included in and made part of the case plan
3 for the child.

4 “(4) As long as a child remains placed in a
5 qualified residential treatment program, the State
6 agency shall submit evidence at each status review
7 and each permanency hearing held with respect to
8 the child—

9 “(A) demonstrating that ongoing assess-
10 ment of the strengths and needs of the child
11 continues to support the determination that the
12 needs of the child cannot be met through place-
13 ment in a foster family home, that the place-
14 ment in a qualified residential treatment pro-
15 gram provides the most effective and appro-
16 priate level of care for the child in the least re-
17 strictive environment, and that the placement is
18 consistent with the short- and long-term goals
19 for the child, as specified in the permanency
20 plan for the child;

21 “(B) documenting the specific treatment or
22 service needs that will be met for the child in
23 the placement and the length of time the child
24 is expected to need the treatment or services;
25 and

1 “(C) documenting the efforts made by the
2 State agency to prepare the child to return
3 home or to be placed with a fit and willing rel-
4 ative, a legal guardian, or an adoptive parent,
5 or in a foster family home.

6 “(5) In the case of any child who is placed in
7 a qualified residential treatment program for more
8 than 12 consecutive months or 18 nonconsecutive
9 months (or, in the case of a child who has not at-
10 tained age 13, for more than 6 consecutive or non-
11 consecutive months), the State agency shall submit
12 to the Secretary—

13 “(A) the most recent versions of the evi-
14 dence and documentation specified in paragraph
15 (4); and

16 “(B) the signed approval of the head of
17 the State agency for the continued placement of
18 the child in that setting.”.

19 **SEC. 20003. PROTOCOLS TO PREVENT INAPPROPRIATE DI-**
20 **AGNOSES.**

21 (a) STATE PLAN REQUIREMENT.—Section
22 422(b)(15)(A) of the Social Security Act (42 U.S.C.
23 622(b)(15)(A)) is amended—

24 (1) in clause (vi), by striking “and” after the
25 semicolon;

1 (2) by redesignating clause (vii) as clause (viii);

2 and

3 (3) by inserting after clause (vi) the following:

4 “(vii) the procedures and protocols
5 the State has established to ensure that
6 children in foster care placements are not
7 inappropriately diagnosed with mental ill-
8 ness, other emotional or behavioral dis-
9 orders, medically fragile conditions, or de-
10 velopmental disabilities, and placed in set-
11 tings that are not foster family homes as
12 a result of the inappropriate diagnoses;
13 and”.

14 (b) EVALUATION.—Section 476 of such Act (42
15 U.S.C. 676), as previously amended, is further amended
16 by adding at the end the following:

17 “(e) EVALUATION OF STATE PROCEDURES AND PRO-
18 TOCOLS TO PREVENT INAPPROPRIATE DIAGNOSES OF
19 MENTAL ILLNESS OR OTHER CONDITIONS.—The Sec-
20 retary shall conduct an evaluation of the procedures and
21 protocols established by States in accordance with the re-
22 quirements of section 422(b)(15)(A)(vii). The evaluation
23 shall analyze the extent to which States comply with and
24 enforce the procedures and protocols and the effectiveness
25 of various State procedures and protocols and shall iden-

1 tify best practices. Not later than January 1, 2019, the
2 Secretary shall submit a report on the results of the eval-
3 uation to Congress.”.

4 **SEC. 20004. ADDITIONAL DATA AND REPORTS REGARDING**
5 **CHILDREN PLACED IN A SETTING THAT IS**
6 **NOT A FOSTER FAMILY HOME.**

7 Section 479A(a)(7)(A) of the Social Security Act (42
8 U.S.C. 679b(a)(7)(A)) is amended by striking clauses (i)
9 through (vi) and inserting the following:

10 “(i) with respect to each such place-
11 ment—

12 “(I) the type of the placement
13 setting, including whether the place-
14 ment is shelter care, a group home
15 and if so, the range of the child popu-
16 lation in the home, a residential treat-
17 ment facility, a hospital or institution
18 providing medical, rehabilitative, or
19 psychiatric care, a setting specializing
20 in providing prenatal, post-partum or
21 parenting supports, or some other
22 kind of child-care institution and if so,
23 what kind;

24 “(II) the number of children in
25 the placement setting and the age,

1 race, ethnicity, and gender of each of
2 the children;

3 “(III) for each child in the place-
4 ment setting, the length of the place-
5 ment of the child in the setting,
6 whether the placement of the child in
7 the setting is the first placement of
8 the child and if not, the number and
9 type of previous placements of the
10 child, and whether the child has spe-
11 cial needs or another diagnosed men-
12 tal or physical illness or condition;
13 and

14 “(IV) the extent of any special-
15 ized education, treatment, counseling,
16 or other services provided in the set-
17 ting; and

18 “(ii) separately, the number and ages
19 of children in the placements who have a
20 permanency plan of another planned per-
21 manent living arrangement; and”.

22 **SEC. 20005. EFFECTIVE DATES; APPLICATION TO WAIVERS.**

23 (a) **EFFECTIVE DATES.**—

1 (1) IN GENERAL.—Subject to paragraph (2)
2 and subsections (b) and (c), the amendments made
3 by this title shall take effect on January 1, 2017.

4 (2) TRANSITION RULE.—In the case of a State
5 plan under part B or E of title IV of the Social Se-
6 curity Act which the Secretary of Health and
7 Human Services determines requires State legisla-
8 tion (other than legislation appropriating funds) in
9 order for the plan to meet the additional require-
10 ments imposed by the amendments made by this
11 title, the State plan shall not be regarded as failing
12 to comply with the requirements of such part solely
13 on the basis of the failure of the plan to meet the
14 additional requirements before the first day of the
15 first calendar quarter beginning after the close of
16 the first regular session of the State legislature that
17 begins after the date of enactment of this Act. For
18 purposes of the previous sentence, in the case of a
19 State that has a 2-year legislative session, each year
20 of the session shall be deemed to be a separate reg-
21 ular session of the State legislature.

22 (b) LIMITATION ON FEDERAL FINANCIAL PARTICI-
23 PATION FOR PLACEMENTS THAT ARE NOT IN FOSTER
24 FAMILY HOMES AND RELATED PROVISIONS.—

1 (1) IN GENERAL.—The amendments made by
2 sections 20001(a), 20001(b), 20001(d), and 20002
3 shall take effect on October 1, 2019.

4 (2) STATE OPTION TO DELAY EFFECTIVE DATE
5 FOR NOT MORE THAN 2 YEARS.—At the sole discre-
6 tion of a State and for not more than 2 years, the
7 Secretary of Health and Human Services shall delay
8 the effective date provided for in paragraph (1) with
9 respect to the State. If the effective date is so de-
10 layed for a period with respect to a State under the
11 preceding sentence, then—

12 (A) notwithstanding section 1904, the date
13 that the amendments made by section 19011(c)
14 take effect with respect to the State shall be de-
15 layed for the period; and

16 (B) in applying section 474(a)(6) of the
17 Social Security Act with respect to the State,
18 “on or after the date this paragraph takes ef-
19 fect with respect to the State” is deemed to be
20 substituted for “after September 30, 2019” in
21 subparagraph (A)(i)(I) of such section.

22 (c) APPLICATION TO STATES WITH WAIVERS.—In
23 the case of a State that, on the date of enactment of this
24 Act, has in effect a waiver approved under section 1130
25 of the Social Security Act (42 U.S.C. 1320a–9), the

1 amendments made by this title shall not apply with respect
2 to the State before the expiration (determined without re-
3 gard to any extensions) of the waiver to the extent the
4 amendments are inconsistent with the terms of the waiver.

5 **TITLE XXI—CONTINUING SUP-**
6 **PORT FOR CHILD AND FAM-**
7 **ILY SERVICES**

8 **SEC. 21001. SUPPORTING AND RETAINING FOSTER FAMI-**
9 **LIES FOR CHILDREN.**

10 (a) SUPPORTING AND RETAINING FOSTER PARENTS
11 AS A FAMILY SUPPORT SERVICE.—Section 431(a)(2)(B)
12 of the Social Security Act (42 U.S.C. 631(a)(2)(B)) is
13 amended by redesignating clauses (iii) through (vi) as
14 clauses (iv) through (vii), respectively, and inserting after
15 clause (ii) the following:

16 “(iii) To support and retain foster
17 families so they can provide quality family-
18 based settings for children in foster care.”.

19 (b) SUPPORT FOR FOSTER FAMILY HOMES.—Section
20 436 of such Act (42 U.S.C. 629f) is amended by adding
21 at the end the following:

22 “(c) SUPPORT FOR FOSTER FAMILY HOMES.—Out
23 of any money in the Treasury of the United States not
24 otherwise appropriated, there are appropriated to the Sec-
25 retary for fiscal year 2018, \$8,000,000 for the Secretary

1 to make competitive grants to States, Indian tribes, or
2 tribal consortia to support the recruitment and retention
3 of high-quality foster families to increase their capacity
4 to place more children in family settings, focused on
5 States, Indian tribes, or tribal consortia with the highest
6 percentage of children in non-family settings. The amount
7 appropriated under this subparagraph shall remain avail-
8 able through fiscal year 2022.”.

9 **SEC. 21002. EXTENSION OF CHILD AND FAMILY SERVICES**
10 **PROGRAMS.**

11 (a) **EXTENSION OF STEPHANIE TUBBS JONES CHILD**
12 **WELFARE SERVICES PROGRAM.**—Section 425 of the So-
13 cial Security Act (42 U.S.C. 625) is amended by striking
14 “2012 through 2016” and inserting “2017 through
15 2021”.

16 (b) **EXTENSION OF PROMOTING SAFE AND STABLE**
17 **FAMILIES PROGRAM AUTHORIZATIONS.**—

18 (1) **IN GENERAL.**—Section 436(a) of such Act
19 (42 U.S.C. 629f(a)) is amended by striking all that
20 follows “\$345,000,000” and inserting “for each of
21 fiscal years 2017 through 2021.”.

22 (2) **DISCRETIONARY GRANTS.**—Section 437(a)
23 of such Act (42 U.S.C. 629g(a)) is amended by
24 striking “2012 through 2016” and inserting “2017
25 through 2021”.

1 (c) EXTENSION OF FUNDING RESERVATIONS FOR
2 MONTHLY CASEWORKER VISITS AND REGIONAL PART-
3 NERSHIP GRANTS.—Section 436(b) of such Act (42
4 U.S.C. 629f(b)) is amended—

5 (1) in paragraph (4)(A), by striking “2012
6 through 2016” and inserting “2017 through 2021”;
7 and

8 (2) in paragraph (5), by striking “2012
9 through 2016” and inserting “2017 through 2021”.

10 (d) REAUTHORIZATION OF FUNDING FOR STATE
11 COURTS.—

12 (1) EXTENSION OF PROGRAM.—Section
13 438(c)(1) of such Act (42 U.S.C. 629h(c)(1)) is
14 amended by striking “2012 through 2016” and in-
15 serting “2017 through 2021”.

16 (2) EXTENSION OF FEDERAL SHARE.—Section
17 438(d) of such Act (42 U.S.C. 629h(d)) is amended
18 by striking “2012 through 2016” and inserting
19 “2017 through 2021”.

20 (e) REPEAL OF EXPIRED PROVISIONS.—Section
21 438(e) of such Act (42 U.S.C. 629h(e)) is repealed.

1 **SEC. 21003. IMPROVEMENTS TO THE JOHN H. CHAFEE FOS-**
2 **TER CARE INDEPENDENCE PROGRAM AND**
3 **RELATED PROVISIONS.**

4 (a) **AUTHORITY TO SERVE FORMER FOSTER YOUTH**
5 **UP TO AGE 23.**—Section 477 of the Social Security Act
6 (42 U.S.C. 677) is amended—

7 (1) in subsection (a)(5), by inserting “(or 23
8 years of age, in the case of a State with a certifi-
9 cation under subsection (b)(3)(A)(ii) to provide as-
10 sistance and services to youths who have aged out
11 of foster care and have not attained such age, in ac-
12 cordance with such subsection)” after “21 years of
13 age”;

14 (2) in subsection (b)(3)(A)—

15 (A) by inserting “(i)” before “A certifi-
16 cation”;

17 (B) by striking “children who have left fos-
18 ter care” and all that follows through the pe-
19 riod and inserting “youths who have aged out
20 of foster care and have not attained 21 years of
21 age.”; and

22 (C) by adding at the end the following:

23 “(ii) If the State has elected under section
24 475(8)(B) to extend eligibility for foster care to
25 all children who have not attained 21 years of
26 age, or if the Secretary determines that the

1 State agency responsible for administering the
2 State plans under this part and part B uses
3 State funds or any other funds not provided
4 under this part to provide services and assist-
5 ance for youths who have aged out of foster
6 care that are comparable to the services and as-
7 sistance the youths would receive if the State
8 had made such an election, the certification re-
9 quired under clause (i) may provide that the
10 State will provide assistance and services to
11 youths who have aged out of foster care and
12 have not attained 23 years of age.”; and

13 (3) in subsection (b)(3)(B), by striking “chil-
14 dren who have left foster care” and all that follows
15 through the period and inserting “youths who have
16 aged out of foster care and have not attained 21
17 years of age (or 23 years of age, in the case of a
18 State with a certification under subparagraph (A)(i)
19 to provide assistance and services to youths who
20 have aged out of foster care and have not attained
21 such age, in accordance with subparagraph
22 (A)(ii).”.

23 (b) AUTHORITY TO REDISTRIBUTE UNSPENT
24 FUNDS.—Section 477(d) of such Act (42 U.S.C. 677(d))
25 is amended—

1 (1) in paragraph (4), by inserting “or does not
2 expend allocated funds within the time period speci-
3 fied under section 477(d)(3)” after “provided by the
4 Secretary”; and

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

6 “(5) REDISTRIBUTION OF UNEXPENDED
7 AMOUNTS.—

8 “(A) AVAILABILITY OF AMOUNTS.—To the
9 extent that amounts paid to States under this
10 section in a fiscal year remain unexpended by
11 the States at the end of the succeeding fiscal
12 year, the Secretary may make the amounts
13 available for redistribution in the second suc-
14 ceeding fiscal year among the States that apply
15 for additional funds under this section for that
16 second succeeding fiscal year.

17 “(B) REDISTRIBUTION.—

18 “(i) IN GENERAL.—The Secretary
19 shall redistribute the amounts made avail-
20 able under subparagraph (A) for a fiscal
21 year among eligible applicant States. In
22 this subparagraph, the term ‘eligible appli-
23 cant State’ means a State that has applied
24 for additional funds for the fiscal year
25 under subparagraph (A) if the Secretary

1 determines that the State will use the
2 funds for the purpose for which originally
3 allotted under this section.

4 “(ii) AMOUNT TO BE REDISTRIB-
5 UTED.—The amount to be redistributed to
6 each eligible applicant State shall be the
7 amount so made available multiplied by the
8 State foster care ratio, (as defined in sub-
9 section (c)(4), except that, in such sub-
10 section, ‘all eligible applicant States (as de-
11 fined in subsection (d)(5)(B)(i))’ shall be
12 substituted for ‘all States’).

13 “(iii) TREATMENT OF REDISTRIBUTED
14 AMOUNT.—Any amount made available to
15 a State under this paragraph shall be re-
16 garded as part of the allotment of the
17 State under this section for the fiscal year
18 in which the redistribution is made.

19 “(C) TRIBES.—For purposes of this para-
20 graph, the term ‘State’ includes an Indian tribe,
21 tribal organization, or tribal consortium that re-
22 ceives an allotment under this section.”.

23 (c) EXPANDING AND CLARIFYING THE USE OF EDU-
24 CATION AND TRAINING VOUCHERS.—

1 (1) IN GENERAL.—Section 477(i)(3) of such
2 Act (42 U.S.C. 677(i)(3)) is amended—

3 (A) by striking “on the date” and all that
4 follows through “23” and inserting “to remain
5 eligible until they attain 26”; and

6 (B) by inserting “, but in no event may a
7 youth participate in the program for more than
8 5 years (whether or not consecutive)” before
9 the period.

10 (2) CONFORMING AMENDMENT.—Section
11 477(i)(1) of such Act (42 U.S.C. 677(i)(1)) is
12 amended by inserting “who have attained 14 years
13 of age” before the period.

14 (d) OTHER IMPROVEMENTS.—Section 477 of such
15 Act (42 U.S.C. 677), as amended by subsections (a), (b),
16 and (c), is amended—

17 (1) in the section heading, by striking “**INDE-**
18 **PENDENCE PROGRAM**” and inserting “**PROGRAM**
19 **FOR SUCCESSFUL TRANSITION TO ADULT-**
20 **HOOD**”;

21 (2) in subsection (a)—

22 (A) in paragraph (1)—

23 (i) by striking “identify children who
24 are likely to remain in foster care until 18
25 years of age and to help these children

1 make the transition to self-sufficiency by
2 providing services” and inserting “support
3 all youth who have experienced foster care
4 at age 14 or older in their transition to
5 adulthood through transitional services”;

6 (ii) by inserting “and post-secondary
7 education” after “high school diploma”;
8 and

9 (iii) by striking “training in daily liv-
10 ing skills, training in budgeting and finan-
11 cial management skills” and inserting
12 “training and opportunities to practice
13 daily living skills (such as financial literacy
14 training and driving instruction)”;

15 (B) in paragraph (2), by striking “who are
16 likely to remain in foster care until 18 years of
17 age receive the education, training, and services
18 necessary to obtain employment” and inserting
19 “who have experienced foster care at age 14 or
20 older achieve meaningful, permanent connec-
21 tions with a caring adult”;

22 (C) in paragraph (3), by striking “who are
23 likely to remain in foster care until 18 years of
24 age prepare for and enter postsecondary train-
25 ing and education institutions” and inserting

1 “who have experienced foster care at age 14 or
2 older engage in age or developmentally appro-
3 priate activities, positive youth development,
4 and experiential learning that reflects what
5 their peers in intact families experience”; and

6 (D) by striking paragraph (4) and redesign-
7 ating paragraphs (5) through (8) as para-
8 graphs (4) through (7);
9 (3) in subsection (b)—

10 (A) in paragraph (2)(D), by striking “ado-
11 lescents” and inserting “youth”; and

12 (B) in paragraph (3)—

13 (i) in subparagraph (D)—

14 (I) by inserting “including train-
15 ing on youth development” after “to
16 provide training”; and

17 (II) by striking “adolescents pre-
18 paring for independent living” and all
19 that follows through the period and
20 inserting “youth preparing for a suc-
21 cessful transition to adulthood and
22 making a permanent connection with
23 a caring adult.”;

1 (ii) in subparagraph (H), by striking
2 “adolescents” each place it appears and in-
3 sserting “youth”; and

4 (iii) in subparagraph (K)—

5 (I) by striking “an adolescent”
6 and inserting “a youth”; and

7 (II) by striking “the adolescent”
8 each place it appears and inserting
9 “the youth”; and

10 (4) in subsection (f), by striking paragraph (2)
11 and inserting the following:

12 “(2) REPORT TO CONGRESS.—Not later than
13 October 1, 2017, the Secretary shall submit to the
14 Committee on Ways and Means of the House of
15 Representatives and the Committee on Finance of
16 the Senate a report on the National Youth in Tran-
17 sition Database and any other databases in which
18 States report outcome measures relating to children
19 in foster care and children who have aged out of fos-
20 ter care or left foster care for kinship guardianship
21 or adoption. The report shall include the following:

22 “(A) A description of the reasons for entry
23 into foster care and of the foster care experi-
24 ences, such as length of stay, number of place-
25 ment settings, case goal, and discharge reason

1 of 17-year-olds who are surveyed by the Na-
2 tional Youth in Transition Database and an
3 analysis of the comparison of that description
4 with the reasons for entry and foster care expe-
5 riences of children of other ages who exit from
6 foster care before attaining age 17.

7 “(B) A description of the characteristics of
8 the individuals who report poor outcomes at
9 ages 19 and 21 to the National Youth in Tran-
10 sition Database.

11 “(C) Benchmarks for determining what
12 constitutes a poor outcome for youth who re-
13 main in or have exited from foster care and
14 plans the Executive branch will take to incor-
15 porate these benchmarks in efforts to evaluate
16 child welfare agency performance in providing
17 services to children transitioning from foster
18 care.

19 “(D) An analysis of the association be-
20 tween types of placement, number of overall
21 placements, time spent in foster care, and other
22 factors, and outcomes at ages 19 and 21.

23 “(E) An analysis of the differences in out-
24 comes for children in and formerly in foster
25 care at age 19 and 21 among States.”.

1 (e) CLARIFYING DOCUMENTATION PROVIDED TO
2 FOSTER YOUTH LEAVING FOSTER CARE.—Section
3 475(5)(I) of such Act (42 U.S.C. 675(5)(I)) is amended
4 by inserting after “REAL ID Act of 2005” the following:
5 “, and any official documentation necessary to prove that
6 the child was previously in foster care”.

7 **TITLE XXII—CONTINUING IN-**
8 **CENTIVES TO STATES TO**
9 **PROMOTE ADOPTION AND**
10 **LEGAL GUARDIANSHIP**

11 **SEC. 22001. REAUTHORIZING ADOPTION AND LEGAL**
12 **GUARDIANSHIP INCENTIVE PROGRAMS.**

13 Section 473A of the Social Security Act (42 U.S.C.
14 673b) is amended—

15 (1) in subsection (b)(4), by striking “2013
16 through 2015” and inserting “2016 through 2020”;

17 (2) in subsection (h)(1)(D), by striking “2016”
18 and inserting “2021”; and

19 (3) in subsection (h)(2), by striking “2016”
20 and inserting “2021”.

1 **TITLE XXIII—TECHNICAL**
2 **CORRECTIONS**

3 **SEC. 23001. TECHNICAL CORRECTIONS TO DATA EXCHANGE**
4 **STANDARDS TO IMPROVE PROGRAM COORDI-**
5 **NATION.**

6 (a) IN GENERAL.—Section 440 of the Social Security
7 Act (42 U.S.C. 629m) is amended to read as follows:

8 **“SEC. 440. DATA EXCHANGE STANDARDS FOR IMPROVED**
9 **INTEROPERABILITY.**

10 “(a) DESIGNATION.—The Secretary shall, in con-
11 sultation with an interagency work group established by
12 the Office of Management and Budget and considering
13 State government perspectives, by rule, designate data ex-
14 change standards to govern, under this part and part E—

15 “(1) necessary categories of information that
16 State agencies operating programs under State
17 plans approved under this part are required under
18 applicable Federal law to electronically exchange
19 with another State agency; and

20 “(2) Federal reporting and data exchange re-
21 quired under applicable Federal law.

22 “(b) REQUIREMENTS.—The data exchange standards
23 required by paragraph (1) shall, to the extent prac-
24 ticable—

1 “(1) incorporate a widely accepted, non-propri-
2 etary, searchable, computer-readable format, such as
3 the eXtensible Markup Language;

4 “(2) contain interoperable standards developed
5 and maintained by intergovernmental partnerships,
6 such as the National Information Exchange Model;

7 “(3) incorporate interoperable standards devel-
8 oped and maintained by Federal entities with au-
9 thority over contracting and financial assistance;

10 “(4) be consistent with and implement applica-
11 ble accounting principles;

12 “(5) be implemented in a manner that is cost-
13 effective and improves program efficiency and effec-
14 tiveness; and

15 “(6) be capable of being continually upgraded
16 as necessary.

17 “(c) RULE OF CONSTRUCTION.—Nothing in this sub-
18 section shall be construed to require a change to existing
19 data exchange standards found to be effective and effi-
20 cient.”.

21 (b) EFFECTIVE DATE.—Not later than the date that
22 is 24 months after the date of the enactment of this sec-
23 tion, the Secretary of Health and Human Services shall
24 issue a proposed rule that—

1 (1) identifies federally required data exchanges,
2 include specification and timing of exchanges to be
3 standardized, and address the factors used in deter-
4 mining whether and when to standardize data ex-
5 changes; and

6 (2) specifies State implementation options and
7 describes future milestones.

8 **SEC. 23002. TECHNICAL CORRECTIONS TO STATE REQUIRE-**
9 **MENT TO ADDRESS THE DEVELOPMENTAL**
10 **NEEDS OF YOUNG CHILDREN.**

11 Section 422(b)(18) of the Social Security Act (42
12 U.S.C. 622(b)(18)) is amended by striking “such chil-
13 dren” and inserting “all vulnerable children under 5 years
14 of age”.

15 **TITLE XXIV—ENSURING STATES**
16 **REINVEST SAVINGS RESULT-**
17 **ING FROM INCREASE IN**
18 **ADOPTION ASSISTANCE**

19 **SEC. 24001. DELAY OF ADOPTION ASSISTANCE PHASE-IN.**

20 (a) IN GENERAL.—The table in section 473(e)(1)(B)
21 of the Social Security Act (42 U.S.C. 673(e)(1)(B)) is
22 amended—

23 (1) by striking “2016” and inserting “2016,
24 2017, 2018, or 2019”;

1 (2) by striking “2017” and inserting “2020”;

2 and

3 (3) by striking “2018” and inserting “2021”.

4 (b) SPECIAL RULE.—Section 473(e) of the Social Se-
5 curity Act (42 U.S.C. 673(e)) is amended by adding at
6 the end the following new paragraph:

7 “(3) ADDITIONAL EXCEPTION.—Notwith-
8 standing paragraph (1) of this subsection, during
9 the period that begins on October 1, 2016, and ends
10 on December 31, 2016, such term shall include a
11 child—

12 “(A) who satisfies the requirements for
13 being considered an applicable child under para-
14 graph (1) (as in effect during that period);

15 “(B) who meets the requirements of sub-
16 section (a)(2)(A)(ii); and

17 “(C) on whose behalf an adoption assist-
18 ance agreement is entered into under this sec-
19 tion during that period.”.

20 (c) EFFECTIVE DATE.—The amendments made by
21 this section take effect on January 1, 2017.

1 **SEC. 24002. GAO STUDY AND REPORT ON STATE REINVEST-**
2 **MENT OF SAVINGS RESULTING FROM IN-**
3 **CREASE IN ADOPTION ASSISTANCE.**

4 (a) STUDY.—The Comptroller General of the United
5 States shall study the extent to which States are com-
6 plying with the requirements of section 473(a)(8) of the
7 Social Security Act relating to the effects of phasing out
8 the AFDC income eligibility requirements for adoption as-
9 sistance payments under section 473 of the Social Security
10 Act, as enacted by section 402 of the Fostering Conne-
11 ctions to Success and Increasing Adoptions Act of 2008
12 (Public Law 110–351; 122 Stat. 3975) and amended by
13 section 206 of the Preventing Sex Trafficking and
14 Strengthening Families Act (Public Law 113–183; 128
15 Stat. 1919). In particular, the Comptroller General shall
16 analyze the extent to which States are complying with the
17 following requirements under section 473(a)(8)(D) of the
18 Social Security Act:

19 (1) The requirement to spend an amount equal
20 to the amount of the savings (if any) in State ex-
21 penditures under part E of title IV of the Social Se-
22 curity resulting from phasing out the AFDC income
23 eligibility requirements for adoption assistance pay-
24 ments under section 473 of such Act to provide to
25 children of families any service that may be provided
26 under part B or E of title IV of such Act.

1 (2) The requirement that a State shall spend
2 not less than 30 percent of the amount of any sav-
3 ings described in subparagraph (A) on post-adoption
4 services, post-guardianship services, and services to
5 support and sustain positive permanent outcomes for
6 children who otherwise might enter into foster care
7 under the responsibility of the State, with at least $\frac{2}{3}$
8 of the spending by the State to comply with the 30
9 percent requirement being spent on post-adoption
10 and post-guardianship services.

11 (b) REPORT.—The Comptroller General of the
12 United States shall submit to the Committee on Finance
13 of the Senate, the Committee on Ways and Means of the
14 House of Representatives, and the Secretary of Health
15 and Human Services a report that contains the results of
16 the study required by subsection (a), including rec-
17 ommendations to ensure compliance with laws referred to
18 in subsection (a).

19 **TITLE XXV—SOCIAL IMPACT**
20 **PARTNERSHIPS TO PAY FOR**
21 **RESULTS**

22 **SEC. 25001. SHORT TITLE.**

23 This title may be cited as the “Social Impact Part-
24 nership to Pay for Results Act”.

1 **SEC. 25002. SOCIAL IMPACT PARTNERSHIPS TO PAY FOR**
2 **RESULTS.**

3 Section 403 of the Social Security Act (42 U.S.C.
4 603) is amended by adding at the end the following:

5 “(c) SOCIAL IMPACT DEMONSTRATION PROJECTS.—

6 “(1) PURPOSES.—The purposes of this sub-
7 section are the following:

8 “(A) To improve the lives of families and
9 individuals in need in the United States by
10 funding social programs that achieve real re-
11 sults.

12 “(B) To redirect funds away from pro-
13 grams that, based on objective data, are ineffec-
14 tive, and into programs that achieve demon-
15 strable, measurable results.

16 “(C) To ensure Federal funds are used ef-
17 fectively on social services to produce positive
18 outcomes for both service recipients and tax-
19 payers.

20 “(D) To establish the use of social impact
21 partnerships to address some of our Nation’s
22 most pressing problems.

23 “(E) To facilitate the creation of public-
24 private partnerships that bundle philanthropic
25 or other private resources with existing public
26 spending to scale up effective social interven-

1 tions already being implemented by private or-
2 ganizations, nonprofits, charitable organiza-
3 tions, and State and local governments across
4 the country.

5 “(F) To bring pay-for-performance to the
6 social sector, allowing the United States to im-
7 prove the impact and effectiveness of vital social
8 services programs while redirecting inefficient
9 or duplicative spending.

10 “(G) To incorporate outcomes measure-
11 ment and randomized controlled trials or other
12 rigorous methodologies for assessing program
13 impact.

14 “(2) SOCIAL IMPACT PARTNERSHIP APPLICA-
15 TION.—

16 “(A) NOTICE.—Not later than 1 year after
17 the date of the enactment of this subsection,
18 the Secretary of the Treasury, in consultation
19 with the Federal Interagency Council on Social
20 Impact Partnerships, shall publish in the Fed-
21 eral Register a request for proposals from
22 States or local governments for social impact
23 partnership projects in accordance with this
24 paragraph.

1 “(B) REQUIRED OUTCOMES FOR SOCIAL
2 IMPACT PARTNERSHIP PROJECT.—To qualify as
3 a social impact partnership project under this
4 subsection, a project must produce one or more
5 measurable, clearly defined outcomes that result
6 in social benefit and Federal, State, or local
7 savings through any of the following:

8 “(i) Increasing work and earnings by
9 individuals in the United States who are
10 unemployed for more than 6 consecutive
11 months.

12 “(ii) Increasing employment and earn-
13 ings of individuals who have attained 16
14 years of age but not 25 years of age.

15 “(iii) Increasing employment among
16 individuals receiving Federal disability ben-
17 efits.

18 “(iv) Reducing the dependence of low-
19 income families on Federal means-tested
20 benefits.

21 “(v) Improving rates of high school
22 graduation.

23 “(vi) Reducing teen and unplanned
24 pregnancies.

1 “(vii) Improving birth outcomes and
2 early childhood health and development
3 among low-income families and individuals.

4 “(viii) Reducing rates of asthma, dia-
5 betes, or other preventable diseases among
6 low-income families and individuals to re-
7 duce the utilization of emergency and other
8 high-cost care.

9 “(ix) Increasing the proportion of chil-
10 dren living in two-parent families.

11 “(x) Reducing incidences and adverse
12 consequences of child abuse and neglect.

13 “(xi) Reducing the number of youth
14 in foster care by increasing adoptions, per-
15 manent guardianship arrangements, reuni-
16 fications, or placements with a fit and will-
17 ing relative, or by avoiding placing children
18 in foster care by ensuring they can be
19 cared for safely in their own homes.

20 “(xii) Reducing the number of chil-
21 dren and youth in foster care residing in
22 group homes, child care institutions, agen-
23 cy-operated foster homes, or other non-
24 family foster homes, unless it is deter-
25 mined that it is in the interest of the

1 child's long-term health, safety, or psycho-
2 logical well-being to not be placed in a
3 family foster home.

4 “(xiii) Reducing the number of chil-
5 dren returning to foster care.

6 “(xiv) Reducing recidivism among ju-
7 venile offenders, individuals released from
8 prison, or other high-risk populations.

9 “(xv) Reducing the rate of homeless-
10 ness among our most vulnerable popu-
11 lations.

12 “(xvi) Improving the health and well-
13 being of those with mental, emotional, and
14 behavioral health needs.

15 “(xvii) Improving the educational out-
16 comes of special-needs or low-income chil-
17 dren.

18 “(xviii) Improving the employment
19 and well-being of returning United States
20 military members.

21 “(xix) Increasing the financial sta-
22 bility of low-income families.

23 “(xx) Increasing the independence and
24 employability of individuals who are phys-
25 ically or mentally disabled.

1 “(xxi) Other measurable outcomes de-
2 fined by the State or local government that
3 result in positive social outcomes and Fed-
4 eral savings.

5 “(C) APPLICATION REQUIRED.—The notice
6 described in subparagraph (A) shall require a
7 State or local government to submit an applica-
8 tion for the social impact partnership project
9 that addresses the following:

10 “(i) The outcome goals of the project.

11 “(ii) A description of each interven-
12 tion in the project and anticipated out-
13 comes of the intervention.

14 “(iii) Rigorous evidence demonstrating
15 that the intervention can be expected to
16 produce the desired outcomes.

17 “(iv) The target population that will
18 be served by the project.

19 “(v) The expected social benefits to
20 participants who receive the intervention
21 and others who may be impacted.

22 “(vi) Projected Federal, State, and
23 local government costs and other costs to
24 conduct the project.

1 “(vii) Projected Federal, State, and
2 local government savings and other sav-
3 ings, including an estimate of the savings
4 to the Federal Government, on a program-
5 by-program basis and in the aggregate, if
6 the project is implemented and the out-
7 comes are achieved as a result of the inter-
8 vention.

9 “(viii) If savings resulting from the
10 successful completion of the project are es-
11 timated to accrue to the State or local gov-
12 ernment, the likelihood of the State or
13 local government to realize those savings.

14 “(ix) A plan for delivering the inter-
15 vention through a social impact partner-
16 ship model.

17 “(x) A description of the expertise of
18 each service provider that will administer
19 the intervention, including a summary of
20 the experience of the service provider in
21 delivering the proposed intervention or a
22 similar intervention, or demonstrating that
23 the service provider has the expertise nec-
24 essary to deliver the proposed intervention.

1 “(xi) An explanation of the experience
2 of the State or local government, the inter-
3 mediary, or the service provider in raising
4 private and philanthropic capital to fund
5 social service investments.

6 “(xii) The detailed roles and respon-
7 sibilities of each entity involved in the
8 project, including any State or local gov-
9 ernment entity, intermediary, service pro-
10 vider, independent evaluator, investor, or
11 other stakeholder.

12 “(xiii) A summary of the experience of
13 the service provider in delivering the pro-
14 posed intervention or a similar interven-
15 tion, or a summary demonstrating the
16 service provider has the expertise necessary
17 to deliver the proposed intervention.

18 “(xiv) A summary of the unmet need
19 in the area where the intervention will be
20 delivered or among the target population
21 who will receive the intervention.

22 “(xv) The proposed payment terms,
23 the methodology used to calculate outcome
24 payments, the payment schedule, and per-
25 formance thresholds.

1 “(xvi) The project budget.

2 “(xvii) The project timeline.

3 “(xviii) The criteria used to determine
4 the eligibility of an individual for the
5 project, including how selected populations
6 will be identified, how they will be referred
7 to the project, and how they will be en-
8 rolled in the project.

9 “(xix) The evaluation design.

10 “(xx) The metrics that will be used in
11 the evaluation to determine whether the
12 outcomes have been achieved as a result of
13 the intervention and how the metrics will
14 be measured.

15 “(xxi) An explanation of how the
16 metrics used in the evaluation to determine
17 whether the outcomes achieved as a result
18 of the intervention are independent, objec-
19 tive indicators of impact and are not sub-
20 ject to manipulation by the service pro-
21 vider, intermediary, or investor.

22 “(xxii) A summary explaining the
23 independence of the evaluator from the
24 other entities involved in the project and
25 the evaluator’s experience in conducting

1 rigorous evaluations of program effective-
2 ness including, where available, well-imple-
3 mented randomized controlled trials on the
4 intervention or similar interventions.

5 “(xxiii) The capacity of the service
6 provider to deliver the intervention to the
7 number of participants the State or local
8 government proposes to serve in the
9 project.

10 “(xxiv) A description of whether and
11 how the State or local government and
12 service providers plan to sustain the inter-
13 vention, if it is timely and appropriate to
14 do so, to ensure that successful interven-
15 tions continue to operate after the period
16 of the social impact partnership.

17 “(D) PROJECT INTERMEDIARY INFORMA-
18 TION REQUIRED.—The application described in
19 subparagraph (C) shall also contain the fol-
20 lowing information about any intermediary for
21 the social impact partnership project (whether
22 an intermediary is a service provider or other
23 entity):

1 “(i) Experience and capacity for pro-
2 viding or facilitating the provision of the
3 type of intervention proposed.

4 “(ii) The mission and goals.

5 “(iii) Information on whether the
6 intermediary is already working with serv-
7 ice providers that provide this intervention
8 or an explanation of the capacity of the
9 intermediary to begin working with service
10 providers to provide the intervention.

11 “(iv) Experience working in a collabo-
12 rative environment across government and
13 nongovernmental entities.

14 “(v) Previous experience collaborating
15 with public or private entities to implement
16 evidence-based programs.

17 “(vi) Ability to raise or provide fund-
18 ing to cover operating costs (if applicable
19 to the project).

20 “(vii) Capacity and infrastructure to
21 track outcomes and measure results, in-
22 cluding—

23 “(I) capacity to track and ana-
24 lyze program performance and assess
25 program impact; and

1 “(II) experience with perform-
2 ance-based awards or performance-
3 based contracting and achieving
4 project milestones and targets.

5 “(viii) Role in delivering the interven-
6 tion.

7 “(ix) How the intermediary would
8 monitor program success, including a de-
9 scription of the interim benchmarks and
10 outcome measures.

11 “(E) FEASIBILITY STUDIES FUNDED
12 THROUGH OTHER SOURCES.—The notice de-
13 scribed in subparagraph (A) shall permit a
14 State or local government to submit an applica-
15 tion for social impact partnership funding that
16 contains information from a feasibility study
17 developed for purposes other than applying for
18 funding under this subsection.

19 “(3) AWARDING SOCIAL IMPACT PARTNERSHIP
20 AGREEMENTS.—

21 “(A) TIMELINE IN AWARDING AGREE-
22 MENT.—Not later than 6 months after receiving
23 an application in accordance with paragraph
24 (2), the Secretary, in consultation with the Fed-
25 eral Interagency Council on Social Impact Part-

1 nerships, shall determine whether to enter into
2 an agreement for a social impact partnership
3 project with a State or local government.

4 “(B) CONSIDERATIONS IN AWARDING
5 AGREEMENT.—In determining whether to enter
6 into an agreement for a social impact partner-
7 ship project (the application for which was sub-
8 mitted under paragraph (2)) the Secretary, in
9 consultation with the Federal Interagency
10 Council on Social Impact Partnerships (estab-
11 lished by paragraph (6)) and the head of any
12 Federal agency administering a similar inter-
13 vention or serving a population similar to that
14 served by the project, shall consider each of the
15 following:

16 “(i) The recommendations made by
17 the Commission on Social Impact Partner-
18 ships.

19 “(ii) The value to the Federal Govern-
20 ment of the outcomes expected to be
21 achieved if the outcomes specified in the
22 agreement are achieved as a result of the
23 intervention.

24 “(iii) The likelihood, based on evi-
25 dence provided in the application and other

1 evidence, that the State or local govern-
2 ment in collaboration with the inter-
3 mediary and the service providers will
4 achieve the outcomes.

5 “(iv) The savings to the Federal Gov-
6 ernment if the outcomes specified in the
7 agreement are achieved as a result of the
8 intervention.

9 “(v) The savings to the State and
10 local governments if the outcomes specified
11 in the agreement are achieved as a result
12 of the intervention.

13 “(vi) The expected quality of the eval-
14 uation that would be conducted with re-
15 spect to the agreement.

16 “(vii) The capacity and commitment
17 of the State or local government to sustain
18 the intervention, if appropriate and timely
19 and if the intervention is successful, be-
20 yond the period of the social impact part-
21 nership.

22 “(C) AGREEMENT AUTHORITY.—

23 “(i) AGREEMENT REQUIREMENTS.—

24 In accordance with this paragraph, the
25 Secretary, in consultation with the Federal

1 Interagency Council on Social Impact
2 Partnerships and the head of any Federal
3 agency administering a similar intervention
4 or serving a population similar to that
5 served by the project, may enter into an
6 agreement for a social impact partnership
7 project with a State or local government if
8 the Secretary, in consultation with the
9 Federal Interagency Council on Social Im-
10 pact Partnerships, determines that each of
11 the following requirements are met:

12 “(I) The State or local govern-
13 ment agrees to achieve one or more
14 outcomes as a result of the interven-
15 tion, as specified in the agreement
16 and validated by independent evalua-
17 tion, in order to receive payment.

18 “(II) The Federal payment to the
19 State or local government for each
20 specified outcome achieved as a result
21 of the intervention is less than or
22 equal to the value of the outcome to
23 the Federal Government over a period
24 not to exceed 10 years, as determined

1 by the Secretary, in consultation with
2 the State or local government.

3 “(III) The duration of the
4 project does not exceed 10 years.

5 “(IV) The State or local govern-
6 ment has demonstrated, through the
7 application submitted under para-
8 graph (2), that, based on prior rig-
9 orous experimental evaluations or rig-
10 orous quasi-experimental studies, the
11 intervention can be expected to
12 achieve each outcome specified in the
13 agreement.

14 “(V) The State, local govern-
15 ment, intermediary, or service pro-
16 vider has experience raising private or
17 philanthropic capital to fund social
18 service investments (if applicable to
19 the project).

20 “(VI) The State or local govern-
21 ment has shown that each service pro-
22 vider has experience delivering the
23 intervention, a similar intervention, or
24 has otherwise demonstrated the exper-

1 tise necessary to deliver the interven-
2 tion.

3 “(ii) PAYMENT.—The Secretary shall
4 pay the State or local government only if
5 the independent evaluator described in
6 paragraph (5) determines that the social
7 impact partnership project has met the re-
8 quirements specified in the agreement and
9 achieved an outcome as a result of the
10 intervention, as specified in the agreement
11 and validated by independent evaluation.

12 “(D) NOTICE OF AGREEMENT AWARD.—
13 Not later than 30 days after entering into an
14 agreement under this paragraph, the Secretary
15 shall publish a notice in the Federal Register
16 that includes, with regard to the agreement, the
17 following:

18 “(i) The outcome goals of the social
19 impact partnership project.

20 “(ii) A description of each interven-
21 tion in the project.

22 “(iii) The target population that will
23 be served by the project.

1 “(iv) The expected social benefits to
2 participants who receive the intervention
3 and others who may be impacted.

4 “(v) The detailed roles, responsibil-
5 ities, and purposes of each Federal, State,
6 or local government entity, intermediary,
7 service provider, independent evaluator, in-
8 vestor, or other stakeholder.

9 “(vi) The payment terms, the method-
10 ology used to calculate outcome payments,
11 the payment schedule, and performance
12 thresholds.

13 “(vii) The project budget.

14 “(viii) The project timeline.

15 “(ix) The project eligibility criteria.

16 “(x) The evaluation design.

17 “(xi) The metrics that will be used in
18 the evaluation to determine whether the
19 outcomes have been achieved as a result of
20 each intervention and how these metrics
21 will be measured.

22 “(xii) The estimate of the savings to
23 the Federal, State, and local government,
24 on a program-by-program basis and in the
25 aggregate, if the agreement is entered into

1 and implemented and the outcomes are
2 achieved as a result of each intervention.

3 “(E) AUTHORITY TO TRANSFER ADMINIS-
4 TRATION OF AGREEMENT.—The Secretary may
5 transfer to the head of another Federal agency
6 the authority to administer (including making
7 payments under) an agreement entered into
8 under subparagraph (C), and any funds nec-
9 essary to do so.

10 “(F) REQUIREMENT ON FUNDING USED TO
11 BENEFIT CHILDREN.—Not less than 50 percent
12 of all Federal payments made to carry out
13 agreements under this paragraph shall be used
14 for initiatives that directly benefit children.

15 “(4) FEASIBILITY STUDY FUNDING.—

16 “(A) REQUESTS FOR FUNDING FOR FEASI-
17 BILITY STUDIES.—The Secretary shall reserve a
18 portion of the amount reserved to carry out this
19 subsection to assist States or local governments
20 in developing feasibility studies to apply for so-
21 cial impact partnership funding under para-
22 graph (2). To be eligible to receive funding to
23 assist with completing a feasibility study, a
24 State or local government shall submit an appli-

1 cation for feasibility study funding addressing
2 the following:

3 “(i) A description of the outcome
4 goals of the social impact partnership
5 project.

6 “(ii) A description of the intervention,
7 including anticipated program design, tar-
8 get population, an estimate regarding the
9 number of individuals to be served, and
10 setting for the intervention.

11 “(iii) Evidence to support the likeli-
12 hood that the intervention will produce the
13 desired outcomes.

14 “(iv) A description of the potential
15 metrics to be used.

16 “(v) The expected social benefits to
17 participants who receive the intervention
18 and others who may be impacted.

19 “(vi) Estimated costs to conduct the
20 project.

21 “(vii) Estimates of Federal, State,
22 and local government savings and other
23 savings if the project is implemented and
24 the outcomes are achieved as a result of
25 each intervention.

1 “(viii) An estimated timeline for im-
2 plementation and completion of the
3 project, which shall not exceed 10 years.

4 “(ix) With respect to a project for
5 which the State or local government selects
6 an intermediary to operate the project, any
7 partnerships needed to successfully execute
8 the project and the ability of the inter-
9 mediary to foster the partnerships.

10 “(x) The expected resources needed to
11 complete the feasibility study for the State
12 or local government to apply for social im-
13 pact partnership funding under paragraph
14 (2).

15 “(B) FEDERAL SELECTION OF APPLICA-
16 TIONS FOR FEASIBILITY STUDY.—Not later
17 than 6 months after receiving an application for
18 feasibility study funding under subparagraph
19 (A), the Secretary, in consultation with the
20 Federal Interagency Council on Social Impact
21 Partnerships and the head of any Federal agen-
22 cy administering a similar intervention or serv-
23 ing a population similar to that served by the
24 project, shall select State or local government

1 feasibility study proposals for funding based on
2 the following:

3 “(i) The recommendations made by
4 the Commission on Social Impact Partner-
5 ships.

6 “(ii) The likelihood that the proposal
7 will achieve the desired outcomes.

8 “(iii) The value of the outcomes ex-
9 pected to be achieved as a result of each
10 intervention.

11 “(iv) The potential savings to the
12 Federal Government if the social impact
13 partnership project is successful.

14 “(v) The potential savings to the
15 State and local governments if the project
16 is successful.

17 “(C) PUBLIC DISCLOSURE.—Not later
18 than 30 days after selecting a State or local
19 government for feasibility study funding under
20 this paragraph, the Secretary shall cause to be
21 published on the website of the Federal Inter-
22 agency Council on Social Impact Partnerships
23 information explaining why a State or local gov-
24 ernment was granted feasibility study funding.

25 “(D) FUNDING RESTRICTION.—

1 “(i) FEASIBILITY STUDY RESTRIC-
2 TION.—The Secretary may not provide fea-
3 sibility study funding under this paragraph
4 for more than 50 percent of the estimated
5 total cost of the feasibility study reported
6 in the State or local government applica-
7 tion submitted under subparagraph (A).

8 “(ii) AGGREGATE RESTRICTION.—Of
9 the total amount reserved to carry out this
10 subsection, the Secretary may not use
11 more than \$10,000,000 to provide feasi-
12 bility study funding to States or local gov-
13 ernments under this paragraph.

14 “(iii) NO GUARANTEE OF FUNDING.—
15 The Secretary shall have the option to
16 award no funding under this paragraph.

17 “(E) SUBMISSION OF FEASIBILITY STUDY
18 REQUIRED.—Not later than 9 months after the
19 receipt of feasibility study funding under this
20 paragraph, a State or local government receiv-
21 ing the funding shall complete the feasibility
22 study and submit the study to the Federal
23 Interagency Council on Social Impact Partner-
24 ships.

1 “(F) DELEGATION OF AUTHORITY.—The
2 Secretary may transfer to the head of another
3 Federal agency the authorities provided in this
4 paragraph and any funds necessary to exercise
5 the authorities.

6 “(5) EVALUATIONS.—

7 “(A) AUTHORITY TO ENTER INTO AGREE-
8 MENTS.—For each State or local government
9 awarded a social impact partnership project ap-
10 proved by the Secretary under this subsection,
11 the head of the relevant agency, as rec-
12 ommended by the Federal Interagency Council
13 on Social Impact Partnerships and determined
14 by the Secretary, shall enter into an agreement
15 with the State or local government to pay for
16 all or part of the independent evaluation to de-
17 termine whether the State or local government
18 project has achieved a specific outcome as a re-
19 sult of the intervention in order for the State
20 or local government to receive outcome pay-
21 ments under this subsection.

22 “(B) EVALUATOR QUALIFICATIONS.—The
23 head of the relevant agency may not enter into
24 an agreement with a State or local government
25 unless the head determines that the evaluator is

1 independent of the other parties to the agree-
2 ment and has demonstrated substantial experi-
3 ence in conducting rigorous evaluations of pro-
4 gram effectiveness including, where available
5 and appropriate, well-implemented randomized
6 controlled trials on the intervention or similar
7 interventions.

8 “(C) **METHODOLOGIES TO BE USED.**—The
9 evaluation used to determine whether a State or
10 local government will receive outcome payments
11 under this subsection shall use experimental de-
12 signs using random assignment or other reli-
13 able, evidence-based research methodologies, as
14 certified by the Federal Interagency Council on
15 Social Impact Partnerships, that allow for the
16 strongest possible causal inferences when ran-
17 dom assignment is not feasible.

18 “(D) **PROGRESS REPORT.**—

19 “(i) **SUBMISSION OF REPORT.**—The
20 independent evaluator shall—

21 “(I) not later than 2 years after
22 a project has been approved by the
23 Secretary and biannually thereafter
24 until the project is concluded, submit
25 to the head of the relevant agency and

1 the Federal Interagency Council on
2 Social Impact Partnerships a written
3 report summarizing the progress that
4 has been made in achieving each out-
5 come specified in the agreement; and

6 “(II) before the scheduled time of
7 the first outcome payment and before
8 the scheduled time of each subsequent
9 payment, submit to the head of the
10 relevant agency and the Federal
11 Interagency Council on Social Impact
12 Partnerships a written report that in-
13 cludes the results of the evaluation
14 conducted to determine whether an
15 outcome payment should be made
16 along with information on the unique
17 factors that contributed to achieving
18 or failing to achieve the outcome, the
19 challenges faced in attempting to
20 achieve the outcome, and information
21 on the improved future delivery of this
22 or similar interventions.

23 “(ii) SUBMISSION TO THE SECRETARY
24 AND CONGRESS.—Not later than 30 days
25 after receipt of the written report pursuant

1 to clause (i)(II), the Federal Interagency
2 Council on Social Impact Partnerships
3 shall submit the report to the Secretary
4 and each committee of jurisdiction in the
5 House of Representatives and the Senate.

6 “(E) FINAL REPORT.—

7 “(i) SUBMISSION OF REPORT.—Within
8 6 months after the social impact partner-
9 ship project is completed, the independent
10 evaluator shall—

11 “(I) evaluate the effects of the
12 activities undertaken pursuant to the
13 agreement with regard to each out-
14 come specified in the agreement; and

15 “(II) submit to the head of the
16 relevant agency and the Federal
17 Interagency Council on Social Impact
18 Partnerships a written report that in-
19 cludes the results of the evaluation
20 and the conclusion of the evaluator as
21 to whether the State or local govern-
22 ment has fulfilled each obligation of
23 the agreement, along with information
24 on the unique factors that contributed
25 to the success or failure of the project,

1 the challenges faced in attempting to
2 achieve the outcome, and information
3 on the improved future delivery of this
4 or similar interventions.

5 “(ii) SUBMISSION TO THE SECRETARY
6 AND CONGRESS.—Not later than 30 days
7 after receipt of the written report pursuant
8 to clause (i)(II), the Federal Interagency
9 Council on Social Impact Partnerships
10 shall submit the report to the Secretary
11 and each committee of jurisdiction in the
12 House of Representatives and the Senate.

13 “(F) LIMITATION ON COST OF EVALUA-
14 TIONS.—Of the amount reserved under this
15 subsection for social impact partnership
16 projects, the Secretary may not obligate more
17 than 15 percent to evaluate the implementation
18 and outcomes of the projects.

19 “(G) DELEGATION OF AUTHORITY.—The
20 Secretary may transfer to the head of another
21 Federal agency the authorities provided in this
22 paragraph and any funds necessary to exercise
23 the authorities.

24 “(6) FEDERAL INTERAGENCY COUNCIL ON SO-
25 CIAL IMPACT PARTNERSHIPS.—

1 “(A) ESTABLISHMENT.—There is estab-
2 lished the Federal Interagency Council on So-
3 cial Impact Partnerships (in this paragraph re-
4 ferred to as the ‘Council’) to—

5 “(i) coordinate with the Secretary on
6 the efforts of social impact partnership
7 projects funded under this subsection;

8 “(ii) advise and assist the Secretary in
9 the development and implementation of the
10 projects;

11 “(iii) advise the Secretary on specific
12 programmatic and policy matter related to
13 the projects;

14 “(iv) provide subject-matter expertise
15 to the Secretary with regard to the
16 projects;

17 “(v) certify to the Secretary that each
18 State or local government that has entered
19 into an agreement with the Secretary for a
20 social impact partnership project under
21 this subsection and each evaluator selected
22 by the head of the relevant agency under
23 paragraph (5) has access to Federal ad-
24 ministrative data to assist the State or
25 local government and the evaluator in eval-

1 uating the performance and outcomes of
2 the project;

3 “(vi) address issues that will influence
4 the future of social impact partnership
5 projects in the United States;

6 “(vii) provide guidance to the execu-
7 tive branch on the future of social impact
8 partnership projects in the United States;

9 “(viii) prior to approval by the Sec-
10 retary, certify that each State and local
11 government application for a social impact
12 partnership contains rigorous, independent
13 data and reliable, evidence-based research
14 methodologies to support the conclusion
15 that the project will yield savings to the
16 State or local government or the Federal
17 Government if the project outcomes are
18 achieved;

19 “(ix) certify to the Secretary, in the
20 case of each approved social impact part-
21 nership that is expected to yield savings to
22 the Federal Government, that the project
23 will yield a projected savings to the Fed-
24 eral Government if the project outcomes
25 are achieved, and coordinate with the rel-

1 evant Federal agency to produce an after-
2 action accounting once the project is com-
3 plete to determine the actual Federal sav-
4 ings realized, and the extent to which ac-
5 tual savings aligned with projected savings;
6 and

7 “(x) provide periodic reports to the
8 Secretary and make available reports peri-
9 odically to Congress and the public on the
10 implementation of this subsection.

11 “(B) COMPOSITION OF COUNCIL.—The
12 Council shall have 11 members, as follows:

13 “(i) CHAIR.—The Chair of the Coun-
14 cil shall be the Director of the Office of
15 Management and Budget.

16 “(ii) OTHER MEMBERS.—The head of
17 each of the following entities shall des-
18 ignate one officer or employee of the entity
19 to be a Council member:

20 “(I) The Department of Labor.

21 “(II) The Department of Health
22 and Human Services.

23 “(III) The Social Security Ad-
24 ministration.

1 “(IV) The Department of Agri-
2 culture.

3 “(V) The Department of Justice.

4 “(VI) The Department of Hous-
5 ing and Urban Development.

6 “(VII) The Department of Edu-
7 cation.

8 “(VIII) The Department of Vet-
9 erans Affairs.

10 “(IX) The Department of the
11 Treasury.

12 “(X) The Corporation for Na-
13 tional and Community Service.

14 “(7) COMMISSION ON SOCIAL IMPACT PARTNER-
15 SHIPS.—

16 “(A) ESTABLISHMENT.—There is estab-
17 lished the Commission on Social Impact Part-
18 nerships (in this paragraph referred to as the
19 ‘Commission’).

20 “(B) DUTIES.—The duties of the Commis-
21 sion shall be to—

22 “(i) assist the Secretary and the Fed-
23 eral Interagency Council on Social Impact
24 Partnerships in reviewing applications for
25 funding under this subsection;

1 “(ii) make recommendations to the
2 Secretary and the Federal Interagency
3 Council on Social Impact Partnerships re-
4 garding the funding of social impact part-
5 nership agreements and feasibility studies;
6 and

7 “(iii) provide other assistance and in-
8 formation as requested by the Secretary or
9 the Federal Interagency Council on Social
10 Impact Partnerships.

11 “(C) COMPOSITION.—The Commission
12 shall be composed of nine members, of whom—

13 “(i) one shall be appointed by the
14 President, who will serve as the Chair of
15 the Commission;

16 “(ii) one shall be appointed by the
17 Majority Leader of the Senate;

18 “(iii) one shall be appointed by the
19 Minority Leader of the Senate;

20 “(iv) one shall be appointed by the
21 Speaker of the House of Representatives;

22 “(v) one shall be appointed by the Mi-
23 nority Leader of the House of Representa-
24 tives;

1 “(vi) one shall be appointed by the
2 Chairman of the Committee on Finance of
3 the Senate;

4 “(vii) one shall be appointed by the
5 ranking member of the Committee on Fi-
6 nance of the Senate;

7 “(viii) one member shall be appointed
8 by the Chairman of the Committee on
9 Ways and Means of the House of Rep-
10 resentatives; and

11 “(ix) one shall be appointed by the
12 ranking member of the Committee on
13 Ways and Means of the House of Rep-
14 resentatives.

15 “(D) QUALIFICATIONS OF COMMISSION
16 MEMBERS.—The members of the Commission
17 shall—

18 “(i) be experienced in finance, eco-
19 nomics, pay for performance, or program
20 evaluation;

21 “(ii) have relevant professional or per-
22 sonal experience in a field related to one or
23 more of the outcomes listed in this sub-
24 section; or

1 “(iii) be qualified to review applica-
2 tions for social impact partnership projects
3 to determine whether the proposed metrics
4 and evaluation methodologies are appro-
5 priately rigorous and reliant upon inde-
6 pendent data and evidence-based research.

7 “(E) TIMING OF APPOINTMENTS.—The ap-
8 pointments of the members of the Commission
9 shall be made not later than 120 days after the
10 date of the enactment of this subsection, or, in
11 the event of a vacancy, not later than 90 days
12 after the date the vacancy arises. If a member
13 of Congress fails to appoint a member by that
14 date, the President may select a member of the
15 President’s choice on behalf of the member of
16 Congress. Notwithstanding the preceding sen-
17 tence, if not all appointments have been made
18 to the Commission as of that date, the Commis-
19 sion may operate with no fewer than five mem-
20 bers until all appointments have been made.

21 “(F) TERM OF APPOINTMENTS.—

22 “(i) IN GENERAL.—The members ap-
23 pointed under subparagraph (C) shall serve
24 as follows:

1 “(I) Three members shall serve
2 for 2 years.

3 “(II) Three members shall serve
4 for 3 years.

5 “(III) Three members (one of
6 which shall be Chair of the Commis-
7 sion appointed by the President) shall
8 serve for 4 years.

9 “(ii) ASSIGNMENT OF TERMS.—The
10 Commission shall designate the term
11 length that each member appointed under
12 subparagraph (C) shall serve by unani-
13 mous agreement. In the event that unani-
14 mous agreement cannot be reached, term
15 lengths shall be assigned to the members
16 by a random process.

17 “(G) VACANCIES.—Subject to subpara-
18 graph (E), in the event of a vacancy in the
19 Commission, whether due to the resignation of
20 a member, the expiration of a member’s term,
21 or any other reason, the vacancy shall be filled
22 in the manner in which the original appoint-
23 ment was made and shall not affect the powers
24 of the Commission.

1 “(H) APPOINTMENT POWER.—Members of
2 the Commission appointed under subparagraph
3 (C) shall not be subject to confirmation by the
4 Senate.

5 “(8) LIMITATION ON USE OF FUNDS.—Of the
6 amounts reserved to carry out this subsection, the
7 Secretary may not use more than \$2,000,000 in any
8 fiscal year to support the review, approval, and over-
9 sight of social impact partnership projects, including
10 activities conducted by—

11 “(A) the Federal Interagency Council on
12 Social Impact Partnerships; and

13 “(B) any other agency consulted by the
14 Secretary before approving a social impact part-
15 nership project or a feasibility study under
16 paragraph (4).

17 “(9) NO FEDERAL FUNDING FOR CREDIT EN-
18 HANCEMENTS.—No amount reserved to carry out
19 this subsection may be used to provide any insur-
20 ance, guarantee, or other credit enhancement to a
21 State or local government under which a Federal
22 payment would be made to a State or local govern-
23 ment as the result of a State or local government
24 failing to achieve an outcome specified in a contract.

1 “(10) AVAILABILITY OF FUNDS.—Amounts re-
2 served to carry out this subsection shall remain
3 available until 10 years after the date of the enact-
4 ment of this subsection.

5 “(11) WEBSITE.—The Federal Interagency
6 Council on Social Impact Partnerships shall estab-
7 lish and maintain a public website that shall display
8 the following:

9 “(A) A copy of, or method of accessing,
10 each notice published regarding a social impact
11 partnership project pursuant to this subsection.

12 “(B) A copy of each feasibility study fund-
13 ed under this subsection.

14 “(C) For each State or local government
15 that has entered into an agreement with the
16 Secretary for a social impact partnership
17 project, the website shall contain the following
18 information:

19 “(i) The outcome goals of the project.

20 “(ii) A description of each interven-
21 tion in the project.

22 “(iii) The target population that will
23 be served by the project.

1 “(iv) The expected social benefits to
2 participants who receive the intervention
3 and others who may be impacted.

4 “(v) The detailed roles, responsibil-
5 ities, and purposes of each Federal, State,
6 or local government entity, intermediary,
7 service provider, independent evaluator, in-
8 vestor, or other stakeholder.

9 “(vi) The payment terms, method-
10 ology used to calculate outcome payments,
11 the payment schedule, and performance
12 thresholds.

13 “(vii) The project budget.

14 “(viii) The project timeline.

15 “(ix) The project eligibility criteria.

16 “(x) The evaluation design.

17 “(xi) The metrics used to determine
18 whether the proposed outcomes have been
19 achieved and how these metrics are meas-
20 ured.

21 “(D) A copy of the progress reports and
22 the final reports relating to each social impact
23 partnership project.

24 “(E) An estimate of the savings to the
25 Federal, State, and local government, on a pro-

1 gram-by-program basis and in the aggregate,
2 resulting from the successful completion of the
3 social impact partnership project.

4 “(12) REGULATIONS.—The Secretary, in con-
5 sultation with the Federal Interagency Council on
6 Social Impact Partnerships, may issue regulations as
7 necessary to carry out this subsection.

8 “(13) DEFINITIONS.—In this subsection:

9 “(A) AGENCY.—The term ‘agency’ has the
10 meaning given that term in section 551 of title
11 5, United States Code.

12 “(B) INTERVENTION.—The term ‘interven-
13 tion’ means a specific service delivered to
14 achieve an impact through a social impact part-
15 nership project.

16 “(C) SECRETARY.—The term ‘Secretary’
17 means the Secretary of the Treasury.

18 “(D) SOCIAL IMPACT PARTNERSHIP
19 PROJECT.—The term ‘social impact partnership
20 project’ means a project that finances social
21 services using a social impact partnership
22 model.

23 “(E) SOCIAL IMPACT PARTNERSHIP
24 MODEL.—The term ‘social impact partnership

1 model' means a method of financing social serv-
2 ices in which—

3 “(i) Federal funds are awarded to a
4 State or local government only if a State
5 or local government achieves certain out-
6 comes agreed on by the State or local gov-
7 ernment and the Secretary; and

8 “(ii) the State or local government co-
9 ordinates with service providers, investors
10 (if applicable to the project), and (if nec-
11 essary) an intermediary to identify—

12 “(I) an intervention expected to
13 produce the outcome;

14 “(II) a service provider to deliver
15 the intervention to the target popu-
16 lation; and

17 “(III) investors to fund the deliv-
18 ery of the intervention.

19 “(F) STATE.—The term ‘State’ means
20 each State of the United States, the District of
21 Columbia, each commonwealth, territory or pos-
22 session of the United States, and each federally
23 recognized Indian tribe.

24 “(14) FUNDING.—Of the amounts made avail-
25 able to carry out subsection (b) for fiscal year 2017,

1 the Secretary shall reserve \$100,000,000 to carry
2 out this subsection.”.

3 **SEC. 25003. EXTENSION OF TANF PROGRAM.**

4 (a) FAMILY ASSISTANCE GRANTS.—Section
5 403(a)(1) of the Social Security Act (42 U.S.C. 603(a)(1))
6 is amended in each of subparagraphs (A) and (C), by
7 striking “2012” and inserting “2017”.

8 (b) HEALTHY MARRIAGE PROMOTION AND RESPON-
9 SIBLE FATHERHOOD GRANTS.—Section 403(a)(2)(D) of
10 such Act (42 U.S.C. 603(a)(2)(D)) is amended by striking
11 “2012” each place it appears and inserting “2017”.

12 (c) TRIBAL GRANTS.—Section 412(a) of such Act (42
13 U.S.C. 612(a)) is amended in each of paragraphs (1)(A)
14 and (2)(A) by striking “2012” and inserting “2017”.

15 (d) CHILD CARE ENTITLEMENT.—Section 418(a)(3)
16 of such Act (42 U.S.C. 618(a)(3)) is amended by striking
17 “2012” and inserting “2017”.

18 (e) GRANTS TO THE TERRITORIES.—Section
19 1108(b)(2) of such Act (42 U.S.C. 1308(b)(2)) is amend-
20 ed by striking “2012” and inserting “2017”.

21 **SEC. 25004. STRENGTHENING WELFARE RESEARCH AND**
22 **EVALUATION AND DEVELOPMENT OF A WHAT**
23 **WORKS CLEARINGHOUSE.**

24 (a) IN GENERAL.—Section 413 of the Social Security
25 Act (42 U.S.C. 613) is amended to read as follows:

1 **“SEC. 413. EVALUATION OF TEMPORARY ASSISTANCE FOR**
2 **NEEDY FAMILIES AND RELATED PROGRAMS.**

3 “(a) **EVALUATION OF THE IMPACTS OF TANF.**—The
4 Secretary shall conduct research on the effect of State pro-
5 grams funded under this part and any other State pro-
6 gram funded with qualified State expenditures (as defined
7 in section 409(a)(7)(B)(i)) on employment, self-suffi-
8 ciency, child well-being, unmarried births, marriage, pov-
9 erty, economic mobility, and other factors as determined
10 by the Secretary.

11 “(b) **EVALUATION OF GRANTS TO IMPROVE CHILD**
12 **WELL-BEING BY PROMOTING HEALTHY MARRIAGE AND**
13 **RESPONSIBLE FATHERHOOD.**—The Secretary shall con-
14 duct research to determine the effects of the grants made
15 under section 403(a)(2) on child well-being, marriage,
16 family stability, economic mobility, poverty, and other fac-
17 tors as determined by the Secretary.

18 “(c) **DISSEMINATION OF INFORMATION.**—The Sec-
19 retary shall, in consultation with States receiving funds
20 provided under this part, develop methods of dissemi-
21 nating information on any research, evaluation, or study
22 conducted under this section, including facilitating the
23 sharing of information and best practices among States
24 and localities.

25 “(d) **STATE-INITIATED EVALUATIONS.**—A State
26 shall be eligible to receive funding to evaluate the State

1 program funded under this part or any other State pro-
2 gram funded with qualified State expenditures (as defined
3 in section 409(a)(7)(B)(i)) if—

4 “(1) the State submits to the Secretary a de-
5 scription of the proposed evaluation;

6 “(2) the Secretary determines that the design
7 and approach of the proposed evaluation is rigorous
8 and is likely to yield information that is credible and
9 will be useful to other States; and

10 “(3) unless waived by the Secretary, the State
11 contributes to the cost of the evaluation, from non-
12 Federal sources, an amount equal to at least 25 per-
13 cent of the cost of the proposed evaluation.

14 “(e) CENSUS BUREAU RESEARCH.—

15 “(1) The Bureau of the Census shall implement
16 or enhance household surveys of program participa-
17 tion, in consultation with the Secretary and the Bu-
18 reau of Labor Statistics and made available to inter-
19 ested parties, to allow for the assessment of the out-
20 comes of continued welfare reform on the economic
21 and child well-being of low-income families with chil-
22 dren, including those who received assistance or
23 services from a State program funded under this
24 part or any other State program funded with quali-
25 fied State expenditures (as defined in section

1 409(a)(7)(B)(i)). The content of the surveys should
2 include such information as may be necessary to ex-
3 amine the issues of unmarried childbearing, mar-
4 riage, welfare dependency and compliance with work
5 requirements, the beginning and ending of spells of
6 assistance, work, earnings and employment stability,
7 and the well-being of children.

8 “(2) To carry out the activities specified in
9 paragraph (1), the Bureau of the Census, the Sec-
10 retary, and the Bureau of Labor Statistics shall con-
11 sider ways to improve the surveys and data derived
12 from the surveys to—

13 “(A) address under reporting of the receipt
14 of means-tested benefits and tax benefits for
15 low-income individuals and families;

16 “(B) increase understanding of poverty
17 spells and long-term poverty, including by facili-
18 tating the matching of information to better un-
19 derstand intergenerational poverty;

20 “(C) generate a better geographical under-
21 standing of poverty such as through State-
22 based estimates and measures of neighborhood
23 poverty;

24 “(D) increase understanding of the effects
25 of means-tested benefits and tax benefits on the

1 earnings and incomes of low-income families;
2 and

3 “(E) improve how poverty and economic
4 well-being are measured, including through the
5 use of consumption measures, material depriva-
6 tion measures, social exclusion measures, and
7 economic and social mobility measures.

8 “(f) RESEARCH AND EVALUATION CONDUCTED
9 UNDER THIS SECTION.—Research and evaluation con-
10 ducted under this section designed to determine the effects
11 of a program or policy (other than research conducted
12 under subsection (e)) shall use experimental designs using
13 random assignment or other reliable, evidence-based re-
14 search methodologies that allow for the strongest possible
15 causal inferences when random assignment is not feasible.

16 “(g) DEVELOPMENT OF WHAT WORKS CLEARING-
17 HOUSE OF PROVEN AND PROMISING APPROACHES TO
18 MOVE WELFARE RECIPIENTS INTO WORK.—

19 “(1) IN GENERAL.—The Secretary, in consulta-
20 tion with the Secretary of Labor, shall develop a
21 database (which shall be referred to as the ‘What
22 Works Clearinghouse of Proven and Promising
23 Projects to Move Welfare Recipients into Work’) of
24 the projects that used a proven approach or a prom-
25 ising approach in moving welfare recipients into

1 work, based on independent, rigorous evaluations of
2 the projects. The database shall include a separate
3 listing of projects that used a developmental ap-
4 proach in delivering services and a further separate
5 listing of the projects with no or negative effects.
6 The Secretary shall add to the What Works Clear-
7 ingshouse of Proven and Promising Projects to Move
8 Welfare Recipients into Work data about the
9 projects that, based on an independent, well-con-
10 ducted experimental evaluation of a program or
11 project, using random assignment or other research
12 methodologies that allow for the strongest possible
13 causal inferences, have shown they are proven,
14 promising, developmental, or ineffective approaches.

15 “(2) CRITERIA FOR EVIDENCE OF EFFECTIVE-
16 NESS OF APPROACH.—The Secretary, in consultation
17 with the Secretary of Labor and organizations with
18 experience in evaluating research on the effective-
19 ness of various approaches in delivering services to
20 move welfare recipients into work, shall—

21 “(A) establish criteria for evidence of effec-
22 tiveness; and

23 “(B) ensure that the process for estab-
24 lishing the criteria—

25 “(i) is transparent;

1 “(ii) is consistent across agencies;

2 “(iii) provides opportunity for public
3 comment; and

4 “(iv) takes into account efforts of
5 Federal agencies to identify and publicize
6 effective interventions, including efforts at
7 the Department of Health and Human
8 Services, the Department of Education,
9 and the Department of Justice.

10 “(3) DEFINITIONS.—In this subsection:

11 “(A) APPROACH.—The term ‘approach’
12 means a process, product, strategy, or practice
13 that is—

14 “(i) research-based, based on the re-
15 sults of one or more empirical studies, and
16 linked to program-determined outcomes;
17 and

18 “(ii) evaluated using rigorous research
19 designs.

20 “(B) PROVEN APPROACH.—The term
21 ‘proven approach’ means an approach that—

22 “(i) meets the requirements of a
23 promising approach; and

24 “(ii) has demonstrated significant and
25 substantively important positive outcomes

1 at more than one site in terms of increas-
2 ing work and earnings of participants, re-
3 ducing poverty and dependence, improving
4 child well-being, or strengthening families.

5 “(C) PROMISING APPROACH.—The term
6 ‘promising approach’ means an approach—

7 “(i) that meets the requirements of
8 subparagraph (D)(i);

9 “(ii) that has been evaluated using
10 well-designed and rigorous randomized
11 controlled trials (or, if not available, rig-
12 orous quasi-experimental research designs);

13 “(iii) that has demonstrated signifi-
14 cant and substantively important positive
15 outcomes at one site in terms of increasing
16 work and earnings of participants, reduc-
17 ing poverty and dependence, improving
18 child well-being, or strengthening families;
19 and

20 “(iv) under which the benefits of the
21 positive outcomes have exceeded the costs
22 of achieving the outcomes.

23 “(D) DEVELOPMENTAL APPROACH.—The
24 term ‘developmental approach’ means an ap-
25 proach that—

1 “(i) is research-based, grounded in
2 relevant empirically-based knowledge, and
3 linked to program-determined outcomes;

4 “(ii) is evaluated using rigorous re-
5 search designs; and

6 “(iii) has yet to demonstrate a signifi-
7 cant positive outcome in terms of increas-
8 ing work and earnings of participants in a
9 cost-effective way.

10 “(h) APPROPRIATION.—

11 “(1) IN GENERAL.—Of the amount appro-
12 priated by section 403(a)(1) for each fiscal year,
13 0.33 percent shall be available for research, technical
14 assistance, and evaluation under this section.

15 “(2) ALLOCATION.—Of the amount made avail-
16 able under paragraph (1) for each fiscal year, the
17 Secretary shall make available \$10,000,000 plus
18 such additional amount as the Secretary deems nec-
19 essary and appropriate, to carry out subsection
20 (e).”.

21 (b) CONFORMING AMENDMENT.—Section
22 403(a)(1)(B) of such Act (42 U.S.C. 603(a)(1)(B)) is
23 amended by inserting “, reduced by the percentage speci-
24 fied in section 413(h) with respect to the fiscal year,” be-
25 fore “as the amount”.

1 **SEC. 25005. TECHNICAL CORRECTIONS TO DATA EXCHANGE**
2 **STANDARDS TO IMPROVE PROGRAM COORDI-**
3 **NATION.**

4 (a) IN GENERAL.—Section 411(d) of the Social Secu-
5 rity Act (42 U.S.C. 611(d)) is amended to read as follows:

6 “(d) DATA EXCHANGE STANDARDS FOR IMPROVED
7 INTEROPERABILITY.—

8 “(1) DESIGNATION.—The Secretary shall, in
9 consultation with an interagency work group estab-
10 lished by the Office of Management and Budget and
11 considering State government perspectives, by rule,
12 designate data exchange standards to govern, under
13 this part—

14 “(A) necessary categories of information
15 that State agencies operating programs under
16 State plans approved under this part are re-
17 quired under applicable Federal law to elec-
18 tronically exchange with another State agency;
19 and

20 “(B) Federal reporting and data exchange
21 required under applicable Federal law.

22 “(2) REQUIREMENTS.—The data exchange
23 standards required by paragraph (1) shall, to the ex-
24 tent practicable—

1 “(A) incorporate a widely accepted, non-
2 proprietary, searchable, computer-readable for-
3 mat, such as the eXtensible Markup Language;

4 “(B) contain interoperable standards devel-
5 oped and maintained by intergovernmental
6 partnerships, such as the National Information
7 Exchange Model;

8 “(C) incorporate interoperable standards
9 developed and maintained by Federal entities
10 with authority over contracting and financial
11 assistance;

12 “(D) be consistent with and implement ap-
13 plicable accounting principles;

14 “(E) be implemented in a manner that is
15 cost-effective and improves program efficiency
16 and effectiveness; and

17 “(F) be capable of being continually up-
18 graded as necessary.

19 “(3) RULE OF CONSTRUCTION.—Nothing in
20 this subsection shall be construed to require a
21 change to existing data exchange standards found to
22 be effective and efficient.”.

23 (b) EFFECTIVE DATE.—Not later than the date that
24 is 24 months after the date of the enactment of this sec-

1 tion, the Secretary of Health and Human Services shall
2 issue a proposed rule that—

3 (1) identifies federally required data exchanges,
4 include specification and timing of exchanges to be
5 standardized, and address the factors used in deter-
6 mining whether and when to standardize data ex-
7 changes; and

8 (2) specifies State implementation options and
9 describes future milestones.

