II

119TH CONGRESS
1ST SESSION

S. 891

To extend expiring health provisions and improve health care delivery.

IN THE SENATE OF THE UNITED STATES

MARCH 6, 2025

Mr. WYDEN (for himself and Mr. SANDERS) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To extend expiring health provisions and improve health care delivery.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Bipartisan Health Care Act''.

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

Sec. 1. Short title; table of contents.

TITLE I—MEDICAID

Sec. 101. Streamlined enrollment process for eligible out-of-state providers under Medicaid and CHIP.
Sec. 102. Making certain adjustments to coverage of home or community-based services under Medicaid.

Sec. 103. Removing certain age restrictions on Medicaid eligibility for working adults with disabilities.
Sec. 104. Medicaid State plan requirement for determining residency and coverage for military families.
Sec. 105. Ensuring the reliability of address information provided under the Medicaid program.
Sec. 106. Codifying certain Medicaid provider screening requirements related to deceased providers.
Sec. 107. Modifying certain State requirements for ensuring deceased individuals do not remain enrolled.
Sec. 108. One-year delay of Medicaid and CHIP requirements for health screenings, referrals, and case management services for eligible juveniles in public institutions; State interim work plans.
Sec. 109. State studies and HHS report on costs of providing maternity, labor, and delivery services.
Sec. 110. Modifying certain disproportionate share hospital allotments.
Sec. 111. Modifying certain limitations on disproportionate share hospital payment adjustments under the Medicaid program.
Sec. 112. Ensuring accurate payments to pharmacies under Medicaid.
Sec. 113. Preventing the use of abusive spread pricing in Medicaid.

TITLE II—MEDICARE

Sec. 201. Extension of increased inpatient hospital payment adjustment for certain low-volume hospitals.
Sec. 202. Extension of the Medicare-dependent hospital (MDH) program.
Sec. 203. Extension of add-on payments for ambulance services.
Sec. 204. Extending incentive payments for participation in eligible alternative payment models.
Sec. 205. Temporary payment increase under the Medicare physician fee schedule to account for exceptional circumstances.
Sec. 206. Extension of funding for quality measure endorsement, input, and selection.
Sec. 207. Extension of funding outreach and assistance for low-income programs.
Sec. 208. Extension of the work geographic index floor.
Sec. 209. Extension of certain telehealth flexibilities.
Sec. 210. Requiring modifier for use of telehealth to conduct face-to-face encounter prior to recertification of eligibility for hospice care.
Sec. 211. Extending acute hospital care at home waiver flexibilities.
Sec. 212. Enhancing certain program integrity requirements for DME under Medicare.
Sec. 213. Guidance on furnishing services via telehealth to individuals with limited English proficiency.
Sec. 214. In-home cardiopulmonary rehabilitation flexibilities.
Sec. 215. Inclusion of virtual diabetes prevention program suppliers in MDPP Expanded Model.
Sec. 216. Medication-induced movement disorder outreach and education.
Sec. 217. Report on wearable medical devices.
Sec. 218. Extension of temporary inclusion of authorized oral antiviral drugs as covered part D drugs.
Sec. 219. Extension of adjustment to calculation of hospice cap amount.
Sec. 220. Multiyear contracting authority for MedPAC and MACPAC.
Sec. 221. Contracting parity for MedPAC and MACPAC.

Sec. 222. Adjustments to Medicare part D cost-sharing reductions for low-income individuals.
Sec. 223. Requiring Enhanced and Accurate Lists of (REAL) Health Providers Act.
Sec. 224. Medicare coverage of multi-cancer early detection screening tests.
Sec. 225. Medicare coverage of external infusion pumps and non-self-administrable home infusion drugs.
Sec. 226. Assuring pharmacy access and choice for Medicare beneficiaries.
Sec. 227. Modernizing and Ensuring PBM Accountability.
Sec. 228. Requiring a separate identification number and an attestation for each off-campus outpatient department of a provider.
Sec. 229. Medicare sequestration.
Sec. 230. Medicare improvement fund.

TITLE III—HUMAN SERVICES

Sec. 301. Sexual risk avoidance education extension.
Sec. 302. Personal responsibility education extension.
Sec. 303. Extension of funding for family-to-family health information centers.

TITLE IV—PUBLIC HEALTH EXTENDERS

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Sec. 402. Extension of special diabetes programs.

Subtitle B—World Trade Center Health Program

Sec. 411. 9/11 responder and survivor health funding corrections.

TITLE V—SUPPORT ACT REAUTHORIZATION

Sec. 501. Short title.

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Sec. 511. Prenatal and postnatal health.
Sec. 512. Monitoring and education regarding infections associated with illicit drug use and other risk factors.
Sec. 513. Preventing overdoses of controlled substances.
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Sec. 515. Promoting State choice in PDMP systems.
Sec. 516. First responder training program.
Sec. 517. Donald J. Cohen National Child Traumatic Stress Initiative.
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Sec. 707. Dr. Lorna Breen health care provider protection.
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Sec. 801. Research into pediatric uses of drugs; additional authorities of Food and Drug Administration regarding molecularly targeted cancer drugs.
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TITLE I—MEDICAID

SEC. 101. STREAMLINED ENROLLMENT PROCESS FOR ELIGIBLE OUT-OF-STATE PROVIDERS UNDER MEDICAID AND CHIP.

(a) IN GENERAL.—Section 1902(kk) of the Social Security Act (42 U.S.C. 1396a(kk)) is amended by adding at the end the following new paragraph:

"(10) STREAMLINED ENROLLMENT PROCESS FOR ELIGIBLE OUT-OF-STATE PROVIDERS.—

"(A) IN GENERAL.—The State—

"(i) adopts and implements a process to allow an eligible out-of-State provider to enroll under the State plan (or a waiver of such plan) to furnish items and services to, or order, prescribe, refer, or certify eligibility for items and services for, qualifying individuals without the imposition of screening or enrollment requirements by such State that exceed the minimum nec-

essary for such State to provide payment to an eligible out-of-State provider under such State plan (or a waiver of such plan), such as the provider's name and National Provider Identifier (and such other information specified by the Secretary); and

''(ii) provides that an eligible out-of-State provider that enrolls as a participating provider in the State plan (or a waiver of such plan) through such process shall be so enrolled for a 5-year period, unless the provider is terminated or excluded from participation during such period.

''(B) DEFINITIONS.—In this paragraph:

''(i) ELIGIBLE OUT-OF-STATE PROVIDER.—The term 'eligible out-of-State provider' means, with respect to a State, a provider—

''(I) that is located in any other State;

''(II) that—

''(aa) was determined by the Secretary to have a limited risk of fraud, waste, and abuse for purposes of determining the level

of screening to be conducted under section 1866(j)(2), has been so screened under such section 1866(j)(2), and is enrolled in the Medicare program under title XVIII; or

''(bb) was determined by the State agency administering or supervising the administration of the State plan (or a waiver of such plan) of such other State to have a limited risk of fraud, waste, and abuse for purposes of determining the level of screening to be conducted under paragraph (1) of this subsection, has been so screened under such paragraph (1), and is enrolled under such State plan (or a waiver of such plan); and

''(III) that has not been—

''(aa) excluded from participation in any Federal health care program pursuant to section 1128 or 1128A;

''(bb) excluded from participation in the State plan (or a waiver of such plan) pursuant to part 1002 of title 42, Code of Federal Regulations (or any successor regulation), or State law; or

''(cc) terminated from participating in a Federal health care program or the State plan (or a waiver of such plan) for a reason described in paragraph (8)(A).

''(ii) QUALIFYING INDIVIDUAL.—The term 'qualifying individual' means an individual under 21 years of age who is enrolled under the State plan (or waiver of such plan).

''(iii) STATE.—The term 'State' means 1 of the 50 States or the District of Columbia.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 1902(a)(77) of the Social Security Act (42 U.S.C. 1396a(a)(77)) is amended by inserting ''enrollment,'' after ''screening,''.

(2) The subsection heading for section 1902(kk) of such Act (42 U.S.C. 1396a(kk)) is amended by inserting ''enrollment,'' after ''screening,''.

(3) Section 2107(e)(1)(G) of such Act (42 U.S.C. 1397gg(e)(1)(G)) is amended by inserting ''enrollment,'' after ''screening,''.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 3 years after the date of enactment of this Act.

SEC. 102. MAKING CERTAIN ADJUSTMENTS TO COVERAGE OF HOME OR COMMUNITY-BASED SERVICES UNDER MEDICAID.

(a) INCREASING TRANSPARENCY OF HCBS COVERAGE UNDER MEDICAID.—

(1) IN GENERAL.—Section 1915(c) of the Social Security Act (42 U.S.C. 1396n(c)) is amended—

(A) in paragraph (2)—

(i) in subparagraph (E)—

(I) by inserting '', not less frequently than'' before ''annually''; and

(II) by inserting ''(including, with respect to such information provided on or after July 9, 2027, the in-

formation specified in paragraph (11))'' before the period at the end; and

(ii) by adding at the end the following flush sentence:

''The Secretary shall make all information provided under subparagraph (E) on or after the date of the enactment of this sentence publicly available on the website of the Centers for Medicare & Medicaid Services.''; and

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

''(11) For purposes of paragraph (2)(E), the information specified in this paragraph is the following:

''(A) In the case of a State that limits the number of individuals who may be provided home or community-based services under a waiver granted under this subsection and maintains a list of individuals waiting to enroll in such waiver, a description of how the State maintains such list, including—

''(i) information on whether the State screens individuals on such list to deter-

mine whether such individuals are eligible to receive such services under such waiver;

''(ii) information on whether (and, if applicable, how often) the State periodically re-screens individuals on such list for eligibility;

''(iii) the number of people on such list of individuals waiting to enroll in such waiver; and

''(iv) the average amount of time that individuals newly enrolled in such waiver within the past 12 months were on such list of individuals waiting to enroll in such waiver.

''(B) With respect to homemaker services, home health aide services, personal care services, and habilitation services furnished under waivers under this subsection, by each such service type—

''(i) for individuals newly receiving such services within the past 12 months, the average amount of time (which may be determined using statistically valid random sampling of such individuals) from when such services are initially approved for

such an individual to when such individual begins receiving such services; and

''(ii) the percentage of authorized hours (which may be determined using statistically valid random sampling of individuals authorized to receive such services) that are provided within the past 12 months.''.

(2) CONFORMING AMENDMENTS.—Section 1915 of the Social Security Act (42 U.S.C. 1396n) is amended—

(A) in subsection (i) by adding at the end the following new paragraph:

''(8) REPORTING REQUIREMENT.—With respect to homemaker services, home health aide services, personal care services, and habilitation services provided under this subsection on or after July 9, 2027, the State, not less frequently than annually, shall provide to the Secretary the same information regarding such services as the State is required to provide under subsection (c)(11)(B).'';

(B) in subsection (j)(2)(E), by inserting after the second sentence the following: ''With respect to any homemaker services, home health aide services, personal care services, and habili-

tation services provided under this subsection on or after July 9, 2027, the State, not less frequently than annually, shall provide to the Secretary the same information regarding such services as the State is required to provide under subsection (c)(11)(B).''; and

(C) in subsection (k)(3)(E)—

(i) by striking ''and'' after ''the cost of such services and supports,''; and

(ii) by inserting before the period, the following: '', and with respect to homemaker services, home health aide services, personal care services, and habilitation services provided under this subsection on or after July 9, 2027, not less frequently than annually, the same information regarding such services as the State is required to provide under subsection (c)(11)(B)''.

(b) DEMONSTRATION PROGRAM TO EXPAND HCBS COVERAGE UNDER SECTION 1915(C) WAIVERS.—Section 1915(c) of the Social Security Act (42 U.S.C. 1396n(c)), as amended by subsection (a), is further amended—

(1) in paragraph (2)(E), by inserting ", and the information specified in paragraph (12)(C)(v), when applicable" after "paragraph (11)"; and

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

"(12) DEMONSTRATION PROGRAM TO EXPAND COVERAGE FOR HOME OR COMMUNITY-BASED SERVICES.—

"(A) IN GENERAL.—

"(i) APPROVAL.—Not later than 24 months after the date on which the planning grants under subparagraph (B) are awarded, notwithstanding paragraph (1), the Secretary may approve a waiver that is standalone from any other waiver approved under this subsection for not more than 5 States, selected in accordance with clause (ii), to include as medical assistance under the State plan of such State, for the 3-year period beginning on the date of such approval, payment for part or all of the cost of home or community-based services (other than room and board (as described in paragraph (1))) approved by the Secretary which are provided pursuant to a

written plan of care to individuals described in subparagraph (C)(iii).

''(ii) SELECTION CRITERIA.—In selecting States for purposes of clause (i), the Secretary shall—

''(I) only select States that received a planning grant under subparagraph (B);

''(II) only select States that meet the requirements specified in subparagraph (C) and such other requirements as the Secretary may determine appropriate;

''(III) select States in a manner that ensures geographic diversity;

''(IV) give preference to States with a higher percentage (relative to other States that apply to be selected for purposes of clause (i)) of the total State population residing in rural areas (as determined by the Secretary);

''(V) give preference to States that have demonstrated more progress in rebalancing long-term services and

supports systems under this title, as determined based on the relative share of individuals who use home or community-based services (as defined by the Secretary) under this title as a percentage of total individuals who use long-term services and supports (as defined by the Secretary) under this title (in the most recent year for which such data is available); and

''(VI) give preference to States that pursue a waiver under this paragraph that incorporates the provision of mental health services for adults with serious mental illness, children with serious emotional disturbances, or individuals with substance use disorder.

''(B) PLANNING GRANTS.—

''(i) IN GENERAL.—

''(I) APPROVAL.—Not later than 18 months after the date of the enactment of this paragraph, the Secretary shall award planning grants of not more than $5,000,000 each to not

more than 10 States for purposes of preparing to submit a request for a waiver under this subsection (including for costs to implement the waiver or other activities to expand the provision of home or community-based services under this section) to provide home or community-based services to individuals described in subparagraph (C)(iii).

''(II) SELECTION CRITERIA.—In awarding planning grants under subclause (I), the Secretary shall use the selection criteria specified in subclauses (III) through (VI) of subparagraph (A)(ii).

''(ii) CONSULTATION.—A State that is awarded a planning grant under clause (i) shall, in preparing to submit a request for a waiver described in such clause, consult with—

''(I) individuals in need of (and not receiving) home or community-based services, individuals receiving

home or community-based services, and the caregivers of such individuals;

"(II) providers furnishing home or community-based services; and

"(III) such other stakeholders, as the Secretary may specify.

"(C) STATE REQUIREMENTS.—In addition to the requirements specified under this subsection (except for the requirements described in subparagraphs (C) and (D) of paragraph (2) and any other requirement the Secretary determines to be inapplicable in the context of a waiver relation to individuals who do not require the level of care described in paragraph (1)), the requirements specified in this paragraph are, with respect to a State, the following:

"(i) As of the date that such State requests a waiver under this subsection to provide home or community-based services to individuals described in clause (iii), all other waivers (if any) granted under this subsection to such State meet the requirements of this subsection.

''(ii) The State demonstrates to the Secretary that approval of a waiver under this subsection with respect to individuals described in clause (iii) will not result in a material increase of the average amount of time that individuals with respect to whom a determination described in paragraph (1) has been made will need to wait to receive home or community-based services under any waiver granted under this subsection, as determined by the Secretary.

''(iii) The State establishes needs-based criteria, subject to the approval of the Secretary, to identify individuals for whom a determination described in paragraph (1) is not applicable, who will be eligible for home or community-based services under a waiver approved under this paragraph, and specifies the home or community-based services such individuals so eligible will receive.

''(iv) The State established needs-based criteria for determining whether an individual described in clause (iii) requires the level of care provided in a hospital,

nursing facility, or an intermediate care facility for individuals with developmental disabilities under the State plan or under any waiver of such plan that are more stringent than the needs-based criteria established under clause (iii) for determining eligibility for home or community-based services.

''(v) The State attests that the State's average per capita expenditure for medical assistance under the State plan (or waiver of such plan) provided with respect to such individuals enrolled in a waiver under this paragraph will not exceed the State's average per capita expenditures for medical assistance for individuals receiving institutional care under the State plan (or waiver of such plan) for the duration that the waiver under this paragraph is in effect.

''(vi) The State provides to the Secretary data (in such form and manner as the Secretary may specify) regarding the number of individuals described in clause (i) with respect to a State seeking approval of a waiver under this subsection, to whom

the State will make such services available under such waiver.

''(vii) The State agrees to provide to the Secretary, not less frequently than annually, data for purposes of paragraph (2)(E) (in such form and manner as the Secretary may specify) regarding, with respect to each preceding year in which a waiver under this subsection to provide home and community-based services to individuals described in clause (iii) was in effect—

''(I) the cost (as such term is defined by the Secretary) of such services furnished to individuals described in clause (iii), broken down by type of service;

''(II) with respect to each type of home and community-based service provided under the waiver, the length of time that such individuals have received such service;

''(III) a comparison between the data described in subclause (I) and any comparable data available with

respect to individuals with respect to whom a determination described in paragraph (1) has been made and with respect to individuals receiving institutional care under this title; and

''(IV) the number of individuals who have received home and community-based services under the waiver during the preceding year.''.

(c) NON-APPLICATION OF THE PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the ''Paperwork Reduction Act of 1995''), shall not apply to the implementation of the amendments made by subsections (a) and (b).

(d) CMS GUIDANCE TO STATES ON INTERIM COVERAGE UNDER SECTION 1915 HOME AND COMMUNITY-BASED SERVICES AUTHORITIES.—Not later than January 1, 2027, the Secretary of Health and Human Services shall issue guidance to the States to clarify how a State may provide, with respect to an individual who is eligible for home and community-based services under section 1915 of the Social Security Act (42 U.S.C. 1396n), coverage of such services pursuant to a provisional written plan of care, pending finalization, with respect to such individual.

(e) FUNDING.—

(1) IN GENERAL.—There are appropriated, out of any funds in the Treasury not otherwise obligated, $71,000,000 for fiscal year 2025, to remain available until expended, to the Secretary of Health and Human Services for purposes of carrying out subsection (d) and the amendments made by subsection (b).

(2) RESERVATION FOR PLANNING GRANTS.—Of the amount appropriated under paragraph (1), the Secretary of Health and Human Services shall reserve $50,000,000 of such amount to award planning grants under the demonstration program established by the amendments made by subsection (b).

SEC. 103. REMOVING CERTAIN AGE RESTRICTIONS ON MEDICAID ELIGIBILITY FOR WORKING ADULTS WITH DISABILITIES.

(a) MODIFICATION OF OPTIONAL BUY-IN GROUPS.—

(1) IN GENERAL.—Section 1902(a)(10)(A)(ii)(XV) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(ii)(XV)) is amended by striking ''but less than 65,''.

(2) DEFINITION MODIFICATION.—Section 1905(v)(1)(A) of the Social Security Act (42 U.S.C.

1396d(v)(1)(A)) is amended by striking ", but less than 65,".

(b) APPLICATION TO CERTAIN STATES.—A State that, as of the date of enactment of this Act, provides for making medical assistance available to individuals described in subclause (XV) or (XVI) of section 1902(a)(10)(A)(ii) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(ii)) shall not be regarded as failing to comply with the requirements of either such subclause (as amended by subsection (a)(1)) or with section 1905(v)(1)(A) of the Social Security Act (42 U.S.C. 1396d(v)(1)(A)) (as amended by subsection (a)(2)) before January 1, 2027.

SEC. 104. MEDICAID STATE PLAN REQUIREMENT FOR DETERMINING RESIDENCY AND COVERAGE FOR MILITARY FAMILIES.

(a) IN GENERAL.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended—

(1) in subsection (a)—

(A) in paragraph (86), by striking "and" at the end;

(B) in paragraph (87), by striking the period at the end and inserting "; and"; and

(C) by inserting after paragraph (87), the following new paragraph:

"(88) beginning January 1, 2028, provide, with respect to an active duty relocated individual (as defined in subsection (uu)(1))—

"(A) that, for purposes of determining eligibility for medical assistance under the State plan (or waiver of such plan), such active duty relocated individual is treated as a resident of the State unless such individual voluntarily elects not to be so treated for such purposes;

"(B) that if, at the time of relocation (as described in subsection (uu)(1)), such active duty relocated individual is on a home and community-based services waiting list (as defined in subsection (uu)(2)), such individual remains on such list until—

"(i) the State completes an assessment and renders a decision with respect to the eligibility of such individual to receive the relevant home and community-based services at the time a slot for such services becomes available and, in the case such decision is a denial of such eligibility, such individual has exhausted the individual's opportunity for a fair hearing; or

''(ii) such individual elects to be removed from such list; and

''(C) payment for medical assistance furnished under the State plan (or a waiver of the plan) on behalf of such active duty relocated individual in the military service relocation State (as referred to in subsection (uu)(1)(B)(i)), to the extent that such assistance is available in such military service relocation State in accordance with such guidance as the Secretary may issue to ensure access to such assistance.''; and

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

''(uu) ACTIVE DUTY RELOCATED INDIVIDUAL; HOME AND COMMUNITY-BASED SERVICES WAITING LIST.—For purposes of subsection (a)(88) and this subsection:

''(1) ACTIVE DUTY RELOCATED INDIVIDUAL.—The term 'active duty relocated individual' means an individual—

''(A) who—

''(i) is enrolled under the State plan (or waiver of such plan); or

''(ii) with respect to an individual described in subparagraph (C)(ii), would be so enrolled pursuant to subsection

(a)(10)(A)(ii)(VI) if such individual began receiving home and community-based services;

"(B) who—

"(i) is a member of the Armed Forces engaged in active duty service and is relocated to another State (in this subsection referred to as the 'military service relocation State') by reason of such service;

"(ii) would be described in clause (i) except that the individual stopped being engaged in active duty service (including by reason of retirement from such service) and the last day on which the individual was engaged in active duty service occurred not more than 12 months ago; or

"(iii) is a dependent (as defined by the Secretary) of a member described in clause (i) or (ii) who relocates to the military service relocation State with such member; and

"(C) who—

"(i) was receiving home and community-based services (as defined in section 9817(a)(2)(B) of the American Rescue

Plan Act of 2021) at the time of such relocation; or

"(ii) if the State maintains a home and community-based services waiting list, was on such home and community-based services waiting list at the time of such relocation.

"(2) HOME AND COMMUNITY-BASED SERVICES WAITING LIST.—The term 'home and community-based services waiting list' means, in the case of a State that has a limit on the number of individuals who may receive home and community-based services under section 1115(a), section 1915(c), or section 1915(j), a list maintained by such State of individuals who are requesting to receive such services under 1 or more such sections but for whom the State has not yet completed an assessment and rendered a decision with respect to the eligibility of such individuals to receive the relevant home and community-based services at the time a slot for such services becomes available due to such limit.".

(b) IMPLEMENTATION FUNDING.—There are appropriated, out of any funds in the Treasury not otherwise obligated, $1,000,000 for each of fiscal years 2025 through 2029, to remain available until expended, to the

Secretary of Health and Human Services for purposes of implementing the amendments made by subsection (a).

SEC. 105. ENSURING THE RELIABILITY OF ADDRESS INFORMATION PROVIDED UNDER THE MEDICAID PROGRAM.

(a) IN GENERAL.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as previously amended by this title, is amended—

(1) in paragraph (87), by striking ''and'' at the end;

(2) in paragraph (88), by striking the period at the end and inserting ''; and''; and

(3) by inserting after paragraph (88) the following new paragraph:

''(89) beginning January 1, 2026, provide for a process to regularly obtain address information for individuals enrolled under such plan (or a waiver of such plan) from reliable data sources (as described in section 435.919(f)(1)(iii) of title 42, Code of Federal Regulations (or a successor regulation)) and act on any changes to such an address based on such information in accordance with such section (or successor regulation), except that this paragraph shall only apply in the case of the 50 States and the District of Columbia.''.

(b) APPLICATION TO CHIP.—Section 2107(e)(1) of the Social Security Act (42 U.S.C. 1397gg(e)(1)) is amended—

(1) by redesignating subparagraphs (H) through (U) as subparagraphs (I) through (V), respectively; and

(2) by inserting after subparagraph (G) the following new subparagraph:

"(H) Section 1902(a)(89) (relating to regularly obtaining address information for enrollees).".

(c) ENSURING TRANSMISSION OF ADDRESS INFORMATION FROM MANAGED CARE ORGANIZATIONS.—Section 1932 of the Social Security Act (42 U.S.C. 1396u–2) is amended by adding at the end the following new subsection:

"(j) TRANSMISSION OF ADDRESS INFORMATION.—Beginning January 1, 2026, each contract under a State plan with a managed care entity under section 1903(m) shall provide that the entity transmits to the State any address information for an individual enrolled with the entity that is provided to such entity directly from, or verified by such entity directly with, such individual.".

SEC. 106. CODIFYING CERTAIN MEDICAID PROVIDER SCREENING REQUIREMENTS RELATED TO DECEASED PROVIDERS.

Section 1902(kk)(1) of the Social Security Act (42 U.S.C. 1396a(kk)(1)) is amended—

(1) by striking ''The State'' and inserting:

''(A) IN GENERAL.—The State''; and

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

''(B) ADDITIONAL PROVIDER SCREENING.—Beginning January 1, 2027, as part of the enrollment (or reenrollment or revalidation of enrollment) of a provider or supplier under this title, and not less frequently than quarterly during the period that such provider or supplier is so enrolled, the State conducts a check of the Death Master File (as such term is defined in section 203(d) of the Bipartisan Budget Act of 2013) to determine whether such provider or supplier is deceased.''.

SEC. 107. MODIFYING CERTAIN STATE REQUIREMENTS FOR ENSURING DECEASED INDIVIDUALS DO NOT REMAIN ENROLLED.

Section 1902 of the Social Security Act (42 U.S.C. 1396a), as previously amended by this title, is amended—

(1) in subsection (a)—

(A) in paragraph (88), by striking ''; and'' and inserting a semicolon;

(B) in paragraph (89), by striking the period at the end and inserting ''; and''; and

(C) by inserting after paragraph (89) the following new paragraph:

''(90) provide that the State shall comply with the eligibility verification requirements under subsection (vv), except that this paragraph shall apply only in the case of the 50 States and the District of Columbia.''; and

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

''(vv) VERIFICATION OF CERTAIN ELIGIBILITY CRITERIA.—

''(1) IN GENERAL.—For purposes of subsection (a)(90), the eligibility verification requirements, beginning January 1, 2026, are as follows:

''(A) QUARTERLY SCREENING TO VERIFY ENROLLEE STATUS.—The State shall, not less frequently than quarterly, review the Death Master File (as such term is defined in section 203(d) of the Bipartisan Budget Act of 2013) to determine whether any individuals enrolled

for medical assistance under the State plan (or waiver of such plan) are deceased.

''(B) DISENROLLMENT UNDER STATE PLAN.—If the State determines, based on information obtained from the Death Master File, that an individual enrolled for medical assistance under the State plan (or waiver of such plan) is deceased, the State shall—

''(i) treat such information as factual information confirming the death of a beneficiary for purposes of section 431.213(a) of title 42, Code of Federal Regulations (or any successor regulation);

''(ii) disenroll such individual from the State plan (or waiver of such plan); and

''(iii) discontinue any payments for medical assistance under this title made on behalf of such individual (other than payments for any items or services furnished to such individual prior to the death of such individual).

''(C) REINSTATEMENT OF COVERAGE IN THE EVENT OF ERROR.—If a State determines that an individual was misidentified as deceased based on information obtained from the Death

Master File, and was erroneously disenrolled from medical assistance under the State plan (or waiver of such plan) based on such misidentification, the State shall immediately reenroll such individual under the State plan (or waiver of such plan), retroactive to the date of such disenrollment.

''(2) RULE OF CONSTRUCTION.—Nothing under this subsection shall be construed to preclude the ability of a State to use other electronic data sources to timely identify potentially deceased beneficiaries, so long as the State is also in compliance with the requirements of this subsection (and all other requirements under this title relating to Medicaid eligibility determination and redetermination).''.

SEC. 108. ONE-YEAR DELAY OF MEDICAID AND CHIP REQUIREMENTS FOR HEALTH SCREENINGS, REFERRALS, AND CASE MANAGEMENT SERVICES FOR ELIGIBLE JUVENILES IN PUBLIC INSTITUTIONS; STATE INTERIM WORK PLANS.

(a) IN GENERAL.—Section 5121(d) of subtitle C of title V of division FF of the Consolidated Appropriations Act, 2023 (Public Law 117–328) is amended—

(1) by striking ''The amendments made by this section'' and inserting the following:

''(1) IN GENERAL.—Subject to paragraph (2), the amendments made by this section''; and

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

''(2) DELAY OF DATE BY WHICH STATES MUST COMPLY WITH CERTAIN JUVENILE JUSTICE-RELATED REQUIREMENTS.—A State shall not be regarded as failing to comply with the requirements of section 1902(a)(84)(D) or 2102(d)(2) of the Social Security Act (42 U.S.C. 1396a(a)(84)(D), 1397bb(d)(2)) before January 1, 2026.''.

(b) CLARIFYING NONAPPLICATION OF REQUIREMENTS TO INDIVIDUALS IN FEDERAL CUSTODY.—

(1) MEDICAID.—

(A) Subparagraph (D) of section 1902(a)(84) of the Social Security Act (42 U.S.C. 1396a(a)(84)), as added by section 5121 of subtitle C of title V of division FF of the Consolidated Appropriations Act, 2023 (Public Law 117–328), is amended by striking ''an individual who is an eligible juvenile'' and inserting ''an individual (other than an individual who is in Federal custody, including as an inmate in a Federal prison) who is an eligible juvenile''.

(B) Section 5122(a) of subtitle C of title V of division FF of the Consolidated Appropriations Act, 2023 (Public Law 117–328) is amended—

(i) by striking ''paragraph (31)'' each place it appears and inserting ''the last numbered paragraph''; and

(ii) in paragraph (1), by striking ''an individual who is an eligible juvenile'' and inserting ''an individual (other than an individual who is in Federal custody, including as an inmate in a Federal prison) who is an eligible juvenile''.

(2) CHIP.—

(A) Subsection (d)(2) of section 2102 of the Social Security Act (42 U.S.C. 1397bb), as added by section 5121 of subtitle C of title V of division FF of the Consolidated Appropriations Act, 2023 (Public Law 117–328), is amended by striking ''a targeted low-income child who'' and inserting ''a targeted low income child (other than a child who is in Federal custody, including as an inmate in a Federal prison) who''.

(B) Section 5122(b)(2) of subtitle C of title V of division FF of the Consolidated Appropriations Act, 2023 (Public Law 117–328) is amended by striking ''a child who is'' and inserting ''a child (other than a child who is in Federal custody, including as an inmate in a Federal prison) who is''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect as if enacted on December 29, 2022.

(c) INTERIM WORK PLAN.—Not later than June 30, 2025, each State (as such term is defined in section 1101(a)(1) of the Social Security Act (42 U.S.C. 1301(a)(1)) for purposes of titles XIX and XXI of such Act) shall submit to the Secretary of Health and Human Services an interim work plan, in such form and containing such information as the Secretary may specify, describing the State's progress towards implementing, and its plans to come into compliance with, the requirements imposed by the amendments made by section 5121 of subtitle C of title V of division FF of the Consolidated Appropriations Act, 2023 (Public Law 117–328), consistent with the guidance issued by the Centers for Medicare & Medicaid Services in State Health Official Letter #24–004 on July 23, 2024.

SEC. 109. STATE STUDIES AND HHS REPORT ON COSTS OF PROVIDING MATERNITY, LABOR, AND DELIVERY SERVICES.

(a) STATE STUDY.—

(1) IN GENERAL.—Not later than 24 months after the date of enactment of this Act, and every 5 years thereafter, each State (as such term is defined in section 1101(a)(1) of the Social Security Act (42 U.S.C. 1301(a)(1)) for purposes of titles XIX and XXI of such Act) shall conduct a study on the costs of providing maternity, labor, and delivery services in applicable hospitals (as defined in paragraph (3)) and submit the results of such study to the Secretary of Health and Human Services (referred to in this section as the ''Secretary'').

(2) CONTENT OF STUDY.—A State study required under paragraph (1) shall include the following information (to the extent practicable) with respect to maternity, labor, and delivery services furnished by applicable hospitals located in the State:

(A) An estimate of the cost of providing maternity, labor, and delivery services at applicable hospitals, based on the expenditures a representative sample of such hospitals incurred for providing such services during the 2 most recent years for which data is available.

(B) An estimate of the cost of providing maternity, labor, and delivery services at applicable hospitals that ceased providing labor and delivery services within the past 5 years, based on the expenditures a representative sample of such hospitals incurred for providing such services during the 2 most recent years for which data is available.

(C) To the extent data allows, an analysis of the extent to which geographic location, community demographics, and local economic factors (as defined by the Secretary) affect the cost of providing maternity, labor, and delivery services at applicable hospitals, including the cost of services that support the provision of maternity, labor, and delivery services.

(D) The amounts applicable hospitals are paid for maternity, labor, and delivery services, by geographic location and hospital size, under—

(i) Medicare;

(ii) the State Medicaid program, including payment amounts for such services under fee-for-service payment arrange-

ments and under managed care (as applicable);

(iii) the State CHIP plan, including payment amounts for such services under fee-for-service payment arrangements and under managed care (as applicable); and

(iv) private health insurance.

(E) A comparative payment rate analysis—

(i) comparing payment rates for maternity, labor, and delivery services (inclusive of all payments received by applicable hospitals for furnishing maternity, labor, and delivery services) under the State Medicaid fee-for-service program to such payment rates for such services under Medicare (as described in section 447.203(b)(3) of title 42, Code of Federal Regulations), other Federally-funded or State-funded programs (including, to the extent data is available, Medicaid managed care rates), and to the payment rates for such services, to the extent data is available, of private health insurers within geographic areas of the State; and

(ii) analyzing different payment methods for such services, such as the use of bundled payments, quality incentives, and low-volume adjustments.

(F) An evaluation, using such methodology and parameters established by the Secretary, of whether each hospital located in the State that furnishes maternity, labor, and delivery services is expected to experience in the next 3 years significant changes in particular expenditures or types of reimbursement for maternity, labor, and delivery services.

(3) APPLICABLE HOSPITAL DEFINED.—For purposes of this subsection, the term ''applicable hospital'' means any hospital located in a State that meets either of the following criteria:

(A) The hospital provides labor and delivery services and more than 50 percent of the hospital's births (in the most recent year for which such data is available) are financed by the Medicaid program or CHIP.

(B) The hospital—

(i) is located in a rural area (as defined by the Federal Office of Rural Health Policy for the purpose of rural

health grant programs administered by such Office);

(ii) based on the most recent 2 years of data available (as determined by the Secretary), furnished services for less than an average of 300 births per year; and

(iii) provides labor and delivery services.

(4) ASSISTANCE TO SMALL HOSPITALS IN COMPILING COST INFORMATION.—There are appropriated to the Secretary for fiscal year 2025, $10,000,000 for the purpose of providing grants and technical assistance to a hospital described in paragraph (3)(B) to enable such hospital to compile detailed information for use in the State studies required under paragraph (1), to remain available until expended.

(5) HHS REPORT ON STATE STUDIES.—For each year in which a State is required to conduct a study under paragraph (1), the Secretary shall issue, not later than 12 months after the date on which the State submits to the Secretary the data described in such paragraph, a publicly available report that compiles and details the results of such

study and includes the information described in paragraph (2).

(b) HHS REPORT ON NATIONAL DATA COLLECTION FINDINGS.—Not later than 3 years after the date of enactment of this Act, the Secretary shall submit to Congress, and make publicly available, a report analyzing the first studies conducted by States under subsection (a)(1), including recommendations for improving data collection on the cost of providing maternity, labor, and delivery services.

(c) IMPLEMENTATION FUNDING.—In addition to the amount appropriated under subsection (a)(4), there are appropriated, out of any funds in the Treasury not otherwise obligated, $3,000,000 for fiscal year 2025, to remain available until expended, to the Secretary of Health and Human Services for purposes of implementing this section.

SEC. 110. MODIFYING CERTAIN DISPROPORTIONATE SHARE HOSPITAL ALLOTMENTS.

(a) EXTENDING TENNESSEE DSH ALLOTMENTS.—Section 1923(f)(6)(A)(vi) of the Social Security Act (42 U.S.C. 1396r–4(f)(6)(A)(vi)) is amended—

(1) in the heading, by striking ''2025'' and inserting ''2026 AND FOR THE 1ST QUARTER OF FISCAL YEAR 2027'';

(2) by striking ''fiscal year 2025'' and inserting ''fiscal year 2026''; and

(3) by inserting '', and the DSH allotment for Tennessee for the 1st quarter of fiscal year 2027, shall be $13,275,000'' before the period.

(b) ELIMINATING AND DELAYING DSH ALLOTMENT REDUCTIONS.—Section 1923(f) of the Social Security Act (42 U.S.C. 1396r–4(f)) is amended—

(1) in paragraph (7)(A)—

(A) in clause (i), in the matter preceding subclause (I), by striking ''April 1, 2025,'' and all that follows through ''2027'' and inserting ''January 1, 2027, and ending September 30, 2027, and for fiscal year 2028''; and

(B) in clause (ii), by striking ''April 1, 2025,'' and all that follows through ''2027'' and inserting ''January 1, 2027, and ending September 30, 2027, and for fiscal year 2028''; and

(2) in paragraph (8), by striking ''2027'' and inserting ''2028''.

SEC. 111. MODIFYING CERTAIN LIMITATIONS ON DISPROPORTIONATE SHARE HOSPITAL PAYMENT ADJUSTMENTS UNDER THE MEDICAID PROGRAM.

(a) IN GENERAL.—Section 1923(g) of the Social Security Act (42 U.S.C. 1396r–4(g)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''(other than a hospital described in paragraph (2)(B))'';

(ii) in clause (i), by inserting ''with respect to such hospital and year'' after ''described in subparagraph (B)''; and

(iii) in clause (ii)—

(I) in subclause (I), by striking ''and'' at the end;

(II) in subclause (II), by striking the period and inserting ''; and''; and

(III) by adding at the end the following new subclause:

''(III) payments made under title XVIII or by an applicable plan (as defined in section 1862(b)(8)(F)) for such services.''; and

(B) in subparagraph (B)—

(i) in the matter preceding clause (i), by striking ''in this clause are'' and inserting ''in this subparagraph are, with respect to a hospital and a year,''; and

(ii) by adding at the end the following new clause:

''(iii) Individuals who are eligible for medical assistance under the State plan or under a waiver of such plan and for whom the State plan or waiver is a payor for such services after application of benefits under title XVIII or under an applicable plan (as defined in section 1862(b)(8)(F)), but only if the hospital has in the aggregate incurred costs exceeding payments under such State plan, waiver, title XVIII, or applicable plan for such services furnished to such individuals during such year.'';

(2) by striking paragraph (2);

(3) by redesignating paragraph (3) as paragraph (2); and

(4) in paragraph (2), as so redesignated, by striking ''Notwithstanding paragraph (2) of this

subsection (as in effect on October 1, 2021), paragraph (2)'' and inserting ''Paragraph (2)''.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section shall apply to payment adjustments made under section 1923 of the Social Security Act (42 U.S.C. 1396r–4) for Medicaid State plan rate years beginning on or after the date of enactment of this Act.

(2) STATE OPTION TO DISTRIBUTE UNSPENT DSH ALLOTMENTS FROM PRIOR YEARS UP TO MODIFIED CAP.—

(A) IN GENERAL.—If, for any Medicaid State plan rate year that begins on or after October 1, 2021, and before the date of enactment of this Act, a State did not spend the full amount of its Federal fiscal year allotment under section 1923 of the Social Security Act (42 U.S.C. 1396r–4) applicable to that State plan rate year, the State may use the unspent portion of such allotment to increase the amount of any payment adjustment made to a hospital for such rate year, provided that—

(i) such payment adjustment (as so increased) is consistent with subsection (g)

of such section (as amended by this section); and

(ii) the total amount of all payment adjustments for the State plan rate year (as so increased) does not exceed the disproportionate share hospital allotment for the State and applicable Federal fiscal year under subsection (f) of such section.

(B) NO RECOUPMENT OF PAYMENTS ALREADY MADE TO HOSPITALS.—A State shall not recoup any payment adjustment made by the State to a hospital for a Medicaid State plan rate year described in subparagraph (A) if such payment adjustment is consistent with section 1923(g) of such Act (42 U.S.C. 1396r–4(g)) as in effect on October 1, 2021.

(C) AUTHORITY TO PERMIT RETROACTIVE MODIFICATION OF STATE PLAN AMENDMENTS TO ALLOW FOR INCREASES.—

(i) IN GENERAL.—Subject to paragraph (2), solely for the purpose of allowing a State to increase the amount of a payment adjustment to a hospital for a Medicaid State plan rate year described in subparagraph (A) pursuant to this para-

graph, a State may retroactively modify a provision of the Medicaid State plan, a waiver of such plan, or a State plan amendment that relates to such rate year and the Secretary may approve such modification.

(ii) DEADLINE.—A State may not submit a request for approval of a retroactive modification to a provision of the Medicaid State plan, a waiver of such plan, or a State plan amendment for a Medicaid State plan rate year after the date by which the State is required to submit the independent certified audit for that State plan rate year as required under section 1923(j)(2) of the Social Security Act (42 U.S.C. 1396r–4(j)(2)).

(D) REPORTING.—If a State increases a payment adjustment made to a hospital for a Medicaid State plan rate year pursuant to this paragraph, the State shall include information on such increased payment adjustment as part of the next annual report submitted by the State under section 1923(j)(1) of the Social Security Act (42 U.S.C. 1396r–4(j)(1)).

SEC. 112. ENSURING ACCURATE PAYMENTS TO PHARMACIES UNDER MEDICAID.

(a) IN GENERAL.—Section 1927(f) of the Social Security Act (42 U.S.C. 1396r–8(f)) is amended—

(1) in paragraph (1)(A)—

(A) by redesignating clause (ii) as clause (iii); and

(B) by striking ''and'' after the semicolon at the end of clause (i) and all that precedes it through ''(1)'' and inserting the following:

''(1) DETERMINING PHARMACY ACTUAL ACQUISITION COSTS.—The Secretary shall conduct a survey of retail community pharmacy drug prices and applicable non-retail pharmacy drug prices to determine national average drug acquisition cost benchmarks (as such term is defined by the Secretary) as follows:

''(A) USE OF VENDOR.—The Secretary may contract services for—

''(i) with respect to retail community pharmacies, the determination of retail survey prices of the national average drug acquisition cost for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts, rebates, and

other price concessions (to the extent any information with respect to such discounts, rebates, and other price concessions is available) based on a monthly survey of such pharmacies;

''(ii) with respect to applicable non-retail pharmacies—

''(I) the determination of survey prices, separate from the survey prices described in clause (i), of the non-retail national average drug acquisition cost for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts, rebates, and other price concessions (to the extent any information with respect to such discounts, rebates, and other price concessions is available) based on a monthly survey of such pharmacies; and

''(II) at the discretion of the Secretary, for each type of applicable non-retail pharmacy, the determination of survey prices, separate from

the survey prices described in clause (i) or subclause (I) of this clause, of the national average drug acquisition cost for such type of pharmacy for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts, rebates, and other price concessions (to the extent any information with respect to such discounts, rebates, and other price concessions is available) based on a monthly survey of such pharmacies; and'';

(2) in subparagraph (B) of paragraph (1), by striking ''subparagraph (A)(ii)'' and inserting ''subparagraph (A)(iii)'';

(3) in subparagraph (D) of paragraph (1), by striking clauses (ii) and (iii) and inserting the following:

''(ii) The vendor must update the Secretary no less often than monthly on the survey prices for covered outpatient drugs.

''(iii) The vendor must differentiate, in collecting and reporting survey data, for

all cost information collected, whether a pharmacy is a retail community pharmacy or an applicable non-retail pharmacy, including whether such pharmacy is an affiliate (as defined in subsection (k)(14)), and, in the case of an applicable non-retail pharmacy, which type of applicable non-retail pharmacy it is using the relevant pharmacy type indicators included in the guidance required by subsection (d)(2) of section 112 of the Bipartisan Health Care Act.'';

(4) by adding at the end of paragraph (1) the following:

''(F) SURVEY REPORTING.—In order to meet the requirement of section 1902(a)(54), a State shall require that any retail community pharmacy or applicable non-retail pharmacy in the State that receives any payment, reimbursement, administrative fee, discount, rebate, or other price concession related to the dispensing of covered outpatient drugs to individuals receiving benefits under this title, regardless of whether such payment, reimbursement, administrative fee, discount, rebate, or other price

concession is received from the State or a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D)) directly or from a pharmacy benefit manager or another entity that has a contract with the State or a managed care entity or other specified entity (as so defined), shall respond to surveys conducted under this paragraph.

''(G) SURVEY INFORMATION.—Information on national drug acquisition prices obtained under this paragraph shall be made publicly available in a form and manner to be determined by the Secretary and shall include at least the following:

''(i) The monthly response rate to the survey including a list of pharmacies not in compliance with subparagraph (F).

''(ii) The sampling methodology and number of pharmacies sampled monthly.

''(iii) Information on price concessions to pharmacies, including discounts, rebates, and other price concessions, to the extent that such information may be pub-

licly released and has been collected by the Secretary as part of the survey.

"(H) PENALTIES.—

"(i) IN GENERAL.—Subject to clauses (ii), (iii), and (iv), the Secretary shall enforce the provisions of this paragraph with respect to a pharmacy through the establishment of civil money penalties applicable to a retail community pharmacy or an applicable non-retail pharmacy.

"(ii) BASIS FOR PENALTIES.—The Secretary shall impose a civil money penalty established under this subparagraph on a retail community pharmacy or applicable non-retail pharmacy if—

"(I) the retail pharmacy or applicable non-retail pharmacy refuses or otherwise fails to respond to a request for information about prices in connection with a survey under this subsection;

"(II) knowingly provides false information in response to such a survey; or

"(III) otherwise fails to comply with the requirements established under this paragraph.

"(iii) PARAMETERS FOR PENALTIES.—

"(I) IN GENERAL.—A civil money penalty established under this subparagraph may be assessed with respect to each violation, and with respect to each non-compliant retail community pharmacy (including a pharmacy that is part of a chain) or non-compliant applicable non-retail pharmacy (including a pharmacy that is part of a chain), in an amount not to exceed $100,000 for each such violation.

"(II) CONSIDERATIONS.—In determining the amount of a civil money penalty imposed under this subparagraph, the Secretary may consider the size, business structure, and type of pharmacy involved, as well as the type of violation and other relevant factors,

as determined appropriate by the Secretary.

''(iv) RULE OF APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a civil money penalty or proceeding under section 1128A(a).

''(I) LIMITATION ON USE OF APPLICABLE NON-RETAIL PHARMACY PRICING INFORMATION.—No State shall use pricing information reported by applicable non-retail pharmacies under subparagraph (A)(ii) to develop or inform payment methodologies for retail community pharmacies.'';

(5) in paragraph (2)—

(A) in subparagraph (A), by inserting '', including payment rates and methodologies for determining ingredient cost reimbursement under managed care entities or other specified entities (as such terms are defined in section 1903(m)(9)(D))'' after ''under this title''; and

(B) in subparagraph (B), by inserting ''and the basis for such dispensing fees'' before the semicolon;

(6) by redesignating paragraph (4) as paragraph (5);

(7) by inserting after paragraph (3) the following new paragraph:

''(4) OVERSIGHT.—

''(A) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct periodic studies of the survey data reported under this subsection, as appropriate, including with respect to substantial variations in acquisition costs or other applicable costs, as well as with respect to how internal transfer prices and related party transactions may influence the costs reported by pharmacies that are affiliates (as defined in subsection (k)(14)) or are owned by, controlled by, or related under a common ownership structure with a wholesaler, distributor, or other entity that acquires covered outpatient drugs relative to costs reported by pharmacies not affiliated with such entities. The Inspector General shall provide periodic updates to Congress on the results

of such studies, as appropriate, in a manner that does not disclose trade secrets or other proprietary information.

''(B) APPROPRIATION.—There is appropriated to the Inspector General of the Department of Health and Human Services, out of any money in the Treasury not otherwise appropriated, $5,000,000 for fiscal year 2025, to remain available until expended, to carry out this paragraph.''; and

(8) in paragraph (5), as so redesignated—

(A) by inserting '', and $9,000,000 for fiscal year 2025 and each fiscal year thereafter,'' after ''2010''; and

(B) by inserting ''Funds appropriated under this paragraph for fiscal year 2025 and any subsequent fiscal year shall remain available until expended.'' after the period.

(b) DEFINITIONS.—Section 1927(k) of the Social Security Act (42 U.S.C. 1396r–8(k)) is amended—

(1) in the matter preceding paragraph (1), by striking ''In the section'' and inserting ''In this section''; and

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

''(12) APPLICABLE NON-RETAIL PHARMACY.—The term 'applicable non-retail pharmacy' means a pharmacy that is licensed as a pharmacy by the State and that is not a retail community pharmacy, including a pharmacy that dispenses prescription medications to patients primarily through mail and specialty pharmacies. Such term does not include nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or low dispensing pharmacies (as defined by the Secretary).

''(13) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled by, or related under a common ownership structure with a pharmacy benefit manager or a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D)).''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by this section shall take effect on the first day of the first quarter that begins on or after the date that is 6 months after the date of enactment of this Act.

(2) DELAYED APPLICATION TO APPLICABLE NON-RETAIL PHARMACIES.—The pharmacy survey requirements established by the amendments to section 1927(f) of the Social Security Act (42 U.S.C. 1396r–8(f)) made by this section shall apply to retail community pharmacies beginning on the effective date described in paragraph (1), but shall not apply to applicable non-retail pharmacies until the first day of the first quarter that begins on or after the date that is 18 months after the date of enactment of this Act.

(d) IDENTIFICATION OF APPLICABLE NON-RETAIL PHARMACIES.—

(1) IN GENERAL.—Not later than January 1, 2026, the Secretary of Health and Human Services shall, in consultation with stakeholders as appropriate, publish guidance specifying pharmacies that meet the definition of applicable non-retail pharmacies (as such term is defined in subsection (k)(12) of section 1927 of the Social Security Act (42 U.S.C. 1396r–8), as added by subsection (b)), and that will be subject to the survey requirements under subsection (f)(1) of such section, as amended by subsection (a).

(2) INCLUSION OF PHARMACY TYPE INDICATORS.—The guidance published under paragraph (1) shall include pharmacy type indicators to distinguish between different types of applicable non-retail pharmacies, such as pharmacies that dispense prescriptions primarily through the mail and pharmacies that dispense prescriptions that require special handling or distribution. An applicable non-retail pharmacy may be identified through multiple pharmacy type indicators.

(e) IMPLEMENTATION.—

(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendments made by this section by program instruction or otherwise.

(2) NONAPPLICATION OF ADMINISTRATIVE PROCEDURE ACT.—Implementation of the amendments made by this section shall be exempt from the requirements of section 553 of title 5, United States Code.

(f) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to any data collection undertaken by the Secretary of Health and Human Services under section

1927(f) of the Social Security Act (42 U.S.C. 1396r–8(f)), as amended by this section.

SEC. 113. PREVENTING THE USE OF ABUSIVE SPREAD PRICING IN MEDICAID.

(a) IN GENERAL.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(1) in subsection (e), by adding at the end the following new paragraph:

''(6) TRANSPARENT PRESCRIPTION DRUG PASS-THROUGH PRICING REQUIRED.—

''(A) IN GENERAL.—A contract between the State and a pharmacy benefit manager (referred to in this paragraph as a 'PBM'), or a contract between the State and a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D) and collectively referred to in this paragraph as the 'entity') that includes provisions making the entity responsible for coverage of covered outpatient drugs dispensed to individuals enrolled with the entity, shall require that payment for such drugs and related administrative services (as applicable), including payments made by a PBM on behalf of the State or entity, is based

on a transparent prescription drug pass-through pricing model under which—

"(i) any payment made by the entity or the PBM (as applicable) for such a drug—

"(I) is limited to—

"(aa) ingredient cost; and

"(bb) a professional dispensing fee that is not less than the professional dispensing fee that the State would pay if the State were making the payment directly in accordance with the State plan;

"(II) is passed through in its entirety (except as reduced under Federal or State laws and regulations in response to instances of waste, fraud, or abuse) by the entity or PBM to the pharmacy or provider that dispenses the drug; and

"(III) is made in a manner that is consistent with sections 447.502, 447.512, 447.514, and 447.518 of title 42, Code of Federal Regulations

(or any successor regulation) as if such requirements applied directly to the entity or the PBM, except that any payment by the entity or the PBM for the ingredient cost of such drug purchased by a covered entity (as defined in subsection (a)(5)(B)) may exceed the actual acquisition cost (as defined in 447.502 of title 42, Code of Federal Regulations, or any successor regulation) for such drug if—

''(aa) such drug was subject to an agreement under section 340B of the Public Health Service Act;

''(bb) such payment for the ingredient cost of such drug does not exceed the maximum payment that would have been made by the entity or the PBM for the ingredient cost of such drug if such drug had not been purchased by such covered entity; and

''(cc) such covered entity reports to the Secretary (in a form and manner specified by the Secretary), on an annual basis and with respect to payments for the ingredient costs of such drugs so purchased by such covered entity that are in excess of the actual acquisition costs for such drugs, the aggregate amount of such excess;

''(ii) payment to the entity or the PBM (as applicable) for administrative services performed by the entity or PBM is limited to an administrative fee that reflects the fair market value (as defined by the Secretary) of such services;

''(iii) the entity or the PBM (as applicable) makes available to the State, and the Secretary upon request in a form and manner specified by the Secretary, all costs and payments related to covered outpatient drugs and accompanying administrative services (as described in clause (ii)) incurred, received, or made by the entity or

the PBM, broken down (as specified by the Secretary), to the extent such costs and payments are attributable to an individual covered outpatient drug, by each such drug, including any ingredient costs, professional dispensing fees, administrative fees (as described in clause (ii)), post-sale and post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees, and any and all other remuneration, as defined by the Secretary; and

''(iv) any form of spread pricing whereby any amount charged or claimed by the entity or the PBM (as applicable) that exceeds the amount paid to the pharmacies or providers on behalf of the State or entity, including any post-sale or post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees or assessments, as defined by the Secretary, (after allowing for an administrative fee as described in clause (ii)) is not allowable for purposes of claiming Federal matching payments under this title.

"(B) PUBLICATION OF INFORMATION.—The Secretary shall publish, not less frequently than on an annual basis and in a manner that does not disclose the identity of a particular covered entity or organization, information received by the Secretary pursuant to subparagraph (A)(iii)(III) that is broken out by State and by each of the following categories of covered entity within each such State:

"(i) Covered entities described in subparagraph (A) of section 340B(a)(4) of the Public Health Service Act.

"(ii) Covered entities described in subparagraphs (B) through (K) of such section.

"(iii) Covered entities described in subparagraph (L) of such section.

"(iv) Covered entities described in subparagraph (M) of such section.

"(v) Covered entities described in subparagraph (N) of such section.

"(vi) Covered entities described in subparagraph (O) of such section."; and

(2) in subsection (k), as previously amended by this title, by adding at the end the following new paragraph:

''(14) PHARMACY BENEFIT MANAGER.—The term 'pharmacy benefit manager' means any person or entity that, either directly or through an intermediary, acts as a price negotiator or group purchaser on behalf of a State, managed care entity (as defined in section 1903(m)(9)(D)), or other specified entity (as so defined), or manages the prescription drug benefits provided by a State, managed care entity, or other specified entity, including the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the managing of appeals or grievances related to the prescription drug benefits, contracting with pharmacies, controlling the cost of covered outpatient drugs, or the provision of services related thereto. Such term includes any person or entity that acts as a price negotiator (with regard to payment amounts to pharmacies and providers for a covered outpatient drug or the net cost of the drug) or group purchaser on behalf of a State, managed care entity, or other specified entity or that carries out 1 or more of the

other activities described in the preceding sentence, irrespective of whether such person or entity calls itself a pharmacy benefit manager.''.

(b) CONFORMING AMENDMENTS.—Section 1903(m) of such Act (42 U.S.C. 1396b(m)) is amended—

(1) in paragraph (2)(A)(xiii)—

(A) by striking ''and (III)'' and inserting ''(III)'';

(B) by inserting before the period at the end the following: '', and (IV) if the contract includes provisions making the entity responsible for coverage of covered outpatient drugs, the entity shall comply with the requirements of section 1927(e)(6)''; and

(C) by moving the margin 2 ems to the left; and

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

''(10) No payment shall be made under this title to a State with respect to expenditures incurred by the State for payment for services provided by an other specified entity (as defined in paragraph (9)(D)(iii)) unless such services are provided in accordance with a contract between the State and such

entity which satisfies the requirements of paragraph (2)(A)(xiii).''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to contracts between States and managed care entities, other specified entities, or pharmacy benefit managers that have an effective date beginning on or after the date that is 18 months after the date of enactment of this Act.

(d) IMPLEMENTATION.—

(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendments made by this section by program instruction or otherwise.

(2) NONAPPLICATION OF ADMINISTRATIVE PROCEDURE ACT.—Implementation of the amendments made by this section shall be exempt from the requirements of section 553 of title 5, United States Code.

(e) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to any data collection undertaken by the Secretary of Health and Human Services under section 1927(e) of the Social Security Act (42 U.S.C. 1396r–8(e)), as amended by this section.

TITLE II—MEDICARE

SEC. 201. EXTENSION OF INCREASED INPATIENT HOSPITAL PAYMENT ADJUSTMENT FOR CERTAIN LOW-VOLUME HOSPITALS.

(a) IN GENERAL.—Section 1886(d)(12) of the Social Security Act (42 U.S.C. 1395ww(d)(12)) is amended—

(1) in subparagraph (B), in the matter preceding clause (i), by striking ''fiscal year 2025 beginning on April 1, 2025, and ending on September 30, 2025, and in fiscal year 2026'' and inserting ''fiscal year 2026 beginning on January 1, 2026, and ending on September 30, 2026, and in fiscal year 2027'';

(2) in subparagraph (C)(i)—

(A) in the matter preceding subclause (I), by striking ''through 2024 and the portion of fiscal year 2025 beginning on October 1, 2024, and ending on March 31, 2025'' and inserting ''through 2025 and the portion of fiscal year 2026 beginning on October 1, 2025, and ending on December 31, 2025'';

(B) in subclause (III), by striking ''through 2024 and the portion of fiscal year 2025 beginning on October 1, 2024, and ending on March 31, 2025'' and inserting ''through

2025 and the portion of fiscal year 2026 beginning on October 1, 2025, and ending on December 31, 2025''; and

(C) in subclause (IV), by striking ''fiscal year 2025 beginning on April 1, 2025, and ending on September 30, 2025, and fiscal year 2026'' and inserting ''fiscal year 2026 beginning on January 1, 2026, and ending on September 30, 2026, and fiscal year 2027''; and

(3) in subparagraph (D)—

(A) in the matter preceding clause (i), by striking ''through 2024 or during the portion of fiscal year 2025 beginning on October 1, 2024, and ending on March 31, 2025'' and inserting ''through 2025 or during the portion of fiscal year 2026 beginning on October 1, 2025, and ending on December 31, 2025''; and

(B) in clause (ii), by striking ''through 2024 and the portion of fiscal year 2025 beginning on October 1, 2024, and ending on March 31, 2025'' and inserting ''through 2025 and the portion of fiscal year 2026 beginning on October 1, 2025, and ending on December 31, 2025''.

(b) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendments made by this section by program instruction or otherwise.

SEC. 202. EXTENSION OF THE MEDICARE-DEPENDENT HOSPITAL (MDH) PROGRAM.

(a) IN GENERAL.—Section 1886(d)(5)(G) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(G)) is amended—

(1) in clause (i), by striking ''April 1, 2025'' and inserting ''January 1, 2026''; and

(2) in clause (ii)(II), by striking ''April 1, 2025'' and inserting ''January 1, 2026''.

(b) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Section 1886(b)(3)(D) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(D)) is amended—

(A) in the matter preceding clause (i), by striking ''April 1, 2025'' and inserting ''January 1, 2026''; and

(B) in clause (iv), by striking ''through fiscal year 2024 and the portion of fiscal year 2025 beginning on October 1, 2024, and ending on March 31, 2025'' and inserting ''through fiscal year 2025 and the portion of fiscal year

2026 beginning on October 1, 2025, and ending on December 31, 2025''.

(2) PERMITTING HOSPITALS TO DECLINE RECLASSIFICATION.—Section 13501(e)(2) of the Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. 1395ww note) is amended by striking ''through fiscal year 2024, or the portion of fiscal year 2025 beginning on October 1, 2024, and ending on March 31, 2025'' and inserting ''through fiscal year 2025, or the portion of fiscal year 2026 beginning on October 1, 2025, and ending on December 31, 2025''.

SEC. 203. EXTENSION OF ADD-ON PAYMENTS FOR AMBULANCE SERVICES.

Section 1834(l) of the Social Security Act (42 U.S.C. 1395m(l)) is amended—

(1) in paragraph (12)(A), by striking ''April 1, 2025'' and inserting ''January 1, 2027''; and

(2) in paragraph (13), by striking ''April 1, 2025'' each place it appears and inserting ''January 1, 2027'' in each such place.

SEC. 204. EXTENDING INCENTIVE PAYMENTS FOR PARTICIPATION IN ELIGIBLE ALTERNATIVE PAYMENT MODELS.

(a) IN GENERAL.—Section 1833(z) of the Social Security Act (42 U.S.C. 1395l(z)) is amended—

(1) in paragraph (1)(A)—

(A) by striking ''with 2026'' and inserting ''with 2027''; and

(B) by inserting '', or, with respect to 2027, 3.53 percent'' after ''1.88 percent'';

(2) in paragraph (2)—

(A) in subparagraph (B)—

(i) in the heading, by striking ''2026'' and inserting ''2027''; and

(ii) in the matter preceding clause (i), by striking ''2026'' and inserting ''2027'';

(B) in subparagraph (C)—

(i) in the heading, by striking ''2027'' and inserting ''2028''; and

(ii) in the matter preceding clause (i), by striking ''2027'' and inserting ''2028''; and

(C) in subparagraph (D), by striking ''and 2026'' and inserting ''2026, and 2027''; and

(3) in paragraph (4)(B), by inserting ''or, with respect to 2027, 3.53 percent'' after ''1.88 percent''.

(b) CONFORMING AMENDMENTS.—Section 1848(q)(1)(C)(iii) of the Social Security Act (42 U.S.C. 1395w–4(q)(1)(C)(iii)) is amended—

(1) in subclause (II), by striking ''2026'' and inserting ''2027''; and

(2) in subclause (III), by striking ''2027'' and inserting ''2028''.

SEC. 205. TEMPORARY PAYMENT INCREASE UNDER THE MEDICARE PHYSICIAN FEE SCHEDULE TO ACCOUNT FOR EXCEPTIONAL CIRCUMSTANCES.

(a) IN GENERAL.—Section 1848(t)(1) of the Social Security Act (42 U.S.C. 1395w–4(t)(1)) is amended—

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

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

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

''(F) such services furnished on or after March 15, 2025, and before January 1, 2026, by 3.5375 percent.''.

(b) CONFORMING AMENDMENT.—Section 1848(c)(2)(B)(iv)(V) is amended by striking ''or 2024'' and inserting ''2024, or 2025''.

SEC. 206. EXTENSION OF FUNDING FOR QUALITY MEASURE ENDORSEMENT, INPUT, AND SELECTION.

Section 1890(d)(2) of the Social Security Act (42 U.S.C. 1395aaa(d)(2)) is amended—

(1) in the first sentence—

(A) by striking ''$11,030,000'' and inserting ''$14,000,000''; and

(B) by striking ''March 31, 2025'' and inserting ''December 31, 2025''; and

(2) in the third sentence, by striking ''March 31, 2025'' and inserting ''December 31, 2025''.

SEC. 207. EXTENSION OF FUNDING OUTREACH AND ASSISTANCE FOR LOW-INCOME PROGRAMS.

(a) STATE HEALTH INSURANCE ASSISTANCE PROGRAMS.—Subsection (a)(1)(B) of section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note) is amended—

(1) in clause (xiii), by striking ''and'' at the end;

(2) in clause (xiv), by striking the period and inserting ''; and''; and

(3) by inserting after clause (xiv) the following new clause:

''(xv) for the period beginning on April 1, 2025, and ending on December 31, 2026, $26,250,000.''.

(b) AREA AGENCIES ON AGING.—Subsection (b)(1)(B) of such section 119 is amended—

(1) in clause (xiii), by striking ''and'' at the end;

(2) in clause (xiv), by striking the period and inserting ''; and''; and

(3) by inserting after clause (xiv) the following new clause:

''(xv) for the period beginning on April 1, 2025, and ending on December 31, 2026, $26,250,000.''.

(c) AGING AND DISABILITY RESOURCE CENTERS.—Subsection (c)(1)(B) of such section 119 is amended—

(1) in clause (xiii), by striking ''and'' at the end;

(2) in clause (xiv), by striking the period and inserting ''; and''; and

(3) by inserting after clause (xiv) the following new clause:

''(xv) for the period beginning on April 1, 2025, and ending on December 31, 2026, $7,750,000.''.

(d) COORDINATION OF EFFORTS TO INFORM OLDER AMERICANS ABOUT BENEFITS AVAILABLE UNDER FEDERAL AND STATE PROGRAMS.—Subsection (d)(2) of such section 119 is amended—

(1) in clause (xiii), by striking ''and'' at the end;

(2) in clause (xiv), by striking the period and inserting ''; and''; and

(3) by inserting after clause (xiv) the following new clause:

''(xv) for the period beginning on April 1, 2025, and ending on December 31, 2026, $26,250,000.''.

SEC. 208. EXTENSION OF THE WORK GEOGRAPHIC INDEX FLOOR.

Section 1848(e)(1)(E) of the Social Security Act (42 U.S.C. 1395w–4(e)(1)(E)) is amended by striking ''April 1, 2025'' and inserting ''January 1, 2026''.

SEC. 209. EXTENSION OF CERTAIN TELEHEALTH FLEXIBILITIES.

(a) REMOVING GEOGRAPHIC REQUIREMENTS AND EXPANDING ORIGINATING SITES FOR TELEHEALTH SERVICES.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended—

(1) in paragraph (2)(B)(iii), by striking ''ending March 31, 2025'' and inserting ''ending December 31, 2026''; and

(2) in paragraph (4)(C)(iii), by striking ''ending on March 31, 2025'' and inserting ''ending on December 31, 2026''.

(b) EXPANDING PRACTITIONERS ELIGIBLE TO FURNISH TELEHEALTH SERVICES.—Section 1834(m)(4)(E) of the Social Security Act (42 U.S.C. 1395m(m)(4)(E)) is amended by striking ''ending on March 31, 2025'' and inserting ''ending on December 31, 2026''.

(c) EXTENDING TELEHEALTH SERVICES FOR FEDERALLY QUALIFIED HEALTH CENTERS AND RURAL HEALTH CLINICS.—Section 1834(m)(8) of the Social Security Act (42 U.S.C. 1395m(m)(8)) is amended—

(1) in subparagraph (A), by striking ''ending on March 31, 2025'' and inserting ''ending on December 31, 2026'';

(2) in subparagraph (B)—

(A) in the subparagraph heading, by inserting ''BEFORE APRIL 1, 2025'' after ''RULE'';

(B) in clause (i), by striking ''during the periods for which subparagraph (A) applies'' and inserting ''before April 1, 2025''; and

(C) in clause (ii), by inserting ''furnished to an eligible telehealth individual before April 1, 2025'' after ''telehealth services''; and

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

"(C) PAYMENT RULE FOR PORTION OF 2025 AND 2026.—

"(i) IN GENERAL.—A telehealth service furnished to an eligible telehealth individual by a Federally qualified health center or rural health clinic on or after April 1, 2025, and before January 1, 2027, shall be paid as a Federally qualified health center service or rural health clinic service (as applicable) under the prospective payment system established under section 1834(o) or the methodology for all-inclusive rates established under section 1833(a)(3), respectively.

"(ii) TREATMENT OF COSTS.—Costs associated with the furnishing of telehealth services by a Federally qualified health center or rural health clinic on or after April 1, 2025, and before January 1, 2027, shall be considered allowable costs for purposes of the prospective payment system established under section 1834(o) and the methodology for all-inclusive rates

established under section 1833(a)(3), as applicable.

"(iii) REQUIRING MODIFIERS.—Not later than July 1, 2025, the Secretary shall establish requirements to include 1 or more codes or modifiers, as determined appropriate by the Secretary, in the case of claims for telehealth services furnished to an eligible telehealth individual by a Federally qualified health center or rural health clinic.".

(d) DELAYING THE IN-PERSON REQUIREMENTS UNDER MEDICARE FOR MENTAL HEALTH SERVICES FURNISHED THROUGH TELEHEALTH AND TELECOMMUNICATIONS TECHNOLOGY.—

(1) DELAY IN REQUIREMENTS FOR MENTAL HEALTH SERVICES FURNISHED THROUGH TELEHEALTH.—Section 1834(m)(7)(B)(i) of the Social Security Act (42 U.S.C. 1395m(m)(7)(B)(i)) is amended, in the matter preceding subclause (I), by striking "April 1, 2025" and inserting "January 1, 2027".

(2) MENTAL HEALTH VISITS FURNISHED BY RURAL HEALTH CLINICS.—Section 1834(y)(2) of the Social Security Act (42 U.S.C. 1395m(y)(2)) is

amended by striking ''April 1, 2025'' and inserting ''January 1, 2027''.

(3) MENTAL HEALTH VISITS FURNISHED BY FEDERALLY QUALIFIED HEALTH CENTERS.—Section 1834(o)(4)(B) of the Social Security Act (42 U.S.C. 1395m(o)(4)(B)) is amended by striking ''April 1, 2025'' and inserting ''January 1, 2027''.

(e) ALLOWING FOR THE FURNISHING OF AUDIO-ONLY TELEHEALTH SERVICES.—Section 1834(m)(9) of the Social Security Act (42 U.S.C. 1395m(m)(9)) is amended by striking ''ending on March 31, 2025'' and inserting ''ending on December 31, 2026''.

(f) EXTENDING USE OF TELEHEALTH TO CONDUCT FACE-TO-FACE ENCOUNTER PRIOR TO RECERTIFICATION OF ELIGIBILITY FOR HOSPICE CARE.—Section 1814(a)(7)(D)(i)(II) of the Social Security Act (42 U.S.C. 1395f(a)(7)(D)(i)(II)) is amended—

(1) by striking ''ending on March 31, 2025'' and inserting ''ending on December 31, 2026''; and

(2) by inserting '', except that this subclause shall not apply in the case of such an encounter with an individual occurring on or after April 1, 2025, if such individual is located in an area that is subject to a moratorium on the enrollment of hospice programs under this title pursuant to section

1866(j)(7), if such individual is receiving hospice care from a provider that is subject to enhanced oversight under this title pursuant to section 1866(j)(3), or if such encounter is performed by a hospice physician or nurse practitioner who is not enrolled under section 1866(j) and is not an opt-out physician or practitioner (as defined in section 1802(b)(6)(D))'' before the semicolon.

(g) REQUIRING MODIFIERS FOR TELEHEALTH SERVICES IN CERTAIN INSTANCES.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended by adding at the end the following new paragraph:

''(10) REQUIRED USE OF MODIFIERS IN CERTAIN INSTANCES.—Not later than January 1, 2026, the Secretary shall establish requirements to include 1 or more codes or modifiers, as determined appropriate by the Secretary, in the case of—

''(A) claims for telehealth services under this subsection that are furnished through a telehealth virtual platform—

''(i) by a physician or practitioner that contracts with an entity that owns such virtual platform; or

"(ii) for which a physician or practitioner has a payment arrangement with an entity for use of such virtual platform; and

"(B) claims for telehealth services under this subsection that are furnished incident to a physician's or practitioner's professional service.".

(h) PROGRAM INSTRUCTION AUTHORITY.—The Secretary of Health and Human Services may implement the amendments made by this section through program instruction or otherwise.

SEC. 210. REQUIRING MODIFIER FOR USE OF TELEHEALTH TO CONDUCT FACE-TO-FACE ENCOUNTER PRIOR TO RECERTIFICATION OF ELIGIBILITY FOR HOSPICE CARE.

Section 1814(a)(7)(D)(i)(II) of the Social Security Act (42 U.S.C. 1395f(a)(7)(D)(i)(II)), as amended by section 209(f), is further amended by inserting ", but only if, in the case of such an encounter occurring on or after January 1, 2026, any hospice claim includes 1 or more modifiers or codes (as specified by the Secretary) to indicate that such encounter was conducted via telehealth" after "as determined appropriate by the Secretary".

SEC. 211. EXTENDING ACUTE HOSPITAL CARE AT HOME WAIVER FLEXIBILITIES.

Section 1866G of the Social Security Act (42 U.S.C. 1395cc–7) is amended—

(1) in the section heading, by inserting ''**THE THOMAS R. CARPER, TIM SCOTT, BRAD R. WENSTRUP, D.P.M., AND EARL BLUMENAUER**'' after ''**EXTENSION OF**'';

(2) in subsection (a)—

(A) in paragraph (1)—

(i) by striking ''March 31, 2025'' and inserting ''December 31, 2029''; and

(ii) by striking ''in the Acute Hospital Care at Home initiative of the Secretary'' and inserting ''in the Thomas R. Carper, Tim Scott, Brad R. Wenstrup, D.P.M., and Earl Blumenauer Acute Hospital Care at Home initiative of the Secretary (in this section referred to as the 'Acute Hospital Care at Home initiative')'';

(B) in paragraph (2), by striking ''of the Secretary''; and

(C) in paragraph (3)(E), by adding at the end the following new flush sentence:

''The Secretary may require that such data and information be submitted through a hospital's

cost report, through such survey instruments as the Secretary may develop, through medical record information, or through such other means as the Secretary determines appropriate.'';

(3) in subsection (b)—

(A) in the subsection heading, by striking ''STUDY'' and inserting ''INITIAL STUDY'';

(B) in paragraph (1)(A), by striking ''of the Secretary''; and

(C) in paragraph (3), by inserting ''or subsection (c)'' before the period at the end;

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

(5) by inserting after subsection (b) the following new subsection:

''(c) SUBSEQUENT STUDY AND REPORT.—

''(1) IN GENERAL.—Not later than September 30, 2028, the Secretary shall conduct a study to—

''(A) analyze, to the extent practicable, the criteria established by hospitals under the Acute Hospital Care at Home initiative to determine which individuals may be furnished services under such initiative; and

''(B) analyze and compare (both within and between hospitals participating in the initiative, and relative to comparable hospitals that do not participate in the initiative, for relevant parameters such as diagnosis-related groups)—

''(i) quality of care furnished to individuals with similar conditions and characteristics in the inpatient setting and through the Acute Hospital Care at Home initiative, including health outcomes, hospital readmission rates (including readmissions both within and beyond 30 days post-discharge), hospital mortality rates, length of stay, infection rates, composition of care team (including the types of labor used, such as contracted labor), the ratio of nursing staff, transfers from the hospital to the home, transfers from the home to the hospital (including the timing, frequency, and causes of such transfers), transfers and discharges to post-acute care settings (including the timing, frequency, and causes of such transfers and dis-

charges), and patient and caregiver experience of care;

''(ii) clinical conditions treated and diagnosis-related groups of discharges from inpatient settings relative to discharges from the Acute Hospital Care at Home initiative;

''(iii) costs incurred by the hospital for furnishing care in inpatient settings relative to costs incurred by the hospital for furnishing care through the Acute Hospital Care at Home initiative, including costs relating to staffing, equipment, food, prescriptions, and other services, as determined by the Secretary;

''(iv) the quantity, mix, and intensity of services (such as in-person visits and virtual contacts with patients and the intensity of such services) furnished in inpatient settings relative to the Acute Hospital Care at Home initiative, and, to the extent practicable, the nature and extent of family or caregiver involvement;

''(v) socioeconomic information on individuals treated in comparable inpatient

settings relative to the initiative, including racial and ethnic data, income, housing, geographic proximity to the brick-and-mortar facility and whether such individuals are dually eligible for benefits under this title and title XIX; and

''(vi) the quality of care, outcomes, costs, quantity and intensity of services, and other relevant metrics between individuals who entered into the Acute Hospital Care at Home initiative directly from an emergency department compared with individuals who entered into the Acute Hospital Care at Home initiative directly from an existing inpatient stay in a hospital.

''(2) SELECTION BIAS.—In conducting the study under paragraph (1), the Secretary shall, to the extent practicable, analyze and compare individuals who participate and do not participate in the initiative controlling for selection bias or other factors that may impact the reliability of data.

''(3) REPORT.—Not later than September 30, 2028, the Secretary of Health and Human Services shall post on a website of the Centers for Medicare

& Medicaid Services a report on the study conducted under paragraph (1).

''(4) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account for fiscal year 2026, out of any amounts in the Treasury not otherwise appropriated, $6,000,000, respectively, to remain available until expended, for purposes of carrying out this section.''.

SEC. 212. ENHANCING CERTAIN PROGRAM INTEGRITY REQUIREMENTS FOR DME UNDER MEDICARE.

(a) DURABLE MEDICAL EQUIPMENT.—

(1) IN GENERAL.—Section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)) is amended by adding at the end the following new paragraph:

''(23) MASTER LIST INCLUSION AND CLAIM REVIEW FOR CERTAIN ITEMS.—

''(A) MASTER LIST INCLUSION.—Beginning January 1, 2028, for purposes of the Master List described in section 414.234(b) of title 42, Code of Federal Regulations (or any successor regulation), an item for which payment may be made under this subsection shall be treated as having aberrant billing patterns (as such term is used for purposes of such section)

if the Secretary determines that, without explanatory contributing factors (such as furnishing emergent care services), a substantial number of claims for such items under this subsection are for such items ordered by a physician or practitioner who has not previously (during a period of not less than 24 months, as established by the Secretary) furnished to the individual involved any item or service for which payment may be made under this title.

''(B) CLAIM REVIEW.—With respect to items furnished on or after January 1, 2028, that are included on the Master List pursuant to subparagraph (A), if such an item is not subject to a determination of coverage in advance pursuant to paragraph (15)(C), the Secretary may conduct prepayment review of claims for payment for such item.''.

(2) CONFORMING AMENDMENT FOR PROSTHETIC DEVICES, ORTHOTICS, AND PROSTHETICS.—Section 1834(h)(3) of the Social Security Act (42 U.S.C. 1395m(h)(3)) is amended by inserting '', and paragraph (23) of subsection (a) shall apply to prosthetic devices, orthotics, and prosthetics in the same manner as such provision applies to items for which

payment may be made under such subsection'' before the period at the end.

(b) REPORT ON IDENTIFYING CLINICAL DIAGNOSTIC LABORATORY TESTS AT HIGH RISK FOR FRAUD AND EFFECTIVE MITIGATION MEASURES.—Not later than January 1, 2026, the Inspector General of the Department of Health and Human Services shall submit to Congress a report assessing fraud risks relating to claims for clinical diagnostic laboratory tests for which payment may be made under section 1834A of the Social Security Act (42 U.S.C. 1395m–1) and effective tools for reducing such fraudulent claims. The report may include information regarding—

(1) which, if any, clinical diagnostic laboratory tests are identified as being at high risk of fraudulent claims, and an analysis of the factors that contribute to such risk;

(2) with respect to a clinical diagnostic laboratory test identified under paragraph (1) as being at high risk of fraudulent claims—

(A) the amount payable under such section 1834A with respect to such test;

(B) the number of such tests furnished to individuals enrolled under part B of title XVIII

of the Social Security Act (42 U.S.C. 1395j et seq.);

(C) whether an order for such a test was more likely to come from a provider with whom the individual involved did not have a prior relationship, as determined on the basis of prior payment experience; and

(D) the frequency with which a claim for payment under such section 1834A included the payment modifier identified by code 59 or 91; and

(3) suggested strategies for reducing the number of fraudulent claims made with respect to tests so identified as being at high risk, including—

(A) an analysis of whether the Centers for Medicare & Medicaid Services can detect aberrant billing patterns with respect to such tests in a timely manner;

(B) any strategies for identifying and monitoring the providers who are outliers with respect to the number of such tests that such providers order; and

(C) targeted education efforts to mitigate improper billing for such tests; and

(4) such other information as the Inspector General determines appropriate.

SEC. 213. GUIDANCE ON FURNISHING SERVICES VIA TELEHEALTH TO INDIVIDUALS WITH LIMITED ENGLISH PROFICIENCY.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Secretary of Health and Human Services, in consultation with 1 or more entities from each of the categories described in paragraphs (1) through (7) of subsection (b), shall issue and disseminate, or update and revise as applicable, guidance for the entities described in such subsection on the following:

(1) Best practices on facilitating and integrating use of interpreters during a telemedicine appointment.

(2) Best practices on providing accessible instructions on how to access telecommunications systems (as such term is used for purposes of section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) for individuals with limited English proficiency.

(3) Best practices on improving access to digital patient portals for individuals with limited English proficiency.

(4) Best practices on integrating the use of video platforms that enable multi-person video calls furnished via a telecommunications system for purposes of providing interpretation during a telemedicine appointment for an individual with limited English proficiency.

(5) Best practices for providing patient materials, communications, and instructions in multiple languages, including text message appointment reminders and prescription information.

(b) ENTITIES DESCRIBED.—For purposes of subsection (a), an entity described in this subsection is an entity in 1 or more of the following categories:

(1) Health information technology service providers, including—

(A) electronic medical record companies;

(B) remote patient monitoring companies; and

(C) telehealth or mobile health vendors and companies.

(2) Health care providers, including—

(A) physicians; and

(B) hospitals.

(3) Health insurers.

(4) Language service companies.

(5) Interpreter or translator professional associations.

(6) Health and language services quality certification organizations.

(7) Patient and consumer advocates, including such advocates that work with individuals with limited English proficiency.

SEC. 214. IN-HOME CARDIOPULMONARY REHABILITATION FLEXIBILITIES.

(a) IN GENERAL.—Section 1861(eee)(2) of the Social Security Act (42 U.S.C. 1395x(eee)(2)) is amended—

(1) in subparagraph (A)(ii), by inserting ''(including, with respect to items and services furnished through audio and video real-time communications technology (excluding audio-only) on or after April 1, 2025, and before January 1, 2027, in the home of an individual who is an outpatient of the hospital)'' after ''outpatient basis''; and

(2) in subparagraph (B), by inserting ''(including, with respect to items and services furnished through audio and video real-time communications technology on or after April 1, 2025, and before January 1, 2027, the virtual presence of such physician, physician assistant, nurse practitioner, or clinical nurse specialist)'' after ''under the program''.

(b) PROGRAM INSTRUCTION AUTHORITY.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendments made by this section by program instruction or otherwise.

SEC. 215. INCLUSION OF VIRTUAL DIABETES PREVENTION PROGRAM SUPPLIERS IN MDPP EXPANDED MODEL.

(a) IN GENERAL.—Not later than January 1, 2026, the Secretary shall revise the regulations under parts 410 and 424 of title 42, Code of Federal Regulations, to provide that, for the period beginning January 1, 2026, and ending December 31, 2030—

(1) an entity may participate in the MDPP by offering only online MDPP services via synchronous or asynchronous technology or telecommunications if such entity meets the conditions for enrollment as an MDPP supplier (as specified in section 424.205(b) of title 42, Code of Federal Regulations (or a successor regulation));

(2) if an entity participates in the MDPP in the manner described in paragraph (1)—

(A) the administrative location of such entity shall be the address of the entity on file

under the Diabetes Prevention Recognition Program; and

(B) in the case of online MDPP services furnished by such entity to an MDPP beneficiary who was not located in the same State as the entity at the time such services were furnished, the entity shall not be prohibited from submitting a claim for payment for such services solely by reason of the location of such beneficiary at such time; and

(3) no limit is applied on the number of times an individual may enroll in the MDPP.

(b) DEFINITIONS.—In this section:

(1) MDPP.—The term ''MDPP'' means the Medicare Diabetes Prevention Program conducted under section 1115A of the Social Security Act (42 U.S.C. 1315a), as described in the final rule published in the Federal Register entitled ''Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic

Health Program'' (88 Fed. Reg. 78818 (November 16, 2023)) (or a successor regulation).

(2) REGULATORY TERMS.—The terms ''Diabetes Prevention Recognition Program'', ''full CDC DPRP recognition'', ''MDPP beneficiary'', ''MDPP services'', and ''MDPP supplier'' have the meanings given each such term in section 410.79(b) of title 42, Code of Federal Regulations.

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 216. MEDICATION-INDUCED MOVEMENT DISORDER OUTREACH AND EDUCATION.

Not later than January 1, 2026, the Secretary shall use existing communications mechanisms to provide education and outreach to physicians and appropriate non-physician practitioners participating under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) with respect to periodic screening for medication-induced movement disorders that are associated with the treatment of mental health disorders in at-risk patients, as well as resources related to clinical guidelines and best practices for furnishing such screening services through telehealth. Such education and outreach shall include information on how to account for such screening services in evaluation and management code selection. The

Secretary shall, to the extent practicable, seek input from relevant stakeholders to inform such education and outreach. Such education and outreach may also address other relevant screening services furnished through telehealth, as the Secretary determines appropriate.

SEC. 217. REPORT ON WEARABLE MEDICAL DEVICES.

Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall conduct a technology assessment of, and submit to Congress a report on, the capabilities and limitations of wearable medical devices used to support clinical decision-making. Such report shall include a description of—

(1) the potential for such devices to accurately prescribe treatments;

(2) an examination of the benefits and challenges of artificial intelligence to augment such capabilities; and

(3) policy options to enhance the benefits and mitigate potential challenges of developing or using such devices.

SEC. 218. EXTENSION OF TEMPORARY INCLUSION OF AUTHORIZED ORAL ANTIVIRAL DRUGS AS COVERED PART D DRUGS.

Section 1860D–2(e)(1)(C) of the Social Security Act (42 U.S.C. 1395w–102(e)(1)(C)) is amended by striking ''March 31, 2025'' and inserting ''December 31, 2025''.

SEC. 219. EXTENSION OF ADJUSTMENT TO CALCULATION OF HOSPICE CAP AMOUNT.

Section 1814(i)(2)(B) of the Social Security Act (42 U.S.C. 1395f(i)(2)(B)) is amended—

(1) in clause (ii), by striking ''2033'' and inserting ''2034''; and

(2) in clause (iii), by striking ''2033'' and inserting ''2034''.

SEC. 220. MULTIYEAR CONTRACTING AUTHORITY FOR MEDPAC AND MACPAC.

Section 3904 of title 41, United States Code, is amended by adding at the end the following new subsections:

''(i) THE MEDICARE PAYMENT ADVISORY COMMISSION.—The Medicare Payment Advisory Commission may use available funds to enter into contracts for the procurement of severable services for a period that begins in one fiscal year and ends in the next fiscal year and may enter into multiyear contracts for the acquisition of property and services to the same extent as executive agencies

under the authority of sections 3902 and 3903 of this title.

''(j) THE MEDICAID AND CHIP PAYMENT AND ACCESS COMMISSION.—The Medicaid and CHIP Payment and Access Commission may use available funds to enter into contracts for the procurement of severable services for a period that begins in one fiscal year and ends in the next fiscal year and may enter into multiyear contracts for the acquisition of property and services to the same extent as executive agencies under the authority of sections 3902 and 3903 of this title.''.

SEC. 221. CONTRACTING PARITY FOR MEDPAC AND MACPAC.

In fiscal year 2025 and thereafter, for all contracts for goods and services to which the Medicare and Payment Advisory Commission or the Medicaid and CHIP Payment and Access Commission is a party, the following Federal Acquisition Regulation (FAR) clauses will apply: FAR 52.232–39 and FAR 52.233–4 (or a successor clause).

SEC. 222. ADJUSTMENTS TO MEDICARE PART D COST-SHARING REDUCTIONS FOR LOW-INCOME INDIVIDUALS.

Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)) is amended—

(1) in paragraph (1)(D)(ii), by striking ''that does not exceed $1 for'' and all that follows through the period at the end and inserting ''that does not exceed—

''(I) for a plan year before 2027—

''(aa) for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)), $1 or, if less, the copayment amount applicable to an individual under clause (iii); and

''(bb) for any other drug, $3 or, if less, the copayment amount applicable to an individual under clause (iii); and

''(II) for plan year 2027 and each subsequent plan year—

''(aa) for a generic drug, $0;

''(bb) for a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)), the dollar amount applied under this clause

for such a drug for the preceding plan year, increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such preceding year, or, if less, the copayment amount applicable to an individual under clause (iii); and

"(cc) for a drug not described in either item (aa) or (bb), the dollar amount applied under this clause for such a drug for the preceding plan year, increased in the manner specified in item (bb), or, if less, the copayment amount applicable to an individual under clause (iii).

Any amount established under item (bb) or (cc) of subclause (II), that is based on an increase of $1 or $3, that is not a multiple of 5 cents or 10 cents, respectively, shall be rounded to the nearest multiple of 5 cents or 10 cents, respectively."; and

(2) in paragraph (4)(A)(ii), by inserting ''(before 2027)'' after ''a subsequent year''.

SEC. 223. REQUIRING ENHANCED AND ACCURATE LISTS OF (REAL) HEALTH PROVIDERS ACT.

(a) IN GENERAL.—Section 1852(c) of the Social Security Act (42 U.S.C. 1395w–22(c)) is amended—

(1) in paragraph (1)(C)—

(A) by striking ''plan, and any'' and inserting ''plan, any''; and

(B) by inserting the following before the period at the end: '', and, in the case of a specified MA plan (as defined in paragraph (3)(C)), for plan year 2027 and subsequent plan years, the information described in paragraph (3)(B)''; and

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

''(3) PROVIDER DIRECTORY ACCURACY.—

''(A) IN GENERAL.—For plan year 2027 and subsequent plan years, each MA organization offering a specified MA plan (as defined in subparagraph (C)) shall, for each such plan offered by the organization—

''(i) maintain, on a publicly available internet website, an accurate provider di-

rectory that includes the information described in subparagraph (B);

"(ii) not less frequently than once every 90 days (or, in the case of a hospital or any other facility determined appropriate by the Secretary, at a lesser frequency specified by the Secretary but in no case less frequently than once every 12 months), verify the provider directory information of each provider listed in such directory and, if applicable, update such provider directory information;

"(iii) if the organization is unable to verify such information with respect to a provider, include in such directory an indication that the information of such provider may not be up-to-date; and

"(iv) remove a provider from such directory within 5 business days if the organization determines that the provider is no longer a provider participating in the network of such plan.

"(B) PROVIDER DIRECTORY INFORMATION.—The information described in this subparagraph is information enrollees may need to

access covered benefits from a provider with which such organization offering such plan has an agreement for furnishing items and services covered under such plan such as name, specialty, contact information, primary office or facility address, whether the provider is accepting new patients, accommodations for people with disabilities, cultural and linguistic capabilities, and telehealth capabilities.

''(C) SPECIFIED MA PLAN.—In this paragraph, the term 'specified MA plan' means—

''(i) a network-based plan (as defined in subsection (d)(5)(C)); or

''(ii) a Medicare Advantage private fee-for-service plan (as defined in section 1859(b)(2)) that meets the access standards under subsection (d)(4), in whole or in part, through entering into contracts or agreements as provided for under subparagraph (B) of such subsection.''.

(b) ACCOUNTABILITY FOR PROVIDER DIRECTORY ACCURACY.—

(1) COST SHARING FOR SERVICES FURNISHED BASED ON RELIANCE ON INCORRECT PROVIDER DIRECTORY INFORMATION.—Section 1852(d) of the

Social Security Act (42 U.S.C. 1395w–22(d)) is amended—

(A) in paragraph (1)(C)—

(i) in clause (ii), by striking ''or'' at the end;

(ii) in clause (iii), by striking the semicolon at the end and inserting '', or''; and

(iii) by adding at the end the following new clause:

''(iv) the services are furnished by a provider that is not participating in the network of a specified MA plan (as defined in subsection (c)(3)(C)) but is listed in the provider directory of such plan on the date on which the appointment is made, as described in paragraph (7)(A);''; and

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

''(7) COST SHARING FOR SERVICES FURNISHED BASED ON RELIANCE ON INCORRECT PROVIDER DIRECTORY INFORMATION.—

''(A) IN GENERAL.—For plan year 2027 and subsequent plan years, if an enrollee is furnished an item or service by a provider that is

not participating in the network of a specified MA plan (as defined in subsection (c)(3)(C)) but is listed in the provider directory of such plan (as required to be provided to an enrollee pursuant to subsection (c)(1)(C)) on the date on which the appointment is made, and if such item or service would otherwise be covered under such plan if furnished by a provider that is participating in the network of such plan, the MA organization offering such plan shall ensure that the enrollee is only responsible for the lesser of—

''(i) the amount of cost sharing that would apply if such provider had been participating in the network of such plan; or

''(ii) the amount of cost sharing that would otherwise apply (without regard to this subparagraph).

''(B) NOTIFICATION REQUIREMENT.—For plan year 2027 and subsequent plan years, each MA organization that offers a specified MA plan shall—

''(i) notify enrollees of their cost-sharing protections under this paragraph and make such notifications, to the extent

practicable, by not later than the first day of an annual, coordinated election period under section 1851(e)(3) with respect to a year;

''(ii) include information regarding such cost-sharing protections in the provider directory of each specified MA plan offered by the MA organization.; and

''(iii) notify enrollees of their cost-sharing protections under this paragraph in an explanation of benefits.''.

(2) REQUIRED PROVIDER DIRECTORY ACCURACY ANALYSIS AND REPORTS.—

(A) IN GENERAL.—Section 1857(e) of the Social Security Act (42 U.S.C. 1395w–27(e)) is amended by adding at the end the following new paragraph:

''(6) PROVIDER DIRECTORY ACCURACY ANALYSIS AND REPORTS.—

''(A) IN GENERAL.—Beginning with plan years beginning on or after January 1, 2027, subject to subparagraph (C), a contract under this section with an MA organization shall require the organization, for each specified MA plan (as defined in section 1852(c)(3)(C)) of-

fered by the organization to annually do the following:

"(i) Conduct an analysis estimating the accuracy of the provider directory information of such plan using a random sample of providers included in such provider directory as follows:

"(I) Such a random sample shall include a random sample of each specialty of providers with a high inaccuracy rate of provider directory information relative to other specialties of providers, as determined by the Secretary.

"(II) For purposes of subclause (I), one type of specialty may be providers specializing in mental health or substance use disorder treatment.

"(ii) Submit to the Secretary a report containing the results of the analysis conducted under clause (i), including an accuracy score for such provider directory information (as determined using a plan verification method specified by the Secretary under subparagraph (B)(i)).

"(B) DETERMINATION OF ACCURACY SCORE.—

"(i) IN GENERAL.—The Secretary shall specify plan verification methods, such as using telephonic verification or other approaches using data sources maintained by an MA organization or using publicly available data sets, that MA organizations may use for estimating accuracy scores of the provider directory information of specified MA plans offered by such organizations.

"(ii) ACCURACY SCORE METHODOLOGY.—With respect to each such method specified by the Secretary as described in clause (i), the Secretary shall specify a methodology for MA organizations to use in estimating such accuracy scores. Each such methodology shall take into account the administrative burden on plans and providers and the relative importance of certain provider directory information on enrollee ability to access care.

"(C) EXCEPTION.—The Secretary may waive the requirements of this paragraph in the

case of a specified MA plan with low enrollment (as defined by the Secretary).

''(D) TRANSPARENCY.—Beginning with plan years beginning on or after January 1, 2028, the Secretary shall post accuracy scores (as reported under subparagraph (A)(ii)), in a machine readable file, on the internet website of the Centers for Medicare & Medicaid Services.''.

(B) PROVISION OF INFORMATION TO BENEFICIARIES.—Section 1851(d)(4) of the Social Security Act (42 U.S.C. 1395w–21(d)(4)) is amended by adding at the end the following new subparagraph:

''(F) PROVIDER DIRECTORY.—Beginning with plan years beginning on or after January 1, 2028, the accuracy score of the plan's provider directory (as reported under section 1857(e)(6)(A)(ii)) listed prominently on the plan's provider directory.''.

(C) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any money in the Treasury not otherwise appropriated, $4,000,000 for fiscal year 2025, to remain

available until expended, to carry out the amendments made by this paragraph.

(3) GAO STUDY AND REPORT.—

(A) ANALYSIS.—The Comptroller General of the United States (in this paragraph referred to as the ''Comptroller General'') shall conduct a study of the implementation of the amendments made by paragraphs (1) and (2). To the extent data are available and reliable, such study shall include an analysis of—

(i) the use of cost-sharing protections required under section 1852(d)(7)(A) of the Social Security Act, as added by paragraph (1);

(ii) the trends in provider directory information accuracy scores under section 1857(e)(6)(A)(ii) of the Social Security Act (as added by paragraph (2)(A)), both overall and among providers specializing in mental health or substance use disorder treatment;

(iii) provider response rates by plan verification methods;

(iv) administrative costs to providers and Medicare Advantage organizations; and

(v) other items determined appropriate by the Comptroller General.

(B) REPORT.—Not later than January 15, 2032, the Comptroller General shall submit to Congress a report containing the results of the study conducted under subparagraph (A), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(c) GUIDANCE ON MAINTAINING ACCURATE PROVIDER DIRECTORIES.—

(1) STAKEHOLDER MEETING.—

(A) IN GENERAL.—Not later than 3 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall hold a public meeting to receive input on approaches for maintaining accurate provider directories for Medicare Advantage plans under part C of title XVIII of the Social Security Act (42 U.S.C. 1395w–21 et seq.), including input on approaches for reducing ad-

ministrative burden, such as data standardization, and best practices to maintain accurate provider directory information.

(B) PARTICIPANTS.—Participants of the meeting under subparagraph (A) shall include representatives from the Centers for Medicare & Medicaid Services and the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology. Such meeting shall be open to the public. To the extent practicable, the Secretary shall include health care providers, companies that specialize in relevant technologies, health insurers, and patient advocates.

(2) GUIDANCE TO MEDICARE ADVANTAGE ORGANIZATIONS.—Not later than 12 months after the date of enactment of this Act, the Secretary shall issue guidance to Medicare Advantage organizations offering Medicare Advantage plans under part C of title XVIII of the Social Security Act (42 U.S.C. 1395w–21 et seq.) on maintaining accurate provider directories for such plans, taking into consideration input received during the stakeholder meeting under paragraph (1). Such guidance may include the following, as determined appropriate by the Secretary:

(A) Best practices for Medicare Advantage organizations on how to work with providers to maintain the accuracy of provider directories and reduce provider and Medicare Advantage organization burden with respect to maintaining the accuracy of provider directories.

(B) Information on data sets and data sources with information that could be used by Medicare Advantage organizations to maintain accurate provider directories.

(C) Approaches for utilizing data sources maintained by Medicare Advantage organizations and publicly available data sets to maintain accurate provider directories.

(D) Information to be included in provider directories that may be useful for Medicare beneficiaries to assess plan networks when selecting a plan and accessing providers participating in plan networks during the plan year.

(3) GUIDANCE TO PART B PROVIDERS.—Not later than 12 months after the date of enactment of this Act, the Secretary shall issue guidance to providers of services and suppliers who furnish items or services for which benefits are available under part B of title XVIII of the Social Security Act (42

U.S.C. 1395j et seq.) on when to update the National Plan and Provider Enumeration System for information changes.

SEC. 224. MEDICARE COVERAGE OF MULTI-CANCER EARLY DETECTION SCREENING TESTS.

(a) COVERAGE.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(1) in subsection (s)(2)—

(A) by striking the semicolon at the end of subparagraph (JJ) and inserting ''; and''; and

(B) by adding at the end the following new subparagraph:

''(KK) multi-cancer early detection screening tests (as defined in subsection (nnn));''; and

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

''(nnn) MULTI-CANCER EARLY DETECTION SCREENING TESTS.—

''(1) IN GENERAL.—The term 'multi-cancer early detection screening test' means a test furnished to an individual for the concurrent detection of multiple cancer types across multiple organ sites on or after January 1, 2029, that—

''(A) is cleared under section 510(k), classified under section 513(f)(2), or approved

under section 515 of the Federal Food, Drug, and Cosmetic Act;

"(B) is—

"(i) a genomic sequencing blood or blood product test that includes the analysis of cell-free nucleic acids; or

"(ii) a test based on samples of biological material that provide results comparable to those obtained with a test described in clause (i), as determined by the Secretary; and

"(C) the Secretary determines is—

"(i) reasonable and necessary for the prevention or early detection of an illness or disability; and

"(ii) appropriate for individuals entitled to benefits under part A or enrolled under part B.

"(2) NCD PROCESS.—In making determinations under paragraph (1)(C) regarding the coverage of a new test, the Secretary shall use the process for making national coverage determinations (as defined in section 1869(f)(1)(B)) under this title.".

(b) PAYMENT AND STANDARDS FOR MULTI-CANCER EARLY DETECTION SCREENING TESTS.—

(1) IN GENERAL.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

"(aa) PAYMENT AND STANDARDS FOR MULTI-CANCER EARLY DETECTION SCREENING TESTS.—

"(1) PAYMENT AMOUNT.—The payment amount for a multi-cancer early detection screening test (as defined in section 1861(nnn)) is—

"(A) with respect to such a test furnished before January 1, 2031, equal to the payment amount in effect on the date of the enactment of this subsection for a multi-target stool screening DNA test covered pursuant to section 1861(pp)(1)(D); and

"(B) with respect to such a test furnished on or after January 1, 2031, equal to the lesser of—

"(i) the amount described in subparagraph (A); or

"(ii) the payment amount determined for such test under section 1834A.

"(2) LIMITATIONS.—

"(A) IN GENERAL.—No payment may be made under this part for a multi-cancer early

detection screening test furnished during a year to an individual if—

"(i) such individual—

"(I) is under 50 years of age; or

"(II) as of January 1 of such year, has attained the age specified in subparagraph (B) for such year; or

"(ii) such a test was furnished to the individual during the previous 11 months.

"(B) AGE SPECIFIED.—For purposes of subparagraph (A)(i)(II), the age specified in this subparagraph is—

"(i) for 2029, 65 years of age; and

"(ii) for a succeeding year, the age specified in this subparagraph for the preceding year, increased by 1 year.

"(C) STANDARDS FOLLOWING USPSTF RATING OF A OR B.—In the case of a multi-cancer early detection screening test that is recommended with a grade of A or B by the United States Preventive Services Task Force, beginning on the date on which coverage for such test is provided pursuant to section 1861(ddd)(1), the preceding provisions of this paragraph shall not apply.".

(2) CONFORMING AMENDMENTS.—

(A) Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—

(i) in subsection (a)—

(I) in paragraph (1)(D)(i)(I), by striking ''section 1834(d)(1)'' and inserting ''subsection (d)(1) or (aa) of section 1834''; and

(II) in paragraph (2)(D)(i)(I), by striking ''section 1834(d)(1)'' and inserting ''subsection (d)(1) or (aa) of section 1834''; and

(ii) in subsection (h)(1)(A), by striking ''section 1834(d)(1)'' and inserting ''subsections (d)(1) and (aa) of section 1834''.

(B) Section 1862(a)(1)(A) of the Social Security Act (42 U.S.C. 1395y(a)(1)(A)) is amended—

(i) by striking ''or additional preventive services'' and inserting '', additional preventive services''; and

(ii) by inserting '', or multi-cancer early detection screening tests (as defined

in section 1861(nnn))'' after ''(as described in section 1861(ddd)(1))''.

(c) RULE OF CONSTRUCTION RELATING TO OTHER CANCER SCREENING TESTS.—Nothing in this section, including the amendments made by this section, shall be construed—

(1) in the case of an individual who undergoes a multi-cancer early detection screening test, to affect coverage under part B of title XVIII of the Social Security Act for other cancer screening tests covered under such title, such as screening tests for breast, cervical, colorectal, lung, or prostate cancer; or

(2) in the case of an individual who undergoes another cancer screening test, to affect coverage under such part for a multi-cancer early detection screening test or the use of such a test as a diagnostic or confirmatory test for a result of the other cancer screening test.

SEC. 225. MEDICARE COVERAGE OF EXTERNAL INFUSION PUMPS AND NON-SELF-ADMINISTRABLE HOME INFUSION DRUGS.

(a) IN GENERAL.—Section 1861(n) of the Social Security Act (42 U.S.C. 1395x(n)) is amended by adding at the end the following new sentence: ''Beginning with

the first calendar quarter beginning on or after the date that is 1 year after the date of the enactment of this sentence, an external infusion pump and associated home infusion drug (as defined in subsection (iii)(3)(C)) or other associated supplies that do not meet the appropriate for use in the home requirement applied to the definition of durable medical equipment under section 414.202 of title 42, Code of Federal Regulations (or any successor to such regulation) shall be treated as meeting such requirement if each of the following criteria is satisfied:

''(1) The prescribing information approved by the Food and Drug Administration for the home infusion drug associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional.

''(2) A qualified home infusion therapy supplier (as defined in subsection (iii)(3)(D)) administers or supervises the administration of the drug or biological in a safe and effective manner in the patient's home (as defined in subsection (iii)(3)(B)).

''(3) The prescribing information described in paragraph (1) instructs that the drug should be infused at least 12 times per year—

''(A) intravenously or subcutaneously; or

''(B) at infusion rates that the Secretary determines would require the use of an external infusion pump.''.

(b) COST SHARING NOTIFICATION.—The Secretary of Health and Human Services shall ensure that patients are notified of the cost sharing for electing home infusion therapy compared to other applicable settings of care for the furnishing of infusion drugs under the Medicare program.

SEC. 226. ASSURING PHARMACY ACCESS AND CHOICE FOR MEDICARE BENEFICIARIES.

(a) IN GENERAL.—Section 1860D–4(b)(1) of the Social Security Act (42 U.S.C. 1395w–104(b)(1)) is amended by striking subparagraph (A) and inserting the following:

''(A) IN GENERAL.—

''(i) PARTICIPATION OF ANY WILLING PHARMACY.—A PDP sponsor offering a prescription drug plan shall permit any pharmacy that meets the standard contract terms and conditions under such plan to participate as a network pharmacy of such plan.

''(ii) CONTRACT TERMS AND CONDITIONS.—

"(I) IN GENERAL.—Notwithstanding any other provision of law, for plan years beginning on or after January 1, 2028, in accordance with clause (i), contract terms and conditions offered by such PDP sponsor shall be reasonable and relevant according to standards established by the Secretary under subclause (II).

"(II) STANDARDS.—Not later than the first Monday in April of 2027, the Secretary shall establish standards for reasonable and relevant contract terms and conditions for purposes of this clause.

"(III) REQUEST FOR INFORMATION.—Not later than April 1, 2026, for purposes of establishing the standards under subclause (II), the Secretary shall issue a request for information to seek input on trends in prescription drug plan and network pharmacy contract terms and conditions, current prescription drug plan and network pharmacy contracting prac-

tices, whether pharmacy reimbursement and dispensing fees paid by PDP sponsors to network pharmacies sufficiently cover the ingredient and operational costs of such pharmacies, the use and application of pharmacy quality measures by PDP sponsors for network pharmacies, PDP sponsor restrictions or limitations on the dispensing of covered part D drugs by network pharmacies (or any subsets of such pharmacies), PDP sponsor auditing practices for network pharmacies, areas in current regulations or program guidance related to contracting between prescription drug plans and network pharmacies requiring clarification or additional specificity, factors for consideration in determining the reasonableness and relevance of contract terms and conditions between prescription drug plans and network pharmacies, and other issues as determined appropriate by the Secretary.''.

(b) ESSENTIAL RETAIL PHARMACIES.—Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152) is amended by adding at the end the following new subsection:

''(e) ESSENTIAL RETAIL PHARMACIES.—

''(1) IN GENERAL.—With respect to plan years beginning on or after January 1, 2028, the Secretary shall publish reports, at least once every 2 years until 2034, and periodically thereafter, that provide information, to the extent feasible, on—

''(A) trends in ingredient cost reimbursement, dispensing fees, incentive payments and other fees paid by PDP sponsors offering prescription drug plans and MA organizations offering MA–PD plans under this part to essential retail pharmacies (as defined in paragraph (2)) with respect to the dispensing of covered part D drugs, including a comparison of such trends between essential retail pharmacies and pharmacies that are not essential retail pharmacies;

''(B) trends in amounts paid to PDP sponsors offering prescription drug plans and MA organizations offering MA–PD plans under this part by essential retail pharmacies with respect

to the dispensing of covered part D drugs, including a comparison of such trends between essential retail pharmacies and pharmacies that are not essential retail pharmacies;

''(C) trends in essential retail pharmacy participation in pharmacy networks and preferred pharmacy networks for prescription drug plans offered by PDP sponsors and MA–PD plans offered by MA organizations under this part, including a comparison of such trends between essential retail pharmacies and pharmacies that are not essential retail pharmacies;

''(D) trends in the number of essential retail pharmacies, including variation in such trends by geographic region or other factors;

''(E) a comparison of cost-sharing for covered part D drugs dispensed by essential retail pharmacies that are network pharmacies for prescription drug plans offered by PDP sponsors and MA–PD plans offered by MA organizations under this part and cost-sharing for covered part D drugs dispensed by other network pharmacies for such plans located in similar geographic areas that are not essential retail pharmacies;

"(F) a comparison of the volume of covered part D drugs dispensed by essential retail pharmacies that are network pharmacies for prescription drug plans offered by PDP sponsors and MA–PD plans offered by MA organizations under this part and such volume of dispensing by network pharmacies for such plans located in similar geographic areas that are not essential retail pharmacies, including information on any patterns or trends in such comparison specific to certain types of covered part D drugs, such as generic drugs or drugs specified as specialty drugs by a PDP sponsor under a prescription drug plan or an MA organization under an MA–PD plan; and

"(G) a comparison of the information described in subparagraphs (A) through (F) between essential retail pharmacies that are network pharmacies for prescription drug plans offered by PDP sponsors under this part and essential retail pharmacies that are network pharmacies for MA–PD plans offered by MA organizations under this part.

"(2) DEFINITION OF ESSENTIAL RETAIL PHARMACY.—In this subsection, the term 'essential retail

pharmacy' means, with respect to a plan year, a retail pharmacy that—

"(A) is not a pharmacy that is an affiliate as defined in paragraph (4); and

"(B) is located in—

"(i) a medically underserved area (as designated pursuant to section 330(b)(3)(A) of the Public Health Service Act);

"(ii) a rural area in which there is no other retail pharmacy within 10 miles, as determined by the Secretary;

"(iii) a suburban area in which there is no other retail pharmacy within 2 miles, as determined by the Secretary; or

"(iv) an urban area in which there is no other retail pharmacy within 1 mile, as determined by the Secretary.

"(3) LIST OF ESSENTIAL RETAIL PHARMACIES.—

"(A) PUBLICATION OF LIST OF ESSENTIAL RETAIL PHARMACIES.—For each plan year (beginning with plan year 2028), the Secretary shall publish, on a publicly available internet website of the Centers for Medicare & Medicaid

Services, a list of pharmacies that meet the criteria described in subparagraphs (A) and (B) of paragraph (2) to be considered an essential retail pharmacy.

''(B) REQUIRED SUBMISSIONS FROM PDP SPONSORS.—For each plan year (beginning with plan year 2028), each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan shall submit to the Secretary, for the purposes of determining retail pharmacies that meet the criterion specified in subparagraph (A) of paragraph (2), a list of retail pharmacies that are affiliates of such sponsor or organization, or are affiliates of a pharmacy benefit manager acting on behalf of such sponsor or organization, at a time, and in a form and manner, specified by the Secretary.

''(C) REPORTING BY PDP SPONSORS AND MA ORGANIZATIONS.—For each plan year beginning with plan year 2027, each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan under this part shall submit to the Secretary information on incentive payments and other fees paid by such sponsor or organization to pharmacies,

insofar as any such payments or fees are not otherwise reported, at a time, and in a form and manner, specified by the Secretary.

''(D) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

''(E) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to the implementation of this paragraph.

''(4) DEFINITION OF AFFILIATE; PHARMACY BENEFIT MANAGER.—In this subsection, the terms 'affiliate' and 'pharmacy benefit manager' have the meaning given those terms in section 1860D–12(h)(7).''.

(c) ENFORCEMENT.—

(1) IN GENERAL.—Section 1860D–4(b)(1) of the Social Security Act (42 U.S.C. 1395w–104(b)(1)) is amended by adding at the end the following new subparagraph:

''(F) ENFORCEMENT OF STANDARDS FOR REASONABLE AND RELEVANT CONTRACT TERMS AND CONDITIONS.—

"(i) ALLEGATION SUBMISSION PROCESS.—

"(I) IN GENERAL.—Not later than January 1, 2028, the Secretary shall establish a process through which a pharmacy may submit to the Secretary an allegation of a violation by a PDP sponsor offering a prescription drug plan of the standards for reasonable and relevant contract terms and conditions under subparagraph (A)(ii), or of subclause (VIII) of this clause.

"(II) FREQUENCY OF SUBMISSION.—

"(aa) IN GENERAL.—Except as provided in item (bb), the allegation submission process under this clause shall allow pharmacies to submit any allegations of violations described in subclause (I) not more frequently than once per plan year per contract between a pharmacy and a PDP sponsor.

"(bb) ALLEGATIONS RELATING TO CONTRACT MODIFICATIONS.—In the case where a contract between a pharmacy and a PDP sponsor is modified following the submission of allegations by a pharmacy with respect to such contract and plan year, the allegation submission process under this clause shall allow such pharmacy to submit an additional allegation related to those modifications with respect to such contract and plan year.

"(III) ACCESS TO RELEVANT DOCUMENTS AND MATERIALS.—A PDP sponsor subject to an allegation under this clause—

"(aa) shall provide documents or materials, as specified by the Secretary, including contract offers made by such sponsor to such pharmacy or correspondence related to such offers, to the Secretary at a time,

and in a form and manner, specified by the Secretary; and

''(bb) shall not prohibit or otherwise limit the ability of a pharmacy to submit such documents or materials to the Secretary for the purpose of submitting an allegation or providing evidence for such an allegation under this clause.

''(IV) STANDARDIZED TEMPLATE.—The Secretary shall establish a standardized template for pharmacies to use for the submission of allegations described in subclause (I). Such template shall require that the submission include a certification by the pharmacy that the information included is accurate, complete, and true to the best of the knowledge, information, and belief of such pharmacy.

''(V) PREVENTING FRIVOLOUS ALLEGATIONS.—In the case where the Secretary determines that a pharmacy has submitted frivolous allegations

under this clause on a routine basis, the Secretary may temporarily prohibit such pharmacy from using the allegation submission process under this clause, as determined appropriate by the Secretary.

''(VI) EXEMPTION FROM FREEDOM OF INFORMATION ACT.—Allegations submitted under this clause shall be exempt from disclosure under section 552 of title 5, United States Code.

''(VII) RULE OF CONSTRUCTION.—Nothing in this clause shall be construed as limiting the ability of a pharmacy to pursue other legal actions or remedies, consistent with applicable Federal or State law, with respect to a potential violation of a requirement described in this subparagraph.

''(VIII) ANTI-RETALIATION AND ANTI-COERCION.—Consistent with applicable Federal or State law, a PDP sponsor shall not—

''(aa) retaliate against a pharmacy for submitting any allegations under this clause; or

''(bb) coerce, intimidate, threaten, or interfere with the ability of a pharmacy to submit any such allegations.

''(ii) INVESTIGATION.—The Secretary shall investigate, as determined appropriate by the Secretary, allegations submitted pursuant to clause (i).

''(iii) ENFORCEMENT.—

''(I) IN GENERAL.—In the case where the Secretary determines that a PDP sponsor offering a prescription drug plan has violated the standards for reasonable and relevant contract terms and conditions under subparagraph (A)(ii), the Secretary may use authorities under sections 1857(g) and 1860D–12(b)(3)(E) to impose civil monetary penalties or other intermediate sanctions.

''(II) APPLICATION OF CIVIL MONETARY PENALTIES.—The provi-

sions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).''.

(2) CONFORMING AMENDMENT.—Section 1857(g)(1) of the Social Security Act (42 U.S.C. 1395w–27(g)(1)) is amended—

(A) in subparagraph (J), by striking ''or'' after the semicolon;

(B) by redesignating subparagraph (K) as subparagraph (L);

(C) by inserting after subparagraph (J), the following new subparagraph:

''(K) fails to comply with the standards for reasonable and relevant contract terms and conditions under subparagraph (A)(ii) of section 1860D–4(b)(1); or'';

(D) in subparagraph (L), as redesignated by subparagraph (B), by striking ''through (J)'' and inserting ''through (K)''; and

(E) in the flush matter following subparagraph (L), as so redesignated, by striking ''sub-

paragraphs (A) through (K)'' and inserting ''subparagraphs (A) through (L)''.

(d) ACCOUNTABILITY OF PHARMACY BENEFIT MANAGERS FOR VIOLATIONS OF REASONABLE AND RELEVANT CONTRACT TERMS AND CONDITIONS.—

(1) IN GENERAL.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112) is amended by adding at the end the following new paragraph:

''(9) ACCOUNTABILITY OF PHARMACY BENEFIT MANAGERS FOR VIOLATIONS OF REASONABLE AND RELEVANT CONTRACT TERMS AND CONDITIONS.—For plan years beginning on or after January 1, 2028, each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that any pharmacy benefit manager acting on behalf of such sponsor has a written agreement with the PDP sponsor under which the pharmacy benefit manager agrees to reimburse the PDP sponsor for any amounts paid by such sponsor under section 1860D–4(b)(1)(F)(iii)(I) to the Secretary as a result of a violation described in such section if such violation is related to a responsibility delegated to the pharmacy benefit manager by such PDP sponsor.''.

(2) MA–PD PLANS.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)) is amended by adding at the end the following new subparagraph:

"(F) ACCOUNTABILITY OF PHARMACY BENEFIT MANAGERS FOR VIOLATIONS OF REASONABLE AND RELEVANT CONTRACT TERMS.—For plan years beginning on or after January 1, 2028, section 1860D–12(b)(9).".

(e) BIENNIAL REPORT ON ENFORCEMENT AND OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by subsection (b), is amended by adding at the end the following new subsection:

"(f) BIENNIAL REPORT ON ENFORCEMENT AND OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of this subsection, and at least once every 2 years thereafter, the Secretary shall publish a report on enforcement and oversight actions and activities undertaken by the Secretary with respect to the requirements under section 1860D–4(b)(1).

"(2) LIMITATION.—A report under paragraph (1) shall not disclose—

"(A) identifiable information about individuals or entities unless such information is otherwise publicly available; or

"(B) trade secrets with respect to any entities.".

(f) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any money in the Treasury not otherwise appropriated, $188,000,000 for fiscal year 2025, to remain available until expended, to carry out this section.

SEC. 227. MODERNIZING AND ENSURING PBM ACCOUNTABILITY.

(a) IN GENERAL.—

(1) PRESCRIPTION DRUG PLANS.—Section 1860D–12 of the Social Security Act (42 U.S.C. 1395w–112) is amended by adding at the end the following new subsection:

"(h) REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.—For plan years beginning on or after January 1, 2028:

"(1) AGREEMENTS WITH PHARMACY BENEFIT MANAGERS.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall

provide that any pharmacy benefit manager acting on behalf of such sponsor has a written agreement with the PDP sponsor under which the pharmacy benefit manager, and any affiliates of such pharmacy benefit manager, as applicable, agree to meet the following requirements:

''(A) NO INCOME OTHER THAN BONA FIDE SERVICE FEES.—

''(i) IN GENERAL.—The pharmacy benefit manager and any affiliate of such pharmacy benefit manager shall not derive any remuneration with respect to any services provided on behalf of any entity or individual, in connection with the utilization of covered part D drugs, from any such entity or individual other than bona fide service fees, subject to clauses (ii) and (iii).

''(ii) INCENTIVE PAYMENTS.—For the purposes of this subsection, an incentive payment (as determined by the Secretary) paid by a PDP sponsor to a pharmacy benefit manager that is performing services on behalf of such sponsor shall be deemed a 'bona fide service fee' (even if such payment does not otherwise meet the

definition of such term under paragraph (7)(B)) if such payment is a flat dollar amount, is consistent with fair market value (as specified by the Secretary), is related to services actually performed by the pharmacy benefit manager or affiliate of such pharmacy benefit manager, on behalf of the PDP sponsor making such payment, in connection with the utilization of covered part D drugs, and meets additional requirements, if any, as determined appropriate by the Secretary.

''(iii) CLARIFICATION ON REBATES AND DISCOUNTS USED TO LOWER COSTS FOR COVERED PART D DRUGS.—Rebates, discounts, and other price concessions received by a pharmacy benefit manager or an affiliate of a pharmacy benefit manager from manufacturers, even if such price concessions are calculated as a percentage of a drug's price, shall not be considered a violation of the requirements of clause (i) if they are fully passed through to a PDP sponsor and are compliant with all regulatory and subregulatory requirements re-

lated to direct and indirect remuneration for manufacturer rebates under this part, including in cases where a PDP sponsor is acting as a pharmacy benefit manager on behalf of a prescription drug plan offered by such PDP sponsor.

''(iv) EVALUATION OF REMUNERATION ARRANGEMENTS.—Components of subsets of remuneration arrangements (such as fees or other forms of compensation paid to or retained by the pharmacy benefit manager or affiliate of such pharmacy benefit manager), as determined appropriate by the Secretary, between pharmacy benefit managers or affiliates of such pharmacy benefit managers, as applicable, and other entities involved in the dispensing or utilization of covered part D drugs (including PDP sponsors, manufacturers, pharmacies, and other entities as determined appropriate by the Secretary) shall be subject to review by the Secretary, in consultation with the Office of the Inspector General of the Department of Health and Human Services, as determined appro-

priate by the Secretary. The Secretary, in consultation with the Office of the Inspector General, shall review whether remuneration under such arrangements is consistent with fair market value (as specified by the Secretary) through reviews and assessments of such remuneration, as determined appropriate.

''(v) DISGORGEMENT.—The pharmacy benefit manager shall disgorge any remuneration paid to such pharmacy benefit manager or an affiliate of such pharmacy benefit manager in violation of this subparagraph to the PDP sponsor.

''(vi) ADDITIONAL REQUIREMENTS.—The pharmacy benefit manager shall—

''(I) enter into a written agreement with any affiliate of such pharmacy benefit manager, under which the affiliate shall identify and disgorge any remuneration described in clause (v) to the pharmacy benefit manager; and

''(II) attest, subject to any requirements determined appropriate by

the Secretary, that the pharmacy benefit manager has entered into a written agreement described in subclause (I) with any relevant affiliate of the pharmacy benefit manager.

''(B) TRANSPARENCY REGARDING GUARANTEES AND COST PERFORMANCE EVALUATIONS.—The pharmacy benefit manager shall—

''(i) define, interpret, and apply, in a fully transparent and consistent manner for purposes of calculating or otherwise evaluating pharmacy benefit manager performance against pricing guarantees or similar cost performance measurements related to rebates, discounts, price concessions, or net costs, terms such as—

''(I) 'generic drug', in a manner consistent with the definition of the term under section 423.4 of title 42, Code of Federal Regulations, or a successor regulation;

''(II) 'brand name drug', in a manner consistent with the definition of the term under section 423.4 of

title 42, Code of Federal Regulations, or a successor regulation;

"(III) 'specialty drug';

"(IV) 'rebate'; and

"(V) 'discount';

"(ii) identify any drugs, claims, or price concessions excluded from any pricing guarantee or other cost performance measure in a clear and consistent manner; and

"(iii) where a pricing guarantee or other cost performance measure is based on a pricing benchmark other than the wholesale acquisition cost (as defined in section 1847A(c)(6)(B)) of a drug, calculate and provide a wholesale acquisition cost-based equivalent to the pricing guarantee or other cost performance measure.

"(C) PROVISION OF INFORMATION.—

"(i) IN GENERAL.—Not later than July 1 of each year, beginning in 2028, the pharmacy benefit manager shall submit to the PDP sponsor, and to the Secretary, a report, in accordance with this subparagraph, and shall make such report avail-

able to such sponsor at no cost to such sponsor in a format specified by the Secretary under paragraph (5). Each such report shall include, with respect to such PDP sponsor and each plan offered by such sponsor, the following information with respect to the previous plan year:

''(I) A list of all drugs covered by the plan that were dispensed including, with respect to each such drug—

''(aa) the brand name, generic or non-proprietary name, and National Drug Code;

''(bb) the number of plan enrollees for whom the drug was dispensed, the total number of prescription claims for the drug (including original prescriptions and refills, counted as separate claims), and the total number of dosage units of the drug dispensed;

''(cc) the number of prescription claims described in item (bb) by each type of dispensing

channel through which the drug was dispensed, including retail, mail order, specialty pharmacy, long term care pharmacy, home infusion pharmacy, or other types of pharmacies or providers;

''(dd) the average wholesale acquisition cost, listed as cost per day's supply, cost per dosage unit, and cost per typical course of treatment (as applicable);

''(ee) the average wholesale price for the drug, listed as price per day's supply, price per dosage unit, and price per typical course of treatment (as applicable);

''(ff) the total out-of-pocket spending by plan enrollees on such drug after application of any benefits under the plan, including plan enrollee spending through copayments, coinsurance, and deductibles;

"(gg) total rebates paid by the manufacturer on the drug as reported under the Detailed DIR Report (or any successor report) submitted by such sponsor to the Centers for Medicare & Medicaid Services;

"(hh) all other direct or indirect remuneration on the drug as reported under the Detailed DIR Report (or any successor report) submitted by such sponsor to the Centers for Medicare & Medicaid Services;

"(ii) the average pharmacy reimbursement amount paid by the plan for the drug in the aggregate and disaggregated by dispensing channel identified in item (cc);

"(jj) the average National Average Drug Acquisition Cost (NADAC); and

"(kk) total manufacturer-derived revenue, inclusive of bona

fide service fees, attributable to the drug and retained by the pharmacy benefit manager and any affiliate of such pharmacy benefit manager.

''(II) In the case of a pharmacy benefit manager that has an affiliate that is a retail, mail order, or specialty pharmacy, with respect to drugs covered by such plan that were dispensed, the following information:

''(aa) The percentage of total prescriptions that were dispensed by pharmacies that are an affiliate of the pharmacy benefit manager for each drug.

''(bb) The interquartile range of the total combined costs paid by the plan and plan enrollees, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply for each drug dispensed by pharmacies that are not an affiliate of the pharmacy benefit manager and

that are included in the pharmacy network of such plan.

''(cc) The interquartile range of the total combined costs paid by the plan and plan enrollees, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply for each drug dispensed by pharmacies that are an affiliate of the pharmacy benefit manager and that are included in the pharmacy network of such plan.

''(dd) The lowest total combined cost paid by the plan and plan enrollees, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, for each drug that is available from any pharmacy included in the pharmacy network of such plan.

''(ee) The difference between the average acquisition cost of the affiliate, such as a pharmacy

or other entity that acquires prescription drugs, that initially acquires the drug and the amount reported under subclause (I)(jj) for each drug.

''(ff) A list inclusive of the brand name, generic or non-proprietary name, and National Drug Code of covered part D drugs subject to an agreement with a covered entity under section 340B of the Public Health Service Act for which the pharmacy benefit manager or an affiliate of the pharmacy benefit manager had a contract or other arrangement with such a covered entity in the service area of such plan.

''(III) Where a drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (referred to in this subclause as the 'listed drug') is covered by the plan, the following information:

''(aa) A list of currently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act pursuant to an application that references such listed drug that are not covered by the plan, are covered on the same formulary tier or a formulary tier typically associated with higher cost-sharing than the listed drug, or are subject to utilization management that the listed drug is not subject to.

''(bb) The estimated average beneficiary cost-sharing under the plan for a 30-day supply of the listed drug.

''(cc) Where a generic drug listed under item (aa) is on a formulary tier typically associated with higher cost-sharing than the listed drug, the estimated average cost-sharing that a beneficiary would have paid for a 30-

day supply of each of the generic drugs described in item (aa), had the plan provided coverage for such drugs on the same formulary tier as the listed drug.

''(dd) A written justification for providing more favorable coverage of the listed drug than the generic drugs described in item (aa).

''(ee) The number of currently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act pursuant to an application that references such listed drug.

''(IV) Where a reference product (as defined in section 351(i) of the Public Health Service Act) is covered by the plan, the following information:

''(aa) A list of currently marketed biosimilar biological products licensed under section 351(k) of the Public Health

Service Act pursuant to an application that refers to such reference product that are not covered by the plan, are covered on the same formulary tier or a formulary tier typically associated with higher cost-sharing than the reference product, or are subject to utilization management that the reference product is not subject to.

''(bb) The estimated average beneficiary cost-sharing under the plan for a 30-day supply of the reference product.

''(cc) Where a biosimilar biological product listed under item (aa) is on a formulary tier typically associated with higher cost-sharing than the reference product, the estimated average cost-sharing that a beneficiary would have paid for a 30-day supply of each of the biosimilar biological products described in item (aa),

had the plan provided coverage for such products on the same formulary tier as the reference product.

''(dd) A written justification for providing more favorable coverage of the reference product than the biosimilar biological product described in item (aa).

''(ee) The number of currently marketed biosimilar biological products licensed under section 351(k) of the Public Health Service Act, pursuant to an application that refers to such reference product.

''(V) Total gross spending on covered part D drugs by the plan, not net of rebates, fees, discounts, or other direct or indirect remuneration.

''(VI) The total amount retained by the pharmacy benefit manager or an affiliate of such pharmacy benefit manager in revenue related to utilization of covered part D drugs under

that plan, inclusive of bona fide service fees.

''(VII) The total spending on covered part D drugs net of rebates, fees, discounts, or other direct and indirect remuneration by the plan.

''(VIII) An explanation of any benefit design parameters under such plan that encourage plan enrollees to fill prescriptions at pharmacies that are an affiliate of such pharmacy benefit manager, such as mail and specialty home delivery programs, and retail and mail auto-refill programs.

''(IX) The following information:

''(aa) A list of all brokers, consultants, advisors, and auditors that receive compensation from the pharmacy benefit manager or an affiliate of such pharmacy benefit manager for referrals, consulting, auditing, or other services offered to PDP sponsors related to pharmacy benefit management services.

''(bb) The amount of compensation provided by such pharmacy benefit manager or affiliate to each such broker, consultant, advisor, and auditor.

''(cc) The methodology for calculating the amount of compensation provided by such pharmacy benefit manager or affiliate, for each such broker, consultant, advisor, and auditor.

''(X) A list of all affiliates of the pharmacy benefit manager.

''(XI) A summary document submitted in a standardized template developed by the Secretary that includes such information described in subclauses (I) through (X).

''(ii) WRITTEN EXPLANATION OF CONTRACTS OR AGREEMENTS WITH DRUG MANUFACTURERS.—

''(I) IN GENERAL.—The pharmacy benefit manager shall, not later than 30 days after the finalization of any contract or agreement between

such pharmacy benefit manager or an affiliate of such pharmacy benefit manager and a drug manufacturer (or subsidiary, agent, or entity affiliated with such drug manufacturer) that makes rebates, discounts, payments, or other financial incentives related to one or more covered part D drugs or other prescription drugs, as applicable, of the manufacturer directly or indirectly contingent upon coverage, formulary placement, or utilization management conditions on any other covered part D drugs or other prescription drugs, as applicable, submit to the PDP sponsor a written explanation of such contract or agreement.

''(II) REQUIREMENTS.—A written explanation under subclause (I) shall—

''(aa) include the manufacturer subject to the contract or agreement, all covered part D drugs and other prescription drugs, as applicable, subject to

the contract or agreement and the manufacturers of such drugs, and a high-level description of the terms of such contract or agreement and how such terms apply to such drugs; and

''(bb) be certified by the Chief Executive Officer, Chief Financial Officer, or General Counsel of such pharmacy benefit manager, or affiliate of such pharmacy benefit manager, as applicable, or an individual delegated with the authority to sign on behalf of one of these officers, who reports directly to the officer.

''(III) DEFINITION OF OTHER PRESCRIPTION DRUGS.—For purposes of this clause, the term 'other prescription drugs' means prescription drugs covered as supplemental benefits under this part or prescription drugs paid outside of this part.

''(D) AUDIT RIGHTS.—

''(i) IN GENERAL.—Not less than once a year, at the request of the PDP sponsor, the pharmacy benefit manager shall allow for an audit of the pharmacy benefit manager to ensure compliance with all terms and conditions under the written agreement described in this paragraph and the accuracy of information reported under subparagraph (C).

''(ii) AUDITOR.—The PDP sponsor shall have the right to select an auditor. The pharmacy benefit manager shall not impose any limitations on the selection of such auditor.

''(iii) PROVISION OF INFORMATION.—The pharmacy benefit manager shall make available to such auditor all records, data, contracts, and other information necessary to confirm the accuracy of information provided under subparagraph (C), subject to reasonable restrictions on how such information must be reported to prevent redisclosure of such information.

''(iv) TIMING.—The pharmacy benefit manager must provide information under

clause (iii) and other information, data, and records relevant to the audit to such auditor within 6 months of the initiation of the audit and respond to requests for additional information from such auditor within 30 days after the request for additional information.

''(v) INFORMATION FROM AFFILIATES.—The pharmacy benefit manager shall be responsible for providing to such auditor information required to be reported under subparagraph (C) or under clause (iii) of this subparagraph that is owned or held by an affiliate of such pharmacy benefit manager.

''(2) ENFORCEMENT.—

''(A) IN GENERAL.—Each PDP sponsor shall—

''(i) disgorge to the Secretary any amounts disgorged to the PDP sponsor by a pharmacy benefit manager under paragraph (1)(A)(v);

''(ii) require, in a written agreement with any pharmacy benefit manager acting on behalf of such sponsor or affiliate of

such pharmacy benefit manager, that such pharmacy benefit manager or affiliate reimburse the PDP sponsor for any civil money penalty imposed on the PDP sponsor as a result of the failure of the pharmacy benefit manager or affiliate to meet the requirements of paragraph (1) that are applicable to the pharmacy benefit manager or affiliate under the agreement; and

''(iii) require, in a written agreement with any such pharmacy benefit manager acting on behalf of such sponsor or affiliate of such pharmacy benefit manager, that such pharmacy benefit manager or affiliate be subject to punitive remedies for breach of contract for failure to comply with the requirements applicable under paragraph (1).

''(B) REPORTING OF ALLEGED VIOLATIONS.—The Secretary shall make available and maintain a mechanism for manufacturers, PDP sponsors, pharmacies, and other entities that have contractual relationships with pharmacy benefit managers or affiliates of such pharmacy benefit managers to report, on a confidential

basis, alleged violations of paragraph (1)(A) or subparagraph (C).

''(C) ANTI-RETALIATION AND ANTI-COERCION.—Consistent with applicable Federal or State law, a PDP sponsor shall not—

''(i) retaliate against an individual or entity for reporting an alleged violation under subparagraph (B); or

''(ii) coerce, intimidate, threaten, or interfere with the ability of an individual or entity to report any such alleged violations.

''(3) CERTIFICATION OF COMPLIANCE.—

''(A) IN GENERAL.—Each PDP sponsor shall furnish to the Secretary (at a time and in a manner specified by the Secretary) an annual certification of compliance with this subsection, as well as such information as the Secretary determines necessary to carry out this subsection.

''(B) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

''(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as—

''(A) prohibiting flat dispensing fees or reimbursement or payment for ingredient costs (including customary, industry-standard discounts directly related to drug acquisition that are retained by pharmacies or wholesalers) to entities that acquire or dispense prescription drugs; or

''(B) modifying regulatory requirements or sub-regulatory program instruction or guidance related to pharmacy payment, reimbursement, or dispensing fees.

''(5) STANDARD FORMATS.—

''(A) IN GENERAL.—Not later than June 1, 2027, the Secretary shall specify standard, machine-readable formats for pharmacy benefit managers to submit annual reports required under paragraph (1)(C)(i).

''(B) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

''(6) CONFIDENTIALITY.—

''(A) IN GENERAL.—Information disclosed by a pharmacy benefit manager, an affiliate of a pharmacy benefit manager, a PDP sponsor,

or a pharmacy under this subsection that is not otherwise publicly available or available for purchase shall not be disclosed by the Secretary or a PDP sponsor receiving the information, except that the Secretary may disclose the information for the following purposes:

''(i) As the Secretary determines necessary to carry out this part.

''(ii) To permit the Comptroller General to review the information provided.

''(iii) To permit the Director of the Congressional Budget Office to review the information provided.

''(iv) To permit the Executive Director of the Medicare Payment Advisory Commission to review the information provided.

''(v) To the Attorney General for the purposes of conducting oversight and enforcement under this title.

''(vi) To the Inspector General of the Department of Health and Human Services in accordance with its authorities under the Inspector General Act of 1978

(section 406 of title 5, United States Code), and other applicable statutes.

''(B) RESTRICTION ON USE OF INFORMATION.—The Secretary, the Comptroller General, the Director of the Congressional Budget Office, and the Executive Director of the Medicare Payment Advisory Commission shall not report on or disclose information disclosed pursuant to subparagraph (A) to the public in a manner that would identify—

''(i) a specific pharmacy benefit manager, affiliate, pharmacy, manufacturer, wholesaler, PDP sponsor, or plan; or

''(ii) contract prices, rebates, discounts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties or of such specific drugs.

''(7) DEFINITIONS.—For purposes of this subsection:

''(A) AFFILIATE.—The term 'affiliate' means, with respect to any pharmacy benefit manager or PDP sponsor, any entity that, directly or indirectly—

"(i) owns or is owned by, controls or is controlled by, or is otherwise related in any ownership structure to such pharmacy benefit manager or PDP sponsor; or

"(ii) acts as a contractor, principal, or agent to such pharmacy benefit manager or PDP sponsor, insofar as such contractor, principal, or agent performs any of the functions described under subparagraph (C).

"(B) BONA FIDE SERVICE FEE.—The term 'bona fide service fee' means a fee that is reflective of the fair market value (as specified by the Secretary, through notice and comment rulemaking) for a bona fide, itemized service actually performed on behalf of an entity, that the entity would otherwise perform (or contract for) in the absence of the service arrangement and that is not passed on in whole or in part to a client or customer, whether or not the entity takes title to the drug. Such fee must be a flat dollar amount and shall not be directly or indirectly based on, or contingent upon—

''(i) drug price, such as wholesale acquisition cost or drug benchmark price (such as average wholesale price);

''(ii) the amount of discounts, rebates, fees, or other direct or indirect remuneration with respect to covered part D drugs dispensed to enrollees in a prescription drug plan, except as permitted pursuant to paragraph (1)(A)(ii);

''(iii) coverage or formulary placement decisions or the volume or value of any referrals or business generated between the parties to the arrangement; or

''(iv) any other amounts or methodologies prohibited by the Secretary.

''(C) PHARMACY BENEFIT MANAGER.—The term 'pharmacy benefit manager' means any person or entity that, either directly or through an intermediary, acts as a price negotiator or group purchaser on behalf of a PDP sponsor or prescription drug plan, or manages the prescription drug benefits provided by such sponsor or plan, including the processing and payment of claims for prescription drugs, the performance of drug utilization review, the proc-

essing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered part D drugs, or the provision of related services. Such term includes any person or entity that carries out one or more of the activities described in the preceding sentence, irrespective of whether such person or entity calls itself a 'pharmacy benefit manager'.''.

(2) MA–PD PLANS.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)), as amended by section 226(d)(2), is amended by adding at the end the following new subparagraph:

''(G) REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.—For plan years beginning on or after January 1, 2028, section 1860D–12(h).''.

(3) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to the implementation of this subsection.

(4) FUNDING.—

(A) SECRETARY.—In addition to amounts otherwise available, there is appropriated to the

Centers for Medicare & Medicaid Services Program Management Account, out of any money in the Treasury not otherwise appropriated, $113,000,000 for fiscal year 2025, to remain available until expended, to carry out this subsection.

(B) OIG.—In addition to amounts otherwise available, there is appropriated to the Inspector General of the Department of Health and Human Services, out of any money in the Treasury not otherwise appropriated, $20,000,000 for fiscal year 2025, to remain available until expended, to carry out this subsection.

(b) GAO STUDY AND REPORT ON PRICE-RELATED COMPENSATION ACROSS THE SUPPLY CHAIN.—

(1) STUDY.—The Comptroller General of the United States (in this subsection referred to as the ''Comptroller General'') shall conduct a study describing the use of compensation and payment structures related to a prescription drug's price within the retail prescription drug supply chain in part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–101 et seq.). Such study shall summarize information from Federal agencies and industry ex-

perts, to the extent available, with respect to the following:

(A) The type, magnitude, other features (such as the pricing benchmarks used), and prevalence of compensation and payment structures related to a prescription drug's price, such as calculating fee amounts as a percentage of a prescription drug's price, between intermediaries in the prescription drug supply chain, including—

(i) pharmacy benefit managers;

(ii) PDP sponsors offering prescription drug plans and Medicare Advantage organizations offering MA–PD plans;

(iii) drug wholesalers;

(iv) pharmacies;

(v) manufacturers;

(vi) pharmacy services administrative organizations;

(vii) brokers, auditors, consultants, and other entities that—

(I) advise PDP sponsors offering prescription drug plans and Medicare Advantage organizations offering MA–

PD plans regarding pharmacy benefits; or

(II) review PDP sponsor and Medicare Advantage organization contracts with pharmacy benefit managers; and

(viii) other service providers that contract with any of the entities described in clauses (i) through (vii) that may use price-related compensation and payment structures, such as rebate aggregators (or other entities that negotiate or process price concessions on behalf of pharmacy benefit managers, plan sponsors, or pharmacies).

(B) The primary business models and compensation structures for each category of intermediary described in subparagraph (A).

(C) Variation in price-related compensation structures between affiliated entities (such as entities with common ownership, either full or partial, and subsidiary relationships) and unaffiliated entities.

(D) Potential conflicts of interest among contracting entities related to the use of pre-

scription drug price-related compensation structures, such as the potential for fees or other payments set as a percentage of a prescription drug's price to advantage formulary selection, distribution, or purchasing of prescription drugs with higher prices.

(E) Notable differences, if any, in the use and level of price-based compensation structures over time and between different market segments, such as under part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–101 et seq.) and the Medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.).

(F) The effects of drug price-related compensation structures and alternative compensation structures on Federal health care programs and program beneficiaries, including with respect to cost-sharing, premiums, Federal outlays, biosimilar and generic drug adoption and utilization, drug shortage risks, and the potential for fees set as a percentage of a drug's price to advantage the formulary selection, distribution, or purchasing of drugs with higher prices.

(G) Other issues determined to be relevant and appropriate by the Comptroller General.

(2) REPORT.—Not later than 2 years after the date of enactment of this section, the Comptroller General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(c) MEDPAC REPORTS ON AGREEMENTS WITH PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRESCRIPTION DRUG PLANS AND MA–PD PLANS.—

(1) IN GENERAL.—The Medicare Payment Advisory Commission shall submit to Congress the following reports:

(A) INITIAL REPORT.—Not later than the first March 15 occurring after the date that is 2 years after the date on which the Secretary makes the data available to the Commission, a report regarding agreements with pharmacy benefit managers with respect to prescription drug plans and MA–PD plans. Such report shall include, to the extent practicable—

(i) a description of trends and patterns, including relevant averages, totals,

and other figures for the types of information submitted;

(ii) an analysis of any differences in agreements and their effects on plan enrollee out-of-pocket spending and average pharmacy reimbursement, and other impacts; and

(iii) any recommendations the Commission determines appropriate.

(B) FINAL REPORT.—Not later than 2 years after the date on which the Commission submits the initial report under subparagraph (A), a report describing any changes with respect to the information described in subparagraph (A) over time, together with any recommendations the Commission determines appropriate.

(2) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Medicare Payment Advisory Commission, out of any money in the Treasury not otherwise appropriated, $1,000,000 for fiscal year 2025, to remain available until expended, to carry out this subsection.

SEC. 228. REQUIRING A SEPARATE IDENTIFICATION NUMBER AND AN ATTESTATION FOR EACH OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.

(a) IN GENERAL.—Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) is amended by adding at the end the following new paragraph:

"(23) USE OF UNIQUE HEALTH IDENTIFIERS; ATTESTATION.—

"(A) IN GENERAL.—No payment may be made under this subsection (or under an applicable payment system pursuant to paragraph (21)) for items and services furnished on or after January 1, 2026, by an off-campus outpatient department of a provider (as defined in subparagraph (C)) unless—

"(i) such department has obtained, and such items and services are billed under, a standard unique health identifier for health care providers (as described in section 1173(b)) that is separate from such identifier for such provider;

"(ii) such provider has submitted to the Secretary, during the 2-year period ending on the date such items and services are so furnished, an initial provider-based

status attestation that such department is compliant with the requirements described in section 413.65 of title 42, Code of Federal Regulations (or a successor regulation); and

"(iii) after such provider has submitted an attestation under clause (ii), such provider has submitted a subsequent attestation within the timeframe specified by the Secretary.

"(B) PROCESS FOR SUBMISSION AND REVIEW.—Not later than 1 year after the date of enactment of this paragraph, the Secretary shall, through notice and comment rulemaking, establish a process for each provider with an off-campus outpatient department of a provider to submit an initial and subsequent attestation pursuant to clauses (ii) and (iii), respectively, of subparagraph (A), and for the Secretary to review each such attestation and determine, through site visits, remote audits, or other means (as determined appropriate by the Secretary), whether such department is compliant with the requirements described in such subparagraph.

''(C) OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER DEFINED.—For purposes of this paragraph, the term 'off-campus outpatient department of a provider' means a department of a provider (as defined in section 413.65 of title 42, Code of Federal Regulations, or any successor regulation) that is not located—

''(i) on the campus (as defined in such section) of such provider; or

''(ii) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section).''.

(b) HHS OIG ANALYSIS.—Not later than January 1, 2030, the Inspector General of the Department of Health and Human Services shall submit to Congress—

(1) an analysis of the process established by the Secretary of Health and Human Services to conduct the reviews and determinations described in section 1833(t)(23)(B) of the Social Security Act, as added by subsection (a) of this section; and

(2) recommendations based on such analysis, as the Inspector General determines appropriate.

SEC. 229. MEDICARE SEQUESTRATION.

Section 251A(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 (2 U.S.C. 901a(6)) is amended—

(1) in subparagraph (D), by striking ''such that,'' and all that follows and inserting ''such that the payment reduction shall be 2.0 percent.''; and

(2) by adding at the end the following:

''(F) On the date on which the President submits the budget under section 1105 of title 31, United States Code, for fiscal year 2033, the President shall order a sequestration of payments for the Medicare programs specified in section 256(d), effective upon issuance, such that, notwithstanding the 2 percent limit specified in subparagraph (A) for such payments—

''(i) with respect to the first 2 months in which such order is effective for such fiscal year, the payment reduction shall be 2.0 percent; and

''(ii) with respect to the last 10 months in which such order is effective for such fiscal year, the payment reduction shall be 0 percent.''.

SEC. 230. MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by striking ''$1,251,000,000'' and inserting ''$1,938,000,000''.

TITLE III—HUMAN SERVICES

SEC. 301. SEXUAL RISK AVOIDANCE EDUCATION EXTENSION.

Section 510 of the Social Security Act (42 U.S.C. 710) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking ''and for the period'' and inserting ''for the period'';

(ii) by inserting ''for the period beginning on April 1, 2025, and ending on September 30, 2025, and for the period beginning on October 1, 2025, and ending on December 31, 2025,'' before ''allot to each State''; and

(iii) by striking ''for fiscal year 2024 or 2025'' and inserting ''for fiscal year 2024, 2025, or 2026''; and

(B) in paragraph (2), by striking ''or 2025'' each place it appears and inserting '', 2025, or 2026''; and

(2) in subsection (f)(1), by striking ''and for the period beginning on October 1, 2024, and ending on March 31, 2025, an amount equal to the pro rata portion of the amount appropriated for the corresponding period for fiscal year 2024'' and inserting ''for the period beginning on October 1, 2024, and ending on March 31, 2025, and for the period beginning on April 1, 2025, and ending on September 30, 2025, an amount equal to the pro rata portion of the amount appropriated for the corresponding period for fiscal year 2024, and for the period beginning on October 1, 2025, and ending on December 31, 2025, an amount equal to the pro rata portion of the amount appropriated for the corresponding period for fiscal year 2025''

SEC. 302. PERSONAL RESPONSIBILITY EDUCATION EXTENSION.

Section 513 of the Social Security Act (42 U.S.C. 713) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (A), in the matter preceding clause (i)—

(i) by striking ''and for the period'' and inserting ''for the period''; and

(ii) by inserting ''for the period beginning on April 1, 2025, and ending on September 30, 2025, and for the period beginning on October 1, 2025, and ending on December 31, 2025,'' before ''the Secretary shall allot''; and

(B) in subparagraph (B)(i)—

(i) by striking ''and for the period'' and inserting ''for the period''; and

(ii) by inserting '', for the period beginning on April 1, 2025, and ending on September 30, 2025, and for the period beginning on October 1, 2025, and ending on December 31, 2025'' before the period;

(2) in subsection (c)(3), by striking ''fiscal year 2024 or 2025'' and inserting ''fiscal year 2024, 2025, or 2026''; and

(3) in subsection (f), by striking ''and for the period beginning on October 1, 2024, and ending on March 31, 2025, an amount equal to the pro rata portion of the amount appropriated for the corresponding period for fiscal year 2024'' and inserting ''for the period beginning on October 1, 2024, and ending on March 31, 2025, and for the period beginning on April 1, 2025, and ending on Sep-

tember 30, 2025, an amount equal to the pro rata portion of the amount appropriated for the corresponding period for fiscal year 2024, and for the period beginning on October 1, 2025, and ending on December 31, 2025, an amount equal to the pro rata portion of the amount appropriated for the corresponding period for fiscal year 2025''.

SEC. 303. EXTENSION OF FUNDING FOR FAMILY-TO-FAMILY HEALTH INFORMATION CENTERS.

Section 501(c)(1)(A)(viii) of the Social Security Act (42 U.S.C. 701(c)(1)(A)(viii)) is amended—

(1) by striking ''$3,000,000'' and inserting ''$7,500,000''; and

(2) by striking ''for the portion of fiscal year 2025 before April 1, 2025'' and inserting ''for the period beginning on October 1, 2024, and ending on December 31, 2025''.

TITLE IV—PUBLIC HEALTH EXTENDERS

Subtitle A—Extensions

SEC. 401. EXTENSION FOR COMMUNITY HEALTH CENTERS, NATIONAL HEALTH SERVICE CORPS, AND TEACHING HEALTH CENTERS THAT OPERATE GME PROGRAMS.

(a) EXTENSION FOR COMMUNITY HEALTH CENTERS.—Section 10503(b)(1) of the Patient Protection and Affordable Care Act (42 U.S.C. 254b–2(b)(1)) is amended—

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

(2) in subparagraph (I), by striking the period and inserting '', and $2,315,342,466 for the period beginning on April 1, 2025, and ending on September 30, 2025; and''; and

(3) by adding at the end the following:

''(J) $4,600,000,000 for fiscal year 2026; and''.

(b) EXTENSION FOR THE NATIONAL HEALTH SERVICE CORPS.—Section 10503(b)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 254b–2(b)(2)) is amended—

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

(2) in subparagraph (J), by striking the period and inserting '', and $176,712,329 for the period beginning on April 1, 2025, and ending on September 30, 2025; and''; and

(3) by adding at the end the following:

''(J) $350,000,000 for fiscal year 2026.''.

(c) TEACHING HEALTH CENTERS THAT OPERATE GRADUATE MEDICAL EDUCATION PROGRAMS.—Section 340H(g)(1) of the Public Health Service Act (42 U.S.C. 256h(g)(1)) is amended—

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

(2) in subparagraph (E), by striking the period and inserting a semicolon; and

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

''(F) $112,849,315 for the period beginning on January 1, 2025, and ending on September 30, 2025;

''(G) $225,000,000 for fiscal year 2026;

''(H) $250,000,000 for fiscal year 2027;

''(I) $275,000,000 for fiscal year 2028; and

''(J) $300,000,000 for fiscal year 2029.''.

(d) APPLICATION OF PROVISIONS.—Amounts appropriated pursuant to the amendments made by this section shall be subject to the requirements contained in Public Law 118–47 for funds for programs authorized under sections 330 through 340 of the Public Health Service Act (42 U.S.C. 254b et seq.).

(e) CONFORMING AMENDMENTS.—Section 3014(h)(4) of title 18, United States Code, is amended by striking ''and section 3101(d) of the Health Extensions and Other Matters Act, 2025'' and inserting ''section 3101(d) of the Health Extensions and Other Matters Act, 2025, and section 401(d) of the Bipartisan Health Care Act''.

SEC. 402. EXTENSION OF SPECIAL DIABETES PROGRAMS.

(a) EXTENSION OF SPECIAL DIABETES PROGRAMS FOR TYPE I DIABETES.—Section 330B(b)(2) of the Public Health Service Act (42 U.S.C. 254c–2(b)(2)) is amended—

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

(2) in subparagraph (F), by striking the period at the end and inserting '', and $110,327,296 for the period beginning on April 1, 2025, and ending on September 30, 2025; and''; and

(3) by adding at the end the following:

''(G) $200,000,000 for fiscal year 2026, to remain available until expended.''.

(b) EXTENDING FUNDING FOR SPECIAL DIABETES PROGRAMS FOR INDIANS.—Section 330C(c)(2) of the Public Health Service Act (42 U.S.C. 254c–3(c)(2)) is amended—

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

(2) in subparagraph (F), by striking the period at the end and inserting '', and $110,327,296 for the period beginning on April 1, 2025, and ending on September 30, 2025; and''; and

(3) by adding at the end the following:

''(G) $200,000,000 for fiscal year 2026, to remain available until expended.''.

Subtitle B—World Trade Center Health Program

SEC. 411. 9/11 RESPONDER AND SURVIVOR HEALTH FUNDING CORRECTIONS.

(a) IN GENERAL.—Section 3351(a)(2)(A) of the Public Health Service Act (42 U.S.C. 300mm–61(a)(2)(A)) is amended—

(1) in clause (x), by striking ''; and'' and inserting a semicolon;

(2) by redesignating clause (xi) as clause (xii); and

(3) by inserting after clause (x), the following:

''(xi) for each of fiscal years 2026 through 2040—

''(I) the amount determined under this subparagraph for the previous fiscal year multiplied by 1.05; multiplied by

''(II) the ratio of—

''(aa) the total number of individuals enrolled in the WTC Program on July 1 of such previous fiscal year; to

''(bb) the total number of individuals so enrolled on July 1 of the fiscal year prior to such previous fiscal year; and''.

(b) REPORT TO CONGRESS.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall conduct an assessment of anticipated budget authority and outlays of the World Trade Center Health Program (referred

to in this subsection as the ''Program'') through the duration of the Program and submit a report summarizing such assessment to—

(A) the Speaker and minority leader of the House of Representatives;

(B) the majority and minority leaders of the Senate;

(C) the Committee on Health, Education, Labor, and Pensions and the Committee on the Budget of the Senate; and

(D) the Committee on Energy and Commerce and the Committee on the Budget of the House of Representatives.

(2) INCLUSIONS.—The report required under paragraph (1) shall include—

(A) a projection of Program budgetary needs on a per-fiscal year basis through fiscal year 2090;

(B) a review of Program modeling for each of fiscal years 2017 through the fiscal year prior to the fiscal year in which the report is issued to assess how anticipated budgetary needs compared to actual expenditures;

(C) an assessment of the projected budget authority and expenditures of the Program through fiscal year 2090 by comparing—

(i) such projected authority and expenditures resulting from application of section 3351(a)(2)(A) of the Public Health Service Act (42 U.S.C. 300mm–61(a)(2)(A)), as amended by subsection (a); and

(ii) such projected authority and expenditures that would result if such section were amended so that the formula under clause (xi) of such section, as amended by subsection (a), were to be extended through fiscal year 2090; and

(D) any recommendations of the Secretary to make changes to the formula under such section 3351(a)(2)(A), as so amended, to fully offset anticipated Program expenditures through fiscal year 2090.

(c) TECHNICAL AMENDMENTS.—Title XXXIII of the Public Health Service Act (42 U.S.C. 300mm et seq.) is amended—

(1) in section 3352(d) (42 U.S.C. 300mm–62(d)), by striking ''Any amounts'' and inserting ''Any unobligated amounts'';

(2) in section 3353(d) (42 U.S.C. 300mm–63(d)), by striking ''Any amounts'' and inserting ''Any unobligated amounts''; and

(3) in section 3354(d) (42 U.S.C. 300mm–64(d)), by striking ''Any amounts'' and inserting ''Any unobligated amounts''.

TITLE V—SUPPORT ACT REAUTHORIZATION

SEC. 501. SHORT TITLE.

This title may be cited as the ''SUPPORT for Patients and Communities Reauthorization Act of 2025''.

Subtitle A—Prevention

SEC. 511. PRENATAL AND POSTNATAL HEALTH.

Section 317L(d) of the Public Health Service Act (42 U.S.C. 247b–13(d)) is amended by striking ''such sums as may be necessary for each of the fiscal years 2019 through 2023'' and inserting ''$4,250,000 for each of fiscal years 2025 through 2029''.

SEC. 512. MONITORING AND EDUCATION REGARDING INFECTIONS ASSOCIATED WITH ILLICIT DRUG USE AND OTHER RISK FACTORS.

Section 317N(d) of the Public Health Service Act (42 U.S.C. 247b–15(d)) is amended by striking ''fiscal years 2019 through 2023'' and inserting ''fiscal years 2025 through 2029''.

SEC. 513. PREVENTING OVERDOSES OF CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 392A of the Public Health Service Act (42 U.S.C. 280b–1) is amended—

(1) in subsection (a)(2)—

(A) in subparagraph (C), by inserting ''and associated risks'' before the period at the end; and

(B) in subparagraph (D), by striking ''opioids'' and inserting ''substances causing overdose''; and

(2) in subsection (b)(2)—

(A) in subparagraph (B), by inserting '', and associated risk factors,'' after ''such overdoses'';

(B) in subparagraph (C), by striking ''coding'' and inserting ''monitoring and identifying'';

(C) in subparagraph (E)—

(i) by inserting a comma after ''public health laboratories''; and

(ii) by inserting ''and other emerging substances related'' after ''analogues''; and

(D) in subparagraph (F), by inserting ''and associated risk factors'' after ''overdoses''.

(b) ADDITIONAL GRANTS.—Section 392A(a)(3) of the Public Health Service Act (42 U.S.C. 280b–1(a)(3)) is amended—

(1) in the matter preceding subparagraph (A), by striking ''and Indian Tribes—'' and inserting ''and Indian Tribes for the following purposes:'';

(2) by amending subparagraph (A) to read as follows:

''(A) To carry out innovative projects for grantees to detect, identify, and rapidly respond to controlled substance misuse, abuse, and overdoses, and associated risk factors, including changes in patterns of such controlled substance use. Such projects may include the use of innovative, evidence-based strategies for detecting such patterns, such as wastewater surveillance, if proven to support actionable prevention strategies, in a manner consistent with

applicable Federal and State privacy laws.''; and

(3) in subparagraph (B), by striking ''for any'' and inserting ''For any''.

(c) AUTHORIZATION OF APPROPRIATIONS.—Section 392A(e) of the Public Health Service Act (42 U.S.C. 280b–1(e)) is amended by striking ''$496,000,000 for each of fiscal years 2019 through 2023'' and inserting ''$505,579,000 for each of fiscal years 2025 through 2029''.

SEC. 514. SUPPORT FOR INDIVIDUALS AND FAMILIES IMPACTED BY FETAL ALCOHOL SPECTRUM DISORDER.

(a) IN GENERAL.—Part O of title III of the Public Health Service Act (42 U.S.C. 280f et seq.) is amended to read as follows:

''PART O—FETAL ALCOHOL SYNDROME PREVENTION AND SERVICES PROGRAM

''SEC. 399H. FETAL ALCOHOL SPECTRUM DISORDERS PREVENTION, INTERVENTION, AND SERVICES DELIVERY PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish or continue activities to support a comprehensive fetal alcohol spectrum disorders (referred to in this section as 'FASD')

education, prevention, identification, intervention, and services delivery program, which may include—

''(1) an education and public awareness program to support, conduct, and evaluate the effectiveness of—

''(A) educational programs targeting health professions schools, social and other supportive services, educators and counselors and other service providers in all phases of childhood development, and other relevant service providers, concerning the prevention, identification, and provision of services for infants, children, adolescents and adults with FASD;

''(B) strategies to educate school-age children, including pregnant and high-risk youth, concerning FASD;

''(C) public and community awareness programs concerning FASD; and

''(D) strategies to coordinate information and services across affected community agencies, including agencies providing social services such as foster care, adoption, and social work, agencies providing health services, and agencies involved in education, vocational training and civil and criminal justice;

''(2) supporting and conducting research on FASD, as appropriate, including to—

''(A) develop appropriate medical diagnostic methods for identifying FASD; and

''(B) develop effective culturally and linguistically appropriate evidence-based or evidence-informed interventions and appropriate supports for preventing prenatal alcohol exposure, which may co-occur with exposure to other substances;

''(3) building State and Tribal capacity for the identification, treatment, and support of individuals with FASD and their families, which may include—

''(A) utilizing and adapting existing Federal, State, or Tribal programs to include FASD identification and FASD-informed support;

''(B) developing and expanding screening and diagnostic capacity for FASD;

''(C) developing, implementing, and evaluating targeted FASD-informed intervention programs for FASD;

''(D) providing training with respect to FASD for professionals across relevant sectors; and

''(E) disseminating information about FASD and support services to affected individuals and their families; and

''(4) an applied research program concerning intervention and prevention to support and conduct service demonstration projects, clinical studies and other research models providing advocacy, educational and vocational training, counseling, medical and mental health, and other supportive services, as well as models that integrate and coordinate such services, that are aimed at the unique challenges facing individuals with Fetal Alcohol Syndrome or Fetal Alcohol Effect and their families.

''(b) GRANTS AND TECHNICAL ASSISTANCE.—

''(1) IN GENERAL.—The Secretary may award grants, cooperative agreements and contracts and provide technical assistance to eligible entities to carry out subsection (a).

''(2) ELIGIBLE ENTITIES.—To be eligible to receive a grant, or enter into a cooperative agreement or contract, under this section, an entity shall—

''(A) be a State, Indian Tribe or Tribal organization, local government, scientific or academic institution, or nonprofit organization; and

"(B) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a description of the activities that the entity intends to carry out using amounts received under this section.

"(3) ADDITIONAL APPLICATION CONTENTS.—The Secretary may require that an eligible entity include in the application submitted under paragraph (2)(B)—

"(A) a designation of an individual to serve as a FASD State or Tribal coordinator of activities such eligible entity proposes to carry out through a grant, cooperative agreement, or contract under this section; and

"(B) a description of an advisory committee the entity will establish to provide guidance for the entity on developing and implementing a statewide or Tribal strategic plan to prevent FASD and provide for the identification, treatment, and support of individuals with FASD and their families.

"(c) DEFINITION OF FASD-INFORMED.—For purposes of this section, the term 'FASD-informed', with respect to support or an intervention program, means that

such support or intervention program uses culturally and linguistically informed evidence-based or practice-based interventions and appropriate resources to support an improved quality of life for an individual with FASD and the family of such individual.

"SEC. 399I. STRENGTHENING CAPACITY AND EDUCATION FOR FETAL ALCOHOL SPECTRUM DISORDERS.

''(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements, as the Secretary determines appropriate, to public or nonprofit private entities with demonstrated expertise in the field of fetal alcohol spectrum disorders (referred to in this section as 'FASD'). Such awards shall be for the purposes of building local, Tribal, State, and nationwide capacities to prevent the occurrence of FASD by carrying out the programs described in subsection (b).

''(b) PROGRAMS.—An entity receiving an award under subsection (a) may use such award for the following purposes:

''(1) Developing and supporting public education and outreach activities to raise public awareness of the risks associated with alcohol consumption during pregnancy.

''(2) Acting as a clearinghouse for evidence-based resources on FASD prevention, identification, and culturally and linguistically appropriate best practices to help inform systems of care for individuals with FASD across their lifespan.

''(3) Increasing awareness and understanding of efficacious, evidence-based screening tools and culturally and linguistically appropriate evidence-based intervention services and best practices, which may include improving the capacity for State, Tribal, and local affiliates.

''(4) Providing technical assistance to recipients of grants, cooperative agreements, or contracts under section 399H, as appropriate.

''(c) APPLICATION.—To be eligible for a grant, contract, or cooperative agreement under this section, an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(d) SUBCONTRACTING.—A public or private nonprofit entity may carry out the following activities required under this section through contracts or cooperative agreements with other public and private nonprofit entities with demonstrated expertise in FASD:

''(1) Resource development and dissemination.

''(2) Intervention services.

''(3) Training and technical assistance.

''SEC. 399J. AUTHORIZATION OF APPROPRIATIONS.

''There are authorized to be appropriated to carry out this part $12,500,000 for each of fiscal years 2025 through 2029.''.

(b) REPORT.—Not later than 4 years after the date of enactment of this Act, and every year thereafter, the Secretary of Health and Human Services shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing—

(1) a review of the activities carried out pursuant to sections 399H and 399I of the Public Health Service Act, as amended, to advance public education and awareness of fetal alcohol spectrum disorders (referred to in this section as ''FASD'');

(2) a description of—

(A) the activities carried out pursuant to such sections 399H and 399I to identify, prevent, and treat FASD; and

(B) methods used to evaluate the outcomes of such activities; and

(3) an assessment of activities carried out pursuant to such sections 399H and 399I to support individuals with FASD.

SEC. 515. PROMOTING STATE CHOICE IN PDMP SYSTEMS.

Section 399O(h) of the Public Health Service Act (42 U.S.C. 280g–3(h)) is amended by adding at the end the following:

''(5) PROMOTING STATE CHOICE.—Nothing in this section shall be construed to authorize the Secretary to require States to use a specific vendor or a specific interoperability connection other than to align with nationally recognized, consensus-based open standards, such as in accordance with sections 3001 and 3004.''.

SEC. 516. FIRST RESPONDER TRAINING PROGRAM.

Section 546 of the Public Health Service Act (42 U.S.C. 290ee–1) is amended—

(1) in subsection (a), by striking ''tribes and tribal'' and inserting ''Tribes and Tribal'';

(2) in subsections (a), (c), and (d)—

(A) by striking ''approved or cleared'' each place it appears and inserting ''approved, cleared, or otherwise legally marketed''; and

(B) by striking ''opioid'' each place it appears;

(3) in subsection (f)—

(A) by striking ''approved or cleared'' each place it appears and inserting ''approved, cleared, or otherwise legally marketed'';

(B) in paragraph (1), by striking ''opioid'';

(C) in paragraph (2)—

(i) by striking ''opioid and heroin'' and inserting ''opioid, heroin, and other drug''; and

(ii) by striking ''opioid overdose'' and inserting ''overdose''; and

(D) in paragraph (3), by striking ''opioid and heroin''; and

(4) in subsection (h), by striking ''$36,000,000 for each of fiscal years 2019 through 2023'' and inserting ''$56,000,000 for each of fiscal years 2025 through 2029''.

SEC. 517. DONALD J. COHEN NATIONAL CHILD TRAUMATIC STRESS INITIATIVE.

(a) TECHNICAL AMENDMENT.—The second part G of title V of the Public Health Service Act (42 U.S.C. 290kk et seq.), as added by section 144 of the Community Renewal Tax Relief Act (Public Law 106–554), is amended—

(1) by redesignating such part as part J; and

(2) by redesignating sections 581 through 584 as sections 596 through 596C, respectively.

(b) IN GENERAL.—Section 582 of the Public Health Service Act (42 U.S.C. 290hh–1) is amended—

(1) in the section heading, by striking ''**VIOLENCE RELATED STRESS**'' and inserting ''**TRAUMATIC EVENTS**'';

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking ''tribes and tribal'' and inserting ''Tribes and Tribal''; and

(B) in paragraph (2), by inserting ''and dissemination'' after ''the development'';

(3) in subsection (b), by inserting ''and dissemination'' after ''the development'';

(4) in subsection (d)—

(A) by striking ''The NCTSI'' and inserting the following:

''(1) COORDINATING CENTER.—The NCTSI''; and

(B) by adding at the end the following:

''(2) NCTSI GRANTEES.—In carrying out subsection (a)(2), NCTSI grantees shall develop trainings and other resources, as applicable and appropriate, to support implementation of the evi-

dence-based practices developed and disseminated under such subsection.'';

(5) in subsection (e)—

(A) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and adjusting the margins accordingly;

(B) in subparagraph (A), as so redesignated, by inserting ''and implementation'' after ''the dissemination'';

(C) by striking ''The NCTSI'' and inserting the following:

''(1) COORDINATING CENTER.—The NCTSI''; and

(D) by adding at the end the following:

''(2) NCTSI GRANTEES.—NCTSI grantees shall, as appropriate, collaborate with other such grantees, the NCTSI coordinating center, and the Secretary in carrying out subsections (a)(2) and (d)(2).'';

(6) by amending subsection (h) to read as follows:

''(h) APPLICATION AND EVALUATION.—To be eligible to receive a grant, contract, or cooperative agreement under subsection (a), a public or nonprofit private entity or an Indian Tribe or Tribal organization shall submit to the Secretary an application at such time, in such manner,

and containing such information and assurances as the Secretary may require, including—

''(1) a plan for the evaluation of the activities funded under the grant, contract, or agreement, including both process and outcomes evaluation, and the submission of an evaluation at the end of the project period; and

''(2) a description of how such entity, Indian Tribe, or Tribal organization will support efforts led by the Secretary or the NCTSI coordinating center, as applicable, to evaluate activities carried out under this section.''; and

(7) by amending subsection (j) to read as follows:

''(j) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section—

''(1) $93,887,000 for fiscal year 2025;

''(2) $95,000,000 for fiscal year 2026;

''(3) $97,000,000 for fiscal year 2027;

''(4) $100,000,000 for fiscal year 2028; and

''(5) $100,000,000 for fiscal year 2029.''.

SEC. 518. PROTECTING SUICIDE PREVENTION LIFELINE FROM CYBERSECURITY INCIDENTS.

(a) NATIONAL SUICIDE PREVENTION LIFELINE PROGRAM.—Section 520E–3(b) of the Public Health Service Act (42 U.S.C. 290bb–36c(b)) is amended—

(1) in paragraph (4), by striking ''and'' at the end;

(2) in paragraph (5), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(6) taking such steps as may be necessary to ensure the suicide prevention hotline is protected from cybersecurity incidents and eliminates known cybersecurity vulnerabilities.''.

(b) REPORTING.—Section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c) is amended—

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

(2) by inserting after subsection (e) the following:

''(f) CYBERSECURITY REPORTING.—

''(1) NOTIFICATION.—

''(A) IN GENERAL.—The program's network administrator receiving Federal funding pursuant to subsection (a) shall report to the Assistant Secretary, in a manner that protects

personal privacy, consistent with applicable Federal and State privacy laws—

"(i) any identified cybersecurity vulnerabilities to the program within a reasonable amount of time after identification of such a vulnerability; and

"(ii) any identified cybersecurity incidents to the program within a reasonable amount of time after identification of such incident.

"(B) LOCAL AND REGIONAL CRISIS CENTERS.—Local and regional crisis centers participating in the program shall report to the program's network administrator identified under subparagraph (A), in a manner that protects personal privacy, consistent with applicable Federal and State privacy laws—

"(i) any identified cybersecurity vulnerabilities to the program within a reasonable amount of time after identification of such vulnerability; and

"(ii) any identified cybersecurity incidents to the program within a reasonable amount of time after identification of such incident.

''(2) NOTIFICATION.—If the program's network administrator receiving funding pursuant to subsection (a) discovers, or is informed by a local or regional crisis center pursuant to paragraph (1)(B) of, a cybersecurity vulnerability or incident, within a reasonable amount of time after such discovery or receipt of information, such entity shall report the vulnerability or incident to the Assistant Secretary.

''(3) CLARIFICATION.—

''(A) OVERSIGHT.—

''(i) LOCAL AND REGIONAL CRISIS CENTERS.—Except as provided in clause (ii), local and regional crisis centers participating in the program shall oversee all technology each center employs in the provision of services as a participant in the program.

''(ii) NETWORK ADMINISTRATOR.—The program's network administrator receiving Federal funding pursuant to subsection (a) shall oversee the technology each crisis center employs in the provision of services as a participant in the program if such oversight responsibilities are estab-

lished in the applicable network participation agreement.

''(B) SUPPLEMENT, NOT SUPPLANT.—The cybersecurity incident reporting requirements under this subsection shall supplement, and not supplant, cybersecurity incident reporting requirements under other provisions of applicable Federal law that are in effect on the date of the enactment of the SUPPORT for Patients and Communities Reauthorization Act of 2025.''.

(c) STUDY.—Not later than 180 days after the date of the enactment of this Act, the Comptroller General of the United States shall—

(1) conduct and complete a study that evaluates cybersecurity risks and vulnerabilities associated with the 9–8–8 National Suicide Prevention Lifeline; and

(2) submit a report on the findings of such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

SEC. 519. BRUCE'S LAW.

(a) YOUTH PREVENTION AND RECOVERY.—Section 7102(c) of the SUPPORT for Patients and Communities Act (42 U.S.C. 290bb–7a(c)) is amended—

(1) in paragraph (3)(A)(i), by inserting '', which may include strategies to increase education and awareness of the potency and dangers of synthetic opioids (including drugs contaminated with fentanyl) and, as appropriate, other emerging drug use or misuse issues'' before the semicolon; and

(2) in paragraph (4)(A), by inserting ''and strategies to increase education and awareness of the potency and dangers of synthetic opioids (including drugs contaminated with fentanyl) and, as appropriate, emerging drug use or misuse issues'' before the semicolon.

(b) INTERDEPARTMENTAL SUBSTANCE USE DISORDERS COORDINATING COMMITTEE.—Section 7022 of the SUPPORT for Patients and Communities Act (42 U.S.C. 290aa note) is amended—

(1) by striking subsection (g) and inserting the following:

''(g) WORKING GROUPS.—

''(1) IN GENERAL.—The Committee may establish working groups for purposes of carrying out the duties described in subsection (e). Any such working

group shall be composed of members of the Committee (or the designees of such members) and may hold such meetings as are necessary to carry out the duties delegated to the working group.

''(2) ADDITIONAL FEDERAL INTERAGENCY WORK GROUP ON FENTANYL CONTAMINATION OF ILLEGAL DRUGS.—

''(A) ESTABLISHMENT.—The Secretary, acting through the Committee, shall establish a Federal Interagency Work Group on Fentanyl Contamination of Illegal Drugs (referred to in this paragraph as the 'Work Group') consisting of representatives from relevant Federal departments and agencies on the Committee.

''(B) CONSULTATION.—The Work Group shall consult with relevant stakeholders and subject matter experts, including—

''(i) State, Tribal, and local subject matter experts in reducing, preventing, and responding to drug overdose caused by fentanyl-contamination of illicit drugs; and

''(ii) family members of both adults and youth who have overdosed by fentanyl-contaminated illicit drugs.

''(C) DUTIES.—The Work Group shall—

"(i) examine Federal efforts to reduce and prevent drug overdose by fentanyl-contaminated illicit drugs;

"(ii) identify strategies to improve State, Tribal, and local responses to overdose by fentanyl-contaminated illicit drugs;

"(iii) coordinate with the Secretary, as appropriate, in carrying out activities to raise public awareness of synthetic opioids and other emerging drug use and misuse issues;

"(iv) make recommendations to Congress for improving Federal programs, including with respect to the coordination of efforts across such programs; and

"(v) make recommendations for educating youth on the potency and dangers of drugs contaminated by fentanyl.

"(D) ANNUAL REPORT TO SECRETARY.—The Work Group shall annually prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce and the Committee on Education and the Workforce of the House of Representa-

tives, a report on the activities carried out by the Work Group under subparagraph (C), including recommendations to reduce and prevent drug overdose by fentanyl contamination of illegal drugs, in all populations, and specifically among youth at risk for substance misuse.''; and

(2) by striking subsection (i) and inserting the following:

''(i) SUNSET.—The Committee shall terminate on September 30, 2029.''.

SEC. 520. GUIDANCE ON AT-HOME DRUG DISPOSAL SYSTEMS.

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Administrator of the Drug Enforcement Administration, shall publish guidance to facilitate the use of at-home safe disposal systems for applicable drugs.

(b) CONTENTS.—The guidance under subsection (a) shall include—

(1) recommended standards for effective at-home drug disposal systems to meet applicable requirements enforced by the Food and Drug Administration;

(2) recommended information to include as instructions for use to disseminate with at-home drug disposal systems;

(3) best practices and educational tools to support the use of an at-home drug disposal system, as appropriate; and

(4) recommended use of licensed health providers for the dissemination of education, instruction, and at-home drug disposal systems, as appropriate.

SEC. 521. ASSESSMENT OF OPIOID DRUGS AND ACTIONS.

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall publish on the website of the Food and Drug Administration (referred to in this section as the ''FDA'') a report that outlines a plan for assessing opioid analgesic drugs that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that addresses the public health effects of such opioid analgesic drugs as part of the benefit-risk assessment and the activities of the FDA that relate to facilitating the development of nonaddictive medical products intended to treat pain or addiction. Such report shall include—

(1) an update on the actions taken by the FDA to consider the effectiveness, safety, benefit-risk profile, and use of approved opioid analgesic drugs;

(2) a timeline for an assessment of the potential need, as appropriate, for labeling changes, revised or additional postmarketing requirements, enforcement actions, or withdrawals for opioid analgesic drugs;

(3) an overview of the steps that the FDA has taken to support the development and approval of nonaddictive medical products intended to treat pain or addiction, and actions planned to further support the development and approval of such products; and

(4) an overview of the consideration by the FDA of clinical trial methodologies for analgesic drugs, including the enriched enrollment randomized withdrawal methodology, and the benefits and drawbacks associated with different trial methodologies for such drugs, incorporating any public input received under subsection (b).

(b) PUBLIC INPUT.—In carrying out subsection (a), the Secretary shall provide an opportunity for public input concerning the regulation by the FDA of opioid analgesic drugs, including scientific evidence that relates to conditions of use, safety, or benefit-risk assessment (including

consideration of the public health effects) of such opioid analgesic drugs.

SEC. 522. GRANT PROGRAM FOR STATE AND TRIBAL RESPONSE TO OPIOID USE DISORDERS.

The activities carried out pursuant to section 1003(b)(4)(A) of the 21st Century Cures Act (42 U.S.C. 290ee–3a(b)(4)(A)) may include facilitating access to products used to prevent overdose deaths by detecting the presence of one or more substances, such as fentanyl and xylazine test strips, to the extent the purchase and possession of such products is consistent with Federal and State law.

Subtitle B—Treatment

SEC. 531. RESIDENTIAL TREATMENT PROGRAM FOR PREGNANT AND POSTPARTUM WOMEN.

Section 508 of the Public Health Service Act (42 U.S.C. 290bb–1) is amended—

(1) in subsection (d)(11)(C), by striking ''providing health services'' and inserting ''providing health care services'';

(2) in subsection (g)—

(A) by inserting ''a plan describing'' after ''will provide''; and

(B) by adding at the end the following: ''Such plan may include a description of how

such applicant will target outreach to women disproportionately impacted by maternal substance use disorder.''; and

(3) in subsection (s), by striking ''$29,931,000 for each of fiscal years 2019 through 2023'' and inserting ''$38,931,000 for each of fiscal years 2025 through 2029''.

SEC. 532. IMPROVING ACCESS TO ADDICTION MEDICINE PROVIDERS.

Section 597 of the Public Health Service Act (42 U.S.C. 290ll) is amended—

(1) in subsection (a)(1), by inserting ''diagnosis,'' after ''related to''; and

(2) in subsection (b), by inserting ''addiction medicine,'' after ''psychiatry,''.

SEC. 533. MENTAL AND BEHAVIORAL HEALTH EDUCATION AND TRAINING GRANTS.

Section 756(f) of the Public Health Service Act (42 U.S.C. 294e–1(f)) is amended by striking ''fiscal years 2023 through 2027'' and inserting ''fiscal years 2025 through 2029''.

SEC. 534. LOAN REPAYMENT PROGRAM FOR SUBSTANCE USE DISORDER TREATMENT WORKFORCE.

Section 781(j) of the Public Health Service Act (42 U.S.C. 295h(j)) is amended by striking ''$25,000,000 for

each of fiscal years 2019 through 2023'' and inserting ''$40,000,000 for each of fiscal years 2025 through 2029''.

SEC. 535. DEVELOPMENT AND DISSEMINATION OF MODEL TRAINING PROGRAMS FOR SUBSTANCE USE DISORDER PATIENT RECORDS.

Section 7053 of the SUPPORT for Patients and Communities Act (42 U.S.C. 290dd–2 note) is amended by striking subsection (e).

SEC. 536. TASK FORCE ON BEST PRACTICES FOR TRAUMA-INFORMED IDENTIFICATION, REFERRAL, AND SUPPORT.

Section 7132 of the SUPPORT for Patients and Communities Act (Public Law 115–271; 132 Stat. 4046) is amended—

(1) in subsection (b)(1)—

(A) by redesignating subparagraph (CC) as subparagraph (DD); and

(B) by inserting after subparagraph (BB) the following:

''(CC) The Administration for Community Living.'';

(2) in subsection (d)(1), in the matter preceding subparagraph (A), by inserting '', develop-

mental disability service providers'' before '', individuals who are''; and

(3) in subsection (i), by striking ''2023'' and inserting ''2029''.

SEC. 537. GRANTS TO ENHANCE ACCESS TO SUBSTANCE USE DISORDER TREATMENT.

Section 3203 of the SUPPORT for Patients and Communities Act (21 U.S.C. 823 note) is amended—

(1) by striking subsection (b); and

(2) by striking ''(a) IN GENERAL.—The Secretary'' and inserting the following: ''The Secretary''.

SEC. 538. STATE GUIDANCE RELATED TO INDIVIDUALS WITH SERIOUS MENTAL ILLNESS AND CHILDREN WITH SERIOUS EMOTIONAL DISTURBANCE.

(a) REVIEW OF USE OF CERTAIN FUNDING.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Assistant Secretary for Mental Health and Substance Use, shall conduct a review of State use of funds made available under the Community Mental Health Services Block Grant program under subpart I of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x et seq.)

(referred to in this section as the ''block grant program'') for first episode psychosis activities. Such review shall consider the following:

(1) How States use funds for evidence-based treatments and services according to the standard of care for individuals with early serious mental illness and children with a serious emotional disturbance.

(2) The percentages of the State funding under the block grant program expended on early serious mental illness and first episode psychosis, and the number of individuals served under such funds.

(b) REPORT AND GUIDANCE.—

(1) REPORT.—Not later than 180 days after the completion of the review under subsection (a), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report describing—

(A) the findings of the review under subsection (a); and

(B) any recommendations for changes to the block grant program that would facilitate improved outcomes for individuals with serious

mental illness and children with serious emotional disturbance.

(2) GUIDANCE.—Not later than 1 year after the date on which the report is submitted under paragraph (1), the Secretary shall update the guidance provided to States under the block grant program on coordinated specialty care and other evidence-based mental health care services for individuals with serious mental illness and children with a serious emotional disturbance, based on the findings and recommendations of such report.

SEC. 539. REVIEWING THE SCHEDULING OF APPROVED PRODUCTS CONTAINING A COMBINATION OF BUPRENORPHINE AND NALOXONE.

(a) SECRETARY OF HHS.—The Secretary of Health and Human Services shall, consistent with the requirements and procedures set forth in sections 201 and 202 of the Controlled Substances Act (21 U.S.C. 811, 812)—

(1) review the relevant data pertaining to the scheduling of products containing a combination of buprenorphine and naloxone that have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); and

(2) if appropriate, request that the Attorney General initiate rulemaking proceedings to revise the schedules accordingly with respect to such products.

(b) ATTORNEY GENERAL.—The Attorney General shall review any request made by the Secretary of Health and Human Services under subsection (a)(2) and determine whether to initiate proceedings to revise the schedules in accordance with the criteria set forth in sections 201 and 202 of the Controlled Substances Act (21 U.S.C. 811, 812).

Subtitle C—Recovery

SEC. 541. BUILDING COMMUNITIES OF RECOVERY.

Section 547(f) of the Public Health Service Act (42 U.S.C. 290ee–2(f)) is amended by striking ''$5,000,000 for each of fiscal years 2019 through 2023'' and inserting ''$16,000,000 for each of fiscal years 2025 through 2029''.

SEC. 542. PEER SUPPORT TECHNICAL ASSISTANCE CENTER.

Section 547A of the Public Health Service Act (42 U.S.C. 290ee–2a) is amended—

(1) in subsection (b)(4), by striking ''building; and'' and inserting the following: ''building, such as—

''(A) professional development of peer support specialists; and

''(B) making recovery support services available in nonclinical settings; and'';

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

(3) by inserting after subsection (c) the following:

''(d) REGIONAL CENTERS.—

''(1) IN GENERAL.—The Secretary may establish one regional technical assistance center (referred to in this subsection as the 'Regional Center'), with existing resources, to assist the Center in carrying out activities described in subsection (b) within the geographic region of such Regional Center in a manner that is tailored to the needs of such region.

''(2) EVALUATION.—Not later than 4 years after the date of enactment of the SUPPORT for Patients and Communities Reauthorization Act of 2025, the Secretary shall evaluate the activities of the Regional Center and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the findings of such evaluation, including—

''(A) a description of the distinct roles and responsibilities of the Regional Center and the Center;

''(B) available information relating to the outcomes of the Regional Center under this subsection, such as any impact on the operations and efficiency of the Center relating to requests for technical assistance and support within the region of such Regional Center;

''(C) a description of any gaps or areas of duplication relating to the activities of the Regional Center and the Center within such region; and

''(D) recommendations relating to the modification, expansion, or termination of the Regional Center under this subsection.

''(3) TERMINATION.—This subsection shall terminate on September 30, 2029.''; and

(4) in subsection (f), as so redesignated, by striking ''$1,000,000 for each of fiscal years 2019 through 2023'' and inserting ''$2,000,000 for each of fiscal years 2025 through 2029''.

SEC. 543. COMPREHENSIVE OPIOID RECOVERY CENTERS.

Section 552 of the Public Health Service Act (42 U.S.C. 290ee–7) is amended—

(1) in subsection (d)(2)—

(A) in the matter preceding subparagraph (A), by striking ''and in such manner'' and inserting '', in such manner, and containing such information and assurances, including relevant documentation,''; and

(B) in subparagraph (A), by striking ''is capable of coordinating with other entities to carry out'' and inserting ''has the demonstrated capability to carry out, through referral or contractual arrangements'';

(2) in subsection (h)—

(A) by redesignating paragraphs (1) through (4) as subparagraphs (A) through (D), respectively, and adjusting the margins accordingly;

(B) by striking ''With respect to'' and inserting the following:

''(1) IN GENERAL.—With respect to''; and

(C) by adding at the end the following:

''(2) ADDITIONAL REPORTING FOR CERTAIN ELIGIBLE ENTITIES.—An entity carrying out activities described in subsection (g) through referral or contractual arrangements shall include in the submissions required under paragraph (1) information re-

lated to the status of such referrals or contractual arrangements, including an assessment of whether such referrals or contractual arrangements are supporting the ability of such entity to carry out such activities.''; and

(3) in subsection (j), by striking ''2019 through 2023'' and inserting ''2025 through 2029''.

SEC. 544. YOUTH PREVENTION AND RECOVERY.

Section 7102(c) of the SUPPORT for Patients and Communities Act (42 U.S.C. 290bb–7a(c)) (as amended by section 110(a)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A)—

(i) in clause (i)—

(I) by inserting '', or a consortium of local educational agencies,'' after ''a local educational agency''; and

(II) by striking ''high schools'' and inserting ''secondary schools''; and

(ii) in clause (vi), by striking ''tribe, or tribal'' and inserting ''Tribe, or Tribal'';

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

"(E) INDIAN TRIBE; TRIBAL ORGANIZATION.—The terms 'Indian Tribe' and 'Tribal organization' have the meanings given such terms in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).";

(C) by redesignating subparagraph (K) as subparagraph (L); and

(D) by inserting after subparagraph (J) the following:

"(K) SECONDARY SCHOOL.—The term 'secondary school' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).";

(2) in paragraph (3)(A), in the matter preceding clause (i)—

(A) by striking "and abuse"; and

(B) by inserting "at increased risk for substance misuse" after "specific populations";

(3) in paragraph (4)—

(A) in the matter preceding subparagraph (A), by striking "Indian tribes" and inserting "Indian Tribes";

(B) in subparagraph (A), by striking ''and abuse''; and

(C) in subparagraph (B), by striking ''peer mentoring'' and inserting ''peer-to-peer support'';

(4) in paragraph (5), by striking ''tribal'' and inserting ''Tribal'';

(5) in paragraph (6)(A)—

(A) in clause (iv), by striking ''; and'' and inserting a semicolon; and

(B) by adding at the end the following:

''(vi) a plan to sustain the activities carried out under the grant program, after the grant program has ended; and'';

(6) in paragraph (8), by striking ''2022'' and inserting ''2027''; and

(7) by amending paragraph (9) to read as follows:

''(9) AUTHORIZATION OF APPROPRIATIONS.—To carry out this subsection, there are authorized to be appropriated—

''(A) $10,000,000 for fiscal year 2025;

''(B) $12,000,000 for fiscal year 2026;

''(C) $13,000,000 for fiscal year 2027;

''(D) $14,000,000 for fiscal year 2028; and

''(E) $15,000,000 for fiscal year 2029.''.

SEC. 545. CAREER ACT.

(a) IN GENERAL.—Section 7183 of the SUPPORT for Patients and Communities Act (42 U.S.C. 290ee–8) is amended—

(1) in the section heading, by inserting ''**; TREATMENT, RECOVERY, AND WORKFORCE SUPPORT GRANTS**'' after ''**CAREER ACT**'';

(2) in subsection (b), by inserting ''each'' before ''for a period'';

(3) in subsection (c)—

(A) in paragraph (1), by striking ''the rates described in paragraph (2)'' and inserting ''the average rates for calendar years 2018 through 2022 described in paragraph (2)''; and

(B) by amending paragraph (2) to read as follows:

''(2) RATES.—The rates described in this paragraph are the following:

''(A) The highest age-adjusted average rates of drug overdose deaths for calendar years 2018 through 2022 based on data from the Centers for Disease Control and Prevention, in-

cluding, if necessary, provisional data for calendar year 2022.

''(B) The highest average rates of unemployment for calendar years 2018 through 2022 based on data provided by the Bureau of Labor Statistics.

''(C) The lowest average labor force participation rates for calendar years 2018 through 2022 based on data provided by the Bureau of Labor Statistics.'';

(4) in subsection (g)—

(A) in each of paragraphs (1) and (3), by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and adjusting the margins accordingly;

(B) by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C), respectively, and adjusting the margins accordingly;

(C) in the matter preceding subparagraph (A) (as so redesignated), by striking ''An entity'' and inserting the following:

''(1) IN GENERAL.—An entity''; and

(D) by adding at the end the following:

''(2) TRANSPORTATION SERVICES.—An entity receiving a grant under this section may use not more than 5 percent of the funds for providing transportation for individuals to participate in an activity supported by a grant under this section, which transportation shall be to or from a place of work or a place where the individual is receiving vocational education or job training services or receiving services directly linked to treatment of or recovery from a substance use disorder.

''(3) LIMITATION.—The Secretary may not require an entity to, or give priority to an entity that plans to, use the funds of a grant under this section for activities that are not specified in this subsection.'';

(5) in subsection (i)(2), by inserting '', which shall include employment and earnings outcomes described in subclauses (I) and (III) of section 116(b)(2)(A)(i) of the Workforce Innovation and Opportunity Act (29 U.S.C. 3141(b)(2)(A)(i)) with respect to the participation of such individuals with a substance use disorder in programs and activities funded by the grant under this section'' after ''subsection (g)'';

(6) in subsection (j)—

(A) in paragraph (1), by inserting ''for grants awarded prior to the date of enactment of the SUPPORT for Patients and Communities Reauthorization Act of 2025'' after ''grant period under this section''; and

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking ''2 years after submitting the preliminary report required under paragraph (1)'' and inserting ''September 30, 2029''; and

(ii) in subparagraph (A), by striking ''(g)(3)'' and inserting ''(g)(1)(C)''; and

(7) in subsection (k), by striking ''$5,000,000 for each of fiscal years 2019 through 2023'' and inserting ''$12,000,000 for each of fiscal years 2025 through 2029''.

(b) REAUTHORIZATION OF THE CAREER ACT; RECOVERY HOUSING PILOT PROGRAM.—

(1) IN GENERAL.—Section 8071 of the SUPPORT for Patients and Communities Act (42 U.S.C. 5301 note; Public Law 115–271) is amended—

(A) by striking the section heading and inserting ''**CAREER ACT; RECOVERY HOUSING PILOT PROGRAM**'';

(B) in subsection (a), by striking ''through 2023'' and inserting ''through 2029'';

(C) in subsection (b)—

(i) in paragraph (1), by striking ''not later than 60 days after the date of enactment of this Act'' and inserting ''not later than 60 days after the date of enactment of the SUPPORT for Patients and Communities Reauthorization Act of 2025''; and

(ii) in paragraph (2)(B)(i)—

(I) in subclause (I)—

(aa) by striking ''for calendar years 2013 through 2017''; and

(bb) by inserting ''for calendar years 2018 through 2022'' after ''rates of unemployment'';

(II) in subclause (II)—

(aa) by striking ''for calendar years 2013 through 2017''; and

(bb) by inserting ''for calendar years 2018 through 2022'' after ''participation rates''; and

(III) by striking subclause (III) and inserting the following:

''(III) The highest age-adjusted average rates of drug overdose deaths for calendar years 2018 through 2022 based on data from the Centers for Disease Control and Prevention, including, if necessary, provisional data for calendar year 2022.''; and

(D) in subsection (f), by striking ''For the 2-year period following the date of enactment of this Act, the'' and inserting ''The''.

(2) CONFORMING AMENDMENT.—Subtitle F of title VIII of the SUPPORT for Patients and Communities Act (Public Law 115–271; 132 Stat. 4095) is amended by striking the subtitle heading and inserting the following: ''**Subtitle F—CAREER Act; Recovery Housing Pilot Program**'' **.**

(c) CLERICAL AMENDMENTS.—The table of contents in section 1(b) of the SUPPORT for Patients and Communities Act (Public Law 115–271; 132 Stat. 3894) is amended—

(1) by striking the item relating to section 7183 and inserting the following:

"Sec. 7183. CAREER Act; treatment, recovery, and workforce support grants.";

(2) by striking the item relating to subtitle F of title VIII and inserting the following:

"Subtitle F—CAREER Act; Recovery Housing Pilot Program"; and

(3) by striking the item relating to section 8071 and inserting the following:

"Sec. 8071. CAREER Act; Recovery Housing Pilot Program.".

SEC. 546. ADDRESSING ECONOMIC AND WORKFORCE IMPACTS OF THE OPIOID CRISIS.

Section 8041(g)(1) of the SUPPORT for Patients and Communities Act (29 U.S.C. 3225a(g)(1)) is amended by striking "2023" and inserting "2029".

Subtitle D—Miscellaneous Matters

SEC. 551. DELIVERY OF A CONTROLLED SUBSTANCE BY A PHARMACY TO A PRESCRIBING PRACTITIONER.

Section 309A(a) of the Controlled Substances Act (21 U.S.C. 829a(a)) is amended by striking paragraph (2) and inserting the following:

"(2) the controlled substance is a drug in schedule III, IV, or V to be administered—

''(A) by injection or implantation for the purpose of maintenance or detoxification treatment; or

''(B) subject to a risk evaluation and mitigation strategy pursuant to section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) that includes elements to assure safe use of the drug described in subsection (f)(3)(E) of such section, including a requirement for post-administration monitoring by a health care provider.''.

SEC. 552. TECHNICAL CORRECTION ON CONTROLLED SUBSTANCES DISPENSING.

Effective as if included in the enactment of Public Law 117–328—

(1) section 1252(a) of division FF of Public Law 117–328 (136 Stat. 5681) is amended, in the matter being inserted into section 302(e) of the Controlled Substances Act, by striking ''303(g)'' and inserting ''303(h)'';

(2) section 1262 of division FF of Public Law 117–328 (136 Stat. 5681) is amended—

(A) in subsection (a)—

(i) in the matter preceding paragraph (1), by striking ''303(g)'' and inserting ''303(h)'';

(ii) in the matter being stricken by subsection (a)(2), by striking ''(g)(1)'' and inserting ''(h)(1)''; and

(iii) in the matter being inserted by subsection (a)(2), by striking ''(g) Practitioners'' and inserting ''(h) Practitioners''; and

(B) in subsection (b)—

(i) in the matter being stricken by paragraph (1), by striking ''303(g)(1)'' and inserting ''303(h)(1)'';

(ii) in the matter being inserted by paragraph (1), by striking ''303(g)'' and inserting ''303(h)'';

(iii) in the matter being stricken by paragraph (2)(A), by striking ''303(g)(2)'' and inserting ''303(h)(2)'';

(iv) in the matter being stricken by paragraph (3), by striking ''303(g)(2)(B)'' and inserting ''303(h)(2)(B)'';

(v) in the matter being stricken by paragraph (5), by striking ''303(g)'' and inserting ''303(h)''; and

(vi) in the matter being stricken by paragraph (6), by striking ''303(g)'' and inserting ''303(h)''; and

(3) section 1263(b) of division FF of Public Law 117–328 (136 Stat. 5685) is amended—

(A) by striking ''303(g)(2)'' and inserting ''303(h)(2)''; and

(B) by striking ''(21 U.S.C. 823(g)(2))'' and inserting ''(21 U.S.C. 823(h)(2))''.

SEC. 553. REQUIRED TRAINING FOR PRESCRIBERS OF CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended—

(1) by redesignating the second subsection designated as subsection (l) as subsection (m); and

(2) in subsection (m)(1), as so redesignated—

(A) in subparagraph (A)—

(i) in clause (iv)—

(I) in subclause (I)—

(aa) by inserting ''the American Academy of Family Physicians, the American Podiatric

Medical Association, the Academy of General Dentistry, the American Optometric Association,'' before ''or any other organization'';

(bb) by striking ''or the Commission'' and inserting ''the Commission''; and

(cc) by inserting '', or the Council on Podiatric Medical Education'' before the semicolon at the end; and

(II) in subclause (III), by inserting ''or the American Academy of Family Physicians'' after ''Association''; and

(ii) in clause (v), in the matter preceding subclause (I)—

(I) by striking ''osteopathic medicine, dental surgery'' and inserting ''osteopathic medicine, podiatric medicine, dental surgery''; and

(II) by striking ''or dental medicine curriculum'' and inserting ''or

dental or podiatric medicine curriculum''; and

(B) in subparagraph (B)—

(i) in clause (i)—

(I) by inserting ''the American Pharmacists Association, the Accreditation Council on Pharmacy Education, the American Psychiatric Nurses Association, the American Academy of Nursing, the American Academy of Family Physicians,'' before ''or any other organization''; and

(II) by inserting '', the American Academy of Family Physicians,'' before ''or the Accreditation Council''; and

(ii) in clause (ii)—

(I) by striking ''or accredited school'' and inserting '', an accredited school''; and

(II) by inserting '', or an accredited school of pharmacy'' before ''in the United States''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if enacted on December 29, 2022.

SEC. 554. EXTENSION OF TEMPORARY ORDER FOR FENTANYL-RELATED SUBSTANCES.

Effective as if included in the enactment of the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (Public Law 116–114), section 2 of such Act is amended by striking ''March 31, 2025'' and inserting ''September 30, 2026''.

TITLE VI—PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND RESPONSE

SEC. 601. SHORT TITLE.

This title may be cited as the ''Pandemic and All-Hazards Preparedness and Response Act''.

Subtitle A—State and Local Readiness and Response

SEC. 611. TEMPORARY REASSIGNMENT OF STATE AND LOCAL PERSONNEL DURING A PUBLIC HEALTH EMERGENCY.

Section 319(e) of the Public Health Service Act (42 U.S.C. 247d(e)) is amended—

(1) in paragraph (1), by striking ''tribal organization or such Governor or tribal organization's des-

ignee'' and inserting ''Tribal organization or the designee of the Governor or Tribal organization, or the State or Tribal health official'';

(2) in paragraph (2)(B)—

(A) in the matter preceding clause (i), by striking ''tribal organization'' and inserting ''Tribal organization, or the State or Tribal health official''; and

(B) in clause (v), by striking ''tribal organization'' and inserting ''Tribal organization or State or Tribal health official'';

(3) in paragraph (6)—

(A) in the matter preceding subparagraph (A)—

(i) by striking ''Reauthorization Act of 2013'' and inserting ''and Response Act''; and

(ii) by striking ''appropriate committees of the Congress'' and inserting ''Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives''; and

(B) in subparagraph (A), by inserting ", including requests from State or Tribal health officials" before the semicolon;

(4) in paragraph (7)(A), by striking "tribal organization" and inserting "Tribal organization"; and

(5) in paragraph (8), by striking "March 31, 2025" and inserting "December 31, 2026".

SEC. 612. PUBLIC HEALTH EMERGENCY PREPAREDNESS PROGRAM.

Section 319C–1 of the Public Health Service Act (42 U.S.C. 247d–3a) is amended—

(1) in subsection (b)(2)—

(A) in subparagraph (A)(ii), by striking "influenza" and inserting "response planning"; and

(B) in subparagraph (H), by inserting ", such as community-based organizations, including faith-based organizations, and other public and private entities" after "stakeholders";

(2) in subsection (g)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by inserting "and the ability of each entity receiving an award under subsection (a) to respond to all-hazards

threats'' before the period at the end of the first sentence;

(B) in paragraph (2)—

(i) in the paragraph heading, by striking ''INFLUENZA'' and inserting ''RESPONSE''; and

(ii) in subparagraph (A)—

(I) by striking ''to pandemic influenza'' and inserting ''to a pathogen causing a pandemic, including pandemic influenza''; and

(II) by striking ''such pandemic influenza'' and inserting ''such pandemic response'';

(C) in paragraph (5)—

(i) in the paragraph heading, by striking ''INFLUENZA'' and inserting ''PANDEMIC RESPONSE'';

(ii) in the matter preceding subparagraph (A), by striking ''2019'' and inserting ''2026'';

(iii) in subparagraph (A), by striking ''2018'' and inserting ''2025''; and

(iv) in subparagraph (B), by striking ''pandemic influenza'' and inserting ''a pathogen causing a pandemic''; and

(D) in paragraph (6)—

(i) in subparagraph (A), in the matter preceding clause (i), by striking ''The amounts described in this paragraph are the following amounts that are payable to an entity for activities described in this section or section 319C–2'' and inserting ''The Secretary shall withhold from an entity pursuant to paragraph (5) for noncompliance with the requirements of this section or section 319C–2 as follows''; and

(ii) in subparagraph (B), by inserting ''with respect to the requirements of this section or section 319C–2'' after ''paragraph (5)''; and

(3) in subsection (h)(1)(A), by striking ''$685,000,000 for each of fiscal years 2019 through 2023'' and inserting ''$735,000,000 for each of fiscal years 2025 and 2026, to remain available through December 31, 2026''.

SEC. 613. HOSPITAL PREPAREDNESS PROGRAM.

(a) INCREASING PARTICIPATION BY EMS IN THE HOSPITAL PREPAREDNESS PROGRAM.—

(1) IN GENERAL.—Section 319C–2 of the Public Health Service Act (42 U.S.C. 247d–3b) is amended—

(A) in subsection (b)(1)(A)—

(i) in clause (iii)(III), by striking ''; and'' and inserting a semicolon; and

(ii) by striking clause (iv) and inserting the following:

''(iv) one or more emergency medical service organizations; and

''(v) to the extent practicable, one or more emergency management organizations; and''; and

(B) in subsection (g)(1)—

(i) by striking ''(1) LOCAL RESPONSE CAPABILITIES'' and inserting:

''(1) LOCAL RESPONSE CAPABILITIES.—

''(A) PROGRAM COORDINATION.—'';

(ii) by striking ''extent practicable, ensure'' and inserting the following: ''extent practicable—

''(i) ensure'';

(iii) by striking the period and inserting ''; and''; and

(iv) by adding at the end the following:

''(ii) seek to increase participation of eligible entities described in subsection (b)(1)(A) with lower participation rates relative to other eligible entities, such as emergency medical services organizations and health care facilities in underserved areas.''.

(2) PREFERENCES.—Section 319C–2(d)(1)(A)(iii) of the Public Health Service Act (42 U.S.C. 247d–3b(d)(1)(A)(iii)) is amended by striking ''subsection (b)(1)(A)(ii)'' and inserting ''clauses (ii) and (iv) of subsection (b)(1)(A)''.

(b) IMPROVING MEDICAL READINESS AND RESPONSE CAPABILITIES.—Section 319C–2 of the Public Health Service Act (42 U.S.C. 247d–3b) is amended—

(1) in subsection (b)(2)—

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

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

(C) by inserting at the end the following:

''(C) designate a lead entity to administer such award and support coordination between entities described in this subsection.'';

(2) in subsection (g)(1), as amended by subsection (a)(1)(B), by adding at the end the following:

''(B) REGIONAL OPERATIONS.—An eligible entity shall establish and maintain, or leverage an existing, capability to enable coordination of regional medical operations, which may include systems to facilitate information sharing and coordination, within a coalition described under subsection (b)(1)(A) and, as appropriate, among multiple coalitions that are in close geographic proximity to each other.''; and

(3) in subsection (j)(1)—

(A) in subparagraph (A), by striking ''for each of fiscal years 2019 through 2023'' and inserting ''for each of fiscal years 2025 and 2026, to remain available through December 31, 2026''; and

(B) in subparagraph (B)(iii), by striking ''September 30, 2023'' and inserting ''December 31, 2026''.

SEC. 614. FACILITIES AND CAPACITIES OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION TO COMBAT PUBLIC HEALTH SECURITY THREATS.

Section 319D(h) of the Public Health Service Act (42 U.S.C. 247d–4(h)) is amended—

(1) in paragraph (1), by striking ''$25,000,000 for each of fiscal years 2022 and 2023'' and inserting ''$40,000,000 for each of fiscal years 2025 and 2026'', to remain available through December 31, 2026; and

(2) in paragraph (2), by striking ''2022 and 2023'' and inserting ''2025 and 2026, to remain available through December 31, 2026''.

SEC. 615. PILOT PROGRAM TO SUPPORT STATE MEDICAL STOCKPILES.

(a) IN GENERAL.—Section 319F–2(i) of the Public Health Service Act (42 U.S.C. 247d–6b(i)) is amended—

(1) in paragraph (2)(B)(i)—

(A) in subclause (I), by striking ''and 2024'' and inserting ''through 2025''; and

(B) in subclause (II), by striking ''2025'' and inserting ''2026'';

(2) in paragraph (4)—

(A) in subparagraph (G), by striking ''; and'' at the end and inserting a semicolon;

(B) by redesignating subparagraph (H) as subparagraph (I);

(C) by inserting after subparagraph (G) the following:

''(H) facilitate the sharing of best practices among States within a consortia of States in receipt of funding related to establishing and maintaining a stockpile of medical products; and''; and

(D) in subparagraph (I), as so redesignated, by striking ''State efforts'' and inserting ''State or regional efforts'';

(3) by redesignating paragraphs (5) through (9) as paragraphs (6) through (10), respectively;

(4) by inserting after paragraph (4) the following:

''(5) COORDINATION.—An entity in receipt of an award under paragraph (1), in carrying out the activities under this subsection, shall coordinate with appropriate health care entities, health officials, and emergency management officials within the jurisdiction of such State or States.''; and

(5) in paragraph (10), as so redesignated, by striking ''$3,500,000,000 for each of fiscal years 2023 and 2024'' and inserting ''$3,365,000,000 for

fiscal year 2025, and $3,265,000,000 for fiscal year 2026''.

(b) GAO REPORT.—Section 2409(b) of the PREVENT Pandemics Act (Public Law 117–328) is amended—

(1) in paragraph (2), by striking ''; and'' and inserting a semicolon;

(2) in paragraph (3), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(4) the impact of any regional stockpiling approaches carried out under subsection (i)(1) of section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b).''.

SEC. 616. ENHANCING DOMESTIC WASTEWATER SURVEILLANCE FOR PATHOGEN DETECTION.

(a) IN GENERAL.—Title III of the Public Health Service Act is amended by inserting after section 317V (42 U.S.C. 247b–24) the following:

''SEC. 317W. WASTEWATER SURVEILLANCE FOR PATHOGEN DETECTION.

''(a) WASTEWATER SURVEILLANCE SYSTEM.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other Federal departments and agencies, shall award

grants, contracts, or cooperative agreements to eligible entities to establish, maintain, or improve activities related to the detection and monitoring of infectious diseases through wastewater for public health emergency preparedness and response purposes.

''(b) ELIGIBLE ENTITIES.—To be eligible to receive an award under this section, an entity shall—

''(1) be a State, Tribal, or local health department, or a partnership between such a health department and other public and private entities; and

''(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may reasonably require, which shall include—

''(A) a description of activities proposed to be carried out pursuant to an award under subsection (a);

''(B) factors such entity proposes to use to select wastewater sampling sites;

''(C) factors such entity proposes to use to determine whether a response to findings from such wastewater sampling may be warranted, and a plan for responding, as appropriate, consistent with applicable plans developed by such entity pursuant to section 319C–1;

"(D) a plan to sustain such wastewater surveillance activities described in such application following the conclusion of the award period; and

"(E) any additional information the Secretary may require.

"(c) CONSIDERATION.—In making awards under subsection (a), the Secretary may give priority to eligible entities that have submitted an application that—

"(1) details plans to provide public access to deidentified data generated through such wastewater surveillance activities in a manner that allows for comparison to such data generated by other recipients of an award under subsection (a); and

"(2) provides an assessment of community needs related to ongoing infectious disease monitoring, including estimates of the incidence and prevalence of infectious diseases that can be detected in wastewater and availability, at the time of the application, of other forms of infectious disease detection in the jurisdiction.

"(d) USE OF FUNDS.—An eligible entity shall, as appropriate, use amounts awarded under this section to—

''(1) establish or enhance existing capacity and capabilities to conduct wastewater sampling, testing, and related analysis;

''(2) conduct wastewater surveillance, as appropriate, in areas or facilities with increased risk of infectious disease outbreaks and limited ability to utilize other forms of infectious disease detection, such as at individual facilities, institutions, and locations in rural areas or areas in which wastewater is not treated through the relevant local utility of the jurisdiction; and

''(3) implement projects that use evidence-based or innovative practices to conduct wastewater surveillance activities.

''(e) PARTNERSHIPS.—In carrying out activities under this section, eligible entities shall identify opportunities to partner with other public or private entities to leverage relevant capabilities maintained by such entities, as appropriate and consistent with this section.

''(f) TECHNICAL ASSISTANCE.—The Secretary, in consultation with the heads of other applicable Federal agencies and departments, as appropriate, shall provide technical assistance to recipients of awards under this section to facilitate the planning, development, and implementation of activities described in subsection (d).

''(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $20,000,000 for each of fiscal years 2025 and 2026, to remain available through December 31, 2026.''.

(b) WASTEWATER SURVEILLANCE RESEARCH.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the ''Secretary'') shall continue to conduct or support research on the use of wastewater surveillance to detect and monitor emerging infectious diseases, which may include—

(A) research to improve the efficiency and effectiveness of wastewater sample collection and analysis and increase the sensitivity and specificity of wastewater testing methods; and

(B) implementation and development of evidence-based practices to facilitate the estimation of the incidence and prevalence of infectious disease within a community.

(2) NON-DUPLICATION OF EFFORT.—The Secretary shall ensure that activities carried out under this subsection do not unnecessarily duplicate efforts of other agencies and offices within the Department of Health and Human Services related to wastewater surveillance.

SEC. 617. REAUTHORIZATION OF MOSQUITO ABATEMENT FOR SAFETY AND HEALTH PROGRAM.

Section 317S of the Public Health Service Act (42 U.S.C. 247b–21) is amended—

(1) in subsection (a)(3)(A), by striking ''subsection (b)(3)'' and inserting ''subsection (b)(4)'';

(2) in subsection (b)—

(A) by redesignating paragraphs (3) through (6) as paragraphs (4) through (7), respectively; and

(B) by inserting after paragraph (2) the following:

''(3) CONSIDERATIONS.—The Secretary may consider the use of innovative and novel technology for mosquito prevention and control in making grants under paragraph (1).'';

(3) by amending subsection (d) to read as follows:

''(d) USES OF FUNDS.—Amounts appropriated under subsection (f) may be used by the Secretary to provide training and technical assistance with respect to the planning, development, and operation of assessments and plans under subsection (a) and control programs under subsection (b). The Secretary may provide such training and technical assistance directly or through awards of grants or contracts to public and private entities.''; and

(4) in subsection (f)(1), by striking ''2019 through 2023'' and inserting ''2025 and 2026, to remain available through December 31, 2026''.

Subtitle B—Federal Planning and Coordination

SEC. 621. ALL-HAZARDS EMERGENCY PREPAREDNESS AND RESPONSE.

Section 2811 of the Public Health Service Act (42 U.S.C. 300hh–10) is amended—

(1) in subsection (b)—

(A) in paragraph (3)—

(i) by striking ''Oversee advanced research, development, and procurement'' and inserting the following:

''(A) IN GENERAL.—Oversee advanced research, development, procurement, and replenishment''; and

(ii) by adding at the end the following:

''(B) DEVELOPMENT OF REQUIREMENTS.—Lead the development and approval, and, on a routine basis, the review and update, of requirements for such countermeasures and products, including related capabilities, to inform the advanced research, development, pro-

curement, and replenishment decisions of the Secretary.'';

(B) in paragraph (4)—

(i) in subparagraph (F)—

(I) in the matter preceding clause (i), by striking ''and in consultation with the Secretary of Homeland Security,''; and

(II) in clause (i), by inserting ''enhance'' after ''capabilities and'';

(ii) in subparagraph (G)—

(I) in the matter preceding clause (i), by inserting ''the Office of Pandemic Preparedness and Response Policy,'' after ''Veterans Affairs,'';

(II) in clause (i), by striking ''based on'' and inserting ''based on—'';

(III) in clause (ii), by striking ''; and'' at the end and inserting a semicolon;

(IV) in clause (iii), by striking the period and inserting ''; and''; and

(V) by adding at the end the following:

''(iv) that include, as appropriate, participation by relevant industry, academia, professional societies, and other stakeholders.'';

(iii) in subparagraph (H)—

(I) by inserting ''and the Director of the Office of Pandemic Preparedness and Response Policy'' after ''Security Affairs''; and

(II) by inserting ''and medical product and supply capacity planning pursuant to subparagraph (J), including discussion of any relevant identified supply chain vulnerabilities'' before the period at the end;

(iv) in subparagraph (I), by inserting ''the Director of the Office of Pandemic Preparedness and Response Policy,'' after ''Security Affairs,''; and

(v) in subparagraph (J)(i), in the matter preceding subclause (I), by inserting ''(including ancillary medical supplies and components of medical products, such as active pharmaceutical ingredients, key starting materials, medical device compo-

nents, testing kits, reagents, and other testing supplies)'' after ''supply needs''; and

(C) in paragraph (7)—

(i) in the matter preceding subparagraph (A), by inserting ''and the requirements developed pursuant to paragraph (3)(B)'' after ''subsection (d)'';

(ii) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively; and

(iii) by inserting after subparagraph (D) the following:

''(E) include a professional judgment of anticipated budget needs for each future fiscal year accounted for in such plan to account for the full range of anticipated medical countermeasure needs and life-cycle costs to address such priorities and requirements;'';

(2) in subsection (d)—

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

''(1) IN GENERAL.—Not later than March 15, 2020, and biennially thereafter, the Assistant Secretary for Preparedness and Response shall develop

and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a coordinated strategy for medical countermeasures to address chemical, biological, radiological, and nuclear threats, informed by the requirements developed pursuant to subsection (b)(3)(B). Not later than 180 days after the submission of such strategy to such committees, the Assistant Secretary for Preparedness and Response shall submit an accompanying implementation plan to such committees. In developing such a strategy and plan, the Assistant Secretary for Preparedness and Response shall consult with the Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1. Such strategy and plan shall be known as the Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan.''; and

(B) in paragraph (2), in the matter preceding subparagraph (A), by inserting ''strategy and'' before ''plan''; and

(3) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by inserting '', includ-

ing such agents that are an emerging infectious disease'' after ''become a pandemic''; and

(B) in paragraph (2)(A), by striking ''$250,000,000 for each of fiscal years 2019 through 2023'' and inserting ''$335,000,000 for each of fiscal years 2025 and 2026, to remain available through December 31, 2026''.

SEC. 622. NATIONAL HEALTH SECURITY STRATEGY.

Section 2802 of the Public Health Service Act (42 U.S.C. 300hh–1) is amended—

(1) in subsection (a)(3)—

(A) by striking ''In 2022, the'' and inserting ''The''; and

(B) by inserting '', maintaining, and sustaining'' after ''establishing''; and

(2) in subsection (b)—

(A) in paragraph (2)—

(i) in subparagraph (A), by inserting ''that support interagency coordination and availability of information, as appropriate'' before the period;

(ii) in subparagraph (B), by inserting ''rapid testing,'' after ''and supplies,'';

(B) in paragraph (3)—

(i) in the matter preceding subparagraph (A), by inserting ''and blood banks'' after ''dental health facilities'';

(ii) in subparagraph (C), by inserting ''and current capacity of facilities within such systems, as applicable'' before the period; and

(iii) in subparagraph (D), by inserting ''and other medical products and medical supplies consistent with the activities carried out under section 2811(b)(4)(J)'' before the period;

(C) in paragraph (5), by inserting ''applicable federally funded activities and'' after ''(including'';

(D) in paragraph (8)—

(i) in subparagraph (A), by inserting ''public health and medical'' before ''activities''; and

(ii) in subparagraph (B), by striking ''familiarity with'' and inserting ''understanding of, and coordination between,'';

(E) by redesignating paragraphs (9) and (10) as paragraphs (10) and (12), respectively;

(F) by inserting after paragraph (8) the following:

''(9) OTHER SETTINGS.—Supporting Federal, State, local, and Tribal coordination and planning with respect to facilities in which there is an increased risk of infectious disease outbreaks, including such facilities that address the needs of at-risk individuals, in the event of a public health emergency declared under section 319.'';

(G) by inserting after subparagraph (10), as so redesignated, the following:

''(11) OTHER HAZARDS.—Assessing current and potential health security threats from natural disasters with respect to public health and medical preparedness and response.'';

(H) by inserting after paragraph (12), as so redesignated, the following:

''(13) CYBERSECURITY RESILIENCY OF HEALTH CARE SYSTEMS.—Consistent with the requirements of section 2218 of the Homeland Security Act of 2002, strengthening the ability of States, local communities, and Tribal communities to prepare for, respond to, and be resilient against cybersecurity vulnerabilities or cybersecurity attacks that affect public health and health information technology, and

encouraging health care facilities to use recognized security practices meeting or exceeding the approaches established under section 405(d) of the Cybersecurity Act of 2015.''; and

(I) by striking ''tribal'' each place it appears and inserting ''Tribal''.

SEC. 623. IMPROVING DEVELOPMENT AND DISTRIBUTION OF DIAGNOSTIC TESTS.

Section 319B of the Public Health Service Act (42 U.S.C. 247d–2) is amended to read as follows:

''SEC. 319B. IMPROVING DEVELOPMENT AND DISTRIBUTION OF DIAGNOSTIC TESTS.

''(a) DIAGNOSTIC TESTING PREPAREDNESS PLAN.—The Secretary shall develop, make publicly available, not later than 1 year after the date of enactment of the Pandemic and All-Hazards Preparedness and Response Act, and update not less frequently than every 3 years thereafter, a plan for the rapid development, validation, authorization, manufacture, procurement, and distribution of diagnostic tests, and for rapid scaling of testing capacity, in response to chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, for which a public health emergency is declared under section 319, or that has significant potential to cause such a public health emergency.

''(b) PURPOSES.—The purpose of the plan under subsection (a) shall be to—

''(1) facilitate the development and utilization of diagnostic tests;

''(2) describe the processes for the rapid development, validation, authorization, manufacture, procurement, and distribution of diagnostic tests, and for rapid scaling of testing capacity; and

''(3) facilitate coordination and collaboration among public and private entities to improve the rapid development and utilization of diagnostic testing during a public health emergency.

''(c) CONSIDERATIONS.—The plan under subsection (a) shall take into consideration—

''(1) domestic capacity, including any such capacity established through partnerships with public and private entities pursuant to subsection (e), to support the development, validation, manufacture, procurement, and distribution of tests, and the rapid scaling of testing capacity;

''(2) novel technologies and platforms that—

''(A) may be used to improve testing capabilities, including—

''(i) high-throughput laboratory diagnostics;

"(ii) point-of-care diagnostics; and

"(iii) rapid at-home diagnostics;

"(B) improve the accessibility of diagnostic tests; and

"(C) facilitate the development and manufacture of diagnostic tests;

"(3) medical supply needs related to testing, including diagnostic testing, equipment, supplies, and component parts, and any potential vulnerabilities related to the availability of such medical supplies and related planning needs, consistent with section 2811(b)(4)(J);

"(4) strategies for the rapid and efficient distribution of tests locally, regionally, or nationwide and appropriate scaling of laboratory testing capacity; and

"(5) assessment of such strategies through drills and operational exercises carried out under section 2811(b)(4)(G), as appropriate.

"(d) COORDINATION.—To inform the development and update of the plan under subsection (a), and in carrying out activities to implement such plan, the Secretary shall coordinate with industry, such as device manufacturers, clinical and reference laboratories, and medical product distributors, States, local governmental entities, In-

dian Tribes and Tribal organizations, and other relevant public and private entities.

''(e) CAPACITY BUILDING.—The Secretary may contract with public and private entities, as appropriate, to increase domestic capacity in the rapid development, validation, authorization, manufacture, procurement, and distribution of diagnostic tests, as appropriate, to State, local, and Tribal health departments and other appropriate entities for immediate public health response activities to address an infectious disease with respect to which a public health emergency is declared under section 319, or that has significant potential to cause such a public health emergency.''.

SEC. 624. COMBATING ANTIMICROBIAL RESISTANCE.

(a) IN GENERAL.—Section 319E of the Public Health Service Act (42 U.S.C. 247d–5) is amended—

(1) in subsection (a)—

(A) in paragraph (1), by inserting ''and activities'' after ''Federal programs'';

(B) in paragraph (2)—

(i) by striking ''public health constituencies, manufacturers, veterinary and medical professional societies and others'' and inserting ''the Advisory Council described

in subsection (b) and relevant public and private entities''; and

(ii) by inserting '', pursuant to paragraph (4),'' after ''comprehensive plan'';

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

''(3) AGENDA.—The task force described in paragraph (1) shall consider factors the Secretary considers appropriate, including factors to—

''(A) slow the emergence of resistant bacteria and fungi and prevent the spread of resistant infections;

''(B) strengthen activities to combat resistance with respect to zoonotic diseases;

''(C) advance development and use of rapid and innovative capabilities, including diagnostic tests, for identification and characterization of resistant bacteria and fungi;

''(D) accelerate basic and applied research and development for new antibiotics, antifungals, and other related therapeutics and vaccines; and

''(E) support international collaboration and capacities for antimicrobial-resistance prevention, detection, and control.'';

(D) by redesignating paragraph (4) as paragraph (5);

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

''(4) ACTION PLAN.—Not later than October 1, 2026, and every 5 years thereafter, the task force described in paragraph (1) shall develop and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a plan regarding Federal programs and activities to combat antimicrobial resistance, including measurable outcomes, as appropriate, informed by—

''(A) the agenda described in paragraph (3);

''(B) input provided by the Advisory Council described in subsection (b); and

''(C) input from other relevant stakeholders provided pursuant to paragraph (2).'';

(2) by redesignating subsections (b) through (o) as subsections (c) through (p), respectively;

(3) by inserting after subsection (a) the following:

''(b) ADVISORY COUNCIL.—

''(1) IN GENERAL.—The Secretary may continue the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, referred to in this subsection as the 'Advisory Council'.

''(2) DUTIES.—The Advisory Council shall advise and provide information and recommendations to the Secretary, acting through the Task Force established under subsection (a), regarding Federal programs and activities intended to reduce or combat antimicrobial-resistant bacteria or fungi that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. Such advice, information, and recommendations may be related to improving Federal efforts related to factors described in subsection (a)(3) and other topics related to antimicrobial resistance, as appropriate.

''(3) MEETINGS AND COORDINATION.—

''(A) MEETINGS.—The Advisory Council shall meet not less frequently than biannually and, to the extent practicable, in coordination with meetings of the task force established under subsection (a).

"(B) COORDINATION.—The Advisory Council shall, to the greatest extent practicable, coordinate activities carried out by the Council with the task force established under subsection (a).

"(4) FACA.—Chapter 10 of title 5, United States Code, shall apply to the activities and duties of the Advisory Council.

"(5) SUNSET.—

"(A) IN GENERAL.—The Advisory Council under this subsection shall terminate on December 31, 2026.

"(B) EXTENSION OF ADVISORY COUNCIL.—Not later than October 1, 2026, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes a recommendation on whether the Advisory Council should be extended, and identifying whether there are other committees, councils, or task forces that have overlapping or similar duties to that of the Advisory Council, and whether such committees, councils, or task forces should be combined, restructured, or

eliminated, including with respect to the task force established under subsection (a).''; and

(4) in subsection (n), as so redesignated, by striking ''(f) through (j)'' and inserting ''(g) through (k)''.

(b) CONFORMING AMENDMENT.—Section 505 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (42 U.S.C. 247d–5 note; Public Law 116–22) is amended by striking subsection (a) and all that follows through ''Not later'' in subsection (e) and inserting the following:

''Not later''.

SEC. 625. STRATEGIC NATIONAL STOCKPILE AND MATERIAL THREATS.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—

(1) in subsection (a)—

(A) in paragraph (2)—

(i) in subparagraph (A), by inserting ''Such review shall include a description of how the Secretary manages and mitigates risks associated with gaps between current inventory levels and stockpiling goals, prioritizes such risks, and tracks progress

toward mitigation of such risks.'' after the first sentence; and

(ii) in subparagraph (B)(i), by amending subclause (IV) to read as follows:

''(IV) the emergency health security threat or threats such countermeasure procurement is intended to address, including—

''(aa) whether such procurement is consistent with meeting emergency health security needs associated with such threat or threats; and

''(bb) in the case of a countermeasure that addresses a biological agent, whether such agent has an increased likelihood to become resistant to, more resistant to, or evade, such countermeasure relative to other available medical countermeasures;'';

(B) in paragraph (3)—

(i) in subparagraph (B), by striking ''are followed, regularly reviewed, and updated with respect to such stockpile'' and

inserting ''with respect to such stockpile are followed, regularly reviewed, and updated to reflect best practices'';

(ii) in subparagraph (I), by inserting '', through a standard operating procedure,'' after ''ensure'';

(iii) by redesignating subparagraphs (H) through (K) as subparagraphs (I) through (L), respectively;

(iv) by inserting after subparagraph (G) the following:

''(H) utilize tools to enable the timely and accurate tracking of the contents of the stockpile throughout the deployment of such contents, including tracking of the location and geographic distribution and utilization of such contents;'';

(v) in subparagraph (K), as so redesignated, by striking ''; and'' at the end and inserting a semicolon;

(vi) in subparagraph (L), as so redesignated, by striking the period and inserting ''; and''; and

(vii) by adding at the end the following:

''(M) communicate to relevant vendors regarding modifications, renewals, extensions, or terminations of contracts, or the intent to exercise options for such contracts, within 30 days, as practicable, of such determination, including through the development of a contract notification process.'';

(C) in paragraph (5)(B), in the matter preceding clause (i), by inserting '', which may accompany the review required under paragraph (2),'' after ''Representatives a report''; and

(D) in paragraph (6)(A)—

(i) by redesignating clauses (viii) through (x) as clauses (ix) through (xi), respectively; and

(ii) by inserting after clause (vii) the following:

''(viii) with respect to any change in the Federal organizational management of the stockpile, an assessment and comparison of any differences in the processes and operations resulting from such change, including—

''(I) planning for potential countermeasure deployment, distribution, or dispensing capabilities;

''(II) organizational structure;

''(III) communication with relevant stakeholders related to procurement decisions;

''(IV) processes related to procurement, deployment, and use of stockpiled countermeasures;

''(V) communication and coordination with the Public Health Emergency Medical Countermeasures Enterprise and other related Federal entities;

''(VI) inventory management; and

''(VII) availability and use of resources for such activities;''; and

(2) in subsection (c)(2)(C), by striking ''promptly'' and inserting '', not later than 60 days after each such determination,'';

(3) in subsection (f)(1), by striking ''$610,000,000 for each of fiscal years 2019 through 2021, and $750,000,000 for each of fiscal years

2022 and 2023'' and inserting ''$1,100,000,000 for fiscal year 2025, and $1,210,000,000 for fiscal year 2026''; and

(4) in subsection (g)(1), by striking ''2019 through 2028'' and inserting ''2025 through 2034''.

SEC. 626. MEDICAL COUNTERMEASURES FOR VIRAL THREATS WITH PANDEMIC POTENTIAL.

Section 319L of the Public Health Service Act (42 U.S.C. 247d–7e) is amended—

(1) in subsection (c)—

(A) in paragraph (4)—

(i) in subparagraph (D)—

(I) in clause (ii), by striking ''; and'' and inserting a semicolon; and

(II) by redesignating clause (iii) as clause (iv); and

(III) by inserting after clause (ii) the following:

''(iii) research and development of medical countermeasures for priority virus families that have significant potential to cause a pandemic, including such countermeasures that take either pathogen-specific or pathogen-agnostic approaches, and platform technologies to improve the develop-

ment and manufacture of such medical countermeasures; and''; and

(ii) in subparagraph (F)(ii), by inserting ''or priority virus families and other viral pathogens that pose a threat due to their significant potential to cause a pandemic,'' after ''pandemic influenza,''; and

(B) in paragraph (5), by adding at the end the following:

''(I) NOTIFICATION.—In awarding contracts, grants, cooperative agreements, or other transactions under this section, the Secretary shall communicate to relevant vendors regarding modifications, renewals, extensions, or terminations of contracts, including through the development of a contract notification process, within 30 days of such determination, as practicable.'';

(2) in subsection (d)(2), by striking ''$611,700,000 for each of fiscal years 2019 through 2023'' and inserting ''$950,000,000 for each of fiscal years 2025 and 2026''; and

(3) in subsection (e)(1), by amending subparagraph (D) to read as follows:

''(D) SUNSET.—This paragraph shall cease to have force or effect after December 31, 2026.''.

SEC. 627. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

Section 2811–1 of the Public Health Service Act (42 U.S.C. 300hh–10a) is amended—

(1) in subsection (b)—

(A) by redesignating paragraph (11) as paragraph (13);

(B) by inserting after paragraph (10) the following:

''(11) The Director of the Biomedical Advanced Research and Development Authority.

''(12) The Director of the Strategic National Stockpile.''; and

(C) in paragraph (13), as so redesignated, by striking ''the Director of the Biomedical Advanced Research and Development Authority, the Director of the Strategic National Stockpile, the Director of the National Institute of Allergy and Infectious Diseases,'' and inserting ''the Director of the National Institute of Allergy and Infectious Diseases''; and

(2) in subsection (c)—

(A) in paragraph (1)—

(i) by redesignating subparagraph (D) as subparagraph (E); and

(ii) by inserting after subparagraph (C) the following:

''(D) Assist the Secretary in developing strategies for appropriate and evidence-based allocation and distribution of countermeasures to jurisdictions, in a manner that supports the availability and use of such countermeasures, for public health and medical preparedness and response needs.'';

(B) in paragraph (2), by inserting ''relevant stakeholders, including industry,'' after ''consider input from''; and

(C) by adding at the end the following:

''(3) INFORMATION SHARING.—The Secretary shall, as appropriate and in a manner that does not compromise national security, communicate and share information related to recommendations made and strategies developed under paragraph (1) with relevant stakeholders, including industry and State, local, and Tribal public health departments.''.

SEC. 628. FELLOWSHIP AND TRAINING PROGRAMS.

Section 317G of the Public Health Service Act (42 U.S.C. 247b–8) is amended—

(1) by striking ''The Secretary,'' and inserting the following:

''(a) IN GENERAL.—The Secretary,''; and

(2) by adding at the end the following:

''(b) NONCOMPETITIVE CONVERSION.—

''(1) IN GENERAL.—The Secretary may noncompetitively convert an individual who has completed an epidemiology, surveillance, or laboratory fellowship or training program under subsection (a) to a career-conditional appointment without regard to the provisions of subchapter I of chapter 33 of title 5, United States Code, provided that such individual meets qualification requirements for the appointment.''.

SEC. 629. REGIONAL BIOCONTAINMENT RESEARCH LABORATORIES.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall make awards to establish or maintain, as applicable, not fewer than 12 regional biocontainment laboratories, for purposes of—

(1) conducting biomedical research to support public health and medical preparedness for, and

rapid response to, biological agents, including emerging infectious diseases;

(2) ensuring the availability of surge capacity for purposes of responding to such biological agents;

(3) supporting information sharing between, and the dissemination of findings to, researchers and other relevant individuals to facilitate collaboration between industry and academia; and

(4) providing, as appropriate and applicable, technical assistance and training to researchers and other relevant individuals to support the biomedical research workforce in improving the management and mitigation of safety and security risks in the conduct of research involving such biological agents.

(b) REQUIREMENTS.—As a condition of receiving a grant under this section, a regional biocontainment laboratory shall agree to such oversight activities as the Secretary determines appropriate, including periodic meetings with relevant officials of the Department of Health and Human Services, facility inspections, and other activities as necessary and appropriate to ensure compliance with the terms and conditions of such award.

(c) WORKING GROUP.—The Secretary shall establish a Working Group, consisting of a representative from each entity in receipt of an award under subsection (a). The

Working Group shall make recommendations to the Secretary in administering awards under this section, for purposes of—

(1) improving the quality and consistency of applicable procedures and practices within laboratories funded pursuant to subsection (a); and

(2) ensuring coordination, as appropriate, of federally funded activities carried out at such laboratories.

(d) DEFINITION.—In this section, the term ''regional biocontainment laboratory'' means a Biosafety or Animal Biosafety Level–3 and Level–2 facility located at an institution in the United States that is designated by the Secretary to carry out the activities described in subsection (a).

(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $52,000,000 for each of fiscal years 2025 and 2026, to remain available through December 31, 2026.

(f) ADMINISTRATIVE EXPENSES.—Of the amount available to carry out this section for a fiscal year, the Secretary may use not more than 5 percent for the administrative expenses of carrying out this section, including expenses related to carrying out subsection (c).

(g) REPORT TO CONGRESS.—Not later than 1 year after the date of the enactment of this Act, and biannually thereafter, the Secretary, in consultation with the heads of applicable Federal departments and agencies shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on—

(1) the activities and accomplishments of the regional biocontainment laboratories;

(2) any published or disseminated research findings based on research conducted in such laboratories in the applicable year;

(3) oversight activities carried out by the Secretary pursuant to subsection (b);

(4) activities undertaken by the Secretary to take into consideration the capacity and capabilities of the network of regional biocontainment laboratories in activities to prepare for and respond to biological agents, which may include leveraging such capacity and capabilities to support the Laboratory Response Network, as applicable and appropriate;

(5) plans for the maintenance and sustainment of federally funded activities conducted at the regional biocontainment laboratories, consistent with the strategy required under section 2312 of the

PREVENT Pandemics Act (Public Law 117–328); and

(6) activities undertaken by the Secretary to coordinate with the heads of other relevant Federal departments and agencies to ensure that work carried out by each such facility on behalf of the Secretary and such other relevant heads is prioritized, is complementary to the work carried out by other such facilities and other relevant federally funded activities, and avoids unnecessary duplication.

SEC. 629A. LIMITATION RELATED TO COUNTRIES OF CONCERN CONDUCTING CERTAIN RESEARCH.

Section 2315(c) of the PREVENT Pandemics Act (42 U.S.C. 6627) is amended to read as follows:

''(c) LIMITATIONS ON COUNTRIES OF CONCERN CONDUCTING CERTAIN RESEARCH.—

''(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall not fund research that may reasonably be anticipated to involve the creation, transfer, and use of enhanced pathogens of pandemic potential or biological agents or toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act if such research is conducted by a foreign entity at a facility located in a country that is

determined to be a country of concern as defined in paragraph (2).

''(2) COUNTRIES OF CONCERN.—

''(A) DEFINITION.—For purposes of this subsection, a 'country of concern' means the People's Republic of China, the Democratic People's Republic of Korea, the Russian Federation, the Islamic Republic of Iran, and any other country as determined pursuant to subparagraph (B).

''(B) ADDITIONAL COUNTRIES.—The Director of National Intelligence (referred to in this subsection as the 'Director') shall, in consultation with the Secretary, add additional countries of concern for purposes of paragraph (1), only if—

''(i) the Director determines that evidence exists that a country has malicious intent related to the creation, enhancement, transfer, or use of pathogens of pandemic potential or biological agents or toxins listed pursuant to such section 351A(a)(1); and

''(ii) in a manner that does not compromise national security, the Director

provides such evidence in a report submitted to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

''(C) LIMITATION.—Paragraph (1) shall not take effect with respect to a country of concern identified under subparagraph (B) until the date that is 15 days after the date on which the Director submits the report described in subparagraph (B)(ii).

''(3) CLARIFICATION.—

''(A) IN GENERAL.—The requirement of paragraph (1) may be waived by the President for the duration of the initial response to an outbreak of a novel emerging infectious disease if the President determines that such requirement impedes the ability of the Federal Government to immediately respond to such outbreak.

''(B) NOTIFICATION.—The President shall notify such committees of Congress not later than 48 hours after exercising the waiver under subparagraph (A), and shall provide updates to such committees related to the use of such waiver every 15 days thereafter.

''(4) SUNSET.—The limitation under this subsection shall expire on December 31, 2026.''.

Subtitle C—Addressing the Needs of All Individuals

SEC. 631. IMPROVING ACCESS TO CERTAIN PROGRAMS.

(a) PROCEDURES RELATED TO THE TRANSITION OF CERTAIN CLAIMS.—

(1) PROCEDURES FOR CORRECTING SUBMISSIONS.—

(A) REQUESTS INITIALLY SUBMITTED UNDER SECTION 319F–4.—

(i) IN GENERAL.—In the case of a request for compensation submitted under section 319F–4 of the Public Health Service Act (42 U.S.C. 247d–6e) for an injury or death related to a medical product for active immunization to prevent coronavirus disease 2019 that the Secretary determines to be ineligible pursuant to subsection (b)(4)(B) of such section 319F–4, the Secretary shall, not later than 30 days after such determination, notify the individual submitting the request of such determination.

(ii) SUBMISSION OF PETITION.—An individual who receives a notification described in clause (i) shall be eligible to submit a petition to the United States Court of Federal Claims under section 2111 of the Public Health Service Act (42 U.S.C. 300aa–11) with respect to the same medical product administration claimed in the request submitted under section 319F–4 of such Act (42 U.S.C. 247d–6e), provided such petition is submitted not later than the later of—

(I) 1 year after receiving such notification under clause (i); or

(II) the last date on which the individual otherwise would be eligible to submit a petition relating to such injury, as specified in section 2116 of such Act (42 U.S.C. 300aa–16).

(iii) ELIGIBILITY.—To be eligible to submit a petition in accordance with clause (ii), the petitioner shall have submitted the request that was determined to be ineligible as described in clause (i) not later

than the applicable deadline for filing a petition under such section 2116.

(B) REQUESTS INITIALLY SUBMITTED UNDER SECTION 2111.—

(i) IN GENERAL.—If a special master determines that—

(I) a petition submitted under section 2111 of the Public Health Service Act (42 U.S.C. 300aa–11) related to a medical product for active immunization to prevent coronavirus disease 2019 that is ineligible for the program under subtitle 2 of title XXI of the Public Health Service Act (42 U.S.C. 300aa–10 et seq.) because it relates to a medical product administered at a time when the medical product was not included in the table under section 2114 of such Act (42 U.S.C. 300aa–14); and

(II) the medical product was administered when it was a covered countermeasure subject to a declaration under section 319F–3(b) of such Act (42 U.S.C. 247d–6d(b)),

the special master shall, not later than 30 days after such determination, notify the petitioner of such determination.

(ii) SUBMISSION OF REQUEST.—An individual who receives a notification described in clause (i) shall be eligible to submit a request for compensation under section 319F–4(b) of the Public Health Service Act (42 U.S.C. 247d–6e(b)) with respect to the same medical product administration claimed in the petition submitted under section 2111 of such Act (42 U.S.C. 300aa–11)—

(I) not later than 1 year after receiving such notification; or

(II) in the case that the notification is issued after judicial review of the petition under subsection (e) or (f) of section 2112 of such Act (42 U.S.C. 300aa–12), not later than 1 year after the judgment of the United States Court of Federal Claims or the mandate is issued by the United States Court of Appeals for the Fed-

eral Circuit pursuant to such subsection (e) or (f).

(iii) ELIGIBILITY.—To be eligible to submit a request for compensation in accordance with clause (ii), the individual submitting the request shall have submitted the petition under section 2111 of the Public Health Service Act (42 U.S.C. 300aa–11) that was determined to be ineligible not later than 1 year after the date of administration of the medical product.

(2) CHANGES TO CERTAIN PROGRAMS.—

(A) SECTION 319F–4.—Section 319F–4 of the Public Health Service Act (42 U.S.C. 247d–6e) is amended—

(i) in subsection (b)(4)—

(I) by striking ''Except as provided'' and inserting the following:

''(A) IN GENERAL.—Except as provided''; and

(II) by adding at the end the following:

''(B) EXCLUSION OF INJURIES ELIGIBLE FOR PETITION UNDER TITLE XXI.—Notwithstanding any other provision of this section, no

individual may be eligible for compensation under this section with respect to a vaccine that, at the time it was administered, was included in the Vaccine Injury Table under section 2114.''; and

(ii) in subsection (d)(3)—

(I) by striking ''This section'' and inserting the following:

''(A) IN GENERAL.—This section''; and

(II) by adding at the end the following:

''(B) EXHAUSTION OF REMEDIES.—A covered individual shall not be considered to have exhausted remedies as described in paragraph (1), nor be eligible to seek remedy under section 319F–3(d), unless such individual has provided to the Secretary all supporting documentation necessary to facilitate the determinations required under subsection (b)(4).''.

(B) TITLE XXI.—Title XXI of the Public Health Service Act (42 U.S.C. 300aa–1 et seq.) is amended—

(i) in section 2111(a)(2)(A) (42 U.S.C. 300aa–11(a)(2)(A)), in the matter preceding clause (i), by inserting ''con-

taining the information required under subsection (c)'' after ''unless a petition'';

(ii) in section 2112(d) (42 U.S.C. 300aa–12(d))—

(I) by adding at the end of paragraph (1) the following: ''Such designation shall not occur until the petitioner has filed all materials required under section 2111(c).''; and

(II) in paragraph (3)(A)(ii), by striking ''the petition was filed'' and inserting ''on which the chief special master makes the designation pursuant to paragraph (1)'';

(iii) in section 2114(e) (42 U.S.C. 300aa–14(e)), by adding at the end the following:

''(4) LICENSURE REQUIREMENT.—Notwithstanding paragraphs (2) and (3), the Secretary may not revise the Vaccine Injury Table to include a vaccine for which the Centers for Disease Control and Prevention has issued a recommendation for routine use in children or pregnant women until at least one application for such vaccine has been approved under section 351. Upon such revision of the Vac-

cine Injury Table, all vaccines in a vaccine category on the Vaccine Injury Table, including vaccines authorized under emergency use pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act, shall be considered included in the Vaccine Injury Table.''; and

(iv) in section 2116 (42 U.S.C. 300aa–16), by adding at the end the following:

''(d) CLARIFICATION.—Notwithstanding subsections (a) and (b), an injury or death related to a vaccine administered at a time when the vaccine was a covered countermeasure subject to a declaration under section 319F–3(b) shall not be eligible for compensation under the Program.''.

(b) ACCELERATING INJURY COMPENSATION PROGRAM ADMINISTRATION AND ENSURING PROGRAM INTEGRITY.—

(1) PETITIONS FOR COMPENSATION.—Section 2111(a)(2)(A)(i) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(2)(A)(i)) is amended—

(A) in subclause (I), by striking '', and'' and inserting a semicolon;

(B) in subclause (II)—

(i) by moving the margin 2 ems to the right; and

(ii) by striking ", or" and inserting "; and"; and

(C) by adding at the end the following:

"(III) the judgment described in subclause (I) does not result from a petitioner's motion to dismiss the case; or".

(2) DETERMINATION OF GOOD FAITH.—Section 2115(e)(1) of the Public Health Service Act (42 U.S.C. 300aa–15(e)(1)) is amended by adding at the end the following: "When making a determination of good faith under this paragraph, the special master or court may consider whether the petitioner demonstrated an intention to obtain compensation on such petition and was not merely seeking to satisfy the exhaustion requirement under section 2121(b).".

(c) EXTENSION OF DEADLINES TO SUBMIT REQUESTS FOR COMPENSATION FOR CERTAIN INJURIES.—

(1) IN GENERAL.—With respect to claims filed under section 319F–4 of the Public Health Service Act (42 U.S.C. 247d–6e) alleging a covered injury caused by the administration or use of a covered countermeasure pursuant to a declaration under section 319F–3(b) of such Act (42 U.S.C. 247d–6d(b))

relating to coronavirus disease 2019, the following shall apply:

(A) Notwithstanding the filing deadline applicable under such section 319F–4, the claim shall be filed within 3 years of the administration or use of the covered countermeasure, or 1 year after the date of enactment of this Act, whichever is later, and, if a claim filed under such section 319F–4 with respect to such administration or use was filed before the date of enactment of this Act and denied on the basis of having not been filed within the time period required under subsection (b)(4) of such section 319F–4, such claim may be refiled pursuant to this subparagraph.

(B) With respect to a claim relating to the administration of a medical product for active immunization to prevent coronavirus disease 2019 such a claim may be filed under the such section 319F–4 only if the administration of such vaccine occurred prior to the addition of the vaccine to the Vaccine Injury Table under section 2114 of the Public Health Service Act (42 U.S.C. 300aa–14).

SEC. 632. SUPPORTING AT-RISK INDIVIDUALS DURING EMERGENCY RESPONSES.

(a) TECHNICAL ASSISTANCE FOR AT-RISK INDIVIDUALS AND DISASTERS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may provide appropriate technical assistance to States, localities, Tribes, and other applicable entities related to addressing the unique needs and considerations of at-risk individuals, as defined in section 2802(b)(4) of the Public Health Service Act (42 U.S.C. 300hh–1(b)(4)), in the event of a public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d).

(2) TECHNICAL ASSISTANCE.—The technical assistance described in paragraph (1) shall include—

(A) developing, identifying, evaluating, and disseminating evidence-based or evidence-informed strategies to improve health and address other near-term or long-term outcomes for at-risk individuals related to public health emergencies, including by addressing such unique needs and considerations in carrying out public health and medical activities to prepare for, re-

spond to, and recover from, such public health emergencies; and

(B) assisting applicable entities, through contracts or cooperative agreements, as appropriate, in the implementation of such evidence-based strategies.

(3) CONSULTATION.—In carrying out activities under paragraph (2), the Secretary shall take into consideration relevant findings and recommendations of, and, as appropriate, consult with, the National Advisory Committee on Individuals with Disabilities and Disasters established under section 2811C of the Public Health Service Act (42 U.S.C. 300hh–10d), the National Advisory Committee on Children and Disasters under section 2811A of such Act (42 U.S.C. 300hh–10b), and the National Advisory Committee on Seniors and Disasters under section 2811B of such Act (42 U.S.C. 300hh–10c).

(b) CRISIS STANDARDS OF CARE.—Not later than 2 years after the date of enactment of this Act, the Secretary, acting through the Director of the Office for Civil Rights of the Department of Health and Human Services, shall issue guidance to States and localities on the development or modification of State and local crisis standards of care for use during the response to a public health

emergency declared by the Governor of a State or by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d), or a major disaster or emergency declared by the President under section 401 or 501, respectively, of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170, 5191) to ensure that such standards of care are consistent with the nondiscrimination requirements of section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), title II of the Americans with Disabilities Act of 1990 (42 U.S.C. 12131 et seq.), and the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.).

SEC. 633. NATIONAL ADVISORY COMMITTEES.

(a) NATIONAL ADVISORY COMMITTEE ON CHILDREN AND DISASTERS.—Subsection (g) of section 2811A of the Public Health Service Act (42 U.S.C. 300hh–10b) is amended to read as follows:

''(g) SUNSET.—

''(1) IN GENERAL.—The Advisory Committee shall terminate on December 31, 2026.

''(2) EXTENSION OF ADVISORY COMMITTEE.—Not later than October 1, 2025, the Secretary shall submit to Congress a recommendation on whether the Advisory Committee should be extended beyond the date described in paragraph (1).''.

(b) NATIONAL ADVISORY COMMITTEE ON SENIORS AND DISASTERS.—Section 2811B of the Public Health Service Act (42 U.S.C. 300hh–10c) is amended—

(1) in subsection (d)—

(A) in paragraph (1)—

(i) by inserting ''and departments'' after ''agencies''; and

(ii) by striking ''17 members'' and inserting ''25 members''; and

(B) in paragraph (2)—

(i) by striking subparagraphs (J) and (K);

(ii) by redesignating subparagraphs (A) through (I) and (L) as clauses (i) through (x), respectively, and adjusting the margins accordingly;

(iii) by inserting before clause (i), as so redesignated, the following:

''(B) FEDERAL MEMBERS.—The Federal members shall include the following:''; and

(iv) by inserting before subparagraph (B), as so designated, the following:

''(A) NON-FEDERAL MEMBERS.—The Secretary in consultation with such other heads of agencies and departments as may be appro-

priate, shall appoint to the Advisory Committee under paragraph (1) at least 13 individuals, including the following:

"(i) At least 3 non-Federal health care providers with expertise in geriatric medical disaster planning, preparedness, response, or recovery.

"(ii) At least 3 representatives of State, local, territorial, or Tribal agencies with expertise in geriatric disaster planning, preparedness, response, or recovery.

"(iii) At least 2 non-Federal professionals with training in gerontology, such as social workers, scientists, human services specialists, or other non-medical professionals, with experience in disaster planning, preparedness, response, or recovery among other adults."; and

(2) by amending subsection (g) to read as follows:

"(g) SUNSET.—The Advisory Committee shall terminate on December 31, 2026.".

(c) NATIONAL ADVISORY COMMITTEE ON INDIVIDUALS WITH DISABILITIES AND DISASTERS.—Section

2811C of the Public Health Service Act (42 U.S.C. 300hh–10d) is amended—

(1) by redesignating subsections (c) through (g) as subsections (d) through (h), respectively;

(2) by inserting after subsection (b) the following:

''(c) ADDITIONAL DUTIES.—The Advisory Committee may provide advice and recommendations to the Secretary with respect to individuals with disabilities and the medical and public health grants and cooperative agreements as applicable to preparedness and response activities under this title and title III.'';

(3) in subsection (d), as so redesignated—

(A) in paragraph (1), by striking ''17 members'' and inserting ''25 members'';

(B) in paragraph (2)—

(i) by striking subparagraphs (K) through (M);

(ii) by redesignating subparagraphs (A) through (J) as clauses (i) through (x), respectively, and adjusting the margins accordingly;

(iii) by inserting before clause (i), as so redesignated, the following:

''(B) FEDERAL MEMBERS.—The Federal members shall include the following:'';

(iv) by adding at the end of subparagraph (B), as so designated, the following:

''(xi) Representatives of such other Federal agencies as the Secretary determines necessary to fulfill the duties of the Advisory Committee.''; and

(v) by inserting before subparagraph (B), as so designated, the following:

''(A) NON-FEDERAL MEMBERS.—The Secretary in consultation with such other heads of agencies and departments as may be appropriate, shall appoint to the Advisory Committee under paragraph (1) at least 13 individuals, including the following:

''(i) At least 4 non-Federal health care professionals with expertise in disability accessibility before, during, and after disasters, medical and mass care disaster planning, preparedness, response, or recovery.

''(ii) At least 3 representatives of State, local, Tribal, or territorial agencies with expertise in disaster planning, pre-

paredness, response, or recovery for individuals with disabilities.

''(iii) At least 4 individuals with a disability with expertise in disaster planning, preparedness, response, or recovery for individuals with disabilities.

''(iv) Other members as the Secretary determines appropriate, of whom—

''(I) at least one such member shall represent a local, State, or national organization with expertise in individuals with disabilities;

''(II) at least one such member shall be an individual with a disability; and

''(III) at least one such member shall be an individual with expertise in the needs of housing services, including during the response to, and recovery from, disasters.''; and

(C) by adding at the end the following:

''(3) CONSIDERATION.—In appointing members, including the Chair, to the Committee under this subsection, the Secretary may give consideration to disability status.''; and

(4) by amending subsection (h), as so redesignated, to read as follows:

''(h) SUNSET.—The Advisory Committee shall terminate on December 31, 2026.''.

SEC. 634. NATIONAL ACADEMIES STUDY ON PRIZES.

(a) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (referred to in this section as the ''National Academies'') to conduct a study to examine—

(1) alternative models for directly funding, or stimulating investment in, biomedical research and development that delink research and development costs from the prices of drugs, including the progressive replacement of patents and regulatory exclusivities on new drugs with a combination of expanded support for research and innovation prizes to reward the successful development of drugs or achievement of related milestones;

(2) the dollar amount of innovation prizes for different stages of research and development of different classes or types of drugs, and total annual funding, that would be necessary to stimulate invest-

ment sufficient to achieve such successful drug development and related milestones;

(3) the relative effectiveness and efficiency of such alternative models in stimulating innovation, compared to the status quo that includes patents and regulatory exclusivities;

(4) strategies to implement such alternative models described in paragraph (1), including a phased transition; and

(5) the anticipated economic and societal impacts of such alternative models, including an assessment of impact on—

(A) the number and variety of new drugs that would be developed, approved, and marketed in the United States, including such new drugs intended to prevent, diagnose, or treat a rare disease or condition;

(B) the rate at which new drugs would be developed, approved, and marketed in the United States;

(C) access to medication;

(D) health outcomes;

(E) average lifespan and disease burden in the United States;

(F) the number of manufacturers that would be seeking approval for a drug or bringing a drug to market for the first time;

(G) Federal discretionary and mandatory spending; and

(H) public and private insurance markets.

(b) REQUIREMENTS.—In conducting the study pursuant to subsection (a), the National Academies shall hold not fewer than 2 public listening sessions to solicit feedback from interested parties, including representatives of academia, professional societies, patient advocates, public health organizations, relevant Federal departments and agencies, drug developers, representatives of other relevant industries, and subject matter experts.

(c) REPORT.—Not later than 2 years after the agreement under subsection (a), the National Academies shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report on the study conducted pursuant to subsection (a).

Subtitle D—Additional Reauthorizations

SEC. 641. MEDICAL COUNTERMEASURE PRIORITY REVIEW VOUCHER.

Section 565A(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4a) is amended by striking ''October 1, 2023'' and inserting ''December 31, 2026''.

SEC. 642. EPIDEMIC INTELLIGENCE SERVICE.

Section 317F(c)(2) of the Public Health Service Act (42 U.S.C. 247b–7(c)(2)) is amended by striking ''2019 through 2023'' and inserting ''2025 and 2026, to remain available through December 31, 2026''.

SEC. 643. MONITORING AND DISTRIBUTION OF CERTAIN MEDICAL COUNTERMEASURES.

Section 319A(e) of the Public Health Service Act (42 U.S.C. 247d–1(e)) is amended by striking ''2019 through 2023'' and inserting ''2025 and 2026, to remain available through December 31, 2026''.

SEC. 644. REGIONAL HEALTH CARE EMERGENCY PREPAREDNESS AND RESPONSE SYSTEMS.

Section 319C–3 of the Public Health Service Act (42 U.S.C. 247d–3c) is amended—

(1) in subsection (b)(3), by striking ''under the'' and all that follows through ''such Act)'' and inserting ''under law''; and

(2) in subsection (e)(2), by striking ''September 30, 2023'' and inserting ''December 31, 2026''.

SEC. 645. EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF VOLUNTEER HEALTH PROFESSIONALS.

(1) IN GENERAL.—Section 319I of the Public Health Service Act (42 U.S.C. 247d–7b) is amended—

(A) in subsection (a), by striking ''Not later than 12 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall link existing State verification systems to maintain a single national interoperable network of systems,'' and inserting ''The Secretary shall continue to maintain a single national interoperable network of verification systems,'' and

(B) in subsection (k), by striking ''2019 through 2023'' and inserting ''2025 and 2026, to remain available through December 31, 2026''.

SEC. 646. ENSURING COLLABORATION AND COORDINATION IN MEDICAL COUNTERMEASURE DEVELOPMENT.

Section 319L–1(b) of the Public Health Service Act (42 U.S.C. 247d–7f(b)) is amended by striking ''March 31, 2025'' and inserting ''December 31, 2026''.

SEC. 647. MILITARY AND CIVILIAN PARTNERSHIP FOR TRAUMA READINESS.

Section 1291(g) of the Public Health Service Act (42 U.S.C. 300d–91(g)) is amended by striking ''2019 through 2023'' and inserting ''2025 and 2026, to remain available through December 31, 2026''.

SEC. 648. NATIONAL DISASTER MEDICAL SYSTEM.

Section 2812 of the Public Health Service Act (42 U.S.C. 300hh–11) is amended—

(1) in subsection (c)(4)(B), by striking ''March 31, 2025'' and inserting ''December 31, 2026''; and

(2) in subsection (g), by striking ''$57,400,000 for each of fiscal years 2019 through 2023'' and inserting ''$65,900,000 for each of fiscal years 2025 and 2026, to remain available through December 31, 2026''.

SEC. 649. VOLUNTEER MEDICAL RESERVE CORPS.

Section 2813(i) of the Public Health Service Act (42 U.S.C. 300hh–15(i)) is amended by striking ''2019

through 2023'' and inserting ''2025 through 2026, to remain available through December 31, 2026''.

SEC. 649A. EPIDEMIOLOGY-LABORATORY CAPACITY.

Section 2821(b) of the Public Health Service Act (42 U.S.C. 300hh–31(b)) is amended, in the matter preceding paragraph (1), by striking ''2019 through 2023'' and inserting ''2025 and 2026, to remain available through December 31, 2026''.

TITLE VII—PUBLIC HEALTH PROGRAMS

SEC. 701. ACTION FOR DENTAL HEALTH.

Section 340G(f) of the Public Health Service Act (42 U.S.C. 256g(f)) is amended by striking ''$13,903,000 for each of fiscal years 2019 through 2023'' and inserting ''$15,000,000 for each of fiscal years 2025 through 2029, to remain available until expended''.

SEC. 702. PREEMIE.

(a) RESEARCH RELATING TO PRETERM LABOR AND DELIVERY AND THE CARE, TREATMENT, AND OUTCOMES OF PRETERM AND LOW BIRTHWEIGHT INFANTS.—

(1) IN GENERAL.—Section 3(e) of the Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act (42 U.S.C. 247b–4f(e)) is amended by striking ''fiscal years

2019 through 2023'' and inserting ''fiscal years 2025 through 2029''.

(2) TECHNICAL CORRECTION.—Effective as if included in the enactment of the PREEMIE Reauthorization Act of 2018 (Public Law 115–328), section 2 of such Act is amended, in the matter preceding paragraph (1), by striking ''Section 2'' and inserting ''Section 3''.

(b) INTERAGENCY WORKING GROUP.—Section 5(a) of the PREEMIE Reauthorization Act of 2018 (Public Law 115–328) is amended by striking ''The Secretary of Health and Human Services, in collaboration with other departments, as appropriate, may establish'' and inserting ''Not later than 18 months after the date of the enactment of the Bipartisan Health Care Act, the Secretary of Health and Human Services, in collaboration with other departments, as appropriate, shall establish''.

(c) STUDY ON PRETERM BIRTHS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall enter into appropriate arrangements with the National Academies of Sciences, Engineering, and Medicine under which the National Academies shall—

(A) not later than 30 days after the date of enactment of this Act, convene a committee

of experts in maternal health to study premature births in the United States; and

(B) upon completion of the study under subparagraph (A)—

(i) approve by consensus a report on the results of such study;

(ii) include in such report—

(I) an assessment of each of the topics listed in paragraph (2);

(II) the analysis required by paragraph (3); and

(III) the raw data used to develop such report; and

(iii) not later than 24 months after the date of enactment of this Act, transmit such report to—

(I) the Secretary of Health and Human Services;

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

(III) the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate.

(2) ASSESSMENT TOPICS.—The topics listed in this subsection are each of the following:

(A) The financial costs of premature birth to society, including—

(i) an analysis of stays in neonatal intensive care units and the cost of such stays;

(ii) long-term costs of stays in such units to society and the family involved post-discharge; and

(iii) health care costs for families post-discharge from such units (such as medications, therapeutic services, co-payments for visits, and specialty equipment).

(B) The factors that impact preterm birth rates.

(C) Opportunities for earlier detection of premature birth risk factors, including—

(i) opportunities to improve maternal and infant health; and

(ii) opportunities for public health programs to provide support and resources for parents in-hospital, in non-hospital settings, and post-discharge.

(3) ANALYSIS.—The analysis required by this subsection is an analysis of—

(A) targeted research strategies to develop effective drugs, treatments, or interventions to bring at-risk pregnancies to term;

(B) State and other programs' best practices with respect to reducing premature birth rates; and

(C) precision medicine and preventative care approaches starting early in the life course (including during pregnancy) with a focus on behavioral and biological influences on premature birth, child health, and the trajectory of such approaches into adulthood.

SEC. 703. PREVENTING MATERNAL DEATHS.

(a) MATERNAL MORTALITY REVIEW COMMITTEE.—Section 317K(d) of the Public Health Service Act (42 U.S.C. 247b–12(d)) is amended—

(1) in paragraph (1)(A), by inserting ''(including obstetricians and gynecologists)'' after ''clinical specialties''; and

(2) in paragraph (3)(A)(i)—

(A) in subclause (I), by striking ''as applicable'' and inserting ''if available''; and

(B) in subclause (III), by striking ", as appropriate" and inserting "and coordinating with death certifiers to improve the collection of death record reports and the quality of death records, including by amending cause of death information on a death certificate, as appropriate".

(b) BEST PRACTICES RELATING TO THE PREVENTION OF MATERNAL MORTALITY.—Section 317K of the Public Health Service Act (42 U.S.C. 247b–12) is amended—

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

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

"(e) BEST PRACTICES RELATING TO THE PREVENTION OF MATERNAL MORTALITY.—

"(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, in consultation with the Administrator of the Health Resources and Services Administration, disseminate to hospitals, State professional society groups, and perinatal quality collaboratives, best practices on how to prevent maternal mortality and morbidity that consider and re-

flect best practices identified through other relevant Federal maternal health programs.

''(2) FREQUENCY.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall disseminate the best practices referred to in paragraph (1) not less than once per fiscal year.''.

(c) EXTENSION.—Subsection (g) of section 317K of the Public Health Service Act (42 U.S.C. 247b–12), as redesignated by subsection (b), is amended by striking ''$58,000,000 for each of fiscal years 2019 through 2023'' and inserting ''$100,000,000 for each of fiscal years 2025 through 2029''.

SEC. 704. SICKLE CELL DISEASE PREVENTION AND TREATMENT.

(a) IN GENERAL.—Section 1106(b) of the Public Health Service Act (42 U.S.C. 300b–5(b)) is amended—

(1) in paragraph (1)(A)(iii), by striking ''prevention and treatment of sickle cell disease'' and inserting ''treatment of sickle cell disease and the prevention and treatment of complications of sickle cell disease'';

(2) in paragraph (2)(D), by striking ''prevention and treatment of sickle cell disease'' and inserting ''treatment of sickle cell disease and the preven-

tion and treatment of complications of sickle cell disease'';

(3) in paragraph (3)—

(A) in subparagraph (A), by striking ''enter into a contract with'' and inserting ''make a grant to, or enter into a contract or cooperative agreement with,''; and

(B) in subparagraph (B), in each of clauses (ii) and (iii), by striking ''prevention and treatment of sickle cell disease'' and inserting ''treatment of sickle cell disease and the prevention and treatment of complications of sickle cell disease''; and

(4) in paragraph (6), by striking ''$4,455,000 for each of fiscal years 2019 through 2023'' and inserting ''$8,205,000 for each of fiscal years 2025 through 2029''.

(b) SENSE OF CONGRESS.—It is the sense of Congress that further research should be undertaken to expand the understanding of the causes of, and to find cures for, heritable blood disorders, including sickle cell disease.

SEC. 705. TRAUMATIC BRAIN INJURIES.

(a) THE BILL PASCRELL, JR., NATIONAL PROGRAM FOR TRAUMATIC BRAIN INJURY SURVEILLANCE AND REGISTRIES.—

(1) PREVENTION OF TRAUMATIC BRAIN INJURY.—Section 393B of the Public Health Service Act (42 U.S.C. 280b–1c) is amended—

(A) in subsection (a), by inserting ''and prevalence'' after ''incidence'';

(B) in subsection (b)—

(i) in paragraph (1), by inserting ''and reduction of associated injuries and fatalities'' before the semicolon;

(ii) in paragraph (2), by inserting ''and related risk factors'' before the semicolon; and

(iii) in paragraph (3)—

(I) in the matter preceding subparagraph (A), by striking ''2020'' each place it appears and inserting ''2030''; and

(II) in subparagraph (A)—

(aa) in clause (i), by striking ''; and'' and inserting a semicolon;

(bb) by redesignating clause (ii) as clause (iv);

(cc) by inserting after clause (i) the following:

"(ii) populations at higher risk of traumatic brain injury, including populations whose increased risk is due to occupational or circumstantial factors;

"(iii) causes of, and risk factors for, traumatic brain injury; and"; and

(dd) in clause (iv), as so redesignated, by striking "arising from traumatic brain injury" and inserting ", which may include related mental health and other conditions, arising from traumatic brain injury, including"; and

(C) in subsection (c), by inserting ", and other relevant Federal departments and agencies" before the period at the end.

(2) NATIONAL PROGRAM FOR TRAUMATIC BRAIN INJURY SURVEILLANCE AND REGISTRIES.—Section 393C of the Public Health Service Act (42 U.S.C. 280b–1d) is amended—

(A) by amending the section heading to read as follows: "**THE BILL PASCRELL, JR., NATIONAL PROGRAM FOR TRAUMATIC**

BRAIN INJURY SURVEILLANCE AND REGISTRIES'';

(B) in subsection (a)—

(i) in the matter preceding paragraph (1), by inserting ''to identify populations that may be at higher risk for traumatic brain injuries, to collect data on the causes of, and risk factors for, traumatic brain injuries,'' after ''related disability,'';

(ii) in paragraph (1), by inserting '', including the occupation of the individual, when relevant to the circumstances surrounding the injury'' before the semicolon; and

(iii) in paragraph (4), by inserting ''short- and long-term'' before ''outcomes'';

(C) by striking subsection (b);

(D) by redesignating subsection (c) as subsection (b);

(E) in subsection (b), as so redesignated, by inserting ''and evidence-based practices to identify and address concussion'' before the period at the end; and

(F) by adding at the end the following:

''(c) AVAILABILITY OF INFORMATION.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make publicly available aggregated information on traumatic brain injury and concussion described in this section, including on the website of the Centers for Disease Control and Prevention. Such website, to the extent feasible, shall include aggregated information on populations that may be at higher risk for traumatic brain injuries and strategies for preventing or reducing risk of traumatic brain injury that are tailored to such populations.''.

(3) AUTHORIZATION OF APPROPRIATIONS.—Section 394A of the Public Health Service Act (42 U.S.C. 280b–3) is amended—

(A) in subsection (a), by striking ''1994, and'' and inserting ''1994,''; and

(B) in subsection (b), by striking ''2020 through 2024'' and inserting ''2025 through 2029''.

(b) STATE GRANT PROGRAMS.—

(1) STATE GRANTS FOR PROJECTS REGARDING TRAUMATIC BRAIN INJURY.—Section 1252 of the Public Health Service Act (42 U.S.C. 300d–52) is amended—

(A) in subsection (b)(2)—

(i) by inserting ", taking into consideration populations that may be at higher risk for traumatic brain injuries" after "outreach programs"; and

(ii) by inserting "Tribal," after "State,";

(B) in subsection (c), by adding at the end the following:

"(3) MAINTENANCE OF EFFORT.—With respect to activities for which a grant awarded under subsection (a) is to be expended, a State or American Indian consortium shall agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the State or American Indian consortium for the fiscal year preceding the fiscal year for which the State or American Indian consortium receives such a grant.

"(4) WAIVER.—The Secretary may, upon the request of a State or American Indian consortium, waive not more than 50 percent of the matching fund amount under paragraph (1), if the Secretary determines that such matching fund amount would result in an inability of the State or American Indian consortium to carry out the purposes under

subsection (a). A waiver provided by the Secretary under this paragraph shall apply only to the fiscal year involved.'';

(C) in subsection (e)(3)(B)—

(i) by striking ''(such as third party payers, State agencies, community-based providers, schools, and educators)''; and

(ii) by inserting ''(such as third party payers, State agencies, community-based providers, schools, and educators)'' after ''professionals'';

(D) in subsection (h), by striking paragraphs (1) and (2) and inserting the following:

''(1) AMERICAN INDIAN CONSORTIUM; STATE.—The terms 'American Indian consortium' and 'State' have the meanings given such terms in section 1253.

''(2) TRAUMATIC BRAIN INJURY.—

''(A) IN GENERAL.—Subject to subparagraph (B), the term 'traumatic brain injury'—

''(i) means an acquired injury to the brain;

''(ii) may include—

''(I) brain injuries caused by anoxia due to trauma; and

''(II) damage to the brain from an internal or external source that results in infection, toxicity, surgery, or vascular disorders not associated with aging; and

''(iii) does not include brain dysfunction caused by congenital or degenerative disorders, or birth trauma.

''(B) REVISIONS TO DEFINITION.—The Secretary may revise the definition of the term 'traumatic brain injury' under this paragraph, as the Secretary determines necessary, after consultation with States and other appropriate public or nonprofit private entities.''; and

(E) in subsection (i), by striking ''2020 through 2024'' and inserting ''2025 through 2029''.

(2) STATE GRANTS FOR PROTECTION AND ADVOCACY SERVICES.—Section 1253(l) of the Public Health Service Act (42 U.S.C. 300d–53(l)) is amended by striking ''2020 through 2024'' and inserting ''2025 through 2029''.

(c) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this Act as

the ''Secretary'') shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that contains—

(1) an overview of populations who may be at higher risk for traumatic brain injury, such as individuals affected by domestic violence or sexual assault and public safety officers as defined in section 1204 of the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10284);

(2) an outline of existing surveys and activities of the Centers for Disease Control and Prevention on traumatic brain injuries and any steps the agency has taken to address gaps in data collection related to such higher risk populations, which may include leveraging surveys such as the National Intimate Partner and Sexual Violence Survey to collect data on traumatic brain injuries;

(3) an overview of any outreach or education efforts to reach such higher risk populations; and

(4) any challenges associated with reaching such higher risk populations.

(d) STUDY ON LONG-TERM SYMPTOMS OR CONDITIONS RELATED TO TRAUMATIC BRAIN INJURY.—

(1) IN GENERAL.—The Secretary, in consultation with stakeholders and the heads of other relevant Federal departments and agencies, as appropriate, shall conduct, either directly or through a contract with a nonprofit private entity, a study to—

(A) examine the incidence and prevalence of long-term or chronic symptoms or conditions in individuals who have experienced a traumatic brain injury;

(B) examine the evidence base of research related to the chronic effects of traumatic brain injury across the lifespan;

(C) examine any correlations between traumatic brain injury and increased risk of other conditions, such as dementia and mental health conditions;

(D) assess existing services available for individuals with such long-term or chronic symptoms or conditions; and

(E) identify any gaps in research related to such long-term or chronic symptoms or conditions of individuals who have experienced a traumatic brain injury.

(2) PUBLIC REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary shall—

(A) submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report detailing the findings, conclusions, and recommendations of the study described in paragraph (1); and

(B) in the case that such study is conducted directly by the Secretary, make the report described in subparagraph (A) publicly available on the website of the Department of Health and Human Services.

SEC. 706. LIFESPAN RESPITE CARE.

(a) DEFINITION OF FAMILY CAREGIVER.—Section 2901(5) of the Public Health Service Act (42 U.S.C. 300ii(5)) is amended by striking ''unpaid adult'' and inserting ''unpaid individual''.

(b) FUNDING.—Section 2905 of the Public Health Service Act (42 U.S.C. 300ii–4) is amended by striking ''fiscal years 2020 through fiscal year 2024'' and inserting ''fiscal years 2025 through 2029''.

SEC. 707. DR. LORNA BREEN HEALTH CARE PROVIDER PROTECTION.

(a) DISSEMINATION OF BEST PRACTICES.— Section 2 of the Dr. Lorna Breen Health Care Provider Protection Act (Public Law 117–105) is amended by striking ''2 years'' and inserting ''5 years''.

(b) EDUCATION AND AWARENESS INITIATIVE ENCOURAGING USE OF MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES BY HEALTH CARE PROFESSIONALS.—Section 3 of the Dr. Lorna Breen Health Care Provider Protection Act (Public Law 117–105) is amended—

(1) in subsection (b), by inserting ''and annually thereafter,'' after ''of this Act,''; and

(2) in subsection (c), by striking ''2022 through 2024'' and inserting ''2025 through 2029''.

(c) PROGRAMS TO PROMOTE MENTAL HEALTH AMONG THE HEALTH PROFESSIONAL WORKFORCE.—The second section 764 of the Public Health Service Act (42 U.S.C. 294t), as added by section 4 of the Dr. Lorna Breen Health Care Provider Protection Act (Public Law 117–105), is amended—

(1) by redesignating such section 764 as section 764A;

(2) in subsection (a)(3)—

(A) by striking ''to eligible entities in'' and inserting ''to eligible entities that—

''(A) are in'';

(B) by striking the period and inserting ''; or''; and

(C) by adding at the end the following:

''(B) have a focus on the reduction of administrative burden on health care workers.'';

(3) in subsection (c), by inserting ''not less than'' after ''period of''; and

(4) in subsection (f), by striking ''2022 through 2024'' and inserting ''2025 through 2029''.

SEC. 708. SCREENS FOR CANCER.

(a) NATIONAL BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM.—Title XV of the Public Health Service Act (42 U.S.C. 300k et seq.) is amended—

(1) in section 1501 (42 U.S.C. 300k)—

(A) in subsection (a)—

(i) in paragraph (2), by striking ''the provision of appropriate follow-up services and support services such as case management'' and inserting ''that appropriate follow-up services are provided'';

(ii) in paragraph (3), by striking ''programs for the detection and control''

and inserting ''for the prevention, detection, and control'';

(iii) in paragraph (4), by striking ''the detection and control'' and inserting ''the prevention, detection, and control'';

(iv) in paragraph (5)—

(I) by striking ''monitor'' and inserting ''ensure''; and

(II) by striking ''; and'' and inserting a semicolon;

(v) by redesignating paragraph (6) as paragraph (9);

(vi) by inserting after paragraph (5) the following:

''(6) to enhance appropriate support activities to increase breast and cervical cancer screenings, such as navigation of health care services, implementation of evidence-based or evidence-informed strategies to increase breast and cervical cancer screening in health care settings, and facilitation of access to health care settings;

''(7) to reduce disparities in breast and cervical cancer incidence, morbidity, and mortality, including in populations with higher than average rates;

''(8) to improve access to breast and cervical cancer screening and diagnostic services and reduce related barriers, including factors that relate to negative health outcomes; and''; and

(vii) in paragraph (9), as so redesignated, by striking ''through (5)'' and inserting ''through (8)''; and

(B) by striking subsection (d);

(2) in section 1503 (42 U.S.C. 300m)—

(A) in subsection (a)—

(i) in paragraph (1), by striking ''that, initially'' and all that follows through the semicolon and inserting ''that appropriate breast and cervical cancer screening and diagnostic services are provided consistent with relevant evidence-based recommendations; and'';

(ii) by striking paragraphs (2) and (4);

(iii) by redesignating paragraph (3) as paragraph (2); and

(iv) in paragraph (2), as so redesignated, by striking ''; and'' and inserting a period; and

(B) by striking subsection (d);

(3) in section 1508(b) (42 U.S.C. 300n–4(b))—

(A) by striking ''1 year after the date of the enactment of the National Breast and Cervical Cancer Early Detection Program Reauthorization of 2007, and annually thereafter,'' and inserting ''2 years after the date of enactment of the Bipartisan Health Care Act, and every 5 years thereafter,'';

(B) by striking ''Labor and Human Resources'' and inserting ''Health, Education, Labor, and Pensions''; and

(C) by striking ''preceding fiscal year'' and inserting ''preceding 2 fiscal years in the case of the first report after the date of enactment of the Bipartisan Health Care Act and preceding 5 fiscal years for each report thereafter''; and

(4) in section 1510(a) (42 U.S.C. 300n–5(a))—

(A) by striking ''2011, and'' and inserting ''2011,''; and

(B) by inserting '', and $235,500,000 for each of fiscal years 2025 through 2029'' before the period at the end before the period at the end.

(b) GAO STUDY.—Not later than September 30, 2027, the Comptroller General of the United States shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the work of the National Breast and Cervical Cancer Early Detection Program, including—

(1) an estimate of the number of individuals eligible for services provided under such program;

(2) a summary of trends in the number of individuals served through such program; and

(3) an assessment of any factors that may be driving the trends identified under paragraph (2), including any barriers to accessing breast and cervical cancer screenings provided by such program.

SEC. 709. DEONDRA DIXON INCLUDE PROJECT.

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

"SEC. 409K. DOWN SYNDROME RESEARCH.

''(a) IN GENERAL.—The Director of NIH shall carry out a program of research, training, and investigation related to Down syndrome to be known as the 'INvestigation of Co-occurring conditions across the Lifespan to Under-

stand Down syndromE Project' or the 'INCLUDE Project'.

''(b) PROGRAM ELEMENTS.—The program under subsection (a) shall include—

''(1) high-risk, high reward research on the effects of trisomy 21 on human development and health;

''(2) promoting research for participants with Down syndrome across the lifespan, including cohort studies to facilitate improved understanding of Down syndrome and co-occurring conditions and development of new interventions;

''(3) expanding the number of clinical trials that are inclusive of, or expressly for, participants with Down syndrome, including novel biomedical and pharmacological interventions and other therapies designed to promote or enhance activities of daily living;

''(4) research on the biological mechanisms in individuals with Down syndrome pertaining to structural, functional, and behavioral anomalies and dysfunction as well as stunted growth;

''(5) supporting research to improve diagnosis and treatment of conditions co-occurring with Down syndrome, including the identification of biomarkers

related to risk factors, diagnosis, and clinical research and therapeutics;

''(6) research on the causes of increased prevalence, and concurrent treatment, of co-occurring conditions, such as Alzheimer's disease and related dementias and autoimmunity, in individuals with Down syndrome; and

''(7) research, training, and investigation on improving the quality of life of individuals with Down syndrome and their families.

''(c) COORDINATION; PRIORITIZING NONDUPLICATIVE RESEARCH.—The Director of NIH shall ensure that—

''(1) the programs and activities of the institutes and centers of the National Institutes of Health relating to Down syndrome and co-occurring conditions are coordinated, including through the Office of the Director of NIH and priority-setting reviews conducted pursuant to section 402(b)(3); and

''(2) such institutes and centers, prioritize, as appropriate, Down syndrome research that does not duplicate existing research activities of the National Institutes of Health.

''(d) CONSULTATION WITH STAKEHOLDERS.—In carrying out activities under this section, the Director of NIH shall, as appropriate and to the maximum extent feasible, consult with relevant stakeholders, including patient advocates, to ensure that such activities take into consideration the needs of individuals with Down syndrome.

''(e) BIENNIAL REPORTS TO CONGRESS.—

''(1) IN GENERAL.—The Director of NIH shall submit, on a biennial basis, to the Committee on Energy and Commerce and the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies of the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies of the Committee on Appropriations of the Senate, a report that catalogs the research conducted or supported under this section.

''(2) CONTENTS.—Each report under paragraph (1) shall include—

''(A) identification of the institute or center involved;

''(B) a statement of whether the research is or was being carried out directly by such in-

stitute or center or by multiple institutes and centers; and

''(C) identification of any resulting real-world evidence that is or may be used for clinical research and medical care for patients with Down syndrome.''.

SEC. 710. IMPROVE INITIATIVE.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.), as amended by section 710, is further amended by adding at the end the following:

''SEC. 409L. IMPROVE INITIATIVE.

''(a) IN GENERAL.—The Director of the National Institutes of Health shall carry out a program of research to improve health outcomes to be known as the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone Initiative (referred to in this section as the 'Initiative').

''(b) OBJECTIVES.—The Initiative shall—

''(1) advance research to—

''(A) reduce preventable causes of maternal mortality and severe maternal morbidity;

''(B) reduce health disparities related to maternal health outcomes, including such disparities associated with medically underserved populations; and

''(C) improve health for pregnant and postpartum women before, during, and after pregnancy;

''(2) use an integrated approach to understand the factors, including biological, behavioral, and other factors, that affect maternal mortality and severe maternal morbidity by building an evidence base for improved outcomes in specific regions of the United States; and

''(3) target health disparities associated with maternal mortality and severe maternal morbidity by—

''(A) implementing and evaluating community-based interventions for disproportionately affected women; and

''(B) identifying risk factors and the underlying biological mechanisms associated with leading causes of maternal mortality and severe maternal morbidity in the United States.

''(c) SUNSET.—The authority under this section shall expire on September 30, 2029.''.

SEC. 711. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

Section 372 of the Public Health Service Act (42 U.S.C. 274) is amended—

(1) in subsection (b)(2)—

(A) by moving the margins of subparagraphs (M) through (O) 2 ems to the left;

(B) in subparagraph (A)—

(i) in clause (i), by striking ‘‘, and’’ and inserting ‘‘; and’’; and

(ii) in clause (ii), by striking the comma at the end and inserting a semicolon;

(C) in subparagraph (C), by striking ‘‘twenty-four-hour telephone service’’ and inserting ‘‘24-hour telephone or information technology service’’;

(D) in each of subparagraphs (B) through (M), by striking the comma at the end and inserting a semicolon;

(E) in subparagraph (N), by striking ‘‘transportation, and’’ and inserting ‘‘transportation;’’;

(F) in subparagraph (O), by striking the period and inserting a semicolon; and

(G) by adding at the end the following:

‘‘(P) encourage the integration of electronic health records systems through application programming interfaces (or successor technologies) among

hospitals, organ procurement organizations, and transplant centers, including the use of automated electronic hospital referrals and the grant of remote, electronic access to hospital electronic health records of potential donors by organ procurement organizations, in a manner that complies with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, at part 160 of title 45, Code of Federal Regulations, and subparts A, C, and E of part 164 of such title (or any successor regulations); and

''(Q) consider establishing a dashboard to display the number of transplants performed, the types of transplants performed, the number and types of organs that entered the Organ Procurement and Transplantation Network system and failed to be transplanted, and other appropriate statistics, which should be updated more frequently than annually.''; and

(2) by adding at the end the following:

''(d) REGISTRATION FEES.—

''(1) IN GENERAL.—The Secretary may collect registration fees from any member of the Organ Procurement and Transplantation Network for each transplant candidate such member places on the list

described in subsection (b)(2)(A)(i). Such registration fees shall be collected and distributed only to support the operation of the Organ Procurement and Transplantation Network. Such registration fees are authorized to remain available until expended.

''(2) COLLECTION.—The Secretary may collect the registration fees under paragraph (1) directly or through awards made under subsection (b)(1)(A).

''(3) DISTRIBUTION.—Any amounts collected under this subsection shall—

''(A) be credited to the currently applicable appropriation, account, or fund of the Department of Health and Human Services as discretionary offsetting collections; and

''(B) be available, only to the extent and in the amounts provided in advance in appropriations Acts, to distribute such fees among awardees described in subsection (b)(1)(A).

''(4) TRANSPARENCY.—The Secretary shall—

''(A) promptly post on the website of the Organ Procurement and Transplantation Network—

''(i) the amount of registration fees collected under this subsection from each

member of the Organ Procurement and Transplantation Network; and

"(ii) a list of activities such fees are used to support; and

"(B) update the information posted pursuant to subparagraph (A), as applicable for each calendar quarter for which fees are collected under paragraph (1).

"(5) GAO REVIEW.—Not later than 2 years after the date of enactment of this subsection, the Comptroller General of the United States shall, to the extent data are available—

"(A) conduct a review concerning the activities under this subsection; and

"(B) submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on such review, including related recommendations, as applicable.

"(6) SUNSET.—The authority to collect registration fees under paragraph (1) shall expire on the date that is 3 years after the date of enactment of the Bipartisan Health Care Act.".

SEC. 712. HONOR OUR LIVING DONORS.

(a) NO CONSIDERATION OF INCOME OF ORGAN RECIPIENT.—Section 377 of the Public Health Service Act (42 U.S.C. 274f) is amended—

(1) by redesignating subsections (c) through (f) as subsections (d) through (g), respectively;

(2) by inserting after subsection (b) the following:

''(c) NO CONSIDERATION OF INCOME OF ORGAN RECIPIENT.—The recipient of a grant under this section, in providing reimbursement to a donating individual through such grant, shall not give any consideration to the income of the organ recipient.''; and

(3) in subsection (f), as so redesignated—

(A) in paragraph (1), by striking ''subsection (c)(1)'' and inserting ''subsection (d)(1)''; and

(B) in paragraph (2), by striking ''subsection (c)(2)'' and inserting ''subsection (d)(2)''.

(b) REMOVAL OF EXPECTATION OF PAYMENTS BY ORGAN RECIPIENTS.—Section 377(e) of the Public Health Service Act (42 U.S.C. 274f(e)), as redesignated by subsection (a)(1), is amended—

(1) in paragraph (1), by adding ''or'' at the end;

(2) in paragraph (2), by striking ''; or'' and inserting a period; and

(3) by striking paragraph (3).

(c) ANNUAL REPORT.—Section 377 of the Public Health Service Act (42 U.S.C. 274f), as amended by subsections (a) and (b), is amended by adding at the end the following:

''(h) ANNUAL REPORT.—Not later than December 31 of each year, beginning in fiscal year 2026, the Secretary shall—

''(1) prepare, submit to the Congress, and make public a report on whether grants under this section provided adequate funding during the preceding fiscal year to reimburse all donating individuals participating in the grant program under this section for all qualifying expenses; and

''(2) include in each such report—

''(A) the estimated number of all donating individuals participating in the grant program under this section who did not receive reimbursement for all qualifying expenses during the preceding fiscal year; and

''(B) the total amount of funding that is estimated to be necessary to fully reimburse all donating individuals participating in the grant

program under this section for all qualifying expenses.''.

SEC. 713. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

Section 409I(d)(1) of the Public Health Service Act (42 U.S.C. 284m(d)(1)) is amended by striking ''section,'' and all that follows through the period at the end and inserting ''section, $25,000,000 for each of fiscal years 2025 through 2027.''.

TITLE VIII—FOOD AND DRUG ADMINISTRATION

Subtitle A—Give Kids a Chance

SEC. 801. RESEARCH INTO PEDIATRIC USES OF DRUGS; ADDITIONAL AUTHORITIES OF FOOD AND DRUG ADMINISTRATION REGARDING MOLECULARLY TARGETED CANCER DRUGS.

(a) IN GENERAL.—

(1) ADDITIONAL ACTIVE INGREDIENT FOR APPLICATION DRUG; LIMITATION REGARDING NOVEL-COMBINATION APPLICATION DRUG.—Section 505B(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(3)) is amended—

(A) by redesignating subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively; and

(B) by striking subparagraph (A) and inserting the following:

''(A) IN GENERAL.—For purposes of paragraph (1)(B), the investigation described in this paragraph is a molecularly targeted pediatric cancer investigation of—

''(i) the drug or biological product for which the application referred to in such paragraph is submitted; or

''(ii) such drug or biological product used in combination with—

''(I) an active ingredient of a drug or biological product—

''(aa) for which an approved application under section 505(j) under this Act or under section 351(k) of the Public Health Service Act is in effect; and

''(bb) that is determined by the Secretary, after consultation with the applicant, to be part of the standard of care for treating a pediatric cancer; or

''(II) an active ingredient of a drug or biological product—

"(aa) for which an approved application under section 505(b) of this Act or section 351(a) of the Public Health Service Act to treat an adult cancer is in effect and is held by the same person submitting the application under paragraph (1)(B); and

"(bb) that is directed at a molecular target that the Secretary determines to be substantially relevant to the growth or progression of a pediatric cancer.

"(B) ADDITIONAL REQUIREMENTS.—

"(i) DESIGN OF INVESTIGATION.—A molecularly targeted pediatric cancer investigation referred to in subparagraph (A) shall be designed to yield clinically meaningful pediatric study data that is gathered using appropriate formulations for each age group for which the study is required, regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling.

"(ii) LIMITATION.—An investigation described in subparagraph (A)(ii) may be required only if the drug or biological product for which the application referred to in paragraph (1)(B) contains either—

"(I) a single new active ingredient; or

"(II) more than one active ingredient, if an application for the combination of active ingredients has not previously been approved but each active ingredient is in a drug product that has been previously approved to treat an adult cancer.

"(iii) RESULTS OF ALREADY-COMPLETED PRECLINICAL STUDIES OF APPLICATION DRUG.—With respect to an investigation required pursuant to paragraph (1)(B), the Secretary may require the results of any completed preclinical studies relevant to the initial pediatric study plan be submitted to the Secretary at the same time that the initial pediatric study plan required under subsection (e)(1) is submitted.

''(iv) RULE OF CONSTRUCTION REGARDING INACTIVE INGREDIENTS.—With respect to a combination of active ingredients referred to in subparagraph (A)(ii), such subparagraph shall not be construed as addressing the use of inactive ingredients with such combination.''.

(2) DETERMINATION OF APPLICABLE REQUIREMENTS.—Section 505B(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(e)(1)) is amended by adding at the end the following: ''The Secretary shall determine whether subparagraph (A) or (B) of subsection (a)(1) applies with respect to an application before the date on which the applicant is required to submit the initial pediatric study plan under paragraph (2)(A).''.

(3) CLARIFYING APPLICABILITY.—Section 505B(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(1)) is amended by adding at the end the following:

''(C) RULE OF CONSTRUCTION.—No application that is subject to the requirements of subparagraph (B) shall be subject to the requirements of subparagraph (A), and no application (or supplement to an application) that is

subject to the requirements of subparagraph (A) shall be subject to the requirements of subparagraph (B).''.

(4) CONFORMING AMENDMENTS.—Section 505B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)) is amended—

(A) in paragraph (3)(C), as redesignated by paragraph (1)(A) of this subsection, by striking ''investigations described in this paragraph'' and inserting ''investigations referred to in subparagraph (A)''; and

(B) in paragraph (3)(D), as redesignated by paragraph (1)(A) of this subsection, by striking ''the assessments under paragraph (2)(B)'' and inserting ''the assessments required under paragraph (1)(A)''.

(b) GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) not later than 12 months after the date of enactment of this Act, issue draft guidance on the implementation of the amendments made by subsection (a); and

(2) not later than 12 months after closing the comment period on such draft guidance, finalize such guidance.

(c) APPLICABILITY.—The amendments made by this section apply with respect to any application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and any application under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), that is submitted on or after the date that is 3 years after the date of enactment of this Act.

(d) REPORTS TO CONGRESS.—

(1) SECRETARY OF HEALTH AND HUMAN SERVICES.—Not later than 6 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the Secretary's efforts, in coordination with industry, to ensure implementation of the amendments made by subsection (a).

(2) GAO STUDY AND REPORT.—

(A) STUDY.—Not later than 8 years after the date of enactment of this Act, the Comptroller General of the United States shall con-

duct a study of the effectiveness of requiring assessments and investigations described in section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.355c), as amended by subsection (a), in the development of drugs and biological products for pediatric cancer indications, including consideration of any benefits to, or burdens on, pediatric cancer drug development.

(B) FINDINGS.—Not later than 10 years after the date of enactment of this Act, the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing the findings of the study conducted under subparagraph (A).

SEC. 802. ENSURING COMPLETION OF PEDIATRIC STUDY REQUIREMENTS.

(a) EQUAL ACCOUNTABILITY FOR PEDIATRIC STUDY REQUIREMENTS.—Section 505B(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)) is amended—

(1) in paragraph (1), by striking ''Beginning 270'' and inserting ''NONCOMPLIANCE LETTER.—Beginning 270'';

(2) in paragraph (2)—

(A) by striking ''The drug or'' and inserting ''EFFECT OF NONCOMPLIANCE.—The drug or''; and

(B) by striking ''(except that the drug or biological product shall not be subject to action under section 303)'' and inserting ''(except that the drug or biological product shall be subject to action under section 303 only if such person demonstrated a lack of due diligence in satisfying the applicable requirement)''; and

(3) by adding at the end the following:

''(3) LIMITATION.—The Secretary shall not issue enforcement actions under section 303 for failures under this subsection in the case of a drug or biological product that is no longer marketed.''.

(b) DUE DILIGENCE.—Section 505B(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)), as amended by subsection (a), is further amended by adding at the end the following:

''(4) DUE DILIGENCE.—Before the Secretary may conclude that a person failed to submit or oth-

erwise meet a requirement as described in the matter preceding paragraph (1), the Secretary shall—

"(A) issue a noncompliance letter pursuant to paragraph (1);

"(B) provide such person with a 45-day period beginning on the date of receipt of such noncompliance letter to respond in writing as set forth in such paragraph; and

"(C) after reviewing such written response, determine whether the person demonstrated a lack of due diligence in satisfying such requirement.".

(c) CONFORMING AMENDMENTS.—Section 303(f)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(4)(A)) is amended by striking "or 505–1" and inserting "505–1, or 505B".

(d) TRANSITION RULE.—The Secretary of Health and Human Services may take enforcement action under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) only for failures described in section 505B(d) of such Act (21 U.S.C. 355c(d)) that occur on or after the date that is 180 days after the date of enactment of this Act.

SEC. 803. FDA REPORT ON PREA ENFORCEMENT.

Section 508(b) of the Food and Drug Administration Safety and Innovation Act (21 U.S.C. 355c–1(b)) is amended—

(1) in paragraph (11), by striking the semicolon at the end and inserting ", including an evaluation of compliance with deadlines provided for in deferrals and deferral extensions;";

(2) in paragraph (15), by striking "and" at the end;

(3) in paragraph (16), by striking the period at the end and inserting "; and"; and

(4) by adding at the end the following:

"(17) a listing of penalties, settlements, or payments under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353) for failure to comply with requirements under such section 505B, including, for each penalty, settlement, or payment, the name of the drug, the sponsor thereof, and the amount of the penalty, settlement, or payment imposed; and".

SEC. 804. EXTENSION OF AUTHORITY TO ISSUE PRIORITY REVIEW VOUCHERS TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

(a) EXTENSION.—Paragraph (5) of section 529(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

360ff(b)) is amended by striking ''December 20, 2024, unless'' and all that follows through the period at the end and inserting ''September 30, 2029.''.

(b) USER FEE PAYMENT.—Section 529(c)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(c)(4)) is amended by striking subparagraph (A) and inserting the following:

''(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351(a) of the Public Health Service Act for which the priority review voucher is used. All other user fees associated with the human drug application shall be due as required by the Secretary or under applicable law.''.

(c) GAO REPORT ON EFFECTIVENESS OF RARE PEDIATRIC DISEASE PRIORITY VOUCHER AWARDS IN INCENTIVIZING RARE PEDIATRIC DISEASE DRUG DEVELOPMENT.—

(1) GAO STUDY.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study of the effectiveness of awarding rare pediatric disease priority vouchers under section 529 of the Fed-

eral Food, Drug, and Cosmetic Act (21 U.S.C. 360ff), as amended by subsection (a), in the development of human drug products that treat or prevent rare pediatric diseases (as defined in such section 529).

(B) CONTENTS OF STUDY.—In conducting the study under subparagraph (A), the Comptroller General shall examine the following:

(i) The indications for each drug or biological product that—

(I) is the subject of a rare pediatric disease product application (as defined in section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff)) for which a priority review voucher was awarded; and

(II) was approved under section 505 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

(ii) Whether, and to what extent, an unmet need related to the treatment or prevention of a rare pediatric disease was

met through the approval or licensure of such a drug or biological product.

(iii) The size of the company to which a priority review voucher was awarded under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) for such a drug or biological product.

(iv) The value of such priority review voucher if transferred.

(v) Identification of each drug for which a priority review voucher awarded under such section 529 was used.

(vi) The size of the company using each priority review voucher awarded under such section 529.

(vii) The length of the period of time between the date on which a priority review voucher was awarded under such section 529 and the date on which it was used.

(viii) Whether, and to what extent, an unmet need related to the treatment or prevention of a rare pediatric disease was met through the approval under section 505 of the Federal Food, Drug, and Cos-

metic Act (42 U.S.C. 355) or licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) of a drug for which a priority review voucher was used.

(ix) Whether, and to what extent, companies were motivated by the availability of priority review vouchers under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) to attempt to develop a drug for a rare pediatric disease.

(x) Whether, and to what extent, pediatric review vouchers awarded under such section were successful in stimulating development and expedited patient access to drug products for treatment or prevention of a rare pediatric disease that wouldn't otherwise take place without the incentive provided by such vouchers.

(xi) The impact of such priority review vouchers on the workload, review process, and public health prioritization efforts of the Food and Drug Administration.

(xii) Any other incentives in Federal law that exist for companies developing drugs or biological products described in clause (i).

(2) REPORT ON FINDINGS.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing the findings of the study conducted under paragraph (1).

SEC. 805. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICENSURE OF ORPHAN DRUGS.

(a) IN GENERAL.—Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

(1) in subsection (a), in the matter following paragraph (2), by striking ''same disease or condition'' and inserting ''same approved use or indication within such rare disease or condition'';

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking ''same rare disease or condition'' and inserting ''same approved use or indication

for which such 7-year period applies to such already approved or licensed drug''; and

(B) in paragraph (1), by inserting '', relating to the approved use or indication,'' after ''the needs'';

(3) in subsection (c)(1), by striking ''same rare disease or condition as the already approved drug'' and inserting ''same use or indication for which the already approved or licensed drug was approved or licensed''; and

(4) by adding at the end the following:

''(f) APPROVED USE OR INDICATION DEFINED.—In this section, the term 'approved use or indication' means the use or indication approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act for a drug designated under section 526 for a rare disease or condition.''.

(b) APPLICATION OF AMENDMENTS.—The amendments made by subsection (a) shall apply with respect to any drug designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regardless of the date on which the drug was so designated, and regardless of the date on which the drug was approved under section 505 of such Act (21 U.S.C. 355) or licensed

under section 351 of the Public Health Service Act (42 U.S.C. 262).

Subtitle B—United States-Abraham Accords Cooperation and Security

SEC. 811. ESTABLISHMENT OF ABRAHAM ACCORDS OFFICE WITHIN FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 1015. ABRAHAM ACCORDS OFFICE.

''(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall establish within the Food and Drug Administration an office, to be known as the Abraham Accords Office, to be headed by a director.

''(b) OFFICE.—Not later than 2 years after the date of enactment of this section, the Secretary shall—

''(1) in consultation with the governments of Abraham Accords countries, as well as appropriate United States Government diplomatic and security personnel—

''(A) select the location of the Abraham Accords Office in an Abraham Accords country; and

''(B) establish such office; and

''(2) assign to such office such personnel of the Food and Drug Administration as the Secretary determines necessary to carry out the functions of such office.

''(c) DUTIES.—The Secretary, acting through the Director of the Abraham Accords Office, shall—

''(1) after the Abraham Accords Office is established—

''(A) as part of the Food and Drug Administration's work to strengthen the international oversight of regulated commodities, provide technical assistance to regulatory partners in Abraham Accords countries on strengthening regulatory oversight and converging regulatory requirements for the oversight of regulated products, including good manufacturing practices and other issues relevant to manufacturing medical products that are regulated by the Food and Drug Administration; and

''(B) facilitate interactions between the Food and Drug Administration and interested parties in Abraham Accords countries, including by sharing relevant information regarding United States regulatory pathways with such parties, and facilitate feedback on the research,

development, and manufacturing of products regulated in accordance with this Act; and

''(2) carry out other functions and activities as the Secretary determines to be necessary to carry out this section.

''(d) ABRAHAM ACCORDS COUNTRY DEFINED.—In this section, the term 'Abraham Accords country' means a country identified by the Department of State as having signed the Abraham Accords Declaration.

''(e) NATIONAL SECURITY.—Nothing in this section shall be construed to require any action inconsistent with a national security recommendation provided by the Federal Government.''.

(b) REPORT TO CONGRESS.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Congress a report on the Abraham Accords Office, including—

(A) an evaluation of how the Office has advanced progress toward conformance with Food and Drug Administration regulatory requirements by manufacturers in the Abraham Accords countries;

(B) a numerical count of parties that the Office has helped facilitate interactions or feedback pursuant to section 1015(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a));

(C) a summary of technical assistance provided to regulatory partners in Abraham Accords countries pursuant to subparagraph (A) of such section 1015(c)(1); and

(D) recommendations for increasing and improving coordination between the Food and Drug Administration and entities in Abraham Accords countries.

(2) ABRAHAM ACCORDS COUNTRY DEFINED.—In this subsection, the term ''Abraham Accords country'' has the meaning given such term in section 1015(d) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

TITLE IX—LOWERING PRESCRIPTION DRUG COSTS

SEC. 901. OVERSIGHT OF PHARMACY BENEFIT MANAGEMENT SERVICES.

(a) PUBLIC HEALTH SERVICE ACT.—Title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended—

(1) in part D (42 U.S.C. 300gg–111 et seq.), by adding at the end the following new section:

"SEC. 2799A–11. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.

''(a) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of this section (referred to in this subsection and subsection (b) as the 'effective date'), a group health plan or a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services on behalf of such a plan or issuer, shall not enter into a contract, including an extension or renewal of a contract, entered into on or after the effective date, with an applicable entity unless such applicable entity agrees to—

''(1) not limit or delay the disclosure of information to the group health plan (including such a plan offered through a health insurance issuer) in such a manner that prevents an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage from making the reports described in subsection (b); and

''(2) provide the entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer relevant information necessary to make the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after the effective date, in the case of any contract between a group health plan or a health insurance issuer offering group health insurance coverage offered in connection with such a plan and an entity providing pharmacy benefit management services on behalf of such plan or issuer, including an extension or renewal of such a contract, entered into on or after the effective date, the entity providing pharmacy benefit management services on behalf of such a group health plan or health insurance issuer, not less frequently than every 6 months (or, at the request of a group health plan, not less frequently than quarterly, and under the same conditions, terms, and cost of the semiannual report under this subsection), shall submit to the group health plan a report in accordance with this section. Each such report shall be made available to such group health plan in plain language, in a machine-readable for-

mat, and as the Secretary may determine, other formats. Each such report shall include the information described in paragraph (2).

''(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), the information described in this paragraph is, with respect to drugs covered by a group health plan or group health insurance coverage offered by a health insurance issuer in connection with a group health plan during each reporting period—

''(A) in the case of a group health plan that is offered by a specified large employer or that is a specified large plan, and is not offered as health insurance coverage, or in the case of health insurance coverage for which the election under paragraph (3) is made for the applicable reporting period—

''(i) a list of drugs for which a claim was filed and, with respect to each such drug on such list—

''(I) the contracted compensation paid by the group health plan or health insurance issuer for each covered drug (identified by the National Drug Code) to the entity providing

pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer;

''(II) the contracted compensation paid to the pharmacy, by any entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer, for each covered drug (identified by the National Drug Code);

''(III) for each such claim, the difference between the amount paid under subclause (I) and the amount paid under subclause (II);

''(IV) the proprietary name, established name or proper name, and the National Drug Code;

''(V) for each claim for the drug (including original prescriptions and refills) and for each dosage unit of the drug for which a claim was filed, the type of dispensing channel used to

furnish the drug, including retail, mail order, or specialty pharmacy;

''(VI) with respect to each drug dispensed, for each type of dispensing channel (including retail, mail order, or specialty pharmacy)—

''(aa) whether such drug is a brand name drug or a generic drug, and—

''(AA) in the case of a brand name drug, the wholesale acquisition cost, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

''(BB) in the case of a generic drug, the average wholesale price, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

''(bb) the total number of—

"(AA) prescription claims (including original prescriptions and refills);

"(BB) participants and beneficiaries for whom a claim for such drug was filed through the applicable dispensing channel;

"(CC) dosage units and dosage units per fill of such drug; and

"(DD) days supply of such drug per fill;

"(VII) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply to the plan or coverage after rebates, fees, alternative discounts, or other remuneration received from applicable entities;

"(VIII) the total amount of out-of-pocket spending by participants and beneficiaries on such drug, including spending through copayments, coinsurance, and deductibles, but not

including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage, or for which no claim is submitted under the plan or coverage;

''(IX) the total net spending on the drug;

''(X) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration;

''(XI) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—

''(aa) for claims incurred during the reporting period; and

''(bb) that is related to utilization of such drug or spending on such drug; and

''(XII) to the extent feasible, information on the total amount of remuneration for such drug, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer), to the participants and beneficiaries enrolled in such plan or coverage;

''(ii) a list of each therapeutic class (as defined by the Secretary) for which a claim was filed under the group health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic class—

''(I) the total gross spending on drugs in such class before rebates, price concessions, alternative discounts, or other remuneration from applicable entities;

''(II) the net spending in such class after such rebates, price conces-

sions, alternative discounts, or other remuneration from applicable entities;

''(III) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—

''(aa) for claims incurred during the reporting period; and

''(bb) that is related to utilization of drugs or drug spending;

''(IV) the average net spending per 30-day supply and per 90-day supply by the plan or by the issuer with respect to such coverage and its participants and beneficiaries, among all drugs within the therapeutic class for which a claim was filed during the reporting period;

''(V) the number of participants and beneficiaries who filled a prescription for a drug in such class, includ-

ing the National Drug Code for each such drug;

''(VI) if applicable, a description of the formulary tiers and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that class; and

''(VII) the total out-of-pocket spending under the plan or coverage by participants and beneficiaries, including spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage or for which no claim is submitted under the plan or coverage;

''(iii) with respect to any drug for which gross spending under the group health plan or health insurance coverage exceeded $10,000 during the reporting period or, in the case that gross spending under the group health plan or coverage exceeded $10,000 during the reporting period with respect to fewer than 50 drugs,

with respect to the 50 prescription drugs with the highest spending during the reporting period—

"(I) a list of all other drugs in the same therapeutic class as such drug;

"(II) if applicable, the rationale for the formulary placement of such drug in that therapeutic category or class, selected from a list of standard rationales established by the Secretary, in consultation with stakeholders; and

"(III) any change in formulary placement compared to the prior plan year; and

"(iv) in the case that such plan or issuer (or an entity providing pharmacy benefit management services on behalf of such plan or issuer) has an affiliated pharmacy or pharmacy under common ownership, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and cost sharing

assistance incentives funded by an entity providing pharmacy benefit services—

"(I) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies;

"(II) the percentage of total prescriptions dispensed by such pharmacies to participants or beneficiaries in such plan or coverage; and

"(III) a list of all drugs dispensed by such pharmacies to participants or beneficiaries enrolled in such plan or coverage, and, with respect to each drug dispensed—

"(aa) the amount charged, per dosage unit, per 30-day supply, or per 90-day supply (as applicable) to the plan or issuer, and to participants and beneficiaries;

"(bb) the median amount charged to such plan or issuer,

and the interquartile range of the costs, per dosage unit, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of such plan or coverage;

''(cc) the lowest cost per dosage unit, per 30-day supply and per 90-day supply, for each such drug, including amounts charged to the plan or coverage and to participants and beneficiaries, that is available from any pharmacy included in the network of such plan or coverage; and

''(dd) the net acquisition cost per dosage unit, per 30-day supply, and per 90-day supply, if

such drug is subject to a maximum price discount; and

''(B) with respect to any group health plan, including group health insurance coverage offered in connection with such a plan, regardless of whether the plan or coverage is offered by a specified large employer or whether it is a specified large plan—

''(i) a summary document for the group health plan that includes such information described in clauses (i) through (iv) of subparagraph (A), as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking), that the Secretary determines useful to group health plans for purposes of selecting pharmacy benefit management services, such as an estimated net price to group health plan and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary;

''(ii) a summary document for plans and issuers to provide to participants and

beneficiaries, which shall be made available to participants or beneficiaries upon request to their group health plan (including in the case of group health insurance coverage offered in connection with such a plan), that—

"(I) contains such information described in clauses (iii), (iv), (v), and (vi), as applicable, as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking) that the Secretary determines useful to participants or beneficiaries in better understanding the plan or coverage or benefits under such plan or coverage;

"(II) contains only aggregate information; and

"(III) states that participants and beneficiaries may request specific, claims-level information required to be furnished under subsection (c) from the group health plan or health insurance issuer; and

''(iii) with respect to drugs covered by such plan or coverage during such reporting period—

''(I) the total net spending by the plan or coverage for all such drugs;

''(II) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration; and

''(III) to the extent feasible, information on the total amount of remuneration for such drugs, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer) to participants and beneficiaries;

''(iv) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section 408(b)(2)(B)(ii)(dd)(AA) of the Employee Retirement Income Security Act) to bro-

kerage firms, brokers, consultants, advisors, or any other individual or firm, for—

''(I) the referral of the group health plan's or health insurance issuer's business to an entity providing pharmacy benefit management services, including the identity of the recipient of such amounts;

''(II) consideration of the entity providing pharmacy benefit management services by the group health plan or health insurance issuer; or

''(III) the retention of the entity by the group health plan or health insurance issuer;

''(v) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in such plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services under such plan or coverage, including mandatory mail and specialty home delivery programs, re-

tail and mail auto-refill programs, and cost-sharing assistance incentives directly or indirectly funded by such entity; and

''(vi) total gross spending on all drugs under the plan or coverage during the reporting period.

''(3) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE OFFERED BY A SPECIFIED LARGE EMPLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In the case of group health insurance coverage offered in connection with a group health plan that is offered by a specified large employer or is a specified large plan, such group health plan may, on an annual basis, for plan years beginning on or after the date that is 30 months after the date of enactment of this section, elect to require an entity providing pharmacy benefit management services on behalf of the health insurance issuer to submit to such group health plan a report that includes all of the information described in paragraph (2)(A), in addition to the information described in paragraph (2)(B).

''(4) PRIVACY REQUIREMENTS.—

''(A) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan or a health insur-

ance issuer offering group health insurance coverage shall report information under paragraph (1) in a manner consistent with the privacy regulations promulgated under section 13402(a) of the Health Information Technology for Economic and Clinical Health Act and consistent with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 in part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (or successor regulations) (referred to in this paragraph as the 'HIPAA privacy regulations') and shall restrict the use and disclosure of such information according to such privacy regulations and such HIPAA privacy regulations.

''(B) ADDITIONAL REQUIREMENTS.—

''(i) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage that submits a report under paragraph (1) shall ensure that such report contains only summary health information, as defined in section

164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

''(ii) RESTRICTIONS.—In carrying out this subsection, a group health plan shall comply with section 164.504(f) of title 45, Code of Federal Regulations (or a successor regulation), and a plan sponsor shall act in accordance with the terms of the agreement described in such section.

''(C) RULE OF CONSTRUCTION.—

''(i) Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the HIPAA privacy regulations.

''(ii) Nothing in this section shall be construed to affect the application of any Federal or State privacy or civil rights law, including the HIPAA privacy regulations, the Genetic Information Nondiscrimination Act of 2008 (Public Law 110–233) (including the amendments made by such Act), the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.), section 504 of the Rehabilitation Act of 1973 (29

U.S.C. 794), section 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. 18116), title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d), and title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e).

''(D) WRITTEN NOTICE.—Each plan year, group health plans, including with respect to group health insurance coverage offered in connection with a group health plan, shall provide to each participant or beneficiary written notice informing the participant or beneficiary of the requirement for entities providing pharmacy benefit management services on behalf of the group health plan or health insurance issuer offering group health insurance coverage to submit reports to group health plans under paragraph (1), as applicable, which may include incorporating such notification in plan documents provided to the participant or beneficiary, or providing individual notification.

''(E) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to the entity from which the report

was received or to that entity's business associates as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations) or as permitted by the HIPAA privacy regulations.

''(F) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section shall prevent an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage, from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such plan, issuer, or entity may not—

''(i) restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, or the Department of the Treasury; or

''(ii) prevent disclosure for the purposes of subsection (c), or any other public disclosure requirement under this section.

''(G) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1)

required with respect to any group health plan established by a plan sponsor that is, or is affiliated with, a drug manufacturer, drug wholesaler, or other direct participant in the drug supply chain, in order to prevent anti-competitive behavior.

''(5) STANDARD FORMAT AND REGULATIONS.—

''(A) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Secretary shall specify through rulemaking a standard format for entities providing pharmacy benefit management services on behalf of group health plans and health insurance issuers offering group health insurance coverage, to submit reports required under paragraph (1).

''(B) ADDITIONAL REGULATIONS.—Not later than 18 months after the date of enactment of this section, the Secretary shall, through rulemaking, promulgate any other final regulations necessary to implement the requirements of this section. In promulgating such regulations, the Secretary shall, to the extent practicable, align the reporting requirements

under this section with the reporting requirements under section 2799A–10.

''(c) REQUIREMENT TO PROVIDE INFORMATION TO PARTICIPANTS OR BENEFICIARIES.—A group health plan, including with respect to group health insurance coverage offered in connection with a group health plan, upon request of a participant or beneficiary, shall provide to such participant or beneficiary—

''(1) the summary document described in subsection (b)(2)(B)(ii); and

''(2) the information described in subsection (b)(2)(A)(i)(III) with respect to a claim made by or on behalf of such participant or beneficiary.

''(d) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary shall enforce this section. The enforcement authority under this subsection shall apply only with respect to group health plans (including group health insurance coverage offered in connection with such a plan) to which the requirements of subparts I and II of part A and part D apply in accordance with section 2722, and with respect to entities providing pharmacy benefit management services on behalf of such plans and applicable entities providing services on behalf of such plans.

''(2) FAILURE TO PROVIDE INFORMATION.—A group health plan, a health insurance issuer offering group health insurance coverage, an entity providing pharmacy benefit management services on behalf of such a plan or issuer, or an applicable entity providing services on behalf of such a plan or issuer that violates subsection (a); an entity providing pharmacy benefit management services on behalf of such a plan or issuer that fails to provide the information required under subsection (b); or a group health plan that fails to provide the information required under subsection (c), shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(3) FALSE INFORMATION.—A health insurance issuer, an entity providing pharmacy benefit management services, or a third party administrator providing services on behalf of such issuer offered by a health insurance issuer that knowingly provides false information under this section shall be subject to a civil monetary penalty in an amount not to exceed $100,000 for each item of false information. Such civil monetary penalty shall be in addition to other penalties as may be prescribed by law.

''(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under such section.

''(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with the requirements in this section.

''(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary to a report described in subsection (b)(1) or information related to compliance with subsections (a), (b), (c), or (d) by such issuer, plan, or entity.

''(f) DEFINITIONS.—In this section:

''(1) APPLICABLE ENTITY.—The term 'applicable entity' means—

"(A) an applicable group purchasing organization, drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), or associated third party;

"(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such a plan or issuer, or any entity described in subparagraph (A); or

"(C) such other entity as the Secretary may specify through rulemaking.

"(2) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term 'applicable group purchasing organization' means a group purchasing organization that is affiliated with or under common ownership with an entity providing pharmacy benefit management services.

"(3) CONTRACTED COMPENSATION.—The term 'contracted compensation' means the sum of any ingredient cost and dispensing fee for a drug (inclusive of the out-of-pocket costs to the participant or beneficiary), or another analogous compensation struc-

ture that the Secretary may specify through regulations.

''(4) GROSS SPENDING.—The term 'gross spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated before the application of rebates, fees, alternative discounts, or other remuneration.

''(5) NET SPENDING.—The term 'net spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the application of rebates, fees, alternative discounts, or other remuneration.

''(6) PLAN SPONSOR.—The term 'plan sponsor' has the meaning given such term in section 3(16)(B) of the Employee Retirement Income Security Act of 1974.

''(7) REMUNERATION.—The term 'remuneration' has the meaning given such term by the Secretary through rulemaking, which shall be reevaluated by the Secretary every 5 years.

''(8) SPECIFIED LARGE EMPLOYER.—The term 'specified large employer' means, in connection with a group health plan (including group health insurance coverage offered in connection with such a plan) established or maintained by a single employer, with respect to a calendar year or a plan year, as applicable, an employer who employed an average of at least 100 employees on business days during the preceding calendar year or plan year and who employs at least 1 employee on the first day of the calendar year or plan year.

''(9) SPECIFIED LARGE PLAN.—The term 'specified large plan' means a group health plan (including group health insurance coverage offered in connection with such a plan) established or maintained by a plan sponsor described in clause (ii) or (iii) of section 3(16)(B) of the Employee Retirement Income Security Act of 1974 that had an average of at least 100 participants on business days during the preceding calendar year or plan year, as applicable.

''(10) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.''; and

(2) in section 2723 (42 U.S.C. 300gg–22)—

(A) in subsection (a)—

(i) in paragraph (1), by inserting ''(other than section 2799A–11)'' after ''part D''; and

(ii) in paragraph (2), by inserting ''(other than section 2799A–11)'' after ''part D''; and

(B) in subsection (b)—

(i) in paragraph (1), by inserting ''(other than section 2799A–11)'' after ''part D'';

(ii) in paragraph (2)(A), by inserting ''(other than section 2799A–11)'' after ''part D''; and

(iii) in paragraph (2)(C)(ii), by inserting ''(other than section 2799A–11)'' after ''part D''.

(b) EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

(1) IN GENERAL.—Subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1021 et seq.) is amended—

(A) in subpart B of part 7 (29 U.S.C. 1185 et seq.), by adding at the end the following:

"SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.

"(a) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of this section (referred to in this subsection and subsection (b) as the 'effective date'), a group health plan or a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services on behalf of such a plan or issuer, shall not enter into a contract, including an extension or renewal of a contract, entered into on or after the effective date, with an applicable entity unless such applicable entity agrees to—

"(1) not limit or delay the disclosure of information to the group health plan (including such a plan offered through a health insurance issuer) in such a manner that prevents an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage from making the reports described in subsection (b); and

''(2) provide the entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer relevant information necessary to make the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after the effective date, in the case of any contract between a group health plan or a health insurance issuer offering group health insurance coverage offered in connection with such a plan and an entity providing pharmacy benefit management services on behalf of such plan or issuer, including an extension or renewal of such a contract, entered into on or after the effective date, the entity providing pharmacy benefit management services on behalf of such a group health plan or health insurance issuer, not less frequently than every 6 months (or, at the request of a group health plan, not less frequently than quarterly, and under the same conditions, terms, and cost of the semiannual report under this subsection), shall submit to the group health plan a report in accordance with this section. Each such report shall be made available to such group health plan in plain language, in a machine-readable for-

mat, and as the Secretary may determine, other formats. Each such report shall include the information described in paragraph (2).

''(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), the information described in this paragraph is, with respect to drugs covered by a group health plan or group health insurance coverage offered by a health insurance issuer in connection with a group health plan during each reporting period—

''(A) in the case of a group health plan that is offered by a specified large employer or that is a specified large plan, and is not offered as health insurance coverage, or in the case of health insurance coverage for which the election under paragraph (3) is made for the applicable reporting period—

''(i) a list of drugs for which a claim was filed and, with respect to each such drug on such list—

''(I) the contracted compensation paid by the group health plan or health insurance issuer for each covered drug (identified by the National Drug Code) to the entity providing

pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer;

''(II) the contracted compensation paid to the pharmacy, by any entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer, for each covered drug (identified by the National Drug Code);

''(III) for each such claim, the difference between the amount paid under subclause (I) and the amount paid under subclause (II);

''(IV) the proprietary name, established name or proper name, and the National Drug Code;

''(V) for each claim for the drug (including original prescriptions and refills) and for each dosage unit of the drug for which a claim was filed, the type of dispensing channel used to

furnish the drug, including retail, mail order, or specialty pharmacy;

''(VI) with respect to each drug dispensed, for each type of dispensing channel (including retail, mail order, or specialty pharmacy)—

''(aa) whether such drug is a brand name drug or a generic drug, and—

''(AA) in the case of a brand name drug, the wholesale acquisition cost, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

''(BB) in the case of a generic drug, the average wholesale price, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

''(bb) the total number of—

"(AA) prescription claims (including original prescriptions and refills);

"(BB) participants and beneficiaries for whom a claim for such drug was filed through the applicable dispensing channel;

"(CC) dosage units and dosage units per fill of such drug; and

"(DD) days supply of such drug per fill;

"(VII) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply to the plan or coverage after rebates, fees, alternative discounts, or other remuneration received from applicable entities;

"(VIII) the total amount of out-of-pocket spending by participants and beneficiaries on such drug, including spending through copayments, coinsurance, and deductibles, but not

including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage, or for which no claim is submitted under the plan or coverage;

''(IX) the total net spending on the drug;

''(X) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration;

''(XI) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—

''(aa) for claims incurred during the reporting period; and

''(bb) that is related to utilization of such drug or spending on such drug; and

''(XII) to the extent feasible, information on the total amount of remuneration for such drug, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer), to the participants and beneficiaries enrolled in such plan or coverage;

''(ii) a list of each therapeutic class (as defined by the Secretary) for which a claim was filed under the group health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic class—

''(I) the total gross spending on drugs in such class before rebates, price concessions, alternative discounts, or other remuneration from applicable entities;

''(II) the net spending in such class after such rebates, price conces-

sions, alternative discounts, or other remuneration from applicable entities;

''(III) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—

''(aa) for claims incurred during the reporting period; and

''(bb) that is related to utilization of drugs or drug spending;

''(IV) the average net spending per 30-day supply and per 90-day supply by the plan or by the issuer with respect to such coverage and its participants and beneficiaries, among all drugs within the therapeutic class for which a claim was filed during the reporting period;

''(V) the number of participants and beneficiaries who filled a prescription for a drug in such class, includ-

ing the National Drug Code for each such drug;

''(VI) if applicable, a description of the formulary tiers and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that class; and

''(VII) the total out-of-pocket spending under the plan or coverage by participants and beneficiaries, including spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage or for which no claim is submitted under the plan or coverage;

''(iii) with respect to any drug for which gross spending under the group health plan or health insurance coverage exceeded $10,000 during the reporting period or, in the case that gross spending under the group health plan or coverage exceeded $10,000 during the reporting period with respect to fewer than 50 drugs,

with respect to the 50 prescription drugs with the highest spending during the reporting period—

"(I) a list of all other drugs in the same therapeutic class as such drug;

"(II) if applicable, the rationale for the formulary placement of such drug in that therapeutic category or class, selected from a list of standard rationales established by the Secretary, in consultation with stakeholders; and

"(III) any change in formulary placement compared to the prior plan year; and

"(iv) in the case that such plan or issuer (or an entity providing pharmacy benefit management services on behalf of such plan or issuer) has an affiliated pharmacy or pharmacy under common ownership, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and cost sharing

assistance incentives funded by an entity providing pharmacy benefit services—

"(I) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies;

"(II) the percentage of total prescriptions dispensed by such pharmacies to participants or beneficiaries in such plan or coverage; and

"(III) a list of all drugs dispensed by such pharmacies to participants or beneficiaries enrolled in such plan or coverage, and, with respect to each drug dispensed—

"(aa) the amount charged, per dosage unit, per 30-day supply, or per 90-day supply (as applicable) to the plan or issuer, and to participants and beneficiaries;

"(bb) the median amount charged to such plan or issuer,

and the interquartile range of the costs, per dosage unit, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of such plan or coverage;

''(cc) the lowest cost per dosage unit, per 30-day supply and per 90-day supply, for each such drug, including amounts charged to the plan or coverage and to participants and beneficiaries, that is available from any pharmacy included in the network of such plan or coverage; and

''(dd) the net acquisition cost per dosage unit, per 30-day supply, and per 90-day supply, if

such drug is subject to a maximum price discount; and

''(B) with respect to any group health plan, including group health insurance coverage offered in connection with such a plan, regardless of whether the plan or coverage is offered by a specified large employer or whether it is a specified large plan—

''(i) a summary document for the group health plan that includes such information described in clauses (i) through (iv) of subparagraph (A), as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking), that the Secretary determines useful to group health plans for purposes of selecting pharmacy benefit management services, such as an estimated net price to group health plan and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary;

''(ii) a summary document for plans and issuers to provide to participants and

beneficiaries, which shall be made available to participants or beneficiaries upon request to their group health plan (including in the case of group health insurance coverage offered in connection with such a plan), that—

"(I) contains such information described in clauses (iii), (iv), (v), and (vi), as applicable, as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking) that the Secretary determines useful to participants or beneficiaries in better understanding the plan or coverage or benefits under such plan or coverage;

"(II) contains only aggregate information; and

"(III) states that participants and beneficiaries may request specific, claims-level information required to be furnished under subsection (c) from the group health plan or health insurance issuer; and

''(iii) with respect to drugs covered by such plan or coverage during such reporting period—

''(I) the total net spending by the plan or coverage for all such drugs;

''(II) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration; and

''(III) to the extent feasible, information on the total amount of remuneration for such drugs, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer) to participants and beneficiaries;

''(iv) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section 408(b)(2)(B)(ii)(dd)(AA)) to brokerage

firms, brokers, consultants, advisors, or any other individual or firm, for—

''(I) the referral of the group health plan's or health insurance issuer's business to an entity providing pharmacy benefit management services, including the identity of the recipient of such amounts;

''(II) consideration of the entity providing pharmacy benefit management services by the group health plan or health insurance issuer; or

''(III) the retention of the entity by the group health plan or health insurance issuer;

''(v) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in such plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services under such plan or coverage, including mandatory mail and specialty home delivery programs, re-

tail and mail auto-refill programs, and cost-sharing assistance incentives directly or indirectly funded by such entity; and

''(vi) total gross spending on all drugs under the plan or coverage during the reporting period.

''(3) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE OFFERED BY A SPECIFIED LARGE EMPLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In the case of group health insurance coverage offered in connection with a group health plan that is offered by a specified large employer or is a specified large plan, such group health plan may, on an annual basis, for plan years beginning on or after the date that is 30 months after the date of enactment of this section, elect to require an entity providing pharmacy benefit management services on behalf of the health insurance issuer to submit to such group health plan a report that includes all of the information described in paragraph (2)(A), in addition to the information described in paragraph (2)(B).

''(4) PRIVACY REQUIREMENTS.—

''(A) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan or a health insur-

ance issuer offering group health insurance coverage shall report information under paragraph (1) in a manner consistent with the privacy regulations promulgated under section 13402(a) of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17932(a)) and consistent with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 in part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (or successor regulations) (referred to in this paragraph as the 'HIPAA privacy regulations') and shall restrict the use and disclosure of such information according to such privacy regulations and such HIPAA privacy regulations.

''(B) ADDITIONAL REQUIREMENTS.—

''(i) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage that submits a report under paragraph (1) shall ensure that such report contains only summary health information, as defined in section

164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

''(ii) RESTRICTIONS.—In carrying out this subsection, a group health plan shall comply with section 164.504(f) of title 45, Code of Federal Regulations (or a successor regulation), and a plan sponsor shall act in accordance with the terms of the agreement described in such section.

''(C) RULE OF CONSTRUCTION.—

''(i) Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the HIPAA privacy regulations.

''(ii) Nothing in this section shall be construed to affect the application of any Federal or State privacy or civil rights law, including the HIPAA privacy regulations, the Genetic Information Nondiscrimination Act of 2008 (Public Law 110–233) (including the amendments made by such Act), the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.), section 504 of the Rehabilitation Act of 1973 (29

U.S.C. 794), section 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. 18116), title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d), and title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e).

''(D) WRITTEN NOTICE.—Each plan year, group health plans, including with respect to group health insurance coverage offered in connection with a group health plan, shall provide to each participant or beneficiary written notice informing the participant or beneficiary of the requirement for entities providing pharmacy benefit management services on behalf of the group health plan or health insurance issuer offering group health insurance coverage to submit reports to group health plans under paragraph (1), as applicable, which may include incorporating such notification in plan documents provided to the participant or beneficiary, or providing individual notification.

''(E) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to the entity from which the report

was received or to that entity's business associates as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations) or as permitted by the HIPAA privacy regulations.

''(F) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section shall prevent an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage, from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such plan, issuer, or entity may not—

''(i) restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, or the Department of the Treasury; or

''(ii) prevent disclosure for the purposes of subsection (c), or any other public disclosure requirement under this section.

''(G) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1)

required with respect to any group health plan established by a plan sponsor that is, or is affiliated with, a drug manufacturer, drug wholesaler, or other direct participant in the drug supply chain, in order to prevent anti-competitive behavior.

''(5) STANDARD FORMAT AND REGULATIONS.—

''(A) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Secretary shall specify through rulemaking a standard format for entities providing pharmacy benefit management services on behalf of group health plans and health insurance issuers offering group health insurance coverage, to submit reports required under paragraph (1).

''(B) ADDITIONAL REGULATIONS.—Not later than 18 months after the date of enactment of this section, the Secretary shall, through rulemaking, promulgate any other final regulations necessary to implement the requirements of this section. In promulgating such regulations, the Secretary shall, to the extent practicable, align the reporting requirements

under this section with the reporting requirements under section 725.

''(c) REQUIREMENT TO PROVIDE INFORMATION TO PARTICIPANTS OR BENEFICIARIES.—A group health plan, including with respect to group health insurance coverage offered in connection with a group health plan, upon request of a participant or beneficiary, shall provide to such participant or beneficiary—

''(1) the summary document described in subsection (b)(2)(B)(ii); and

''(2) the information described in subsection (b)(2)(A)(i)(III) with respect to a claim made by or on behalf of such participant or beneficiary.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary to a report described in subsection (b)(1) or information related to compliance with subsections (a), (b), or (c) of this section or section 502(c)(13) by such issuer, plan, or entity.

''(e) DEFINITIONS.—In this section:

''(1) APPLICABLE ENTITY.—The term 'applicable entity' means—

''(A) an applicable group purchasing organization, drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), or associated third party;

''(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such a plan or issuer, or any entity described in subparagraph (A); or

''(C) such other entity as the Secretary may specify through rulemaking.

''(2) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term 'applicable group purchasing organization' means a group purchasing organization that is affiliated with or under common ownership with an entity providing pharmacy benefit management services.

''(3) CONTRACTED COMPENSATION.—The term 'contracted compensation' means the sum of any ingredient cost and dispensing fee for a drug (inclusive of the out-of-pocket costs to the participant or bene-

ficiary), or another analogous compensation structure that the Secretary may specify through regulations.

''(4) GROSS SPENDING.—The term 'gross spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated before the application of rebates, fees, alternative discounts, or other remuneration.

''(5) NET SPENDING.—The term 'net spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the application of rebates, fees, alternative discounts, or other remuneration.

''(6) PLAN SPONSOR.—The term 'plan sponsor' has the meaning given such term in section 3(16)(B).

''(7) REMUNERATION.—The term 'remuneration' has the meaning given such term by the Secretary through rulemaking, which shall be reevaluated by the Secretary every 5 years.

''(8) SPECIFIED LARGE EMPLOYER.—The term 'specified large employer' means, in connection with a group health plan (including group health insurance coverage offered in connection with such a plan) established or maintained by a single employer, with respect to a calendar year or a plan year, as applicable, an employer who employed an average of at least 100 employees on business days during the preceding calendar year or plan year and who employs at least 1 employee on the first day of the calendar year or plan year.

''(9) SPECIFIED LARGE PLAN.—The term 'specified large plan' means a group health plan (including group health insurance coverage offered in connection with such a plan) established or maintained by a plan sponsor described in clause (ii) or (iii) of section 3(16)(B) that had an average of at least 100 participants on business days during the preceding calendar year or plan year, as applicable.

''(10) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).'';

(B) in section 502 (29 U.S.C. 1132)—

(i) in subsection (a)(6), by striking ''or (9)'' and inserting ''(9), or (13)'';

(ii) in subsection (b)(3), by striking ''under subsection (c)(9)'' and inserting ''under paragraphs (9) and (13) of subsection (c)''; and

(iii) in subsection (c), by adding at the end the following:

''(13) SECRETARIAL ENFORCEMENT AUTHORITY RELATING TO OVERSIGHT OF PHARMACY BENEFIT MANAGEMENT SERVICES.—

''(A) FAILURE TO PROVIDE INFORMATION.—The Secretary may impose a penalty against a plan administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services on behalf of such a plan or issuer, or an applicable entity (as defined in section 726(f)) that violates section 726(a); an entity providing pharmacy benefit management services on behalf of such a plan or issuer that fails to provide the information required under section 726(b); or any person who causes a group health plan to fail to provide the information

required under section 726(c), in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(B) FALSE INFORMATION.—The Secretary may impose a penalty against a plan administrator of a group health plan, a health insurance issuer offering group health insurance coverage, an entity providing pharmacy benefit management services, or an applicable entity (as defined in section 726(f)) that knowingly provides false information under section 726, in an amount not to exceed $100,000 for each item of false information. Such penalty shall be in addition to other penalties as may be prescribed by law.

''(C) WAIVERS.—The Secretary may waive penalties under subparagraph (A), or extend the period of time for compliance with a requirement of this section, for an entity in violation of section 726 that has made a good-faith effort to comply with the requirements of section 726.''; and

(C) in section 732(a) (29 U.S.C. 1191a(a)), by striking ''section 711'' and inserting ''sections 711 and 726''.

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item relating to section 725 the following new item:

''Sec. 726. Oversight of entities that provide pharmacy benefit management services.''.

(c) INTERNAL REVENUE CODE OF 1986.—

(1) IN GENERAL.—Chapter 100 of the Internal Revenue Code of 1986 is amended—

(A) by adding at the end of subchapter B the following:

''SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.

''(a) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of this section (referred to in this subsection and subsection (b) as the 'effective date'), a group health plan, or an entity providing pharmacy benefit management services on behalf of such a plan, shall not enter into a contract, including an extension or renewal of a contract, entered into on or after the effective date, with an applicable entity unless such applicable entity agrees to—

''(1) not limit or delay the disclosure of information to the group health plan in such a manner that prevents an entity providing pharmacy benefit management services on behalf of a group health plan from making the reports described in subsection (b); and

''(2) provide the entity providing pharmacy benefit management services on behalf of a group health plan relevant information necessary to make the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after the effective date, in the case of any contract between a group health plan and an entity providing pharmacy benefit management services on behalf of such plan, including an extension or renewal of such a contract, entered into on or after the effective date, the entity providing pharmacy benefit management services on behalf of such a group health plan, not less frequently than every 6 months (or, at the request of a group health plan, not less frequently than quarterly, and under the same conditions, terms, and cost of the semiannual report under this subsection), shall submit to the group health plan a report in accordance with this section.

Each such report shall be made available to such group health plan in plain language, in a machine-readable format, and as the Secretary may determine, other formats. Each such report shall include the information described in paragraph (2).

''(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), the information described in this paragraph is, with respect to drugs covered by a group health plan during each reporting period—

''(A) in the case of a group health plan that is offered by a specified large employer or that is a specified large plan, and is not offered as health insurance coverage, or in the case of health insurance coverage for which the election under paragraph (3) is made for the applicable reporting period—

''(i) a list of drugs for which a claim was filed and, with respect to each such drug on such list—

''(I) the contracted compensation paid by the group health plan for each covered drug (identified by the National Drug Code) to the entity providing pharmacy benefit management

services or other applicable entity on behalf of the group health plan;

''(II) the contracted compensation paid to the pharmacy, by any entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan, for each covered drug (identified by the National Drug Code);

''(III) for each such claim, the difference between the amount paid under subclause (I) and the amount paid under subclause (II);

''(IV) the proprietary name, established name or proper name, and the National Drug Code;

''(V) for each claim for the drug (including original prescriptions and refills) and for each dosage unit of the drug for which a claim was filed, the type of dispensing channel used to furnish the drug, including retail, mail order, or specialty pharmacy;

''(VI) with respect to each drug dispensed, for each type of dispensing

channel (including retail, mail order, or specialty pharmacy)—

"(aa) whether such drug is a brand name drug or a generic drug, and—

"(AA) in the case of a brand name drug, the wholesale acquisition cost, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

"(BB) in the case of a generic drug, the average wholesale price, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

"(bb) the total number of—

"(AA) prescription claims (including original prescriptions and refills);

"(BB) participants and beneficiaries for whom a

claim for such drug was filed through the applicable dispensing channel;

"(CC) dosage units and dosage units per fill of such drug; and

"(DD) days supply of such drug per fill;

"(VII) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply to the plan after rebates, fees, alternative discounts, or other remuneration received from applicable entities;

"(VIII) the total amount of out-of-pocket spending by participants and beneficiaries on such drug, including spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan, or for which no claim is submitted under the plan;

''(IX) the total net spending on the drug;

''(X) the total amount received, or expected to be received, by the plan from any applicable entity in rebates, fees, alternative discounts, or other remuneration;

''(XI) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—

''(aa) for claims incurred during the reporting period; and

''(bb) that is related to utilization of such drug or spending on such drug; and

''(XII) to the extent feasible, information on the total amount of remuneration for such drug, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manu-

facturer (or entity administering co-payment assistance on behalf of such drug manufacturer), to the participants and beneficiaries enrolled in such plan;

''(ii) a list of each therapeutic class (as defined by the Secretary) for which a claim was filed under the group health plan during the reporting period, and, with respect to each such therapeutic class—

''(I) the total gross spending on drugs in such class before rebates, price concessions, alternative discounts, or other remuneration from applicable entities;

''(II) the net spending in such class after such rebates, price concessions, alternative discounts, or other remuneration from applicable entities;

''(III) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative dis-

counts, or other remuneration from such entities—

"(aa) for claims incurred during the reporting period; and

"(bb) that is related to utilization of drugs or drug spending;

"(IV) the average net spending per 30-day supply and per 90-day supply by the plan and its participants and beneficiaries, among all drugs within the therapeutic class for which a claim was filed during the reporting period;

"(V) the number of participants and beneficiaries who filled a prescription for a drug in such class, including the National Drug Code for each such drug;

"(VI) if applicable, a description of the formulary tiers and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that class; and

"(VII) the total out-of-pocket spending under the plan by partici-

pants and beneficiaries, including spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or for which no claim is submitted under the plan;

''(iii) with respect to any drug for which gross spending under the group health plan exceeded $10,000 during the reporting period or, in the case that gross spending under the group health plan exceeded $10,000 during the reporting period with respect to fewer than 50 drugs, with respect to the 50 prescription drugs with the highest spending during the reporting period—

''(I) a list of all other drugs in the same therapeutic class as such drug;

''(II) if applicable, the rationale for the formulary placement of such drug in that therapeutic category or class, selected from a list of standard rationales established by the Sec-

retary, in consultation with stakeholders; and

''(III) any change in formulary placement compared to the prior plan year; and

''(iv) in the case that such plan (or an entity providing pharmacy benefit management services on behalf of such plan) has an affiliated pharmacy or pharmacy under common ownership, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and cost sharing assistance incentives funded by an entity providing pharmacy benefit services—

''(I) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan to fill prescriptions at mail order, specialty, or retail pharmacies;

''(II) the percentage of total prescriptions dispensed by such pharmacies to participants or beneficiaries in such plan; and

"(III) a list of all drugs dispensed by such pharmacies to participants or beneficiaries enrolled in such plan, and, with respect to each drug dispensed—

"(aa) the amount charged, per dosage unit, per 30-day supply, or per 90-day supply (as applicable) to the plan, and to participants and beneficiaries;

"(bb) the median amount charged to such plan, and the interquartile range of the costs, per dosage unit, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of such plan;

"(cc) the lowest cost per dosage unit, per 30-day supply

and per 90-day supply, for each such drug, including amounts charged to the plan and to participants and beneficiaries, that is available from any pharmacy included in the network of such plan; and

''(dd) the net acquisition cost per dosage unit, per 30-day supply, and per 90-day supply, if such drug is subject to a maximum price discount; and

''(B) with respect to any group health plan, regardless of whether the plan is offered by a specified large employer or whether it is a specified large plan—

''(i) a summary document for the group health plan that includes such information described in clauses (i) through (iv) of subparagraph (A), as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking), that the Secretary determines useful to group health plans for purposes of select-

ing pharmacy benefit management services, such as an estimated net price to group health plan and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary;

''(ii) a summary document for plans to provide to participants and beneficiaries, which shall be made available to participants or beneficiaries upon request to their group health plan, that—

''(I) contains such information described in clauses (iii), (iv), (v), and (vi), as applicable, as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking) that the Secretary determines useful to participants or beneficiaries in better understanding the plan or benefits under such plan;

''(II) contains only aggregate information; and

''(III) states that participants and beneficiaries may request specific,

claims-level information required to be furnished under subsection (c) from the group health plan; and

''(iii) with respect to drugs covered by such plan during such reporting period—

''(I) the total net spending by the plan for all such drugs;

''(II) the total amount received, or expected to be received, by the plan from any applicable entity in rebates, fees, alternative discounts, or other remuneration; and

''(III) to the extent feasible, information on the total amount of remuneration for such drugs, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer) to participants and beneficiaries;

''(iv) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section

408(b)(2)(B)(ii)(dd)(AA) of the Employee Retirement Income Security Act (29 U.S.C. 1108(b)(2)(B)(ii)(dd)(AA))) to brokerage firms, brokers, consultants, advisors, or any other individual or firm, for—

''(I) the referral of the group health plan's business to an entity providing pharmacy benefit management services, including the identity of the recipient of such amounts;

''(II) consideration of the entity providing pharmacy benefit management services by the group health plan; or

''(III) the retention of the entity by the group health plan;

''(v) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in such plan to fill prescriptions at mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services under such plan, including mandatory mail and specialty home delivery pro-

grams, retail and mail auto-refill programs, and cost-sharing assistance incentives directly or indirectly funded by such entity; and

''(vi) total gross spending on all drugs under the plan during the reporting period.

''(3) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE OFFERED BY A SPECIFIED LARGE EMPLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In the case of group health insurance coverage offered in connection with a group health plan that is offered by a specified large employer or is a specified large plan, such group health plan may, on an annual basis, for plan years beginning on or after the date that is 30 months after the date of enactment of this section, elect to require an entity providing pharmacy benefit management services on behalf of the health insurance issuer to submit to such group health plan a report that includes all of the information described in paragraph (2)(A), in addition to the information described in paragraph (2)(B).

''(4) PRIVACY REQUIREMENTS.—

''(A) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan shall report infor-

mation under paragraph (1) in a manner consistent with the privacy regulations promulgated under section 13402(a) of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17932(a)) and consistent with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 in part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (or successor regulations) (referred to in this paragraph as the 'HIPAA privacy regulations') and shall restrict the use and disclosure of such information according to such privacy regulations and such HIPAA privacy regulations.

''(B) ADDITIONAL REQUIREMENTS.—

''(i) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan that submits a report under paragraph (1) shall ensure that such report contains only summary health information, as defined in section 164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

''(ii) RESTRICTIONS.—In carrying out this subsection, a group health plan shall comply with section 164.504(f) of title 45, Code of Federal Regulations (or a successor regulation), and a plan sponsor shall act in accordance with the terms of the agreement described in such section.

''(C) RULE OF CONSTRUCTION.—

''(i) Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the HIPAA privacy regulations.

''(ii) Nothing in this section shall be construed to affect the application of any Federal or State privacy or civil rights law, including the HIPAA privacy regulations, the Genetic Information Nondiscrimination Act of 2008 (Public Law 110–233) (including the amendments made by such Act), the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.), section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), section 1557 of the Patient Protection and Affordable Care Act (42

U.S.C. 18116), title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d), and title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e).

''(D) WRITTEN NOTICE.—Each plan year, group health plans shall provide to each participant or beneficiary written notice informing the participant or beneficiary of the requirement for entities providing pharmacy benefit management services on behalf of the group health plan to submit reports to group health plans under paragraph (1), as applicable, which may include incorporating such notification in plan documents provided to the participant or beneficiary, or providing individual notification.

''(E) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to the entity from which the report was received or to that entity's business associates as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations) or as permitted by the HIPAA privacy regulations.

''(F) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section shall prevent an entity providing pharmacy benefit management services on behalf of a group health plan, from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such plan or entity may not—

''(i) restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, or the Department of the Treasury; or

''(ii) prevent disclosure for the purposes of subsection (c), or any other public disclosure requirement under this section.

''(G) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required with respect to any group health plan established by a plan sponsor that is, or is affiliated with, a drug manufacturer, drug wholesaler, or other direct participant in the drug supply chain, in order to prevent anti-competitive behavior.

"(5) STANDARD FORMAT AND REGULATIONS.—

"(A) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Secretary shall specify through rulemaking a standard format for entities providing pharmacy benefit management services on behalf of group health plans, to submit reports required under paragraph (1).

"(B) ADDITIONAL REGULATIONS.—Not later than 18 months after the date of enactment of this section, the Secretary shall, through rulemaking, promulgate any other final regulations necessary to implement the requirements of this section. In promulgating such regulations, the Secretary shall, to the extent practicable, align the reporting requirements under this section with the reporting requirements under section 9825.

"(c) REQUIREMENT TO PROVIDE INFORMATION TO PARTICIPANTS OR BENEFICIARIES.—A group health plan, upon request of a participant or beneficiary, shall provide to such participant or beneficiary—

"(1) the summary document described in subsection (b)(2)(B)(ii); and

''(2) the information described in subsection (b)(2)(A)(i)(III) with respect to a claim made by or on behalf of such participant or beneficiary.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary to a report described in subsection (b)(1) or information related to compliance with subsections (a), (b), or (c) of this section or section 4980D(g) by such issuer, plan, or entity.

''(e) DEFINITIONS.—In this section:

''(1) APPLICABLE ENTITY.—The term 'applicable entity' means—

''(A) an applicable group purchasing organization, drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), or associated third party;

''(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such

a plan or issuer, or any entity described in subparagraph (A); or

''(C) such other entity as the Secretary may specify through rulemaking.

''(2) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term 'applicable group purchasing organization' means a group purchasing organization that is affiliated with or under common ownership with an entity providing pharmacy benefit management services.

''(3) CONTRACTED COMPENSATION.—The term 'contracted compensation' means the sum of any ingredient cost and dispensing fee for a drug (inclusive of the out-of-pocket costs to the participant or beneficiary), or another analogous compensation structure that the Secretary may specify through regulations.

''(4) GROSS SPENDING.—The term 'gross spending', with respect to prescription drug benefits under a group health plan, means the amount spent by a group health plan on prescription drug benefits, calculated before the application of rebates, fees, alternative discounts, or other remuneration.

''(5) NET SPENDING.—The term 'net spending', with respect to prescription drug benefits under a

group health plan, means the amount spent by a group health plan on prescription drug benefits, calculated after the application of rebates, fees, alternative discounts, or other remuneration.

''(6) PLAN SPONSOR.—The term 'plan sponsor' has the meaning given such term in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(16)(B)).

''(7) REMUNERATION.—The term 'remuneration' has the meaning given such term by the Secretary, through rulemaking, which shall be reevaluated by the Secretary every 5 years.

''(8) SPECIFIED LARGE EMPLOYER.—The term 'specified large employer' means, in connection with a group health plan established or maintained by a single employer, with respect to a calendar year or a plan year, as applicable, an employer who employed an average of at least 100 employees on business days during the preceding calendar year or plan year and who employs at least 1 employee on the first day of the calendar year or plan year.

''(9) SPECIFIED LARGE PLAN.—The term 'specified large plan' means a group health plan established or maintained by a plan sponsor described in clause (ii) or (iii) of section 3(16)(B) of the Em-

ployee Retirement Income Security Act of 1974 (29 U.S.C. 1002(16)(B)) that had an average of at least 100 participants on business days during the preceding calendar year or plan year, as applicable.

''(10) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).'';

(2) EXCEPTION FOR CERTAIN GROUP HEALTH PLANS.—Section 9831(a)(2) of the Internal Revenue Code of 1986 is amended by inserting ''other than with respect to section 9826,'' before ''any group health plan''.

(3) ENFORCEMENT.—Section 4980D of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

''(g) APPLICATION TO REQUIREMENTS IMPOSED ON CERTAIN ENTITIES PROVIDING PHARMACY BENEFIT MANAGEMENT SERVICES.—In the case of any requirement under section 9826 that applies with respect to an entity providing pharmacy benefit management services on behalf of a group health plan, any reference in this section to such group health plan (and the reference in subsection

(e)(1) to the employer) shall be treated as including a reference to such entity.''.

(4) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

''Sec. 9826. Oversight of entities that provide pharmacy benefit management services.''.

SEC. 902. FULL REBATE PASS THROUGH TO PLAN; EXCEPTION FOR INNOCENT PLAN FIDUCIARIES.

(a) IN GENERAL.—Section 408(b)(2) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)) is amended—

(1) in subparagraph (B)(viii)—

(A) by redesignating subclauses (II) through (IV) as subclauses (III) through (V), respectively;

(B) in subclause (I)—

(i) by striking ''subclause (II)'' and inserting ''subclause (III)''; and

(ii) by striking ''subclauses (II) and (III)'' and inserting ''subclauses (III) and (IV)''; and

(C) by inserting after subclause (I) the following:

''(II) Pursuant to subsection (a), subparagraphs (C) and (D) of section 406(a)(1) shall not apply to a responsible plan fiduciary, notwithstanding any failure to remit required amounts under subparagraph (C)(i), if the following conditions are met:

''(aa) The responsible plan fiduciary did not know that the covered service provider failed or would fail to make required remittances and reasonably believed that the covered service provider remitted such required amounts.

''(bb) The responsible plan fiduciary, upon discovering that the covered service provider failed to remit the required amounts, requests in writing that the covered service provider remit such amounts.

''(cc) If the covered service provider fails to comply with a written request described in subclause (III) within 90 days of the request, the responsible plan fiduciary notifies the Secretary of the covered service provider's failure, in accordance with subclauses (III) and (IV).''; and

(2) by adding at the end the following:

''(C)(i)(I) For plan years beginning on or after the date that is 30 months after the date of enactment of this subparagraph (referred to in this clause as the 'effective date'), no contract or arrangement or renewal or extension of a contract or arrangement, entered into on or after the effective date, for services between a covered plan and a covered service provider, through a health insurance issuer offering group health insurance coverage, a third-party administrator, an entity providing pharmacy benefit management services, or other entity, for pharmacy benefit management services, is reasonable within the meaning of this paragraph unless such entity providing pharmacy benefit management services—

''(aa) remits 100 percent of rebates, fees, alternative discounts, and other remuneration received from any applicable entity that are related to utilization of drugs or drug spending under such health plan or health insurance coverage, to the group health plan or health insurance issuer offering group health insurance coverage; and

''(bb) does not enter into any contract for pharmacy benefit management services on behalf of such a plan or coverage, with an applica-

ble entity unless 100 percent of rebates, fees, alternative discounts, and other remuneration received under such contract that are related to the utilization of drugs or drug spending under such group health plan or health insurance coverage are remitted to the group health plan or health insurance issuer by the entity providing pharmacy benefit management services.

''(II) Nothing in subclause (I) shall be construed to affect the term of a contract or arrangement, as in effect on the effective date (as described in such subclause), except that such subclause shall apply to any renewal or extension of such a contract or arrangement entered into on or after such effective date, as so described.

''(ii) With respect to such rebates, fees, alternative discounts, and other remuneration—

''(I) the rebates, fees, alternative discounts, and other remuneration under clause (i)(I) shall be—

''(aa) remitted—

''(AA) on a quarterly basis, to the group health plan or the group health insurance issuer, not later than

90 days after the end of each quarter; or

''(BB) in the case of an underpayment in a remittance for a prior quarter, as soon as practicable, but not later than 90 days after notice of the underpayment is first given;

''(bb) fully disclosed and enumerated to the group health plan or health insurance issuer; and

''(cc) returned to the covered service provider for pharmacy benefit management services on behalf of the group health plan if any audit by a plan sponsor, issuer or a third party designated by a plan sponsor, indicates that the amounts received are incorrect after such amounts have been paid to the group health plan or health insurance issuer;

''(II) the Secretary may establish procedures for the remittance of rebates fees, alternative discounts, and other remuneration under subclause (I)(aa) and the disclosure of rebates, fees, alternative discounts, and other remuneration under subclause (I)(bb); and

"(III) the records of such rebates, fees, alternative discounts, and other remuneration shall be available for audit by the plan sponsor, issuer, or a third party designated by a plan sponsor, not less than once per plan year.

"(iii) To ensure that an entity providing pharmacy benefit management services is able to meet the requirements of clause (ii)(I), a rebate aggregator (or other purchasing entity designed to aggregate rebates) and an applicable group purchasing organization shall remit such rebates to the entity providing pharmacy benefit management services not later than 45 days after the end of each quarter.

"(iv) A third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or a covered service provider for pharmacy benefit management services under such health plan or health insurance coverage shall make rebate contracts with rebate aggregators or drug manufacturers available for audit by such plan sponsor or designated third party, subject to reasonable restrictions (as determined by the Secretary) on confidentiality to prevent re-disclosure of

such contracts or use of such information in audits for purposes unrelated to this section.

''(v) Audits carried out under clauses (ii)(III) and (iv) shall be performed by an auditor selected by the responsible plan fiduciary. Payment for such audits shall not be made, whether directly or indirectly, by the entity providing pharmacy benefit management services.

''(vi) Nothing in this subparagraph shall be construed to—

''(I) prohibit reasonable payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not described in this subparagraph, provided that such fees are transparent and quantifiable to group health plans and health insurance issuers;

''(II) require a third-party administrator of a group health plan or covered service provider for pharmacy benefit management services under such health plan or health insurance coverage to remit bona fide service fees to the group health plan;

''(III) limit the ability of a group health plan or health insurance issuer to pass through

rebates, fees, alternative discounts, and other remuneration to the participant or beneficiary; or

''(IV) modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 in part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (or successor regulations).

''(vii) For purposes of this subparagraph—

''(I) the terms 'applicable entity' and 'applicable group purchasing organization' have the meanings given such terms in section 726(e);

''(II) the terms 'covered plan', 'covered service provider', and 'responsible plan fiduciary' have the meanings given such terms in subparagraph (B); and

''(III) the terms 'group health insurance coverage', 'health insurance coverage', and 'health insurance issuer' have the meanings given such terms in section 733.''.

(b) RULE OF CONSTRUCTION.—Subclause (II)(aa) of section 408(b)(2)(B)(viii) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)(B)(viii)), as amended by subsection (a), shall not be construed to relieve or limit a responsible plan fiduciary from the duty to monitor the practices of any covered service provider that contracts with the applicable covered plan, including for the purposes of ensuring the reasonableness of compensation. For purposes of this subsection, the terms ''covered plan'', ''covered service provider'', and ''responsible plan fiduciary'' have the meanings given such terms in section 408(b)(2)(B)(ii) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)(B)(ii)).

(c) CLARIFICATION OF COVERED SERVICE PROVIDER.—

(1) SERVICES.—

(A) IN GENERAL.—Section 408(b)(2)(B)(ii)(I)(bb) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)(B)(ii)(I)(bb)) is amended—

(i) in subitem (AA) by striking ''Brokerage services,'' and inserting ''Services (including brokerage services),''; and

(ii) in subitem (BB)—

(I) by striking ''Consulting,'' and inserting ''Other services,''; and

(II) by striking ''related to the development or implementation of plan design'' and all that follows through the period at the end and inserting ''including any of the following: plan design, insurance or insurance product selection (including vision and dental), recordkeeping, medical management, benefits administration selection (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness design and management services, transparency tools, group purchasing organization agreements and services, participation in and services from preferred vendor panels, disease management, compliance services, employee assistance programs, or third-party administration services, or consulting services related to any such services.''.

(B) SENSE OF CONGRESS.—It is the sense of Congress that the amendment made by subparagraph (A) clarifies the existing requirement of covered service providers with respect to services described in section 408(b)(2)(B)(ii)(I)(bb)(BB) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)(B)(ii)(I)(bb)(BB)) that were in effect since the application date described in section 202(e) of the No Surprises Act (Public Law 116–260; 29 U.S.C. 1108 note), and does not impose any additional requirement under section 408(b)(2)(B) of such Act.

(2) CERTAIN ARRANGEMENTS FOR PHARMACY BENEFIT MANAGEMENT SERVICES CONSIDERED AS INDIRECT.—

(A) IN GENERAL.—Section 408(b)(2)(B)(i) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)(B)(i)) is amended—

(i) by striking ''requirements of this clause'' and inserting ''requirements of this subparagraph''; and

(ii) by adding at the end the following: ''For purposes of applying section

406(a)(1)(C) with respect to a transaction described under this subparagraph or subparagraph (C), a contract or arrangement for services between a covered plan and an entity providing services to the plan, including a health insurance issuer providing health insurance coverage in connection with the covered plan, in which such entity contracts, in connection with such plan, with a service provider for pharmacy benefit management services, shall be considered an indirect furnishing of goods, services, or facilities between the covered plan and the service provider for pharmacy benefit management services acting as the party in interest.''.

(B) HEALTH INSURANCE ISSUER AND HEALTH INSURANCE COVERAGE DEFINED.—Section 408(b)(2)(B)(ii)(I)(aa) of such Act (29 U.S.C. 1108(b)(2)(B)(ii)(I)(aa)) is amended by inserting before the period at the end ''and the terms 'health insurance coverage' and 'health insurance issuer' have the meanings given such terms in section 733(b)''.

(C) TECHNICAL AMENDMENT.—Section 408(b)(2)(B)(ii)(I)(aa) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)(B)(ii)(I)(aa)) is amended by inserting ''in'' after ''defined''.

SEC. 903. INCREASING TRANSPARENCY IN GENERIC DRUG APPLICATIONS.

(a) IN GENERAL.—Section 505(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)) is amended by adding at the end the following:

''(H)(i) Upon request (in controlled correspondence or an analogous process) by a person that has submitted or intends to submit an abbreviated application under this subsection for a drug that is required by regulation to contain one or more of the same inactive ingredients in the same concentrations as the listed drug referred to, or for which the Secretary determines there is a scientific justification for an approach that is in vitro, in whole or in part, to be used to demonstrate bioequivalence for a drug if such a drug contains one or more of the same inactive ingredients in the same concentrations as the listed drug referred to, the Secretary shall inform the person whether such drug is qualitatively and quantitatively the same as the listed drug. The Secretary may also provide such information to such a person on the Secretary's own initiative

during the review of an abbreviated application under this subsection for such drug.

''(ii) Notwithstanding section 301(j), if the Secretary determines that such drug is not qualitatively or quantitatively the same as the listed drug, the Secretary shall identify and disclose to the person—

''(I) the ingredient or ingredients that cause such drug not to be qualitatively or quantitatively the same as the listed drug; and

''(II) for any ingredient for which there is an identified quantitative deviation, the amount of such deviation.

''(iii) If the Secretary determines that such drug is qualitatively and quantitatively the same as the listed drug, the Secretary shall not change or rescind such determination after the submission of an abbreviated application for such drug under this subsection unless—

''(I) the formulation of the listed drug has been changed and the Secretary has determined that the prior listed drug formulation was withdrawn for reasons of safety or effectiveness; or

''(II) the Secretary makes a written determination that the prior determination must be changed because an error has been identified.

''(iv) If the Secretary makes a written determination described in clause (iii)(II), the Secretary shall provide notice and a copy of the written determination to the person making the request under clause (i).

''(v) The disclosures authorized under clauses (i) and (ii) are disclosures authorized by law, including for purposes of section 1905 of title 18, United States Code. This subparagraph shall not otherwise be construed to authorize the disclosure of nonpublic qualitative or quantitative information about the ingredients in a listed drug, or to affect the status, if any, of such information as trade secret or confidential commercial information for purposes of section 301(j) of this Act, section 552 of title 5, United States Code, or section 1905 of title 18, United States Code.''.

(b) GUIDANCE.—

(1) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance, or update guidance, describing how the Secretary will determine whether a drug is qualitatively and quantitatively the same as the listed drug (as such terms are used in section 505(j)(3)(H) of the Federal Food, Drug, and Cos-

metic Act, as added by subsection (a)), including with respect to assessing pH adjusters.

(2) PROCESS.—In issuing guidance under this subsection, the Secretary of Health and Human Services shall—

(A) publish draft guidance;

(B) provide a period of at least 60 days for comment on the draft guidance; and

(C) after considering any comments received and not later than one year after the close of the comment period on the draft guidance, publish final guidance.

(c) APPLICABILITY.—Section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies beginning on the date of enactment of this Act, irrespective of the date on which the guidance required by subsection (b) is finalized.

SEC. 904. TITLE 35 AMENDMENTS.

(a) IN GENERAL.—Section 271(e) of title 35, United States Code, is amended—

(1) in paragraph (2)(C), in the flush text following clause (ii), by adding at the end the following: ''With respect to a submission described in clause (ii), the act of infringement shall extend to any patent that claims the biological product, a

method of using the biological product, or a method or product used to manufacture the biological product.''; and

(2) by adding at the end the following:

''(7)(A) Subject to subparagraphs (C), (D), and (E), if the sponsor of an approved application for a reference product, as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) (referred to in this paragraph as the 'reference product sponsor'), brings an action for infringement under this section against an applicant for approval of a biological product under section 351(k) of such Act that references that reference product (referred to in this paragraph as the 'subsection (k) applicant'), the reference product sponsor may assert in the action a total of not more than 20 patents of the type described in subparagraph (B), not more than 10 of which shall have issued after the date specified in section 351(l)(7)(A) of such Act.

''(B) The patents described in this subparagraph are patents that satisfy each of the following requirements:

''(i) Patents that claim the biological product that is the subject of an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) (or a use of that product) or a method or

product used in the manufacture of such biological product.

''(ii) Patents that are included on the list of patents described in paragraph (3)(A) of section 351(l) of the Public Health Service Act (42 U.S.C. 262(l)), including as provided under paragraph (7) of such section 351(l).

''(iii) Patents that—

''(I) have an actual filing date of more than 4 years after the date on which the reference product is approved; or

''(II) include a claim to a method in a manufacturing process that is not used by the reference product sponsor.

''(C) The court in which an action described in subparagraph (A) is brought may increase the number of patents limited under that subparagraph—

''(i) if the request to increase that number is made without undue delay; and

''(ii)(I) if the interest of justice so requires; or

''(II) for good cause shown, which—

''(aa) shall be established if the subsection (k) applicant fails to provide information required section 351(k)(2)(A) of the Public Health Service Act (42 U.S.C. 262(k)(2)(A))

that would enable the reference product sponsor to form a reasonable belief with respect to whether a claim of infringement under this section could reasonably be asserted; and

''(bb) may be established—

''(AA) if there is a material change to the biological product (or process with respect to the biological product) of the subsection (k) applicant that is the subject of the application;

''(BB) if, with respect to a patent on the supplemental list described in section 351(l)(7)(A) of Public Health Service Act (42 U.S.C. 262(l)(7)(A)), the patent would have issued before the date specified in such section 351(l)(7)(A) but for the failure of the Office to issue the patent or a delay in the issuance of the patent, as described in paragraph (1) of section 154(b) and subject to the limitations under paragraph (2) of such section 154(b); or

''(CC) for another reason that shows good cause, as determined appropriate by the court.

''(D) In determining whether good cause has been shown for the purposes of subparagraph (C)(ii)(II), a court may consider whether the reference product sponsor has provided a reasonable description of the identity and relevance of any information beyond the subsection (k) application that the court believes is necessary to enable the court to form a belief with respect to whether a claim of infringement under this section could reasonably be asserted.

''(E) The limitation imposed under subparagraph (A)—

''(i) shall apply only if the subsection (k) applicant completes all actions required under paragraphs (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of section 351(l) of the Public Health Service Act (42 U.S.C. 262(l)); and

''(ii) shall not apply with respect to any patent that claims, with respect to a biological product, a method for using that product in therapy, diagnosis, or prophylaxis, such as an indication or method of treatment or other condition of use.''.

(b) APPLICABILITY.—The amendments made by subsection (a) shall apply with respect to an application submitted under section 351(k) of the Public Health Service

Act (42 U.S.C. 262(k)) on or after the date of enactment of this Act.

TITLE X—MISCELLANEOUS

SEC. 1001. EXTENSION OF SAFE HARBOR FOR ABSENCE OF DEDUCTIBLE FOR TELEHEALTH.

Section 223(c)(2)(E)(ii) of the Internal Revenue Code of 1986 is amended to read as follows:

''(ii) SAFE HARBOR FOR ABSENCE OF DEDUCTIBLE FOR TELEHEALTH.—

''(I) IN GENERAL.—In the case of an eligible month or an eligible plan year, a plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for telehealth and other remote care services.

''(II) ELIGIBLE MONTH.—For purposes of this clause, the term 'eligible month' means months beginning after March 31, 2022, and before January 1, 2023, and months beginning after March 31, 2025, and before January 1, 2026.

''(III) ELIGIBLE PLAN YEAR.—For purposes of this clause, the term

‘eligible plan year’ means plan years beginning—

“(aa) on or before December 31, 2021,

“(bb) after December 31, 2022, and before January 1, 2025, or

“(cc) after December 31, 2024, and before January 1, 2027.”.

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