

1                   **DIVISION \_\_\_\_\_—HEALTH**

2   **SEC. 1. SHORT TITLE; TABLE OF CONTENTS.**

3           (a) SHORT TITLE.—This division may be cited as the  
4   “**[\_\_\_\_\_]**”.

5           (b) TABLE OF CONTENTS.—The table of contents for  
6   this division 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

#### Subtitle A—Reauthorize Child Welfare Services and Strengthen State and Tribal Child Support Program

- Sec. 301. Short title.

#### PART 1—CHILD WELFARE REAUTHORIZATION AND MODERNIZATION

- Sec. 311. Short title; references.
- Sec. 312. Reauthorization of child welfare programs.
- Sec. 313. Enhancements to the court improvement program.
- Sec. 314. Expanding regional partnership grants to address parental substance use disorder as cause of child removal.
- Sec. 315. Modernization; reducing administrative burden.
- Sec. 316. Streamlining funding for Indian tribes.
- Sec. 317. Accelerating access to Family First prevention services.
- Sec. 318. Strengthening support for youth aging out of foster care.
- Sec. 319. Recognizing the importance of relative and kinship caregivers.

- Sec. 320. Avoiding neglect by addressing poverty.
- Sec. 321. Strengthening support for caseworkers.
- Sec. 322. Demonstration projects for improving relationships between incarcerated parents and children in foster care.
- Sec. 323. Guidance to States on improving data collection and reporting for youth in residential treatment programs.
- Sec. 324. Streamlining research, training, and technical assistance funding.
- Sec. 325. Report on post adoption and subsidized guardianship services.
- Sec. 326. Effective date.

#### PART 2—STRENGTHENING STATE AND TRIBAL CHILD SUPPORT

- Sec. 331. Short title.
- Sec. 332. Improving the effectiveness of tribal child support enforcement agencies.

##### Subtitle B—Other Matters

- Sec. 341. Sexual risk avoidance education extension.
- Sec. 342. Personal responsibility education extension.
- Sec. 343. Extension of funding for family-to-family health information centers.

#### 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.
- 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.

##### Subtitle A—Prevention

- 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.
- Sec. 514. Support for individuals and families impacted by fetal alcohol spectrum disorder.
- Sec. 515. Promoting state choice in PDMP systems.
- Sec. 516. First responder training program.
- Sec. 517. Donald J. Cohen National Child Traumatic Stress Initiative.
- Sec. 518. Protecting suicide prevention lifeline from cybersecurity incidents.
- Sec. 519. Bruce's law.
- Sec. 520. Guidance on at-home drug disposal systems.
- Sec. 521. Assessment of opioid drugs and actions.
- Sec. 522. Grant program for State and Tribal response to opioid use disorders.

##### Subtitle B—Treatment

- Sec. 531. Residential treatment program for pregnant and postpartum women.

- Sec. 532. Improving access to addiction medicine providers.
- Sec. 533. Mental and behavioral health education and training grants.
- Sec. 534. Loan repayment program for substance use disorder treatment workforce.
- Sec. 535. Development and dissemination of model training programs for substance use disorder patient records.
- Sec. 536. Task force on best practices for trauma-informed identification, referral, and support.
- Sec. 537. Grants to enhance access to substance use disorder treatment.
- Sec. 538. State guidance related to individuals with serious mental illness and children with serious emotional disturbance.
- Sec. 539. Reviewing the scheduling of approved products containing a combination of buprenorphine and naloxone.

#### Subtitle C—Recovery

- Sec. 541. Building communities of recovery.
- Sec. 542. Peer support technical assistance center.
- Sec. 543. Comprehensive opioid recovery centers.
- Sec. 544. Youth prevention and recovery.
- Sec. 545. CAREER Act.
- Sec. 546. Addressing economic and workforce impacts of the opioid crisis.

#### Subtitle D—Miscellaneous Matters

- Sec. 551. Delivery of a controlled substance by a pharmacy to a prescribing practitioner.
- Sec. 552. Technical correction on controlled substances dispensing.
- Sec. 553. Required training for prescribers of controlled substances.
- Sec. 554. Extension of temporary order for fentanyl-related substances.

### TITLE VI—PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND RESPONSE

- Sec. 601. Short title.

#### Subtitle A—State and Local Readiness and Response

- Sec. 611. Temporary reassignment of State and local personnel during a public health emergency.
- Sec. 612. Public Health Emergency Preparedness program.
- Sec. 613. Hospital Preparedness Program.
- Sec. 614. Facilities and capacities of the Centers for Disease Control and Prevention to combat public health security threats.
- Sec. 615. Pilot program to support State medical stockpiles.
- Sec. 616. Enhancing domestic wastewater surveillance for pathogen detection.
- Sec. 617. Reauthorization of Mosquito Abatement for Safety and Health program.

#### Subtitle B—Federal Planning and Coordination

- Sec. 621. All-Hazards Emergency Preparedness and Response.
- Sec. 622. National Health Security Strategy.
- Sec. 623. Improving development and distribution of diagnostic tests.
- Sec. 624. Combating antimicrobial resistance.
- Sec. 625. Strategic National Stockpile and material threats.
- Sec. 626. Medical countermeasures for viral threats with pandemic potential.

- Sec. 627. Public Health Emergency Medical Countermeasures Enterprise.
- Sec. 628. Fellowship and training programs.
- Sec. 629. Regional biocontainment research laboratories.
- Sec. 629A. Limitation related to countries of concern conducting certain research.

#### Subtitle C—Addressing the Needs of All Individuals

- Sec. 631. Improving access to certain programs.
- Sec. 632. Supporting at-risk individuals during emergency responses.
- Sec. 633. National advisory committees.
- Sec. 634. National Academies study on prizes.

#### Subtitle D—Additional Reauthorizations

- Sec. 641. Medical countermeasure priority review voucher.
- Sec. 642. Epidemic Intelligence Service.
- Sec. 643. Monitoring and distribution of certain medical countermeasures.
- Sec. 644. Regional health care emergency preparedness and response systems.
- Sec. 645. Emergency system for advance registration of volunteer health professionals.
- Sec. 646. Ensuring collaboration and coordination in medical countermeasure development.
- Sec. 647. Military and civilian partnership for trauma readiness.
- Sec. 648. National Disaster Medical System.
- Sec. 649. Volunteer Medical Reserve Corps.
- Sec. 649A. Epidemiology-laboratory capacity.

### TITLE VII—PUBLIC HEALTH PROGRAMS

- Sec. 701. Action for dental health.
- Sec. 702. PREEMIE.
- Sec. 703. Preventing maternal deaths.
- Sec. 704. Sickle cell disease prevention and treatment.
- Sec. 705. Traumatic brain injuries.
- Sec. 706. Lifespan respite care.
- Sec. 707. Dr. Lorna Breen health care provider protection.
- Sec. 708. Gabriella Miller kids first research.
- Sec. 709. SCREENS for Cancer.
- Sec. 710. DeOndra Dixon INCLUDE Project.
- Sec. 711. IMPROVE Initiative.
- Sec. 712. Organ Procurement and Transplantation Network.
- Sec. 713. Honor Our Living Donors.
- Sec. 714. Program for pediatric studies of drugs.

### 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.
- Sec. 802. Ensuring completion of pediatric study requirements.
- Sec. 803. FDA report on PREA enforcement.
- Sec. 804. Extension of authority to issue priority review vouchers to encourage treatments for rare pediatric diseases.
- Sec. 805. Limitations on exclusive approval or licensure of orphan drugs.

## Subtitle B—United States-Abraham Accords Cooperation and Security

Sec. 811. Establishment of Abraham Accords Office within Food and Drug Administration.

## TITLE IX—LOWERING PRESCRIPTION DRUG COSTS

Sec. 901. Oversight of pharmacy benefit management services.

Sec. 902. Full rebate pass through to plan; exception for innocent plan fiduciaries.

Sec. 903. Increasing transparency in generic drug applications.

Sec. 904. Title 35 amendments.

## TITLE X—MISCELLANEOUS

Sec. 1001. Two-year extension of safe harbor for absence of deductible for telehealth.

**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

1           such State that exceed the minimum nec-  
2           essary for such State to provide payment  
3           to an eligible out-of-State provider under  
4           such State plan (or a waiver of such plan),  
5           such as the provider’s name and National  
6           Provider Identifier (and such other infor-  
7           mation specified by the Secretary); and

8           “(ii) provides that an eligible out-of-  
9           State provider that enrolls as a partici-  
10          pating provider in the State plan (or a  
11          waiver of such plan) through such process  
12          shall be so enrolled for a 5-year period, un-  
13          less the provider is terminated or excluded  
14          from participation during such period.

15          “(B) DEFINITIONS.—In this paragraph:

16               “(i) ELIGIBLE OUT-OF-STATE PRO-  
17          VIDER.—The term ‘eligible out-of-State  
18          provider’ means, with respect to a State, a  
19          provider—

20                       “(I) that is located in any other  
21                       State;

22                       “(II) that—

23                               “(aa) was determined by the  
24                               Secretary to have a limited risk  
25                               of fraud, waste, and abuse for

1 purposes of determining the level  
2 of screening to be conducted  
3 under section 1866(j)(2), has  
4 been so screened under such sec-  
5 tion 1866(j)(2), and is enrolled in  
6 the Medicare program under title  
7 XVIII; or

8 “(bb) was determined by the  
9 State agency administering or su-  
10 pervising the administration of  
11 the State plan (or a waiver of  
12 such plan) of such other State to  
13 have a limited risk of fraud,  
14 waste, and abuse for purposes of  
15 determining the level of screening  
16 to be conducted under paragraph  
17 (1) of this subsection, has been  
18 so screened under such para-  
19 graph (1), and is enrolled under  
20 such State plan (or a waiver of  
21 such plan); and

22 “(III) that has not been—

23 “(aa) excluded from partici-  
24 pation in any Federal health care



1 program pursuant to section  
2 1128 or 1128A;

3 “(bb) excluded from partici-  
4 pation in the State plan (or a  
5 waiver of such plan) pursuant to  
6 part 1002 of title 42, Code of  
7 Federal Regulations (or any suc-  
8 cessor regulation), or State law;  
9 or

10 “(cc) terminated from par-  
11 ticipating in a Federal health  
12 care program or the State plan  
13 (or a waiver of such plan) for a  
14 reason described in paragraph  
15 (8)(A).

16 “(ii) QUALIFYING INDIVIDUAL.—The  
17 term ‘qualifying individual’ means an indi-  
18 vidual under 21 years of age who is en-  
19 rolled under the State plan (or waiver of  
20 such plan).

21 “(iii) STATE.—The term ‘State’  
22 means 1 of the 50 States or the District  
23 of Columbia.”.

24 (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,”.

8                   (3) Section 2107(e)(1)(G) of such Act (42  
9                   U.S.C. 1397gg(e)(1)(G)) is amended by inserting  
10                  “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.

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

(a) INCREASING TRANSPARENCY OF HCBS COV-  
ERAGE UNDER MEDICAID.—

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

22 (A) in paragraph (2)—

23 (i) in subparagraph (E)—

24 (I) by inserting “, not less fre-  
25 quently than” before “annually”; and

1 (II) by inserting “(including,  
2 with respect to such information pro-  
3 vided on or after July 9, 2027, the in-  
4 formation specified in paragraph  
5 (11))” before the period at the end;  
6 and

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

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

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

16 “(11) For purposes of paragraph (2)(E), the  
17 information specified in this paragraph is the fol-  
18 lowing:

19 “(A) In the case of a State that limits the  
20 number of individuals who may be provided  
21 home or community-based services under a  
22 waiver granted under this subsection and main-  
23 tains a list of individuals waiting to enroll in  
24 such waiver, a description of how the State  
25 maintains such list, including—

1 “(i) information on whether the State  
2 screens individuals on such list to deter-  
3 mine whether such individuals are eligible  
4 to receive such services under such waiver;

5 “(ii) information on whether (and, if  
6 applicable, how often) the State periodi-  
7 cally re-screens individuals on such list for  
8 eligibility;

9 “(iii) the number of people on such  
10 list of individuals waiting to enroll in such  
11 waiver; and

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

17 “(B) With respect to homemaker services,  
18 home health aide services, personal care serv-  
19 ices, and habilitation services furnished under  
20 waivers under this subsection, by each such  
21 service type—

22 “(i) for individuals newly receiving  
23 such services within the past 12 months,  
24 the average amount of time (which may be  
25 determined using statistically valid random

1 sampling of such individuals) from when  
2 such services are initially approved for  
3 such an individual to when such individual  
4 begins receiving such services; and

5 “(ii) the percentage of authorized  
6 hours (which may be determined using sta-  
7 tistically valid random sampling of individ-  
8 uals authorized to receive such services)  
9 that are provided within the past 12  
10 months.”.

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

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

16 “(8) REPORTING REQUIREMENT.—With respect  
17 to homemaker services, home health aide services,  
18 personal care services, and habilitation services pro-  
19 vided under this subsection on or after July 9, 2027,  
20 the State, not less frequently than annually, shall  
21 provide to the Secretary the same information re-  
22 garding such services as the State is required to pro-  
23 vide under subsection (c)(11)(B).”;

24 (B) in subsection (j)(2)(E), by inserting  
25 after the second sentence the following: “With

1           respect to any homemaker services, home health  
2           aide services, personal care services, and habili-  
3           tation services provided under this subsection  
4           on or after July 9, 2027, the State, not less fre-  
5           quently than annually, shall provide to the Sec-  
6           retary the same information regarding such  
7           services as the State is required to provide  
8           under subsection (c)(11)(B).”; and

9           (C) in subsection (k)(3)(E)—

10           (i) by striking “and” after “the cost  
11           of such services and supports,”; and

12           (ii) by inserting before the period, the  
13           following: “, and with respect to home-  
14           maker services, home health aide services,  
15           personal care services, and habilitation  
16           services provided under this subsection on  
17           or after July 9, 2027, not less frequently  
18           than annually, the same information re-  
19           garding such services as the State is re-  
20           quired to provide under subsection  
21           (c)(11)(B)”.

22           (b) DEMONSTRATION PROGRAM TO EXPAND HCBS  
23           COVERAGE UNDER SECTION 1915(C) WAIVERS.—Section  
24           1915(c) of the Social Security Act (42 U.S.C. 1396n(c)),  
25           as amended by subsection (a), is further amended—

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

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

6 “(12) DEMONSTRATION PROGRAM TO EXPAND  
7 COVERAGE FOR HOME OR COMMUNITY-BASED SERV-  
8 ICES.—

9 “(A) IN GENERAL.—

10 “(i) APPROVAL.—Not later than 24  
11 months after the date on which the plan-  
12 ning grants under subparagraph (B) are  
13 awarded, notwithstanding paragraph (1),  
14 the Secretary may approve a waiver that is  
15 standalone from any other waiver approved  
16 under this subsection for not more than 5  
17 States, selected in accordance with clause  
18 (ii), to include as medical assistance under  
19 the State plan of such State, for the 3-year  
20 period beginning on the date of such ap-  
21 proval, payment for part or all of the cost  
22 of home or community-based services  
23 (other than room and board (as described  
24 in paragraph (1))) approved by the Sec-  
25 retary which are provided pursuant to a

1 written plan of care to individuals de-  
2 scribed in subparagraph (C)(iii).

3 “(ii) SELECTION CRITERIA.—In se-  
4 lecting States for purposes of clause (i),  
5 the Secretary shall—

6 “(I) only select States that re-  
7 ceived a planning grant under sub-  
8 paragraph (B);

9 “(II) only select States that meet  
10 the requirements specified in subpara-  
11 graph (C) and such other require-  
12 ments as the Secretary may determine  
13 appropriate;

14 “(III) select States in a manner  
15 that ensures geographic diversity;

16 “(IV) give preference to States  
17 with a higher percentage (relative to  
18 other States that apply to be selected  
19 for purposes of clause (i)) of the total  
20 State population residing in rural  
21 areas (as determined by the Sec-  
22 retary);

23 “(V) give preference to States  
24 that have demonstrated more progress  
25 in rebalancing long-term services and



1 supports systems under this title, as  
2 determined based on the relative share  
3 of individuals who use home or com-  
4 munity-based services (as defined by  
5 the Secretary) under this title as a  
6 percentage of total individuals who  
7 use long-term services and supports  
8 (as defined by the Secretary) under  
9 this title (in the most recent year for  
10 which such data is available); and

11 “(VI) give preference to States  
12 that pursue a waiver under this para-  
13 graph that incorporates the provision  
14 of mental health services for adults  
15 with serious mental illness, children  
16 with serious emotional disturbances,  
17 or individuals with substance use dis-  
18 order.

19 “(B) PLANNING GRANTS.—

20 “(i) IN GENERAL.—

21 “(I) APPROVAL.—Not later than  
22 18 months after the date of the enact-  
23 ment of this paragraph, the Secretary  
24 shall award planning grants of not  
25 more than \$5,000,000 each to not

1 more than 10 States for purposes of  
2 preparing to submit a request for a  
3 waiver under this subsection (includ-  
4 ing for costs to implement the waiver  
5 or other activities to expand the provi-  
6 sion of home or community-based  
7 services under this section) to provide  
8 home or community-based services to  
9 individuals described in subparagraph  
10 (C)(iii).

11 “(II) SELECTION CRITERIA.—In  
12 awarding planning grants under sub-  
13 clause (I), the Secretary shall use the  
14 selection criteria specified in sub-  
15 clauses (III) through (VI) of subpara-  
16 graph (A)(ii).

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

22 “(I) individuals in need of (and  
23 not receiving) home or community-  
24 based services, individuals receiving

1 home or community-based services,  
2 and the caregivers of such individuals;  
3 “(II) providers furnishing home  
4 or community-based services; and  
5 “(III) such other stakeholders, as  
6 the Secretary may specify.

7 “(C) STATE REQUIREMENTS.—In addition  
8 to the requirements specified under this sub-  
9 section (except for the requirements described  
10 in subparagraphs (C) and (D) of paragraph (2)  
11 and any other requirement the Secretary deter-  
12 mines to be inapplicable in the context of a  
13 waiver relation to individuals who do not re-  
14 quire the level of care described in paragraph  
15 (1)), the requirements specified in this para-  
16 graph are, with respect to a State, the fol-  
17 lowing:

18 “(i) As of the date that such State re-  
19 quests a waiver under this subsection to  
20 provide home or community-based services  
21 to individuals described in clause (iii), all  
22 other waivers (if any) granted under this  
23 subsection to such State meet the require-  
24 ments of this subsection.

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

12                  “(iii) The State establishes needs-  
13                  based criteria, subject to the approval of  
14                  the Secretary, to identify individuals for  
15                  whom a determination described in para-  
16                  graph (1) is not applicable, who will be eli-  
17                  gible for home or community-based serv-  
18                  ices under a waiver approved under this  
19                  paragraph, and specifies the home or com-  
20                  munity-based services such individuals so  
21                  eligible will receive.

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

1 nursing facility, or an intermediate care fa-  
2 cility for individuals with developmental  
3 disabilities under the State plan or under  
4 any waiver of such plan that are more  
5 stringent than the needs-based criteria es-  
6 tablished under clause (iii) for determining  
7 eligibility for home or community-based  
8 services.

9 “(v) The State attests that the State’s  
10 average per capita expenditure for medical  
11 assistance under the State plan (or waiver  
12 of such plan) provided with respect to such  
13 individuals enrolled in a waiver under this  
14 paragraph will not exceed the State’s aver-  
15 age per capita expenditures for medical as-  
16 sistance for individuals receiving institu-  
17 tional care under the State plan (or waiver  
18 of such plan) for the duration that the  
19 waiver under this paragraph is in effect.

20 “(vi) The State provides to the Sec-  
21 retary data (in such form and manner as  
22 the Secretary may specify) regarding the  
23 number of individuals described in clause  
24 (i) with respect to a State seeking approval  
25 of a waiver under this subsection, to whom

1 the State will make such services available  
2 under such waiver.

3 “(vii) The State agrees to provide to  
4 the Secretary, not less frequently than an-  
5 nually, data for purposes of paragraph  
6 (2)(E) (in such form and manner as the  
7 Secretary may specify) regarding, with re-  
8 spect to each preceding year in which a  
9 waiver under this subsection to provide  
10 home and community-based services to in-  
11 dividuals described in clause (iii) was in ef-  
12 fect—

13 “(I) the cost (as such term is de-  
14 fined by the Secretary) of such serv-  
15 ices furnished to individuals described  
16 in clause (iii), broken down by type of  
17 service;

18 “(II) with respect to each type of  
19 home and community-based service  
20 provided under the waiver, the length  
21 of time that such individuals have re-  
22 ceived such service;

23 “(III) a comparison between the  
24 data described in subclause (I) and  
25 any comparable data available with

1                   respect to individuals with respect to  
2                   whom a determination described in  
3                   paragraph (1) has been made and  
4                   with respect to individuals receiving  
5                   institutional care under this title; and  
6                   “(IV) the number of individuals  
7                   who have received home and commu-  
8                   nity-based services under the waiver  
9                   during the preceding year.”.

10           (c) NON-APPLICATION OF THE PAPERWORK REDUC-  
11   TION ACT.—Chapter 35 of title 44, United States Code  
12   (commonly referred to as the “Paperwork Reduction Act  
13   of 1995”), shall not apply to the implementation of the  
14   amendments made by subsections (a) and (b).

15           (d) CMS GUIDANCE TO STATES ON INTERIM COV-  
16   ERAGE UNDER SECTION 1915 HOME AND COMMUNITY-  
17   BASED SERVICES AUTHORITIES.—Not later than January  
18   1, 2027, the Secretary of Health and Human Services  
19   shall issue guidance to the States to clarify how a State  
20   may provide, with respect to an individual who is eligible  
21   for home and community-based services under section  
22   1915 of the Social Security Act (42 U.S.C. 1396n), cov-  
23   erage of such services pursuant to a provisional written  
24   plan of care, pending finalization, with respect to such in-  
25   dividual.

1 (e) FUNDING.—

2 (1) IN GENERAL.—There are appropriated, out  
3 of any funds in the Treasury not otherwise obli-  
4 gated, \$71,000,000 for fiscal year 2025, to remain  
5 available until expended, to the Secretary of Health  
6 and Human Services for purposes of carrying out  
7 subsection (d) and the amendments made by sub-  
8 section (b).

9 (2) RESERVATION FOR PLANNING GRANTS.—Of  
10 the amount appropriated under paragraph (1), the  
11 Secretary of Health and Human Services shall re-  
12 serve \$50,000,000 of such amount to award plan-  
13 ning grants under the demonstration program estab-  
14 lished by the amendments made by subsection (b).

15 **SEC. 103. REMOVING CERTAIN AGE RESTRICTIONS ON MED-**  
16 **ICAID ELIGIBILITY FOR WORKING ADULTS**  
17 **WITH DISABILITIES.**

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

19 (1) IN GENERAL.—Section  
20 1902(a)(10)(A)(ii)(XV) of the Social Security Act  
21 (42 U.S.C. 1396a(a)(10)(A)(ii)(XV)) is amended by  
22 striking “but less than 65,”.

23 (2) DEFINITION MODIFICATION.—Section  
24 1905(v)(1)(A) of the Social Security Act (42 U.S.C.



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

3       (b) APPLICATION TO CERTAIN STATES.—A State  
4       that, as of the date of enactment of this Act, provides for  
5       making medical assistance available to individuals de-  
6       scribed in subclause (XV) or (XVI) of section  
7       1902(a)(10)(A)(ii) of the Social Security Act (42 U.S.C.  
8       1396a(a)(10)(A)(ii)) shall not be regarded as failing to  
9       comply with the requirements of either such subclause (as  
10      amended by subsection (a)(1)) or with section  
11      1905(v)(1)(A) of the Social Security Act (42 U.S.C.  
12      1396d(v)(1)(A)) (as amended by subsection (a)(2)) before  
13      January 1, 2027.

14      **SEC. 104. MEDICAID STATE PLAN REQUIREMENT FOR DE-**  
15                                   **TERMINING RESIDENCY AND COVERAGE FOR**  
16                                   **MILITARY FAMILIES.**

17      (a) IN GENERAL.—Section 1902 of the Social Secu-  
18      rity Act (42 U.S.C. 1396a) is amended—

19                   (1) in subsection (a)—

20                           (A) in paragraph (86), by striking “and”  
21                           at the end;

22                           (B) in paragraph (87), by striking the pe-  
23                           riod at the end and inserting “; and”; and

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

1           “(88) beginning January 1, 2028, provide, with  
2       respect to an active duty relocated individual (as de-  
3       fined in subsection (uu)(1))—

4           “(A) that, for purposes of determining eli-  
5       gibility for medical assistance under the State  
6       plan (or waiver of such plan), such active duty  
7       relocated individual is treated as a resident of  
8       the State unless such individual voluntarily  
9       elects not to be so treated for such purposes;

10          “(B) that if, at the time of relocation (as  
11       described in subsection (uu)(1)), such active  
12       duty relocated individual is on a home and com-  
13       munity-based services waiting list (as defined in  
14       subsection (uu)(2)), such individual remains on  
15       such list until—

16          “(i) the State completes an assess-  
17       ment and renders a decision with respect  
18       to the eligibility of such individual to re-  
19       ceive the relevant home and community-  
20       based services at the time a slot for such  
21       services becomes available and, in the case  
22       such decision is a denial of such eligibility,  
23       such individual has exhausted the individ-  
24       ual’s opportunity for a fair hearing; or

1                   “(ii) such individual elects to be re-  
2                   moved from such list; and

3                   “(C) payment for medical assistance fur-  
4                   nished under the State plan (or a waiver of the  
5                   plan) on behalf of such active duty relocated in-  
6                   dividual in the military service relocation State  
7                   (as referred to in subsection (uu)(1)(B)(i)), to  
8                   the extent that such assistance is available in  
9                   such military service relocation State in accord-  
10                  ance with such guidance as the Secretary may  
11                  issue to ensure access to such assistance.”; and  
12                  (2) by adding at the end the following new sub-  
13                  section:

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

17                  “(1) ACTIVE DUTY RELOCATED INDIVIDUAL.—  
18                  The term ‘active duty relocated individual’ means an  
19                  individual—

20                         “(A) who—

21                                 “(i) is enrolled under the State plan  
22                                 (or waiver of such plan); or

23                                 “(ii) with respect to an individual de-  
24                                 scribed in subparagraph (C)(ii), would be  
25                                 so enrolled pursuant to subsection

1 (a)(10)(A)(ii)(VI) if such individual began  
2 receiving home and community-based serv-  
3 ices;

4 “(B) who—

5 “(i) is a member of the Armed Forces  
6 engaged in active duty service and is relo-  
7 cated to another State (in this subsection  
8 referred to as the ‘military service reloca-  
9 tion State’) by reason of such service;

10 “(ii) would be described in clause (i)  
11 except that the individual stopped being  
12 engaged in active duty service (including  
13 by reason of retirement from such service)  
14 and the last day on which the individual  
15 was engaged in active duty service oc-  
16 curred not more than 12 months ago; or

17 “(iii) is a dependent (as defined by  
18 the Secretary) of a member described in  
19 clause (i) or (ii) who relocates to the mili-  
20 tary service relocation State with such  
21 member; and

22 “(C) who—

23 “(i) was receiving home and commu-  
24 nity-based services (as defined in section  
25 9817(a)(2)(B) of the American Rescue

1 Plan Act of 2021) at the time of such relo-  
2 cation; or

3 “(ii) if the State maintains a home  
4 and community-based services waiting list,  
5 was on such home and community-based  
6 services waiting list at the time of such re-  
7 location.

8 “(2) HOME AND COMMUNITY-BASED SERVICES  
9 WAITING LIST.—The term ‘home and community-  
10 based services waiting list’ means, in the case of a  
11 State that has a limit on the number of individuals  
12 who may receive home and community-based services  
13 under section 1115(a), section 1915(c), or section  
14 1915(j), a list maintained by such State of individ-  
15 uals who are requesting to receive such services  
16 under 1 or more such sections but for whom the  
17 State has not yet completed an assessment and ren-  
18 dered a decision with respect to the eligibility of  
19 such individuals to receive the relevant home and  
20 community-based services at the time a slot for such  
21 services becomes available due to such limit.”.

22 (b) IMPLEMENTATION FUNDING.—There are appro-  
23 priated, out of any funds in the Treasury not otherwise  
24 obligated, \$1,000,000 for each of fiscal years 2025  
25 through 2029, to remain available until expended, to the

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

3 **SEC. 105. ENSURING THE RELIABILITY OF ADDRESS INFOR-**  
4 **MATION PROVIDED UNDER THE MEDICAID**  
5 **PROGRAM.**

6 (a) IN GENERAL.—Section 1902(a) of the Social Se-  
7 curity Act (42 U.S.C. 1396a(a)), as previously amended  
8 by this title, is amended—

9 (1) in paragraph (87), by striking “and” at the  
10 end;

11 (2) in paragraph (88), by striking the period at  
12 the end and inserting “; and”; and

13 (3) by inserting after paragraph (88) the fol-  
14 lowing new paragraph:

15 “(89) beginning January 1, 2026, provide for a  
16 process to regularly obtain address information for  
17 individuals enrolled under such plan (or a waiver of  
18 such plan) from reliable data sources (as described  
19 in section 435.919(f)(1)(iii) of title 42, Code of Fed-  
20 eral Regulations (or a successor regulation)) and act  
21 on any changes to such an address based on such in-  
22 formation in accordance with such section (or suc-  
23 cessor regulation), except that this paragraph shall  
24 only apply in the case of the 50 States and the Dis-  
25 trict of Columbia.”.

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

4 (1) by redesignating subparagraphs (H)  
5 through (U) as subparagraphs (I) through (V), re-  
6 spectively; and

7 (2) by inserting after subparagraph (G) the fol-  
8 lowing new subparagraph:

9 “(H) Section 1902(a)(89) (relating to reg-  
10 ularly obtaining address information for enroll-  
11 ees).”.

12 (c) ENSURING TRANSMISSION OF ADDRESS INFOR-  
13 MATION FROM MANAGED CARE ORGANIZATIONS.—Sec-  
14 tion 1932 of the Social Security Act (42 U.S.C. 1396u-  
15 2) is amended by adding at the end the following new sub-  
16 section:

17 “(j) TRANSMISSION OF ADDRESS INFORMATION.—  
18 Beginning January 1, 2026, each contract under a State  
19 plan with a managed care entity under section 1903(m)  
20 shall provide that the entity transmits to the State any  
21 address information for an individual enrolled with the en-  
22 tity that is provided to such entity directly from, or  
23 verified by such entity directly with, such individual.”.

1   **SEC. 106. CODIFYING CERTAIN MEDICAID PROVIDER**  
2                   **SCREENING REQUIREMENTS RELATED TO**  
3                   **DECEASED PROVIDERS.**

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

6               (1) by striking “The State” and inserting:

7                   “(A) IN GENERAL.—The State”; and

8               (2) by adding at the end the following new sub-  
9   paragraph:

10               “(B) ADDITIONAL PROVIDER SCREEN-  
11       ING.—Beginning January 1, 2027, as part of  
12       the enrollment (or reenrollment or revalidation  
13       of enrollment) of a provider or supplier under  
14       this title, and not less frequently than quarterly  
15       during the period that such provider or supplier  
16       is so enrolled, the State conducts a check of the  
17       Death Master File (as such term is defined in  
18       section 203(d) of the Bipartisan Budget Act of  
19       2013) to determine whether such provider or  
20       supplier is deceased.”.

21   **SEC. 107. MODIFYING CERTAIN STATE REQUIREMENTS FOR**  
22                   **ENSURING DECEASED INDIVIDUALS DO NOT**  
23                   **REMAIN ENROLLED.**

24       Section 1902 of the Social Security Act (42 U.S.C.  
25   1396a), as previously amended by this title, is amended—

26               (1) in subsection (a)—



1 (A) in paragraph (88), by striking “; and”  
2 and inserting a semicolon;

3 (B) in paragraph (89), by striking the pe-  
4 riod at the end and inserting “; and”; and

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

7 “(90) provide that the State shall comply with  
8 the eligibility verification requirements under sub-  
9 section (vv), except that this paragraph shall apply  
10 only in the case of the 50 States and the District  
11 of Columbia.”; and

12 (2) by adding at the end the following new sub-  
13 section:

14 “(vv) VERIFICATION OF CERTAIN ELIGIBILITY CRI-  
15 TERIA.—

16 “(1) IN GENERAL.—For purposes of subsection  
17 (a)(90), the eligibility verification requirements, be-  
18 ginning January 1, 2026, are as follows:

19 “(A) QUARTERLY SCREENING TO VERIFY  
20 ENROLLEE STATUS.—The State shall, not less  
21 frequently than quarterly, review the Death  
22 Master File (as such term is defined in section  
23 203(d) of the Bipartisan Budget Act of 2013)  
24 to determine whether any individuals enrolled

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

3           “(B)   DISENROLLMENT   UNDER   STATE  
4           PLAN.—If the State determines, based on infor-  
5           mation obtained from the Death Master File,  
6           that an individual enrolled for medical assist-  
7           ance under the State plan (or waiver of such  
8           plan) is deceased, the State shall—

9                   “(i) treat such information as factual  
10           information confirming the death of a ben-  
11           eficiary for purposes of section 431.213(a)  
12           of title 42, Code of Federal Regulations (or  
13           any successor regulation);

14                   “(ii) disenroll such individual from the  
15           State plan (or waiver of such plan); and

16                   “(iii) discontinue any payments for  
17           medical assistance under this title made on  
18           behalf of such individual (other than pay-  
19           ments for any items or services furnished  
20           to such individual prior to the death of  
21           such individual).

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

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

8 “(2) RULE OF CONSTRUCTION.—Nothing under  
9 this subsection shall be construed to preclude the  
10 ability of a State to use other electronic data sources  
11 to timely identify potentially deceased beneficiaries,  
12 so long as the State is also in compliance with the  
13 requirements of this subsection (and all other re-  
14 quirements under this title relating to Medicaid eli-  
15 gibility determination and redetermination).”.

16 **SEC. 108. ONE-YEAR DELAY OF MEDICAID AND CHIP RE-**  
17 **QUIREMENTS FOR HEALTH SCREENINGS, RE-**  
18 **FERRALS, AND CASE MANAGEMENT SERV-**  
19 **ICES FOR ELIGIBLE JUVENILES IN PUBLIC**  
20 **INSTITUTIONS; STATE INTERIM WORK PLANS.**

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

24 (1) by striking “The amendments made by this  
25 section” and inserting the following:

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

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

5 “(2) DELAY OF DATE BY WHICH STATES MUST  
6 COMPLY WITH CERTAIN JUVENILE JUSTICE-RE-  
7 LATED REQUIREMENTS.—A State shall not be re-  
8 garded as failing to comply with the requirements of  
9 section 1902(a)(84)(D) or 2102(d)(2) of the Social  
10 Security Act (42 U.S.C. 1396a(a)(84)(D),  
11 1397bb(d)(2)) before January 1, 2026.”.

12 (b) CLARIFYING NONAPPLICATION OF REQUIRE-  
13 MENTS TO INDIVIDUALS IN FEDERAL CUSTODY.—

14 (1) MEDICAID.—

15 (A) Subparagraph (D) of section  
16 1902(a)(84) of the Social Security Act (42  
17 U.S.C. 1396a(a)(84)), as added by section 5121  
18 of subtitle C of title V of division FF of the  
19 Consolidated Appropriations Act, 2023 (Public  
20 Law 117–328), is amended by striking “an in-  
21 dividual who is an eligible juvenile” and insert-  
22 ing “an individual (other than an individual  
23 who is in Federal custody, including as an in-  
24 mate in a Federal prison) who is an eligible ju-  
25 venile”.

1 (B) Section 5122(a) of subtitle C of title  
2 V of division FF of the Consolidated Appropria-  
3 tions Act, 2023 (Public Law 117–328) is  
4 amended—

5 (i) by striking “paragraph (31)” each  
6 place it appears and inserting “the last  
7 numbered paragraph”; and

8 (ii) in paragraph (1), by striking “an  
9 individual who is an eligible juvenile” and  
10 inserting “an individual (other than an in-  
11 dividual who is in Federal custody, includ-  
12 ing as an inmate in a Federal prison) who  
13 is an eligible juvenile”.

14 (2) CHIP.—

15 (A) Subsection (d)(2) of section 2102 of  
16 the Social Security Act (42 U.S.C. 1397bb), as  
17 added by section 5121 of subtitle C of title V  
18 of division FF of the Consolidated Appropria-  
19 tions Act, 2023 (Public Law 117–328), is  
20 amended by striking “a targeted low-income  
21 child who” and inserting “a targeted low in-  
22 come child (other than a child who is in Federal  
23 custody, including as an inmate in a Federal  
24 prison) who”.

1 (B) Section 5122(b)(2) of subtitle C of  
2 title V of division FF of the Consolidated Ap-  
3 propriations Act, 2023 (Public Law 117–328)  
4 is amended by striking “a child who is” and in-  
5 serting “a child (other than a child who is in  
6 Federal custody, including as an inmate in a  
7 Federal prison) who is”.

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

11 (c) INTERIM WORK PLAN.—Not later than June 30,  
12 2025, each State (as such term is defined in section  
13 1101(a)(1) of the Social Security Act (42 U.S.C.  
14 1301(a)(1)) for purposes of titles XIX and XXI of such  
15 Act) shall submit to the Secretary of Health and Human  
16 Services an interim work plan, in such form and con-  
17 taining such information as the Secretary may specify, de-  
18 scribing the State’s progress towards implementing, and  
19 its plans to come into compliance with, the requirements  
20 imposed by the amendments made by section 5121 of sub-  
21 title C of title V of division FF of the Consolidated Appro-  
22 priations Act, 2023 (Public Law 117–328), consistent  
23 with the guidance issued by the Centers for Medicare &  
24 Medicaid Services in State Health Official Letter #24–  
25 004 on July 23, 2024.

1 **SEC. 109. STATE STUDIES AND HHS REPORT ON COSTS OF**  
2 **PROVIDING MATERNITY, LABOR, AND DELIV-**  
3 **ERY SERVICES.**

4 (a) STATE STUDY.—

5 (1) IN GENERAL.—Not later than 24 months  
6 after the date of enactment of this Act, and every  
7 5 years thereafter, each State (as such term is de-  
8 fined in section 1101(a)(1) of the Social Security  
9 Act (42 U.S.C. 1301(a)(1)) for purposes of titles  
10 XIX and XXI of such Act) shall conduct a study on  
11 the costs of providing maternity, labor, and delivery  
12 services in applicable hospitals (as defined in para-  
13 graph (3)) and submit the results of such study to  
14 the Secretary of Health and Human Services (re-  
15 ferred to in this section as the “Secretary”).

16 (2) CONTENT OF STUDY.—A State study re-  
17 quired under paragraph (1) shall include the fol-  
18 lowing information (to the extent practicable) with  
19 respect to maternity, labor, and delivery services fur-  
20 nished by applicable hospitals located in the State:

21 (A) An estimate of the cost of providing  
22 maternity, labor, and delivery services at appli-  
23 cable hospitals, based on the expenditures a  
24 representative sample of such hospitals incurred  
25 for providing such services during the 2 most  
26 recent years for which data is available.

1           (B) An estimate of the cost of providing  
2           maternity, labor, and delivery services at appli-  
3           cable hospitals that ceased providing labor and  
4           delivery services within the past 5 years, based  
5           on the expenditures a representative sample of  
6           such hospitals incurred for providing such serv-  
7           ices during the 2 most recent years for which  
8           data is available.

9           (C) To the extent data allows, an analysis  
10          of the extent to which geographic location, com-  
11          munity demographics, and local economic fac-  
12          tors (as defined by the Secretary) affect the  
13          cost of providing maternity, labor, and delivery  
14          services at applicable hospitals, including the  
15          cost of services that support the provision of  
16          maternity, labor, and delivery services.

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

21                   (i) Medicare;

22                   (ii) the State Medicaid program, in-  
23                   cluding payment amounts for such services  
24                   under fee-for-service payment arrange-



1                   ments and under managed care (as appli-  
2                   cable);

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

7                   (iv) private health insurance.

8                   (E) A comparative payment rate anal-  
9                   ysis—

10                   (i) comparing payment rates for ma-  
11                   ternity, labor, and delivery services (inclu-  
12                   sive of all payments received by applicable  
13                   hospitals for furnishing maternity, labor,  
14                   and delivery services) under the State  
15                   Medicaid fee-for-service program to such  
16                   payment rates for such services under  
17                   Medicare (as described in section  
18                   447.203(b)(3) of title 42, Code of Federal  
19                   Regulations), other Federally-funded or  
20                   State-funded programs (including, to the  
21                   extent data is available, Medicaid managed  
22                   care rates), and to the payment rates for  
23                   such services, to the extent data is avail-  
24                   able, of private health insurers within geo-  
25                   graphic areas of the State; and

1 (ii) analyzing different payment meth-  
2 ods for such services, such as the use of  
3 bundled payments, quality incentives, and  
4 low-volume adjustments.

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

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

17 (A) The hospital provides labor and deliv-  
18 ery services and more than 50 percent of the  
19 hospital’s births (in the most recent year for  
20 which such data is available) are financed by  
21 the Medicaid program or CHIP.

22 (B) The hospital—

23 (i) is located in a rural area (as de-  
24 fined by the Federal Office of Rural  
25 Health Policy for the purpose of rural

1 health grant programs administered by  
2 such Office);

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

7 (iii) provides labor and delivery serv-  
8 ices.

9 (4) ASSISTANCE TO SMALL HOSPITALS IN COM-  
10 PILING COST INFORMATION.—There are appro-  
11 priated to the Secretary for fiscal year 2025,  
12 \$10,000,000 for the purpose of providing grants and  
13 technical assistance to a hospital described in para-  
14 graph (3)(B) to enable such hospital to compile de-  
15 tailed information for use in the State studies re-  
16 quired under paragraph (1), to remain available  
17 until expended.

18 (5) HHS REPORT ON STATE STUDIES.—For  
19 each year in which a State is required to conduct a  
20 study under paragraph (1), the Secretary shall issue,  
21 not later than 12 months after the date on which  
22 the State submits to the Secretary the data de-  
23 scribed in such paragraph, a publicly available re-  
24 port that compiles and details the results of such

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

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

11 (c) IMPLEMENTATION FUNDING.—In addition to the  
12 amount appropriated under subsection (a)(4), there are  
13 appropriated, out of any funds in the Treasury not other-  
14 wise obligated, \$3,000,000 for fiscal year 2025, to remain  
15 available until expended, to the Secretary of Health and  
16 Human Services for purposes of implementing this sec-  
17 tion.

18 **SEC. 110. MODIFYING CERTAIN DISPROPORTIONATE SHARE**  
19 **HOSPITAL ALLOTMENTS.**

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

23 (1) in the heading, by striking “2025” and in-  
24 serting “2026 AND FOR THE 1ST QUARTER OF FISCAL  
25 YEAR 2027”;

1           (2) by striking “fiscal year 2025” and inserting  
2           “fiscal year 2026”; and

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

6           (b) ELIMINATING AND DELAYING DSH ALLOTMENT  
7   REDUCTIONS.—Section 1923(f) of the Social Security Act  
8   (42 U.S.C. 1396r–4(f)) is amended—

9           (1) in paragraph (7)(A)—

10           (A) in clause (i), in the matter preceding  
11           subclause (I), by striking “January 1, 2025,”  
12           and all that follows through “2027” and insert-  
13           ing “January 1, 2027, and ending September  
14           30, 2027, and for fiscal year 2028”; and

15           (B) in clause (ii), by striking “January 1,  
16           2025,” and all that follows through “2027” and  
17           inserting “January 1, 2027, and ending Sep-  
18           tember 30, 2027, and for fiscal year 2028”;  
19           and

20           (2) in paragraph (8), by striking “2027” and  
21           inserting “2028”.

1 **SEC. 111. MODIFYING CERTAIN LIMITATIONS ON DIS-**  
2 **PROPORTIONATE SHARE HOSPITAL PAY-**  
3 **MENT ADJUSTMENTS UNDER THE MEDICAID**  
4 **PROGRAM.**

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

7 (1) in paragraph (1)—

8 (A) in subparagraph (A)—

9 (i) in the matter preceding clause (i),  
10 by striking “(other than a hospital de-  
11 scribed in paragraph (2)(B))”;

12 (ii) in clause (i), by inserting “with  
13 respect to such hospital and year” after  
14 “described in subparagraph (B)”; and

15 (iii) in clause (ii)—

16 (I) in subclause (I), by striking  
17 “and” at the end;

18 (II) in subclause (II), by striking  
19 the period and inserting “; and”; and

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

22 “(III) payments made under title  
23 XVIII or by an applicable plan (as de-  
24 fined in section 1862(b)(8)(F)) for  
25 such services.”; and

26 (B) in subparagraph (B)—

1 (i) in the matter preceding clause (i),  
2 by striking “in this clause are” and insert-  
3 ing “in this subparagraph are, with respect  
4 to a hospital and a year,”; and

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

7 “(iii) Individuals who are eligible for  
8 medical assistance under the State plan or  
9 under a waiver of such plan and for whom  
10 the State plan or waiver is a payor for  
11 such services after application of benefits  
12 under title XVIII or under an applicable  
13 plan (as defined in section 1862(b)(8)(F)),  
14 but only if the hospital has in the aggre-  
15 gate incurred costs exceeding payments  
16 under such State plan, waiver, title XVIII,  
17 or applicable plan for such services fur-  
18 nished to such individuals during such  
19 year.”;

20 (2) by striking paragraph (2);

21 (3) by redesignating paragraph (3) as para-  
22 graph (2); and

23 (4) in paragraph (2), as so redesignated, by  
24 striking “Notwithstanding paragraph (2) of this

1 subsection (as in effect on October 1, 2021), para-  
2 graph (2)” and inserting “Paragraph (2)”.

3 (b) EFFECTIVE DATE.—

4 (1) IN GENERAL.—Except as provided in para-  
5 graph (2), the amendments made by this section  
6 shall apply to payment adjustments made under sec-  
7 tion 1923 of the Social Security Act (42 U.S.C.  
8 1396r–4) for Medicaid State plan rate years begin-  
9 ning on or after the date of enactment of this Act.

10 (2) STATE OPTION TO DISTRIBUTE UNSPENT  
11 DSH ALLOTMENTS FROM PRIOR YEARS UP TO MODI-  
12 FIED CAP.—

13 (A) IN GENERAL.—If, for any Medicaid  
14 State plan rate year that begins on or after Oc-  
15 tober 1, 2021, and before the date of enactment  
16 of this Act, a State did not spend the full  
17 amount of its Federal fiscal year allotment  
18 under section 1923 of the Social Security Act  
19 (42 U.S.C. 1396r–4) applicable to that State  
20 plan rate year, the State may use the unspent  
21 portion of such allotment to increase the  
22 amount of any payment adjustment made to a  
23 hospital for such rate year, provided that—

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



1 of such section (as amended by this sec-  
2 tion); and

3 (ii) the total amount of all payment  
4 adjustments for the State plan rate year  
5 (as so increased) does not exceed the dis-  
6 proportionate share hospital allotment for  
7 the State and applicable Federal fiscal  
8 year under subsection (f) of such section.

9 (B) NO RECOUPMENT OF PAYMENTS AL-  
10 READY MADE TO HOSPITALS.—A State shall not  
11 recoup any payment adjustment made by the  
12 State to a hospital for a Medicaid State plan  
13 rate year described in subparagraph (A) if such  
14 payment adjustment is consistent with section  
15 1923(g) of such Act (42 U.S.C. 1396r-4(g)) as  
16 in effect on October 1, 2021.

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

20 (i) IN GENERAL.—Subject to para-  
21 graph (2), solely for the purpose of allow-  
22 ing a State to increase the amount of a  
23 payment adjustment to a hospital for a  
24 Medicaid State plan rate year described in  
25 subparagraph (A) pursuant to this para-

1 graph, a State may retroactively modify a  
2 provision of the Medicaid State plan, a  
3 waiver of such plan, or a State plan  
4 amendment that relates to such rate year  
5 and the Secretary may approve such modi-  
6 fication.

7 (ii) DEADLINE.—A State may not  
8 submit a request for approval of a retro-  
9 active modification to a provision of the  
10 Medicaid State plan, a waiver of such plan,  
11 or a State plan amendment for a Medicaid  
12 State plan rate year after the date by  
13 which the State is required to submit the  
14 independent certified audit for that State  
15 plan rate year as required under section  
16 1923(j)(2) of the Social Security Act (42  
17 U.S.C. 1396r–4(j)(2)).

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

1 **SEC. 112. ENSURING ACCURATE PAYMENTS TO PHAR-**  
2 **MACIES UNDER MEDICAID.**

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

5 (1) in paragraph (1)(A)—

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

8 (B) by striking “and” after the semicolon  
9 at the end of clause (i) and all that precedes it  
10 through “(1)” and inserting the following:

11 “(1) DETERMINING PHARMACY ACTUAL ACQUI-  
12 SITION COSTS.—The Secretary shall conduct a sur-  
13 vey of retail community pharmacy drug prices and  
14 applicable non-retail pharmacy drug prices to deter-  
15 mine national average drug acquisition cost bench-  
16 marks (as such term is defined by the Secretary) as  
17 follows:

18 “(A) USE OF VENDOR.—The Secretary  
19 may contract services for—

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

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

6 “(ii) with respect to applicable non-re-  
7 tail pharmacies—

8 “(I) the determination of survey  
9 prices, separate from the survey prices  
10 described in clause (i), of the non-re-  
11 tail national average drug acquisition  
12 cost for covered outpatient drugs that  
13 represent a nationwide average of con-  
14 sumer purchase prices for such drugs,  
15 net of all discounts, rebates, and other  
16 price concessions (to the extent any  
17 information with respect to such dis-  
18 counts, rebates, and other price con-  
19 ceSSIONS is available) based on a  
20 monthly survey of such pharmacies;  
21 and

22 “(II) at the discretion of the Sec-  
23 retary, for each type of applicable  
24 non-retail pharmacy, the determina-  
25 tion of survey prices, separate from

1 the survey prices described in clause  
2 (i) or subclause (I) of this clause, of  
3 the national average drug acquisition  
4 cost for such type of pharmacy for  
5 covered outpatient drugs that rep-  
6 resent a nationwide average of con-  
7 sumer purchase prices for such drugs,  
8 net of all discounts, rebates, and other  
9 price concessions (to the extent any  
10 information with respect to such dis-  
11 counts, rebates, and other price con-  
12 cessions is available) based on a  
13 monthly survey of such pharmacies;  
14 and”;

15 (2) in subparagraph (B) of paragraph (1), by  
16 striking “subparagraph (A)(ii)” and inserting “sub-  
17 paragraph (A)(iii)”;

18 (3) in subparagraph (D) of paragraph (1), by  
19 striking clauses (ii) and (iii) and inserting the fol-  
20 lowing:

21 “(ii) The vendor must update the Sec-  
22 retary no less often than monthly on the  
23 survey prices for covered outpatient drugs.

24 “(iii) The vendor must differentiate,  
25 in collecting and reporting survey data, for

1 all cost information collected, whether a  
2 pharmacy is a retail community pharmacy  
3 or an applicable non-retail pharmacy, in-  
4 cluding whether such pharmacy is an affil-  
5 iate (as defined in subsection (k)(14)),  
6 and, in the case of an applicable non-retail  
7 pharmacy, which type of applicable non-re-  
8 tail pharmacy it is using the relevant phar-  
9 macy type indicators included in the guid-  
10 ance required by subsection (d)(2) of sec-  
11 tion 112 of the **\_\_\_\_\_**.”;

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

14 “(F) SURVEY REPORTING.—In order to  
15 meet the requirement of section 1902(a)(54), a  
16 State shall require that any retail community  
17 pharmacy or applicable non-retail pharmacy in  
18 the State that receives any payment, reimburse-  
19 ment, administrative fee, discount, rebate, or  
20 other price concession related to the dispensing  
21 of covered outpatient drugs to individuals re-  
22 ceiving benefits under this title, regardless of  
23 whether such payment, reimbursement, admin-  
24 istrative fee, discount, rebate, or other price  
25 concession is received from the State or a man-

1           aged care entity or other specified entity (as  
2           such terms are defined in section  
3           1903(m)(9)(D)) directly or from a pharmacy  
4           benefit manager or another entity that has a  
5           contract with the State or a managed care enti-  
6           ty or other specified entity (as so defined), shall  
7           respond to surveys conducted under this para-  
8           graph.

9           “(G) SURVEY INFORMATION.—Information  
10          on national drug acquisition prices obtained  
11          under this paragraph shall be made publicly  
12          available in a form and manner to be deter-  
13          mined by the Secretary and shall include at  
14          least the following:

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

18               “(ii) The sampling methodology and  
19               number of pharmacies sampled monthly.

20               “(iii) Information on price concessions  
21               to pharmacies, including discounts, re-  
22               bates, and other price concessions, to the  
23               extent that such information may be pub-  
24               licly released and has been collected by the  
25               Secretary as part of the survey.

1 “(H) PENALTIES.—

2 “(i) IN GENERAL.—Subject to clauses  
3 (ii), (iii), and (iv), the Secretary shall en-  
4 force the provisions of this paragraph with  
5 respect to a pharmacy through the estab-  
6 lishment of civil money penalties applicable  
7 to a retail community pharmacy or an ap-  
8 plicable non-retail pharmacy.

9 “(ii) BASIS FOR PENALTIES.—The  
10 Secretary shall impose a civil money pen-  
11 alty established under this subparagraph  
12 on a retail community pharmacy or appli-  
13 cable non-retail pharmacy if—

14 “(I) the retail pharmacy or appli-  
15 cable non-retail pharmacy refuses or  
16 otherwise fails to respond to a request  
17 for information about prices in con-  
18 nection with a survey under this sub-  
19 section;

20 “(II) knowingly provides false in-  
21 formation in response to such a sur-  
22 vey; or

23 “(III) otherwise fails to comply  
24 with the requirements established  
25 under this paragraph.



1 “(iii) PARAMETERS FOR PEN-  
2 ALTIES.—

3 “(I) IN GENERAL.—A civil money  
4 penalty established under this sub-  
5 paragraph may be assessed with re-  
6 spect to each violation, and with re-  
7 spect to each non-compliant retail  
8 community pharmacy (including a  
9 pharmacy that is part of a chain) or  
10 non-compliant applicable non-retail  
11 pharmacy (including a pharmacy that  
12 is part of a chain), in an amount not  
13 to exceed \$100,000 for each such vio-  
14 lation.

15 “(II) CONSIDERATIONS.—In de-  
16 termining the amount of a civil money  
17 penalty imposed under this subpara-  
18 graph, the Secretary may consider the  
19 size, business structure, and type of  
20 pharmacy involved, as well as the type  
21 of violation and other relevant factors,  
22 as determined appropriate by the Sec-  
23 retary.

24 “(iv) RULE OF APPLICATION.—The  
25 provisions of section 1128A (other than

1 subsections (a) and (b)) shall apply to a  
2 civil money penalty under this subpara-  
3 graph in the same manner as such provi-  
4 sions apply to a civil money penalty or pro-  
5 ceeding under section 1128A(a).

6 “(I) LIMITATION ON USE OF APPLICABLE  
7 NON-RETAIL PHARMACY PRICING INFORMA-  
8 TION.—No State shall use pricing information  
9 reported by applicable non-retail pharmacies  
10 under subparagraph (A)(ii) to develop or inform  
11 payment methodologies for retail community  
12 pharmacies.”;

13 (5) in paragraph (2)—

14 (A) in subparagraph (A), by inserting “,  
15 including payment rates and methodologies for  
16 determining ingredient cost reimbursement  
17 under managed care entities or other specified  
18 entities (as such terms are defined in section  
19 1903(m)(9)(D)),” after “under this title”; and

20 (B) in subparagraph (B), by inserting  
21 “and the basis for such dispensing fees” before  
22 the semicolon;

23 (6) by redesignating paragraph (4) as para-  
24 graph (5);

1           (7) by inserting after paragraph (3) the fol-  
2       lowing new paragraph:

3           “(4) OVERSIGHT.—

4                   “(A) IN GENERAL.—The Inspector General  
5       of the Department of Health and Human Serv-  
6       ices shall conduct periodic studies of the survey  
7       data reported under this subsection, as appro-  
8       priate, including with respect to substantial  
9       variations in acquisition costs or other applica-  
10      ble costs, as well as with respect to how internal  
11      transfer prices and related party transactions  
12      may influence the costs reported by pharmacies  
13      that are affiliates (as defined in subsection  
14      (k)(14)) or are owned by, controlled by, or re-  
15      lated under a common ownership structure with  
16      a wholesaler, distributor, or other entity that  
17      acquires covered outpatient drugs relative to  
18      costs reported by pharmacies not affiliated with  
19      such entities. The Inspector General shall pro-  
20      vide periodic updates to Congress on the results  
21      of such studies, as appropriate, in a manner  
22      that does not disclose trade secrets or other  
23      proprietary information.

24                   “(B) APPROPRIATION.—There is appro-  
25      priated to the Inspector General of the Depart-

1           ment of Health and Human Services, out of  
2           any money in the Treasury not otherwise ap-  
3           propriated, \$5,000,000 for fiscal year 2025, to  
4           remain available until expended, to carry out  
5           this paragraph.”; and

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

7                 (A) by inserting “, and \$9,000,000 for fis-  
8                 cal year 2025 and each fiscal year thereafter,”  
9                 after “2010”; and

10                (B) by inserting “Funds appropriated  
11                under this paragraph for fiscal year 2025 and  
12                any subsequent fiscal year shall remain avail-  
13                able until expended.” after the period.

14           (b) DEFINITIONS.—Section 1927(k) of the Social Se-  
15           curity Act (42 U.S.C. 1396r–8(k)) is amended—

16                (1) in the matter preceding paragraph (1), by  
17                striking “In the section” and inserting “In this sec-  
18                tion”; and

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

21                “(12) APPLICABLE NON-RETAIL PHARMACY.—

22                The term ‘applicable non-retail pharmacy’ means a  
23                pharmacy that is licensed as a pharmacy by the  
24                State and that is not a retail community pharmacy,  
25                including a pharmacy that dispenses prescription

1 medications to patients primarily through mail and  
2 specialty pharmacies. Such term does not include  
3 nursing home pharmacies, long-term care facility  
4 pharmacies, hospital pharmacies, clinics, charitable  
5 or not-for-profit pharmacies, government phar-  
6 macies, or low dispensing pharmacies (as defined by  
7 the Secretary).

8 “(13) AFFILIATE.—The term ‘affiliate’ means  
9 any entity that is owned by, controlled by, or related  
10 under a common ownership structure with a phar-  
11 macy benefit manager or a managed care entity or  
12 other specified entity (as such terms are defined in  
13 section 1903(m)(9)(D)).”.

14 (c) EFFECTIVE DATE.—

15 (1) IN GENERAL.—Subject to paragraph (2),  
16 the amendments made by this section shall take ef-  
17 fect on the first day of the first quarter that begins  
18 on or after the date that is 6 months after the date  
19 of enactment of this Act.

20 (2) DELAYED APPLICATION TO APPLICABLE  
21 NON-RETAIL PHARMACIES.—The pharmacy survey  
22 requirements established by the amendments to sec-  
23 tion 1927(f) of the Social Security Act (42 U.S.C.  
24 1396r–8(f)) made by this section shall apply to re-  
25 tail community pharmacies beginning on the effec-

1       tive date described in paragraph (1), but shall not  
2       apply to applicable non-retail pharmacies until the  
3       first day of the first quarter that begins on or after  
4       the date that is 18 months after the date of enact-  
5       ment of this Act.

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

8               (1) IN GENERAL.—Not later than January 1,  
9       2026, the Secretary of Health and Human Services  
10      shall, in consultation with stakeholders as appro-  
11      priate, publish guidance specifying pharmacies that  
12      meet the definition of applicable non-retail phar-  
13      macies (as such term is defined in subsection  
14      (k)(12) of section 1927 of the Social Security Act  
15      (42 U.S.C. 1396r–8), as added by subsection (b)),  
16      and that will be subject to the survey requirements  
17      under subsection (f)(1) of such section, as amended  
18      by subsection (a).

19              (2) INCLUSION OF PHARMACY TYPE INDICA-  
20      TORS.—The guidance published under paragraph (1)  
21      shall include pharmacy type indicators to distinguish  
22      between different types of applicable non-retail phar-  
23      macies, such as pharmacies that dispense prescrip-  
24      tions primarily through the mail and pharmacies  
25      that dispense prescriptions that require special han-

1 dling or distribution. An applicable non-retail phar-  
2 macy may be identified through multiple pharmacy  
3 type indicators.

4 (e) IMPLEMENTATION.—

5 (1) IN GENERAL.—Notwithstanding any other  
6 provision of law, the Secretary of Health and  
7 Human Services may implement the amendments  
8 made by this section by program instruction or oth-  
9 erwise.

10 (2) NONAPPLICATION OF ADMINISTRATIVE PRO-  
11 CEDURE ACT.—Implementation of the amendments  
12 made by this section shall be exempt from the re-  
13 quirements of section 553 of title 5, United States  
14 Code.

15 (f) NONAPPLICATION OF PAPERWORK REDUCTION  
16 ACT.—Chapter 35 of title 44, United States Code, shall  
17 not apply to any data collection undertaken by the Sec-  
18 retary of Health and Human Services under section  
19 1927(f) of the Social Security Act (42 U.S.C. 1396r–8(f)),  
20 as amended by this section.

21 **SEC. 113. PREVENTING THE USE OF ABUSIVE SPREAD PRIC-**  
22 **ING IN MEDICAID.**

23 (a) IN GENERAL.—Section 1927 of the Social Secu-  
24 rity Act (42 U.S.C. 1396r–8) is amended—

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

3           “(6) TRANSPARENT PRESCRIPTION DRUG PASS-  
4 THROUGH PRICING REQUIRED.—

5           “(A) IN GENERAL.—A contract between  
6 the State and a pharmacy benefit manager (re-  
7 ferred to in this paragraph as a ‘PBM’), or a  
8 contract between the State and a managed care  
9 entity or other specified entity (as such terms  
10 are defined in section 1903(m)(9)(D) and col-  
11 lectively referred to in this paragraph as the  
12 ‘entity’) that includes provisions making the en-  
13 tity responsible for coverage of covered out-  
14 patient drugs dispensed to individuals enrolled  
15 with the entity, shall require that payment for  
16 such drugs and related administrative services  
17 (as applicable), including payments made by a  
18 PBM on behalf of the State or entity, is based  
19 on a transparent prescription drug pass-  
20 through pricing model under which—

21           “(i) any payment made by the entity  
22 or the PBM (as applicable) for such a  
23 drug—

24           “(I) is limited to—

25           “(aa) ingredient cost; and



1                   “(bb) a professional dis-  
2                   pensing fee that is not less than  
3                   the professional dispensing fee  
4                   that the State would pay if the  
5                   State were making the payment  
6                   directly in accordance with the  
7                   State plan;

8                   “(II) is passed through in its en-  
9                   tirety (except as reduced under Fed-  
10                  eral or State laws and regulations in  
11                  response to instances of waste, fraud,  
12                  or abuse) by the entity or PBM to the  
13                  pharmacy or provider that dispenses  
14                  the drug; and

15                  “(III) is made in a manner that  
16                  is consistent with sections 447.502,  
17                  447.512, 447.514, and 447.518 of  
18                  title 42, Code of Federal Regulations  
19                  (or any successor regulation) as if  
20                  such requirements applied directly to  
21                  the entity or the PBM, except that  
22                  any payment by the entity or the  
23                  PBM for the ingredient cost of such  
24                  drug purchased by a covered entity  
25                  (as defined in subsection (a)(5)(B))

1                   may exceed the actual acquisition cost  
2                   (as defined in 447.502 of title 42,  
3                   Code of Federal Regulations, or any  
4                   successor regulation) for such drug  
5                   if—

6                   “(aa) such drug was subject  
7                   to an agreement under section  
8                   340B of the Public Health Serv-  
9                   ice Act;

10                  “(bb) such payment for the  
11                  ingredient cost of such drug does  
12                  not exceed the maximum pay-  
13                  ment that would have been made  
14                  by the entity or the PBM for the  
15                  ingredient cost of such drug if  
16                  such drug had not been pur-  
17                  chased by such covered entity;  
18                  and

19                  “(cc) such covered entity re-  
20                  ports to the Secretary (in a form  
21                  and manner specified by the Sec-  
22                  retary), on an annual basis and  
23                  with respect to payments for the  
24                  ingredient costs of such drugs so  
25                  purchased by such covered entity

1                   that are in excess of the actual  
2                   acquisition costs for such drugs,  
3                   the aggregate amount of such ex-  
4                   cess;

5                   “(ii) payment to the entity or the  
6                   PBM (as applicable) for administrative  
7                   services performed by the entity or PBM is  
8                   limited to an administrative fee that re-  
9                   flects the fair market value (as defined by  
10                  the Secretary) of such services;

11                  “(iii) the entity or the PBM (as appli-  
12                  cable) makes available to the State, and  
13                  the Secretary upon request in a form and  
14                  manner specified by the Secretary, all costs  
15                  and payments related to covered outpatient  
16                  drugs and accompanying administrative  
17                  services (as described in clause (ii)) in-  
18                  curred, received, or made by the entity or  
19                  the PBM, broken down (as specified by the  
20                  Secretary), to the extent such costs and  
21                  payments are attributable to an individual  
22                  covered outpatient drug, by each such  
23                  drug, including any ingredient costs, pro-  
24                  fessional dispensing fees, administrative  
25                  fees (as described in clause (ii)), post-sale

1 and post-invoice fees, discounts, or related  
2 adjustments such as direct and indirect re-  
3 muneration fees, and any and all other re-  
4 muneration, as defined by the Secretary;  
5 and

6 “(iv) any form of spread pricing  
7 whereby any amount charged or claimed by  
8 the entity or the PBM (as applicable) that  
9 exceeds the amount paid to the pharmacies  
10 or providers on behalf of the State or enti-  
11 ty, including any post-sale or post-invoice  
12 fees, discounts, or related adjustments  
13 such as direct and indirect remuneration  
14 fees or assessments, as defined by the Sec-  
15 retary, (after allowing for an administra-  
16 tive fee as described in clause (ii)) is not  
17 allowable for purposes of claiming Federal  
18 matching payments under this title.

19 “(B) PUBLICATION OF INFORMATION.—  
20 The Secretary shall publish, not less frequently  
21 than on an annual basis and in a manner that  
22 does not disclose the identity of a particular  
23 covered entity or organization, information re-  
24 ceived by the Secretary pursuant to subpara-  
25 graph (A)(iii)(III) that is broken out by State

1 and by each of the following categories of cov-  
2 ered entity within each such State:

3 “(i) Covered entities described in sub-  
4 paragraph (A) of section 340B(a)(4) of the  
5 Public Health Service Act.

6 “(ii) Covered entities described in sub-  
7 paragraphs (B) through (K) of such sec-  
8 tion.

9 “(iii) Covered entities described in  
10 subparagraph (L) of such section.

11 “(iv) Covered entities described in  
12 subparagraph (M) of such section.

13 “(v) Covered entities described in sub-  
14 paragraph (N) of such section.

15 “(vi) Covered entities described in  
16 subparagraph (O) of such section.”; and

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

20 “(14) PHARMACY BENEFIT MANAGER.—The  
21 term ‘pharmacy benefit manager’ means any person  
22 or entity that, either directly or through an inter-  
23 mediary, acts as a price negotiator or group pur-  
24 chaser on behalf of a State, managed care entity (as  
25 defined in section 1903(m)(9)(D)), or other specified

1       entity (as so defined), or manages the prescription  
2       drug benefits provided by a State, managed care en-  
3       tity, or other specified entity, including the proc-  
4       essing and payment of claims for prescription drugs,  
5       the performance of drug utilization review, the proc-  
6       essing of drug prior authorization requests, the man-  
7       aging of appeals or grievances related to the pre-  
8       scription drug benefits, contracting with pharmacies,  
9       controlling the cost of covered outpatient drugs, or  
10      the provision of services related thereto. Such term  
11      includes any person or entity that acts as a price ne-  
12      gotiator (with regard to payment amounts to phar-  
13      macies and providers for a covered outpatient drug  
14      or the net cost of the drug) or group purchaser on  
15      behalf of a State, managed care entity, or other  
16      specified entity or that carries out 1 or more of the  
17      other activities described in the preceding sentence,  
18      irrespective of whether such person or entity calls  
19      itself a pharmacy benefit manager.”.

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

22              (1) in paragraph (2)(A)(xiii)—

23                      (A) by striking “and (III)” and inserting  
24                      “(III)”;

1 (B) by inserting before the period at the  
2 end the following: “, and (IV) if the contract in-  
3 cludes provisions making the entity responsible  
4 for coverage of covered outpatient drugs, the  
5 entity shall comply with the requirements of  
6 section 1927(e)(6)”;

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

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

11 “(10) No payment shall be made under this  
12 title to a State with respect to expenditures incurred  
13 by the State for payment for services provided by an  
14 other specified entity (as defined in paragraph  
15 (9)(D)(iii)) unless such services are provided in ac-  
16 cordance with a contract between the State and such  
17 entity which satisfies the requirements of paragraph  
18 (2)(A)(xiii).”.

19 (c) EFFECTIVE DATE.—The amendments made by  
20 this section shall apply to contracts between States and  
21 managed care entities, other specified entities, or phar-  
22 macy benefit managers that have an effective date begin-  
23 ning on or after the date that is 18 months after the date  
24 of enactment of this Act.

25 (d) IMPLEMENTATION.—

1           (1) IN GENERAL.—Notwithstanding any other  
2       provision of law, the Secretary of Health and  
3       Human Services may implement the amendments  
4       made by this section by program instruction or otherwise.  
5

6           (2) NONAPPLICATION OF ADMINISTRATIVE PRO-  
7       CEDURE ACT.—Implementation of the amendments  
8       made by this section shall be exempt from the re-  
9       quirements of section 553 of title 5, United States  
10      Code.

11       (e) NONAPPLICATION OF PAPERWORK REDUCTION  
12    ACT.—Chapter 35 of title 44, United States Code, shall  
13    not apply to any data collection undertaken by the Sec-  
14    retary of Health and Human Services under section  
15    1927(e) of the Social Security Act (42 U.S.C. 1396r-  
16    8(e)), as amended by this section.

## 17                   **TITLE II—MEDICARE**

### 18   **SEC. 201. EXTENSION OF INCREASED INPATIENT HOSPITAL** 19                   **PAYMENT ADJUSTMENT FOR CERTAIN LOW-** 20                   **VOLUME HOSPITALS.**

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

23           (1) in subparagraph (B), in the matter pre-  
24       ceding clause (i), by striking “fiscal year 2025 be-  
25       ginning on January 1, 2025, and ending on Sep-



1       tember 30, 2025, and in fiscal year 2026” and in-  
2       serting “fiscal year 2026 beginning on January 1,  
3       2026, and ending on September 30, 2026, and in  
4       fiscal year 2027”;

5               (2) in subparagraph (C)(i)—

6                       (A) in the matter preceding subclause

7               (I)—

8                               (i) by striking “through 2024” and  
9                               inserting “through 2025”;

10                              (ii) by striking “fiscal year 2025” and  
11                              inserting “fiscal year 2026”;

12                              (iii) by striking “October 1, 2024”  
13                              and inserting “October 1, 2025”; and

14                              (iv) by striking “December 31, 2024”  
15                              and inserting “December 31, 2025”;

16               (B) in subclause (III)—

17                               (i) by striking “through 2024” and  
18                               inserting “through 2025”;

19                              (ii) by striking “fiscal year 2025” and  
20                              inserting “fiscal year 2026”;

21                              (iii) by striking “October 1, 2024”  
22                              and inserting “October 1, 2025”; and

23                              (iv) by striking “December 31, 2024”  
24                              and inserting “December 31, 2025”; and

25               (C) in subclause (IV)—

1 (i) by striking “fiscal year 2025” and  
2 inserting “fiscal year 2026”;

3 (ii) by striking “January 1, 2025”  
4 and inserting “January 1, 2026”;

5 (iii) by striking “September 30,  
6 2025” and inserting “September 30,  
7 2026”; and

8 (iv) by striking “fiscal year 2026”  
9 and inserting “fiscal year 2027”; and

10 (3) in subparagraph (D)—

11 (A) in the matter preceding clause (i)—

12 (i) by striking “through 2024” and  
13 inserting “through 2025”;

14 (ii) by striking “fiscal year 2025” and  
15 inserting “fiscal year 2026”;

16 (iii) by striking “October 1, 2024”  
17 and inserting “October 1, 2025”; and

18 (iv) by striking “December 31, 2024”  
19 and inserting “December 31, 2025”; and

20 (B) in clause (ii)—

21 (i) by striking “through 2024” and  
22 inserting “through 2025”;

23 (ii) by striking “fiscal year 2025” and  
24 inserting “fiscal year 2026”;

1 (iii) by striking “October 1, 2024”  
2 and inserting “October 1, 2025”; and  
3 (iv) by striking “December 31, 2024”  
4 and inserting “December 31, 2025”.

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

9 **SEC. 202. EXTENSION OF THE MEDICARE-DEPENDENT HOS-**  
10 **PITAL (MDH) PROGRAM.**

11 (a) IN GENERAL.—Section 1886(d)(5)(G) of the So-  
12 cial Security Act (42 U.S.C. 1395ww(d)(5)(G)) is amend-  
13 ed—

14 (1) in clause (i), by striking “January 1, 2025”  
15 and inserting “January 1, 2026”; and  
16 (2) in clause (ii)(II), by striking “January 1,  
17 2025” and inserting “January 1, 2026”.

18 (b) CONFORMING AMENDMENTS.—

19 (1) IN GENERAL.—Section 1886(b)(3)(D) of  
20 the Social Security Act (42 U.S.C.  
21 1395ww(b)(3)(D)) is amended—

22 (A) in the matter preceding clause (i), by  
23 striking “January 1, 2025” and inserting “Jan-  
24 uary 1, 2026”; and

25 (B) in clause (iv)—

- 1 (i) by striking “fiscal year 2024” and  
2 inserting “fiscal year 2025”;  
3 (ii) by striking “fiscal year 2025” and  
4 inserting “fiscal year 2026”;  
5 (iii) by striking “October 1, 2024”  
6 and inserting “October 1, 2025”; and  
7 (iv) by striking “December 31, 2024”  
8 and inserting “December 31, 2025”.

9 (2) PERMITTING HOSPITALS TO DECLINE RE-  
10 CLASSIFICATION.—Section 13501(e)(2) of the Omni-  
11 bus Budget Reconciliation Act of 1993 (42 U.S.C.  
12 1395ww note) is amended—

13 (A) by striking “through 2024” and insert-  
14 ing “through 2025”;

15 (B) by striking “fiscal year 2025” and in-  
16 serting “fiscal year 2026”;

17 (C) by striking “October 1, 2024” and in-  
18 serting “October 1, 2025”; and

19 (D) by striking “December 31, 2024” and  
20 inserting “December 31, 2025”.

21 **SEC. 203. EXTENSION OF ADD-ON PAYMENTS FOR AMBU-**  
22 **LANCE SERVICES.**

23 Section 1834(l) of the Social Security Act (42 U.S.C.  
24 1395m(l)) is amended—

1 (1) in paragraph (12)(A), by striking “January  
2 1, 2025” and inserting “January 1, 2027”; and

3 (2) in paragraph (13), by striking “January 1,  
4 2025” each place it appears and inserting “January  
5 1, 2027” in each such place.

6 **SEC. 204. EXTENDING INCENTIVE PAYMENTS FOR PARTICI-**  
7 **PATION IN ELIGIBLE ALTERNATIVE PAYMENT**  
8 **MODELS.**

9 (a) IN GENERAL.—Section 1833(z) of the Social Se-  
10 curity Act (42 U.S.C. 1395l(z)) is amended—

11 (1) in paragraph (1)(A)—

12 (A) by striking “with 2026” and inserting  
13 “with 2027”; and

14 (B) by inserting “, or, with respect to  
15 2027, 3.53 percent” after “1.88 percent”;

16 (2) in paragraph (2)—

17 (A) in subparagraph (B)—

18 (i) in the heading, by striking “2026”  
19 and inserting “2027”; and

20 (ii) in the matter preceding clause (i),  
21 by striking “2026” and inserting “2027”;

22 (B) in subparagraph (C)—

23 (i) in the heading, by striking “2027”  
24 and inserting “2028”; and

1 (ii) in the matter preceding clause (i),  
2 by striking “2027” and inserting “2028”;  
3 and

4 (C) in subparagraph (D), by striking “and  
5 2026” and inserting “2026, and 2027”; and

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

8 (b) CONFORMING AMENDMENTS.—Section  
9 1848(q)(1)(C)(iii) of the Social Security Act (42 U.S.C.  
10 1395w–4(q)(1)(C)(iii)) is amended—

11 (1) in subclause (II), by striking “2026” and  
12 inserting “2027”; and

13 (2) in subclause (III), by striking “2027” and  
14 inserting “2028”.

15 **SEC. 205. TEMPORARY PAYMENT INCREASE UNDER THE**  
16 **MEDICARE PHYSICIAN FEE SCHEDULE TO AC-**  
17 **COUNT FOR EXCEPTIONAL CIRCUMSTANCES.**

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

20 (1) in subparagraph (D), by striking “and” at  
21 the end;

22 (2) in subparagraph (E), by striking the period  
23 at the end and inserting “; and”; and

24 (3) by adding at the end the following new sub-  
25 paragraph:

1           “(F) such services furnished on or after  
2           January 1, 2025, and before January 1, 2026,  
3           by 2.5 percent.”.

4           (b)           CONFORMING           AMENDMENT.—Section  
5   1848(c)(2)(B)(iv)(V) is amended by striking “or 2024”  
6   and inserting “2024, or 2025”.

7   **SEC. 206. EXTENSION OF FUNDING FOR QUALITY MEASURE**

8                   **ENDORSEMENT, INPUT, AND SELECTION.**

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

11           (1) in the first sentence—

12                   (A) by striking “and \$9,000,000” and in-  
13                   serting “\$9,000,000”; and

14                   (B) by inserting “, and \$5,000,000 for the  
15                   period beginning on January 1, 2025, and end-  
16                   ing on December 31, 2025” after “December  
17                   31, 2024”; and

18           (2) in the third sentence—

19                   (A) by striking “and the period” and in-  
20                   serting “, the period”;

21                   (B) by inserting “and the period beginning  
22                   on January 1, 2025, and ending on December  
23                   31, 2025,” after “December 31, 2024,”; and

24                   (C) by inserting “or period” after “pre-  
25                   ceding fiscal year”.

1   **SEC. 207. EXTENSION OF FUNDING OUTREACH AND ASSIST-**  
2                   **ANCE FOR LOW-INCOME PROGRAMS.**

3           (a) STATE HEALTH INSURANCE ASSISTANCE PRO-  
4 GRAMS.—Subsection (a)(1)(B) of section 119 of the Medi-  
5 care Improvements for Patients and Providers Act of 2008  
6 (42 U.S.C. 1395b–3 note) is amended—

7               (1) in clause (xiii), by striking “and” at the  
8           end;

9               (2) in clause (xiv), by striking the period and  
10           inserting “; and”; and

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

13                               “(xv) for the period beginning on Jan-  
14                               uary 1, 2025, and ending on December 31,  
15                               2026, \$30,000,000.”.

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

18               (1) in clause (xiii), by striking “and” at the  
19           end;

20               (2) in clause (xiv), by striking the period and  
21           inserting “; and”; and

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

24                               “(xv) for the period beginning on Jan-  
25                               uary 1, 2025, and ending on December 31,  
26                               2026, \$30,000,000.”.



1 (c) AGING AND DISABILITY RESOURCE CENTERS.—

2 Subsection (c)(1)(B) of such section 119 is amended—

3 (1) in clause (xiii), by striking “and” at the  
4 end;

5 (2) in clause (xiv), by striking the period and  
6 inserting “; and”; and

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

9 “(xv) for the period beginning on Jan-  
10 uary 1, 2025, and ending on December 31,  
11 2026, \$10,000,000.”.

12 (d) COORDINATION OF EFFORTS TO INFORM OLDER  
13 AMERICANS ABOUT BENEFITS AVAILABLE UNDER FED-  
14 ERAL AND STATE PROGRAMS.—Subsection (d)(2) of such  
15 section 119 is amended—

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

18 (2) in clause (xiv), by striking the period and  
19 inserting “; and”; and

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

22 “(xv) for the period beginning on Jan-  
23 uary 1, 2025, and ending on December 31,  
24 2026, \$30,000,000.”.

1   **SEC. 208. EXTENSION OF THE WORK GEOGRAPHIC INDEX**

2                   **FLOOR.**

3           Section 1848(e)(1)(E) of the Social Security Act (42  
4   U.S.C. 1395w-4(e)(1)(E)) is amended by striking “Janu-  
5   ary 1, 2025” and inserting “January 1, 2026”.

6   **SEC. 209. EXTENSION OF CERTAIN TELEHEALTH FLEXIBILI-**

7                   **TIES.**

8           (a) REMOVING GEOGRAPHIC REQUIREMENTS AND  
9   EXPANDING ORIGINATING SITES FOR TELEHEALTH  
10   SERVICES.—Section 1834(m) of the Social Security Act  
11   (42 U.S.C. 1395m(m)) is amended—

12               (1) in paragraph (2)(B)(iii), by striking “end-  
13       ing December 31, 2024” and inserting “ending De-  
14       cember 31, 2026”; and

15               (2) in paragraph (4)(C)(iii), by striking “ending  
16       on December 31, 2024” and inserting “ending on  
17       December 31, 2026”.

18           (b) EXPANDING PRACTITIONERS ELIGIBLE TO FUR-  
19   NISH TELEHEALTH SERVICES.—Section 1834(m)(4)(E)  
20   of the Social Security Act (42 U.S.C. 1395m(m)(4)(E))  
21   is amended by striking “ending on December 31, 2024”  
22   and inserting “ending on December 31, 2026”.

23           (c) EXTENDING TELEHEALTH SERVICES FOR FED-  
24   ERALLY QUALIFIED HEALTH CENTERS AND RURAL  
25   HEALTH CLINICS.—Section 1834(m)(8) of the Social Se-  
26   curity Act (42 U.S.C. 1395m(m)(8)) is amended—

1 (1) in subparagraph (A), by striking “ending on  
2 December 31, 2024” and inserting “ending on De-  
3 cember 31, 2026”;

4 (2) in subparagraph (B)—

5 (A) in the subparagraph heading, by in-  
6 serting “BEFORE 2025” after “RULE”;

7 (B) in clause (i), by striking “during the  
8 periods for which subparagraph (A) applies”  
9 and inserting “before January 1, 2025”; and

10 (C) in clause (ii), by inserting “furnished  
11 to an eligible telehealth individual before Janu-  
12 ary 1, 2025” after “telehealth services”; and

13 (3) by adding at the end the following new sub-  
14 paragraph:

15 “(C) PAYMENT RULE FOR 2025 AND  
16 2026.—

17 “(i) IN GENERAL.—A telehealth serv-  
18 ice furnished to an eligible telehealth indi-  
19 vidual by a Federally qualified health cen-  
20 ter or rural health clinic on or after Janu-  
21 ary 1, 2025, and before January 1, 2027,  
22 shall be paid as a Federally qualified  
23 health center service or rural health clinic  
24 service (as applicable) under the prospec-  
25 tive payment system established under sec-

1           tion 1834(o) or the methodology for all-in-  
2           clusive rates established under section  
3           1833(a)(3), respectively.

4           “(ii) TREATMENT OF COSTS.—Costs  
5           associated with the furnishing of telehealth  
6           services by a Federally qualified health  
7           center or rural health clinic on or after  
8           January 1, 2025, and before January 1,  
9           2027, shall be considered allowable costs  
10          for purposes of the prospective payment  
11          system established under section 1834(o)  
12          and the methodology for all-inclusive rates  
13          established under section 1833(a)(3), as  
14          applicable.

15          “(iii) REQUIRING MODIFIERS.—Not  
16          later than July 1, 2025, the Secretary  
17          shall establish requirements to include 1 or  
18          more codes or modifiers, as determined ap-  
19          propriate by the Secretary, in the case of  
20          claims for telehealth services furnished to  
21          an eligible telehealth individual by a Feder-  
22          ally qualified health center or rural health  
23          clinic.”.

24          (d) DELAYING THE IN-PERSON REQUIREMENTS  
25          UNDER MEDICARE FOR MENTAL HEALTH SERVICES

1 FURNISHED THROUGH TELEHEALTH AND TELE-  
2 COMMUNICATIONS TECHNOLOGY.—

3 (1) DELAY IN REQUIREMENTS FOR MENTAL  
4 HEALTH SERVICES FURNISHED THROUGH TELE-  
5 HEALTH.—Section 1834(m)(7)(B)(i) of the Social  
6 Security Act (42 U.S.C. 1395m(m)(7)(B)(i)) is  
7 amended, in the matter preceding subclause (I), by  
8 striking “on or after” and all that follows through  
9 “described in section 1135(g)(1)(B))” and inserting  
10 “on or after January 1, 2027”.

11 (2) MENTAL HEALTH VISITS FURNISHED BY  
12 RURAL HEALTH CLINICS.—Section 1834(y)(2) of the  
13 Social Security Act (42 U.S.C. 1395m(y)(2)) is  
14 amended by striking “January 1, 2025” and all that  
15 follows through the period at the end and inserting  
16 “January 1, 2027.”.

17 (3) MENTAL HEALTH VISITS FURNISHED BY  
18 FEDERALLY QUALIFIED HEALTH CENTERS.—Section  
19 1834(o)(4)(B) of the Social Security Act (42 U.S.C.  
20 1395m(o)(4)(B)) is amended by striking “January  
21 1, 2025” and all that follows through the period at  
22 the end and inserting “January 1, 2027.”.

23 (e) ALLOWING FOR THE FURNISHING OF AUDIO-  
24 ONLY TELEHEALTH SERVICES.—Section 1834(m)(9) of  
25 the Social Security Act (42 U.S.C. 1395m(m)(9)) is

1 amended by striking “ending on December 31, 2024” and  
2 inserting “ending on December 31, 2026”.

3 (f) EXTENDING USE OF TELEHEALTH TO CONDUCT  
4 FACE-TO-FACE ENCOUNTER PRIOR TO RECERTIFICATION  
5 OF ELIGIBILITY FOR HOSPICE CARE.—Section  
6 1814(a)(7)(D)(i)(II) of the Social Security Act (42 U.S.C.  
7 1395f(a)(7)(D)(i)(II)) is amended—

8 (1) by striking “ending on December 31, 2024”  
9 and inserting “ending on December 31, 2026”; and

10 (2) by inserting “, except that this subclause  
11 shall not apply in the case of such an encounter with  
12 an individual occurring on or after January 1, 2025,  
13 if such individual is located in an area that is sub-  
14 ject to a moratorium on the enrollment of hospice  
15 programs under this title pursuant to section  
16 1866(j)(7), if such individual is receiving hospice  
17 care from a provider that is subject to enhanced  
18 oversight under this title pursuant to section  
19 1866(j)(3), or if such encounter is performed by a  
20 hospice physician or nurse practitioner who is not  
21 enrolled under section 1866(j) and is not an opt-out  
22 physician or practitioner (as defined in section  
23 1802(b)(6)(D))” before the semicolon.

24 (g) REQUIRING MODIFIERS FOR TELEHEALTH SERV-  
25 ICES IN CERTAIN INSTANCES.—Section 1834(m) of the

1 Social Security Act (42 U.S.C. 1395m(m)) is amended by  
2 adding at the end the following new paragraph:

3 “(10) REQUIRED USE OF MODIFIERS IN CER-  
4 TAIN INSTANCES.—Not later than January 1, 2026,  
5 the Secretary shall establish requirements to include  
6 1 or more codes or modifiers, as determined appro-  
7 priate by the Secretary, in the case of—

8 “(A) claims for telehealth services under  
9 this subsection that are furnished through a  
10 telehealth virtual platform—

11 “(i) by a physician or practitioner  
12 that contracts with an entity that owns  
13 such virtual platform; or

14 “(ii) for which a physician or practi-  
15 tioner has a payment arrangement with an  
16 entity for use of such virtual platform; and

17 “(B) claims for telehealth services under  
18 this subsection that are furnished incident to a  
19 physician’s or practitioner’s professional serv-  
20 ice.”.

21 (h) PROGRAM INSTRUCTION AUTHORITY.—The Sec-  
22 retary of Health and Human Services may implement the  
23 amendments made by this section through program in-  
24 struction or otherwise.

1 **SEC. 210. REQUIRING MODIFIER FOR USE OF TELEHEALTH**  
2 **TO CONDUCT FACE-TO-FACE ENCOUNTER**  
3 **PRIOR TO RECERTIFICATION OF ELIGIBILITY**  
4 **FOR HOSPICE CARE.**

5 Section 1814(a)(7)(D)(i)(II) of the Social Security  
6 Act (42 U.S.C. 1395f(a)(7)(D)(i)(II)), as amended by sec-  
7 tion 209(f) of the **[\_\_\_\_\_]**, is further  
8 amended by inserting “, but only if, in the case of such  
9 an encounter occurring on or after January 1, 2026, any  
10 hospice claim includes 1 or more modifiers or codes (as  
11 specified by the Secretary) to indicate that such encounter  
12 was conducted via telehealth” after “as determined appro-  
13 priate by the Secretary”.

14 **SEC. 211. EXTENDING ACUTE HOSPITAL CARE AT HOME**  
15 **WAIVER FLEXIBILITIES.**

16 Section 1866G of the Social Security Act (42 U.S.C.  
17 1395cc–7) is amended—

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

22 (2) in subsection (a)—

23 (A) in paragraph (1)—

24 (i) by striking “2024” and inserting  
25 “2029”; and



1 (ii) by striking “in the Acute Hospital  
2 Care at Home initiative of the Secretary”  
3 and inserting “in the Thomas R. Carper,  
4 Tim Scott, Brad R. Wenstrup, D.P.M.,  
5 and Earl Blumenauer Acute Hospital Care  
6 at Home initiative of the Secretary (in this  
7 section referred to as the ‘Acute Hospital  
8 Care at Home initiative’)”;

9 (B) in paragraph (2), by striking “of the  
10 Secretary”; and

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

13 “The Secretary may require that such data and  
14 information be submitted through a hospital’s  
15 cost report, through such survey instruments as  
16 the Secretary may develop, through medical  
17 record information, or through such other  
18 means as the Secretary determines appro-  
19 priate.”;

20 (3) in subsection (b)—

21 (A) in the subsection heading, by striking  
22 “STUDY” and inserting “INITIAL STUDY”;

23 (B) in paragraph (1)(A), by striking “of  
24 the Secretary”; and

1 (C) in paragraph (3), by inserting “or sub-  
2 section (c)” before the period at the end;

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

5 (5) by inserting after subsection (b) the fol-  
6 lowing new subsection:

7 “(c) SUBSEQUENT STUDY AND REPORT.—

8 “(1) IN GENERAL.—Not later than September  
9 30, 2028, the Secretary shall conduct a study to—

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

15 “(B) analyze and compare (both within  
16 and between hospitals participating in the ini-  
17 tiative, and relative to comparable hospitals  
18 that do not participate in the initiative, for rel-  
19 evant parameters such as diagnosis-related  
20 groups)—

21 “(i) quality of care furnished to indi-  
22 viduals with similar conditions and charac-  
23 teristics in the inpatient setting and  
24 through the Acute Hospital Care at Home  
25 initiative, including health outcomes, hos-

1           pital readmission rates (including readmis-  
2           sions both within and beyond 30 days post-  
3           discharge), hospital mortality rates, length  
4           of stay, infection rates, composition of care  
5           team (including the types of labor used,  
6           such as contracted labor), the ratio of  
7           nursing staff, transfers from the hospital  
8           to the home, transfers from the home to  
9           the hospital (including the timing, fre-  
10          quency, and causes of such transfers),  
11          transfers and discharges to post-acute care  
12          settings (including the timing, frequency,  
13          and causes of such transfers and dis-  
14          charges), and patient and caregiver experi-  
15          ence of care;

16               “(ii) clinical conditions treated and di-  
17               agnosis-related groups of discharges from  
18               inpatient settings relative to discharges  
19               from the Acute Hospital Care at Home ini-  
20               tiative;

21               “(iii) costs incurred by the hospital  
22               for furnishing care in inpatient settings  
23               relative to costs incurred by the hospital  
24               for furnishing care through the Acute Hos-  
25               pital Care at Home initiative, including

1 costs relating to staffing, equipment, food,  
2 prescriptions, and other services, as deter-  
3 mined by the Secretary;

4 “(iv) the quantity, mix, and intensity  
5 of services (such as in-person visits and  
6 virtual contacts with patients and the in-  
7 tensity of such services) furnished in inpa-  
8 tient settings relative to the Acute Hospital  
9 Care at Home initiative, and, to the extent  
10 practicable, the nature and extent of family  
11 or caregiver involvement;

12 “(v) socioeconomic information on in-  
13 dividuals treated in comparable inpatient  
14 settings relative to the initiative, including  
15 racial and ethnic data, income, housing,  
16 geographic proximity to the brick-and-mor-  
17 tar facility and whether such individuals  
18 are dually eligible for benefits under this  
19 title and title XIX; and

20 “(vi) the quality of care, outcomes,  
21 costs, quantity and intensity of services,  
22 and other relevant metrics between individ-  
23 uals who entered into the Acute Hospital  
24 Care at Home initiative directly from an  
25 emergency department compared with indi-

1                   viduals who entered into the Acute Hos-  
2                   pital Care at Home initiative directly from  
3                   an existing inpatient stay in a hospital.

4                   “(2) SELECTION BIAS.—In conducting the  
5                   study under paragraph (1), the Secretary shall, to  
6                   the extent practicable, analyze and compare individ-  
7                   uals who participate and do not participate in the  
8                   initiative controlling for selection bias or other fac-  
9                   tors that may impact the reliability of data.

10                  “(3) REPORT.—Not later than September 30,  
11                  2028, the Secretary of Health and Human Services  
12                  shall post on a website of the Centers for Medicare  
13                  & Medicaid Services a report on the study conducted  
14                  under paragraph (1).

15                  “(4) FUNDING.—In addition to amounts other-  
16                  wise available, there is appropriated to the Centers  
17                  for Medicare & Medicaid Services Program Manage-  
18                  ment Account for fiscal year 2025, out of any  
19                  amounts in the Treasury not otherwise appropriated,  
20                  \$6,000,000, respectively, to remain available until  
21                  expended, for purposes of carrying out this section.”.

22   **SEC. 212. ENHANCING CERTAIN PROGRAM INTEGRITY RE-**  
23                   **QUIREMENTS FOR DME UNDER MEDICARE.**

24                  (a) DURABLE MEDICAL EQUIPMENT.—

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

4           “(23) MASTER LIST INCLUSION AND CLAIM RE-  
5           VIEW FOR CERTAIN ITEMS.—

6           “(A) MASTER LIST INCLUSION.—Begin-  
7           ning January 1, 2028, for purposes of the Mas-  
8           ter List described in section 414.234(b) of title  
9           42, Code of Federal Regulations (or any suc-  
10          cessor regulation), an item for which payment  
11          may be made under this subsection shall be  
12          treated as having aberrant billing patterns (as  
13          such term is used for purposes of such section)  
14          if the Secretary determines that, without ex-  
15          planatory contributing factors (such as fur-  
16          nishing emergent care services), a substantial  
17          number of claims for such items under this sub-  
18          section are for such items ordered by a physi-  
19          cian or practitioner who has not previously  
20          (during a period of not less than 24 months, as  
21          established by the Secretary) furnished to the  
22          individual involved any item or service for which  
23          payment may be made under this title.

24          “(B) CLAIM REVIEW.—With respect to  
25          items furnished on or after January 1, 2028,

1           that are included on the Master List pursuant  
2           to subparagraph (A), if such an item is not sub-  
3           ject to a determination of coverage in advance  
4           pursuant to paragraph (15)(C), the Secretary  
5           may conduct prepayment review of claims for  
6           payment for such item.”.

7           (2) CONFORMING AMENDMENT FOR PROS-  
8           THETIC DEVICES, ORTHOTICS, AND PROSTHETICS.—  
9           Section 1834(h)(3) of the Social Security Act (42  
10          U.S.C. 1395m(h)(3)) is amended by inserting “, and  
11          paragraph (23) of subsection (a) shall apply to pros-  
12          thetic devices, orthotics, and prosthetics in the same  
13          manner as such provision applies to items for which  
14          payment may be made under such subsection” be-  
15          fore the period at the end.

16          (b) REPORT ON IDENTIFYING CLINICAL DIAGNOSTIC  
17          LABORATORY TESTS AT HIGH RISK FOR FRAUD AND EF-  
18          FECTIVE MITIGATION MEASURES.—Not later than Janu-  
19          ary 1, 2026, the Inspector General of the Department of  
20          Health and Human Services shall submit to Congress a  
21          report assessing fraud risks relating to claims for clinical  
22          diagnostic laboratory tests for which payment may be  
23          made under section 1834A of the Social Security Act (42  
24          U.S.C. 1395m–1) and effective tools for reducing such

1 fraudulent claims. The report may include information re-  
2 garding—

3 (1) which, if any, clinical diagnostic laboratory  
4 tests are identified as being at high risk of fraudu-  
5 lent claims, and an analysis of the factors that con-  
6 tribute to such risk;

7 (2) with respect to a clinical diagnostic labora-  
8 tory test identified under paragraph (1) as being at  
9 high risk of fraudulent claims—

10 (A) the amount payable under such section  
11 1834A with respect to such test;

12 (B) the number of such tests furnished to  
13 individuals enrolled under part B of title XVIII  
14 of the Social Security Act (42 U.S.C. 1395j et  
15 seq.);

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

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



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

4           (A) an analysis of whether the Centers for  
5       Medicare & Medicaid Services can detect aber-  
6       rant billing patterns with respect to such tests  
7       in a timely manner;

8           (B) any strategies for identifying and mon-  
9       itoring the providers who are outliers with re-  
10      spect to the number of such tests that such pro-  
11      viders order; and

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

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

16 **SEC. 213. GUIDANCE ON FURNISHING SERVICES VIA TELE-**  
17 **HEALTH TO INDIVIDUALS WITH LIMITED**  
18 **ENGLISH PROFICIENCY.**

19          (a) IN GENERAL.—Not later than 1 year after the  
20      date of the enactment of this section, the Secretary of  
21      Health and Human Services, in consultation with 1 or  
22      more entities from each of the categories described in  
23      paragraphs (1) through (7) of subsection (b), shall issue  
24      and disseminate, or update and revise as applicable, guid-

1   ance for the entities described in such subsection on the  
2   following:

3           (1) Best practices on facilitating and inte-  
4           grating use of interpreters during a telemedicine ap-  
5           pointment.

6           (2) Best practices on providing accessible in-  
7           structions on how to access telecommunications sys-  
8           tems (as such term is used for purposes of section  
9           1834(m) of the Social Security Act (42 U.S.C.  
10          1395m(m)) for individuals with limited English pro-  
11          ficiency.

12          (3) Best practices on improving access to dig-  
13          ital patient portals for individuals with limited  
14          English proficiency.

15          (4) Best practices on integrating the use of  
16          video platforms that enable multi-person video calls  
17          furnished via a telecommunications system for pur-  
18          poses of providing interpretation during a telemedi-  
19          cine appointment for an individual with limited  
20          English proficiency.

21          (5) Best practices for providing patient mate-  
22          rials, communications, and instructions in multiple  
23          languages, including text message appointment re-  
24          minders and prescription information.

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

4 (1) Health information technology service pro-  
5 viders, including—

6 (A) electronic medical record companies;

7 (B) remote patient monitoring companies;

8 and

9 (C) telehealth or mobile health vendors and  
10 companies.

11 (2) Health care providers, including—

12 (A) physicians; and

13 (B) hospitals.

14 (3) Health insurers.

15 (4) Language service companies.

16 (5) Interpreter or translator professional asso-  
17 ciations.

18 (6) Health and language services quality certifi-  
19 cation organizations.

20 (7) Patient and consumer advocates, including  
21 such advocates that work with individuals with lim-  
22 ited English proficiency.

1 **SEC. 214. IN-HOME CARDIOPULMONARY REHABILITATION**  
2 **FLEXIBILITIES.**

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

5 (1) in subparagraph (A)(ii), by inserting “(in-  
6 cluding, with respect to items and services furnished  
7 through audio and video real-time communications  
8 technology (excluding audio-only) on or after Janu-  
9 ary 1, 2025, and before January 1, 2027, in the  
10 home of an individual who is an outpatient of the  
11 hospital)” after “outpatient basis”; and

12 (2) in subparagraph (B), by inserting “(includ-  
13 ing, with respect to items and services furnished  
14 through audio and video real-time communications  
15 technology on or after January 1, 2025, and before  
16 January 1, 2027, the virtual presence of such physi-  
17 cian, physician assistant, nurse practitioner, or clin-  
18 ical nurse specialist)” after “under the program”.

19 (b) PROGRAM INSTRUCTION AUTHORITY.—Notwith-  
20 standing any other provision of law, the Secretary of  
21 Health and Human Services may implement the amend-  
22 ments made by this section by program instruction or oth-  
23 erwise.

1 **SEC. 215. INCLUSION OF VIRTUAL DIABETES PREVENTION**  
2 **PROGRAM SUPPLIERS IN MDPP EXPANDED**  
3 **MODEL.**

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

9 (1) an entity may participate in the MDPP by  
10 offering only online MDPP services via synchronous  
11 or asynchronous technology or telecommunications if  
12 such entity meets the conditions for enrollment as  
13 an MDPP supplier (as specified in section  
14 424.205(b) of title 42, Code of Federal Regulations  
15 (or a successor regulation));

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

18 (A) the administrative location of such en-  
19 tity shall be the address of the entity on file  
20 under the Diabetes Prevention Recognition Pro-  
21 gram; and

22 (B) in the case of online MDPP services  
23 furnished by such entity to an MDPP bene-  
24 ficiary who was not located in the same State  
25 as the entity at the time such services were fur-  
26 nished, the entity shall not be prohibited from

1 submitting a claim for payment for such serv-  
2 ices solely by reason of the location of such ben-  
3 eficiary at such time; and

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

6 (b) DEFINITIONS.—In this section:

7 (1) MDPP.—The term “MDPP” means the  
8 Medicare Diabetes Prevention Program conducted  
9 under section 1115A of the Social Security Act (42  
10 U.S.C. 1315a), as described in the final rule pub-  
11 lished in the Federal Register entitled “Medicare  
12 and Medicaid Programs; CY 2024 Payment Policies  
13 Under the Physician Fee Schedule and Other  
14 Changes to Part B Payment and Coverage Policies;  
15 Medicare Shared Savings Program Requirements;  
16 Medicare Advantage; Medicare and Medicaid Pro-  
17 vider and Supplier Enrollment Policies; and Basic  
18 Health Program” (88 Fed. Reg. 78818 (November  
19 16, 2023)) (or a successor regulation).

20 (2) REGULATORY TERMS.—The terms “Diabe-  
21 tes Prevention Recognition Program”, “full CDC  
22 DPRP recognition”, “MDPP beneficiary”, “MDPP  
23 services”, and “MDPP supplier” have the meanings  
24 given each such term in section 410.79(b) of title  
25 42, Code of Federal Regulations.

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

3 **SEC. 216. MEDICATION-INDUCED MOVEMENT DISORDER**  
4 **OUTREACH AND EDUCATION.**

5 Not later than January 1, 2026, the Secretary shall  
6 use existing communications mechanisms to provide edu-  
7 cation and outreach to physicians and appropriate non-  
8 physician practitioners participating under the Medicare  
9 program under title XVIII of the Social Security Act (42  
10 U.S.C. 1395 et seq.) with respect to periodic screening for  
11 medication-induced movement disorders that are associ-  
12 ated with the treatment of mental health disorders in at-  
13 risk patients, as well as resources related to clinical guide-  
14 lines and best practices for furnishing such screening serv-  
15 ices through telehealth. Such education and outreach shall  
16 include information on how to account for such screening  
17 services in evaluation and management code selection. The  
18 Secretary shall, to the extent practicable, seek input from  
19 relevant stakeholders to inform such education and out-  
20 reach. Such education and outreach may also address  
21 other relevant screening services furnished through tele-  
22 health, as the Secretary determines appropriate.

23 **SEC. 217. REPORT ON WEARABLE MEDICAL DEVICES.**

24 Not later than 18 months after the date of the enact-  
25 ment of this Act, the Comptroller General of the United

1 States shall conduct a technology assessment of, and sub-  
2 mit to Congress a report on, the capabilities and limita-  
3 tions of wearable medical devices used to support clinical  
4 decision-making. Such report shall include a description  
5 of—

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

8 (2) an examination of the benefits and chal-  
9 lenges of artificial intelligence to augment such ca-  
10 pabilities; and

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

14 **SEC. 218. EXTENSION OF TEMPORARY INCLUSION OF AU-**  
15 **THORIZED ORAL ANTIVIRAL DRUGS AS COV-**  
16 **ERED PART D DRUGS.**

17 Section 1860D–2(e)(1)(C) of the Social Security Act  
18 (42 U.S.C. 1395w–102(e)(1)(C)) is amended by striking  
19 “December 31, 2024” and inserting “December 31,  
20 2025”.

21 **SEC. 219. EXTENSION OF ADJUSTMENT TO CALCULATION**  
22 **OF HOSPICE CAP AMOUNT.**

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



1           (1) in clause (ii), by striking “2033” and in-  
2       serting “2034”; and

3           (2) in clause (iii), by striking “2033” and in-  
4       serting “2034”.

5   **SEC. 220. MULTIYEAR CONTRACTING AUTHORITY FOR**  
6                           **MEDPAC AND MACPAC.**

7       Section 3904 of title 41, United States Code, is  
8   amended by adding at the end the following new sub-  
9   sections:

10       “(i) THE MEDICARE PAYMENT ADVISORY COMMIS-  
11   SION.—The Medicare Payment Advisory Commission may  
12   use available funds to enter into contracts for the procure-  
13   ment of severable services for a period that begins in one  
14   fiscal year and ends in the next fiscal year and may enter  
15   into multiyear contracts for the acquisition of property  
16   and services to the same extent as executive agencies  
17   under the authority of sections 3902 and 3903 of this  
18   title.

19       “(j) THE MEDICAID AND CHIP PAYMENT AND AC-  
20   CESS COMMISSION.—The Medicaid and CHIP Payment  
21   and Access Commission may use available funds to enter  
22   into contracts for the procurement of severable services  
23   for a period that begins in one fiscal year and ends in  
24   the next fiscal year and may enter into multiyear contracts  
25   for the acquisition of property and services to the same

1 extent as executive agencies under the authority of sec-  
2 tions 3902 and 3903 of this title.”.

3 **SEC. 221. CONTRACTING PARITY FOR MEDPAC AND**  
4 **MACPAC.**

5 In fiscal year 2025 and thereafter, for all contracts  
6 for goods and services to which the Medicare and Payment  
7 Advisory Commission or the Medicaid and CHIP Payment  
8 and Access Commission is a party, the following Federal  
9 Acquisition Regulation (FAR) clauses will apply: FAR  
10 52.232–39 and FAR 52.233–4 (or a successor clause).

11 **SEC. 222. ADJUSTMENTS TO MEDICARE PART D COST-SHAR-**  
12 **ING REDUCTIONS FOR LOW-INCOME INDIVID-**  
13 **UALS.**

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

16 (1) in paragraph (1)(D)(ii), by striking “that  
17 does not exceed \$1 for” and all that follows through  
18 the period at the end and inserting “that does not  
19 exceed—

20 “(I) for a plan year before  
21 2027—

22 “(aa) for a generic drug or a  
23 preferred drug that is a multiple  
24 source drug (as defined in section  
25 1927(k)(7)(A)(i)), \$1 or, if less,

1 the copayment amount applicable  
2 to an individual under clause  
3 (iii); and

4 “(bb) for any other drug, \$3  
5 or, if less, the copayment amount  
6 applicable to an individual under  
7 clause (iii); and

8 “(II) for plan year 2027 and  
9 each subsequent plan year—

10 “(aa) for a generic drug, \$0;

11 “(bb) for a preferred drug  
12 that is a multiple source drug (as  
13 defined in section  
14 1927(k)(7)(A)(i)), the dollar  
15 amount applied under this clause  
16 for such a drug for the preceding  
17 plan year, increased by the an-  
18 nual percentage increase in the  
19 consumer price index (all items;  
20 U.S. city average) as of Sep-  
21 tember of such preceding year,  
22 or, if less, the copayment amount  
23 applicable to an individual under  
24 clause (iii); and

1 “(cc) for a drug not de-  
2 scribed in either item (aa) or  
3 (bb), the dollar amount applied  
4 under this clause for such a drug  
5 for the preceding plan year, in-  
6 creased in the manner specified  
7 in item (bb), or, if less, the co-  
8 payment amount applicable to an  
9 individual under clause (iii).

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

16 (2) in paragraph (4)(A)(ii), by inserting “(be-  
17 fore 2027)” after “a subsequent year”.

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

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

22 (1) in paragraph (1)(C)—

23 (A) by striking “plan, and any” and insert-  
24 ing “plan, any”; and

1 (B) by inserting the following before the  
2 period at the end: “, and, in the case of a speci-  
3 fied MA plan (as defined in paragraph (3)(C)),  
4 for plan year 2027 and subsequent plan years,  
5 the information described in paragraph (3)(B)”;  
6 and

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

9 “(3) PROVIDER DIRECTORY ACCURACY.—

10 “(A) IN GENERAL.—For plan year 2027  
11 and subsequent plan years, each MA organiza-  
12 tion offering a specified MA plan (as defined in  
13 subparagraph (C)) shall, for each such plan of-  
14 fered by the organization—

15 “(i) maintain, on a publicly available  
16 internet website, an accurate provider di-  
17 rectory that includes the information de-  
18 scribed in subparagraph (B);

19 “(ii) not less frequently than once  
20 every 90 days (or, in the case of a hospital  
21 or any other facility determined appro-  
22 priate by the Secretary, at a lesser fre-  
23 quency specified by the Secretary but in no  
24 case less frequently than once every 12  
25 months), verify the provider directory in-

1           formation of each provider listed in such  
2           directory and, if applicable, update such  
3           provider directory information;

4           “(iii) if the organization is unable to  
5           verify such information with respect to a  
6           provider, include in such directory an indi-  
7           cation that the information of such pro-  
8           vider may not be up to date; and

9           “(iv) remove a provider from such di-  
10          rectory within 5 business days if the orga-  
11          nization determines that the provider is no  
12          longer a provider participating in the net-  
13          work of such plan.

14          “(B) PROVIDER DIRECTORY INFORMA-  
15          TION.—The information described in this sub-  
16          paragraph is information enrollees may need to  
17          access covered benefits from a provider with  
18          which such organization offering such plan has  
19          an agreement for furnishing items and services  
20          covered under such plan such as name, spe-  
21          cialty, contact information, primary office or fa-  
22          cility address, whether the provider is accepting  
23          new patients, accommodations for people with  
24          disabilities, cultural and linguistic capabilities,  
25          and telehealth capabilities.

1                   “(C) SPECIFIED MA PLAN.—In this para-  
2 graph, the term ‘specified MA plan’ means—

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

5                   “(ii) a Medicare Advantage private  
6 fee-for-service plan (as defined in section  
7 1859(b)(2)) that meets the access stand-  
8 ards under subsection (d)(4), in whole or  
9 in part, through entering into contracts or  
10 agreements as provided for under subpara-  
11 graph (B) of such subsection.”.

12       (b) ACCOUNTABILITY FOR PROVIDER DIRECTORY  
13 ACCURACY.—

14           (1) COST SHARING FOR SERVICES FURNISHED  
15 BASED ON RELIANCE ON INCORRECT PROVIDER DI-  
16 RECTORY INFORMATION.—Section 1852(d) of the  
17 Social Security Act (42 U.S.C. 1395w–22(d)) is  
18 amended—

19           (A) in paragraph (1)(C)—

20                   (i) in clause (ii), by striking “or” at  
21 the end;

22                   (ii) in clause (iii), by striking the  
23 semicolon at the end and inserting “, or”;  
24 and

1 (iii) by adding at the end the fol-  
2 lowing new clause:

3 “(iv) the services are furnished by a  
4 provider that is not participating in the  
5 network of a specified MA plan (as defined  
6 in subsection (c)(3)(C)) but is listed in the  
7 provider directory of such plan on the date  
8 on which the appointment is made, as de-  
9 scribed in paragraph (7)(A);” and

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

12 “(7) COST SHARING FOR SERVICES FURNISHED  
13 BASED ON RELIANCE ON INCORRECT PROVIDER DI-  
14 RECTORY INFORMATION.—

15 “(A) IN GENERAL.—For plan year 2027  
16 and subsequent plan years, if an enrollee is fur-  
17 nished an item or service by a provider that is  
18 not participating in the network of a specified  
19 MA plan (as defined in subsection (c)(3)(C))  
20 but is listed in the provider directory of such  
21 plan (as required to be provided to an enrollee  
22 pursuant to subsection (c)(1)(C)) on the date  
23 on which the appointment is made, and if such  
24 item or service would otherwise be covered  
25 under such plan if furnished by a provider that



1 is participating in the network of such plan, the  
2 MA organization offering such plan shall ensure  
3 that the enrollee is only responsible for the less-  
4 er of—

5 “(i) the amount of cost sharing that  
6 would apply if such provider had been par-  
7 ticipating in the network of such plan; or

8 “(ii) the amount of cost sharing that  
9 would otherwise apply (without regard to  
10 this subparagraph).

11 “(B) NOTIFICATION REQUIREMENT.—For  
12 plan year 2027 and subsequent plan years, each  
13 MA organization that offers a specified MA  
14 plan shall—

15 “(i) notify enrollees of their cost-shar-  
16 ing protections under this paragraph and  
17 make such notifications, to the extent  
18 practicable, by not later than the first day  
19 of an annual, coordinated election period  
20 under section 1851(e)(3) with respect to a  
21 year;

22 “(ii) include information regarding  
23 such cost-sharing protections in the pro-  
24 vider directory of each specified MA plan  
25 offered by the MA organization.; and

1 “(iii) notify enrollees of their cost-  
2 sharing protections under this paragraph  
3 in an explanation of benefits.”.

4 (2) REQUIRED PROVIDER DIRECTORY ACCU-  
5 RACY ANALYSIS AND REPORTS.—

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

10 “(6) PROVIDER DIRECTORY ACCURACY ANAL-  
11 YSIS AND REPORTS.—

12 “(A) IN GENERAL.—Beginning with plan  
13 years beginning on or after January 1, 2027,  
14 subject to subparagraph (C), a contract under  
15 this section with an MA organization shall re-  
16 quire the organization, for each specified MA  
17 plan (as defined in section 1852(c)(3)(C)) of-  
18 fered by the organization to annually do the fol-  
19 lowing:

20 “(i) Conduct an analysis estimating  
21 the accuracy of the provider directory in-  
22 formation of such plan using a random  
23 sample of providers included in such pro-  
24 vider directory as follows:

1                   “(I) Such a random sample shall  
2                   include a random sample of each spe-  
3                   cialty of providers with a high inaccu-  
4                   racy rate of provider directory infor-  
5                   mation relative to other specialties of  
6                   providers, as determined by the Sec-  
7                   retary.

8                   “(II) For purposes of subclause  
9                   (I), one type of specialty may be pro-  
10                  viders specializing in mental health or  
11                  substance use disorder treatment.

12                  “(ii) Submit to the Secretary a report  
13                  containing the results of the analysis con-  
14                  ducted under clause (i), including an accu-  
15                  racy score for such provider directory in-  
16                  formation (as determined using a plan  
17                  verification method specified by the Sec-  
18                  retary under subparagraph (B)(i)).

19                  “(B) DETERMINATION OF ACCURACY  
20                  SCORE.—

21                  “(i) IN GENERAL.—The Secretary  
22                  shall specify plan verification methods,  
23                  such as using telephonic verification or  
24                  other approaches using data sources main-  
25                  tained by an MA organization or using

1 publicly available data sets, that MA orga-  
2 nizations may use for estimating accuracy  
3 scores of the provider directory information  
4 of specified MA plans offered by such or-  
5 ganizations.

6 “(ii) ACCURACY SCORE METHOD-  
7 OLOGY.—With respect to each such meth-  
8 od specified by the Secretary as described  
9 in clause (i), the Secretary shall specify a  
10 methodology for MA organizations to use  
11 in estimating such accuracy scores. Each  
12 such methodology shall take into account  
13 the administrative burden on plans and  
14 providers and the relative importance of  
15 certain provider directory information on  
16 enrollee ability to access care.

17 “(C) EXCEPTION.—The Secretary may  
18 waive the requirements of this paragraph in the  
19 case of a specified MA plan with low enrollment  
20 (as defined by the Secretary).

21 “(D) TRANSPARENCY.—Beginning with  
22 plan years beginning on or after January 1,  
23 2028, the Secretary shall post accuracy scores  
24 (as reported under subparagraph (A)(ii)), in a

1 machine readable file, on the internet website of  
2 the Centers for Medicare & Medicaid Services.”.

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

8 “(F) PROVIDER DIRECTORY.—Beginning  
9 with plan years beginning on or after January  
10 1, 2028, the accuracy score of the plan’s pro-  
11 vider directory (as reported under section  
12 1857(e)(6)(A)(ii)) listed prominently on the  
13 plan’s provider directory.”.

14 (C) FUNDING.—In addition to amounts  
15 otherwise available, there is appropriated to the  
16 Centers for Medicare & Medicaid Services Pro-  
17 gram Management Account, out of any money  
18 in the Treasury not otherwise appropriated,  
19 \$4,000,000 for fiscal year 2025, to remain  
20 available until expended, to carry out the  
21 amendments made by this paragraph.

22 (3) GAO STUDY AND REPORT.—

23 (A) ANALYSIS.—The Comptroller General  
24 of the United States (in this paragraph referred  
25 to as the “Comptroller General”) shall conduct

1 a study of the implementation of the amend-  
2 ments made by paragraphs (1) and (2). To the  
3 extent data are available and reliable, such  
4 study shall include an analysis of—

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

9 (ii) the trends in provider directory in-  
10 formation accuracy scores under section  
11 1857(e)(6)(A)(ii) of the Social Security  
12 Act (as added by paragraph (2)(A)), both  
13 overall and among providers specializing in  
14 mental health or substance use disorder  
15 treatment;

16 (iii) provider response rates by plan  
17 verification methods;

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

21 (v) other items determined appro-  
22 priate by the Comptroller General.

23 (B) REPORT.—Not later than January 15,  
24 2032, the Comptroller General shall submit to  
25 Congress a report containing the results of the

1 study conducted under subparagraph (A), to-  
2 gether with recommendations for such legisla-  
3 tion and administrative action as the Comp-  
4 troller General determines appropriate.

5 (c) GUIDANCE ON MAINTAINING ACCURATE PRO-  
6 VIDER DIRECTORIES.—

7 (1) STAKEHOLDER MEETING.—

8 (A) IN GENERAL.—Not later than 3  
9 months after the date of enactment of this Act,  
10 the Secretary of Health and Human Services  
11 (referred to in this subsection as the “Sec-  
12 retary”) shall hold a public meeting to receive  
13 input on approaches for maintaining accurate  
14 provider directories for Medicare Advantage  
15 plans under part C of title XVIII of the Social  
16 Security Act (42 U.S.C. 1395w–21 et seq.), in-  
17 cluding input on approaches for reducing ad-  
18 ministrative burden, such as data standardiza-  
19 tion, and best practices to maintain accurate  
20 provider directory information.

21 (B) PARTICIPANTS.—Participants of the  
22 meeting under subparagraph (A) shall include  
23 representatives from the Centers for Medicare &  
24 Medicaid Services and the Assistant Secretary  
25 for Technology Policy and Office of the Na-

1           tional Coordinator for Health Information  
2           Technology. Such meeting shall be open to the  
3           public. To the extent practicable, the Secretary  
4           shall include health care providers, companies  
5           that specialize in relevant technologies, health  
6           insurers, and patient advocates.

7           (2) GUIDANCE TO MEDICARE ADVANTAGE OR-  
8           GANIZATIONS.—Not later than 12 months after the  
9           date of enactment of this Act, the Secretary shall  
10          issue guidance to Medicare Advantage organizations  
11          offering Medicare Advantage plans under part C of  
12          title XVIII of the Social Security Act (42 U.S.C.  
13          1395w–21 et seq.) on maintaining accurate provider  
14          directories for such plans, taking into consideration  
15          input received during the stakeholder meeting under  
16          paragraph (1). Such guidance may include the fol-  
17          lowing, as determined appropriate by the Secretary:

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

24                (B) Information on data sets and data  
25                sources with information that could be used by



1 Medicare Advantage organizations to maintain  
2 accurate provider directories.

3 (C) Approaches for utilizing data sources  
4 maintained by Medicare Advantage organiza-  
5 tions and publicly available data sets to main-  
6 tain accurate provider directories.

7 (D) Information to be included in provider  
8 directories that may be useful for Medicare  
9 beneficiaries to assess plan networks when se-  
10 lecting a plan and accessing providers partici-  
11 pating in plan networks during the plan year.

12 (3) GUIDANCE TO PART B PROVIDERS.—Not  
13 later than 12 months after the date of enactment of  
14 this Act, the Secretary shall issue guidance to pro-  
15 viders of services and suppliers who furnish items or  
16 services for which benefits are available under part  
17 B of title XVIII of the Social Security Act (42  
18 U.S.C. 1395j et seq.) on when to update the Na-  
19 tional Plan and Provider Enumeration System for  
20 information changes.

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

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

25 (1) in subsection (s)(2)—

1 (A) by striking the semicolon at the end of  
2 subparagraph (JJ) and inserting “; and”; and

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

5 “(KK) multi-cancer early detection screen-  
6 ing tests (as defined in subsection (nn));”; and

7 (2) by adding at the end the following new sub-  
8 section:

9 “(nn) MULTI-CANCER EARLY DETECTION SCREEN-  
10 ING TESTS.—

11 “(1) IN GENERAL.—The term ‘multi-cancer  
12 early detection screening test’ means a test fur-  
13 nished to an individual for the concurrent detection  
14 of multiple cancer types across multiple organ sites  
15 on or after January 1, 2029, that—

16 “(A) is cleared under section 510(k), clas-  
17 sified under section 513(f)(2), or approved  
18 under section 515 of the Federal Food, Drug,  
19 and Cosmetic Act;

20 “(B) is—

21 “(i) a genomic sequencing blood or  
22 blood product test that includes the anal-  
23 ysis of cell-free nucleic acids; or

24 “(ii) a test based on samples of bio-  
25 logical material that provide results com-

1                   parable to those obtained with a test de-  
2                   scribed in clause (i), as determined by the  
3                   Secretary; and

4                   “(C) the Secretary determines is—

5                   “(i) reasonable and necessary for the  
6                   prevention or early detection of an illness  
7                   or disability; and

8                   “(ii) appropriate for individuals enti-  
9                   tled to benefits under part A or enrolled  
10                  under part B.

11               “(2) NCD PROCESS.—In making determina-  
12               tions under paragraph (1)(C) regarding the coverage  
13               of a new test, the Secretary shall use the process for  
14               making national coverage determinations (as defined  
15               in section 1869(f)(1)(B)) under this title.”.

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

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

21               “(aa) PAYMENT AND STANDARDS FOR MULTI-CAN-  
22               CER EARLY DETECTION SCREENING TESTS.—

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

1           “(A) with respect to such a test furnished  
2 before January 1, 2031, equal to the payment  
3 amount in effect on the date of the enactment  
4 of this subsection for a multi-target stool  
5 screening DNA test covered pursuant to section  
6 1861(pp)(1)(D); and

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

10           “(i) the amount described in subpara-  
11 graph (A); or

12           “(ii) the payment amount determined  
13 for such test under section 1834A.

14           “(2) LIMITATIONS.—

15           “(A) IN GENERAL.—No payment may be  
16 made under this part for a multi-cancer early  
17 detection screening test furnished during a year  
18 to an individual if—

19           “(i) such individual—

20           “(I) is under 50 years of age; or

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

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

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

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

5                   “(ii) for a succeeding year, the age  
6           specified in this subparagraph for the pre-  
7           ceding year, increased by 1 year.

8           “(C) STANDARDS FOLLOWING USPSTF  
9           RATING OF A OR B.—In the case of a multi-can-  
10          cer early detection screening test that is rec-  
11          ommended with a grade of A or B by the  
12          United States Preventive Services Task Force,  
13          beginning on the date on which coverage for  
14          such test is provided pursuant to section  
15          1861(ddd)(1), the preceding provisions of this  
16          paragraph shall not apply.”.

17          (2) CONFORMING AMENDMENTS.—

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

20                   (i) in subsection (a)—

21                                 (I) in paragraph (1)(D)(i)(I), by  
22                                 striking “section 1834(d)(1)” and in-  
23                                 serting “subsection (d)(1) or (aa) of  
24                                 section 1834”; and

1 (II) in paragraph (2)(D)(i)(I), by  
2 striking “section 1834(d)(1)” and in-  
3 serting “subsection (d)(1) or (aa) of  
4 section 1834”; and

5 (ii) in subsection (h)(1)(A), by strik-  
6 ing “section 1834(d)(1)” and inserting  
7 “subsections (d)(1) and (aa) of section  
8 1834”.

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

12 (i) by striking “or additional preven-  
13 tive services” and inserting “, additional  
14 preventive services”; and

15 (ii) by inserting “, or multi-cancer  
16 early detection screening tests (as defined  
17 in section 1861(nnn))” after “(as de-  
18 scribed in section 1861(ddd)(1))”.

19 (c) RULE OF CONSTRUCTION RELATING TO OTHER  
20 CANCER SCREENING TESTS.—Nothing in this section, in-  
21 cluding the amendments made by this section, shall be  
22 construed—

23 (1) in the case of an individual who undergoes  
24 a multi-cancer early detection screening test, to af-  
25 fect coverage under part B of title XVIII of the So-

1        cial Security Act for other cancer screening tests  
2        covered under such title, such as screening tests for  
3        breast, cervical, colorectal, lung, or prostate cancer;  
4        or

5            (2) in the case of an individual who undergoes  
6        another cancer screening test, to affect coverage  
7        under such part for a multi-cancer early detection  
8        screening test or the use of such a test as a diag-  
9        nostic or confirmatory test for a result of the other  
10       cancer screening test.

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

14        (a) IN GENERAL.—Section 1861(n) of the Social Se-  
15        curity Act (42 U.S.C. 1395x(n)) is amended by adding  
16        at the end the following new sentence: “Beginning with  
17        the first calendar quarter beginning on or after the date  
18        that is 1 year after the date of the enactment of this sen-  
19        tence, an external infusion pump and associated home in-  
20        fusion drug (as defined in subsection (iii)(3)(C)) or other  
21        associated supplies that do not meet the appropriate for  
22        use in the home requirement applied to the definition of  
23        durable medical equipment under section 414.202 of title  
24        42, Code of Federal Regulations (or any successor to such

1 regulation) shall be treated as meeting such requirement  
2 if each of the following criteria is satisfied:

3           “(1) The prescribing information approved by  
4           the Food and Drug Administration for the home in-  
5           fusion drug associated with the pump instructs that  
6           the drug should be administered by or under the su-  
7           pervision of a health care professional.

8           “(2) A qualified home infusion therapy supplier  
9           (as defined in subsection (iii)(3)(D)) administers or  
10          supervises the administration of the drug or biologi-  
11          cal in a safe and effective manner in the patient’s  
12          home (as defined in subsection (iii)(3)(B)).

13          “(3) The prescribing information described in  
14          paragraph (1) instructs that the drug should be in-  
15          fused at least 12 times per year—

16                 “(A) intravenously or subcutaneously; or

17                 “(B) at infusion rates that the Secretary  
18                 determines would require the use of an external  
19                 infusion pump.”.

20          (b) COST SHARING NOTIFICATION.—The Secretary  
21          of Health and Human Services shall ensure that patients  
22          are notified of the cost sharing for electing home infusion  
23          therapy compared to other applicable settings of care for  
24          the furnishing of infusion drugs under the Medicare pro-  
25          gram.



1   **SEC. 226. ASSURING PHARMACY ACCESS AND CHOICE FOR**  
2                   **MEDICARE BENEFICIARIES.**

3           (a) IN GENERAL.—Section 1860D–4(b)(1) of the So-  
4   cial Security Act (42 U.S.C. 1395w–104(b)(1)) is amend-  
5   ed by striking subparagraph (A) and inserting the fol-  
6   lowing:

7                   “(A) IN GENERAL.—

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

15                  “(ii) CONTRACT TERMS AND CONDI-  
16                  TIONS.—

17                  “(I) IN GENERAL.—Notwith-  
18                  standing any other provision of law,  
19                  for plan years beginning on or after  
20                  January 1, 2028, in accordance with  
21                  clause (i), contract terms and condi-  
22                  tions offered by such PDP sponsor  
23                  shall be reasonable and relevant ac-  
24                  cording to standards established by  
25                  the Secretary under subclause (II).

1                   “(II) STANDARDS.—Not later  
2                   than the first Monday in April of  
3                   2027, the Secretary shall establish  
4                   standards for reasonable and relevant  
5                   contract terms and conditions for pur-  
6                   poses of this clause.

7                   “(III) REQUEST FOR INFORMA-  
8                   TION.—Not later than April 1, 2026,  
9                   for purposes of establishing the stand-  
10                  ards under subclause (II), the Sec-  
11                  retary shall issue a request for infor-  
12                  mation to seek input on trends in pre-  
13                  scription drug plan and network phar-  
14                  macy contract terms and conditions,  
15                  current prescription drug plan and  
16                  network pharmacy contracting prac-  
17                  tices, whether pharmacy reimburse-  
18                  ment and dispensing fees paid by  
19                  PDP sponsors to network pharmacies  
20                  sufficiently cover the ingredient and  
21                  operational costs of such pharmacies,  
22                  the use and application of pharmacy  
23                  quality measures by PDP sponsors for  
24                  network pharmacies, PDP sponsor re-  
25                  strictions or limitations on the dis-

1           pensing of covered part D drugs by  
2           network pharmacies (or any subsets of  
3           such pharmacies), PDP sponsor au-  
4           diting practices for network phar-  
5           macies, areas in current regulations or  
6           program guidance related to con-  
7           tracting between prescription drug  
8           plans and network pharmacies requir-  
9           ing clarification or additional speci-  
10          ficity, factors for consideration in de-  
11          termining the reasonableness and rel-  
12          evance of contract terms and condi-  
13          tions between prescription drug plans  
14          and network pharmacies, and other  
15          issues as determined appropriate by  
16          the Secretary.”.

17       (b) ESSENTIAL RETAIL PHARMACIES.—Section  
18 1860D–42 of the Social Security Act (42 U.S.C. 1395w–  
19 152) is amended by adding at the end the following new  
20 subsection:

21       “(e) ESSENTIAL RETAIL PHARMACIES.—

22           “(1) IN GENERAL.—With respect to plan years  
23       beginning on or after January 1, 2028, the Sec-  
24       retary shall publish reports, at least once every 2

1       years until 2034, and periodically thereafter, that  
2       provide information, to the extent feasible, on—

3               “(A) trends in ingredient cost reimburse-  
4               ment, dispensing fees, incentive payments and  
5               other fees paid by PDP sponsors offering pre-  
6               scription drug plans and MA organizations of-  
7               fering MA–PD plans under this part to essen-  
8               tial retail pharmacies (as defined in paragraph  
9               (2)) with respect to the dispensing of covered  
10              part D drugs, including a comparison of such  
11              trends between essential retail pharmacies and  
12              pharmacies that are not essential retail phar-  
13              macies;

14              “(B) trends in amounts paid to PDP spon-  
15              sors offering prescription drug plans and MA  
16              organizations offering MA–PD plans under this  
17              part by essential retail pharmacies with respect  
18              to the dispensing of covered part D drugs, in-  
19              cluding a comparison of such trends between  
20              essential retail pharmacies and pharmacies that  
21              are not essential retail pharmacies;

22              “(C) trends in essential retail pharmacy  
23              participation in pharmacy networks and pre-  
24              ferred pharmacy networks for prescription drug  
25              plans offered by PDP sponsors and MA–PD

1 plans offered by MA organizations under this  
2 part, including a comparison of such trends be-  
3 tween essential retail pharmacies and phar-  
4 macies that are not essential retail pharmacies;

5 “(D) trends in the number of essential re-  
6 tail pharmacies, including variation in such  
7 trends by geographic region or other factors;

8 “(E) a comparison of cost-sharing for cov-  
9 ered part D drugs dispensed by essential retail  
10 pharmacies that are network pharmacies for  
11 prescription drug plans offered by PDP spon-  
12 sors and MA–PD plans offered by MA organi-  
13 zations under this part and cost-sharing for  
14 covered part D drugs dispensed by other net-  
15 work pharmacies for such plans located in simi-  
16 lar geographic areas that are not essential retail  
17 pharmacies;

18 “(F) a comparison of the volume of cov-  
19 ered part D drugs dispensed by essential retail  
20 pharmacies that are network pharmacies for  
21 prescription drug plans offered by PDP spon-  
22 sors and MA–PD plans offered by MA organi-  
23 zations under this part and such volume of dis-  
24 pensing by network pharmacies for such plans  
25 located in similar geographic areas that are not

1 essential retail pharmacies, including informa-  
2 tion on any patterns or trends in such compari-  
3 son specific to certain types of covered part D  
4 drugs, such as generic drugs or drugs specified  
5 as specialty drugs by a PDP sponsor under a  
6 prescription drug plan or an MA organization  
7 under an MA–PD plan; and

8 “(G) a comparison of the information de-  
9 scribed in subparagraphs (A) through (F) be-  
10 tween essential retail pharmacies that are net-  
11 work pharmacies for prescription drug plans of-  
12 fered by PDP sponsors under this part and es-  
13 sential retail pharmacies that are network phar-  
14 macies for MA–PD plans offered by MA organi-  
15 zations under this part.

16 “(2) DEFINITION OF ESSENTIAL RETAIL PHAR-  
17 MACY.—In this subsection, the term ‘essential retail  
18 pharmacy’ means, with respect to a plan year, a re-  
19 tail pharmacy that—

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

22 “(B) is located in—

23 “(i) a medically underserved area (as  
24 designated pursuant to section

1                   330(b)(3)(A) of the Public Health Service  
2                   Act);

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

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

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

12                 “(3) LIST OF ESSENTIAL RETAIL PHAR-  
13                 MACIES.—

14                 “(A) PUBLICATION OF LIST OF ESSENTIAL  
15                 RETAIL PHARMACIES.—For each plan year (be-  
16                 ginning with plan year 2028), the Secretary  
17                 shall publish, on a publicly available internet  
18                 website of the Centers for Medicare & Medicaid  
19                 Services, a list of pharmacies that meet the cri-  
20                 teria described in subparagraphs (A) and (B) of  
21                 paragraph (2) to be considered an essential re-  
22                 tail pharmacy.

23                 “(B) REQUIRED SUBMISSIONS FROM PDP  
24                 SPONSORS.—For each plan year (beginning  
25                 with plan year 2028), each PDP sponsor offer-

1           ing a prescription drug plan and each MA orga-  
2           nization offering an MA–PD plan shall submit  
3           to the Secretary, for the purposes of deter-  
4           mining retail pharmacies that meet the criterion  
5           specified in subparagraph (A) of paragraph (2),  
6           a list of retail pharmacies that are affiliates of  
7           such sponsor or organization, or are affiliates of  
8           a pharmacy benefit manager acting on behalf of  
9           such sponsor or organization, at a time, and in  
10          a form and manner, specified by the Secretary.

11                 “(C) REPORTING BY PDP SPONSORS AND  
12           MA ORGANIZATIONS.—For each plan year be-  
13           ginning with plan year 2027, each PDP sponsor  
14           offering a prescription drug plan and each MA  
15           organization offering an MA–PD plan under  
16           this part shall submit to the Secretary informa-  
17           tion on incentive payments and other fees paid  
18           by such sponsor or organization to pharmacies,  
19           insofar as any such payments or fees are not  
20           otherwise reported, at a time, and in a form  
21           and manner, specified by the Secretary.

22                 “(D) IMPLEMENTATION.—Notwithstanding  
23           any other provision of law, the Secretary may  
24           implement this paragraph by program instruc-  
25           tion or otherwise.



1                   “(E) NONAPPLICATION OF PAPERWORK  
2                   REDUCTION ACT.—Chapter 35 of title 44,  
3                   United States Code, shall not apply to the im-  
4                   plementation of this paragraph.

5                   “(4) DEFINITION OF AFFILIATE; PHARMACY  
6                   BENEFIT MANAGER.—In this subsection, the terms  
7                   ‘affiliate’ and ‘pharmacy benefit manager’ have the  
8                   meaning given those terms in section 1860D–  
9                   12(h)(7).”.

10                  (c) ENFORCEMENT.—

11                  (1) IN GENERAL.—Section 1860D–4(b)(1) of  
12                  the Social Security Act (42 U.S.C. 1395w–  
13                  104(b)(1)) is amended by adding at the end the fol-  
14                  lowing new subparagraph:

15                         “(F) ENFORCEMENT OF STANDARDS FOR  
16                         REASONABLE AND RELEVANT CONTRACT TERMS  
17                         AND CONDITIONS.—

18                                 “(i) ALLEGATION SUBMISSION PROC-  
19                                 ESS.—

20   “(I) IN GENERAL.—Not later  
21   than January 1, 2028, the Secretary  
22   shall establish a process through  
23   which a pharmacy may submit to the  
24   Secretary an allegation of a violation  
25   by a PDP sponsor offering a prescrip-

1           tion drug plan of the standards for  
2           reasonable and relevant contract  
3           terms and conditions under subpara-  
4           graph (A)(ii), or of subclause (VIII)  
5           of this clause.

6           “(II) FREQUENCY OF SUBMIS-  
7           SION.—

8                   “(aa) IN GENERAL.—Except  
9                   as provided in item (bb), the alle-  
10                  gation submission process under  
11                  this clause shall allow pharmacies  
12                  to submit any allegations of vio-  
13                  lations described in subclause (I)  
14                  not more frequently than once  
15                  per plan year per contract be-  
16                  tween a pharmacy and a PDP  
17                  sponsor.

18                   “(bb) ALLEGATIONS RELAT-  
19                   ING TO CONTRACT MODIFICA-  
20                  TIONS.—In the case where a con-  
21                  tract between a pharmacy and a  
22                  PDP sponsor is modified fol-  
23                  lowing the submission of allega-  
24                  tions by a pharmacy with respect  
25                  to such contract and plan year,

1 the allegation submission process  
2 under this clause shall allow such  
3 pharmacy to submit an additional  
4 allegation related to those modi-  
5 fications with respect to such  
6 contract and plan year.

7 “(III) ACCESS TO RELEVANT  
8 DOCUMENTS AND MATERIALS.—A  
9 PDP sponsor subject to an allegation  
10 under this clause—

11 “(aa) shall provide docu-  
12 ments or materials, as specified  
13 by the Secretary, including con-  
14 tract offers made by such spon-  
15 sor to such pharmacy or cor-  
16 respondence related to such of-  
17 fers, to the Secretary at a time,  
18 and in a form and manner, speci-  
19 fied by the Secretary; and

20 “(bb) shall not prohibit or  
21 otherwise limit the ability of a  
22 pharmacy to submit such docu-  
23 ments or materials to the Sec-  
24 retary for the purpose of submit-  
25 ting an allegation or providing

1 evidence for such an allegation  
2 under this clause.

3 “(IV) STANDARDIZED TEM-  
4 PLATE.—The Secretary shall establish  
5 a standardized template for phar-  
6 macies to use for the submission of al-  
7 legations described in subclause (I).  
8 Such template shall require that the  
9 submission include a certification by  
10 the pharmacy that the information in-  
11 cluded is accurate, complete, and true  
12 to the best of the knowledge, informa-  
13 tion, and belief of such pharmacy.

14 “(V) PREVENTING FRIVOLOUS  
15 ALLEGATIONS.—In the case where the  
16 Secretary determines that a pharmacy  
17 has submitted frivolous allegations  
18 under this clause on a routine basis,  
19 the Secretary may temporarily pro-  
20 hibit such pharmacy from using the  
21 allegation submission process under  
22 this clause, as determined appropriate  
23 by the Secretary.

24 “(VI) EXEMPTION FROM FREE-  
25 DOM OF INFORMATION ACT.—Allega-

1           tions submitted under this clause shall  
2           be exempt from disclosure under sec-  
3           tion 552 of title 5, United States  
4           Code.

5                   “(VII) RULE OF CONSTRUC-  
6           TION.—Nothing in this clause shall be  
7           construed as limiting the ability of a  
8           pharmacy to pursue other legal ac-  
9           tions or remedies, consistent with ap-  
10          plicable Federal or State law, with re-  
11          spect to a potential violation of a re-  
12          quirement described in this subpara-  
13          graph.

14                   “(VIII) ANTI-RETALIATION AND  
15          ANTI-COERCION.—Consistent with ap-  
16          plicable Federal or State law, a PDP  
17          sponsor shall not—

18                   “(aa) retaliate against a  
19                  pharmacy for submitting any al-  
20                  legations under this clause; or

21                   “(bb) coerce, intimidate,  
22                  threaten, or interfere with the  
23                  ability of a pharmacy to submit  
24                  any such allegations.

1 “(ii) INVESTIGATION.—The Secretary  
2 shall investigate, as determined appro-  
3 priate by the Secretary, allegations sub-  
4 mitted pursuant to clause (i).

5 “(iii) ENFORCEMENT.—

6 “(I) IN GENERAL.—In the case  
7 where the Secretary determines that a  
8 PDP sponsor offering a prescription  
9 drug plan has violated the standards  
10 for reasonable and relevant contract  
11 terms and conditions under subpara-  
12 graph (A)(ii), the Secretary may use  
13 authorities under sections 1857(g)  
14 and 1860D–12(b)(3)(E) to impose  
15 civil monetary penalties or other inter-  
16 mediate sanctions.

17 “(II) APPLICATION OF CIVIL  
18 MONETARY PENALTIES.—The provi-  
19 sions of section 1128A (other than  
20 subsections (a) and (b)) shall apply to  
21 a civil monetary penalty under this  
22 clause in the same manner as such  
23 provisions apply to a penalty or pro-  
24 ceeding under section 1128A(a).”.

1           (2) CONFORMING AMENDMENT.—Section  
2       1857(g)(1) of the Social Security Act (42 U.S.C.  
3       1395w–27(g)(1)) is amended—

4           (A) in subparagraph (J), by striking “or”  
5       after the semicolon;

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

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

10          “(K) fails to comply with the standards for  
11       reasonable and relevant contract terms and con-  
12       ditions under subparagraph (A)(ii) of section  
13       1860D–4(b)(1); or”;

14          (D) in subparagraph (L), as redesignated  
15       by subparagraph (B), by striking “through (J)”  
16       and inserting “through (K)”;

17          (E) in the flush matter following subpara-  
18       graph (L), as so redesignated, by striking “sub-  
19       paragraphs (A) through (K)” and inserting  
20       “subparagraphs (A) through (L)”.

21       (d) ACCOUNTABILITY OF PHARMACY BENEFIT MAN-  
22       AGERS FOR VIOLATIONS OF REASONABLE AND RELEVANT  
23       CONTRACT TERMS AND CONDITIONS.—

24           (1) IN GENERAL.—Section 1860D–12(b) of the  
25       Social Security Act (42 U.S.C. 1395w–112) is

1       amended by adding at the end the following new  
2       paragraph:

3               “(9) ACCOUNTABILITY OF PHARMACY BENEFIT  
4       MANAGERS FOR VIOLATIONS OF REASONABLE AND  
5       RELEVANT CONTRACT TERMS AND CONDITIONS.—  
6       For plan years beginning on or after January 1,  
7       2028, each contract entered into with a PDP spon-  
8       sor under this part with respect to a prescription  
9       drug plan offered by such sponsor shall provide that  
10      any pharmacy benefit manager acting on behalf of  
11      such sponsor has a written agreement with the PDP  
12      sponsor under which the pharmacy benefit manager  
13      agrees to reimburse the PDP sponsor for any  
14      amounts paid by such sponsor under section 1860D–  
15      4(b)(1)(F)(iii)(I) to the Secretary as a result of a  
16      violation described in such section if such violation  
17      is related to a responsibility delegated to the phar-  
18      macy benefit manager by such PDP sponsor.”.

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

23               “(F) ACCOUNTABILITY OF PHARMACY  
24      BENEFIT MANAGERS FOR VIOLATIONS OF REA-  
25      SONABLE AND RELEVANT CONTRACT TERMS.—



1           For plan years beginning on or after January  
2           1, 2028, section 1860D–12(b)(9).”.

3           (e) BIENNIAL REPORT ON ENFORCEMENT AND  
4 OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—  
5 Section 1860D–42 of the Social Security Act (42 U.S.C.  
6 1395w–152), as amended by subsection (b), is amended  
7 by adding at the end the following new subsection:

8           “(f) BIENNIAL REPORT ON ENFORCEMENT AND  
9 OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—

10           “(1) IN GENERAL.—Not later than 2 years  
11 after the date of enactment of this subsection, and  
12 at least once every 2 years thereafter, the Secretary  
13 shall publish a report on enforcement and oversight  
14 actions and activities undertaken by the Secretary  
15 with respect to the requirements under section  
16 1860D–4(b)(1).

17           “(2) LIMITATION.—A report under paragraph  
18 (1) shall not disclose—

19           “(A) identifiable information about individ-  
20 uals or entities unless such information is oth-  
21 erwise publicly available; or

22           “(B) trade secrets with respect to any enti-  
23 ties.”.

24           (f) FUNDING.—In addition to amounts otherwise  
25 available, there is appropriated to the Centers for Medi-

1 care & Medicaid Services Program Management Account,  
2 out of any money in the Treasury not otherwise appro-  
3 priated, \$188,000,000 for fiscal year 2025, to remain  
4 available until expended, to carry out this section.

5 **SEC. 227. MODERNIZING AND ENSURING PBM ACCOUNT-**  
6 **ABILITY.**

7 (a) IN GENERAL.—

8 (1) PRESCRIPTION DRUG PLANS.—Section  
9 1860D–12 of the Social Security Act (42 U.S.C.  
10 1395w–112) is amended by adding at the end the  
11 following new subsection:

12 “(h) REQUIREMENTS RELATING TO PHARMACY BEN-  
13 EFIT MANAGERS.—For plan years beginning on or after  
14 January 1, 2028:

15 “(1) AGREEMENTS WITH PHARMACY BENEFIT  
16 MANAGERS.—Each contract entered into with a  
17 PDP sponsor under this part with respect to a pre-  
18 scription drug plan offered by such sponsor shall  
19 provide that any pharmacy benefit manager acting  
20 on behalf of such sponsor has a written agreement  
21 with the PDP sponsor under which the pharmacy  
22 benefit manager, and any affiliates of such phar-  
23 macy benefit manager, as applicable, agree to meet  
24 the following requirements:

1                   “(A) NO INCOME OTHER THAN BONA FIDE  
2                   SERVICE FEES.—

3                   “(i) IN GENERAL.—The pharmacy  
4                   benefit manager and any affiliate of such  
5                   pharmacy benefit manager shall not derive  
6                   any remuneration with respect to any serv-  
7                   ices provided on behalf of any entity or in-  
8                   dividual, in connection with the utilization  
9                   of covered part D drugs, from any such en-  
10                  tity or individual other than bona fide serv-  
11                  ice fees, subject to clauses (ii) and (iii).

12                  “(ii) INCENTIVE PAYMENTS.—For the  
13                  purposes of this subsection, an incentive  
14                  payment (as determined by the Secretary)  
15                  paid by a PDP sponsor to a pharmacy  
16                  benefit manager that is performing serv-  
17                  ices on behalf of such sponsor shall be  
18                  deemed a ‘bona fide service fee’ (even if  
19                  such payment does not otherwise meet the  
20                  definition of such term under paragraph  
21                  (7)(B)) if such payment is a flat dollar  
22                  amount, is consistent with fair market  
23                  value (as specified by the Secretary), is re-  
24                  lated to services actually performed by the  
25                  pharmacy benefit manager or affiliate of

1           such pharmacy benefit manager, on behalf  
2           of the PDP sponsor making such payment,  
3           in connection with the utilization of cov-  
4           ered part D drugs, and meets additional  
5           requirements, if any, as determined appro-  
6           priate by the Secretary.

7           “(iii) CLARIFICATION ON REBATES  
8           AND DISCOUNTS USED TO LOWER COSTS  
9           FOR COVERED PART D DRUGS.—Rebates,  
10          discounts, and other price concessions re-  
11          ceived by a pharmacy benefit manager or  
12          an affiliate of a pharmacy benefit manager  
13          from manufacturers, even if such price  
14          concessions are calculated as a percentage  
15          of a drug’s price, shall not be considered a  
16          violation of the requirements of clause (i)  
17          if they are fully passed through to a PDP  
18          sponsor and are compliant with all regu-  
19          latory and subregulatory requirements re-  
20          lated to direct and indirect remuneration  
21          for manufacturer rebates under this part,  
22          including in cases where a PDP sponsor is  
23          acting as a pharmacy benefit manager on  
24          behalf of a prescription drug plan offered  
25          by such PDP sponsor.

1                   “(iv) EVALUATION OF REMUNERATION  
2                   ARRANGEMENTS.—Components of subsets  
3                   of remuneration arrangements (such as  
4                   fees or other forms of compensation paid  
5                   to or retained by the pharmacy benefit  
6                   manager or affiliate of such pharmacy ben-  
7                   efit manager), as determined appropriate  
8                   by the Secretary, between pharmacy ben-  
9                   efit managers or affiliates of such phar-  
10                  macy benefit managers, as applicable, and  
11                  other entities involved in the dispensing or  
12                  utilization of covered part D drugs (includ-  
13                  ing PDP sponsors, manufacturers, phar-  
14                  macies, and other entities as determined  
15                  appropriate by the Secretary) shall be sub-  
16                  ject to review by the Secretary, in con-  
17                  sultation with the Office of the Inspector  
18                  General of the Department of Health and  
19                  Human Services, as determined appro-  
20                  priate by the Secretary. The Secretary, in  
21                  consultation with the Office of the Inspec-  
22                  tor General, shall review whether remu-  
23                  neration under such arrangements is con-  
24                  sistent with fair market value (as specified  
25                  by the Secretary) through reviews and as-

1                   sessments of such remuneration, as deter-  
2                   mined appropriate.

3                   “(v) DISGORGEMENT.—The pharmacy  
4                   benefit manager shall disgorge any remu-  
5                   neration paid to such pharmacy benefit  
6                   manager or an affiliate of such pharmacy  
7                   benefit manager in violation of this sub-  
8                   paragraph to the PDP sponsor.

9                   “(vi) ADDITIONAL REQUIREMENTS.—  
10                  The pharmacy benefit manager shall—

11                   “(I) enter into a written agree-  
12                   ment with any affiliate of such phar-  
13                   macy benefit manager, under which  
14                   the affiliate shall identify and disgorge  
15                   any remuneration described in clause  
16                   (v) to the pharmacy benefit manager;  
17                   and

18                   “(II) attest, subject to any re-  
19                   quirements determined appropriate by  
20                   the Secretary, that the pharmacy ben-  
21                   efit manager has entered into a writ-  
22                   ten agreement described in subclause  
23                   (I) with any relevant affiliate of the  
24                   pharmacy benefit manager.

1                   “(B) TRANSPARENCY REGARDING GUARAN-  
2                   TEES AND COST PERFORMANCE EVALUA-  
3                   TIONS.—The pharmacy benefit manager shall—

4                   “(i) define, interpret, and apply, in a  
5                   fully transparent and consistent manner  
6                   for purposes of calculating or otherwise  
7                   evaluating pharmacy benefit manager per-  
8                   formance against pricing guarantees or  
9                   similar cost performance measurements re-  
10                  lated to rebates, discounts, price conces-  
11                  sions, or net costs, terms such as—

12                  “(I) ‘generic drug’, in a manner  
13                  consistent with the definition of the  
14                  term under section 423.4 of title 42,  
15                  Code of Federal Regulations, or a suc-  
16                  cessor regulation;

17                  “(II) ‘brand name drug’, in a  
18                  manner consistent with the definition  
19                  of the term under section 423.4 of  
20                  title 42, Code of Federal Regulations,  
21                  or a successor regulation;

22                  “(III) ‘specialty drug’;

23                  “(IV) ‘rebate’; and

24                  “(V) ‘discount’;

1 “(ii) identify any drugs, claims, or  
2 price concessions excluded from any pric-  
3 ing guarantee or other cost performance  
4 measure in a clear and consistent manner;  
5 and

6 “(iii) where a pricing guarantee or  
7 other cost performance measure is based  
8 on a pricing benchmark other than the  
9 wholesale acquisition cost (as defined in  
10 section 1847A(c)(6)(B)) of a drug, cal-  
11 culate and provide a wholesale acquisition  
12 cost-based equivalent to the pricing guar-  
13 antee or other cost performance measure.

14 “(C) PROVISION OF INFORMATION.—

15 “(i) IN GENERAL.—Not later than  
16 July 1 of each year, beginning in 2028, the  
17 pharmacy benefit manager shall submit to  
18 the PDP sponsor, and to the Secretary, a  
19 report, in accordance with this subpara-  
20 graph, and shall make such report avail-  
21 able to such sponsor at no cost to such  
22 sponsor in a format specified by the Sec-  
23 retary under paragraph (5). Each such re-  
24 port shall include, with respect to such  
25 PDP sponsor and each plan offered by



1           such sponsor, the following information  
2           with respect to the previous plan year:

3                   “(I) A list of all drugs covered by  
4           the plan that were dispensed includ-  
5           ing, with respect to each such drug—

6                   “(aa) the brand name, ge-  
7           neric or non-proprietary name,  
8           and National Drug Code;

9                   “(bb) the number of plan  
10          enrollees for whom the drug was  
11          dispensed, the total number of  
12          prescription claims for the drug  
13          (including original prescriptions  
14          and refills, counted as separate  
15          claims), and the total number of  
16          dosage units of the drug dis-  
17          pensed;

18                  “(cc) the number of pre-  
19          scription claims described in item  
20          (bb) by each type of dispensing  
21          channel through which the drug  
22          was dispensed, including retail,  
23          mail order, specialty pharmacy,  
24          long term care pharmacy, home

1 infusion pharmacy, or other types  
2 of pharmacies or providers;

3 “(dd) the average wholesale  
4 acquisition cost, listed as cost per  
5 day’s supply, cost per dosage  
6 unit, and cost per typical course  
7 of treatment (as applicable);

8 “(ee) the average wholesale  
9 price for the drug, listed as price  
10 per day’s supply, price per dos-  
11 age unit, and price per typical  
12 course of treatment (as applica-  
13 ble);

14 “(ff) the total out-of-pocket  
15 spending by plan enrollees on  
16 such drug after application of  
17 any benefits under the plan, in-  
18 cluding plan enrollee spending  
19 through copayments, coinsurance,  
20 and deductibles;

21 “(gg) total rebates paid by  
22 the manufacturer on the drug as  
23 reported under the Detailed DIR  
24 Report (or any successor report)  
25 submitted by such sponsor to the

1 Centers for Medicare & Medicaid  
2 Services;

3 “(hh) all other direct or in-  
4 direct remuneration on the drug  
5 as reported under the Detailed  
6 DIR Report (or any successor re-  
7 port) submitted by such sponsor  
8 to the Centers for Medicare &  
9 Medicaid Services;

10 “(ii) the average pharmacy  
11 reimbursement amount paid by  
12 the plan for the drug in the ag-  
13 gregate and disaggregated by dis-  
14 pensing channel identified in item  
15 (cc);

16 “(jj) the average National  
17 Average Drug Acquisition Cost  
18 (NADAC); and

19 “(kk) total manufacturer-de-  
20 rived revenue, inclusive of bona  
21 fide service fees, attributable to  
22 the drug and retained by the  
23 pharmacy benefit manager and  
24 any affiliate of such pharmacy  
25 benefit manager.

1                   “(II) In the case of a pharmacy  
2                   benefit manager that has an affiliate  
3                   that is a retail, mail order, or spe-  
4                   cialty pharmacy, with respect to drugs  
5                   covered by such plan that were dis-  
6                   pensed, the following information:

7                               “(aa) The percentage of  
8                               total prescriptions that were dis-  
9                               pensed by pharmacies that are an  
10                              affiliate of the pharmacy benefit  
11                              manager for each drug.

12                             “(bb) The interquartile  
13                             range of the total combined costs  
14                             paid by the plan and plan enroll-  
15                             ees, per dosage unit, per course  
16                             of treatment, per 30-day supply,  
17                             and per 90-day supply for each  
18                             drug dispensed by pharmacies  
19                             that are not an affiliate of the  
20                             pharmacy benefit manager and  
21                             that are included in the phar-  
22                             macy network of such plan.

23                             “(cc) The interquartile  
24                             range of the total combined costs  
25                             paid by the plan and plan enroll-

1           ees, per dosage unit, per course  
2           of treatment, per 30-day supply,  
3           and per 90-day supply for each  
4           drug dispensed by pharmacies  
5           that are an affiliate of the phar-  
6           macy benefit manager and that  
7           are included in the pharmacy  
8           network of such plan.

9                     “(dd) The lowest total com-  
10           bined cost paid by the plan and  
11           plan enrollees, per dosage unit,  
12           per course of treatment, per 30-  
13           day supply, and per 90-day sup-  
14           ply, for each drug that is avail-  
15           able from any pharmacy included  
16           in the pharmacy network of such  
17           plan.

18                     “(ee) The difference between  
19           the average acquisition cost of  
20           the affiliate, such as a pharmacy  
21           or other entity that acquires pre-  
22           scription drugs, that initially ac-  
23           quires the drug and the amount  
24           reported under subclause (I)(jj)  
25           for each drug.

1                   “(ff) A list inclusive of the  
2                   brand name, generic or non-pro-  
3                   prietary name, and National  
4                   Drug Code of covered part D  
5                   drugs subject to an agreement  
6                   with a covered entity under sec-  
7                   tion 340B of the Public Health  
8                   Service Act for which the phar-  
9                   macy benefit manager or an affil-  
10                  iate of the pharmacy benefit  
11                  manager had a contract or other  
12                  arrangement with such a covered  
13                  entity in the service area of such  
14                  plan.

15                  “(III) Where a drug approved  
16                  under section 505(c) of the Federal  
17                  Food, Drug, and Cosmetic Act (re-  
18                  ferred to in this subclause as the ‘list-  
19                  ed drug’) is covered by the plan, the  
20                  following information:

21                       “(aa) A list of currently  
22                       marketed generic drugs approved  
23                       under section 505(j) of the Fed-  
24                       eral Food, Drug, and Cosmetic  
25                       Act pursuant to an application

1 that references such listed drug  
2 that are not covered by the plan,  
3 are covered on the same for-  
4 mulary tier or a formulary tier  
5 typically associated with higher  
6 cost-sharing than the listed drug,  
7 or are subject to utilization man-  
8 agement that the listed drug is  
9 not subject to.

10 “(bb) The estimated average  
11 beneficiary cost-sharing under  
12 the plan for a 30-day supply of  
13 the listed drug.

14 “(cc) Where a generic drug  
15 listed under item (aa) is on a for-  
16 mulary tier typically associated  
17 with higher cost-sharing than the  
18 listed drug, the estimated aver-  
19 age cost-sharing that a bene-  
20 ficiary would have paid for a 30-  
21 day supply of each of the generic  
22 drugs described in item (aa), had  
23 the plan provided coverage for  
24 such drugs on the same for-  
25 mulary tier as the listed drug.

1 “(dd) A written justification  
2 for providing more favorable cov-  
3 erage of the listed drug than the  
4 generic drugs described in item  
5 (aa).

6 “(ee) The number of cur-  
7 rently marketed generic drugs  
8 approved under section 505(j) of  
9 the Federal Food, Drug, and  
10 Cosmetic Act pursuant to an ap-  
11 plication that references such  
12 listed drug.

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

17 “(aa) A list of currently  
18 marketed biosimilar biological  
19 products licensed under section  
20 351(k) of the Public Health  
21 Service Act pursuant to an appli-  
22 cation that refers to such ref-  
23 erence product that are not cov-  
24 ered by the plan, are covered on  
25 the same formulary tier or a for-



1                   mulary tier typically associated  
2                   with higher cost-sharing than the  
3                   reference product, or are subject  
4                   to utilization management that  
5                   the reference product is not sub-  
6                   ject to.

7                   “(bb) The estimated average  
8                   beneficiary cost-sharing under  
9                   the plan for a 30-day supply of  
10                  the reference product.

11                  “(cc) Where a biosimilar bi-  
12                  ological product listed under item  
13                  (aa) is on a formulary tier typi-  
14                  cally associated with higher cost-  
15                  sharing than the reference prod-  
16                  uct, the estimated average cost-  
17                  sharing that a beneficiary would  
18                  have paid for a 30-day supply of  
19                  each of the biosimilar biological  
20                  products described in item (aa),  
21                  had the plan provided coverage  
22                  for such products on the same  
23                  formulary tier as the reference  
24                  product.

1                   “(dd) A written justification  
2                   for providing more favorable cov-  
3                   erage of the reference product  
4                   than the biosimilar biological  
5                   product described in item (aa).

6                   “(ee) The number of cur-  
7                   rently marketed biosimilar bio-  
8                   logical products licensed under  
9                   section 351(k) of the Public  
10                  Health Service Act, pursuant to  
11                  an application that refers to such  
12                  reference product.

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

17                 “(VI) The total amount retained  
18                 by the pharmacy benefit manager or  
19                 an affiliate of such pharmacy benefit  
20                 manager in revenue related to utiliza-  
21                 tion of covered part D drugs under  
22                 that plan, inclusive of bona fide serv-  
23                 ice fees.

24                 “(VII) The total spending on cov-  
25                 ered part D drugs net of rebates, fees,

1 discounts, or other direct and indirect  
2 remuneration by the plan.

3 “(VIII) An explanation of any  
4 benefit design parameters under such  
5 plan that encourage plan enrollees to  
6 fill prescriptions at pharmacies that  
7 are an affiliate of such pharmacy ben-  
8 efit manager, such as mail and spe-  
9 cialty home delivery programs, and re-  
10 tail and mail auto-refill programs.

11 “(IX) The following information:

12 “(aa) A list of all brokers,  
13 consultants, advisors, and audi-  
14 tors that receive compensation  
15 from the pharmacy benefit man-  
16 ager or an affiliate of such phar-  
17 macy benefit manager for refer-  
18 rals, consulting, auditing, or  
19 other services offered to PDP  
20 sponsors related to pharmacy  
21 benefit management services.

22 “(bb) The amount of com-  
23 pensation provided by such phar-  
24 macy benefit manager or affiliate

1 to each such broker, consultant,  
2 advisor, and auditor.

3 “(cc) The methodology for  
4 calculating the amount of com-  
5 pensation provided by such phar-  
6 macy benefit manager or affil-  
7 iate, for each such broker, con-  
8 sultant, advisor, and auditor.

9 “(X) A list of all affiliates of the  
10 pharmacy benefit manager.

11 “(XI) A summary document sub-  
12 mitted in a standardized template de-  
13 veloped by the Secretary that includes  
14 such information described in sub-  
15 clauses (I) through (X).

16 “(ii) WRITTEN EXPLANATION OF CON-  
17 TRACTS OR AGREEMENTS WITH DRUG  
18 MANUFACTURERS.—

19 “(I) IN GENERAL.—The phar-  
20 macy benefit manager shall, not later  
21 than 30 days after the finalization of  
22 any contract or agreement between  
23 such pharmacy benefit manager or an  
24 affiliate of such pharmacy benefit  
25 manager and a drug manufacturer (or

1 subsidiary, agent, or entity affiliated  
2 with such drug manufacturer) that  
3 makes rebates, discounts, payments,  
4 or other financial incentives related to  
5 one or more covered part D drugs or  
6 other prescription drugs, as applica-  
7 ble, of the manufacturer directly or  
8 indirectly contingent upon coverage,  
9 formulary placement, or utilization  
10 management conditions on any other  
11 covered part D drugs or other pre-  
12 scription drugs, as applicable, submit  
13 to the PDP sponsor a written expla-  
14 nation of such contract or agreement.

15 “(II) REQUIREMENTS.—A writ-  
16 ten explanation under subclause (I)  
17 shall—

18 “(aa) include the manufac-  
19 turer subject to the contract or  
20 agreement, all covered part D  
21 drugs and other prescription  
22 drugs, as applicable, subject to  
23 the contract or agreement and  
24 the manufacturers of such drugs,  
25 and a high-level description of

1 the terms of such contract or  
2 agreement and how such terms  
3 apply to such drugs; and

4 “(bb) be certified by the  
5 Chief Executive Officer, Chief Fi-  
6 nancial Officer, or General Coun-  
7 sel of such pharmacy benefit  
8 manager, or affiliate of such  
9 pharmacy benefit manager, as  
10 applicable, or an individual dele-  
11 gated with the authority to sign  
12 on behalf of one of these officers,  
13 who reports directly to the offi-  
14 cer.

15 “(III) DEFINITION OF OTHER  
16 PRESCRIPTION DRUGS.—For purposes  
17 of this clause, the term ‘other pre-  
18 scription drugs’ means prescription  
19 drugs covered as supplemental bene-  
20 fits under this part or prescription  
21 drugs paid outside of this part.

22 “(D) AUDIT RIGHTS.—

23 “(i) IN GENERAL.—Not less than once  
24 a year, at the request of the PDP sponsor,  
25 the pharmacy benefit manager shall allow

1 for an audit of the pharmacy benefit man-  
2 ager to ensure compliance with all terms  
3 and conditions under the written agree-  
4 ment described in this paragraph and the  
5 accuracy of information reported under  
6 subparagraph (C).

7 “(ii) AUDITOR.—The PDP sponsor  
8 shall have the right to select an auditor.  
9 The pharmacy benefit manager shall not  
10 impose any limitations on the selection of  
11 such auditor.

12 “(iii) PROVISION OF INFORMATION.—  
13 The pharmacy benefit manager shall make  
14 available to such auditor all records, data,  
15 contracts, and other information necessary  
16 to confirm the accuracy of information  
17 provided under subparagraph (C), subject  
18 to reasonable restrictions on how such in-  
19 formation must be reported to prevent re-  
20 disclosure of such information.

21 “(iv) TIMING.—The pharmacy benefit  
22 manager must provide information under  
23 clause (iii) and other information, data,  
24 and records relevant to the audit to such  
25 auditor within 6 months of the initiation of

1 the audit and respond to requests for addi-  
2 tional information from such auditor with-  
3 in 30 days after the request for additional  
4 information.

5 “(v) INFORMATION FROM AFFILI-  
6 ATES.—The pharmacy benefit manager  
7 shall be responsible for providing to such  
8 auditor information required to be reported  
9 under subparagraph (C) or under clause  
10 (iii) of this subparagraph that is owned or  
11 held by an affiliate of such pharmacy ben-  
12 efit manager.

13 “(2) ENFORCEMENT.—

14 “(A) IN GENERAL.—Each PDP sponsor  
15 shall—

16 “(i) disgorge to the Secretary any  
17 amounts disgorged to the PDP sponsor by  
18 a pharmacy benefit manager under para-  
19 graph (1)(A)(v);

20 “(ii) require, in a written agreement  
21 with any pharmacy benefit manager acting  
22 on behalf of such sponsor or affiliate of  
23 such pharmacy benefit manager, that such  
24 pharmacy benefit manager or affiliate re-  
25 imburse the PDP sponsor for any civil



1 money penalty imposed on the PDP spon-  
2 sor as a result of the failure of the phar-  
3 macy benefit manager or affiliate to meet  
4 the requirements of paragraph (1) that are  
5 applicable to the pharmacy benefit man-  
6 ager or affiliate under the agreement; and  
7 “(iii) require, in a written agreement  
8 with any such pharmacy benefit manager  
9 acting on behalf of such sponsor or affil-  
10 iate of such pharmacy benefit manager,  
11 that such pharmacy benefit manager or af-  
12 filiate be subject to punitive remedies for  
13 breach of contract for failure to comply  
14 with the requirements applicable under  
15 paragraph (1).

16 “(B) REPORTING OF ALLEGED VIOLA-  
17 TIONS.—The Secretary shall make available and  
18 maintain a mechanism for manufacturers, PDP  
19 sponsors, pharmacies, and other entities that  
20 have contractual relationships with pharmacy  
21 benefit managers or affiliates of such pharmacy  
22 benefit managers to report, on a confidential  
23 basis, alleged violations of paragraph (1)(A) or  
24 subparagraph (C).

1           “(C) ANTI-RETALIATION AND ANTI-COER-  
2           CION.—Consistent with applicable Federal or  
3           State law, a PDP sponsor shall not—

4                   “(i) retaliate against an individual or  
5                   entity for reporting an alleged violation  
6                   under subparagraph (B); or

7                   “(ii) coerce, intimidate, threaten, or  
8                   interfere with the ability of an individual  
9                   or entity to report any such alleged viola-  
10                  tions.

11          “(3) CERTIFICATION OF COMPLIANCE.—

12               “(A) IN GENERAL.—Each PDP sponsor  
13               shall furnish to the Secretary (at a time and in  
14               a manner specified by the Secretary) an annual  
15               certification of compliance with this subsection,  
16               as well as such information as the Secretary de-  
17               termines necessary to carry out this subsection.

18               “(B) IMPLEMENTATION.—Notwithstanding  
19               any other provision of law, the Secretary may  
20               implement this paragraph by program instruc-  
21               tion or otherwise.

22          “(4) RULE OF CONSTRUCTION.—Nothing in  
23          this subsection shall be construed as—

24               “(A) prohibiting flat dispensing fees or re-  
25               imbursement or payment for ingredient costs

1 (including customary, industry-standard dis-  
2 counts directly related to drug acquisition that  
3 are retained by pharmacies or wholesalers) to  
4 entities that acquire or dispense prescription  
5 drugs; or

6 “(B) modifying regulatory requirements or  
7 sub-regulatory program instruction or guidance  
8 related to pharmacy payment, reimbursement,  
9 or dispensing fees.

10 “(5) STANDARD FORMATS.—

11 “(A) IN GENERAL.—Not later than June  
12 1, 2027, the Secretary shall specify standard,  
13 machine-readable formats for pharmacy benefit  
14 managers to submit annual reports required  
15 under paragraph (1)(C)(i).

16 “(B) IMPLEMENTATION.—Notwithstanding  
17 any other provision of law, the Secretary may  
18 implement this paragraph by program instruc-  
19 tion or otherwise.

20 “(6) CONFIDENTIALITY.—

21 “(A) IN GENERAL.—Information disclosed  
22 by a pharmacy benefit manager, an affiliate of  
23 a pharmacy benefit manager, a PDP sponsor,  
24 or a pharmacy under this subsection that is not  
25 otherwise publicly available or available for pur-

1           chase shall not be disclosed by the Secretary or  
2           a PDP sponsor receiving the information, ex-  
3           cept that the Secretary may disclose the infor-  
4           mation for the following purposes:

5                   “(i) As the Secretary determines nec-  
6                   essary to carry out this part.

7                   “(ii) To permit the Comptroller Gen-  
8                   eral to review the information provided.

9                   “(iii) To permit the Director of the  
10                  Congressional Budget Office to review the  
11                  information provided.

12                  “(iv) To permit the Executive Direc-  
13                  tor of the Medicare Payment Advisory  
14                  Commission to review the information pro-  
15                  vided.

16                  “(v) To the Attorney General for the  
17                  purposes of conducting oversight and en-  
18                  forcement under this title.

19                  “(vi) To the Inspector General of the  
20                  Department of Health and Human Serv-  
21                  ices in accordance with its authorities  
22                  under the Inspector General Act of 1978  
23                  (section 406 of title 5, United States  
24                  Code), and other applicable statutes.

1           “(B) RESTRICTION ON USE OF INFORMA-  
2           TION.—The Secretary, the Comptroller General,  
3           the Director of the Congressional Budget Of-  
4           fice, and the Executive Director of the Medicare  
5           Payment Advisory Commission shall not report  
6           on or disclose information disclosed pursuant to  
7           subparagraph (A) to the public in a manner  
8           that would identify—

9                   “(i) a specific pharmacy benefit man-  
10                  ager, affiliate, pharmacy, manufacturer,  
11                  wholesaler, PDP sponsor, or plan; or

12                  “(ii) contract prices, rebates, dis-  
13                  counts, or other remuneration for specific  
14                  drugs in a manner that may allow the  
15                  identification of specific contracting parties  
16                  or of such specific drugs.

17           “(7) DEFINITIONS.—For purposes of this sub-  
18           section:

19                   “(A) AFFILIATE.—The term ‘affiliate’  
20                  means, with respect to any pharmacy benefit  
21                  manager or PDP sponsor, any entity that, di-  
22                  rectly or indirectly—

23                   “(i) owns or is owned by, controls or  
24                  is controlled by, or is otherwise related in

1                   any ownership structure to such pharmacy  
2                   benefit manager or PDP sponsor; or

3                   “(ii) acts as a contractor, principal, or  
4                   agent to such pharmacy benefit manager  
5                   or PDP sponsor, insofar as such con-  
6                   tractor, principal, or agent performs any of  
7                   the functions described under subpara-  
8                   graph (C).

9                   “(B) BONA FIDE SERVICE FEE.—The term  
10                  ‘bona fide service fee’ means a fee that is reflec-  
11                  tive of the fair market value (as specified by the  
12                  Secretary, through notice and comment rule-  
13                  making) for a bona fide, itemized service actu-  
14                  ally performed on behalf of an entity, that the  
15                  entity would otherwise perform (or contract for)  
16                  in the absence of the service arrangement and  
17                  that is not passed on in whole or in part to a  
18                  client or customer, whether or not the entity  
19                  takes title to the drug. Such fee must be a flat  
20                  dollar amount and shall not be directly or indi-  
21                  rectly based on, or contingent upon—

22                  “(i) drug price, such as wholesale ac-  
23                  quisition cost or drug benchmark price  
24                  (such as average wholesale price);

1 “(ii) the amount of discounts, rebates,  
2 fees, or other direct or indirect remunera-  
3 tion with respect to covered part D drugs  
4 dispensed to enrollees in a prescription  
5 drug plan, except as permitted pursuant to  
6 paragraph (1)(A)(ii);

7 “(iii) coverage or formulary placement  
8 decisions or the volume or value of any re-  
9 ferrals or business generated between the  
10 parties to the arrangement; or

11 “(iv) any other amounts or meth-  
12 odologies prohibited by the Secretary.

13 “(C) PHARMACY BENEFIT MANAGER.—The  
14 term ‘pharmacy benefit manager’ means any  
15 person or entity that, either directly or through  
16 an intermediary, acts as a price negotiator or  
17 group purchaser on behalf of a PDP sponsor or  
18 prescription drug plan, or manages the pre-  
19 scription drug benefits provided by such spon-  
20 sor or plan, including the processing and pay-  
21 ment of claims for prescription drugs, the per-  
22 formance of drug utilization review, the proc-  
23 essing of drug prior authorization requests, the  
24 adjudication of appeals or grievances related to  
25 the prescription drug benefit, contracting with

1 network pharmacies, controlling the cost of cov-  
2 ered part D drugs, or the provision of related  
3 services. Such term includes any person or enti-  
4 ty that carries out one or more of the activities  
5 described in the preceding sentence, irrespective  
6 of whether such person or entity calls itself a  
7 ‘pharmacy benefit manager’.”.

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

12 “(F) REQUIREMENTS RELATING TO PHAR-  
13 MACY BENEFIT MANAGERS.—For plan years be-  
14 ginning on or after January 1, 2028, section  
15 1860D–12(h).”.

16 (3) NONAPPLICATION OF PAPERWORK REDUC-  
17 TION ACT.—Chapter 35 of title 44, United States  
18 Code, shall not apply to the implementation of this  
19 subsection.

20 (4) FUNDING.—

21 (A) SECRETARY.—In addition to amounts  
22 otherwise available, there is appropriated to the  
23 Centers for Medicare & Medicaid Services Pro-  
24 gram Management Account, out of any money  
25 in the Treasury not otherwise appropriated,



1           \$113,000,000 for fiscal year 2025, to remain  
2           available until expended, to carry out this sub-  
3           section.

4           (B) OIG.—In addition to amounts other-  
5           wise available, there is appropriated to the In-  
6           specter General of the Department of Health  
7           and Human Services, out of any money in the  
8           Treasury not otherwise appropriated,  
9           \$20,000,000 for fiscal year 2025, to remain  
10          available until expended, to carry out this sub-  
11          section.

12          (b) GAO STUDY AND REPORT ON PRICE-RELATED  
13          COMPENSATION ACROSS THE SUPPLY CHAIN.—

14           (1) STUDY.—The Comptroller General of the  
15          United States (in this subsection referred to as the  
16          “Comptroller General”) shall conduct a study de-  
17          scribing the use of compensation and payment struc-  
18          tures related to a prescription drug’s price within  
19          the retail prescription drug supply chain in part D  
20          of title XVIII of the Social Security Act (42 U.S.C.  
21          1395w–101 et seq.). Such study shall summarize in-  
22          formation from Federal agencies and industry ex-  
23          perts, to the extent available, with respect to the fol-  
24          lowing:

1           (A) The type, magnitude, other features  
2           (such as the pricing benchmarks used), and  
3           prevalence of compensation and payment struc-  
4           tures related to a prescription drug's price,  
5           such as calculating fee amounts as a percentage  
6           of a prescription drug's price, between inter-  
7           mediaries in the prescription drug supply chain,  
8           including—

- 9                   (i) pharmacy benefit managers;  
10                   (ii) PDP sponsors offering prescrip-  
11                   tion drug plans and Medicare Advantage  
12                   organizations offering MA–PD plans;  
13                   (iii) drug wholesalers;  
14                   (iv) pharmacies;  
15                   (v) manufacturers;  
16                   (vi) pharmacy services administrative  
17                   organizations;  
18                   (vii) brokers, auditors, consultants,  
19                   and other entities that—

20                   (I) advise PDP sponsors offering  
21                   prescription drug plans and Medicare  
22                   Advantage organizations offering MA–  
23                   PD plans regarding pharmacy bene-  
24                   fits; or

1 (II) review PDP sponsor and  
2 Medicare Advantage organization con-  
3 tracts with pharmacy benefit man-  
4 agers; and

5 (viii) other service providers that con-  
6 tract with any of the entities described in  
7 clauses (i) through (vii) that may use  
8 price-related compensation and payment  
9 structures, such as rebate aggregators (or  
10 other entities that negotiate or process  
11 price concessions on behalf of pharmacy  
12 benefit managers, plan sponsors, or phar-  
13 macies).

14 (B) The primary business models and com-  
15 pensation structures for each category of inter-  
16 mediary described in subparagraph (A).

17 (C) Variation in price-related compensation  
18 structures between affiliated entities (such as  
19 entities with common ownership, either full or  
20 partial, and subsidiary relationships) and unaf-  
21 filiated entities.

22 (D) Potential conflicts of interest among  
23 contracting entities related to the use of pre-  
24 scription drug price-related compensation struc-  
25 tures, such as the potential for fees or other

1           payments set as a percentage of a prescription  
2           drug's price to advantage formulary selection,  
3           distribution, or purchasing of prescription drugs  
4           with higher prices.

5           (E) Notable differences, if any, in the use  
6           and level of price-based compensation struc-  
7           tures over time and between different market  
8           segments, such as under part D of title XVIII  
9           of the Social Security Act (42 U.S.C. 1395w-  
10          101 et seq.) and the Medicaid program under  
11          title XIX of such Act (42 U.S.C. 1396 et seq.).

12          (F) The effects of drug price-related com-  
13          pensation structures and alternative compensa-  
14          tion structures on Federal health care programs  
15          and program beneficiaries, including with re-  
16          spect to cost-sharing, premiums, Federal out-  
17          lays, biosimilar and generic drug adoption and  
18          utilization, drug shortage risks, and the poten-  
19          tial for fees set as a percentage of a drug's  
20          price to advantage the formulary selection, dis-  
21          tribution, or purchasing of drugs with higher  
22          prices.

23          (G) Other issues determined to be relevant  
24          and appropriate by the Comptroller General.

1           (2) REPORT.—Not later than 2 years after the  
2       date of enactment of this section, the Comptroller  
3       General shall submit to Congress a report containing  
4       the results of the study conducted under paragraph  
5       (1), together with recommendations for such legisla-  
6       tion and administrative action as the Comptroller  
7       General determines appropriate.

8       (c) MEDPAC REPORTS ON AGREEMENTS WITH  
9       PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRE-  
10      SCRIPTION DRUG PLANS AND MA-PD PLANS.—

11           (1) IN GENERAL.—The Medicare Payment Ad-  
12      visory Commission shall submit to Congress the fol-  
13      lowing reports:

14           (A) INITIAL REPORT.—Not later than the  
15      first March 15 occurring after the date that is  
16      2 years after the date on which the Secretary  
17      makes the data available to the Commission, a  
18      report regarding agreements with pharmacy  
19      benefit managers with respect to prescription  
20      drug plans and MA–PD plans. Such report  
21      shall include, to the extent practicable—

22           (i) a description of trends and pat-  
23      terns, including relevant averages, totals,  
24      and other figures for the types of informa-  
25      tion submitted;

1                   (ii) an analysis of any differences in  
2                   agreements and their effects on plan en-  
3                   rollee out-of-pocket spending and average  
4                   pharmacy reimbursement, and other im-  
5                   pacts; and

6                   (iii) any recommendations the Com-  
7                   mission determines appropriate.

8                   (B) FINAL REPORT.—Not later than 2  
9                   years after the date on which the Commission  
10                  submits the initial report under subparagraph  
11                  (A), a report describing any changes with re-  
12                  spect to the information described in subpara-  
13                  graph (A) over time, together with any rec-  
14                  ommendations the Commission determines ap-  
15                  propriate.

16                  (2) FUNDING.—In addition to amounts other-  
17                  wise available, there is appropriated to the Medicare  
18                  Payment Advisory Commission, out of any money in  
19                  the Treasury not otherwise appropriated,  
20                  \$1,000,000 for fiscal year 2025, to remain available  
21                  until expended, to carry out this subsection.

1 **SEC. 228. REQUIRING A SEPARATE IDENTIFICATION NUM-**  
2 **BER AND AN ATTESTATION FOR EACH OFF-**  
3 **CAMPUS OUTPATIENT DEPARTMENT OF A**  
4 **PROVIDER.**

5 (a) IN GENERAL.—Section 1833(t) of the Social Se-  
6 curity Act (42 U.S.C. 1395l(t)) is amended by adding at  
7 the end the following new paragraph:

8 “(23) USE OF UNIQUE HEALTH IDENTIFIERS;  
9 ATTESTATION.—

10 “(A) IN GENERAL.—No payment may be  
11 made under this subsection (or under an appli-  
12 cable payment system pursuant to paragraph  
13 (21)) for items and services furnished on or  
14 after January 1, 2026, by an off-campus out-  
15 patient department of a provider (as defined in  
16 subparagraph (C)) unless—

17 “(i) such department has obtained,  
18 and such items and services are billed  
19 under, a standard unique health identifier  
20 for health care providers (as described in  
21 section 1173(b)) that is separate from  
22 such identifier for such provider;

23 “(ii) such provider has submitted to  
24 the Secretary, during the 2-year period  
25 ending on the date such items and services  
26 are so furnished, an initial provider-based

1 status attestation that such department is  
2 compliant with the requirements described  
3 in section 413.65 of title 42, Code of Fed-  
4 eral Regulations (or a successor regula-  
5 tion); and

6 “(iii) after such provider has sub-  
7 mitted an attestation under clause (ii),  
8 such provider has submitted a subsequent  
9 attestation within the timeframe specified  
10 by the Secretary.

11 “(B) PROCESS FOR SUBMISSION AND RE-  
12 VIEW.—Not later than 1 year after the date of  
13 enactment of this paragraph, the Secretary  
14 shall, through notice and comment rulemaking,  
15 establish a process for each provider with an  
16 off-campus outpatient department of a provider  
17 to submit an initial and subsequent attestation  
18 pursuant to clauses (ii) and (iii), respectively, of  
19 subparagraph (A), and for the Secretary to re-  
20 view each such attestation and determine,  
21 through site visits, remote audits, or other  
22 means (as determined appropriate by the Sec-  
23 retary), whether such department is compliant  
24 with the requirements described in such sub-  
25 paragraph.



1                   “(C) OFF-CAMPUS OUTPATIENT DEPART-  
2                   MENT OF A PROVIDER DEFINED.—For purposes  
3                   of this paragraph, the term ‘off-campus out-  
4                   patient department of a provider’ means a de-  
5                   partment of a provider (as defined in section  
6                   413.65 of title 42, Code of Federal Regulations,  
7                   or any successor regulation) that is not lo-  
8                   cated—

9                   “(i) on the campus (as defined in such  
10                  section) of such provider; or

11                  “(ii) within the distance (described in  
12                  such definition of campus) from a remote  
13                  location of a hospital facility (as defined in  
14                  such section).”.

15           (b) HHS OIG ANALYSIS.—Not later than January  
16 1, 2030, the Inspector General of the Department of  
17 Health and Human Services shall submit to Congress—

18           (1) an analysis of the process established by the  
19           Secretary of Health and Human Services to conduct  
20           the reviews and determinations described in section  
21           1833(t)(23)(B) of the Social Security Act, as added  
22           by subsection (a) of this section; and

23           (2) recommendations based on such analysis, as  
24           the Inspector General determines appropriate.

1 **SEC. 229. MEDICARE SEQUESTRATION.**

2 Section 251A(6) of the Balanced Budget and Emer-  
3 gency Deficit Control Act of 1985 (2 U.S.C. 901a(6)) is  
4 amended—

5 (1) in subparagraph (D), by striking “such  
6 that,” and all that follows and inserting “such that  
7 the payment reduction shall be 2.0 percent.”; and

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

9 “(F) On the date on which the President sub-  
10 mits the budget under section 1105 of title 31,  
11 United States Code, for fiscal year 2033, the Presi-  
12 dent shall order a sequestration of payments for the  
13 Medicare programs specified in section 256(d), effec-  
14 tive upon issuance, such that, notwithstanding the 2  
15 percent limit specified in subparagraph (A) for such  
16 payments—

17 “(i) with respect to the first 2 months in  
18 which such order is effective for such fiscal  
19 year, the payment reduction shall be 2.0 per-  
20 cent; and

21 “(ii) with respect to the last 10 months in  
22 which such order is effective for such fiscal  
23 year, the payment reduction shall be 0 per-  
24 cent.”.

1 **SEC. 230. MEDICARE IMPROVEMENT FUND.**

2 Section 1898(b)(1) of the Social Security Act (42  
3 U.S.C. 1395iii(b)(1)) is amended by striking  
4 “\$3,197,000,000” and inserting “\$1,891,500,000”.

5 **TITLE III—HUMAN SERVICES**

6 **Subtitle A—Reauthorize Child Wel-**  
7 **fare Services and Strengthen**  
8 **State and Tribal Child Support**  
9 **Program**

10 **SEC. 301. SHORT TITLE.**

11 This subtitle may be cited as the “Supporting Amer-  
12 ica’s Children and Families Act”.

13 **PART 1—CHILD WELFARE REAUTHORIZATION**  
14 **AND MODERNIZATION**

15 **SEC. 311. SHORT TITLE; REFERENCES.**

16 (a) **SHORT TITLE.**—This part may be cited as the  
17 “Protecting America’s Children by Strengthening Fami-  
18 lies Act”.

19 (b) **REFERENCES.**—Except as otherwise expressly  
20 provided, wherever in this part an amendment or repeal  
21 is expressed in terms of an amendment to, or repeal of,  
22 a section or other provision, the reference shall be consid-  
23 ered to be made to that section or other provision of the  
24 Social Security Act.

1   **SEC. 312. REAUTHORIZATION OF CHILD WELFARE PRO-**  
2                   **GRAMS.**

3           (a) REAUTHORIZATION OF SUBPART 1; DISCRE-  
4   TIONARY FUNDING.—Section 425 (42 U.S.C. 625) is  
5   amended by striking “2017 through 2023” and inserting  
6   “2025 through 2029”.

7           (b) REAUTHORIZATION OF SUBPART 2; ENHANCED  
8   SUPPORT.—Section 436(a) (42 U.S.C. 629f(a)) is amend-  
9   ed by striking “each of fiscal years 2017 through 2023”  
10   and inserting “fiscal year 2025 and \$420,000,000 for  
11   each of fiscal years 2026 through 2029”.

12          (c) REAUTHORIZATION OF SUBPART 2; DISCRE-  
13   TIONARY FUNDING.—Section 437(a) (42 U.S.C. 629g(a))  
14   is amended by striking “2017 through 2023” and insert-  
15   ing “2025 through 2029”.

16          (d) FUNDING LIMITATION.—Section 423(a)(2)(A)  
17   (42 U.S.C. 623(a)(2)(A)) is amended by inserting “, not  
18   to exceed \$10,000,000” before the semicolon.

19   **SEC. 313. ENHANCEMENTS TO THE COURT IMPROVEMENT**  
20                   **PROGRAM.**

21          (a) INCREASE IN RESERVATION OF FUNDS.—Section  
22   436(b)(2) (42 U.S.C. 629f(b)(2)) is amended by inserting  
23   “for fiscal year 2025 and \$40,000,000 for fiscal year 2026  
24   and each succeeding fiscal year” before “for grants”.

25          (b) EXTENSION OF STATE MATCH REQUIREMENT.—  
26   Section 438(d) (42 U.S.C. 629h(d)) is amended by strik-

1 ing “2017 through 2023” and inserting “2025 through  
2 2029”.

3 (c) PROGRAM IMPROVEMENTS.—Section 438(a) (42  
4 U.S.C. 629h(a)) is amended—

5 (1) in paragraph (1), by adding at the end the  
6 following:

7 “(F) that determine the appropriateness  
8 and best practices for use of technology to con-  
9 duct remote hearings, subject to participant  
10 consent, including to ensure maximum partici-  
11 pation of individuals involved in proceedings  
12 and to enable courts to maintain operations in  
13 times of public health or other emergencies;”;

14 (2) in paragraph (2)(C), by striking “per-  
15 sonnel.” and inserting “personnel and supporting  
16 optimal use of remote hearing technology; and”; and

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

18 “(3) to ensure continuity of needed court serv-  
19 ices, prevent disruption of the services, and enable  
20 their recovery from threats such as public health cri-  
21 ses, natural disasters or cyberattacks, including  
22 through—

23 “(A) support for technology that allows  
24 court proceedings to occur remotely subject to

1 participant consent, including hearings and  
2 legal representation;

3 “(B) the development of guidance and pro-  
4 tocols for responding to the occurrences and co-  
5 ordinating with other agencies; and

6 “(C) other activities carried out to ensure  
7 backup systems are in place.”.

8 (d) IMPLEMENTATION GUIDANCE ON SHARING BEST  
9 PRACTICES FOR TECHNOLOGICAL CHANGES NEEDED FOR  
10 REMOTE COURT PROCEEDINGS FOR FOSTER CARE OR  
11 ADOPTION.—Section 438 (42 U.S.C. 629h) is amended by  
12 adding at the end the following:

13 “(e) GUIDANCE.—

14 “(1) IN GENERAL.—Every 5 years, the Sec-  
15 retary shall issue implementation guidance for shar-  
16 ing information on best practices for—

17 “(A) technological changes needed for  
18 court proceedings for foster care, guardianship,  
19 or adoption to be conducted remotely in a way  
20 that maximizes engagement and protects the  
21 privacy of participants; and

22 “(B) the manner in which the proceedings  
23 should be conducted.

24 “(2) INITIAL ISSUANCE.—The Secretary shall  
25 issue initial guidance required by paragraph (1) with

1 preliminary information on best practices not later  
2 than October 1, 2025.

3 “(3) ADDITIONAL CONSULTATION.—The Sec-  
4 retary shall consult with Indian tribes on the devel-  
5 opment of appropriate guidelines for State court  
6 proceedings involving Indian children to maximize  
7 engagement of Indian tribes and provide appropriate  
8 guidelines on conducting State court proceedings  
9 subject to the Indian Child Welfare Act of 1978 (25  
10 U.S.C. 1901 et seq.).”.

11 **SEC. 314. EXPANDING REGIONAL PARTNERSHIP GRANTS**  
12 **TO ADDRESS PARENTAL SUBSTANCE USE DIS-**  
13 **ORDER AS CAUSE OF CHILD REMOVAL.**

14 (a) INCREASE IN RESERVATION OF FUNDS.—Section  
15 436(b)(5) (42 U.S.C. 629f(b)(5)) is amended by striking  
16 “each of fiscal years 2017 through 2023” and inserting  
17 “fiscal year 2025 and \$30,000,000 for fiscal year 2026  
18 and each succeeding fiscal year”.

19 (b) REAUTHORIZATION.—Section 437(f) (42 U.S.C.  
20 629g(f)) is amended—

21 (1) in paragraph (3)(A)—

22 (A) by striking “In addition to amounts  
23 authorized to be appropriated to carry out this  
24 section, the” and inserting “The”; and

1 (B) by striking “2017 through 2023” and  
2 inserting “2025 through 2029”; and  
3 (2) in paragraph (10), by striking “for each of  
4 fiscal years 2017 through 2023”.

5 (c) AUTHORITY TO WAIVE PLANNING PHASE.—Sec-  
6 tion 437(f)(3)(B)(iii) (42 U.S.C. 629g(f)(3)(B)(iii)) is  
7 amended—

8 (1) by striking all that precedes “grant award-  
9 ed” and inserting the following:

10 “(iii) SUFFICIENT PLANNING.—

11 “(I) IN GENERAL.—A”; and

12 (2) by striking “may not exceed \$250,000,  
13 and”; and

14 (3) by adding after and below the end the fol-  
15 lowing:

16 “(II) EXCEPTION.—The Sec-  
17 retary, on a case-by-case basis, may  
18 waive the planning phase for a part-  
19 nership that demonstrates that the  
20 partnership has engaged in sufficient  
21 planning before submitting an appli-  
22 cation for a grant under this sub-  
23 section.”.

24 (d) EXPANDING AVAILABILITY OF EVIDENCE-BASED  
25 SERVICES.—



1           (1) IN GENERAL.—Section 437(f)(1) (42 U.S.C.  
2       629g(f)(1)) is amended by inserting “, and expand  
3       the scope of the evidence-based services that may be  
4       approved by the clearinghouse established under sec-  
5       tion 476(d)” before the period.

6           (2)     CONSIDERATIONS     FOR     AWARDING  
7       GRANTS.—Section 437(f)(7) (42 U.S.C. 629g(f)(7))  
8       is amended—

9                   (A) by striking “and” at the end of sub-  
10       paragraph (D);

11                   (B) by striking the period at the end of  
12       subparagraph (E) and inserting “; and”; and

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

14                   “(F) have submitted information pursuant  
15       to paragraph (4)(F) that demonstrates the ca-  
16       pability to participate in rigorous evaluation of  
17       program effectiveness.”.

18       (e) TECHNICAL ASSISTANCE ON USING REGIONAL  
19       PARTNERSHIP GRANT FUNDS IN COORDINATION WITH  
20       OTHER FEDERAL FUNDS TO BETTER SERVE FAMILIES  
21       AFFECTED BY A SUBSTANCE USE DISORDER.—Section  
22       435(d) (42 U.S.C. 629e(d)) is amended—

23                   (1) by striking “and” at the end of paragraph  
24       (4);

1 (2) by striking the period at the end of para-  
2 graph (5) and inserting “; and”; and

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

4 “(6) use grants under section 437(f) in coordi-  
5 nation with other Federal funds to better serve fami-  
6 lies in the child welfare system that are affected by  
7 a substance use disorder.”.

8 (f) PERFORMANCE INDICATORS.—Section  
9 437(f)(8)(A) (42 U.S.C. 629g(f)(8)(A)) is amended in the  
10 1st sentence—

11 (1) by striking “this subsection” the 1st place  
12 it appears and inserting “the Protecting America’s  
13 Children by Strengthening Families Act”;

14 (2) by inserting “child permanency, reunifica-  
15 tion, re-entry into care,” before “parental recovery”;  
16 and

17 (3) by inserting “, and access to services for  
18 families with substance use disorder, including those  
19 with children who are overrepresented in foster care,  
20 difficult to place, or have disproportionately low per-  
21 manency rates” before the period.

22 (g) PERFORMANCE INDICATOR CONSULTATION RE-  
23 QUIRED.—Section 437(f)(8)(B) (42 U.S.C.  
24 629g(f)(8)(B)) is amended by redesignating clause (iii) as  
25 clause (iv) and inserting after clause (ii) the following:

1                   “(iii) The Administrator of the Na-  
2                   tional Institute on Drug Abuse.”.

3           (h) REPORTS TO CONGRESS.—Section 437(f)(9)(B)  
4 (42 U.S.C. 629g(f)(9)(B)) is amended—

5                   (1) by striking “and” at the end of clause (ii);

6                   (2) by striking the period at the end of clause

7                   (iii) and inserting “; and”; and

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

9                               “(iv) whether any programs funded by  
10                   the grants were submitted to the clearing-  
11                   house established under section 476(d) for  
12                   review and the results of any such re-  
13                   view.”.

14           (i) PRIORITY FOR STATEWIDE SERVICE GROWTH.—  
15 Section 437(f)(7) (42 U.S.C. 629g(f)(7)), as amended by  
16 subsection (d)(2) of this section, is amended—

17                   (1) by striking “and” at the end of subpara-  
18                   graph (E);

19                   (2) by striking the period at the end of sub-  
20                   paragraph (F) and inserting “; and”; and

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

22                               “(G) are a State or public agency, or out-  
23                   line a plan to increase the availability of serv-  
24                   ices funded under the grant statewide.”.

1 (j) ADDITION OF JUVENILE COURT AS REQUIRED  
2 PARTNER.—Section 437(f)(2)(A) (42 U.S.C.  
3 629g(f)(2)(A)) is amended by adding at the end the fol-  
4 lowing:

5 “(iii) The most appropriate adminis-  
6 trative office of the juvenile court or State  
7 court overseeing court proceedings involv-  
8 ing families who come to the attention of  
9 the court due to child abuse or neglect.”.

10 (k) ADDITIONAL OPTIONAL PARTNER.—Section  
11 437(f)(2)(C) (42 U.S.C. 629g(f)(2)(C)) is amended by re-  
12 designating clause (ix) as clause (x) and inserting after  
13 clause (viii) the following:

14 “(ix) State or local agencies that ad-  
15 minister Federal health care, housing, fam-  
16 ily support, or other related programs.”.

17 (l) CONFORMING AMENDMENTS.—

18 (1) Section 437(f)(2)(D) (42 U.S.C.  
19 629g(f)(2)(D)) is amended—

20 (A) by adding “and” at the end of clause  
21 (i);

22 (B) by striking “; and” at the end of  
23 clause (ii) and inserting a period; and

24 (C) by striking clause (iii).

1           (2) Section 437(f)(2) (42 U.S.C. 629g(f)(2)) is  
2           amended by striking subparagraph (B) and redesign-  
3           nating subparagraphs (C) and (D) as subparagraphs  
4           (B) and (C), respectively

5   **SEC. 315. MODERNIZATION; REDUCING ADMINISTRATIVE**  
6                           **BURDEN.**

7           (a) IN GENERAL.—Section 431 (42 U.S.C. 629a) is  
8           amended by adding at the end the following:

9           “(c) USE OF TECHNOLOGY.—

10           “(1) USE OF PORTAL.—The services referred to  
11           in subsection (a) may include the means of access to  
12           and use of an electronic or digital portal to facilitate  
13           the provision of community support to care for and  
14           meet specific needs of families and children.

15           “(2) LIMITATION.—Such a portal shall not re-  
16           tain or share personally identifiable information  
17           about a beneficiary without consent or for any pur-  
18           pose other than referral.”.

19           (b) ALLOWING SUPPORT FOR FAMILY RESOURCE  
20           CENTERS.—Section 431(a) (42 U.S.C. 629a(a)) is amend-  
21           ed—

22           (1) in paragraph (2)(A), by inserting “, includ-  
23           ing services provided by family resource centers,”  
24           before “designed”; and

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

1 “(10) FAMILY RESOURCE CENTER.—

2 “(A) IN GENERAL.—The term ‘family re-  
3 source center’ means a community or school-  
4 based hub of support services for families  
5 that—

6 “(i) utilizes an approach that is multi-  
7 generational, strengths-based, and family-  
8 centered;

9 “(ii) reflects, and is responsive to,  
10 community needs and interests;

11 “(iii) provides support at no or low  
12 cost for participants; and

13 “(iv) builds communities of peer sup-  
14 port for families, including kinship fami-  
15 lies, to develop social connections that re-  
16 duce isolation and stress.

17 “(B) SPECIAL RULE.—For purposes of  
18 this subpart, an expenditure for a service pro-  
19 vided by a family resource center may be treat-  
20 ed as an expenditure for any 1 or more of fam-  
21 ily support services, family preservation serv-  
22 ices, family reunification services, or adoption  
23 promotion and support services as long as the  
24 expenditure is related to serving the children  
25 and families in the specified category and con-

1           sistent with the overall purpose of the cat-  
2           egory.”.

3           (c) UPDATING STATE PLAN REQUIREMENT.—Sec-  
4   tion 422(b)(1) (42 U.S.C. 622(b)(1)) is amended to read  
5   as follows:

6           “(1) provide that a State agency will administer  
7       or supervise the administration of the plan under  
8       this subpart;”.

9           (d) ACCESS TO LEGAL REPRESENTATION.—Section  
10   422(b)(4) (42 U.S.C. 622(b)(4)) is amended—

11           (1) by striking “and” at the end of subpara-  
12       graph (A);

13           (2) by adding “and” at the end of subpara-  
14       graph (B); and

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

16           “(C) the steps that the State will take to  
17       ensure that, with respect to any judicial pro-  
18       ceeding involving a child and in which there is  
19       an allegation of child abuse or neglect, includ-  
20       ing a proceeding on dependency, adoption,  
21       guardianship, or termination of parental rights,  
22       information about available independent legal  
23       representation is provided to—

24           “(i) the child, as appropriate; and

1 “(ii) any individual who is a parent or  
2 guardian, or has legal custody, of the  
3 child;”.

4 (e) SUPPORTING MENTAL HEALTH AND WELL-  
5 BEING OF CHILDREN IN FOSTER CARE.—Section  
6 422(b)(15)(A) (42 U.S.C. 622(b)(15) is amended—

7 (1) in the matter preceding clause (i)—

8 (A) by inserting “and, if applicable, the  
9 State agency responsible for mental health serv-  
10 ices,” before “and in consultation”; and

11 (B) by inserting “mental health pro-  
12 viders,” before “other experts”;

13 (2) in clause (ii), by inserting “a list of services  
14 provided to support the physical and” before “emo-  
15 tional”;

16 (3) in clause (iv), by inserting “and mental  
17 health” before “services”;

18 (4) in clause (v), by inserting “, informed con-  
19 sent of youth, and compliance with professional  
20 practice guidelines” before the semicolon; and

21 (5) in clause (vi), by inserting “, licensed men-  
22 tal health providers,” before “or other”.

23 (f) REDUCTION OF ADMINISTRATIVE BURDEN.—

24 (1) IN GENERAL.—Subpart 3 of part B of title  
25 IV (42 U.S.C. 629m) is amended by redesignating



1 section 440 as section 443 and inserting before such  
2 section the following:

3 **“SEC. 441. REDUCTION OF ADMINISTRATIVE BURDEN.**

4 “(a) IN GENERAL.—The Secretary shall reduce the  
5 burden of administering this part imposed on the recipi-  
6 ents of funds under this part, by—

7 “(1) reviewing and revising administrative data  
8 collection instruments and forms to eliminate dupli-  
9 cation and streamline reporting requirements for the  
10 recipients while collecting all data required under  
11 this part;

12 “(2) in coordination with activities required  
13 under the Paperwork Reduction Act, conducting an  
14 analysis of the total number of hours reported by  
15 the recipients to comply with paperwork require-  
16 ments and exploring, in consultation with the recipi-  
17 ents, how to reduce the number of hours required  
18 for the compliance by at least 15 percent;

19 “(3) collecting input from the recipients with  
20 respect to fiscal and oversight requirements and  
21 making changes to ensure consistency with stand-  
22 ards and guidelines for other Federal formula grant  
23 programs based on the input; and

24 “(4) respecting the sovereignty of Indian tribes  
25 when complying with this subsection.

1       “(b) LIMITATION ON APPLICABILITY.—Subsection  
2 (a) of this section shall not apply to any reporting or data  
3 collection otherwise required by law that would affect the  
4 ability of the Secretary to monitor and ensure compliance  
5 with State plans approved under this part or ensure that  
6 funds are expended consistent with this part.

7       **“SEC. 442. PUBLIC ACCESS TO STATE PLANS.**

8       “The Secretary shall—

9               “(1) create a standardized format for State  
10 plans required under sections 422 and 432 used to  
11 monitor compliance with those sections;

12               “(2) produce comparisons and analyses of  
13 trends in State plans to inform future technical as-  
14 sistance and policy development;

15               “(3) make the State plans available on a public  
16 website; and

17               “(4) include on the website aggregated national  
18 summaries of State submissions as the Secretary  
19 deems appropriate.”.

20       (2) IMPLEMENTATION.—Within 2 years after  
21 the date of the enactment of this Act, the Secretary  
22 of Health and Human Services shall—

23               (A) comply with section 441 of the Social  
24 Security Act, as added by the amendment made  
25 by paragraph (1); and

1 (B) notify each recipient of funds under  
2 part B of title IV of the Social Security Act of  
3 any change made by the Secretary pursuant to  
4 such section affecting the recipient.

5 (3) REPORT.—Within 3 years after the date of  
6 the enactment of this Act, the Secretary of Health  
7 and Human Services shall submit to the Committee  
8 on Ways and Means of the House of Representatives  
9 and the Committee on Finance of the Senate a re-  
10 port describing the efforts of the Secretary to com-  
11 ply with section 441 of the Social Security Act, as  
12 added by the amendment made by paragraph (1), in-  
13 cluding the specific actions to comply with each  
14 paragraph of such section.

15 (g) PRIMARY PREVENTION PARTNERS.—Section  
16 435(a)(2)(B) (42 U.S.C. 429e(a)(2)(B)) is amended by in-  
17 serting “including community-based partners with exper-  
18 tise in preventing unnecessary child welfare system in-  
19 volvement” before the semicolon.

20 **SEC. 316. STREAMLINING FUNDING FOR INDIAN TRIBES.**

21 (a) SUBPART 1.—

22 (1) TRIBAL SET-ASIDE; DIRECT PAYMENTS TO  
23 TRIBES; EXEMPTIVE AUTHORITY.—

1 (A) IN GENERAL.—Section 428 (42 U.S.C.  
2 628) is amended by striking subsections (a) and  
3 (b) and inserting the following:

4 “(a) RESERVATION OF FUNDS; DIRECT PAY-  
5 MENTS.—Out of any amount appropriated pursuant to  
6 section 425 for a fiscal year, the Secretary shall reserve  
7 3 percent for grants to Indian tribes and tribal organiza-  
8 tions, which shall be paid directly to Indian tribes and  
9 tribal organizations with a plan approved under this sub-  
10 part, in accordance with section 433(a).”.

11 (B) CONFORMING AMENDMENT.—Section  
12 423(a) (42 U.S.C. 623(a)) is amended by strik-  
13 ing “the sum appropriated pursuant to section  
14 425 for each fiscal year” and inserting “for  
15 each fiscal year, the sum appropriated pursuant  
16 to section 425 remaining after applying section  
17 428(a)”.

18 (C) TECHNICAL AMENDMENT.—Section  
19 428(c) (42 U.S.C. 628(c)) is amended by strik-  
20 ing “450b” and inserting “5304”.

21 (2) IMPROVING COMPLIANCE WITH THE INDIAN  
22 CHILD WELFARE ACT.—

23 (A) STATE PLAN REQUIREMENT.—Section  
24 422(b)(9) (42 U.S.C. 622(b)(9)) is amended by  
25 striking “Act;” and inserting “Act of 1978, in-

1 cluding how the State will ensure timely notice  
2 to Indian tribes of State custody proceedings  
3 involving Indian children, foster care or adop-  
4 tive placements of Indian children, and case  
5 recordkeeping as such matters relate to trans-  
6 fers of jurisdiction, termination of parental  
7 rights, and active efforts;”.

8 (B) TECHNICAL ASSISTANCE.—Subpart 1  
9 of part B of title IV (42 U.S.C. 621 et seq.) is  
10 amended by adding at the end the following:

11 **“SEC. 429B. EFFECTIVE IMPLEMENTATION OF THE INDIAN**  
12 **CHILD WELFARE ACT OF 1978.**

13 “(a) IN GENERAL.—Not later than October 1, 2025,  
14 the Secretary, in consultation with Indian tribal organiza-  
15 tions and States, shall develop a plan and provide tech-  
16 nical assistance supporting effective implementation of the  
17 Indian Child Welfare Act of 1978, including specific meas-  
18 ures identified in State plans as required by section  
19 422(b)(9) of this Act. The technical assistance plan shall  
20 be based on data sufficient to assess State strengths and  
21 areas for improvement in implementing Federal standards  
22 established under the Indian Child Welfare Act of 1978,  
23 including, at a minimum, the following:

24 “(1) Timely identification of Indian children  
25 and extended family members.

1           “(2) Timely tribal notice of State child custody  
2           proceedings involving an Indian child.

3           “(3) Reports of cases in which a transfer of ju-  
4           risdiction (as defined under the Indian Child Wel-  
5           fare Act of 1978) was granted or was not granted,  
6           and reasons specified for denial in cases where  
7           transfer was denied.

8           “(4) In cases in which a State court orders a  
9           foster care placement of an Indian child, whether re-  
10          quirements for active efforts to prevent the breakup  
11          of the Indian family, testimony of a qualified expert  
12          witness, and evidentiary standards were met.

13          “(5) Whether an Indian child was placed in a  
14          placement that is required to be preferred under the  
15          Indian Child Welfare Act of 1978, and if not, the  
16          reasons specified.

17          “(6) In cases in which a State court orders the  
18          termination of parental rights to an Indian child,  
19          whether requirements for active efforts to prevent  
20          the breakup of the Indian family, testimony of a  
21          qualified expert witness, and evidentiary standards  
22          were met.

23          “(b) INTERAGENCY COORDINATION.—On request of  
24          the Secretary, the Secretary of the Interior shall provide  
25          the Secretary with such guidance and assistance as may

1 be necessary to facilitate informing States and public child  
2 welfare agencies on how to comply with the Indian Child  
3 Welfare Act of 1978, including specific measures identi-  
4 fied in State plans as required by section 422(b)(9) of this  
5 Act.

6 “(c) BIENNIAL REPORTS TO CONGRESS.—The Sec-  
7 retary shall biennially submit to the Committee on Ways  
8 and Means of the House of Representatives and the Com-  
9 mittee on Finance of the Senate a written report on how—

10 “(1) the States are complying with the Indian  
11 Child Welfare Act of 1978 and section 422(b)(9) of  
12 this Act, as informed by data collected under this  
13 section; and

14 “(2) the Secretary is assisting States and In-  
15 dian tribes to improve implementation of Federal  
16 standards established under the Indian Child Wel-  
17 fare Act of 1978.”.

18 (3) REPORTING REQUIREMENTS; ADMINISTRA-  
19 TIVE COSTS.—

20 (A) IN GENERAL.—Section 428 (42 U.S.C.  
21 628) is amended by redesignating subsection (c)  
22 as subsection (d) and inserting before such sub-  
23 section the following:

24 “(b) AUTHORITY TO STREAMLINE REPORTING RE-  
25 QUIREMENTS.—The Secretary shall, in consultation with

1 the affected Indian tribes, modify any reporting require-  
2 ment imposed by or under this part on an Indian tribe,  
3 tribal organization, or tribal consortium if the total of the  
4 amounts allotted to the Indian tribe, tribal organization,  
5 or tribal consortium under this part for the fiscal year is  
6 not more than \$50,000, and in a manner that limits the  
7 administrative burden on any tribe to which not more than  
8 \$50,000 is allotted under this subpart for the fiscal year.

9 “(c) TRIBAL AUTHORITY TO SUBSTITUTE THE FED-  
10 ERAL NEGOTIATED INDIRECT COST RATE FOR ADMINIS-  
11 TRATIVE COSTS CAP.—For purposes of sections  
12 422(b)(14) and 424(e), an Indian tribal organization may  
13 elect to have the weighted average of the indirect cost  
14 rates in effect under part 220 of title 2, Code of Federal  
15 Regulations with respect to the administrative costs of the  
16 Indian tribal organization apply in lieu of the percentage  
17 specified in each such section.”.

18 (B) CONFORMING AMENDMENTS.—Section  
19 431(a) (42 U.S.C. 629a(a)) is amended in each  
20 of paragraphs (5) and (6) by striking “428(c)”  
21 and inserting “428(d)”.

22 (b) SUBPART 2.—

23 (1) TRIBAL PLAN EXEMPTION.—Section  
24 432(b)(2)(B) (42 U.S.C. 629b(b)(2)(B)) is amend-  
25 ed—



1 (A) by striking “section 433(a)” the 1st  
2 place it appears and inserting “sections 433(a)  
3 and 437(c)(1) combined”; and

4 (B) by striking “section 433(a)” the 2nd  
5 place it appears and inserting “such sections”.

6 (2) APPLICATION OF TRIBAL SET-ASIDE BE-  
7 FORE OTHER SET-ASIDES.—Section 436(b)(3) (42  
8 U.S.C. 429f(b)(3)) is amended by striking “After  
9 applying paragraphs (4) and (5) (but before apply-  
10 ing paragraphs (1) or (2)), the” and inserting  
11 “The”.

12 (3) INCREASE IN FUNDING FOR TRIBAL COURT  
13 IMPROVEMENT PROGRAM.—Section 438(c)(3) (42  
14 U.S.C. 629h(c)(3)) is amended by inserting “for fis-  
15 cal year 2025, and \$2,000,000 for each of fiscal  
16 years 2026 through 2029,” before “for grants”.

17 **SEC. 317. ACCELERATING ACCESS TO FAMILY FIRST PRE-**  
18 **VENTION SERVICES.**

19 (a) IN GENERAL.—Section 435 (42 U.S.C. 629e) is  
20 amended by adding at the end the following:

21 “(f) PREVENTION SERVICES EVALUATION PARTNER-  
22 SHIPS.—

23 “(1) PURPOSE.—The purpose of this subsection  
24 is to authorize the Secretary to make competitive  
25 grants to support the timely evaluation of—

1                   “(A) services and programs described in  
2                   section 471(e); or

3                   “(B) kinship navigator programs described  
4                   in section 474(a)(7).

5                   “(2) GRANTS.—In accordance with applications  
6                   approved under this subsection, the Secretary may  
7                   make grants, on a competitive basis, to eligible enti-  
8                   ties to carry out projects designed to evaluate a serv-  
9                   ice or program provided by the eligible entity, or an  
10                  entity in partnership with the eligible entity, with re-  
11                  spect to the requirements for a promising practice,  
12                  supported practice, or well-supported practice de-  
13                  scribed in section 471(e)(4)(C).

14                  “(3) APPLICATIONS.—

15                  “(A) IN GENERAL.—An eligible entity may  
16                  apply to the Secretary for a grant under this  
17                  subsection to carry out a project that meets the  
18                  following requirements:

19                         “(i) The project is designed in accord-  
20                         ance with paragraph (2).

21                         “(ii) The project is to be carried out  
22                         by the applicant in partnership with—

23                                 “(I) a State agency that admin-  
24                                 isters, or supervises the administra-  
25                                 tion of, the State plan approved under

1 part E, or an agency administering  
2 the plan under the supervision of the  
3 State agency; and

4 “(II) if the applicant is unable or  
5 unwilling to do so, at least 1 external  
6 evaluator to carry out the evaluation  
7 of the service or program provided by  
8 the applicant.

9 “(B) CONTENTS.—The application shall  
10 contain the following:

11 “(i) A description of the project, in-  
12 cluding—

13 “(I) a statement explaining why  
14 a grant is necessary to carry out the  
15 project; and

16 “(II) the amount of grant funds  
17 that would be disbursed to each entity  
18 described in subparagraph (A)(ii) in  
19 partnership with the applicant.

20 “(ii) A certification from each entity  
21 described in subparagraph (A)(ii) that pro-  
22 vides assurances that the individual or en-  
23 tity is in partnership with the applicant  
24 and will fulfill the responsibilities of the  
25 entity specified in the description provided

1                   pursuant to clause (i) of this subpara-  
2                   graph.

3                   “(iii) A certification from the appli-  
4                   cant that provides assurances that the ap-  
5                   plicant intends to comply with subpara-  
6                   graph (A)(ii)(II), if applicable.

7                   “(iv) At the option of the eligible enti-  
8                   ty, a certification from the applicant that  
9                   the applicant requires an external eval-  
10                  uator secured by the Secretary pursuant to  
11                  paragraph (5), if applicable.

12               “(4) PRIORITIES.—In approving applications  
13               under this subsection, the Secretary shall prioritize  
14               the following:

15               “(A) Addressing, with respect to the clear-  
16               inghouse of practices described in section  
17               476(d)(2), deficiencies or gaps identified by the  
18               Secretary in consultation with—

19               “(i) States, political subdivisions of a  
20               State, and tribal communities carrying out,  
21               or receiving the benefits of, a service or  
22               program; and

23               “(ii) child welfare experts, including  
24               individuals with lived experience.

1           “(B) Maximizing the number of evidence-  
2           based services or programs to be included in the  
3           clearinghouse of practices described in section  
4           476(d)(2).

5           “(C) Timely completion of evaluations and  
6           the production of evidence.

7           “(D) Supporting services or programs that  
8           are based on, or are adaptations to new popu-  
9           lation settings of, a service or program with re-  
10          liable evidence about the benefits and risks of  
11          the service or program.

12          “(5) AVAILABILITY OF EXTERNAL EVAL-  
13          UATORS.—

14               “(A) IN GENERAL.—Before accepting ap-  
15               plications under this subsection, the Secretary  
16               shall make reasonable efforts to identify at least  
17               1 entity to serve as an external evaluator for  
18               any eligible entity that includes a certification  
19               under paragraph (3)(B)(iv) with an application  
20               under this subsection.

21               “(B) NO EFFECT ON CONSIDERATION OF  
22               APPLICATION.—The Secretary may not consider  
23               whether an eligible entity is in partnership with  
24               an external evaluator described in paragraph

1 (A) in approving an application under this sub-  
2 section submitted by the eligible entity.

3 “(6) REPORTS.—

4 “(A) BY GRANT RECIPIENTS.—Within 1  
5 year after receiving a grant under this sub-  
6 section, and every year thereafter for the next  
7 5 years, the grant recipient shall submit to the  
8 Secretary a written report on—

9 “(i) the use of grant funds;

10 “(ii) whether the program or service  
11 evaluated by the project meets a require-  
12 ment specified in section 471(e)(4)(C), in-  
13 cluding information about—

14 “(I) how the program or service  
15 is being carried out in accordance  
16 with standards specified in the re-  
17 quirement;

18 “(II) any outcomes of the pro-  
19 gram or service; and

20 “(III) any outcome with respect  
21 to which the service or program com-  
22 pares favorably to a comparison prac-  
23 tice; and

24 “(iii) whether the Secretary has in-  
25 cluded the program or service in an update

1 to the clearinghouse of practices described  
2 in section 476(d)(2).

3 “(B) BY THE SECRETARY.—The Secretary  
4 shall submit to the Committee on Ways and  
5 Means of the House of Representatives and to  
6 the Committee on Finance of the Senate an an-  
7 nual written report on—

8 “(i) the grants awarded under this  
9 subsection;

10 “(ii) the programs funded by the  
11 grants;

12 “(iii) any technical assistance pro-  
13 vided by the Secretary in carrying out this  
14 subsection, including with respect to the  
15 efforts to secure external evaluators pursu-  
16 ant to paragraph (5); and

17 “(iv) any efforts by the Secretary to  
18 support program evaluation and review  
19 pursuant to section 471(e) and inclusion of  
20 programs in the pre-approved list of serv-  
21 ices and programs described in section  
22 471(e)(4)(D) or the clearinghouse of prac-  
23 tices described in section 476(d)(2).

24 “(7) FUNDING.—

1           “(A) LIMITATIONS.—Of the amounts avail-  
2           able to carry out this subsection, the Secretary  
3           may use not more than 5 percent to provide  
4           technical assistance.

5           “(B) CARRYOVER.—Amounts made avail-  
6           able to carry out this subsection shall remain  
7           available until expended.

8           “(8) DEFINITIONS.—In this subsection:

9           “(A) ELIGIBLE ENTITY.—The term ‘eligi-  
10          ble entity’ means any of the following providing  
11          a service or program or, in the sole determina-  
12          tion of the Secretary, able to provide a service  
13          or program if awarded a grant under this sub-  
14          section:

15               “(i) A State, a political subdivision of  
16               a State, or an agency or department of a  
17               State or political subdivision of a State.

18               “(ii) An entity described in subpara-  
19               graph (A) or (B) of section 426(a)(1).

20               “(iii) An Indian tribe or tribal organi-  
21               zation.

22           “(B) EXTERNAL EVALUATOR.—The term  
23           ‘external evaluator’ means an entity with the  
24           ability and willingness to evaluate a service or



1           program pursuant to paragraph (2) that is not  
2           provided by the entity.

3           “(C) SERVICE OR PROGRAM.—The term  
4           ‘service or program’—

5           “(i) means a service or program de-  
6           scribed in section 471(e); and

7           “(ii) includes a kinship navigator pro-  
8           gram described in section 474(a)(7).”.

9           (b) FUNDING.—Section 437(b) (42 U.S.C. 629g(b))  
10          is amended by adding at the end the following:

11           “(5) PREVENTIVE SERVICES EVALUATION  
12          PARTNERSHIPS.—The Secretary shall reserve  
13          \$5,000,000 for grants under section 435(f) for each  
14          of fiscal years 2026 through 2029.”.

15   **SEC. 318. STRENGTHENING SUPPORT FOR YOUTH AGING**  
16                   **OUT OF FOSTER CARE.**

17          (a) CASEWORKER VISITS.—Section 422(b)(17) (42  
18          U.S.C. 622(b)(17)) is amended by inserting “, and include  
19          a description of how the State may offer virtual case-  
20          worker visits to youth in care who have attained the age  
21          of 18 years and provided informed consent for virtual vis-  
22          its” before the semicolon.

23          (b) YOUTH AND FAMILY ENGAGEMENT IN CHILD  
24          WELFARE PROGRAM PLANNING.—Section 432(b)(1) (42  
25          U.S.C. 629b(b)(1)) is amended to read as follows:

1           “(1) IN GENERAL.—The Secretary shall ap-  
2           prove a plan that meets the requirements of sub-  
3           section (a) only if—

4                   “(A) the plan was developed jointly by the  
5           Secretary and the State, and the State, in de-  
6           veloping the plan, consulted with—

7                           “(i) appropriate public and nonprofit  
8                           private agencies;

9                           “(ii) community-based organizations  
10                          involved in providing services for children  
11                          and families in the areas of family preser-  
12                          vation, family support, family reunifica-  
13                          tion, foster care, kinship, and adoption  
14                          promotion and support;

15                          “(iii) parents with child welfare expe-  
16                          rience, foster parents, adoptive parents,  
17                          and kinship caregivers; and

18                          “(iv) children, youth, and young  
19                          adults with experience in the child welfare  
20                          system, including State boards and coun-  
21                          cils comprised of youth with lived experi-  
22                          ence who represent the diversity of chil-  
23                          dren in the State to whom the plan would  
24                          apply; and

1           “(B) the State has made publicly acces-  
2           sible on a website of the State agency a report  
3           that outlines how the State has implemented  
4           the suggestions of the children and youth re-  
5           ferred to in subparagraph (A)(iv).”.

6 **SEC. 319. RECOGNIZING THE IMPORTANCE OF RELATIVE**  
7 **AND KINSHIP CAREGIVERS.**

8           (a) IN GENERAL.—Section 431(a) (42 U.S.C.  
9 629a(a)), as amended by section 316(b)(2) of this part,  
10 is amended—

11           (1) in paragraph (1)—

12           (A) in the matter preceding subparagraph  
13 (A)—

14           (i) by striking “children” and insert-  
15 ing “children, youth,”; and

16           (ii) by striking “adoptive and ex-  
17 tended” and inserting “kinship and adop-  
18 tive”;

19           (B) in subparagraph (D), by striking “par-  
20 ents and other caregivers (including foster par-  
21 ents)” and inserting “parents, kinship care-  
22 givers, and foster parents”;

23           (C) by striking “and” at the end of sub-  
24 paragraph (E);

1 (D) by striking the period at the end of  
2 subparagraph (F) and inserting “ ; and”; and

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

4 “(G)(i) peer-to-peer mentoring and support  
5 programs with demonstrated experience fos-  
6 tering constructive relationships between chil-  
7 dren and families and mentors with relevant  
8 lived experience or interactions with the child  
9 welfare system; and

10 “(ii) for purposes of this subpart, an ex-  
11 penditure for a service described in clause (i)  
12 may be treated as an expenditure for any 1 or  
13 more of family support services, family preser-  
14 vation services, family reunification services, or  
15 adoption promotion and support services, as  
16 long as the expenditure is related to serving the  
17 children and families in the specified category  
18 and consistent with the overall purpose of the  
19 category.”;

20 (2) in paragraph (2)(B)—

21 (A) in clause (i), by striking “children”  
22 and inserting “children, youth,”; and

23 (B) in clause (ii), by striking “extended”  
24 and inserting “kinship”;

1 (3) in paragraph (7)(A), by inserting “with kin-  
2 ship caregivers or” before “in a foster family home”;  
3 and

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

5 “(11) YOUTH.—The term ‘youth’ means an in-  
6 dividual who has not attained 26 years of age.”.

7 (b) KINSHIP NAVIGATORS.—

8 (1) IN GENERAL.—Section 427 (42 U.S.C. 627)  
9 is amended—

10 (A) in the section heading, by striking  
11 “**FAMILY CONNECTION GRANTS**” and insert-  
12 ing “**KINSHIP NAVIGATORS**”;

13 (B) in subsection (a)—

14 (i) in the matter preceding paragraph  
15 (1), by striking “helping” and inserting  
16 “administering programs to help”;

17 (ii) by striking “of—” and all that  
18 follows through “a kinship” and inserting  
19 “of a kinship”;

20 (iii) in paragraph (1)(C)—

21 (I) by striking “and” at the end  
22 of clause (iii);

23 (II) by adding “and” at the end  
24 of clause (iv); and

1 (III) by adding at the end the  
2 following:

3 “(v) connections to individualized as-  
4 sistance, as needed;”;

5 (iv) by striking paragraphs (2)  
6 through (4);

7 (v) by redesignating subparagraphs  
8 (A) through (G) of paragraph (1) as para-  
9 graphs (1) through (7), respectively;

10 (vi) by redesignating clauses (i)  
11 through (iv) and clause (v) (as added by  
12 clause (iii)(III) of this subparagraph) as  
13 subparagraphs (A) through (E), respec-  
14 tively;

15 (vii) by moving each provision so re-  
16 designated 2 ems to the left; and

17 (viii) by striking “caregiving;” and in-  
18 serting “caregiving.”;

19 (C) in subsection (b)—

20 (i) in paragraph (1), by striking “1 or  
21 more of”;

22 (ii) by redesignating paragraphs (3)  
23 and (4) as paragraphs (4) and (5), respec-  
24 tively, and inserting after paragraph (2)  
25 the following:

1           “(3) a description of how the entity will directly  
2           fund, or provide data to the Secretary for, an eval-  
3           uation which will publish and submit information to  
4           the clearinghouse described in section 476(d)(2) and  
5           which is designed to meet the requirements of sec-  
6           tion 471(e)(4)(C), or a description of how the funds  
7           will be used to help the State transition to a pro-  
8           gram for which the State will seek reimbursement  
9           under section 474(a)(7);”;

10                   (iii) in paragraph (4) (as so redesign-  
11                   nated), by striking “and” at the end;

12                   (iv) in paragraph (5) (as so redesign-  
13                   nated), by striking the period and inserting  
14                   “; and”; and

15                   (v) by adding at the end the following:

16           “(6) if the entity is a State, local or tribal child  
17           welfare agency—

18                   “(A) documentation of support from a rel-  
19                   evant community-based organization with expe-  
20                   rience serving kinship families when applicable;  
21                   or

22                   “(B) a description of how the organization  
23                   plans to coordinate its services and activities  
24                   with those offered by the relevant community-  
25                   based organizations.”;

1 (D) by striking subsection (d) and insert-  
2 ing the following:

3 “(d) FEDERAL SHARE.—An entity to which a grant  
4 is made under this section may use the grant to pay not  
5 more than 75 percent of the cost of the activities to be  
6 carried out by the entity pursuant to this section.”;

7 (E) in subsection (g)—

8 (i) by striking all that precedes “2  
9 percent” and inserting the following:

10 “(g) RESERVATION OF FUNDS FOR TECHNICAL AS-  
11 SISTANCE.—The Secretary may reserve”; and

12 (ii) by striking “subsection (h)” the  
13 2nd place it appears and inserting “section  
14 437(b)(6)”; and

15 (F) by striking subsection (h).

16 (2) RESERVATION OF DISCRETIONARY  
17 FUNDS.—Section 437(b) (42 U.S.C. 629g(b)), as  
18 amended by section 318(b) of this part, is amended  
19 by adding at the end the following:

20 “(6) KINSHIP NAVIGATORS.—The Secretary  
21 shall reserve \$10,000,000 for grants under section  
22 427 for each of fiscal years 2026 through 2029.”.

23 (3) CONFORMING AMENDMENT.—Section  
24 474(a)(7) (42 U.S.C. 674(a)(7)) is amended by  
25 striking “427(a)(1)” and inserting “427(a)”.



1 **SEC. 320. AVOIDING NEGLECT BY ADDRESSING POVERTY.**

2 (a) FAMILY PRESERVATION SERVICES.—Section  
3 431(a)(1) (42 U.S.C. 629a(a)(1)), as amended by section  
4 320(a)(1) of this part, is amended—

5 (1) in subparagraph (F), by striking “and”  
6 after the semicolon;

7 (2) in subparagraph (G), by striking the period  
8 and inserting “; and”; and

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

10 “(H)(i) services providing nonrecurring  
11 short term benefits (including supports related  
12 to housing instability, utilities, transportation,  
13 and food assistance, among other basic needs)  
14 that address immediate needs related to a spe-  
15 cific crisis, situation, or event affecting the abil-  
16 ity of a child to remain in a home established  
17 for the child that is not intended to meet an on-  
18 going need; and

19 “(ii) for purposes of this subpart, an ex-  
20 penditure for a service described in clause (i)  
21 may be treated as an expenditure for any 1 or  
22 more of family support services, family preser-  
23 vation services, family reunification services, or  
24 adoption promotion and support services as  
25 long as the expenditure is related to serving the  
26 children and families in the specified category

1           and consistent with the overall purpose of the  
2           category.”.

3           (b) STATE PLAN REQUIREMENTS.—Section 432(a)  
4 (42 U.S.C. 629b(a)) is amended—

5           (1) in paragraph (9), by striking “and” after  
6           the semicolon;

7           (2) in paragraph (10), by striking the period  
8           and inserting “; and”; and

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

10           “(11) provides a description of policies in place,  
11           including training for employees, to address child  
12           welfare reports and investigations of neglect con-  
13           cerning the living arrangements or subsistence needs  
14           of a child with the goal to prevent the separation of  
15           a child from a parent of the child solely due to pov-  
16           erty, to ensure access to services described in section  
17           431(a)(1)(H).”.

18 **SEC. 321. STRENGTHENING SUPPORT FOR CASEWORKERS.**

19           (a) REAUTHORIZATION OF, AND INCREASE IN FUND-  
20           ING FOR, CASEWORKER VISITS.—Section 436(b)(4)(A)  
21 (42 U.S.C. 629f(b)(4)(A)) is amended by striking “each  
22 of fiscal years 2017 through 2023” and inserting “fiscal  
23 year 2025 and \$26,000,000 for fiscal year 2026 and each  
24 succeeding fiscal year”.

1 (b) MINIMUM GRANT AMOUNT.—Section 433(e) (42  
2 U.S.C. 629c(e)) is amended by striking paragraphs (1)  
3 and (2) and inserting the following:

4 “(1) BASE ALLOTMENT.—From the amount re-  
5 served pursuant to section 436(b)(4)(A) for any fis-  
6 cal year, the Secretary shall first allot to each State  
7 (other than an Indian tribe) that has provided to the  
8 Secretary such documentation as may be necessary  
9 to verify that the jurisdiction has complied with sec-  
10 tion 436(b)(4)(B)(ii) during the fiscal year, a base  
11 allotment of \$100,000, and shall then allot to each  
12 of those States an amount determined in paragraph  
13 (2) or (3) of this subsection, as applicable.

14 “(2) TERRITORIES.—From the amount reserved  
15 pursuant to section 436(b)(4)(A) for any fiscal year  
16 that remains after applying paragraph (1) of this  
17 subsection for the fiscal year, the Secretary shall  
18 allot to each jurisdiction specified in subsection (b)  
19 of this section to which a base allotment is made  
20 under such paragraph (1) an amount determined in  
21 the same manner as the allotment to each of such  
22 jurisdictions is determined under section 423 (with-  
23 out regard to the initial allotment of \$70,000 to  
24 each State).

1           “(3) OTHER STATES.—From the amount re-  
2       served pursuant to section 436(b)(4)(A) for any fis-  
3       cal year that remains after applying paragraphs (1)  
4       and (2) of this subsection for the fiscal year, the  
5       Secretary shall allot to each State (other than an In-  
6       dian tribe) not specified in subsection (b) of this sec-  
7       tion to which a base allotment was made under  
8       paragraph (1) of this subsection an amount equal to  
9       such remaining amount multiplied by the supple-  
10      mental nutrition assistance program benefits per-  
11      centage of the State (as defined in subsection (c)(2)  
12      of this section) for the fiscal year, except that in ap-  
13      plying subsection (c)(2)(A) of this section, ‘sub-  
14      section (e)(3)’ shall be substituted for ‘such para-  
15      graph (1)’.”.

16      (c) REQUIREMENT TO USE FUNDS TO IMPROVE  
17      QUALITY OF CASEWORKER VISITS WITH FOSTER CHIL-  
18      DREN.—Section       436(b)(4)(B)(i)       (42       U.S.C.  
19      629f(b)(4)(B)(i)) is amended to read as follows:

20           “(i) IN GENERAL.—A State to which  
21           an amount is paid from amounts reserved  
22           under subparagraph (A) shall use the  
23           amount to improve the quality of monthly  
24           caseworker visits with children who are in

1 foster care under the responsibility of the  
2 State, with an emphasis on—

3 “(I) reducing caseload ratios and  
4 the administrative burden on case-  
5 workers, to improve caseworker deci-  
6 sion making on the safety, perma-  
7 nency, and well-being of foster chil-  
8 dren and on activities designed to in-  
9 crease retention, recruitment, and  
10 training of caseworkers;

11 “(II) implementing technology  
12 solutions to streamline caseworker du-  
13 ties and modernize systems, ensuring  
14 improved efficiency and effectiveness  
15 in child welfare services;

16 “(III) improving caseworker safe-  
17 ty;

18 “(IV) mental health resources to  
19 support caseworker well-being, includ-  
20 ing peer-to-peer support programs;  
21 and

22 “(V) recruitment campaigns  
23 aimed at attracting qualified case-  
24 worker candidates.”.

1 (d) ELIMINATION OF COST-SHARE PENALTY TIED TO  
2 MONTHLY CASEWORKER VISIT STANDARD.—Section  
3 424(f) (42 U.S.C. 624(f)) is amended—

4 (1) by striking “(1)(A)”; and  
5 (2) by striking paragraphs (1)(B) and (2).

6 **SEC. 322. DEMONSTRATION PROJECTS FOR IMPROVING RE-**  
7 **LATIONSHIPS BETWEEN INCARCERATED**  
8 **PARENTS AND CHILDREN IN FOSTER CARE.**

9 (a) IN GENERAL.—Section 439 (42 U.S.C. 629i) is  
10 amended to read as follows:

11 **“SEC. 439. STATE PARTNERSHIP PLANNING AND DEM-**  
12 **ONSTRATION GRANTS TO SUPPORT MEAN-**  
13 **INGFUL RELATIONSHIPS BETWEEN FOSTER**  
14 **CHILDREN AND THE INCARCERATED PAR-**  
15 **ENTS OF THE CHILDREN.**

16 “(a) AUTHORITY.—

17 “(1) IN GENERAL.—The Secretary may make  
18 demonstration grants to eligible State partnerships  
19 to develop, implement, and provide support for pro-  
20 grams that enable and sustain meaningful relation-  
21 ships between covered foster children and the incar-  
22 cerated parents of the children.

23 “(2) PAYMENT OF ANNUAL INSTALLMENTS.—  
24 The Secretary shall pay each demonstration grant in  
25 5 annual installments.

1           “(3) 1-YEAR PLANNING GRANTS.—The Sec-  
2       retary may make a planning grant to a recipient of  
3       a demonstration grant, to be paid to the recipient 1  
4       year before payment of the 1st annual installment of  
5       the demonstration grant and in an amount not  
6       greater than any installment of the demonstration  
7       grant, if—

8           “(A) the recipient includes a request for a  
9       planning grant in the application under sub-  
10      section (c); and

11          “(B) the Secretary determines that a plan-  
12      ning grant would assist the recipient and im-  
13      prove the effectiveness of the demonstration  
14      grant.

15      “(b) ELIGIBLE STATE PARTNERSHIP DEFINED.—

16          “(1) IN GENERAL.—In this section, the term  
17      ‘eligible State partnership’ means an agreement en-  
18      tered into by, at a minimum, the following:

19           “(A) The State child welfare agency re-  
20      sponsible for the administration of the State  
21      plans under this part.

22           “(B) The State agency responsible for  
23      adult corrections.

24          “(2) ADDITIONAL PARTNERS.—For purposes of  
25      this section, an eligible State partnership may in-

1       clude any entity with experience in serving incarcerated  
2       ated parents and their children.

3               “(3) PARTNERSHIPS ENTERED INTO BY INDIAN  
4       TRIBES OR TRIBAL CONSORTIA.—Notwithstanding  
5       paragraph (1), if an Indian tribe or tribal consor-  
6       tium enters into a partnership pursuant to this sec-  
7       tion that does not consist solely of tribal child wel-  
8       fare agencies (or a consortium of the agencies), the  
9       partnership shall be considered an eligible State  
10      partnership for purposes of this section.

11      “(c) APPLICATION REQUIREMENTS.—An eligible  
12      State partnership seeking a demonstration grant under  
13      this section to carry out a program described in subsection  
14      (a)(1) shall submit an application to the Secretary at such  
15      time, in such manner, and containing such information as  
16      the Secretary may require. The application shall include  
17      the following:

18              “(1) A summary of the program, including how  
19      the program will support a meaningful relationship  
20      between a covered foster child and an incarcerated  
21      parent of the child.

22              “(2) A description of the activities to be carried  
23      out by the program, which must include all of the  
24      activities described in subsection (d) that are in the  
25      best interest of the covered foster child.



1           “(3) A framework for identifying—

2           “(A) each covered foster child eligible for  
3           services under the program, including, to the  
4           extent practicable, coordination of data between  
5           relevant State child welfare agencies and court  
6           systems; and

7           “(B) the roles and responsibilities of the  
8           entities in the partnership.

9           “(4) Documentation that the applicant is an eli-  
10          gible State partnership.

11          “(5) Assurances that the applicant will partici-  
12          pate fully in the evaluation described in subsection  
13          (f)(2) and shall maintain records for the program,  
14          including demographic information disaggregated by  
15          relevant characteristics with respect to covered foster  
16          children and incarcerated parents who participate in  
17          the program.

18          “(d) PROGRAM ACTIVITIES.—To the extent that the  
19          activities are in the best interest of the covered foster  
20          child, the activities referred to in subsection (c)(2) shall  
21          include the following:

22          “(1) REVISION OF POLICIES.—Through con-  
23          sultation with incarcerated parents and their fami-  
24          lies, grantees shall promote organizational policies of  
25          participating child welfare entities and collaborating

1       correctional facilities to promote meaningful rela-  
2       tionships through regular and developmentally ap-  
3       propriate communication and visitation between cov-  
4       ered foster children and the incarcerated parents, in-  
5       cluding, when appropriate, the following:

6               “(A) For child welfare entities—

7                       “(i) inclusion of parents in case plan-  
8                       ning and decision making for children;

9                       “(ii) regular sharing of information  
10                      and responses to requests for information  
11                      between caseworkers and incarcerated par-  
12                      ents with respect to the case information  
13                      of a child, any changes to a case, perma-  
14                      nency plans, requirements to maintain pa-  
15                      rental rights, and any efforts to terminate  
16                      parental rights;

17                      “(iii) appropriate opportunities for in-  
18                      carcerated parents to demonstrate their re-  
19                      lationship with a covered foster child given  
20                      their incarceration, including training and  
21                      courses required for a service plan; and

22                      “(iv) the enhanced visitation described  
23                      in paragraph (2).

1           “(B) For correctional facilities, fostering  
2           visitation and communication that is develop-  
3           mentally appropriate in terms of—

4           “(i) the nature of communication and  
5           visitation, including—

6           “(I) the ability to physically  
7           touch parents;

8           “(II) engaging with parents in lo-  
9           cations that are appropriate for the  
10          age and development of the child;

11          “(III) exchanging items that are  
12          appropriate to the age and develop-  
13          ment of the child, include expectations  
14          that are appropriate for the age and  
15          development of the child related to be-  
16          havior, attire, and wait times; and

17          “(IV) allowing appropriate adults  
18          to bring children if legal guardians  
19          are not available to promote regular  
20          contact;

21          “(ii) reasonable inclusion of all chil-  
22          dren of the parent;

23          “(iii) communication and visitation at  
24          times when the children are available;

1 “(iv) security procedures to comfort  
2 children and be minimally invasive; and

3 “(v) promoting parent-child relation-  
4 ships regardless of the sentence imposed  
5 on the parent.

6 “(2) ENHANCED VISITATION.—

7 “(A) Grantees shall facilitate weekly com-  
8 munication and, for at least 9 days each year,  
9 in-person visitation between a covered foster  
10 child and any incarcerated parent of the child.

11 “(B) Electronic visitation (such as live  
12 video visits, phone calls, and recorded books)  
13 may be used but shall not be the sole method  
14 to promote a meaningful relationship for pur-  
15 poses of the grant.

16 “(C) Enhanced visitation programs shall—

17 “(i) integrate best practices for visita-  
18 tion programs with incarcerated parents  
19 and their children;

20 “(ii) adopt developmentally appro-  
21 priate visitation policies and procedures  
22 such as those described in paragraph  
23 (1)(B);

24 “(iii) reduce or eliminate the cost of  
25 developmentally appropriate communica-

1                   tion and visitation for the covered foster  
2                   child, which may include the purchase of  
3                   communication technology, covering trans-  
4                   portation, insurance, and lodging costs,  
5                   costs related to providing appropriate visi-  
6                   tation spaces and activities, and other rel-  
7                   evant costs;

8                   “(iv) to the extent practicable, inte-  
9                   grate appropriate parenting education to  
10                  help prepare and process visits; and

11                  “(v) avoid restricting visitation and  
12                  communication as a punishment for the in-  
13                  carcerated parents.

14                  “(3) TRAINING.—Grantees shall incorporate on-  
15                  going training for child welfare workers, correctional  
16                  facility staff, and other program providers to under-  
17                  stand the importance of promoting meaningful rela-  
18                  tionships between children and incarcerated parents.

19                  “(4) CASE MANAGEMENT.—Grantees shall pro-  
20                  vide case management services for the incarcerated  
21                  parents of a covered foster child to promote the rela-  
22                  tionship, access to services, and coordination with  
23                  the caseworkers of the covered foster child to  
24                  strengthen the relationship.

1           “(5) LEGAL ASSISTANCE.—Grantees shall facili-  
2           tate access to necessary legal services and may use  
3           grant funds for services that are not reimbursable  
4           under other Federal programs.

5           “(e) FEDERAL SHARE.—The Federal share of the  
6           cost of any activity carried out using a grant made under  
7           this section shall be not greater than 75 percent.

8           “(f) TECHNICAL ASSISTANCE, EVALUATIONS, AND  
9           REPORTS.—

10           “(1) TECHNICAL ASSISTANCE.—The Secretary  
11           shall provide technical assistance with respect to  
12           grants under this section, including by—

13                   “(A) assisting grantees in understanding  
14                   best practices in promoting meaningful relation-  
15                   ships between incarcerated parents and their  
16                   children as well as consulting with appropriate  
17                   stakeholders when developing their programs;

18                   “(B) assisting grantees with establishing  
19                   and analyzing implementation and performance  
20                   indicators; and

21                   “(C) conducting an annual technical assist-  
22                   ance and training meeting and an annual grant-  
23                   ee meeting so that grantees can learn from the  
24                   experiences of other grantees.

1           “(2) EVALUATIONS.—The Secretary shall con-  
2       duct an evaluation of program outcomes, including  
3       with respect to parent and child well-being, parent-  
4       child interactions, parental involvement, awareness  
5       of child development and parenting practices, place-  
6       ment stability, and termination of parental rights  
7       with respect to covered foster children and incarcer-  
8       ated parents, to measure program effectiveness, as  
9       determined by the Secretary, and identify opportuni-  
10      ties for improved program practices and implemen-  
11      tation.

12           “(3) REPORTS TO THE CONGRESS.—

13           “(A) INITIAL REPORT.—Not later than 3  
14      years after the date of the enactment of this  
15      section, the Secretary shall submit to the Com-  
16      mittee on Ways and Means of the House of  
17      Representatives and the Committee on Finance  
18      of the Senate a report that includes—

19                   “(i) the number of applications for  
20                   grants under this section;

21                   “(ii) the number of grants awarded,  
22                   and the amounts for each grant; and

23                   “(iii) information on the grants, in-  
24                   cluding—

1 “(I) interim results of the evalua-  
2 tion described in paragraph (2);

3 “(II) disaggregated data on cov-  
4 ered foster children and incarcerated  
5 parents;

6 “(III) information on the com-  
7 position of eligible State partnerships;

8 “(IV) best practices for facili-  
9 tating meaningful relationships be-  
10 tween covered foster children and in-  
11 carcerated parents; and

12 “(V) barriers to implementation  
13 or expansion of programs funded  
14 under this section.

15 “(B) FINAL REPORT.—Not later than 6  
16 years after the date of the enactment of this  
17 section, the Secretary shall submit to the Com-  
18 mittee on Ways and Means of the House of  
19 Representatives and the Committee on Finance  
20 of the Senate a report that includes—

21 “(i) the final results of the evaluation  
22 described in paragraph (2); and

23 “(ii) recommendations for refinements  
24 to grant requirements to improve program  
25 outcomes.



1       “(g) AUTHORITY OF SECRETARY WITH RESPECT TO  
2 INDIAN TRIBES AND TRIBAL ORGANIZATIONS.—

3               “(1) WAIVER OR MODIFICATION OF REQUIRE-  
4 MENTS.—In making a grant to an Indian tribe or  
5 tribal organization under this section, the Secretary  
6 may waive the matching requirement of subsection  
7 (e) or modify an application requirement imposed by  
8 or under subsection (c) if the Secretary determines  
9 that the waiver or modification is appropriate to the  
10 needs, culture, and circumstances of the Indian tribe  
11 or tribal organization.

12              “(2) EVALUATION.—The Secretary shall use  
13 tribally relevant data in carrying out the evaluation  
14 under subsection (f)(2) with respect to an Indian  
15 tribe or tribal organization.

16       “(h) LIMITATIONS ON AUTHORIZATION OF APPRO-  
17 PRIATIONS.—There is authorized to be appropriated to the  
18 Secretary not more than \$35,000,000 for each of fiscal  
19 years 2026 through 2029 to carry out this section.

20       “(i) DEFINITION OF COVERED FOSTER CHILD.—In  
21 this section, the term ‘covered foster child’ means a child  
22 that—

23               “(1) is in foster care; and

24               “(2) has at least 1 parent incarcerated in a  
25 Federal, State, or local correctional facility.”.

1 (b) CONFORMING AMENDMENTS.—

2 (1) Section 431(a)(2)(B)(vii) (42 U.S.C.  
3 629a(a)(2)(B)(vii)) is amended by striking “(as de-  
4 fined in section 439(b)(2))”.

5 (2) Section 431(a) (42 U.S.C. 629a(a)), as  
6 amended by sections 316(b)(2) and 320(a)(4) of this  
7 part, is amended by adding at the end the following:

8 “(12) MENTORING.—The term ‘mentoring’  
9 means a structured, managed program in which chil-  
10 dren are appropriately matched with screened and  
11 trained adult volunteers for one on-one relationships,  
12 involving meetings and activities on a regular basis,  
13 intended to meet, in part, the child’s need for in-  
14 volvement with a caring and supportive adult who  
15 provides a positive role model.”.

16 **SEC. 323. GUIDANCE TO STATES ON IMPROVING DATA COL-**  
17 **LECTION AND REPORTING FOR YOUTH IN**  
18 **RESIDENTIAL TREATMENT PROGRAMS.**

19 Within 2 years after the date of the enactment of this  
20 Act, the Secretary of Health and Human Services, in con-  
21 sultation with the Department of Education, the Adminis-  
22 tration for Children and Families, the Centers for Medi-  
23 care and Medicaid Services, the Administration for Com-  
24 munity Living, the Department of Justice, and other rel-  
25 evant policy experts, as determined by the Secretary, shall

1 issue and disseminate, or update and revise, as applicable,  
2 guidance to State agencies in administering State plans  
3 approved under parts B and E of title IV of the Social  
4 Security Act on the following:

5 (1) Best practices for Federal and State agen-  
6 cies to collect data and share information related to  
7 the well-being of youth residing in residential treat-  
8 ment facilities, including those facilities operating in  
9 multiple States or serving out-of-state youth.

10 (2) Best practices on improving State collection  
11 and sharing of data related to incidences of mal-  
12 treatment of youth residing in residential treatment  
13 facilities, including with respect to meeting the re-  
14 quirement of section 471(a)(9)(A) of such Act for  
15 such youth in foster care.

16 (3) Best practices on improving oversight of  
17 youth residential programs receiving Federal fund-  
18 ing, and research-based strategies for risk assess-  
19 ment related to the health, safety, and well-being of  
20 youth in the facilities.

21 **SEC. 324. STREAMLINING RESEARCH, TRAINING, AND**  
22 **TECHNICAL ASSISTANCE FUNDING.**

23 (a) REPURPOSING DISCRETIONARY RESEARCH SET-  
24 ASIDE.—Section 435(c) (42 U.S.C. 629e(c)) is amended  
25 to read as follows:

1       “(c) EVALUATION, RESEARCH, AND TECHNICAL AS-  
2       SISTANCE WITH RESPECT TO TARGETED PROGRAM RE-  
3       SOURCES.—Of the amount reserved under section  
4       437(b)(1) for a fiscal year, the Secretary shall use not less  
5       than—

6               “(1) \$1,000,000 for technical assistance to  
7       grantees under section 437(f) and to support design  
8       of local site evaluations with the goal of publishing  
9       and submitting evaluation findings to the clearing-  
10      house established under section 476(d), or to award  
11      grants to allow current or former grantees under  
12      section 437(f) to analyze, publish, and submit to the  
13      clearinghouse data collected during past grants; and

14              “(2) \$1,000,000 for technical assistance re-  
15      quired under section 429B of this Act to support ef-  
16      fective implementation of the Indian Child Welfare  
17      Act of 1978 and to support development of associ-  
18      ated State plan measures described pursuant to sec-  
19      tion 422(b)(9) of this Act.”.

20      (b) ELIMINATION OF RESEARCH SET-ASIDE FROM  
21      MANDATORY FUNDS.—

22              (1) IN GENERAL.—Section 436(b) (42 U.S.C.  
23      629f(b)), as amended by the preceding provisions of  
24      this Act, is amended by striking paragraph (1) and

1 redesignating paragraphs (2) through (5) as para-  
2 graphs (1) through (4), respectively.

3 (2) CONFORMING AMENDMENTS.—

4 (A) Section 433(a) (42 U.S.C. 629c(a)) is  
5 amended by striking “436(b)(3)” and inserting  
6 “436(b)(2)”.

7 (B) Section 433(e) (42 U.S.C. 629c(e)), as  
8 amended by section 322(b) of this part, is  
9 amended by striking “436(b)(4)(A)” and insert-  
10 ing “436(b)(3)(A)” each place it appears.

11 (C) Section 434(a)(2)(A) (42 U.S.C.  
12 629d(a)(2)(A)) is amended by striking  
13 “436(b)(4)(B)” and inserting “436(b)(3)(B)”.

14 (D) Section 437(b)(1) (42 U.S.C.  
15 629g(b)(1)) is amended by striking “436(b)(1)”  
16 and inserting “435”.

17 (E) Section 437(f)(3) (42 U.S.C.  
18 629g(f)(3)) is amended by striking “436(b)(5)”  
19 and inserting “436(b)(4)”.

20 (F) Section 438(c) (42 U.S.C. 629g(c)) is  
21 amended in each of paragraphs (1) through (3)  
22 is amended by striking “436(b)(2)” and insert-  
23 ing “436(b)(1)”.

1   **SEC. 325. REPORT ON POST ADOPTION AND SUBSIDIZED**  
2                   **GUARDIANSHIP SERVICES.**

3           (a) IN GENERAL.—Within 2 years after the date of  
4 the enactment of this Act, the Secretary of Health and  
5 Human Services shall prepare and submit to the Com-  
6 mittee on Ways and Means of the House of Representa-  
7 tives and the Committee on Finance of the Senate a report  
8 on children who enter into foster care under the super-  
9 vision of a State administering a plan approved under part  
10 B or E of title IV of the Social Security Act after finaliza-  
11 tion of an adoption or legal guardianship.

12          (b) INFORMATION.—The Secretary shall include in  
13 the report information, to the extent available through the  
14 Adoption and Foster Care Analysis and Reporting System  
15 and other data sources, regarding the incidence of adop-  
16 tion disruption and dissolution affecting children described  
17 in subsection (a) and factors associated with such cir-  
18 cumstances, including—

19               (1) whether affected individuals received pre- or  
20               post-legal adoption services; and

21               (2) other relevant information, such as the age  
22               of the child involved.

23          (c) POST-ADOPTION SERVICES AND GUARDIAN-  
24 SHIP.—The Secretary shall include in the report—

25               (1) a summary of post-adoption services and  
26               guardianship in each State that are available to fam-

1 ilies that adopted children from foster care and the  
2 extent to which the services are evidence-based or  
3 evidence-informed.

4 (2) a summary of funding and funding sources  
5 for the services in each State, including set-asides  
6 under the Promoting Safe and Stable Families pro-  
7 gram.

8 **SEC. 326. EFFECTIVE DATE.**

9 (a) IN GENERAL.—The amendments made by this  
10 part shall take effect on October 1, 2025, and shall apply  
11 to payments under part B of title IV of the Social Security  
12 Act for calendar quarters beginning on or after such date.

13 (b) DELAY PERMITTED IF STATE LEGISLATION RE-  
14 QUIRED.—If the Secretary of Health and Human Services  
15 determines that State legislation (other than legislation  
16 appropriating funds) is required in order for a State plan  
17 developed pursuant to part B of title IV of the Social Se-  
18 curity Act to meet the additional requirements imposed  
19 by the amendments made by this part, the plan shall not  
20 be regarded as failing to meet any of the additional re-  
21 quirements before the 1st day of the 1st calendar quarter  
22 beginning after the first regular session of the State legis-  
23 lature that begins after the date of the enactment of this  
24 Act. For purposes of the preceding sentence, if the State  
25 has a 2-year legislative session, each year of the session

1 is deemed to be a separate regular session of the State  
2 legislature.

3 (c) APPLICATION TO PROGRAMS OPERATED BY IN-  
4 DIAN TRIBAL ORGANIZATIONS.—In the case of an Indian  
5 tribe, tribal organization, or tribal consortium that the  
6 Secretary of Health and Human Services determines re-  
7 quires time to take action necessary to comply with the  
8 additional requirements imposed by the amendments made  
9 by this part (whether the tribe, organization, or tribal con-  
10 sortium has a plan under section 479B of the Social Secu-  
11 rity Act or a cooperative agreement or contract entered  
12 into with a State), the Secretary shall provide the tribe,  
13 organization, or tribal consortium with such additional  
14 time as the Secretary determines is necessary for the tribe,  
15 organization, or tribal consortium to take the action to  
16 comply with the additional requirements before being re-  
17 garded as failing to comply with the requirements.

18 **PART 2—STRENGTHENING STATE AND TRIBAL**  
19 **CHILD SUPPORT**

20 **SEC. 331. SHORT TITLE.**

21 This part may be cited as the “Strengthening State  
22 and Tribal Child Support Enforcement Act”.



1   **SEC. 332. IMPROVING THE EFFECTIVENESS OF TRIBAL**  
2                   **CHILD SUPPORT ENFORCEMENT AGENCIES.**

3           (a) IMPROVING THE COLLECTION OF PAST-DUE  
4 CHILD SUPPORT THROUGH STATE AND TRIBAL PARITY  
5 IN THE ALLOWABLE USE OF TAX INFORMATION.—

6           (1) AMENDMENT TO THE SOCIAL SECURITY  
7 ACT.—Section 464 of the Social Security Act (42  
8 U.S.C. 664) is amended by adding at the end the  
9 following:

10          “(d) APPLICABILITY TO INDIAN TRIBES AND TRIBAL  
11 ORGANIZATIONS RECEIVING A GRANT UNDER THIS  
12 PART.—This section, except for the requirement to dis-  
13 tribute amounts in accordance with section 457, shall  
14 apply to an Indian tribe or tribal organization receiving  
15 a grant under section 455(f) in the same manner in which  
16 this section applies to a State with a plan approved under  
17 this part.”.

18           (2) AMENDMENTS TO THE INTERNAL REVENUE  
19 CODE.—

20           (A) Section 6103(a)(2) of the Internal  
21 Revenue Code of 1986 is amended by striking  
22 “any local child support enforcement agency”  
23 and inserting “any tribal or local child support  
24 enforcement agency”.

25           (B) Section 6103(a)(3) of such Code is  
26 amended by inserting “, (8)” after “(6)”.

1 (C) Section 6103(l) of such Code is  
2 amended—

3 (i) in paragraph (6)—

4 (I) by striking “or local” in sub-  
5 paragraph (A) and inserting “tribal,  
6 or local”;

7 (II) by striking “AND LOCAL” in  
8 the heading thereof and inserting  
9 “TRIBAL, AND LOCAL”;

10 (III) by striking “The following”  
11 in subparagraph (B) and inserting  
12 “The”;

13 (IV) by striking the colon and all  
14 that follows in subparagraph (B) and  
15 inserting a period; and

16 (V) by adding at the end the fol-  
17 lowing:

18 “(D) STATE, TRIBAL, OR LOCAL CHILD  
19 SUPPORT ENFORCEMENT AGENCY.—For pur-  
20 poses of this paragraph, the following shall be  
21 treated as a State, tribal, or local child support  
22 enforcement agency:

23 “(i) Any agency of a State or political  
24 subdivision thereof operating pursuant to a  
25 plan described in section 454 of the Social

1 Security Act which has been approved by  
2 the Secretary of Health and Human Serv-  
3 ices under part D of title IV of such Act.

4 “(ii) Any child support enforcement  
5 agency of an Indian tribe or tribal organi-  
6 zation receiving a grant under section  
7 455(f) of the Social Security Act.”;

8 (ii) in paragraph (8)—

9 (I) in subparagraph (A), by strik-  
10 ing “or State or local” and inserting  
11 “, State, tribal, or local”;

12 (II) in subparagraph (B), by  
13 striking “enforced pursuant to a plan  
14 described” and all that follows  
15 through “of such Act” and inserting  
16 “enforced pursuant to the provisions  
17 of part D of title IV of the Social Se-  
18 curity Act”;

19 (III) by adding at the end of sub-  
20 paragraph (B) the following: “The in-  
21 formation disclosed to any child sup-  
22 port enforcement agency under sub-  
23 paragraph (A) with respect to any in-  
24 dividual with respect to whom child  
25 support obligations are sought to be

1 established or enforced may be dis-  
2 closed by such agency to any agent of  
3 such agency which is under contract  
4 with such agency for purposes of, and  
5 to the extent necessary in, estab-  
6 lishing and collecting child support  
7 obligations from, and locating, individ-  
8 uals owing such obligations.”;

9 (IV) by striking subparagraph  
10 (C) and inserting the following:

11 “(C) STATE, TRIBAL, OR LOCAL CHILD  
12 SUPPORT ENFORCEMENT AGENCY.—For pur-  
13 poses of this paragraph, the term ‘State, tribal,  
14 or local child support enforcement agency’ has  
15 the same meaning as when used in paragraph  
16 (6)(D).”; and

17 (V) by striking “AND LOCAL” in  
18 the heading thereof and inserting  
19 “TRIBAL, AND LOCAL”; and

20 (iii) in paragraph (10)(B), by adding  
21 at the end the following new clause:

22 “(iii) The information disclosed to any  
23 child support enforcement agency under  
24 subparagraph (A) with respect to any indi-  
25 vidual with respect to whom child support

1 obligations are sought to be established or  
2 enforced may be disclosed by such agency  
3 to any agent of such agency which is under  
4 contract with such agency for purposes of,  
5 and to the extent necessary in, establishing  
6 and collecting child support obligations  
7 from, and locating, individuals owing such  
8 obligations.”.

9 (D) Section 6103(p)(4) of such Code is  
10 amended—

11 (i) by striking “subsection (l)(10),  
12 (13)(A), (13)(B), (13)(C), (13)(D)(i), (16),  
13 (18), (19), or (20), or any entity” in the  
14 matter preceding subparagraph (A) and in-  
15 serting “subsection (l)(6), (8), (10),  
16 (13)(A), (13)(B), (13)(C), (13)(D)(i), (16),  
17 (18), (19), or (20), or any Indian tribe or  
18 tribal organization receiving a grant under  
19 section 455(f) of the Social Security Act,  
20 or any entity”;

21 (ii) by striking “subsection (l)(10)” in  
22 subparagraph (F)(i) and inserting “sub-  
23 section (l)(6), (8), (10)”;

24 (iii) by striking “subsection (l)(10),  
25 (13)(A), (13)(B), (13)(C), (13)(D)(i), (16),

1 (18), (19), or (20) or any entity” each  
2 place it appears in the matter following  
3 subparagraph (F)(iii) and inserting “sub-  
4 section (l)(6), (8), (10), (13)(A), (13)(B),  
5 (13)(C), (13)(D)(i), (16), (18), (19), or  
6 (20), or any Indian tribe or tribal organi-  
7 zation receiving a grant under section  
8 455(f) of the Social Security Act, or any  
9 entity”; and

10 (iv) by inserting “, (8)” after “para-  
11 graph (6)(A)” in the matter following sub-  
12 paragraph (F)(iii).

13 (E) Section 6103(p)(9) of such Code is  
14 amended by striking “or local” and inserting  
15 “tribal, or local”.

16 (F) Section 6402(c) of such Code is  
17 amended by adding at the end the following:  
18 “For purposes of this subsection, any reference  
19 to a State shall include a reference to any In-  
20 dian tribe or tribal organization receiving a  
21 grant under section 455(f) of the Social Secu-  
22 rity Act.”.

23 (b) REIMBURSEMENT FOR REPORTS.—Section  
24 453(g) of the Social Security Act (42 U.S.C. 653(g)) is  
25 amended—

1 (1) in the subsection heading, by striking  
2 “STATE”; and

3 (2) by striking “and State” and inserting “,  
4 State, and tribal”.

5 (c) TECHNICAL AMENDMENTS.—Paragraphs (7) and  
6 (33) of section 454 of the Social Security Act (42 U.S.C.  
7 654) are each amended by striking “450b” and inserting  
8 “5304”.

## 9 **Subtitle B—Other Matters**

### 10 **SEC. 341. SEXUAL RISK AVOIDANCE EDUCATION EXTEN-** 11 **SION.**

12 Section 510 of the Social Security Act (42 U.S.C.  
13 710) is amended—

14 (1) in subsection (a)—

15 (A) in paragraph (1)—

16 (i) by striking “and for the period”  
17 and inserting “for the period”;

18 (ii) by striking “December 31, 2024”  
19 and inserting “September 30, 2025”;

20 (iii) by inserting “and for the period  
21 beginning on October 1, 2025, and ending  
22 on December 31, 2025,” before “allot to  
23 each State”; and

1 (iv) by striking “for fiscal year 2024  
2 or 2025” and inserting “for fiscal year  
3 2024, 2025, or 2026”; and

4 (B) in paragraph (2), by striking “or  
5 2025” each place it appears and inserting “,  
6 2025, or 2026”; and

7 (2) in subsection (f)(1)—

8 (A) by striking “and for the period” and  
9 inserting “for the period”;

10 (B) by striking “December 31, 2024” and  
11 inserting “September 30, 2025”; and

12 (C) by inserting “, and for the period be-  
13 ginning on October 1, 2025, and ending on De-  
14 cember 31, 2025, an amount equal to the pro  
15 rata portion of the amount appropriated for the  
16 corresponding period for fiscal year 2025” after  
17 “corresponding period for fiscal year 2024”.

18 **SEC. 342. PERSONAL RESPONSIBILITY EDUCATION EXTEN-**  
19 **SION.**

20 Section 513 of the Social Security Act (42 U.S.C.  
21 713) is amended—

22 (1) in subsection (a)(1)—

23 (A) in subparagraph (A), in the matter  
24 preceding clause (i)—



1 (i) by striking “and for the period”  
2 and inserting “for the period”;

3 (ii) by striking “December 31, 2024”  
4 and inserting “September 30, 2025”; and

5 (iii) by inserting “and for the period  
6 beginning on October 1, 2025, and ending  
7 on December 31, 2025,” before “the Sec-  
8 retary shall allot”; and

9 (B) in subparagraph (B)(i)—

10 (i) by striking “and for the period”  
11 and inserting “for the period”;

12 (ii) by striking “December 31, 2024”  
13 and inserting “September 30, 2025”; and

14 (iii) by inserting “, and for the period  
15 beginning on October 1, 2025, and ending  
16 on December 31, 2025” before the period;

17 (2) in subsection (c)(3), by striking “fiscal year  
18 2024 or 2025” and inserting “fiscal year 2024,  
19 2025, or 2026”; and

20 (3) in subsection (f)—

21 (A) by striking “and for the period” and  
22 inserting “for the period”;

23 (B) by striking “December 31, 2024” and  
24 inserting “September 30, 2025”; and

1 (C) by inserting “, and for the period be-  
2 ginning on October 1, 2025, and ending on De-  
3 cember 31, 2025, an amount equal to the pro  
4 rata portion of the amount appropriated for the  
5 corresponding period for fiscal year 2025” after  
6 “corresponding period for fiscal year 2024”.

7 **SEC. 343. EXTENSION OF FUNDING FOR FAMILY-TO-FAMILY**  
8 **HEALTH INFORMATION CENTERS.**

9 Section 501(c)(1)(A)(viii) of the Social Security Act  
10 (42 U.S.C. 701(c)(1)(A)(viii)) is amended—

11 (1) by striking “\$1,500,000” and inserting  
12 “\$7,500,000”; and

13 (2) by striking “for the portion of fiscal year  
14 2025 before January 1, 2025” and inserting “for  
15 the period beginning on October 1, 2024, and ending  
16 on December 31, 2025”.

17 **TITLE IV—PUBLIC HEALTH**  
18 **EXTENDERS**

19 **Subtitle A—Extensions**

20 **SEC. 401. EXTENSION FOR COMMUNITY HEALTH CENTERS,**  
21 **NATIONAL HEALTH SERVICE CORPS, AND**  
22 **TEACHING HEALTH CENTERS THAT OPERATE**  
23 **GME PROGRAMS.**

24 (a) EXTENSION FOR COMMUNITY HEALTH CEN-  
25 TERS.—Section 10503(b)(1) of the Patient Protection and

1 Affordable Care Act (42 U.S.C. 254b–2(b)(1)) is amend-  
2 ed—

3 (1) in subparagraph (E), by striking “and” at  
4 the end;

5 (2) in subparagraph (F), by striking “,  
6 \$4,000,000,000 for each of fiscal years 2019  
7 through 2023” and all that follows through “and  
8 ending on December 31, 2024; and” and inserting  
9 a semicolon; and

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

11 “(G) \$4,000,000,000 for each of fiscal  
12 years 2019 through 2023;

13 “(H) \$526,027,397 for the period begin-  
14 ning on October 1, 2023, and ending on No-  
15 vember 17, 2023, \$690,410,959 for the period  
16 beginning on November 18, 2023, and ending  
17 on January 19, 2024, \$536,986,301 for the pe-  
18 riod beginning on January 20, 2024, and end-  
19 ing on March 8, 2024, and \$3,592,328,767 for  
20 the period beginning on October 1, 2023, and  
21 ending on December 31, 2024;

22 “(I) \$3,365,753,425 for the period begin-  
23 ning on January 1, 2025, and ending on Sep-  
24 tember 30, 2025; and

1                   “(J) \$4,600,000,000 for fiscal year 2026;  
2                   and”.

3           (b) EXTENSION FOR THE NATIONAL HEALTH SERV-  
4 ICE CORPS.—Section 10503(b)(2) of the Patient Protec-  
5 tion and Affordable Care Act (42 U.S.C. 254b–2(b)(2))  
6 is amended—

7           (1) in subparagraph (H), by striking “and” at  
8           the end;

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

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

12                   “(J) \$261,780,822 for the period begin-  
13                   ning on January 1, 2025, and ending on Sep-  
14                   tember 30, 2025; and

15                   “(K) \$350,000,000 for fiscal year 2026.”.

16          (c) TEACHING HEALTH CENTERS THAT OPERATE  
17 GRADUATE MEDICAL EDUCATION PROGRAMS.—Section  
18 340H(g)(1) of the Public Health Service Act (42 U.S.C.  
19 256h(g)(1)) is amended—

20           (1) by striking “not to exceed \$230,000,000”  
21           and all that follows through “and ending on Decem-  
22           ber 31, 2024,”; and

23           (2) by striking the period at the end and insert-  
24           ing the following: “, not to exceed—

1           “(A) \$230,000,000, for the period of fiscal  
2           years 2011 through 2015;

3           “(B) \$60,000,000 for each of fiscal years  
4           2016 and 2017;

5           “(C) \$126,500,000 for each of fiscal years  
6           2018 through 2023;

7           “(D) \$16,635,616 for the period beginning  
8           on October 1, 2023, and ending on November  
9           17, 2023, \$21,834,247 for the period beginning  
10          on November 18, 2023, and ending on January  
11          19, 2024, \$16,982,192 for the period beginning  
12          on January 20, 2024, and ending on March 8,  
13          2024, and \$164,136,986 for the period begin-  
14          ning on October 1, 2023, and ending on De-  
15          cember 31, 2024;

16          “(E) \$156,000,000 for the period begin-  
17          ning on January 1, 2025, and ending on Sep-  
18          tember 30, 2025;

19          “(F) \$225,000,000 for fiscal year 2026;

20          “(G) \$250,000,000 for fiscal year 2027;

21          “(H) \$275,000,000 for fiscal year 2028;

22          and

23          “(I) \$300,000,000 for fiscal year 2029.”.

24          (d) APPLICATION OF PROVISIONS.—Amounts appro-  
25          priated pursuant to the amendments made by this section

1 shall be subject to the requirements contained in Public  
2 Law 117–328 for funds for programs authorized under  
3 sections 330 through 340 of the Public Health Service Act  
4 (42 U.S.C. 254b et seq.).

5 (e) CONFORMING AMENDMENTS.—Section 3014(h)  
6 of title 18, United States Code, is amended—

7 (1) in paragraph (1), by striking “under sub-  
8 paragraphs (E) and (F) of section 10503(b)(1) of  
9 the Patient Protection and Affordable Care Act (42  
10 U.S.C. 254b–2(b)(1))” and inserting “under section  
11 10503(b)(1) of the Patient Protection and Afford-  
12 able Care Act (42 U.S.C. 254b–2(b)(1)) for fiscal  
13 year 2015 and each subsequent fiscal year (or period  
14 thereof)”; and

15 (2) in paragraph (4), by striking “and section  
16 101(d) of the Consolidated Appropriations Act,  
17 2024” and inserting “section 101(d) of the Consoli-  
18 dated Appropriations Act, 2024, and section 401 of  
19 the [ ]”.

20 **SEC. 402. EXTENSION OF SPECIAL DIABETES PROGRAMS.**

21 (a) EXTENSION OF SPECIAL DIABETES PROGRAMS  
22 FOR TYPE I DIABETES.—Section 330B(b)(2) of the Pub-  
23 lic Health Service Act (42 U.S.C. 254c–2(b)(2)) is amend-  
24 ed—

1           (1) in subparagraph (D), by striking “and” at  
2     the end;

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

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

6                 “(F) \$149,589,041 for the period begin-  
7     ning on January 1, 2025, and ending on Sep-  
8     tember 30, 2025, to remain available until ex-  
9     pended; and

10                “(G) \$200,000,000 for fiscal year 2026, to  
11     remain available until expended.”.

12       (b) EXTENDING FUNDING FOR SPECIAL DIABETES  
13     PROGRAMS FOR INDIANS.—Section 330C(c)(2) of the  
14     Public Health Service Act (42 U.S.C. 254c–3(c)(2)) is  
15     amended—

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

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

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

21                 “(F) \$149,589,041 for the period begin-  
22     ning on January 1, 2025, and ending on Sep-  
23     tember 30, 2025, to remain available until ex-  
24     pended; and

1 “(G) \$200,000,000 for fiscal year 2026, to  
2 remain available until expended.”.

3 **Subtitle B—World Trade Center**  
4 **Health Program**

5 **SEC. 411. 9/11 RESPONDER AND SURVIVOR HEALTH FUND-**  
6 **ING CORRECTIONS.**

7 (a) IN GENERAL.—Section 3351(a)(2)(A) of the  
8 Public Health Service Act (42 U.S.C. 300mm–  
9 61(a)(2)(A)) is amended—

10 (1) in clause (x), by striking “; and” and insert-  
11 ing a semicolon;

12 (2) by redesignating clause (xi) as clause (xii);  
13 and

14 (3) by inserting after clause (x), the following:

15 “(xi) for each of fiscal years 2026  
16 through 2040—

17 “(I) the amount determined  
18 under this subparagraph for the pre-  
19 vious fiscal year multiplied by 1.05;  
20 multiplied by

21 “(II) the ratio of—

22 “(aa) the total number of  
23 individuals enrolled in the WTC  
24 Program on July 1 of such pre-  
25 vious fiscal year; to



1 “(bb) the total number of  
2 individuals so enrolled on July 1  
3 of the fiscal year prior to such  
4 previous fiscal year; and”.

5 (b) REPORT TO CONGRESS.—

6 (1) IN GENERAL.—Not later than 3 years after  
7 the date of enactment of this Act, the Secretary of  
8 Health and Human Services (referred to in this sub-  
9 section as the “Secretary”) shall conduct an assess-  
10 ment of anticipated budget authority and outlays of  
11 the World Trade Center Health Program (referred  
12 to in this subsection as the “Program”) through the  
13 duration of the Program and submit a report sum-  
14 marizing such assessment to—

15 (A) the Speaker and minority leader of the  
16 House of Representatives;

17 (B) the majority and minority leaders of  
18 the Senate;

19 (C) the Committee on Health, Education,  
20 Labor, and Pensions and Committee on the  
21 Budget of the Senate; and

22 (D) the Committee on Energy and Com-  
23 merce and the Committee on the Budget of the  
24 House of Representatives.

1           (2) INCLUSIONS.—The report required under  
2 paragraph (1) shall include—

3           (A) a projection of Program budgetary  
4 needs on a per-fiscal year basis through fiscal  
5 year 2090;

6           (B) a review of Program modeling for each  
7 of fiscal years 2017 through the fiscal year  
8 prior to the fiscal year in which the report is  
9 issued to assess how anticipated budgetary  
10 needs compared to actual expenditures;

11          (C) an assessment of the projected budget  
12 authority and expenditures of the Program  
13 through fiscal year 2090 by comparing—

14           (i) such projected authority and ex-  
15 penditures resulting from application of  
16 section 3351(a)(2)(A) of the Public Health  
17 Service Act (42 U.S.C. 300mm–  
18 61(a)(2)(A)), as amended by subsection  
19 (a); and

20           (ii) such projected authority and ex-  
21 penditures that would result if such section  
22 were amended so that the formula under  
23 clause (xi) of such section, as amended by  
24 subsection (a), were to be extended  
25 through fiscal year 2090; and

1 (D) any recommendations of the Secretary  
2 to make changes to the formula under such sec-  
3 tion 3351(a)(2)(A), as so amended, to fully off-  
4 set anticipated Program expenditures through  
5 fiscal year 2090.

6 (c) TECHNICAL AMENDMENTS.—Title XXXIII of the  
7 Public Health Service Act (42 U.S.C. 300mm et seq.) is  
8 amended—

9 (1) in section 3352(d) (42 U.S.C. 300mm–  
10 62(d)), by striking “Any amounts” and inserting  
11 “Any unobligated amounts”;

12 (2) in section 3353(d) (42 U.S.C. 300mm–  
13 63(d)), by striking “Any amounts” and inserting  
14 “Any unobligated amounts”; and

15 (3) in section 3354(d) (42 U.S.C. 300mm–  
16 64(d)), by striking “Any amounts” and inserting  
17 “Any unobligated amounts”.

18 **TITLE V—SUPPORT ACT**  
19 **REAUTHORIZATION**

20 **SEC. 501. SHORT TITLE.**

21 This title may be cited as the “SUPPORT for Pa-  
22 tients and Communities Reauthorization Act of 2024”.

1                   **Subtitle A—Prevention**

2   **SEC. 511. PRENATAL AND POSTNATAL HEALTH.**

3           Section 317L(d) of the Public Health Service Act (42  
4   U.S.C. 247b–13(d)) is amended by striking “such sums  
5   as may be necessary for each of the fiscal years 2019  
6   through 2023” and inserting “\$4,250,000 for each of fis-  
7   cal years 2025 through 2029”.

8   **SEC. 512. MONITORING AND EDUCATION REGARDING IN-**  
9                   **FECTIONS ASSOCIATED WITH ILLICIT DRUG**  
10                   **USE AND OTHER RISK FACTORS.**

11          Section 317N(d) of the Public Health Service Act (42  
12   U.S.C. 247b–15(d)) is amended by striking “fiscal years  
13   2019 through 2023” and inserting “fiscal years 2025  
14   through 2029”.

15   **SEC. 513. PREVENTING OVERDOSES OF CONTROLLED SUB-**  
16                   **STANCES.**

17          (a) IN GENERAL.—Section 392A of the Public  
18   Health Service Act (42 U.S.C. 280b–1) is amended—

19               (1) in subsection (a)(2)—

20                       (A) in subparagraph (C), by inserting “and  
21                       associated risks” before the period at the end;  
22                       and

23                       (B) in subparagraph (D), by striking  
24                       “opioids” and inserting “substances causing  
25                       overdose”; and

1 (2) in subsection (b)(2)—

2 (A) in subparagraph (B), by inserting “,  
3 and associated risk factors,” after “such  
4 overdoses”;

5 (B) in subparagraph (C), by striking “cod-  
6 ing” and inserting “monitoring and identi-  
7 fying”;

8 (C) in subparagraph (E)—

9 (i) by inserting a comma after “public  
10 health laboratories”; and

11 (ii) by inserting “and other emerging  
12 substances related” after “analogues”; and

13 (D) in subparagraph (F), by inserting  
14 “and associated risk factors” after “overdoses”.

15 (b) ADDITIONAL GRANTS.—Section 392A(a)(3) of  
16 the Public Health Service Act (42 U.S.C. 280b–1(a)(3))  
17 is amended—

18 (1) in the matter preceding subparagraph (A),  
19 by striking “and Indian Tribes—” and inserting  
20 “and Indian Tribes for the following purposes.”;

21 (2) by amending subparagraph (A) to read as  
22 follows:

23 “(A) To carry out innovative projects for  
24 grantees to detect, identify, and rapidly respond  
25 to controlled substance misuse, abuse, and

1 overdoses, and associated risk factors, including  
2 changes in patterns of such controlled sub-  
3 stance use. Such projects may include the use  
4 of innovative, evidence-based strategies for de-  
5 tecting such patterns, such as wastewater sur-  
6 veillance, if proven to support actionable pre-  
7 vention strategies, in a manner consistent with  
8 applicable Federal and State privacy laws.”;  
9 and  
10 (3) in subparagraph (B), by striking “for any”  
11 and inserting “For any”.

12 (c) AUTHORIZATION OF APPROPRIATIONS.—Section  
13 392A(e) of the Public Health Service Act (42 U.S.C.  
14 280b–1(e)) is amended by striking “\$496,000,000 for  
15 each of fiscal years 2019 through 2023” and inserting  
16 “\$505,579,000 for each of fiscal years 2025 through  
17 2029”.

18 **SEC. 514. SUPPORT FOR INDIVIDUALS AND FAMILIES IM-**  
19 **PACTED BY FETAL ALCOHOL SPECTRUM DIS-**  
20 **ORDER.**

21 (a) IN GENERAL.—Part O of title III of the Public  
22 Health Service Act (42 U.S.C. 280f et seq.) is amended  
23 to read as follows:

1           **“PART O—FETAL ALCOHOL SYNDROME**  
2           **PREVENTION AND SERVICES PROGRAM**  
3   **“SEC. 399H. FETAL ALCOHOL SPECTRUM DISORDERS PRE-**  
4                   **VENTION, INTERVENTION, AND SERVICES DE-**  
5                   **LIVERY PROGRAM.**

6           “(a) IN GENERAL.—The Secretary shall establish or  
7 continue activities to support a comprehensive fetal alcohol  
8 spectrum disorders (referred to in this section as ‘FASD’)  
9 education, prevention, identification, intervention, and  
10 services delivery program, which may include—

11           “(1) an education and public awareness pro-  
12 gram to support, conduct, and evaluate the effective-  
13 ness of—

14           “(A) educational programs targeting  
15 health professions schools, social and other sup-  
16 portive services, educators and counselors and  
17 other service providers in all phases of child-  
18 hood development, and other relevant service  
19 providers, concerning the prevention, identifica-  
20 tion, and provision of services for infants, chil-  
21 dren, adolescents and adults with FASD;

22           “(B) strategies to educate school-age chil-  
23 dren, including pregnant and high-risk youth,  
24 concerning FASD;

25           “(C) public and community awareness pro-  
26 grams concerning FASD; and

1           “(D) strategies to coordinate information  
2           and services across affected community agen-  
3           cies, including agencies providing social services  
4           such as foster care, adoption, and social work,  
5           agencies providing health services, and agencies  
6           involved in education, vocational training and  
7           civil and criminal justice;

8           “(2) supporting and conducting research on  
9           FASD, as appropriate, including to—

10           “(A) develop appropriate medical diag-  
11           nostic methods for identifying FASD; and

12           “(B) develop effective culturally and lin-  
13           guistically appropriate evidence-based or evi-  
14           dence-informed interventions and appropriate  
15           supports for preventing prenatal alcohol expo-  
16           sure, which may co-occur with exposure to other  
17           substances;

18           “(3) building State and Tribal capacity for the  
19           identification, treatment, and support of individuals  
20           with FASD and their families, which may include—

21           “(A) utilizing and adapting existing Fed-  
22           eral, State, or Tribal programs to include  
23           FASD identification and FASD-informed sup-  
24           port;



1           “(B) developing and expanding screening  
2           and diagnostic capacity for FASD;

3           “(C) developing, implementing, and evalu-  
4           ating targeted FASD-informed intervention  
5           programs for FASD;

6           “(D) providing training with respect to  
7           FASD for professionals across relevant sectors;  
8           and

9           “(E) disseminating information about  
10          FASD and support services to affected individ-  
11          uals and their families; and

12          “(4) an applied research program concerning  
13          intervention and prevention to support and conduct  
14          service demonstration projects, clinical studies and  
15          other research models providing advocacy, edu-  
16          cational and vocational training, counseling, medical  
17          and mental health, and other supportive services, as  
18          well as models that integrate and coordinate such  
19          services, that are aimed at the unique challenges fac-  
20          ing individuals with Fetal Alcohol Syndrome or  
21          Fetal Alcohol Effect and their families.

22          “(b) GRANTS AND TECHNICAL ASSISTANCE.—

23                 “(1) IN GENERAL.—The Secretary may award  
24          grants, cooperative agreements and contracts and

1 provide technical assistance to eligible entities to  
2 carry out subsection (a).

3 “(2) ELIGIBLE ENTITIES.—To be eligible to re-  
4 ceive a grant, or enter into a cooperative agreement  
5 or contract, under this section, an entity shall—

6 “(A) be a State, Indian Tribe or Tribal or-  
7 ganization, local government, scientific or aca-  
8 demic institution, or nonprofit organization;  
9 and

10 “(B) prepare and submit to the Secretary  
11 an application at such time, in such manner,  
12 and containing such information as the Sec-  
13 retary may require, including a description of  
14 the activities that the entity intends to carry  
15 out using amounts received under this section.

16 “(3) ADDITIONAL APPLICATION CONTENTS.—  
17 The Secretary may require that an eligible entity in-  
18 clude in the application submitted under paragraph  
19 (2)(B)—

20 “(A) a designation of an individual to  
21 serve as a FASD State or Tribal coordinator of  
22 activities such eligible entity proposes to carry  
23 out through a grant, cooperative agreement, or  
24 contract under this section; and

1           “(B) a description of an advisory com-  
2           mittee the entity will establish to provide guid-  
3           ance for the entity on developing and imple-  
4           menting a statewide or Tribal strategic plan to  
5           prevent FASD and provide for the identifica-  
6           tion, treatment, and support of individuals with  
7           FASD and their families.

8           “(c) DEFINITION OF FASD-INFORMED.—For pur-  
9           poses of this section, the term ‘FASD-informed’, with re-  
10          spect to support or an intervention program, means that  
11          such support or intervention program uses culturally and  
12          linguistically informed evidence-based or practice-based  
13          interventions and appropriate resources to support an im-  
14          proved quality of life for an individual with FASD and  
15          the family of such individual.

16       **“SEC. 399I. STRENGTHENING CAPACITY AND EDUCATION**  
17                       **FOR FETAL ALCOHOL SPECTRUM DIS-**  
18                       **ORDERS.**

19          “(a) IN GENERAL.—The Secretary shall award  
20          grants, contracts, or cooperative agreements, as the Sec-  
21          retary determines appropriate, to public or nonprofit pri-  
22          vate entities with demonstrated expertise in the field of  
23          fetal alcohol spectrum disorders (referred to in this section  
24          as ‘FASD’). Such awards shall be for the purposes of  
25          building local, Tribal, State, and nationwide capacities to

1 prevent the occurrence of FASD by carrying out the pro-  
2 grams described in subsection (b).

3 “(b) PROGRAMS.—An entity receiving an award  
4 under subsection (a) may use such award for the following  
5 purposes:

6 “(1) Developing and supporting public edu-  
7 cation and outreach activities to raise public aware-  
8 ness of the risks associated with alcohol consumption  
9 during pregnancy.

10 “(2) Acting as a clearinghouse for evidence-  
11 based resources on FASD prevention, identification,  
12 and culturally and linguistically appropriate best  
13 practices to help inform systems of care for individ-  
14 uals with FASD across their lifespan.

15 “(3) Increasing awareness and understanding  
16 of efficacious, evidence-based screening tools and  
17 culturally and linguistically appropriate evidence-  
18 based intervention services and best practices, which  
19 may include improving the capacity for State, Trib-  
20 al, and local affiliates.

21 “(4) Providing technical assistance to recipients  
22 of grants, cooperative agreements, or contracts  
23 under section 399H, as appropriate.

24 “(c) APPLICATION.—To be eligible for a grant, con-  
25 tract, or cooperative agreement under this section, an enti-

1 ty shall submit to the Secretary an application at such  
2 time, in such manner, and containing such information as  
3 the Secretary may require.

4 “(d) SUBCONTRACTING.—A public or private non-  
5 profit entity may carry out the following activities required  
6 under this section through contracts or cooperative agree-  
7 ments with other public and private nonprofit entities with  
8 demonstrated expertise in FASD:

9 “(1) Resource development and dissemination.

10 “(2) Intervention services.

11 “(3) Training and technical assistance.

12 **“SEC. 399J. AUTHORIZATION OF APPROPRIATIONS.**

13 “There are authorized to be appropriated to carry out  
14 this part \$12,500,000 for each of fiscal years 2025  
15 through 2029.”.

16 (b) REPORT.—Not later than 4 years after the date  
17 of enactment of this Act, and every year thereafter, the  
18 Secretary of Health and Human Services shall prepare  
19 and submit to the Committee on Health, Education,  
20 Labor, and Pensions of the Senate and the Committee on  
21 Energy and Commerce of the House of Representatives  
22 a report containing—

23 (1) a review of the activities carried out pursu-  
24 ant to sections 399H and 399I of the Public Health  
25 Service Act, as amended, to advance public edu-

1 cation and awareness of fetal alcohol spectrum dis-  
2 orders (referred to in this section as “FASD”);

3 (2) a description of—

4 (A) the activities carried out pursuant to  
5 such sections 399H and 399I to identify, pre-  
6 vent, and treat FASD; and

7 (B) methods used to evaluate the outcomes  
8 of such activities; and

9 (3) an assessment of activities carried out pur-  
10 suant to such sections 399H and 399I to support in-  
11 dividuals with FASD.

12 **SEC. 515. PROMOTING STATE CHOICE IN PDMP SYSTEMS.**

13 Section 399O(h) of the Public Health Service Act (42  
14 U.S.C. 280g–3(h)) is amended by adding at the end the  
15 following:

16 “(5) PROMOTING STATE CHOICE.—Nothing in  
17 this section shall be construed to authorize the Sec-  
18 retary to require States to use a specific vendor or  
19 a specific interoperability connection other than to  
20 align with nationally recognized, consensus-based  
21 open standards, such as in accordance with sections  
22 3001 and 3004.”.

23 **SEC. 516. FIRST RESPONDER TRAINING PROGRAM.**

24 Section 546 of the Public Health Service Act (42  
25 U.S.C. 290ee–1) is amended—

1 (1) in subsection (a), by striking “tribes and  
2 tribal” and inserting “Tribes and Tribal”;

3 (2) in subsections (a), (c), and (d)—

4 (A) by striking “approved or cleared” each  
5 place it appears and inserting “approved,  
6 cleared, or otherwise legally marketed”; and

7 (B) by striking “opioid” each place it ap-  
8 pears;

9 (3) in subsection (f)—

10 (A) by striking “approved or cleared” each  
11 place it appears and inserting “approved,  
12 cleared, or otherwise legally marketed”;

13 (B) in paragraph (1), by striking “opioid”;

14 (C) in paragraph (2)—

15 (i) by striking “opioid and heroin”  
16 and inserting “opioid, heroin, and other  
17 drug”; and

18 (ii) by striking “opioid overdose” and  
19 inserting “overdose”; and

20 (D) in paragraph (3), by striking “opioid  
21 and heroin”; and

22 (4) in subsection (h), by striking “\$36,000,000  
23 for each of fiscal years 2019 through 2023” and in-  
24 serting “\$56,000,000 for each of fiscal years 2025  
25 through 2029”.

1   **SEC. 517. DONALD J. COHEN NATIONAL CHILD TRAUMATIC**  
2                   **STRESS INITIATIVE.**

3           (a) **TECHNICAL AMENDMENT.**—The second part G of  
4 title V of the Public Health Service Act (42 U.S.C. 290kk  
5 et seq.), as added by section 144 of the Community Re-  
6 newal Tax Relief Act (Public Law 106–554), is amend-  
7 ed—

8                   (1) by redesignating such part as part J; and

9                   (2) by redesignating sections 581 through 584  
10 as sections 596 through 596C, respectively.

11          (b) **IN GENERAL.**—Section 582 of the Public Health  
12 Service Act (42 U.S.C. 290hh–1) is amended—

13                   (1) in the section heading, by striking “**VIO-**  
14           **LENCE RELATED STRESS**” and inserting “**TRAU-**  
15           **MATIC EVENTS**”;

16                   (2) in subsection (a)—

17                           (A) in the matter preceding paragraph (1),  
18 by striking “tribes and tribal” and inserting  
19 “Tribes and Tribal”; and

20                           (B) in paragraph (2), by inserting “and  
21 dissemination” after “the development”;

22                   (3) in subsection (b), by inserting “and dissemi-  
23 nation” after “the development”;

24                   (4) in subsection (d)—

25                           (A) by striking “The NCTSI” and insert-  
26 ing the following:



1 “(1) COORDINATING CENTER.—The NCTSI”;

2 and

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

4 “(2) NCTSI GRANTEES.—In carrying out sub-  
5 section (a)(2), NCTSI grantees shall develop  
6 trainings and other resources, as applicable and ap-  
7 propriate, to support implementation of the evi-  
8 dence-based practices developed and disseminated  
9 under such subsection.”;

10 (5) in subsection (e)—

11 (A) by redesignating paragraphs (1) and  
12 (2) as subparagraphs (A) and (B), respectively,  
13 and adjusting the margins accordingly;

14 (B) in subparagraph (A), as so redesign-  
15 nated, by inserting “and implementation” after  
16 “the dissemination”;

17 (C) by striking “The NCTSI” and insert-  
18 ing the following:

19 “(1) COORDINATING CENTER.—The NCTSI”;

20 and

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

22 “(2) NCTSI GRANTEES.—NCTSI grantees shall,  
23 as appropriate, collaborate with other such grantees,  
24 the NCTSI coordinating center, and the Secretary in  
25 carrying out subsections (a)(2) and (d)(2).”;

1           (6) by amending subsection (h) to read as fol-  
2       lows:

3       “(h) APPLICATION AND EVALUATION.—To be eligible  
4 to receive a grant, contract, or cooperative agreement  
5 under subsection (a), a public or nonprofit private entity  
6 or an Indian Tribe or Tribal organization shall submit to  
7 the Secretary an application at such time, in such manner,  
8 and containing such information and assurances as the  
9 Secretary may require, including—

10           “(1) a plan for the evaluation of the activities  
11 funded under the grant, contract, or agreement, in-  
12 cluding both process and outcomes evaluation, and  
13 the submission of an evaluation at the end of the  
14 project period; and

15           “(2) a description of how such entity, Indian  
16 Tribe, or Tribal organization will support efforts led  
17 by the Secretary or the NCTSI coordinating center,  
18 as applicable, to evaluate activities carried out under  
19 this section.”; and

20           (7) by amending subsection (j) to read as fol-  
21 lows:

22       “(j) AUTHORIZATION OF APPROPRIATIONS.—There  
23 is authorized to be appropriated to carry out this section—

24           “(1) \$93,887,000 for fiscal year 2025;

25           “(2) \$95,000,000 for fiscal year 2026;

1 “(3) \$97,000,000 for fiscal year 2027;

2 “(4) \$100,000,000 for fiscal year 2028; and

3 “(5) \$100,000,000 for fiscal year 2029.”.

4 **SEC. 518. PROTECTING SUICIDE PREVENTION LIFELINE**

5 **FROM CYBERSECURITY INCIDENTS.**

6 (a) NATIONAL SUICIDE PREVENTION LIFELINE PRO-

7 GRAM.—Section 520E–3(b) of the Public Health Service

8 Act (42 U.S.C. 290bb–36c(b)) is amended—

9 (1) in paragraph (4), by striking “and” at the  
10 end;

11 (2) in paragraph (5), by striking the period at  
12 the end and inserting “; and”; and

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

14 “(6) taking such steps as may be necessary to  
15 ensure the suicide prevention hotline is protected  
16 from cybersecurity incidents and eliminates known  
17 cybersecurity vulnerabilities.”.

18 (b) REPORTING.—Section 520E–3 of the Public  
19 Health Service Act (42 U.S.C. 290bb–36c) is amended—

20 (1) by redesignating subsection (f) as sub-  
21 section (g); and

22 (2) by inserting after subsection (e) the fol-  
23 lowing:

24 “(f) CYBERSECURITY REPORTING.—

25 “(1) NOTIFICATION.—

1           “(A) IN GENERAL.—The program’s net-  
2           work administrator receiving Federal funding  
3           pursuant to subsection (a) shall report to the  
4           Assistant Secretary, in a manner that protects  
5           personal privacy, consistent with applicable  
6           Federal and State privacy laws—

7                   “(i) any identified cybersecurity  
8                   vulnerabilities to the program within a rea-  
9                   sonable amount of time after identification  
10                  of such a vulnerability; and

11                  “(ii) any identified cybersecurity inci-  
12                  dents to the program within a reasonable  
13                  amount of time after identification of such  
14                  incident.

15           “(B) LOCAL AND REGIONAL CRISIS CEN-  
16           TERS.—Local and regional crisis centers par-  
17           ticipating in the program shall report to the  
18           program’s network administrator identified  
19           under subparagraph (A), in a manner that pro-  
20           tects personal privacy, consistent with applica-  
21           ble Federal and State privacy laws—

22                   “(i) any identified cybersecurity  
23                   vulnerabilities to the program within a rea-  
24                   sonable amount of time after identification  
25                  of such vulnerability; and

1                   “(ii) any identified cybersecurity inci-  
2                   dents to the program within a reasonable  
3                   amount of time after identification of such  
4                   incident.

5                   “(2) NOTIFICATION.—If the program’s network  
6                   administrator receiving funding pursuant to sub-  
7                   section (a) discovers, or is informed by a local or re-  
8                   gional crisis center pursuant to paragraph (1)(B) of,  
9                   a cybersecurity vulnerability or incident, within a  
10                  reasonable amount of time after such discovery or  
11                  receipt of information, such entity shall report the  
12                  vulnerability or incident to the Assistant Secretary.

13                  “(3) CLARIFICATION.—

14                  “(A) OVERSIGHT.—

15                         “(i) LOCAL AND REGIONAL CRISIS  
16                         CENTERS.—Except as provided in clause  
17                         (ii), local and regional crisis centers par-  
18                         ticipating in the program shall oversee all  
19                         technology each center employs in the pro-  
20                         vision of services as a participant in the  
21                         program.

22                         “(ii) NETWORK ADMINISTRATOR.—  
23                         The program’s network administrator re-  
24                         ceiving Federal funding pursuant to sub-  
25                         section (a) shall oversee the technology

1           each crisis center employs in the provision  
2           of services as a participant in the program  
3           if such oversight responsibilities are estab-  
4           lished in the applicable network participa-  
5           tion agreement.

6           “(B) SUPPLEMENT, NOT SUPPLANT.—The  
7           cybersecurity incident reporting requirements  
8           under this subsection shall supplement, and not  
9           supplant, cybersecurity incident reporting re-  
10          quirements under other provisions of applicable  
11          Federal law that are in effect on the date of the  
12          enactment of the SUPPORT for Patients and  
13          Communities Reauthorization Act of 2024.”.

14          (c) STUDY.—Not later than 180 days after the date  
15          of the enactment of this Act, the Comptroller General of  
16          the United States shall—

17               (1) conduct and complete a study that evaluates  
18               cybersecurity risks and vulnerabilities associated  
19               with the 9–8–8 National Suicide Prevention Lifeline;  
20               and

21               (2) submit a report on the findings of such  
22               study to the Committee on Health, Education,  
23               Labor, and Pensions of the Senate and the Com-  
24               mittee on Energy and Commerce of the House of  
25               Representatives.

1 **SEC. 519. BRUCE’S LAW.**

2 (a) YOUTH PREVENTION AND RECOVERY.—Section  
3 7102(c) of the SUPPORT for Patients and Communities  
4 Act (42 U.S.C. 290bb–7a(c)) is amended—

5 (1) in paragraph (3)(A)(i), by inserting “,  
6 which may include strategies to increase education  
7 and awareness of the potency and dangers of syn-  
8 thetic opioids (including drugs contaminated with  
9 fentanyl) and, as appropriate, other emerging drug  
10 use or misuse issues” before the semicolon; and

11 (2) in paragraph (4)(A), by inserting “and  
12 strategies to increase education and awareness of  
13 the potency and dangers of synthetic opioids (includ-  
14 ing drugs contaminated with fentanyl) and, as ap-  
15 propriate, emerging drug use or misuse issues” be-  
16 fore the semicolon.

17 (b) INTERDEPARTMENTAL SUBSTANCE USE DIS-  
18 ORDERS COORDINATING COMMITTEE.—Section 7022 of  
19 the SUPPORT for Patients and Communities Act (42  
20 U.S.C. 290aa note) is amended—

21 (1) by striking subsection (g) and inserting the  
22 following:

23 “(g) WORKING GROUPS.—

24 “(1) IN GENERAL.—The Committee may estab-  
25 lish working groups for purposes of carrying out the  
26 duties described in subsection (e). Any such working

1 group shall be composed of members of the Com-  
2 mittee (or the designees of such members) and may  
3 hold such meetings as are necessary to carry out the  
4 duties delegated to the working group.

5 “(2) ADDITIONAL FEDERAL INTERAGENCY  
6 WORK GROUP ON FENTANYL CONTAMINATION OF IL-  
7 LEGAL DRUGS.—

8 “(A) ESTABLISHMENT.—The Secretary,  
9 acting through the Committee, shall establish a  
10 Federal Interagency Work Group on Fentanyl  
11 Contamination of Illegal Drugs (referred to in  
12 this paragraph as the ‘Work Group’) consisting  
13 of representatives from relevant Federal depart-  
14 ments and agencies on the Committee.

15 “(B) CONSULTATION.—The Work Group  
16 shall consult with relevant stakeholders and  
17 subject matter experts, including—

18 “(i) State, Tribal, and local subject  
19 matter experts in reducing, preventing, and  
20 responding to drug overdose caused by  
21 fentanyl contamination of illicit drugs; and

22 “(ii) family members of both adults  
23 and youth who have overdosed by fentanyl  
24 contaminated illicit drugs.

25 “(C) DUTIES.—The Work Group shall—



1 “(i) examine Federal efforts to reduce  
2 and prevent drug overdose by fentanyl-con-  
3 taminated illicit drugs;

4 “(ii) identify strategies to improve  
5 State, Tribal, and local responses to over-  
6 dose by fentanyl-contaminated illicit drugs;

7 “(iii) coordinate with the Secretary, as  
8 appropriate, in carrying out activities to  
9 raise public awareness of synthetic opioids  
10 and other emerging drug use and misuse  
11 issues;

12 “(iv) make recommendations to Con-  
13 gress for improving Federal programs, in-  
14 cluding with respect to the coordination of  
15 efforts across such programs; and

16 “(v) make recommendations for edu-  
17 cating youth on the potency and dangers of  
18 drugs contaminated by fentanyl.

19 “(D) ANNUAL REPORT TO SECRETARY.—  
20 The Work Group shall annually prepare and  
21 submit to the Secretary, the Committee on  
22 Health, Education, Labor, and Pensions of the  
23 Senate, and the Committee on Energy and  
24 Commerce and the Committee on Education  
25 and the Workforce of the House of Representa-

1           tives, a report on the activities carried out by  
2           the Work Group under subparagraph (C), in-  
3           cluding recommendations to reduce and prevent  
4           drug overdose by fentanyl contamination of ille-  
5           gal drugs, in all populations, and specifically  
6           among youth at risk for substance misuse.”;  
7           and

8           (2) by striking subsection (i) and inserting the  
9       following:

10                       “(i) SUNSET.—The Committee shall  
11                       terminate on September 30, 2029.”.

12       **SEC. 520. GUIDANCE ON AT-HOME DRUG DISPOSAL SYS-**  
13                       **TEMS.**

14       (a) IN GENERAL.—Not later than one year after the  
15       date of enactment of this Act, the Secretary of Health and  
16       Human Services, in consultation with the Administrator  
17       of the Drug Enforcement Administration, shall publish  
18       guidance to facilitate the use of at-home safe disposal sys-  
19       tems for applicable drugs.

20       (b) CONTENTS.—The guidance under subsection (a)  
21       shall include—

22               (1) recommended standards for effective at-  
23       home drug disposal systems to meet applicable re-  
24       quirements enforced by the Food and Drug Adminis-  
25       tration;

1           (2) recommended information to include as in-  
2       structions for use to disseminate with at-home drug  
3       disposal systems;

4           (3) best practices and educational tools to sup-  
5       port the use of an at-home drug disposal system, as  
6       appropriate; and

7           (4) recommended use of licensed health pro-  
8       viders for the dissemination of education, instruc-  
9       tion, and at-home drug disposal systems, as appro-  
10      prium.

11 **SEC. 521. ASSESSMENT OF OPIOID DRUGS AND ACTIONS.**

12       (a) IN GENERAL.—Not later than one year after the  
13      date of enactment of this Act, the Secretary of Health and  
14      Human Services (referred to in this section as the “Sec-  
15      retary”) shall publish on the website of the Food and  
16      Drug Administration (referred to in this section as the  
17      “FDA”) a report that outlines a plan for assessing opioid  
18      analgesic drugs that are approved under section 505 of  
19      the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
20      355) that addresses the public health effects of such opioid  
21      analgesic drugs as part of the benefit-risk assessment and  
22      the activities of the FDA that relate to facilitating the de-  
23      velopment of nonaddictive medical products intended to  
24      treat pain or addiction. Such report shall include—

1           (1) an update on the actions taken by the FDA  
2           to consider the effectiveness, safety, benefit-risk pro-  
3           file, and use of approved opioid analgesic drugs;

4           (2) a timeline for an assessment of the potential  
5           need, as appropriate, for labeling changes, revised or  
6           additional postmarketing requirements, enforcement  
7           actions, or withdrawals for opioid analgesic drugs;

8           (3) an overview of the steps that the FDA has  
9           taken to support the development and approval of  
10          nonaddictive medical products intended to treat pain  
11          or addiction, and actions planned to further support  
12          the development and approval of such products; and

13          (4) an overview of the consideration by the  
14          FDA of clinical trial methodologies for analgesic  
15          drugs, including the enriched enrollment randomized  
16          withdrawal methodology, and the benefits and draw-  
17          backs associated with different trial methodologies  
18          for such drugs, incorporating any public input re-  
19          ceived under subsection (b).

20          (b) PUBLIC INPUT.—In carrying out subsection (a),  
21          the Secretary shall provide an opportunity for public input  
22          concerning the regulation by the FDA of opioid analgesic  
23          drugs, including scientific evidence that relates to condi-  
24          tions of use, safety, or benefit-risk assessment (including

1 consideration of the public health effects) of such opioid  
2 analgesic drugs.

3 **SEC. 522. GRANT PROGRAM FOR STATE AND TRIBAL RE-**  
4 **SPONSE TO OPIOID USE DISORDERS.**

5 The activities carried out pursuant to section  
6 1003(b)(4)(A) of the 21st Century Cures Act (42 U.S.C.  
7 290ee–3a(b)(4)(A)) may include facilitating access to  
8 products used to prevent overdose deaths by detecting the  
9 presence of one or more substances, such as fentanyl and  
10 xylazine test strips, to the extent the purchase and posses-  
11 sion of such products is consistent with Federal and State  
12 law.

13 **Subtitle B—Treatment**

14 **SEC. 531. RESIDENTIAL TREATMENT PROGRAM FOR PREG-**  
15 **NANT AND POSTPARTUM WOMEN.**

16 Section 508 of the Public Health Service Act (42  
17 U.S.C. 290bb–1) is amended—

18 (1) in subsection (d)(11)(C), by striking “pro-  
19 viding health services” and inserting “providing  
20 health care services”;

21 (2) in subsection (g)—

22 (A) by inserting “a plan describing” after  
23 “will provide”; and

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

25 “Such plan may include a description of how

1           such applicant will target outreach to women  
2           disproportionately impacted by maternal sub-  
3           stance use disorder.”; and

4           (3) in subsection (s), by striking “\$29,931,000  
5           for each of fiscal years 2019 through 2023” and in-  
6           serting “\$38,931,000 for each of fiscal years 2025  
7           through 2029”.

8   **SEC. 532. IMPROVING ACCESS TO ADDICTION MEDICINE**  
9           **PROVIDERS.**

10          Section 597 of the Public Health Service Act (42  
11   U.S.C. 290ll) is amended—

12           (1) in subsection (a)(1), by inserting “diag-  
13          nosis,” after “related to”; and

14           (2) in subsection (b), by inserting “addiction  
15          medicine,” after “psychiatry,”.

16   **SEC. 533. MENTAL AND BEHAVIORAL HEALTH EDUCATION**  
17           **AND TRAINING GRANTS.**

18          Section 756(f) of the Public Health Service Act (42  
19   U.S.C. 294e–1(f)) is amended by striking “fiscal years  
20   2023 through 2027” and inserting “fiscal years 2025  
21   through 2029”.

22   **SEC. 534. LOAN REPAYMENT PROGRAM FOR SUBSTANCE**  
23           **USE DISORDER TREATMENT WORKFORCE.**

24          Section 781(j) of the Public Health Service Act (42  
25   U.S.C. 295h(j)) is amended by striking “\$25,000,000 for

1 each of fiscal years 2019 through 2023” and inserting  
2 “\$40,000,000 for each of fiscal years 2025 through  
3 2029”.

4 **SEC. 535. DEVELOPMENT AND DISSEMINATION OF MODEL**  
5 **TRAINING PROGRAMS FOR SUBSTANCE USE**  
6 **DISORDER PATIENT RECORDS.**

7 Section 7053 of the SUPPORT for Patients and  
8 Communities Act (42 U.S.C. 290dd–2 note) is amended  
9 by striking subsection (e).

10 **SEC. 536. TASK FORCE ON BEST PRACTICES FOR TRAUMA-**  
11 **INFORMED IDENTIFICATION, REFERRAL, AND**  
12 **SUPPORT.**

13 Section 7132 of the SUPPORT for Patients and  
14 Communities Act (Public Law 115–271; 132 Stat. 4046)  
15 is amended—

16 (1) in subsection (b)(1)—

17 (A) by redesignating subparagraph (CC) as  
18 subparagraph (DD); and

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

21 “(CC) The Administration for Community  
22 Living.”;

23 (2) in subsection (d)(1), in the matter pre-  
24 ceding subparagraph (A), by inserting “, develop-

1       mental disability service providers” before “, individ-  
2       uals who are”; and

3               (3) in subsection (i), by striking “2023” and in-  
4       serting “2029”.

5   **SEC. 537. GRANTS TO ENHANCE ACCESS TO SUBSTANCE**  
6               **USE DISORDER TREATMENT.**

7       Section 3203 of the SUPPORT for Patients and  
8   Communities Act (21 U.S.C. 823 note) is amended—

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

10              (2) by striking “(a) IN GENERAL.—The Sec-  
11       retary” and inserting the following: “The Sec-  
12       retary”.

13   **SEC. 538. STATE GUIDANCE RELATED TO INDIVIDUALS**  
14               **WITH SERIOUS MENTAL ILLNESS AND CHIL-**  
15               **DREN WITH SERIOUS EMOTIONAL DISTURB-**  
16               **ANCE.**

17       (a) REVIEW OF USE OF CERTAIN FUNDING.—Not  
18   later than 1 year after the date of enactment of this Act,  
19   the Secretary of Health and Human Services (referred to  
20   in this section as the “Secretary”), acting through the As-  
21   sistant Secretary for Mental Health and Substance Use,  
22   shall conduct a review of State use of funds made available  
23   under the Community Mental Health Services Block  
24   Grant program under subpart I of part B of title XIX  
25   of the Public Health Service Act (42 U.S.C. 300x et seq.)



1 (referred to in this section as the “block grant program”)  
2 for first episode psychosis activities. Such review shall con-  
3 sider the following:

4 (1) How States use funds for evidence-based  
5 treatments and services according to the standard of  
6 care for individuals with early serious mental illness  
7 and children with a serious emotional disturbance.

8 (2) The percentages of the State funding under  
9 the block grant program expended on early serious  
10 mental illness and first episode psychosis, and the  
11 number of individuals served under such funds.

12 (b) REPORT AND GUIDANCE.—

13 (1) REPORT.—Not later than 180 days after  
14 the completion of the review under subsection (a),  
15 the Secretary shall submit to the Committee on  
16 Health, Education, Labor, and Pensions and the  
17 Committee on Appropriations of the Senate and the  
18 Committee on Energy and Commerce and the Com-  
19 mittee on Appropriations of the House of Represent-  
20 atives a report describing—

21 (A) the findings of the review under sub-  
22 section (a); and

23 (B) any recommendations for changes to  
24 the block grant program that would facilitate  
25 improved outcomes for individuals with serious

1           mental illness and children with serious emo-  
2           tional disturbance.

3           (2) GUIDANCE.—Not later than 1 year after  
4           the date on which the report is submitted under  
5           paragraph (1), the Secretary shall update the guid-  
6           ance provided to States under the block grant pro-  
7           gram on coordinated specialty care and other evi-  
8           dence-based mental health care services for individ-  
9           uals with serious mental illness and children with a  
10          serious emotional disturbance, based on the findings  
11          and recommendations of such report.

12 **SEC. 539. REVIEWING THE SCHEDULING OF APPROVED**  
13 **PRODUCTS CONTAINING A COMBINATION OF**  
14 **BUPRENORPHINE AND NALOXONE.**

15          (a) SECRETARY OF HHS.—The Secretary of Health  
16          and Human Services shall, consistent with the require-  
17          ments and procedures set forth in sections 201 and 202  
18          of the Controlled Substances Act (21 U.S.C. 811, 812)—

19               (1) review the relevant data pertaining to the  
20               scheduling of products containing a combination of  
21               buprenorphine and naloxone that have been ap-  
22               proved under section 505 of the Federal Food,  
23               Drug, and Cosmetic Act (21 U.S.C. 355); and

1 (2) if appropriate, request that the Attorney  
2 General initiate rulemaking proceedings to revise the  
3 schedules accordingly with respect to such products.

4 (b) ATTORNEY GENERAL.—The Attorney General  
5 shall review any request made by the Secretary of Health  
6 and Human Services under subsection (a)(2) and deter-  
7 mine whether to initiate proceedings to revise the sched-  
8 ules in accordance with the criteria set forth in sections  
9 201 and 202 of the Controlled Substances Act (21 U.S.C.  
10 811, 812).

## 11 **Subtitle C—Recovery**

### 12 **SEC. 541. BUILDING COMMUNITIES OF RECOVERY.**

13 Section 547(f) of the Public Health Service Act (42  
14 U.S.C. 290ee–2(f)) is amended by striking “\$5,000,000  
15 for each of fiscal years 2019 through 2023” and inserting  
16 “\$16,000,000 for each of fiscal years 2025 through  
17 2029”.

### 18 **SEC. 542. PEER SUPPORT TECHNICAL ASSISTANCE CEN-** 19 **TER.**

20 Section 547A of the Public Health Service Act (42  
21 U.S.C. 290ee–2a) is amended—

22 (1) in subsection (b)(4), by striking “building;  
23 and” and inserting the following: “building, such  
24 as—

1                   “(A) professional development of peer sup-  
2                   port specialists; and

3                   “(B) making recovery support services  
4                   available in nonclinical settings; and”;

5                   (2) by redesignating subsections (d) and (e) as  
6                   subsections (e) and (f), respectively;

7                   (3) by inserting after subsection (c) the fol-  
8                   lowing:

9                   “(d) REGIONAL CENTERS.—

10                  “(1) IN GENERAL.—The Secretary may estab-  
11                  lish one regional technical assistance center (referred  
12                  to in this subsection as the ‘Regional Center’), with  
13                  existing resources, to assist the Center in carrying  
14                  out activities described in subsection (b) within the  
15                  geographic region of such Regional Center in a man-  
16                  ner that is tailored to the needs of such region.

17                  “(2) EVALUATION.—Not later than 4 years  
18                  after the date of enactment of the SUPPORT for  
19                  Patients and Communities Reauthorization Act of  
20                  2024, the Secretary shall evaluate the activities of  
21                  the Regional Center and submit to the Committee  
22                  on Health, Education, Labor, and Pensions of the  
23                  Senate and the Committee on Energy and Com-  
24                  merce of the House of Representatives a report on  
25                  the findings of such evaluation, including—

1 “(A) a description of the distinct roles and  
2 responsibilities of the Regional Center and the  
3 Center;

4 “(B) available information relating to the  
5 outcomes of the Regional Center under this  
6 subsection, such as any impact on the oper-  
7 ations and efficiency of the Center relating to  
8 requests for technical assistance and support  
9 within the region of such Regional Center;

10 “(C) a description of any gaps or areas of  
11 duplication relating to the activities of the Re-  
12 gional Center and the Center within such re-  
13 gion; and

14 “(D) recommendations relating to the  
15 modification, expansion, or termination of the  
16 Regional Center under this subsection.

17 “(3) TERMINATION.—This subsection shall ter-  
18minate on September 30, 2029.”; and

19 (4) in subsection (f), as so redesignated, by  
20 striking “\$1,000,000 for each of fiscal years 2019  
21 through 2023” and inserting “\$2,000,000 for each  
22 of fiscal years 2025 through 2029”.

23 **SEC. 543. COMPREHENSIVE OPIOID RECOVERY CENTERS.**

24 Section 552 of the Public Health Service Act (42  
25 U.S.C. 290ee–7) is amended—

1 (1) in subsection (d)(2)—

2 (A) in the matter preceding subparagraph  
3 (A), by striking “and in such manner” and in-  
4 serting “, in such manner, and containing such  
5 information and assurances, including relevant  
6 documentation,”; and

7 (B) in subparagraph (A), by striking “is  
8 capable of coordinating with other entities to  
9 carry out” and inserting “has the demonstrated  
10 capability to carry out, through referral or con-  
11 tractual arrangements”;

12 (2) in subsection (h)—

13 (A) by redesignating paragraphs (1)  
14 through (4) as subparagraphs (A) through (D),  
15 respectively, and adjusting the margins accord-  
16 ingly;

17 (B) by striking “With respect to” and in-  
18 serting the following:

19 “(1) IN GENERAL.—With respect to”; and

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

21 “(2) ADDITIONAL REPORTING FOR CERTAIN EL-  
22 IGIBLE ENTITIES.—An entity carrying out activities  
23 described in subsection (g) through referral or con-  
24 tractual arrangements shall include in the submis-  
25 sions required under paragraph (1) information re-

1       lated to the status of such referrals or contractual  
2       arrangements, including an assessment of whether  
3       such referrals or contractual arrangements are sup-  
4       porting the ability of such entity to carry out such  
5       activities.”; and

6               (3) in subsection (j), by striking “2019 through  
7       2023” and inserting “2025 through 2029”.

8       **SEC. 544. YOUTH PREVENTION AND RECOVERY.**

9       Section 7102(c) of the SUPPORT for Patients and  
10      Communities Act (42 U.S.C. 290bb–7a(c)) (as amended  
11      by section 110(a)) is amended—

12              (1) in paragraph (2)—

13                      (A) in subparagraph (A)—

14                              (i) in clause (i)—

15                                      (I) by inserting “, or a consor-  
16                                      tium of local educational agencies,”  
17                                      after “a local educational agency”;  
18                                      and

19                                      (II) by striking “high schools”  
20                                      and inserting “secondary schools”;  
21                                      and

22                              (ii) in clause (vi), by striking “tribe,  
23                              or tribal” and inserting “Tribe, or Tribal”;

24                      (B) by amending subparagraph (E) to read  
25              as follows:

1           “(E) INDIAN TRIBE; TRIBAL ORGANIZA-  
2           TION.—The terms ‘Indian Tribe’ and ‘Tribal  
3           organization’ have the meanings given such  
4           terms in section 4 of the Indian Self-Deter-  
5           mination and Education Assistance Act (25  
6           U.S.C. 5304).”;

7           (C) by redesignating subparagraph (K) as  
8           subparagraph (L); and

9           (D) by inserting after subparagraph (J)  
10          the following:

11          “(K) SECONDARY SCHOOL.—The term  
12          ‘secondary school’ has the meaning given such  
13          term in section 8101 of the Elementary and  
14          Secondary Education Act of 1965 (20 U.S.C.  
15          7801).”;

16          (2) in paragraph (3)(A), in the matter pre-  
17          ceding clause (i)—

18               (A) by striking “and abuse”; and

19               (B) by inserting “at increased risk for sub-  
20          stance misuse” after “specific populations”;

21          (3) in paragraph (4)—

22               (A) in the matter preceding subparagraph  
23          (A), by striking “Indian tribes” and inserting  
24          “Indian Tribes”;



1 (B) in subparagraph (A), by striking “and  
2 abuse”; and

3 (C) in subparagraph (B), by striking “peer  
4 mentoring” and inserting “peer-to-peer sup-  
5 port”;

6 (4) in paragraph (5), by striking “tribal” and  
7 inserting “Tribal”;

8 (5) in paragraph (6)(A)—

9 (A) in clause (iv), by striking “; and” and  
10 inserting a semicolon; and

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

12 “(vi) a plan to sustain the activities  
13 carried out under the grant program, after  
14 the grant program has ended; and”;

15 (6) in paragraph (8), by striking “2022” and  
16 inserting “2027”; and

17 (7) by amending paragraph (9) to read as fol-  
18 lows:

19 “(9) AUTHORIZATION OF APPROPRIATIONS.—  
20 To carry out this subsection, there are authorized to  
21 be appropriated—

22 “(A) \$10,000,000 for fiscal year 2025;

23 “(B) \$12,000,000 for fiscal year 2026;

24 “(C) \$13,000,000 for fiscal year 2027;

1 “(D) \$14,000,000 for fiscal year 2028;

2 and

3 “(E) \$15,000,000 for fiscal year 2029.”.

4 **SEC. 545. CAREER ACT.**

5 (a) IN GENERAL.—Section 7183 of the SUPPORT  
6 for Patients and Communities Act (42 U.S.C. 290ee–8)  
7 is amended—

8 (1) in the section heading, by inserting “;

9 **TREATMENT, RECOVERY, AND WORKFORCE**  
10 **SUPPORT GRANTS”** after “**CAREER ACT**”;

11 (2) in subsection (b), by inserting “each” before  
12 “for a period”;

13 (3) in subsection (c)—

14 (A) in paragraph (1), by striking “the  
15 rates described in paragraph (2)” and inserting  
16 “the average rates for calendar years 2018  
17 through 2022 described in paragraph (2)”; and

18 (B) by amending paragraph (2) to read as  
19 follows:

20 “(2) RATES.—The rates described in this para-  
21 graph are the following:

22 “(A) The highest age-adjusted average  
23 rates of drug overdose deaths for calendar years  
24 2018 through 2022 based on data from the  
25 Centers for Disease Control and Prevention, in-

1 cluding, if necessary, provisional data for cal-  
2 endar year 2022.

3 “(B) The highest average rates of unem-  
4 ployment for calendar years 2018 through 2022  
5 based on data provided by the Bureau of Labor  
6 Statistics.

7 “(C) The lowest average labor force par-  
8 ticipation rates for calendar years 2018 through  
9 2022 based on data provided by the Bureau of  
10 Labor Statistics.”;

11 (4) in subsection (g)—

12 (A) in each of paragraphs (1) and (3), by  
13 redesignating subparagraphs (A) and (B) as  
14 clauses (i) and (ii), respectively, and adjusting  
15 the margins accordingly;

16 (B) by redesignating paragraphs (1)  
17 through (3) as subparagraphs (A) through (C),  
18 respectively, and adjusting the margins accord-  
19 ingly;

20 (C) in the matter preceding subparagraph  
21 (A) (as so redesignated), by striking “An enti-  
22 ty” and inserting the following:

23 “(1) IN GENERAL.—An entity”; and

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

1           “(2) TRANSPORTATION SERVICES.—An entity  
2           receiving a grant under this section may use not  
3           more than 5 percent of the funds for providing  
4           transportation for individuals to participate in an ac-  
5           tivity supported by a grant under this section, which  
6           transportation shall be to or from a place of work  
7           or a place where the individual is receiving voca-  
8           tional education or job training services or receiving  
9           services directly linked to treatment of or recovery  
10          from a substance use disorder.

11          “(3) LIMITATION.—The Secretary may not re-  
12          quire an entity to, or give priority to an entity that  
13          plans to, use the funds of a grant under this section  
14          for activities that are not specified in this sub-  
15          section.”;

16          (5) in subsection (i)(2), by inserting “, which  
17          shall include employment and earnings outcomes de-  
18          scribed in subclauses (I) and (III) of section  
19          116(b)(2)(A)(i) of the Workforce Innovation and  
20          Opportunity Act (29 U.S.C. 3141(b)(2)(A)(i)) with  
21          respect to the participation of such individuals with  
22          a substance use disorder in programs and activities  
23          funded by the grant under this section” after “sub-  
24          section (g)”;

25          (6) in subsection (j)—

1 (A) in paragraph (1), by inserting “for  
2 grants awarded prior to the date of enactment  
3 of the SUPPORT for Patients and Commu-  
4 nities Reauthorization Act of 2024” after  
5 “grant period under this section”; and

6 (B) in paragraph (2)—

7 (i) in the matter preceding subpara-  
8 graph (A), by striking “2 years after sub-  
9 mitting the preliminary report required  
10 under paragraph (1)” and inserting “Sep-  
11 tember 30, 2029”; and

12 (ii) in subparagraph (A), by striking  
13 “(g)(3)” and inserting “(g)(1)(C)”; and

14 (7) in subsection (k), by striking “\$5,000,000  
15 for each of fiscal years 2019 through 2023” and in-  
16 serting “\$12,000,000 for each of fiscal years 2025  
17 through 2029”.

18 (b) REAUTHORIZATION OF THE CAREER ACT; RE-  
19 COVERY HOUSING PILOT PROGRAM.—

20 (1) IN GENERAL.—Section 8071 of the SUP-  
21 PORT for Patients and Communities Act (42  
22 U.S.C. 5301 note; Public Law 115–271) is amend-  
23 ed—

1 (A) by striking the section heading and in-  
2 serting “**CAREER ACT; RECOVERY HOUSING**  
3 **PILOT PROGRAM**”;

4 (B) in subsection (a), by striking “through  
5 2023” and inserting “through 2029”;

6 (C) in subsection (b)—

7 (i) in paragraph (1), by striking “not  
8 later than 60 days after the date of enact-  
9 ment of this Act” and inserting “not later  
10 than 60 days after the date of enactment  
11 of the SUPPORT for Patients and Com-  
12 munities Reauthorization Act of 2024”;  
13 and

14 (ii) in paragraph (2)(B)(i)—

15 (I) in subclause (I)—

16 (aa) by striking “for cal-  
17 endar years 2013 through 2017”;  
18 and

19 (bb) by inserting “for cal-  
20 endar years 2018 through 2022”  
21 after “rates of unemployment”;

22 (II) in subclause (II)—

23 (aa) by striking “for cal-  
24 endar years 2013 through 2017”;  
25 and

1 (bb) by inserting “for cal-  
2 endar years 2018 through 2022”  
3 after “participation rates”; and  
4 (III) by striking subclause (III)  
5 and inserting the following:

6 “(III) The highest age-adjusted  
7 average rates of drug overdose deaths  
8 for calendar years 2018 through 2022  
9 based on data from the Centers for  
10 Disease Control and Prevention, in-  
11 cluding, if necessary, provisional data  
12 for calendar year 2022.”; and

13 (D) in subsection (f), by striking “For the  
14 2-year period following the date of enactment of  
15 this Act, the” and inserting “The”.

16 (2) CONFORMING AMENDMENT.—Subtitle F of  
17 title VIII of the SUPPORT for Patients and Com-  
18 munities Act (Public Law 115–271; 132 Stat. 4095)  
19 is amended by striking the subtitle heading and in-  
20 serting the following: “**Subtitle F—CAREER**  
21 **Act; Recovery Housing Pilot Program**” .

22 (c) CLERICAL AMENDMENTS.—The table of contents  
23 in section 1(b) of the SUPPORT for Patients and Com-  
24 munities Act (Public Law 115–271; 132 Stat. 3894) is  
25 amended—

1 (1) by striking the item relating to section 7183  
2 and inserting the following:

“Sec. 7183. CAREER Act; treatment, recovery, and workforce support grants.”;

3 (2) by striking the item relating to subtitle F  
4 of title VIII and inserting the following:

“Subtitle F—CAREER Act; Recovery Housing Pilot Program”; and

5 (3) by striking the item relating to section 8071  
6 and inserting the following:

“Sec. 8071. CAREER Act; Recovery Housing Pilot Program.”.

7 **SEC. 546. ADDRESSING ECONOMIC AND WORKFORCE IM-**  
8 **PACTS OF THE OPIOID CRISIS.**

9 Section 8041(g)(1) of the SUPPORT for Patients  
10 and Communities Act (29 U.S.C. 3225a(g)(1)) is amended  
11 by striking “2023” and inserting “2029”.

12 **Subtitle D—Miscellaneous Matters**

13 **SEC. 551. DELIVERY OF A CONTROLLED SUBSTANCE BY A**  
14 **PHARMACY TO A PRESCRIBING PRACTI-**  
15 **TIONER.**

16 Section 309A(a) of the Controlled Substances Act  
17 (21 U.S.C. 829a(a)) is amended by striking paragraph (2)  
18 and inserting the following:

19 “(2) the controlled substance is a drug in  
20 schedule III, IV, or V to be administered—



1           “(A) by injection or implantation for the  
2           purpose of maintenance or detoxification treat-  
3           ment; or

4           “(B) subject to a risk evaluation and miti-  
5           gation strategy pursuant to section 505–1 of  
6           the Federal Food, Drug, and Cosmetic Act (21  
7           U.S.C. 355–1) that includes elements to assure  
8           safe use of the drug described in subsection  
9           (f)(3)(E) of such section, including a require-  
10          ment for post-administration monitoring by a  
11          health care provider.”.

12 **SEC. 552. TECHNICAL CORRECTION ON CONTROLLED SUB-**  
13 **STANCES DISPENSING.**

14          Effective as if included in the enactment of Public  
15          Law 117–328—

16               (1) section 1252(a) of division FF of Public  
17          Law 117–328 (136 Stat. 5681) is amended, in the  
18          matter being inserted into section 302(e) of the Con-  
19          trolled Substances Act, by striking “303(g)” and in-  
20          serting “303(h)”;

21               (2) section 1262 of division FF of Public Law  
22          117–328 (136 Stat. 5681) is amended—

23                       (A) in subsection (a)—

1 (i) in the matter preceding paragraph  
2 (1), by striking “303(g)” and inserting  
3 “303(h)”;

4 (ii) in the matter being stricken by  
5 subsection (a)(2), by striking “(g)(1)” and  
6 inserting “(h)(1)”; and

7 (iii) in the matter being inserted by  
8 subsection (a)(2), by striking “(g) Practi-  
9 tioners” and inserting “(h) Practitioners”;  
10 and

11 (B) in subsection (b)—

12 (i) in the matter being stricken by  
13 paragraph (1), by striking “303(g)(1)”  
14 and inserting “303(h)(1)”;

15 (ii) in the matter being inserted by  
16 paragraph (1), by striking “303(g)” and  
17 inserting “303(h)”;

18 (iii) in the matter being stricken by  
19 paragraph (2)(A), by striking “303(g)(2)”  
20 and inserting “303(h)(2)”;

21 (iv) in the matter being stricken by  
22 paragraph (3), by striking “303(g)(2)(B)”  
23 and inserting “303(h)(2)(B)”;

1 (v) in the matter being stricken by  
2 paragraph (5), by striking “303(g)” and  
3 inserting “303(h)”;

4 (vi) in the matter being stricken by  
5 paragraph (6), by striking “303(g)” and  
6 inserting “303(h)”;

7 (3) section 1263(b) of division FF of Public  
8 Law 117–328 (136 Stat. 5685) is amended—

9 (A) by striking “303(g)(2)” and inserting  
10 “303(h)(2)”;

11 (B) by striking “(21 U.S.C. 823(g)(2))”  
12 and inserting “(21 U.S.C. 823(h)(2))”.

13 **SEC. 553. REQUIRED TRAINING FOR PRESCRIBERS OF CON-**  
14 **TROLLED SUBSTANCES.**

15 (a) IN GENERAL.—Section 303 of the Controlled  
16 Substances Act (21 U.S.C. 823) is amended—

17 (1) by redesignating the second subsection des-  
18 ignated as subsection (l) as subsection (m); and

19 (2) in subsection (m)(1), as so redesignated—

20 (A) in subparagraph (A)—

21 (i) in clause (iv)—

22 (I) in subclause (I)—

23 (aa) by inserting “the Amer-  
24 ican Academy of Family Physi-  
25 cians, the American Podiatric

1 Medical Association, the Acad-  
2 emy of General Dentistry, the  
3 American Optometric Associa-  
4 tion,” before “or any other orga-  
5 nization”;

6 (bb) by striking “or the  
7 Commission” and inserting “the  
8 Commission”; and

9 (cc) by inserting “, or the  
10 Council on Podiatric Medical  
11 Education” before the semicolon  
12 at the end; and

13 (II) in subclause (III), by insert-  
14 ing “or the American Academy of  
15 Family Physicians” after “Associa-  
16 tion”; and

17 (ii) in clause (v), in the matter pre-  
18 ceding subclause (I)—

19 (I) by striking “osteopathic medi-  
20 cine, dental surgery” and inserting  
21 “osteopathic medicine, podiatric medi-  
22 cine, dental surgery”; and

23 (II) by striking “or dental medi-  
24 cine curriculum” and inserting “or

1 dental or podiatric medicine cur-  
2 riculum”; and

3 (B) in subparagraph (B)—

4 (i) in clause (i)—

5 (I) by inserting “the American  
6 Pharmacists Association, the Accredi-  
7 tation Council on Pharmacy Edu-  
8 cation, the American Psychiatric  
9 Nurses Association, the American  
10 Academy of Nursing, the American  
11 Academy of Family Physicians,” be-  
12 fore “or any other organization”; and

13 (II) by inserting “, the American  
14 Academy of Family Physicians,” be-  
15 fore “or the Accreditation Council”;  
16 and

17 (ii) in clause (ii)—

18 (I) by striking “or accredited  
19 school” and inserting “, an accredited  
20 school”; and

21 (II) by inserting “, or an accred-  
22 ited school of pharmacy” before “in  
23 the United States”.

1 (b) EFFECTIVE DATE.—The amendment made by  
2 subsection (a) shall take effect as if enacted on December  
3 29, 2022.

4 **SEC. 554. EXTENSION OF TEMPORARY ORDER FOR**  
5 **FENTANYL-RELATED SUBSTANCES.**

6 Effective as if included in the enactment of the Tem-  
7 porary Reauthorization and Study of the Emergency  
8 Scheduling of Fentanyl Analogues Act (Public Law 116–  
9 114), section 2 of such Act is amended by striking “De-  
10 cember 31, 2024” and inserting “September 30, 2026”.

11 **TITLE VI—PANDEMIC AND ALL-**  
12 **HAZARDS PREPAREDNESS**  
13 **AND RESPONSE**

14 **SEC. 601. SHORT TITLE.**

15 This title may be cited as the “Pandemic and All-  
16 Hazards Preparedness and Response Act”.

17 **Subtitle A—State and Local**  
18 **Readiness and Response**

19 **SEC. 611. TEMPORARY REASSIGNMENT OF STATE AND**  
20 **LOCAL PERSONNEL DURING A PUBLIC**  
21 **HEALTH EMERGENCY.**

22 Section 319(e) of the Public Health Service Act (42  
23 U.S.C. 247d(e)) is amended—

24 (1) in paragraph (1), by striking “tribal organi-  
25 zation or such Governor or tribal organization’s des-

1       ignee” and inserting “Tribal organization or the des-  
2       ignee of the Governor or Tribal organization, or the  
3       State or Tribal health official”;

4               (2) in paragraph (2)(B)—

5                   (A) in the matter preceding clause (i), by  
6               striking “tribal organization” and inserting  
7               “Tribal organization, or the State or Tribal  
8               health official”; and

9                   (B) in clause (v), by striking “tribal orga-  
10              nization” and inserting “Tribal organization or  
11              State or Tribal health official”;

12              (3) in paragraph (6)—

13                   (A) in the matter preceding subparagraph

14              (A)—

15                           (i) by striking “Reauthorization Act  
16                           of 2013” and inserting “and Response  
17                           Act”; and

18                           (ii) by striking “appropriate commit-  
19                           tees of the Congress” and inserting “Com-  
20                           mittee on Health, Education, Labor, and  
21                           Pensions of the Senate and the Committee  
22                           on Energy and Commerce of the House of  
23                           Representatives”; and

1 (B) in subparagraph (A), by inserting “,  
2 including requests from State or Tribal health  
3 officials” before the semicolon;

4 (4) in paragraph (7)(A), by striking “tribal or-  
5 ganization” and inserting “Tribal organization”; and

6 (5) in paragraph (8), by striking “December  
7 31, 2024” and inserting “December 31, 2026”.

8 **SEC. 612. PUBLIC HEALTH EMERGENCY PREPAREDNESS**  
9 **PROGRAM.**

10 Section 319C–1 of the Public Health Service Act (42  
11 U.S.C. 247d–3a) is amended—

12 (1) in subsection (b)(2)—

13 (A) in subparagraph (A)(ii), by striking  
14 “influenza” and inserting “response planning”;  
15 and

16 (B) in subparagraph (H), by inserting “,  
17 such as community-based organizations, includ-  
18 ing faith-based organizations, and other public  
19 and private entities” after “stakeholders”;

20 (2) in subsection (g)—

21 (A) in paragraph (1), in the matter pre-  
22 ceding subparagraph (A), by inserting “and the  
23 ability of each entity receiving an award under  
24 subsection (a) to respond to all-hazards



1           threats” before the period at the end of the  
2           first sentence;

3           (B) in paragraph (2)—

4                 (i) in the paragraph heading, by strik-  
5                 ing “INFLUENZA” and inserting “RE-  
6                 SPONSE”; and

7                 (ii) in subparagraph (A)—

8                         (I) by striking “to pandemic in-  
9                         fluenza” and inserting “to a pathogen  
10                        causing a pandemic, including pan-  
11                        demic influenza”; and

12                       (II) by striking “such pandemic  
13                        influenza” and inserting “such pan-  
14                        demic response”;

15           (C) in paragraph (5)—

16                 (i) in the paragraph heading, by strik-  
17                 ing “INFLUENZA” and inserting “PAN-  
18                 DEMIC RESPONSE”;

19                 (ii) in the matter preceding subpara-  
20                 graph (A), by striking “2019” and insert-  
21                 ing “2026”;

22                 (iii) in subparagraph (A), by striking  
23                 “2018” and inserting “2025”; and

1 (iv) in subparagraph (B), by striking  
2 “pandemic influenza” and inserting “a  
3 pathogen causing a pandemic”; and  
4 (D) in paragraph (6)—

5 (i) in subparagraph (A), in the matter  
6 preceding clause (i), by striking “The  
7 amounts described in this paragraph are  
8 the following amounts that are payable to  
9 an entity for activities described in this  
10 section or section 319C–2” and inserting  
11 “The Secretary shall withhold from an en-  
12 tity pursuant to paragraph (5) for non-  
13 compliance with the requirements of this  
14 section or section 319C–2 as follows”; and

15 (ii) in subparagraph (B), by inserting  
16 “with respect to the requirements of this  
17 section or section 319C–2” after “para-  
18 graph (5)”; and

19 (3) in subsection (h)(1)(A), by striking  
20 “\$685,000,000 for each of fiscal years 2019 through  
21 2023” and inserting “\$735,000,000 for each of fis-  
22 cal years 2025 and 2026, to remain available  
23 through December 31, 2026”.

1 **SEC. 613. HOSPITAL PREPAREDNESS PROGRAM.**

2 (a) INCREASING PARTICIPATION BY EMS IN THE  
3 HOSPITAL PREPAREDNESS PROGRAM.—

4 (1) IN GENERAL.—Section 319C–2 of the Pub-  
5 lic Health Service Act (42 U.S.C. 247d–3b) is  
6 amended—

7 (A) in subsection (b)(1)(A)—

8 (i) in clause (iii)(III), by striking “;  
9 and” and inserting a semicolon; and

10 (ii) by striking clause (iv) and insert-  
11 ing the following:

12 “(iv) one or more emergency medical  
13 service organizations; and

14 “(v) to the extent practicable, one or  
15 more emergency management organiza-  
16 tions; and”; and

17 (B) in subsection (g)(1)—

18 (i) by striking “(1) LOCAL RESPONSE  
19 CAPABILITIES” and inserting:

20 “(1) LOCAL RESPONSE CAPABILITIES.—

21 “(A) PROGRAM COORDINATION.—”;

22 (ii) by striking “extent practicable,  
23 ensure” and inserting the following: “ex-  
24 tent practicable—

25 “(i) ensure”;

1 (iii) by striking the period and insert-  
2 ing “; and”; and

3 (iv) by adding at the end the fol-  
4 lowing:

5 “(ii) seek to increase participation of  
6 eligible entities described in subsection  
7 (b)(1)(A) with lower participation rates  
8 relative to other eligible entities, such as  
9 emergency medical services organizations  
10 and health care facilities in underserved  
11 areas.”.

12 (2) PREFERENCES.—Section 319C–  
13 2(d)(1)(A)(iii) of the Public Health Service Act (42  
14 U.S.C. 247d–3b(d)(1)(A)(iii)) is amended by strik-  
15 ing “subsection (b)(1)(A)(ii)” and inserting “clauses  
16 (ii) and (iv) of subsection (b)(1)(A)”.

17 (b) IMPROVING MEDICAL READINESS AND RESPONSE  
18 CAPABILITIES.—Section 319C–2 of the Public Health  
19 Service Act (42 U.S.C. 247d–3b) is amended—  
20 (1) in subsection (b)(2)—

21 (A) in subparagraph (A), by striking  
22 “and” at the end;

23 (B) in subparagraph (B), by striking the  
24 period and inserting “; and”; and

25 (C) by inserting at the end the following:

1           “(C) designate a lead entity to administer such  
2           award and support coordination between entities de-  
3           scribed in this subsection.”;

4           (2) in subsection (g)(1), as amended by sub-  
5           section (a)(1)(B), by adding at the end the fol-  
6           lowing:

7                   “(B) REGIONAL OPERATIONS.—An eligible  
8           entity shall establish and maintain, or leverage  
9           an existing, capability to enable coordination of  
10          regional medical operations, which may include  
11          systems to facilitate information sharing and  
12          coordination, within a coalition described under  
13          subsection (b)(1)(A) and, as appropriate,  
14          among multiple coalitions that are in close geo-  
15          graphic proximity to each other.”; and

16          (3) in subsection (j)(1)—

17                  (A) in subparagraph (A), by striking “for  
18                  each of fiscal years 2019 through 2023” and  
19                  inserting “for each of fiscal years 2025 and  
20                  2026, to remain available through December  
21                  31, 2026”; and

22                  (B) in subparagraph (B)(iii), by striking  
23                  “September 30, 2023” and inserting “Decem-  
24                  ber 31, 2026”.

1   **SEC. 614. FACILITIES AND CAPACITIES OF THE CENTERS**  
2                   **FOR DISEASE CONTROL AND PREVENTION TO**  
3                   **COMBAT     PUBLIC     HEALTH     SECURITY**  
4                   **THREATS.**

5       Section 319D(h) of the Public Health Service Act (42  
6 U.S.C. 247d–4(h)) is amended—

7           (1) in paragraph (1), by striking “\$25,000,000  
8       for each of fiscal years 2022 and 2023” and insert-  
9       ing “\$40,000,000 for each of fiscal years 2025 and  
10      2026”, to remain available through December 31,  
11      2026; and

12          (2) in paragraph (2), by striking “2022 and  
13      2023” and inserting “2025 and 2026, to remain  
14      available through December 31, 2026”.

15   **SEC. 615. PILOT PROGRAM TO SUPPORT STATE MEDICAL**  
16                   **STOCKPILES.**

17       (a) IN GENERAL.—Section 319F–2(i) of the Public  
18   Health Service Act (42 U.S.C. 247d–6b(i)) is amended—

19           (1) in paragraph (2)(B)(i)—

20               (A) in subclause (I), by striking “and  
21      2024” and inserting “through 2025”; and

22               (B) in subclause (II), by striking “2025”  
23      and inserting “2026”;

24           (2) in paragraph (4)—

25               (A) in subparagraph (G), by striking “;  
26      and” at the end and inserting a semicolon;

1 (B) by redesignating subparagraph (H) as  
2 subparagraph (I);

3 (C) by inserting after subparagraph (G)  
4 the following:

5 “(H) facilitate the sharing of best practices  
6 among States within a consortia of States in re-  
7 ceipt of funding related to establishing and  
8 maintaining a stockpile of medical products;  
9 and”; and

10 (D) in subparagraph (I), as so redesign-  
11 nated, by striking “State efforts” and inserting  
12 “State or regional efforts”;

13 (3) by redesignating paragraphs (5) through  
14 (9) as paragraphs (6) through (10), respectively;

15 (4) by inserting after paragraph (4) the fol-  
16 lowing:

17 “(5) COORDINATION.—An entity in receipt of  
18 an award under paragraph (1), in carrying out the  
19 activities under this subsection, shall coordinate with  
20 appropriate health care entities, health officials, and  
21 emergency management officials within the jurisdic-  
22 tion of such State or States.”; and

23 (5) in paragraph (10), as so redesignated, by  
24 striking “\$3,500,000,000 for each of fiscal years  
25 2023 and 2024” and inserting “\$3,365,000,000 for

1       fiscal year 2025, and \$3,265,000,000 for fiscal year  
2       2026”.

3       (b) GAO REPORT.—Section 2409(b) of the PRE-  
4 VENT Pandemics Act (Public Law 117–328) is amend-  
5 ed—

6           (1) in paragraph (2), by striking “; and” and  
7       inserting a semicolon;

8           (2) in paragraph (3), by striking the period and  
9       inserting “; and”; and

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

11           “(4) the impact of any regional stockpiling ap-  
12       proaches carried out under subsection (i)(1) of sec-  
13       tion 319F–2 of the Public Health Service Act (42  
14       U.S.C. 247d–6b).”.

15 **SEC. 616. ENHANCING DOMESTIC WASTEWATER SURVEIL-**  
16 **LANCE FOR PATHOGEN DETECTION.**

17       (a) IN GENERAL.—Title III of the Public Health  
18 Service Act is amended by inserting after section 317V  
19 (42 U.S.C. 247b–24) the following:

20 **“SEC. 317W. WASTEWATER SURVEILLANCE FOR PATHOGEN**  
21 **DETECTION.**

22       “(a) WASTEWATER SURVEILLANCE SYSTEM.—The  
23 Secretary, acting through the Director of the Centers for  
24 Disease Control and Prevention and in coordination with  
25 other Federal departments and agencies, shall award



1 grants, contracts, or cooperative agreements to eligible en-  
2 tities to establish, maintain, or improve activities related  
3 to the detection and monitoring of infectious diseases  
4 through wastewater for public health emergency prepared-  
5 ness and response purposes.

6 “(b) ELIGIBLE ENTITIES.—To be eligible to receive  
7 an award under this section, an entity shall—

8 “(1) be a State, Tribal, or local health depart-  
9 ment, or a partnership between such a health de-  
10 partment and other public and private entities; and

11 “(2) submit to the Secretary an application at  
12 such time, in such manner, and containing such in-  
13 formation as the Secretary may reasonably require,  
14 which shall include—

15 “(A) a description of activities proposed to  
16 be carried out pursuant to an award under sub-  
17 section (a);

18 “(B) factors such entity proposes to use to  
19 select wastewater sampling sites;

20 “(C) factors such entity proposes to use to  
21 determine whether a response to findings from  
22 such wastewater sampling may be warranted,  
23 and a plan for responding, as appropriate, con-  
24 sistent with applicable plans developed by such  
25 entity pursuant to section 319C–1;

1           “(D) a plan to sustain such wastewater  
2           surveillance activities described in such applica-  
3           tion following the conclusion of the award pe-  
4           riod; and

5           “(E) any additional information the Sec-  
6           retary may require.

7           “(c) CONSIDERATION.—In making awards under sub-  
8           section (a), the Secretary may give priority to eligible enti-  
9           ties that have submitted an application that—

10           “(1) details plans to provide public access to  
11           deidentified data generated through such wastewater  
12           surveillance activities in a manner that allows for  
13           comparison to such data generated by other recipi-  
14           ents of an award under subsection (a); and

15           “(2) provides an assessment of community  
16           needs related to ongoing infectious disease moni-  
17           toring, including estimates of the incidence and  
18           prevalence of infectious diseases that can be detected  
19           in wastewater and availability, at the time of the ap-  
20           plication, of other forms of infectious disease detec-  
21           tion in the jurisdiction.

22           “(d) USE OF FUNDS.—An eligible entity shall, as ap-  
23           propriate, use amounts awarded under this section to—

1           “(1) establish or enhance existing capacity and  
2           capabilities to conduct wastewater sampling, testing,  
3           and related analysis;

4           “(2) conduct wastewater surveillance, as appro-  
5           priate, in areas or facilities with increased risk of in-  
6           fectious disease outbreaks and limited ability to uti-  
7           lize other forms of infectious disease detection, such  
8           as at individual facilities, institutions, and locations  
9           in rural areas or areas in which wastewater is not  
10          treated through the relevant local utility of the juris-  
11          diction; and

12          “(3) implement projects that use evidence-based  
13          or innovative practices to conduct wastewater sur-  
14          veillance activities.

15          “(e) PARTNERSHIPS.—In carrying out activities  
16          under this section, eligible entities shall identify opportuni-  
17          ties to partner with other public or private entities to le-  
18          verage relevant capabilities maintained by such entities,  
19          as appropriate and consistent with this section.

20          “(f) TECHNICAL ASSISTANCE.—The Secretary, in  
21          consultation with the heads of other applicable Federal  
22          agencies and departments, as appropriate, shall provide  
23          technical assistance to recipients of awards under this sec-  
24          tion to facilitate the planning, development, and imple-  
25          mentation of activities described in subsection (d).

1       “(g) AUTHORIZATION OF APPROPRIATIONS.—To  
2 carry out this section, there is authorized to be appro-  
3 priated \$20,000,000 for each of fiscal years 2025 and  
4 2026, to remain available through December 31, 2026.”.

5       (b) WASTEWATER SURVEILLANCE RESEARCH.—

6           (1) IN GENERAL.—The Secretary of Health and  
7 Human Services (in this subsection referred to as  
8 the “Secretary”) shall continue to conduct or sup-  
9 port research on the use of wastewater surveillance  
10 to detect and monitor emerging infectious diseases,  
11 which may include—

12           (A) research to improve the efficiency and  
13 effectiveness of wastewater sample collection  
14 and analysis and increase the sensitivity and  
15 specificity of wastewater testing methods; and

16           (B) implementation and development of  
17 evidence-based practices to facilitate the esti-  
18 mation of the incidence and prevalence of infec-  
19 tious disease within a community.

20       (2) NON-DUPLICATION OF EFFORT.—The Sec-  
21 retary shall ensure that activities carried out under  
22 this subsection do not unnecessarily duplicate efforts  
23 of other agencies and offices within the Department  
24 of Health and Human Services related to wastewater  
25 surveillance.

1 **SEC. 617. REAUTHORIZATION OF MOSQUITO ABATEMENT**  
2 **FOR SAFETY AND HEALTH PROGRAM.**

3 Section 317S of the Public Health Service Act (42  
4 U.S.C. 247b–21) is amended—

5 (1) in subsection (a)(3)(A), by striking “sub-  
6 section (b)(3)” and inserting “subsection (b)(4)”;

7 (2) in subsection (b)—

8 (A) by redesignating paragraphs (3)  
9 through (6) as paragraphs (4) through (7), re-  
10 spectively; and

11 (B) by inserting after paragraph (2) the  
12 following:

13 “(3) CONSIDERATIONS.—The Secretary may  
14 consider the use of innovative and novel technology  
15 for mosquito prevention and control in making  
16 grants under paragraph (1).”;

17 (3) by amending subsection (d) to read as fol-  
18 lows:

19 “(d) USES OF FUNDS.—Amounts appropriated under  
20 subsection (f) may be used by the Secretary to provide  
21 training and technical assistance with respect to the plan-  
22 ning, development, and operation of assessments and  
23 plans under subsection (a) and control programs under  
24 subsection (b). The Secretary may provide such training  
25 and technical assistance directly or through awards of  
26 grants or contracts to public and private entities.”; and

1 (4) in subsection (f)(1), by striking “2019  
2 through 2023” and inserting “2025 and 2026, to re-  
3 main available through December 31, 2026”.

4 **Subtitle B—Federal Planning and**  
5 **Coordination**

6 **SEC. 621. ALL-HAZARDS EMERGENCY PREPAREDNESS AND**  
7 **RESPONSE.**

8 Section 2811 of the Public Health Service Act (42  
9 U.S.C. 300hh–10) is amended—

10 (1) in subsection (b)—

11 (A) in paragraph (3)—

12 (i) by striking “Oversee advanced re-  
13 search, development, and procurement”  
14 and inserting the following:

15 “(A) IN GENERAL.—Oversee advanced re-  
16 search, development, procurement, and replen-  
17 ishment”; and

18 (ii) by adding at the end the fol-  
19 lowing:

20 “(B) DEVELOPMENT OF REQUIRE-  
21 MENTS.—Lead the development and approval,  
22 and, on a routine basis, the review and update,  
23 of requirements for such countermeasures and  
24 products, including related capabilities, to in-  
25 form the advanced research, development, pro-

1           curement, and replenishment decisions of the  
2           Secretary.”;

3           (B) in paragraph (4)—

4           (i) in subparagraph (F)—

5           (I) in the matter preceding clause  
6           (i), by striking “and in consultation  
7           with the Secretary of Homeland Secu-  
8           rity,”; and

9           (II) in clause (i), by inserting  
10          “enhance” after “capabilities and”;

11          (ii) in subparagraph (G)—

12          (I) in the matter preceding clause  
13          (i), by inserting “the Office of Pan-  
14          demic Preparedness and Response  
15          Policy,” after “Veterans Affairs,”;

16          (II) in clause (i), by striking  
17          “based on” and inserting “based on—  
18          ”;

19          (III) in clause (ii), by striking “;  
20          and” at the end and inserting a semi-  
21          colon;

22          (IV) in clause (iii), by striking  
23          the period and inserting “; and”; and

24          (V) by adding at the end the fol-  
25          lowing:

1 “(iv) that include, as appropriate, par-  
2 ticipation by relevant industry, academia,  
3 professional societies, and other stake-  
4 holders.”;

5 (iii) in subparagraph (H)—

6 (I) by inserting “and the Direc-  
7 tor of the Office of Pandemic Pre-  
8 paredness and Response Policy” after  
9 “Security Affairs”; and

10 (II) by inserting “and medical  
11 product and supply capacity planning  
12 pursuant to subparagraph (J), includ-  
13 ing discussion of any relevant identi-  
14 fied supply chain vulnerabilities” be-  
15 fore the period at the end;

16 (iv) in subparagraph (I), by inserting  
17 “the Director of the Office of Pandemic  
18 Preparedness and Response Policy,” after  
19 “Security Affairs,”; and

20 (v) in subparagraph (J)(i), in the  
21 matter preceding subclause (I), by insert-  
22 ing “(including ancillary medical supplies  
23 and components of medical products, such  
24 as active pharmaceutical ingredients, key  
25 starting materials, medical device compo-



1 nents, testing kits, reagents, and other  
2 testing supplies)” after “supply needs”;  
3 and

4 (C) in paragraph (7)—

5 (i) in the matter preceding subpara-  
6 graph (A), by inserting “and the require-  
7 ments developed pursuant to paragraph  
8 (3)(B)” after “subsection (d)”;

9 (ii) by redesignating subparagraphs  
10 (E) and (F) as subparagraphs (F) and  
11 (G), respectively; and

12 (iii) by inserting after subparagraph  
13 (D) the following:

14 “(E) include a professional judgment of  
15 anticipated budget needs for each future fiscal  
16 year accounted for in such plan to account for  
17 the full range of anticipated medical counter-  
18 measure needs and life-cycle costs to address  
19 such priorities and requirements;”;

20 (2) in subsection (d)—

21 (A) by amending paragraph (1) to read as  
22 follows:

23 “(1) IN GENERAL.—Not later than March 15,  
24 2020, and biennially thereafter, the Assistant Sec-  
25 retary for Preparedness and Response shall develop

1       and submit to the Committee on Health, Education,  
2       Labor, and Pensions of the Senate and the Com-  
3       mittee on Energy and Commerce of the House of  
4       Representatives a coordinated strategy for medical  
5       countermeasures to address chemical, biological, ra-  
6       diological, and nuclear threats, informed by the re-  
7       quirements developed pursuant to subsection  
8       (b)(3)(B). Not later than 180 days after the submis-  
9       sion of such strategy to such committees, the Assist-  
10      ant Secretary for Preparedness and Response shall  
11      submit an accompanying implementation plan to  
12      such committees. In developing such a strategy and  
13      plan, the Assistant Secretary for Preparedness and  
14      Response shall consult with the Public Health Emer-  
15      gency Medical Countermeasures Enterprise estab-  
16      lished under section 2811–1. Such strategy and plan  
17      shall be known as the Public Health Emergency  
18      Medical Countermeasures Enterprise Strategy and  
19      Implementation Plan.”; and

20               (B) in paragraph (2), in the matter pre-  
21               ceding subparagraph (A), by inserting “strategy  
22               and” before “plan”; and

23               (3) in subsection (f)—

24               (A) in paragraph (1), in the matter pre-  
25               ceding subparagraph (A), by inserting “, includ-

1 ing such agents that are an emerging infectious  
2 disease” after “become a pandemic”; and

3 (B) in paragraph (2)(A), by striking  
4 “\$250,000,000 for each of fiscal years 2019  
5 through 2023” and inserting “\$335,000,000  
6 for each of fiscal years 2025 and 2026, to re-  
7 main available through December 31, 2026”.

8 **SEC. 622. NATIONAL HEALTH SECURITY STRATEGY.**

9 Section 2802 of the Public Health Service Act (42  
10 U.S.C. 300hh–1) is amended—

11 (1) in subsection (a)(3)—

12 (A) by striking “In 2022, the” and insert-  
13 ing “The”; and

14 (B) by inserting “, maintaining, and sus-  
15 taining” after “establishing”; and

16 (2) in subsection (b)—

17 (A) in paragraph (2)—

18 (i) in subparagraph (A), by inserting  
19 “that support interagency coordination and  
20 availability of information, as appropriate”  
21 before the period;

22 (ii) in subparagraph (B), by inserting  
23 “rapid testing,” after “and supplies,”;

24 (B) in paragraph (3)—

1 (i) in the matter preceding subpara-  
2 graph (A), by inserting “and blood banks”  
3 after “dental health facilities”;

4 (ii) in subparagraph (C), by inserting  
5 “and current capacity of facilities within  
6 such systems, as applicable” before the pe-  
7 riod; and

8 (iii) in subparagraph (D), by inserting  
9 “and other medical products and medical  
10 supplies consistent with the activities car-  
11 ried out under section 2811(b)(4)(J)” be-  
12 fore the period;

13 (C) in paragraph (5), by inserting “appli-  
14 cable federally funded activities and” after “(in-  
15 cluding”;

16 (D) in paragraph (8)—

17 (i) in subparagraph (A), by inserting  
18 “public health and medical” before “activi-  
19 ties”; and

20 (ii) in subparagraph (B), by striking  
21 “familiarity with” and inserting “under-  
22 standing of, and coordination between,”;

23 (E) by redesignating paragraphs (9) and  
24 (10) as paragraphs (10) and (12), respectively;

1 (F) by inserting after paragraph (8) the  
2 following:

3 “(9) OTHER SETTINGS.—Supporting Federal,  
4 State, local, and Tribal coordination and planning  
5 with respect to facilities in which there is an in-  
6 creased risk of infectious disease outbreaks, includ-  
7 ing such facilities that address the needs of at-risk  
8 individuals, in the event of a public health emer-  
9 gency declared under section 319.”;

10 (G) by inserting after subparagraph (10),  
11 as so redesignated, the following:

12 “(11) OTHER HAZARDS.—Assessing current  
13 and potential health security threats from natural  
14 disasters with respect to public health and medical  
15 preparedness and response.”;

16 (H) by inserting after paragraph (12), as  
17 so redesignated, the following:

18 “(13) CYBERSECURITY RESILIENCY OF HEALTH  
19 CARE SYSTEMS.—Consistent with the requirements  
20 of section 2218 of the Homeland Security Act of  
21 2002, strengthening the ability of States, local com-  
22 munities, and Tribal communities to prepare for, re-  
23 spond to, and be resilient against cybersecurity  
24 vulnerabilities or cybersecurity attacks that affect  
25 public health and health information technology, and

1 encouraging health care facilities to use recognized  
2 security practices meeting or exceeding the ap-  
3 proaches established under section 405(d) of the Cy-  
4 bersecurity Act of 2015.”; and

5 (I) by striking “tribal” each place it ap-  
6 pears and inserting “Tribal”.

7 **SEC. 623. IMPROVING DEVELOPMENT AND DISTRIBUTION**  
8 **OF DIAGNOSTIC TESTS.**

9 Section 319B of the Public Health Service Act (42  
10 U.S.C. 247d–2) is amended to read as follows:

11 **“SEC. 319B. IMPROVING DEVELOPMENT AND DISTRIBUTION**  
12 **OF DIAGNOSTIC TESTS.**

13 “(a) **DIAGNOSTIC TESTING PREPAREDNESS PLAN.**—  
14 The Secretary shall develop, make publicly available, not  
15 later than 1 year after the date of enactment of the Pan-  
16 demic and All-Hazards Preparedness and Response Act,  
17 and update not less frequently than every 3 years there-  
18 after, a plan for the rapid development, validation, author-  
19 ization, manufacture, procurement, and distribution of di-  
20 agnostic tests, and for rapid scaling of testing capacity,  
21 in response to chemical, biological, radiological, or nuclear  
22 threats, including emerging infectious diseases, for which  
23 a public health emergency is declared under section 319,  
24 or that has significant potential to cause such a public  
25 health emergency.

1 “(b) PURPOSES.—The purpose of the plan under sub-  
2 section (a) shall be to—

3 “(1) facilitate the development and utilization  
4 of diagnostic tests;

5 “(2) describe the processes for the rapid devel-  
6 opment, validation, authorization, manufacture, pro-  
7 curement, and distribution of diagnostic tests, and  
8 for rapid scaling of testing capacity; and

9 “(3) facilitate coordination and collaboration  
10 among public and private entities to improve the  
11 rapid development and utilization of diagnostic test-  
12 ing during a public health emergency.

13 “(c) CONSIDERATIONS.—The plan under subsection  
14 (a) shall take into consideration—

15 “(1) domestic capacity, including any such ca-  
16 pacity established through partnerships with public  
17 and private entities pursuant to subsection (e), to  
18 support the development, validation, manufacture,  
19 procurement, and distribution of tests, and the rapid  
20 scaling of testing capacity;

21 “(2) novel technologies and platforms that—

22 “(A) may be used to improve testing capa-  
23 bilities, including—

24 “(i) high-throughput laboratory  
25 diagnostics;

1 “(ii) point-of-care diagnostics; and

2 “(iii) rapid at-home diagnostics;

3 “(B) improve the accessibility of diagnostic  
4 tests; and

5 “(C) facilitate the development and manu-  
6 facture of diagnostic tests;

7 “(3) medical supply needs related to testing, in-  
8 cluding diagnostic testing, equipment, supplies, and  
9 component parts, and any potential vulnerabilities  
10 related to the availability of such medical supplies  
11 and related planning needs, consistent with section  
12 2811(b)(4)(J);

13 “(4) strategies for the rapid and efficient dis-  
14 tribution of tests locally, regionally, or nationwide  
15 and appropriate scaling of laboratory testing capac-  
16 ity; and

17 “(5) assessment of such strategies through  
18 drills and operational exercises carried out under  
19 section 2811(b)(4)(G), as appropriate.

20 “(d) COORDINATION.—To inform the development  
21 and update of the plan under subsection (a), and in car-  
22 rying out activities to implement such plan, the Secretary  
23 shall coordinate with industry, such as device manufactur-  
24 ers, clinical and reference laboratories, and medical prod-  
25 uct distributors, States, local governmental entities, In-



1 dian Tribes and Tribal organizations, and other relevant  
2 public and private entities.

3 “(e) CAPACITY BUILDING.—The Secretary may con-  
4 tract with public and private entities, as appropriate, to  
5 increase domestic capacity in the rapid development, vali-  
6 dation, authorization, manufacture, procurement, and dis-  
7 tribution of diagnostic tests, as appropriate, to State,  
8 local, and Tribal health departments and other appro-  
9 priate entities for immediate public health response activi-  
10 ties to address an infectious disease with respect to which  
11 a public health emergency is declared under section 319,  
12 or that has significant potential to cause such a public  
13 health emergency.”.

14 **SEC. 624. COMBATING ANTIMICROBIAL RESISTANCE.**

15 (a) IN GENERAL.—Section 319E of the Public  
16 Health Service Act (42 U.S.C. 247d–5) is amended—

17 (1) in subsection (a)—

18 (A) in paragraph (1), by inserting “and ac-  
19 tivities” after “Federal programs”;

20 (B) in paragraph (2)—

21 (i) by striking “public health constitu-  
22 encies, manufacturers, veterinary and med-  
23 ical professional societies and others” and  
24 inserting “the Advisory Council described

1 in subsection (b) and relevant public and  
2 private entities”; and

3 (ii) by inserting “, pursuant to para-  
4 graph (4),” after “comprehensive plan”;

5 (C) by amending paragraph (3) to read as  
6 follows:

7 “(3) AGENDA.—The task force described in  
8 paragraph (1) shall consider factors the Secretary  
9 considers appropriate, including factors to—

10 “(A) slow the emergence of resistant bac-  
11 teria and fungi and prevent the spread of re-  
12 sistant infections;

13 “(B) strengthen activities to combat resist-  
14 ance with respect to zoonotic diseases;

15 “(C) advance development and use of rapid  
16 and innovative capabilities, including diagnostic  
17 tests, for identification and characterization of  
18 resistant bacteria and fungi;

19 “(D) accelerate basic and applied research  
20 and development for new antibiotics,  
21 antifungals, and other related therapeutics and  
22 vaccines; and

23 “(E) support international collaboration  
24 and capacities for antimicrobial-resistance pre-  
25 vention, detection, and control.”;

1 (D) by redesignating paragraph (4) as  
2 paragraph (5);

3 (E) by inserting after paragraph (3) the  
4 following:

5 “(4) ACTION PLAN.—Not later than October 1,  
6 2026, and every 5 years thereafter, the task force  
7 described in paragraph (1) shall develop and submit  
8 to the Committee on Health, Education, Labor, and  
9 Pensions and the Committee on Appropriations of  
10 the Senate and the Committee on Energy and Com-  
11 merce and the Committee on Appropriations of the  
12 House of Representatives a plan regarding Federal  
13 programs and activities to combat antimicrobial re-  
14 sistance, including measurable outcomes, as appro-  
15 priate, informed by—

16 “(A) the agenda described in paragraph  
17 (3);

18 “(B) input provided by the Advisory Coun-  
19 cil described in subsection (b); and

20 “(C) input from other relevant stake-  
21 holders provided pursuant to paragraph (2).”;

22 (2) by redesignating subsections (b) through (o)  
23 as subsections (c) through (p), respectively;

24 (3) by inserting after subsection (a) the fol-  
25 lowing:

1 “(b) ADVISORY COUNCIL.—

2 “(1) IN GENERAL.—The Secretary may con-  
3 tinue the Presidential Advisory Council on Com-  
4 bating Antibiotic-Resistant Bacteria, referred to in  
5 this subsection as the ‘Advisory Council’.

6 “(2) DUTIES.—The Advisory Council shall ad-  
7 vise and provide information and recommendations  
8 to the Secretary, acting through the Task Force es-  
9 tablished under subsection (a), regarding Federal  
10 programs and activities intended to reduce or com-  
11 bat antimicrobial-resistant bacteria or fungi that  
12 may present a public health threat and improve ca-  
13 pabilities to prevent, diagnose, mitigate, or treat  
14 such resistance. Such advice, information, and rec-  
15 ommendations may be related to improving Federal  
16 efforts related to factors described in subsection  
17 (a)(3) and other topics related to antimicrobial re-  
18 sistance, as appropriate.

19 “(3) MEETINGS AND COORDINATION.—

20 “(A) MEETINGS.—The Advisory Council  
21 shall meet not less frequently than biannually  
22 and, to the extent practicable, in coordination  
23 with meetings of the task force established  
24 under subsection (a).

1                   “(B) COORDINATION.—The Advisory  
2                   Council shall, to the greatest extent practicable,  
3                   coordinate activities carried out by the Council  
4                   with the task force established under subsection  
5                   (a).

6                   “(4) FACA.—Chapter 10 of title 5, United  
7                   States Code, shall apply to the activities and duties  
8                   of the Advisory Council.

9                   “(5) SUNSET.—

10                   “(A) IN GENERAL.—The Advisory Council  
11                   under this subsection shall terminate on De-  
12                   cember 31, 2026.

13                   “(B) EXTENSION OF ADVISORY COUN-  
14                   CIL.—Not later than October 1, 2026, the Sec-  
15                   retary shall submit to the Committee on  
16                   Health, Education, Labor, and Pensions of the  
17                   Senate and the Committee on Energy and Com-  
18                   merce of the House of Representatives a report  
19                   that includes a recommendation on whether the  
20                   Advisory Council should be extended, and iden-  
21                   tifying whether there are other committees,  
22                   councils, or task forces that have overlapping or  
23                   similar duties to that of the Advisory Council,  
24                   and whether such committees, councils, or task  
25                   forces should be combined, restructured, or

1 eliminated, including with respect to the task  
2 force established under subsection (a).”; and  
3 (4) in subsection (n), as so redesignated, by  
4 striking “(f) through (j)” and inserting “(g) through  
5 (k)”.

6 (b) CONFORMING AMENDMENT.—Section 505 of the  
7 Pandemic and All-Hazards Preparedness and Advancing  
8 Innovation Act of 2019 (42 U.S.C. 247d–5 note; Public  
9 Law 116–22) is amended by striking subsection (a) and  
10 all that follows through “Not later” in subsection (e) and  
11 inserting the following:

12 “Not later”.

13 **SEC. 625. STRATEGIC NATIONAL STOCKPILE AND MATE-**  
14 **RIAL THREATS.**

15 Section 319F–2 of the Public Health Service Act (42  
16 U.S.C. 247d–6b) is amended—

17 (1) in subsection (a)—

18 (A) in paragraph (2)—

19 (i) in subparagraph (A), by inserting  
20 “Such review shall include a description of  
21 how the Secretary manages and mitigates  
22 risks associated with gaps between current  
23 inventory levels and stockpiling goals,  
24 prioritizes such risks, and tracks progress

1                   toward mitigation of such risks.” after the  
2                   first sentence; and

3                   (ii) in subparagraph (B)(i), by amend-  
4                   ing subclause (IV) to read as follows:

5                   “(IV) the emergency health secu-  
6                   rity threat or threats such counter-  
7                   measure procurement is intended to  
8                   address, including—

9                   “(aa) whether such procure-  
10                  ment is consistent with meeting  
11                  emergency health security needs  
12                  associated with such threat or  
13                  threats; and

14                  “(bb) in the case of a coun-  
15                  termeasure that addresses a bio-  
16                  logical agent, whether such agent  
17                  has an increased likelihood to be-  
18                  come resistant to, more resistant  
19                  to, or evade, such counter-  
20                  measure relative to other avail-  
21                  able medical countermeasures;”;

22                  (B) in paragraph (3)—

23                  (i) in subparagraph (B), by striking  
24                  “are followed, regularly reviewed, and up-  
25                  dated with respect to such stockpile” and

1 inserting “with respect to such stockpile  
2 are followed, regularly reviewed, and up-  
3 dated to reflect best practices”;

4 (ii) in subparagraph (I), by inserting  
5 “, through a standard operating proce-  
6 dure,” after “ensure”;

7 (iii) by redesignating subparagraphs  
8 (H) through (K) as subparagraphs (I)  
9 through (L), respectively;

10 (iv) by inserting after subparagraph  
11 (G) the following:

12 “(H) utilize tools to enable the timely and  
13 accurate tracking of the contents of the stock-  
14 pile throughout the deployment of such con-  
15 tents, including tracking of the location and ge-  
16 ographic distribution and utilization of such  
17 contents;”;

18 (v) in subparagraph (K), as so redes-  
19 ignated, by striking “; and” at the end and  
20 inserting a semicolon;

21 (vi) in subparagraph (L), as so redes-  
22 ignated, by striking the period and insert-  
23 ing “; and”; and

24 (vii) by adding at the end the fol-  
25 lowing:



1           “(M) communicate to relevant vendors re-  
2           garding modifications, renewals, extensions, or  
3           terminations of contracts, or the intent to exer-  
4           cise options for such contracts, within 30 days,  
5           as practicable, of such determination, including  
6           through the development of a contract notifica-  
7           tion process.”;

8           (C) in paragraph (5)(B), in the matter  
9           preceding clause (i), by inserting “, which may  
10          accompany the review required under paragraph  
11          (2),” after “Representatives a report”; and

12          (D) in paragraph (6)(A)—

13               (i) by redesignating clauses (viii)  
14               through (x) as clauses (ix) through (xi), re-  
15               spectively; and

16               (ii) by inserting after clause (vii) the  
17               following:

18                       “(viii) with respect to any change in  
19                       the Federal organizational management of  
20                       the stockpile, an assessment and compari-  
21                       son of any differences in the processes and  
22                       operations resulting from such change, in-  
23                       cluding—

1 “(I) planning for potential coun-  
2 termeasure deployment, distribution,  
3 or dispensing capabilities;

4 “(II) organizational structure;

5 “(III) communication with rel-  
6 evant stakeholders related to procure-  
7 ment decisions;

8 “(IV) processes related to pro-  
9 curement, deployment, and use of  
10 stockpiled countermeasures;

11 “(V) communication and coordi-  
12 nation with the Public Health Emer-  
13 gency Medical Countermeasures En-  
14 terprise and other related Federal en-  
15 tities;

16 “(VI) inventory management;  
17 and

18 “(VII) availability and use of re-  
19 sources for such activities;”; and

20 (2) in subsection (c)(2)(C), by striking  
21 “promptly” and inserting “, not later than 60 days  
22 after each such determination,”;

23 (3) in subsection (f)(1), by striking  
24 “\$610,000,000 for each of fiscal years 2019 through  
25 2021, and \$750,000,000 for each of fiscal years

1       2022 and 2023” and inserting “\$1,100,000,000 for  
2       fiscal year 2025, and \$1,210,000,000 for fiscal year  
3       2026”; and

4               (4) in subsection (g)(1), by striking “2019  
5       through 2028” and inserting “2025 through 2034”.

6 **SEC. 626. MEDICAL COUNTERMEASURES FOR VIRAL**  
7 **THREATS WITH PANDEMIC POTENTIAL.**

8       Section 319L of the Public Health Service Act (42  
9 U.S.C. 247d–7e) is amended—

10               (1) in subsection (c)—

11                       (A) in paragraph (4)—

12                               (i) in subparagraph (D)—

13                                       (I) in clause (ii), by striking “;  
14                                       and” and inserting a semicolon; and

15                                       (II) by redesignating clause (iii)  
16                                       as clause (iv); and

17                                       (III) by inserting after clause (ii)  
18                                       the following:

19                               “(iii) research and development of  
20                               medical countermeasures for priority virus  
21                               families that have significant potential to  
22                               cause a pandemic, including such counter-  
23                               measures that take either pathogen-specific  
24                               or pathogen-agnostic approaches, and plat-  
25                               form technologies to improve the develop-

1                   ment and manufacture of such medical  
2                   countermeasures; and”; and

3                   (ii) in subparagraph (F)(ii), by insert-  
4                   ing “or priority virus families and other  
5                   viral pathogens that pose a threat due to  
6                   their significant potential to cause a pan-  
7                   demic,” after “pandemic influenza,”; and

8                   (B) in paragraph (5), by adding at the end  
9                   the following:

10                  “(I) NOTIFICATION.—In awarding con-  
11                  tracts, grants, cooperative agreements, or other  
12                  transactions under this section, the Secretary  
13                  shall communicate to relevant vendors regard-  
14                  ing modifications, renewals, extensions, or ter-  
15                  minations of contracts, including through the  
16                  development of a contract notification process,  
17                  within 30 days of such determination, as prac-  
18                  ticable.”;

19                  (2) in subsection (d)(2), by striking  
20                  “\$611,700,000 for each of fiscal years 2019 through  
21                  2023” and inserting “\$950,000,000 for each of fis-  
22                  cal years 2025 and 2026”; and

23                  (3) in subsection (e)(1), by amending subpara-  
24                  graph (D) to read as follows:

1 “(D) SUNSET.—This paragraph shall cease  
2 to have force or effect after December 31,  
3 2026.”.

4 **SEC. 627. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**  
5 **TERMEASURES ENTERPRISE.**

6 Section 2811–1 of the Public Health Service Act (42  
7 U.S.C. 300hh–10a) is amended—

8 (1) in subsection (b)—

9 (A) by redesignating paragraph (11) as  
10 paragraph (13);

11 (B) by inserting after paragraph (10) the  
12 following:

13 “(11) The Director of the Biomedical Advanced  
14 Research and Development Authority.

15 “(12) The Director of the Strategic National  
16 Stockpile.”; and

17 (C) in paragraph (13), as so redesignated,  
18 by striking “the Director of the Biomedical Ad-  
19 vanced Research and Development Authority,  
20 the Director of the Strategic National Stock-  
21 pile, the Director of the National Institute of  
22 Allergy and Infectious Diseases,” and inserting  
23 “the Director of the National Institute of Al-  
24 lergy and Infectious Diseases”; and

25 (2) in subsection (c)—

1 (A) in paragraph (1)—

2 (i) by redesignating subparagraph (D)

3 as subparagraph (E); and

4 (ii) by inserting after subparagraph

5 (C) the following:

6 “(D) Assist the Secretary in developing  
7 strategies for appropriate and evidence-based  
8 allocation and distribution of countermeasures  
9 to jurisdictions, in a manner that supports the  
10 availability and use of such countermeasures,  
11 for public health and medical preparedness and  
12 response needs.”;

13 (B) in paragraph (2), by inserting “rel-  
14 evant stakeholders, including industry,” after  
15 “consider input from”; and

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

17 “(3) INFORMATION SHARING.—The Secretary  
18 shall, as appropriate and in a manner that does not  
19 compromise national security, communicate and  
20 share information related to recommendations made  
21 and strategies developed under paragraph (1) with  
22 relevant stakeholders, including industry and State,  
23 local, and Tribal public health departments.”.

1 **SEC. 628. FELLOWSHIP AND TRAINING PROGRAMS.**

2 Section 317G of the Public Health Service Act (42  
3 U.S.C. 247b–8) is amended—

4 (1) by striking “The Secretary,” and inserting  
5 the following:

6 “(a) IN GENERAL.—The Secretary,”; and

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

8 “(b) NONCOMPETITIVE CONVERSION.—

9 “(1) IN GENERAL.—The Secretary may non-  
10 competitively convert an individual who has com-  
11 pleted an epidemiology, surveillance, or laboratory  
12 fellowship or training program under subsection (a)  
13 to a career-conditional appointment without regard  
14 to the provisions of subchapter I of chapter 33 of  
15 title 5, United States Code, provided that such indi-  
16 vidual meets qualification requirements for the ap-  
17 pointment.”.

18 **SEC. 629. REGIONAL BIOCONTAINMENT RESEARCH LAB-**  
19 **ORATORIES.**

20 (a) IN GENERAL.—The Secretary of Health and  
21 Human Services (referred to in this section as the “Sec-  
22 retary”) shall make awards to establish or maintain, as  
23 applicable, not fewer than 12 regional biocontainment lab-  
24 oratories, for purposes of—

25 (1) conducting biomedical research to support  
26 public health and medical preparedness for, and

1 rapid response to, biological agents, including emerg-  
2 ing infectious diseases;

3 (2) ensuring the availability of surge capacity  
4 for purposes of responding to such biological agents;

5 (3) supporting information sharing between,  
6 and the dissemination of findings to, researchers and  
7 other relevant individuals to facilitate collaboration  
8 between industry and academia; and

9 (4) providing, as appropriate and applicable,  
10 technical assistance and training to researchers and  
11 other relevant individuals to support the biomedical  
12 research workforce in improving the management  
13 and mitigation of safety and security risks in the  
14 conduct of research involving such biological agents.

15 (b) REQUIREMENTS.—As a condition of receiving a  
16 grant under this section, a regional biocontainment labora-  
17 tory shall agree to such oversight activities as the Sec-  
18 retary determines appropriate, including periodic meetings  
19 with relevant officials of the Department of Health and  
20 Human Services, facility inspections, and other activities  
21 as necessary and appropriate to ensure compliance with  
22 the terms and conditions of such award.

23 (c) WORKING GROUP.—The Secretary shall establish  
24 a Working Group, consisting of a representative from each  
25 entity in receipt of an award under subsection (a). The



1 Working Group shall make recommendations to the Sec-  
2 retary in administering awards under this section, for pur-  
3 poses of—

4 (1) improving the quality and consistency of ap-  
5 plicable procedures and practices within laboratories  
6 funded pursuant to subsection (a); and

7 (2) ensuring coordination, as appropriate, of  
8 federally funded activities carried out at such labora-  
9 tories.

10 (d) DEFINITION.—In this section, the term “regional  
11 biocontainment laboratory” means a Biosafety or Animal  
12 Biosafety Level–3 and Level–2 facility located at an insti-  
13 tution in the United States that is designated by the Sec-  
14 retary to carry out the activities described in subsection  
15 (a).

16 (e) AUTHORIZATION OF APPROPRIATIONS.—To carry  
17 out this section, there are authorized to be appropriated  
18 \$52,000,000 for each of fiscal years 2025 and 2026, to  
19 remain available through December 31, 2026.

20 (f) ADMINISTRATIVE EXPENSES.—Of the amount  
21 available to carry out this section for a fiscal year, the  
22 Secretary may use not more than 5 percent for the admin-  
23 istrative expenses of carrying out this section, including  
24 expenses related to carrying out subsection (c).

1 (g) REPORT TO CONGRESS.—Not later than 1 year  
2 after the date of the enactment of this Act, and biannually  
3 thereafter, the Secretary, in consultation with the heads  
4 of applicable Federal departments and agencies shall re-  
5 port to the Committee on Health, Education, Labor, and  
6 Pensions of the Senate and the Committee on Energy and  
7 Commerce of the House of Representatives on—

8 (1) the activities and accomplishments of the  
9 regional biocontainment laboratories;

10 (2) any published or disseminated research  
11 findings based on research conducted in such labora-  
12 tories in the applicable year;

13 (3) oversight activities carried out by the Sec-  
14 retary pursuant to subsection (b);

15 (4) activities undertaken by the Secretary to  
16 take into consideration the capacity and capabilities  
17 of the network of regional biocontainment labora-  
18 tories in activities to prepare for and respond to bio-  
19 logical agents, which may include leveraging such ca-  
20 pacity and capabilities to support the Laboratory  
21 Response Network, as applicable and appropriate;

22 (5) plans for the maintenance and sustainment  
23 of federally funded activities conducted at the re-  
24 gional biocontainment laboratories, consistent with  
25 the strategy required under section 2312 of the

1       PREVENT Pandemics Act (Public Law 117–328);  
2       and

3           (6) activities undertaken by the Secretary to co-  
4       ordinate with the heads of other relevant Federal de-  
5       partments and agencies to ensure that work carried  
6       out by each such facility on behalf of the Secretary  
7       and such other relevant heads is prioritized, is com-  
8       plementary to the work carried out by other such fa-  
9       cilities and other relevant federally funded activities,  
10      and avoids unnecessary duplication.

11   **SEC. 629A. LIMITATION RELATED TO COUNTRIES OF CON-**  
12                   **CERN CONDUCTING CERTAIN RESEARCH.**

13       Section 2315(c) of the PREVENT Pandemics Act  
14   (42 U.S.C. 6627) is amended to read as follows:

15       “(c) LIMITATIONS ON COUNTRIES OF CONCERN CON-  
16   DUCTING CERTAIN RESEARCH.—

17           “(1) IN GENERAL.—The Secretary of Health  
18       and Human Services (referred to in this subsection  
19       as the ‘Secretary’) shall not fund research that may  
20       reasonably be anticipated to involve the creation,  
21       transfer, and use of enhanced pathogens of pan-  
22       demic potential or biological agents or toxins listed  
23       pursuant to section 351A(a)(1) of the Public Health  
24       Service Act if such research is conducted by a for-  
25       eign entity at a facility located in a country that is

1       determined to be a country of concern as defined in  
2       paragraph (2).

3           “(2) COUNTRIES OF CONCERN.—

4                   “(A) DEFINITION.—For purposes of this  
5       subsection, a ‘country of concern’ means the  
6       People’s Republic of China, the Democratic  
7       People’s Republic of Korea, the Russian Fed-  
8       eration, the Islamic Republic of Iran, and any  
9       other country as determined pursuant to sub-  
10      paragraph (B).

11                  “(B) ADDITIONAL COUNTRIES.—The Di-  
12      rector of National Intelligence (referred to in  
13      this subsection as the ‘Director’) shall, in con-  
14      sultation with the Secretary, add additional  
15      countries of concern for purposes of paragraph  
16      (1), only if—

17                   “(i) the Director determines that evi-  
18      dence exists that a country has malicious  
19      intent related to the creation, enhance-  
20      ment, transfer, or use of pathogens of pan-  
21      demic potential or biological agents or tox-  
22      ins listed pursuant to such section  
23      351A(a)(1); and

24                   “(ii) in a manner that does not com-  
25      promise national security, the Director

1 provides such evidence in a report sub-  
2 mitted to the Committee on Health, Edu-  
3 cation, Labor, and Pensions of the Senate  
4 and the Committee on Energy and Com-  
5 merce of the House of Representatives.

6 “(C) LIMITATION.—Paragraph (1) shall  
7 not take effect with respect to a country of con-  
8 cern identified under subparagraph (B) until  
9 the date that is 15 days after the date on which  
10 the Director submits the report described in  
11 subparagraph (B)(ii).

12 “(3) CLARIFICATION.—

13 “(A) IN GENERAL.—The requirement of  
14 paragraph (1) may be waived by the President  
15 for the duration of the initial response to an  
16 outbreak of a novel emerging infectious disease  
17 if the President determines that such require-  
18 ment impedes the ability of the Federal Govern-  
19 ment to immediately respond to such outbreak.

20 “(B) NOTIFICATION.—The President shall  
21 notify such committees of Congress not later  
22 than 48 hours after exercising the waiver under  
23 subparagraph (A), and shall provide updates to  
24 such committees related to the use of such  
25 waiver every 15 days thereafter.

1 “(4) SUNSET.—The limitation under this sub-  
2 section shall expire on December 31, 2026.”.

3 **Subtitle C—Addressing the Needs**  
4 **of All Individuals**

5 **SEC. 631. IMPROVING ACCESS TO CERTAIN PROGRAMS.**

6 (a) PROCEDURES RELATED TO THE TRANSITION OF  
7 CERTAIN CLAIMS.—

8 (1) PROCEDURES FOR CORRECTING SUBMIS-  
9 SIONS.—

10 (A) REQUESTS INITIALLY SUBMITTED  
11 UNDER SECTION 319F–4.—

12 (i) IN GENERAL.—In the case of a re-  
13 quest for compensation submitted under  
14 section 319F–4 of the Public Health Serv-  
15 ice Act (42 U.S.C. 247d–6e) for an injury  
16 or death related to a medical product for  
17 active immunization to prevent coronavirus  
18 disease 2019 that the Secretary determines  
19 to be ineligible pursuant to subsection  
20 (b)(4)(B) of such section 319F–4, the Sec-  
21 retary shall, not later than 30 days after  
22 such determination, notify the individual  
23 submitting the request of such determina-  
24 tion.

1                   (ii) SUBMISSION OF PETITION.—An  
2                   individual who receives a notification de-  
3                   scribed in clause (i) shall be eligible to sub-  
4                   mit a petition to the United States Court  
5                   of Federal Claims under section 2111 of  
6                   the Public Health Service Act (42 U.S.C.  
7                   300aa–11) with respect to the same med-  
8                   ical product administration claimed in the  
9                   request submitted under section 319F–4 of  
10                  such Act (42 U.S.C. 247d–6e), provided  
11                  such petition is submitted not later than  
12                  the later of—

13                   (I) 1 year after receiving such  
14                   notification under clause (i); or

15                   (II) the last date on which the  
16                   individual otherwise would be eligible  
17                   to submit a petition relating to such  
18                   injury, as specified in section 2116 of  
19                   such Act (42 U.S.C. 300aa–16).

20                  (iii) ELIGIBILITY.—To be eligible to  
21                  submit a petition in accordance with clause  
22                  (ii), the petitioner shall have submitted the  
23                  request that was determined to be ineli-  
24                  gible as described in clause (i) not later

1           than the applicable deadline for filing a pe-  
2           tition under such section 2116.

3           (B) REQUESTS INITIALLY SUBMITTED  
4           UNDER SECTION 2111.—

5           (i) IN GENERAL.—If a special master  
6           determines that—

7                   (I) a petition submitted under  
8                   section 2111 of the Public Health  
9                   Service Act (42 U.S.C. 300aa–11) re-  
10                  lated to a medical product for active  
11                  immunization to prevent coronavirus  
12                  disease 2019 that is ineligible for the  
13                  program under subtitle 2 of title XXI  
14                  of the Public Health Service Act (42  
15                  U.S.C. 300aa–10 et seq.) because it  
16                  relates to a medical product adminis-  
17                  tered at a time when the medical  
18                  product was not included in the table  
19                  under section 2114 of such Act (42  
20                  U.S.C. 300aa–14); and

21                   (II) the medical product was ad-  
22                   ministered when it was a covered  
23                   countermeasure subject to a declara-  
24                   tion under section 319F–3(b) of such  
25                   Act (42 U.S.C. 247d–6d(b)),



1 the special master shall, not later than 30  
2 days after such determination, notify the  
3 petitioner of such determination.

4 (ii) SUBMISSION OF REQUEST.—An  
5 individual who receives a notification de-  
6 scribed in clause (i) shall be eligible to sub-  
7 mit a request for compensation under sec-  
8 tion 319F–4(b) of the Public Health Serv-  
9 ice Act (42 U.S.C. 247d–6e(b)) with re-  
10 spect to the same medical product adminis-  
11 tration claimed in the petition submitted  
12 under section 2111 of such Act (42 U.S.C.  
13 300aa–11)—

14 (I) not later than 1 year after re-  
15 ceiving such notification; or

16 (II) in the case that the notifica-  
17 tion is issued after judicial review of  
18 the petition under subsection (e) or  
19 (f) of section 2112 of such Act (42  
20 U.S.C. 300aa–12), not later than 1  
21 year after the judgment of the United  
22 States Court of Federal Claims or the  
23 mandate is issued by the United  
24 States Court of Appeals for the Fed-

1                   eral Circuit pursuant to such sub-  
2                   section (e) or (f).

3                   (iii) ELIGIBILITY.—To be eligible to  
4                   submit a request for compensation in ac-  
5                   cordance with clause (ii), the individual  
6                   submitting the request shall have sub-  
7                   mitted the petition under section 2111 of  
8                   the Public Health Service Act (42 U.S.C.  
9                   300aa–11) that was determined to be ineli-  
10                  gible not later than 1 year after the date  
11                  of administration of the medical product.

12                  (2) CHANGES TO CERTAIN PROGRAMS.—

13                  (A) SECTION 319F–4.—Section 319F–4 of  
14                  the Public Health Service Act (42 U.S.C.  
15                  247d–6e) is amended—

16                         (i) in subsection (b)(4)—

17                                 (I) by striking “Except as pro-  
18                                 vided” and inserting the following:

19                                 “(A) IN GENERAL.—Except as provided”;

20                                 and

21                                 (II) by adding at the end the fol-  
22                                 lowing:

23                                 “(B) EXCLUSION OF INJURIES ELIGIBLE  
24                                 FOR PETITION UNDER TITLE XXI.—Notwith-  
25                                 standing any other provision of this section, no

1 individual may be eligible for compensation  
2 under this section with respect to a vaccine  
3 that, at the time it was administered, was in-  
4 cluded in the Vaccine Injury Table under sec-  
5 tion 2114.”; and

6 (ii) in subsection (d)(3)—

7 (I) by striking “This section”  
8 and inserting the following:

9 “(A) IN GENERAL.—This section”; and

10 (II) by adding at the end the fol-  
11 lowing:

12 “(B) EXHAUSTION OF REMEDIES.—A cov-  
13 ered individual shall not be considered to have  
14 exhausted remedies as described in paragraph  
15 (1), nor be eligible to seek remedy under section  
16 319F–3(d), unless such individual has provided  
17 to the Secretary all supporting documentation  
18 necessary to facilitate the determinations re-  
19 quired under subsection (b)(4).”.

20 (B) TITLE XXI.—Title XXI of the Public  
21 Health Service Act (42 U.S.C. 300aa–1 et seq.)  
22 is amended—

23 (i) in section 2111(a)(2)(A) (42  
24 U.S.C. 300aa–11(a)(2)(A)), in the matter  
25 preceding clause (i), by inserting “con-

1           taining the information required under  
2           subsection (c)” after “unless a petition”;

3           (ii) in section 2112(d) (42 U.S.C.  
4           300aa–12(d))—

5           (I) by adding at the end of para-  
6           graph (1) the following: “Such des-  
7           ignation shall not occur until the peti-  
8           tioner has filed all materials required  
9           under section 2111(c).”; and

10          (II) in paragraph (3)(A)(ii), by  
11          striking “the petition was filed” and  
12          inserting “on which the chief special  
13          master makes the designation pursu-  
14          ant to paragraph (1)”;

15          (iii) in section 2114(e) (42 U.S.C.  
16          300aa–14(e)), by adding at the end the  
17          following:

18          “(4)    LICENSURE    REQUIREMENT.—Notwith-  
19          standing paragraphs (2) and (3), the Secretary may  
20          not revise the Vaccine Injury Table to include a vac-  
21          cine for which the Centers for Disease Control and  
22          Prevention has issued a recommendation for routine  
23          use in children or pregnant women until at least one  
24          application for such vaccine has been approved  
25          under section 351. Upon such revision of the Vac-

1        cine Injury Table, all vaccines in a vaccine category  
2        on the Vaccine Injury Table, including vaccines au-  
3        thorized under emergency use pursuant to section  
4        564 of the Federal Food, Drug, and Cosmetic Act,  
5        shall be considered included in the Vaccine Injury  
6        Table.”; and

7                                (iv) in section 2116 (42 U.S.C.  
8                                300aa–16), by adding at the end the fol-  
9                                lowing:

10        “(d) CLARIFICATION.—Notwithstanding subsections  
11        (a) and (b), an injury or death related to a vaccine admin-  
12        istered at a time when the vaccine was a covered counter-  
13        measure subject to a declaration under section 319F–3(b)  
14        shall not be eligible for compensation under the Pro-  
15        gram.”.

16        (b) ACCELERATING INJURY COMPENSATION PRO-  
17        GRAM ADMINISTRATION AND ENSURING PROGRAM INTEG-  
18        RITY.—

19                                (1) PETITIONS FOR COMPENSATION.—Section  
20        2111(a)(2)(A)(i) of the Public Health Service Act  
21        (42 U.S.C. 300aa–11(a)(2)(A)(i)) is amended—

22                                (A) in subclause (I), by striking “, and”  
23        and inserting a semicolon;

24                                (B) in subclause (II)—

1 (i) by moving the margin 2 ems to the  
2 right; and

3 (ii) by striking “, or” and inserting “;  
4 and”; and

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

6 “(III) the judgment described in subclause  
7 (I) does not result from a petitioner’s motion to  
8 dismiss the case; or”.

9 (2) DETERMINATION OF GOOD FAITH.—Section  
10 2115(e)(1) of the Public Health Service Act (42  
11 U.S.C. 300aa–15(e)(1)) is amended by adding at the  
12 end the following: “When making a determination of  
13 good faith under this paragraph, the special master  
14 or court may consider whether the petitioner dem-  
15 onstrated an intention to obtain compensation on  
16 such petition and was not merely seeking to satisfy  
17 the exhaustion requirement under section 2121(b).”.

18 (c) EXTENSION OF DEADLINES TO SUBMIT RE-  
19 QUESTS FOR COMPENSATION FOR CERTAIN INJURIES.—

20 (1) IN GENERAL.—With respect to claims filed  
21 under section 319F–4 of the Public Health Service  
22 Act (42 U.S.C. 247d–6e) alleging a covered injury  
23 caused by the administration or use of a covered  
24 countermeasure pursuant to a declaration under sec-  
25 tion 319F–3(b) of such Act (42 U.S.C. 247d–6d(b))

1 relating to coronavirus disease 2019, the following  
2 shall apply:

3 (A) Notwithstanding the filing deadline ap-  
4 plicable under such section 319F–4, the claim  
5 shall be filed within 3 years of the administra-  
6 tion or use of the covered countermeasure, or 1  
7 year after the date of enactment of this Act,  
8 whichever is later, and, if a claim filed under  
9 such section 319F–4 with respect to such ad-  
10 ministration or use was filed before the date of  
11 enactment of this Act and denied on the basis  
12 of having not been filed within the time period  
13 required under subsection (b)(4) of such section  
14 319F–4, such claim may be refiled pursuant to  
15 this subparagraph.

16 (B) With respect to a claim relating to the  
17 administration of a medical product for active  
18 immunization to prevent coronavirus disease  
19 2019 such a claim may be filed under the such  
20 section 319F–4 only if the administration of  
21 such vaccine occurred prior to the addition of  
22 the vaccine to the Vaccine Injury Table under  
23 section 2114 of the Public Health Service Act  
24 (42 U.S.C. 300aa–14).

1 **SEC. 632. SUPPORTING AT-RISK INDIVIDUALS DURING**  
2 **EMERGENCY RESPONSES.**

3 (a) TECHNICAL ASSISTANCE FOR AT-RISK INDIVID-  
4 UALS AND DISASTERS.—

5 (1) IN GENERAL.—The Secretary of Health and  
6 Human Services (referred to in this section as the  
7 “Secretary”) may provide appropriate technical as-  
8 sistance to States, localities, Tribes, and other appli-  
9 cable entities related to addressing the unique needs  
10 and considerations of at-risk individuals, as defined  
11 in section 2802(b)(4) of the Public Health Service  
12 Act (42 U.S.C. 300hh–1(b)(4)), in the event of a  
13 public health emergency declared by the Secretary  
14 pursuant to section 319 of the Public Health Service  
15 Act (42 U.S.C. 247d).

16 (2) TECHNICAL ASSISTANCE.—The technical  
17 assistance described in paragraph (1) shall include—

18 (A) developing, identifying, evaluating, and  
19 disseminating evidence-based or evidence-in-  
20 formed strategies to improve health and address  
21 other near-term or long-term outcomes for at-  
22 risk individuals related to public health emer-  
23 gencies, including by addressing such unique  
24 needs and considerations in carrying out public  
25 health and medical activities to prepare for, re-



1           spond to, and recover from, such public health  
2           emergencies; and

3           (B) assisting applicable entities, through  
4           contracts or cooperative agreements, as appro-  
5           priate, in the implementation of such evidence-  
6           based strategies.

7           (3) CONSULTATION.—In carrying out activities  
8           under paragraph (2), the Secretary shall take into  
9           consideration relevant findings and recommendations  
10          of, and, as appropriate, consult with, the National  
11          Advisory Committee on Individuals with Disabilities  
12          and Disasters established under section 2811C of  
13          the Public Health Service Act (42 U.S.C. 300hh–  
14          10d), the National Advisory Committee on Children  
15          and Disasters under section 2811A of such Act (42  
16          U.S.C. 300hh–10b), and the National Advisory  
17          Committee on Seniors and Disasters under section  
18          2811B of such Act (42 U.S.C. 300hh–10c).

19          (b) CRISIS STANDARDS OF CARE.—Not later than 2  
20          years after the date of enactment of this Act, the Sec-  
21          retary, acting through the Director of the Office for Civil  
22          Rights of the Department of Health and Human Services,  
23          shall issue guidance to States and localities on the develop-  
24          ment or modification of State and local crisis standards  
25          of care for use during the response to a public health

1 emergency declared by the Governor of a State or by the  
2 Secretary under section 319 of the Public Health Service  
3 Act (42 U.S.C. 247d), or a major disaster or emergency  
4 declared by the President under section 401 or 501, re-  
5 spectively, of the Robert T. Stafford Disaster Relief and  
6 Emergency Assistance Act (42 U.S.C. 5170, 5191) to en-  
7 sure that such standards of care are consistent with the  
8 nondiscrimination requirements of section 504 of the Re-  
9 habilitation Act of 1973 (29 U.S.C. 794), title II of the  
10 Americans with Disabilities Act of 1990 (42 U.S.C. 12131  
11 et seq.), and the Age Discrimination Act of 1975 (42  
12 U.S.C. 6101 et seq.).

13 **SEC. 633. NATIONAL ADVISORY COMMITTEES.**

14 (a) NATIONAL ADVISORY COMMITTEE ON CHILDREN  
15 AND DISASTERS.—Subsection (g) of section 2811A of the  
16 Public Health Service Act (42 U.S.C. 300hh–10b) is  
17 amended to read as follows:

18 “(g) SUNSET.—

19 “(1) IN GENERAL.—The Advisory Committee  
20 shall terminate on December 31, 2026.

21 “(2) EXTENSION OF ADVISORY COMMITTEE.—

22 Not later than October 1, 2025, the Secretary shall  
23 submit to Congress a recommendation on whether  
24 the Advisory Committee should be extended beyond  
25 the date described in paragraph (1).”.

1 (b) NATIONAL ADVISORY COMMITTEE ON SENIORS  
2 AND DISASTERS.—Section 2811B of the Public Health  
3 Service Act (42 U.S.C. 300hh–10c) is amended—

4 (1) in subsection (d)—

5 (A) in paragraph (1)—

6 (i) by inserting “and departments”  
7 after “agencies”; and

8 (ii) by striking “17 members” and in-  
9 serting “25 members”; and

10 (B) in paragraph (2)—

11 (i) by striking subparagraphs (J) and  
12 (K);

13 (ii) by redesignating subparagraphs  
14 (A) through (I) and (L) as clauses (i)  
15 through (x), respectively, and adjusting the  
16 margins accordingly;

17 (iii) by inserting before clause (i), as  
18 so redesignated, the following:

19 “(B) FEDERAL MEMBERS.—The Federal  
20 members shall include the following.”; and

21 (iv) by inserting before subparagraph  
22 (B), as so designated, the following:

23 “(A) NON-FEDERAL MEMBERS.—The Sec-  
24 retary in consultation with such other heads of  
25 agencies and departments as may be appro-

1           priate, shall appoint to the Advisory Committee  
2           under paragraph (1) at least 13 individuals, in-  
3           cluding the following:

4                   “(i) At least 3 non-Federal health  
5           care providers with expertise in geriatric  
6           medical disaster planning, preparedness,  
7           response, or recovery.

8                   “(ii) At least 3 representatives of  
9           State, local, territorial, or Tribal agencies  
10          with expertise in geriatric disaster plan-  
11          ning, preparedness, response, or recovery.

12                   “(iii) At least 2 non-Federal profes-  
13          sionals with training in gerontology, such  
14          as social workers, scientists, human serv-  
15          ices specialists, or other non-medical pro-  
16          fessionals, with experience in disaster plan-  
17          ning, preparedness, response, or recovery  
18          among other adults.”; and

19           (2) by amending subsection (g) to read as fol-  
20          lows:

21           “(g) SUNSET.—The Advisory Committee shall termi-  
22          nate on December 31, 2026.”.

23           (c) NATIONAL ADVISORY COMMITTEE ON INDIVID-  
24          UALS WITH DISABILITIES AND DISASTERS.—Section

1 2811C of the Public Health Service Act (42 U.S.C.  
2 300hh–10d) is amended—

3 (1) by redesignating subsections (c) through (g)  
4 as subsections (d) through (h), respectively;

5 (2) by inserting after subsection (b) the fol-  
6 lowing:

7 “(c) ADDITIONAL DUTIES.—The Advisory Committee  
8 may provide advice and recommendations to the Secretary  
9 with respect to individuals with disabilities and the med-  
10 ical and public health grants and cooperative agreements  
11 as applicable to preparedness and response activities  
12 under this title and title III.”;

13 (3) in subsection (d), as so redesignated—

14 (A) in paragraph (1), by striking “17  
15 members” and inserting “25 members”;

16 (B) in paragraph (2)—

17 (i) by striking subparagraphs (K)  
18 through (M);

19 (ii) by redesignating subparagraphs  
20 (A) through (J) as clauses (i) through (x),  
21 respectively, and adjusting the margins ac-  
22 cordingly;

23 (iii) by inserting before clause (i), as  
24 so redesignated, the following:

1 “(B) FEDERAL MEMBERS.—The Federal  
2 members shall include the following.”;

3 (iv) by adding at the end of subpara-  
4 graph (B), as so designated, the following:

5 “(xi) Representatives of such other  
6 Federal agencies as the Secretary deter-  
7 mines necessary to fulfill the duties of the  
8 Advisory Committee.”; and

9 (v) by inserting before subparagraph  
10 (B), as so designated, the following:

11 “(A) NON-FEDERAL MEMBERS.—The Sec-  
12 retary in consultation with such other heads of  
13 agencies and departments as may be appro-  
14 priate, shall appoint to the Advisory Committee  
15 under paragraph (1) at least 13 individuals, in-  
16 cluding the following:

17 “(i) At least 4 non-Federal health  
18 care professionals with expertise in dis-  
19 ability accessibility before, during, and  
20 after disasters, medical and mass care dis-  
21 aster planning, preparedness, response, or  
22 recovery.

23 “(ii) At least 3 representatives of  
24 State, local, Tribal, or territorial agencies  
25 with expertise in disaster planning, pre-

1           paredness, response, or recovery for indi-  
2           viduals with disabilities.

3           “(iii) At least 4 individuals with a dis-  
4           ability with expertise in disaster planning,  
5           preparedness, response, or recovery for in-  
6           dividuals with disabilities.

7           “(iv) Other members as the Secretary  
8           determines appropriate, of whom—

9           “(I) at least one such member  
10          shall represent a local, State, or na-  
11          tional organization with expertise in  
12          individuals with disabilities;

13          “(II) at least one such member  
14          shall be an individual with a dis-  
15          ability; and

16          “(III) at least one such member  
17          shall be an individual with expertise in  
18          the needs of housing services, includ-  
19          ing during the response to, and recov-  
20          ery from, disasters.”; and

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

22          “(3) CONSIDERATION.—In appointing members,  
23          including the Chair, to the Committee under this  
24          subsection, the Secretary may give consideration to  
25          disability status.”; and

1           (4) by amending subsection (h), as so redesign-  
2       nated, to read as follows:

3       “(h) SUNSET.—The Advisory Committee shall termi-  
4       nate on December 31, 2026.”.

5       **SEC. 634. NATIONAL ACADEMIES STUDY ON PRIZES.**

6       (a) IN GENERAL.—Not later than 90 days after the  
7       date of enactment of this Act, the Secretary of Health and  
8       Human Services shall seek to enter into an agreement  
9       with the National Academies of Sciences, Engineering,  
10      and Medicine (referred to in this section as the “National  
11      Academies”) to conduct a study to examine—

12           (1) alternative models for directly funding, or  
13      stimulating investment in, biomedical research and  
14      development that delink research and development  
15      costs from the prices of drugs, including the pro-  
16      gressive replacement of patents and regulatory  
17      exclusivities on new drugs with a combination of ex-  
18      panded support for research and innovation prizes to  
19      reward the successful development of drugs or  
20      achievement of related milestones;

21           (2) the dollar amount of innovation prizes for  
22      different stages of research and development of dif-  
23      ferent classes or types of drugs, and total annual  
24      funding, that would be necessary to stimulate invest-



1       ment sufficient to achieve such successful drug de-  
2       velopment and related milestones;

3           (3) the relative effectiveness and efficiency of  
4       such alternative models in stimulating innovation,  
5       compared to the status quo that includes patents  
6       and regulatory exclusivities;

7           (4) strategies to implement such alternative  
8       models described in paragraph (1), including a  
9       phased transition; and

10          (5) the anticipated economic and societal im-  
11       pacts of such alternative models, including an as-  
12       sessment of impact on—

13           (A) the number and variety of new drugs  
14       that would be developed, approved, and mar-  
15       keted in the United States, including such new  
16       drugs intended to prevent, diagnose, or treat a  
17       rare disease or condition;

18           (B) the rate at which new drugs would be  
19       developed, approved, and marketed in the  
20       United States;

21           (C) access to medication;

22           (D) health outcomes;

23           (E) average lifespan and disease burden in  
24       the United States;

1 (F) the number of manufacturers that  
2 would be seeking approval for a drug or bring-  
3 ing a drug to market for the first time;

4 (G) Federal discretionary and mandatory  
5 spending; and

6 (H) public and private insurance markets.

7 (b) REQUIREMENTS.—In conducting the study pursu-  
8 ant to subsection (a), the National Academies shall hold  
9 not fewer than 2 public listening sessions to solicit feed-  
10 back from interested parties, including representatives of  
11 academia, professional societies, patient advocates, public  
12 health organizations, relevant Federal departments and  
13 agencies, drug developers, representatives of other rel-  
14 evant industries, and subject matter experts.

15 (c) REPORT.—Not later than 2 years after the agree-  
16 ment under subsection (a), the National Academies shall  
17 submit to the Committee on Health, Education, Labor,  
18 and Pensions and the Committee on Appropriations of the  
19 Senate and the Committee on Energy and Commerce and  
20 the Committee on Appropriations of the House of Rep-  
21 resentatives a report on the study conducted pursuant to  
22 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

1 (2) in subsection (e)(2), by striking “September  
2 30, 2023” and inserting “December 31, 2026”.

3 **SEC. 645. EMERGENCY SYSTEM FOR ADVANCE REGISTRA-**  
4 **TION OF VOLUNTEER HEALTH PROFES-**  
5 **SIONALS.**

6 (1) IN GENERAL.—Section 319I of the Public  
7 Health Service Act (42 U.S.C. 247d–7b) is amend-  
8 ed—

9 (A) in subsection (a), by striking “Not  
10 later than 12 months after the date of enact-  
11 ment of the Pandemic and All-Hazards Pre-  
12 paredness Act, the Secretary shall link existing  
13 State verification systems to maintain a single  
14 national interoperable network of systems,” and  
15 inserting “The Secretary shall continue to  
16 maintain a single national interoperable net-  
17 work of verification systems,” and

18 (B) in subsection (k), by striking “2019  
19 through 2023” and inserting “2025 and 2026,  
20 to remain available through December 31,  
21 2026”.

1   **SEC. 646. ENSURING COLLABORATION AND COORDINATION**  
2                   **IN MEDICAL COUNTERMEASURE DEVELOP-**  
3                   **MENT.**

4       Section 319L–1(b) of the Public Health Service Act  
5   (42 U.S.C. 247d–7f(b)) is amended by striking “Decem-  
6   ber 31, 2024” and inserting “December 31, 2026”.

7   **SEC. 647. MILITARY AND CIVILIAN PARTNERSHIP FOR**  
8                   **TRAUMA READINESS.**

9       Section 1291(g) of the Public Health Service Act (42  
10   U.S.C. 300d–91(g)) is amended by striking “2019  
11   through 2023” and inserting “2025 and 2026, to remain  
12   available through December 31, 2026”.

13   **SEC. 648. NATIONAL DISASTER MEDICAL SYSTEM.**

14       Section 2812 of the Public Health Service Act (42  
15   U.S.C. 300hh–11) is amended—

16           (1) in subsection (c)(4)(B), by striking “Decem-  
17       ber 31, 2024” and inserting “December 31, 2026”;  
18       and

19           (2) in subsection (g), by striking “\$57,400,000  
20       for each of fiscal years 2019 through 2023” and in-  
21       serting “\$65,900,000 for each of fiscal years 2025  
22       and 2026, to remain available through December 31,  
23       2026”.

24   **SEC. 649. VOLUNTEER MEDICAL RESERVE CORPS.**

25       Section 2813(i) of the Public Health Service Act (42  
26   U.S.C. 300hh–15(i)) is amended by striking “2019

1 through 2023” and inserting “2025 through 2026, to re-  
2 main available through December 31, 2026”.

3 **SEC. 649A. EPIDEMIOLOGY-LABORATORY CAPACITY.**

4 Section 2821(b) of the Public Health Service Act (42  
5 U.S.C. 300hh–31(b)) is amended, in the matter preceding  
6 paragraph (1), by striking “2019 through 2023” and in-  
7 serting “2025 and 2026, to remain available through De-  
8 cember 31, 2026”.

9 **TITLE VII—PUBLIC HEALTH**  
10 **PROGRAMS**

11 **SEC. 701. ACTION FOR DENTAL HEALTH.**

12 Section 340G(f) of the Public Health Service Act (42  
13 U.S.C. 256g(f)) is amended by striking “\$13,903,000 for  
14 each of fiscal years 2019 through 2023” and inserting  
15 “\$15,000,000 for each of fiscal years 2025 through 2029,  
16 to remain available until expended”.

17 **SEC. 702. PREEMIE.**

18 (a) RESEARCH RELATING TO PRETERM LABOR AND  
19 DELIVERY AND THE CARE, TREATMENT, AND OUTCOMES  
20 OF PRETERM AND LOW BIRTHWEIGHT INFANTS.—

21 (1) IN GENERAL.—Section 3(e) of the Pre-  
22 maturity Research Expansion and Education for  
23 Mothers who deliver Infants Early Act (42 U.S.C.  
24 247b–4f(e)) is amended by striking “fiscal years

1       2019 through 2023” and inserting “fiscal years  
2       2025 through 2029”.

3           (2) TECHNICAL CORRECTION.—Effective as if  
4       included in the enactment of the PREEMIE Reau-  
5       thorization Act of 2018 (Public Law 115–328), sec-  
6       tion 2 of such Act is amended, in the matter pre-  
7       ceding paragraph (1), by striking “Section 2” and  
8       inserting “Section 3”.

9           (b) INTERAGENCY WORKING GROUP.—Section 5(a)  
10      of the PREEMIE Reauthorization Act of 2018 (Public  
11      Law 115–328) is amended by striking “The Secretary of  
12      Health and Human Services, in collaboration with other  
13      departments, as appropriate, may establish” and inserting  
14      “Not later than 18 months after the date of the enactment  
15      of the [\_\_\_\_\_], the Secretary of Health and  
16      Human Services, in collaboration with other departments,  
17      as appropriate, shall establish”.

18           (c) STUDY ON PRETERM BIRTHS.—

19           (1) IN GENERAL.—The Secretary of Health and  
20      Human Services shall enter into appropriate ar-  
21      rangements with the National Academies of  
22      Sciences, Engineering, and Medicine under which  
23      the National Academies shall—

24           (A) not later than 30 days after the date  
25      of enactment of this Act, convene a committee

1 of experts in maternal health to study pre-  
2 mature births in the United States; and

3 (B) upon completion of the study under  
4 subparagraph (A)—

5 (i) approve by consensus a report on  
6 the results of such study;

7 (ii) include in such report—

8 (I) an assessment of each of the  
9 topics listed in paragraph (2);

10 (II) the analysis required by  
11 paragraph (3); and

12 (III) the raw data used to de-  
13 velop such report; and

14 (iii) not later than 24 months after  
15 the date of enactment of this Act, transmit  
16 such report to—

17 (I) the Secretary of Health and  
18 Human Services;

19 (II) the Committee on Energy  
20 and Commerce of the House of Rep-  
21 resentatives; and

22 (III) the Committee on Finance  
23 and the Committee on Health, Edu-  
24 cation, Labor, and Pensions of the  
25 Senate.



1           (2) ASSESSMENT TOPICS.—The topics listed in  
2       this subsection are each of the following:

3           (A) The financial costs of premature birth  
4       to society, including—

5           (i) an analysis of stays in neonatal in-  
6       tensive care units and the cost of such  
7       stays;

8           (ii) long-term costs of stays in such  
9       units to society and the family involved  
10      post-discharge; and

11          (iii) health care costs for families  
12      post-discharge from such units (such as  
13      medications, therapeutic services, co-pay-  
14      ments for visits, and specialty equipment).

15          (B) The factors that impact preterm birth  
16      rates.

17          (C) Opportunities for earlier detection of  
18      premature birth risk factors, including—

19           (i) opportunities to improve maternal  
20      and infant health; and

21           (ii) opportunities for public health  
22      programs to provide support and resources  
23      for parents in-hospital, in non-hospital set-  
24      tings, and post-discharge.

1           (3) ANALYSIS.—The analysis required by this  
2 subsection is an analysis of—

3           (A) targeted research strategies to develop  
4 effective drugs, treatments, or interventions to  
5 bring at-risk pregnancies to term;

6           (B) State and other programs’ best prac-  
7 tices with respect to reducing premature birth  
8 rates; and

9           (C) precision medicine and preventative  
10 care approaches starting early in the life course  
11 (including during pregnancy) with a focus on  
12 behavioral and biological influences on pre-  
13 mature birth, child health, and the trajectory of  
14 such approaches into adulthood.

15 **SEC. 703. PREVENTING MATERNAL DEATHS.**

16       (a) MATERNAL MORTALITY REVIEW COMMITTEE.—  
17 Section 317K(d) of the Public Health Service Act (42  
18 U.S.C. 247b–12(d)) is amended—

19           (1) in paragraph (1)(A), by inserting “(includ-  
20 ing obstetricians and gynecologists)” after “clinical  
21 specialties”; and

22           (2) in paragraph (3)(A)(i)—

23           (A) in subclause (I), by striking “as appli-  
24 cable” and inserting “if available”; and

1 (B) in subclause (III), by striking “, as ap-  
2 propriate” and inserting “and coordinating with  
3 death certifiers to improve the collection of  
4 death record reports and the quality of death  
5 records, including by amending cause-of-death  
6 information on a death certificate, as appro-  
7 priate”.

8 (b) BEST PRACTICES RELATING TO THE PREVEN-  
9 TION OF MATERNAL MORTALITY.—Section 317K of the  
10 Public Health Service Act (42 U.S.C. 247b–12) is amend-  
11 ed—

12 (1) by redesignating subsections (e) and (f) as  
13 subsections (f) and (g), respectively; and

14 (2) by inserting after subsection (d) the fol-  
15 lowing:

16 “(e) BEST PRACTICES RELATING TO THE PREVEN-  
17 TION OF MATERNAL MORTALITY.—

18 “(1) IN GENERAL.—The Secretary, acting  
19 through the Director of the Centers for Disease  
20 Control and Prevention, shall, in consultation with  
21 the Administrator of the Health Resources and Serv-  
22 ices Administration, disseminate to hospitals, State  
23 professional society groups, and perinatal quality  
24 collaboratives, best practices on how to prevent ma-  
25 ternal mortality and morbidity that consider and re-

1 flect best practices identified through other relevant  
2 Federal maternal health programs.

3 “(2) FREQUENCY.—The Secretary, acting  
4 through the Director of the Centers for Disease  
5 Control and Prevention, shall disseminate the best  
6 practices referred to in paragraph (1) not less than  
7 once per fiscal year.”.

8 (c) EXTENSION.—Subsection (g) of section 317K of  
9 the Public Health Service Act (42 U.S.C. 247b–12), as  
10 redesignated by subsection (b), is amended by striking  
11 “\$58,000,000 for each of fiscal years 2019 through 2023”  
12 and inserting “\$100,000,000 for each of fiscal years 2025  
13 through 2029”.

14 **SEC. 704. SICKLE CELL DISEASE PREVENTION AND TREAT-**  
15 **MENT.**

16 (a) IN GENERAL.—Section 1106(b) of the Public  
17 Health Service Act (42 U.S.C. 300b–5(b)) is amended—

18 (1) in paragraph (1)(A)(iii), by striking “pre-  
19 vention and treatment of sickle cell disease” and in-  
20 serting “treatment of sickle cell disease and the pre-  
21 vention and treatment of complications of sickle cell  
22 disease”;

23 (2) in paragraph (2)(D), by striking “preven-  
24 tion and treatment of sickle cell disease” and insert-  
25 ing “treatment of sickle cell disease and the preven-

1       tion and treatment of complications of sickle cell dis-  
2       ease”;

3       (3) in paragraph (3)—

4             (A) in subparagraph (A), by striking  
5       “enter into a contract with” and inserting  
6       “make a grant to, or enter into a contract or  
7       cooperative agreement with,”; and

8             (B) in subparagraph (B), in each of  
9       clauses (ii) and (iii), by striking “prevention  
10      and treatment of sickle cell disease” and insert-  
11      ing “treatment of sickle cell disease and the  
12      prevention and treatment of complications of  
13      sickle cell disease”; and

14       (4) in paragraph (6), by striking “\$4,455,000  
15      for each of fiscal years 2019 through 2023” and in-  
16      serting “\$8,205,000 for each of fiscal years 2025  
17      through 2029”.

18      (b) SENSE OF CONGRESS.—It is the sense of Con-  
19      gress that further research should be undertaken to ex-  
20      pand the understanding of the causes of, and to find cures  
21      for, heritable blood disorders, including sickle cell disease.

22      **SEC. 705. TRAUMATIC BRAIN INJURIES.**

23       (a) THE BILL PASCRELL, JR., NATIONAL PROGRAM  
24      FOR TRAUMATIC BRAIN INJURY SURVEILLANCE AND  
25      REGISTRIES.—

1           (1) PREVENTION OF TRAUMATIC BRAIN IN-  
2           JURY.—Section 393B of the Public Health Service  
3           Act (42 U.S.C. 280b–1c) is amended—

4                   (A) in subsection (a), by inserting “and  
5           prevalence” after “incidence”;

6                   (B) in subsection (b)—

7                           (i) in paragraph (1), by inserting  
8                           “and reduction of associated injuries and  
9                           fatalities” before the semicolon;

10                           (ii) in paragraph (2), by inserting  
11                           “and related risk factors” before the semi-  
12                           colon; and

13                           (iii) in paragraph (3)—

14                                   (I) in the matter preceding sub-  
15                                   paragraph (A), by striking “2020”  
16                                   each place it appears and inserting  
17                                   “2030”; and

18                                   (II) in subparagraph (A)—

19   (aa) in clause (i), by striking  
20   “; and” and inserting a semi-  
21   colon;

22   (bb) by redesignating clause  
23   (ii) as clause (iv);

24   (cc) by inserting after clause  
25   (i) the following:

1                   “(ii) populations at higher risk of  
2                   traumatic brain injury, including popu-  
3                   lations whose increased risk is due to occu-  
4                   pational or circumstantial factors;

5                   “(iii) causes of, and risk factors for,  
6                   traumatic brain injury; and”; and

7                   (dd) in clause (iv), as so re-  
8                   designated, by striking “arising  
9                   from traumatic brain injury” and  
10                  inserting “, which may include  
11                  related mental health and other  
12                  conditions, arising from trau-  
13                  matic brain injury, including”;  
14                  and

15                  (C) in subsection (c), by inserting “, and  
16                  other relevant Federal departments and agen-  
17                  cies” before the period at the end.

18                  (2) NATIONAL PROGRAM FOR TRAUMATIC  
19                  BRAIN INJURY SURVEILLANCE AND REGISTRIES.—  
20                  Section 393C of the Public Health Service Act (42  
21                  U.S.C. 280b–1d) is amended—

22                  (A) by amending the section heading to  
23                  read as follows: “**THE BILL PASCRELL, JR.,**  
24                  **NATIONAL PROGRAM FOR TRAUMATIC**

**BRAIN INJURY SURVEILLANCE AND REG-  
ISTRIES”;**

(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:



1       “(c) AVAILABILITY OF INFORMATION.—The Sec-  
2   retary, acting through the Director of the Centers for Dis-  
3   ease Control and Prevention, shall make publicly available  
4   aggregated information on traumatic brain injury and  
5   concussion described in this section, including on the  
6   website of the Centers for Disease Control and Prevention.  
7   Such website, to the extent feasible, shall include aggre-  
8   gated information on populations that may be at higher  
9   risk for traumatic brain injuries and strategies for pre-  
10   venting or reducing risk of traumatic brain injury that are  
11   tailored to such populations.”.

12           (3) AUTHORIZATION OF APPROPRIATIONS.—  
13       Section 394A of the Public Health Service Act (42  
14       U.S.C. 280b–3) is amended—

15           (A) in subsection (a), by striking “1994,  
16           and” and inserting “1994,”; and

17           (B) in subsection (b), by striking “2020  
18           through 2024” and inserting “2025 through  
19           2029”.

20       (b) STATE GRANT PROGRAMS.—

21           (1) STATE GRANTS FOR PROJECTS REGARDING  
22       TRAUMATIC BRAIN INJURY.—Section 1252 of the  
23       Public Health Service Act (42 U.S.C. 300d–52) is  
24       amended—

25           (A) in subsection (b)(2)—

1 (i) by inserting “, taking into consid-  
2 eration populations that may be at higher  
3 risk for traumatic brain injuries” after  
4 “outreach programs”; and

5 (ii) by inserting “Tribal,” after  
6 “State,”;

7 (B) in subsection (c), by adding at the end  
8 the following:

9 “(3) MAINTENANCE OF EFFORT.—With respect  
10 to activities for which a grant awarded under sub-  
11 section (a) is to be expended, a State or American  
12 Indian consortium shall agree to maintain expendi-  
13 tures of non-Federal amounts for such activities at  
14 a level that is not less than the level of such expendi-  
15 tures maintained by the State or American Indian  
16 consortium for the fiscal year preceding the fiscal  
17 year for which the State or American Indian consor-  
18 tium receives such a grant.

19 “(4) WAIVER.—The Secretary may, upon the  
20 request of a State or American Indian consortium,  
21 waive not more than 50 percent of the matching  
22 fund amount under paragraph (1), if the Secretary  
23 determines that such matching fund amount would  
24 result in an inability of the State or American In-  
25 dian consortium to carry out the purposes under

1 subsection (a). A waiver provided by the Secretary  
2 under this paragraph shall apply only to the fiscal  
3 year involved.”;

4 (C) in subsection (e)(3)(B)—

5 (i) by striking “(such as third party  
6 payers, State agencies, community-based  
7 providers, schools, and educators)”;

8 (ii) by inserting “(such as third party  
9 payers, State agencies, community-based  
10 providers, schools, and educators)” after  
11 “professionals”;

12 (D) in subsection (h), by striking para-  
13 graphs (1) and (2) and inserting the following:

14 “(1) AMERICAN INDIAN CONSORTIUM; STATE.—

15 The terms ‘American Indian consortium’ and ‘State’  
16 have the meanings given such terms in section 1253.

17 “(2) TRAUMATIC BRAIN INJURY.—

18 “(A) IN GENERAL.—Subject to subpara-  
19 graph (B), the term ‘traumatic brain injury’—

20 “(i) means an acquired injury to the  
21 brain;

22 “(ii) may include—

23 “(I) brain injuries caused by an-  
24 oxia due to trauma; and

1 “(II) damage to the brain from  
2 an internal or external source that re-  
3 sults in infection, toxicity, surgery, or  
4 vascular disorders not associated with  
5 aging; and

6 “(iii) does not include brain dysfunc-  
7 tion caused by congenital or degenerative  
8 disorders, or birth trauma.

9 “(B) REVISIONS TO DEFINITION.—The  
10 Secretary may revise the definition of the term  
11 ‘traumatic brain injury’ under this paragraph,  
12 as the Secretary determines necessary, after  
13 consultation with States and other appropriate  
14 public or nonprofit private entities.”; and

15 (E) in subsection (i), by striking “2020  
16 through 2024” and inserting “2025 through  
17 2029”.

18 (2) STATE GRANTS FOR PROTECTION AND AD-  
19 VOCACY SERVICES.—Section 1253(l) of the Public  
20 Health Service Act (42 U.S.C. 300d–53(l)) is  
21 amended by striking “2020 through 2024” and in-  
22 serting “2025 through 2029”.

23 (c) REPORT TO CONGRESS.—Not later than 2 years  
24 after the date of enactment of this Act, the Secretary of  
25 Health and Human Services (referred to in this Act as

1 the “Secretary”) shall submit to the Committee on  
2 Health, Education, Labor, and Pensions of the Senate and  
3 the Committee on Energy and Commerce of the House  
4 of Representatives a report that contains—

5 (1) an overview of populations who may be at  
6 higher risk for traumatic brain injury, such as indi-  
7 viduals affected by domestic violence or sexual as-  
8 sault and public safety officers as defined in section  
9 1204 of the Omnibus Crime Control and Safe  
10 Streets Act of 1968 (34 U.S.C. 10284);

11 (2) an outline of existing surveys and activities  
12 of the Centers for Disease Control and Prevention  
13 on traumatic brain injuries and any steps the agency  
14 has taken to address gaps in data collection related  
15 to such higher risk populations, which may include  
16 leveraging surveys such as the National Intimate  
17 Partner and Sexual Violence Survey to collect data  
18 on traumatic brain injuries;

19 (3) an overview of any outreach or education ef-  
20 forts to reach such higher risk populations; and

21 (4) any challenges associated with reaching  
22 such higher risk populations.

23 (d) STUDY ON LONG-TERM SYMPTOMS OR CONDI-  
24 TIONS RELATED TO TRAUMATIC BRAIN INJURY.—

1           (1) IN GENERAL.—The Secretary, in consulta-  
2           tion with stakeholders and the heads of other rel-  
3           evant Federal departments and agencies, as appro-  
4           priate, shall conduct, either directly or through a  
5           contract with a nonprofit private entity, a study to—

6                   (A) examine the incidence and prevalence  
7                   of long-term or chronic symptoms or conditions  
8                   in individuals who have experienced a traumatic  
9                   brain injury;

10                   (B) examine the evidence base of research  
11                   related to the chronic effects of traumatic brain  
12                   injury across the lifespan;

13                   (C) examine any correlations between trau-  
14                   matic brain injury and increased risk of other  
15                   conditions, such as dementia and mental health  
16                   conditions;

17                   (D) assess existing services available for  
18                   individuals with such long-term or chronic  
19                   symptoms or conditions; and

20                   (E) identify any gaps in research related to  
21                   such long-term or chronic symptoms or condi-  
22                   tions of individuals who have experienced a  
23                   traumatic brain injury.

1           (2) PUBLIC REPORT.—Not later than 2 years  
2       after the date of enactment of this Act, the Sec-  
3       retary shall—

4           (A) submit to the Committee on Energy  
5       and Commerce of the House of Representatives  
6       and the Committee on Health, Education,  
7       Labor, and Pensions of the Senate a report de-  
8       tailing the findings, conclusions, and rec-  
9       ommendations of the study described in para-  
10      graph (1); and

11          (B) in the case that such study is con-  
12      ducted directly by the Secretary, make the re-  
13      port described in subparagraph (A) publicly  
14      available on the website of the Department of  
15      Health and Human Services.

16   **SEC. 706. LIFESPAN RESPITE CARE.**

17      (a) DEFINITION OF FAMILY CAREGIVER.—Section  
18   2901(5) of the Public Health Service Act (42 U.S.C.  
19   300ii(5)) is amended by striking “unpaid adult” and in-  
20   serting “unpaid individual”.

21      (b) FUNDING.—Section 2905 of the Public Health  
22   Service Act (42 U.S.C. 300ii–4) is amended by striking  
23   “fiscal years 2020 through fiscal year 2024” and inserting  
24   “fiscal years 2025 through 2029”.

1   **SEC. 707. DR. LORNA BREEN HEALTH CARE PROVIDER PRO-**  
2                   **TECTION.**

3           (a) DISSEMINATION OF BEST PRACTICES.— Section  
4   2 of the Dr. Lorna Breen Health Care Provider Protection  
5   Act (Public Law 117–105) is amended by striking “2  
6   years” and inserting “5 years”.

7           (b) EDUCATION AND AWARENESS INITIATIVE EN-  
8   COURAGING USE OF MENTAL HEALTH AND SUBSTANCE  
9   USE DISORDER SERVICES BY HEALTH CARE PROFES-  
10   SIONALS.—Section 3 of the Dr. Lorna Breen Health Care  
11   Provider Protection Act (Public Law 117–105) is amend-  
12   ed—

13               (1) in subsection (b), by inserting “and annu-  
14       ally thereafter,” after “of this Act,”; and

15               (2) in subsection (c), by striking “2022 through  
16       2024” and inserting “2025 through 2029”.

17           (c) PROGRAMS TO PROMOTE MENTAL HEALTH  
18   AMONG THE HEALTH PROFESSIONAL WORKFORCE.—The  
19   second section 764 of the Public Health Service Act (42  
20   U.S.C. 294t), as added by section 4 of the Dr. Lorna  
21   Breen Health Care Provider Protection Act (Public Law  
22   117–105), is amended—

23               (1) by redesignating such section 764 as section  
24       764A;

25               (2) in subsection (a)(3)—



1 (A) by striking “to eligible entities in” and  
2 inserting “to eligible entities that—

3 “(A) are in”;

4 (B) by striking the period and inserting “;  
5 or”; and

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

7 “(B) have a focus on the reduction of ad-  
8 ministrative burden on health care workers.”;

9 (3) in subsection (c), by inserting “not less  
10 than” after “period of”; and

11 (4) in subsection (f), by striking “2022 through  
12 2024” and inserting “2025 through 2029”.

13 **SEC. 708. GABRIELLA MILLER KIDS FIRST RESEARCH.**

14 (a) FUNDING FOR THE PEDIATRIC RESEARCH INI-  
15 TIATIVE.—

16 (1) IN GENERAL.—The Public Health Service  
17 Act (42 U.S.C. 201 et seq.) is amended—

18 (A) in section 402A(a)(2) (42 U.S.C.  
19 282a(a)(2))—

20 (i) in the heading—

21 (I) by striking “10-YEAR”; and

22 (II) by striking “THROUGH COM-  
23 MON FUND”;

24 (ii) by striking “to the Common  
25 Fund” and inserting “to the Division of

1                   Program Coordination, Planning, and  
2                   Strategic Initiatives”;

3                   (iii) by striking “10-Year”;

4                   (iv) by striking “and reserved under  
5                   subsection (c)(1)(B)(i) of this section”;  
6                   and

7                   (v) by striking “2014 through 2023”  
8                   and inserting “2025 through 2031”;

9                   (B) in each of paragraphs (1)(A) and  
10                  (2)(C) of section 402A(c) (42 U.S.C. 282a(c)),  
11                  by striking “section 402(b)(7)(B)” and insert-  
12                  ing “section 402(b)(7)(B)(i)”; and

13                  (C) in section 402(b)(7)(B)(ii) (42 U.S.C.  
14                  282(b)(7)(B)(ii)), by striking “the Common  
15                  Fund” and inserting “the Division of Program  
16                  Coordination, Planning, and Strategic Initia-  
17                  tives”.

18                  (2) CONFORMING AMENDMENT.—Section  
19                  9008(i)(2) of the Internal Revenue Code of 1986  
20                  (26 U.S.C. 9008(i)(2)) is amended by striking “10-  
21                  Year”.

22                  (b) COORDINATION OF NIH FUNDING FOR PEDI-  
23                  ATRIC RESEARCH.—

24                  (1) SENSE OF CONGRESS.—It is the sense of  
25                  the Congress that the Director of the National Insti-

1       tutes of Health should continue to oversee and co-  
2       ordinate research that is conducted or supported by  
3       the National Institutes of Health for research on pe-  
4       diatric cancer and other pediatric diseases and con-  
5       ditions, including through the Pediatric Research  
6       Initiative Fund.

7               (2)        AVOIDING        DUPLICATION.—Section  
8       402(b)(7)(B)(ii) of the Public Health Service Act  
9       (42 U.S.C. 282(b)(7)(B)(ii)) is amended by inserting  
10      “and shall prioritize, as appropriate, such pediatric  
11      research that does not duplicate existing research  
12      activities of the National Institutes of Health” be-  
13      fore “; and”.

14      (c) REPORT ON PROGRESS AND INVESTMENTS IN PE-  
15      DIATRIC RESEARCH.—Not later than 5 years after the  
16      date of the enactment of this Act, the Secretary of Health  
17      and Human Services shall submit to the Committee on  
18      Energy and Commerce of the House of Representatives  
19      and the Committee on Health, Education, Labor, and  
20      Pensions of the Senate a report that—

21               (1) details pediatric research projects and ini-  
22      tiatives receiving funds allocated pursuant to section  
23      402(b)(7)(B)(ii) of the Public Health Service Act  
24      (42 U.S.C. 282(b)(7)(B)(ii)); and

1           (2) summarizes advancements made in pediatric  
2       research with funds allocated pursuant to such sec-  
3       tion.

4   **SEC. 709. SCREENS FOR CANCER.**

5       (a) NATIONAL BREAST AND CERVICAL CANCER  
6   EARLY DETECTION PROGRAM.—Title XV of the Public  
7   Health Service Act (42 U.S.C. 300k et seq.) is amended—

8           (1) in section 1501 (42 U.S.C. 300k)—

9               (A) in subsection (a)—

10                   (i) in paragraph (2), by striking “the  
11                   provision of appropriate follow-up services  
12                   and support services such as case manage-  
13                   ment” and inserting “that appropriate fol-  
14                   low-up services are provided”;

15                   (ii) in paragraph (3), by striking  
16                   “programs for the detection and control”  
17                   and inserting “for the prevention, detec-  
18                   tion, and control”;

19                   (iii) in paragraph (4), by striking “the  
20                   detection and control” and inserting “the  
21                   prevention, detection, and control”;

22                   (iv) in paragraph (5)—

23                       (I) by striking “monitor” and in-  
24                       serting “ensure”; and

1 (II) by striking “; and” and in-  
2 serting a semicolon;

3 (v) by redesignating paragraph (6) as  
4 paragraph (9);

5 (vi) by inserting after paragraph (5)  
6 the following:

7 “(6) to enhance appropriate support activities  
8 to increase breast and cervical cancer screenings,  
9 such as navigation of health care services, implemen-  
10 tation of evidence-based or evidence-informed strate-  
11 gies to increase breast and cervical cancer screening  
12 in health care settings, and facilitation of access to  
13 health care settings;

14 “(7) to reduce disparities in breast and cervical  
15 cancer incidence, morbidity, and mortality, including  
16 in populations with higher than average rates;

17 “(8) to improve access to breast and cervical  
18 cancer screening and diagnostic services and reduce  
19 related barriers, including factors that relate to neg-  
20 ative health outcomes; and”; and

21 (vii) in paragraph (9), as so redesign-  
22 nated, by striking “through (5)” and in-  
23 serting “through (8)”; and

24 (B) by striking subsection (d);

25 (2) in section 1503 (42 U.S.C. 300m)—

1 (A) in subsection (a)—

2 (i) in paragraph (1), by striking  
3 “that, initially” and all that follows  
4 through the semicolon and inserting “that  
5 appropriate breast and cervical cancer  
6 screening and diagnostic services are pro-  
7 vided consistent with relevant evidence-  
8 based recommendations; and”;

9 (ii) by striking paragraphs (2) and  
10 (4);

11 (iii) by redesignating paragraph (3) as  
12 paragraph (2); and

13 (iv) in paragraph (2), as so redesign-  
14 ated, by striking “; and” and inserting a  
15 period; and

16 (B) by striking subsection (d);

17 (3) in section 1508(b) (42 U.S.C. 300n–4(b))—

18 (A) by striking “1 year after the date of  
19 the enactment of the National Breast and Cer-  
20 vical Cancer Early Detection Program Reau-  
21 thorization of 2007, and annually thereafter,”  
22 and inserting “2 years after the date of enact-  
23 ment of the [\_\_\_\_\_], and every 5  
24 years thereafter,”;

1 (B) by striking “Labor and Human Re-  
2 sources” and inserting “Health, Education,  
3 Labor, and Pensions”; and

4 (C) by striking “preceding fiscal year” and  
5 inserting “preceding 2 fiscal years in the case  
6 of the first report after the date of enactment  
7 of the [ ] and preceding 5 fis-  
8 cal years for each report thereafter”; and

9 (4) in section 1510(a) (42 U.S.C. 300n–5(a))—

10 (A) by striking “2011, and” and inserting  
11 “2011,”; and

12 (B) by inserting “, and \$235,500,000 for  
13 each of fiscal years 2025 through 2029” before  
14 the period at the end before the period at the  
15 end.

16 (b) GAO STUDY.—Not later than September 30,  
17 2027, the Comptroller General of the United States shall  
18 report to the Committee on Health, Education, Labor, and  
19 Pensions of the Senate and the Committee on Energy and  
20 Commerce of the House of Representatives on the work  
21 of the National Breast and Cervical Cancer Early Detec-  
22 tion Program, including—

23 (1) an estimate of the number of individuals eli-  
24 gible for services provided under such program;

1           (2) a summary of trends in the number of indi-  
2       viduals served through such program; and

3           (3) an assessment of any factors that may be  
4       driving the trends identified under paragraph (2),  
5       including any barriers to accessing breast and cer-  
6       vical cancer screenings provided by such program.

7   **SEC. 710. DEONDRA DIXON INCLUDE PROJECT.**

8       Part B of title IV of the Public Health Service Act  
9   (42 U.S.C. 284 et seq.) is amended by adding at the end  
10  the following:

11   **“SEC. 409K. DOWN SYNDROME RESEARCH.**

12       “(a) IN GENERAL.—The Director of NIH shall carry  
13   out a program of research, training, and investigation re-  
14   lated to Down syndrome to be known as the ‘INvestigation  
15   of Co-occurring conditions across the Lifespan to Under-  
16   stand Down syndromE Project’ or the ‘INCLUDE  
17   Project’.

18       “(b) PROGRAM ELEMENTS.—The program under  
19   subsection (a) shall include—

20           “(1) high-risk, high reward research on the ef-  
21       fects of trisomy 21 on human development and  
22       health;

23           “(2) promoting research for participants with  
24       Down syndrome across the lifespan, including cohort  
25       studies to facilitate improved understanding of



1 Down syndrome and co-occurring conditions and de-  
2 velopment of new interventions;

3 “(3) expanding the number of clinical trials  
4 that are inclusive of, or expressly for, participants  
5 with Down syndrome, including novel biomedical and  
6 pharmacological interventions and other therapies  
7 designed to promote or enhance activities of daily  
8 living;

9 “(4) research on the biological mechanisms in  
10 individuals with Down syndrome pertaining to struc-  
11 tural, functional, and behavioral anomalies and dys-  
12 function as well as stunted growth;

13 “(5) supporting research to improve diagnosis  
14 and treatment of conditions co-occurring with Down  
15 syndrome, including the identification of biomarkers  
16 related to risk factors, diagnosis, and clinical re-  
17 search and therapeutics;

18 “(6) research on the causes of increased preva-  
19 lence, and concurrent treatment, of co-occurring con-  
20 ditions, such as Alzheimer’s disease and related de-  
21 mentias and autoimmunity, in individuals with Down  
22 syndrome; and

23 “(7) research, training, and investigation on im-  
24 proving the quality of life of individuals with Down  
25 syndrome and their families.

1       “(c) COORDINATION; PRIORITIZING NONDUPLICA-  
2 TIVE RESEARCH.—The Director of NIH shall ensure  
3 that—

4           “(1) the programs and activities of the insti-  
5 tutes and centers of the National Institutes of  
6 Health relating to Down syndrome and co-occurring  
7 conditions are coordinated, including through the  
8 Office of the Director of NIH and priority-setting  
9 reviews conducted pursuant to section 402(b)(3);  
10 and

11           “(2) such institutes and centers, prioritize, as  
12 appropriate, Down syndrome research that does not  
13 duplicate existing research activities of the National  
14 Institutes of Health.

15       “(d) CONSULTATION WITH STAKEHOLDERS.—In  
16 carrying out activities under this section, the Director of  
17 NIH shall, as appropriate and to the maximum extent fea-  
18 sible, consult with relevant stakeholders, including patient  
19 advocates, to ensure that such activities take into consid-  
20 eration the needs of individuals with Down syndrome.

21       “(e) BIENNIAL REPORTS TO CONGRESS.—

22           “(1) IN GENERAL.—The Director of NIH shall  
23 submit, on a biennial basis, to the Committee on  
24 Energy and Commerce and the Subcommittee on  
25 Labor, Health and Human Services, Education, and

1       Related Agencies of the Committee on Appropria-  
2       tions of the House of Representatives and the Com-  
3       mittee on Health, Education, Labor, and Pensions  
4       and the Subcommittee on Labor, Health and  
5       Human Services, Education, and Related Agencies  
6       of the Committee on Appropriations of the Senate,  
7       a report that catalogs the research conducted or  
8       supported under this section.

9               “(2) CONTENTS.—Each report under para-  
10       graph (1) shall include—

11               “(A) identification of the institute or cen-  
12       ter involved;

13               “(B) a statement of whether the research  
14       is or was being carried out directly by such in-  
15       stitute or center or by multiple institutes and  
16       centers; and

17               “(C) identification of any resulting real-  
18       world evidence that is or may be used for clin-  
19       ical research and medical care for patients with  
20       Down syndrome.”.

21   **SEC. 711. IMPROVE INITIATIVE.**

22       Part B of title IV of the Public Health Service Act  
23   (42 U.S.C. 284 et seq.), as amended by section 710, is  
24   further amended by adding at the end the following:

1   **“SEC. 409L. IMPROVE INITIATIVE.**

2           “(a) IN GENERAL.—The Director of the National In-  
3   stitutes of Health shall carry out a program of research  
4   to improve health outcomes to be known as the Imple-  
5   menting a Maternal health and PRegnancy Outcomes Vi-  
6   sion for Everyone Initiative (referred to in this section as  
7   the ‘Initiative’).

8           “(b) OBJECTIVES.—The Initiative shall—

9               “(1) advance research to—

10                   “(A) reduce preventable causes of maternal  
11                   mortality and severe maternal morbidity;

12                   “(B) reduce health disparities related to  
13                   maternal health outcomes, including such dis-  
14                   parities associated with medically underserved  
15                   populations; and

16                   “(C) improve health for pregnant and  
17                   postpartum women before, during, and after  
18                   pregnancy;

19               “(2) use an integrated approach to understand  
20           the factors, including biological, behavioral, and  
21           other factors, that affect maternal mortality and se-  
22           vere maternal morbidity by building an evidence  
23           base for improved outcomes in specific regions of the  
24           United States; and

1 “(3) target health disparities associated with  
2 maternal mortality and severe maternal morbidity  
3 by—

4 “(A) implementing and evaluating commu-  
5 nity-based interventions for disproportionately  
6 affected women; and

7 “(B) identifying risk factors and the un-  
8 derlying biological mechanisms associated with  
9 leading causes of maternal mortality and severe  
10 maternal morbidity in the United States.

11 “(c) SUNSET.—The authority under this section shall  
12 expire on September 30, 2029.”.

13 **SEC. 712. ORGAN PROCUREMENT AND TRANSPLANTATION**  
14 **NETWORK.**

15 Section 372 of the Public Health Service Act (42  
16 U.S.C. 274) is amended—

17 (1) in subsection (b)(2)—

18 (A) by moving the margins of subpara-  
19 graphs (M) through (O) 2 ems to the left;

20 (B) in subparagraph (A)—

21 (i) in clause (i), by striking “, and”  
22 and inserting “; and”; and

23 (ii) in clause (ii), by striking the  
24 comma at the end and inserting a semi-  
25 colon;

1 (C) in subparagraph (C), by striking  
2 “twenty-four-hour telephone service” and in-  
3 serting “24-hour telephone or information tech-  
4 nology service”;

5 (D) in each of subparagraphs (B) through  
6 (M), by striking the comma at the end and in-  
7 serting a semicolon;

8 (E) in subparagraph (N), by striking  
9 “transportation, and” and inserting “transpor-  
10 tation;”;

11 (F) in subparagraph (O), by striking the  
12 period and inserting a semicolon; and

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

14 “(P) encourage the integration of elec-  
15 tronic health records systems through applica-  
16 tion programming interfaces (or successor tech-  
17 nologies) among hospitals, organ procurement  
18 organizations, and transplant centers, including  
19 the use of automated electronic hospital refer-  
20 rals and the grant of remote, electronic access  
21 to hospital electronic health records of potential  
22 donors by organ procurement organizations, in  
23 a manner that complies with the privacy regula-  
24 tions promulgated under the Health Insurance  
25 Portability and Accountability Act of 1996, at

1 part 160 of title 45, Code of Federal Regula-  
2 tions, and subparts A, C, and E of part 164 of  
3 such title (or any successor regulations); and

4 “(Q) consider establishing a dashboard to  
5 display the number of transplants performed,  
6 the types of transplants performed, the number  
7 and types of organs that entered the Organ  
8 Procurement and Transplantation Network sys-  
9 tem and failed to be transplanted, and other  
10 appropriate statistics, which should be updated  
11 more frequently than annually.”; and

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

13 “(d) REGISTRATION FEES.—

14 “(1) IN GENERAL.—The Secretary may collect  
15 registration fees from any member of the Organ  
16 Procurement and Transplantation Network for each  
17 transplant candidate such member places on the list  
18 described in subsection (b)(2)(A)(i). Such registra-  
19 tion fees shall be collected and distributed only to  
20 support the operation of the Organ Procurement  
21 and Transplantation Network. Such registration fees  
22 are authorized to remain available until expended.

23 “(2) COLLECTION.—The Secretary may collect  
24 the registration fees under paragraph (1) directly or  
25 through awards made under subsection (b)(1)(A).

1           “(3) DISTRIBUTION.—Any amounts collected  
2           under this subsection shall—

3                   “(A) be credited to the currently applicable  
4                   appropriation, account, or fund of the Depart-  
5                   ment of Health and Human Services as discre-  
6                   tionary offsetting collections; and

7                   “(B) be available, only to the extent and in  
8                   the amounts provided in advance in appropria-  
9                   tions Acts, to distribute such fees among  
10                  awardees described in subsection (b)(1)(A).

11          “(4) TRANSPARENCY.—The Secretary shall—

12                  “(A) promptly post on the website of the  
13                  Organ Procurement and Transplantation Net-  
14                  work—

15                          “(i) the amount of registration fees  
16                          collected under this subsection from each  
17                          member of the Organ Procurement and  
18                          Transplantation Network; and

19                          “(ii) a list of activities such fees are  
20                          used to support; and

21                  “(B) update the information posted pursu-  
22                  ant to subparagraph (A), as applicable for each  
23                  calendar quarter for which fees are collected  
24                  under paragraph (1).



1           “(5) GAO REVIEW.—Not later than 2 years  
2           after the date of enactment of this subsection, the  
3           Comptroller General of the United States shall, to  
4           the extent data are available—

5                   “(A) conduct a review concerning the ac-  
6                   tivities under this subsection; and

7                   “(B) submit to the Committee on Health,  
8                   Education, Labor, and Pensions and the Com-  
9                   mittee on Finance of the Senate and the Com-  
10                  mittee on Energy and Commerce of the House  
11                  of Representatives, a report on such review, in-  
12                  cluding related recommendations, as applicable.

13           “(6) SUNSET.—The authority to collect reg-  
14           istration fees under paragraph (1) shall expire on  
15           the date that is 3 years after the date of enactment  
16           of the [\_\_\_\_\_].”.

17 **SEC. 713. HONOR OUR LIVING DONORS.**

18           (a) NO CONSIDERATION OF INCOME OF ORGAN RE-  
19           CIPIENT.—Section 377 of the Public Health Service Act  
20           (42 U.S.C. 274f) is amended—

21                   (1) by redesignating subsections (c) through (f)  
22                   as subsections (d) through (g), respectively;

23                   (2) by inserting after subsection (b) the fol-  
24                   lowing:

1       “(c) NO CONSIDERATION OF INCOME OF ORGAN RE-  
2       CIPIENT.—The recipient of a grant under this section, in  
3       providing reimbursement to a donating individual through  
4       such grant, shall not give any consideration to the income  
5       of the organ recipient.”; and

6               (3) in subsection (f), as so redesignated—

7                       (A) in paragraph (1), by striking “sub-  
8                       section (c)(1)” and inserting “subsection  
9                       (d)(1)”; and

10                      (B) in paragraph (2), by striking “sub-  
11                      section (c)(2)” and inserting “subsection  
12                      (d)(2)”.

13       (b) REMOVAL OF EXPECTATION OF PAYMENTS BY  
14       ORGAN RECIPIENTS.—Section 377(e) of the Public  
15       Health Service Act (42 U.S.C. 274f(e)), as redesignated  
16       by section 2(1), is amended—

17               (1) in paragraph (1), by adding “or” at the  
18       end;

19               (2) in paragraph (2), by striking “; or” and in-  
20       serting a period; and

21               (3) by striking paragraph (3).

22       (c) ANNUAL REPORT.—Section 377 of the Public  
23       Health Service Act (42 U.S.C. 274f), as amended by sec-  
24       tions 2 and 3, is amended by adding at the end the fol-  
25       lowing:

1 “(h) ANNUAL REPORT.—Not later than December 31  
2 of each year, beginning in Fiscal Year 2026, the Secretary  
3 shall—

4 “(1) prepare, submit to the Congress, and make  
5 public a report on whether grants under this section  
6 provided adequate funding during the preceding fis-  
7 cal year to reimburse all donating individuals par-  
8 ticipating in the grant program under this section  
9 for all qualifying expenses; and

10 “(2) include in each such report—

11 “(A) the estimated number of all donating  
12 individuals participating in the grant program  
13 under this section who did not receive reim-  
14 bursement for all qualifying expenses during  
15 the preceding fiscal year; and

16 “(B) the total amount of funding that is  
17 estimated to be necessary to fully reimburse all  
18 donating individuals participating in the grant  
19 program under this section for all qualifying ex-  
20 penses.”.

21 **SEC. 714. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

22 Section 409I(d)(1) of the Public Health Service Act  
23 (42 U.S.C. 284m(d)(1)) is amended by striking “section,”  
24 and all that follows through the period at the end and

1 inserting “section, \$25,000,000 for each of fiscal years  
2 2025 through 2027.”.

3 **TITLE VIII—FOOD AND DRUG**  
4 **ADMINISTRATION**  
5 **Subtitle A—Give Kids a Chance**

6 **SEC. 801. RESEARCH INTO PEDIATRIC USES OF DRUGS; AD-**  
7 **DITIONAL AUTHORITIES OF FOOD AND DRUG**  
8 **ADMINISTRATION REGARDING MOLEC-**  
9 **ULARLY TARGETED CANCER DRUGS.**

10 (a) IN GENERAL.—

11 (1) ADDITIONAL ACTIVE INGREDIENT FOR AP-  
12 PPLICATION DRUG; LIMITATION REGARDING NOVEL-  
13 COMBINATION APPLICATION DRUG.—Section  
14 505B(a)(3) of the Federal Food, Drug, and Cos-  
15 metic Act (21 U.S.C. 355c(a)(3)) is amended—

16 (A) by redesignating subparagraphs (B)  
17 and (C) as subparagraphs (C) and (D), respec-  
18 tively; and

19 (B) by striking subparagraph (A) and in-  
20 serting the following:

21 “(A) IN GENERAL.—For purposes of para-  
22 graph (1)(B), the investigation described in this  
23 paragraph is a molecularly targeted pediatric  
24 cancer investigation of—

1 “(i) the drug or biological product for  
2 which the application referred to in such  
3 paragraph is submitted; or

4 “(ii) such drug or biological product  
5 used in combination with—

6 “(I) an active ingredient of a  
7 drug or biological product—

8 “(aa) for which an approved  
9 application under section 505(j)  
10 under this Act or under section  
11 351(k) of the Public Health  
12 Service Act is in effect; and

13 “(bb) that is determined by  
14 the Secretary, after consultation  
15 with the applicant, to be part of  
16 the standard of care for treating  
17 a pediatric cancer; or

18 “(II) an active ingredient of a  
19 drug or biological product—

20 “(aa) for which an approved  
21 application under section 505(b)  
22 of this Act or section 351(a) of  
23 the Public Health Service Act to  
24 treat an adult cancer is in effect  
25 and is held by the same person

1 submitting the application under  
2 paragraph (1)(B); and

3 “(bb) that is directed at a  
4 molecular target that the Sec-  
5 retary determines to be substan-  
6 tially relevant to the growth or  
7 progression of a pediatric cancer.

8 “(B) ADDITIONAL REQUIREMENTS.—

9 “(i) DESIGN OF INVESTIGATION.—A  
10 molecularly targeted pediatric cancer inves-  
11 tigation referred to in subparagraph (A)  
12 shall be designed to yield clinically mean-  
13 ingful pediatric study data that is gathered  
14 using appropriate formulations for each  
15 age group for which the study is required,  
16 regarding dosing, safety, and preliminary  
17 efficacy to inform potential pediatric label-  
18 ing.

19 “(ii) LIMITATION.—An investigation  
20 described in subparagraph (A)(ii) may be  
21 required only if the drug or biological  
22 product for which the application referred  
23 to in paragraph (1)(B) contains either—

24 “(I) a single new active ingre-  
25 dient; or

1                   “(II) more than one active ingre-  
2                   dient, if an application for the com-  
3                   bination of active ingredients has not  
4                   previously been approved but each ac-  
5                   tive ingredient is in a drug product  
6                   that has been previously approved to  
7                   treat an adult cancer.

8                   “(iii) RESULTS OF ALREADY-COM-  
9                   PLETED PRECLINICAL STUDIES OF APPLI-  
10                  CATION DRUG.—With respect to an inves-  
11                  tigation required pursuant to paragraph  
12                  (1)(B), the Secretary may require the re-  
13                  sults of any completed preclinical studies  
14                  relevant to the initial pediatric study plan  
15                  be submitted to the Secretary at the same  
16                  time that the initial pediatric study plan  
17                  required under subsection (e)(1) is sub-  
18                  mitted.

19                  “(iv) RULE OF CONSTRUCTION RE-  
20                  GARDING INACTIVE INGREDIENTS.—With  
21                  respect to a combination of active ingredi-  
22                  ents referred to in subparagraph (A)(ii),  
23                  such subparagraph shall not be construed  
24                  as addressing the use of inactive ingredi-  
25                  ents with such combination.”.

1           (2) DETERMINATION OF APPLICABLE REQUIRE-  
2           MENTS.—Section 505B(e)(1) of the Federal Food,  
3           Drug, and Cosmetic Act (21 U.S.C. 355c(e)(1)) is  
4           amended by adding at the end the following: “The  
5           Secretary shall determine whether subparagraph (A)  
6           or (B) of subsection (a)(1) applies with respect to an  
7           application before the date on which the applicant is  
8           required to submit the initial pediatric study plan  
9           under paragraph (2)(A).”.

10          (3) CLARIFYING APPLICABILITY.—Section  
11          505B(a)(1) of the Federal Food, Drug, and Cos-  
12          metic Act (21 U.S.C. 355c(a)(1)) is amended by  
13          adding at the end the following:

14               “(C) RULE OF CONSTRUCTION.—No appli-  
15               cation that is subject to the requirements of  
16               subparagraph (B) shall be subject to the re-  
17               quirements of subparagraph (A), and no appli-  
18               cation (or supplement to an application) that is  
19               subject to the requirements of subparagraph  
20               (A) shall be subject to the requirements of sub-  
21               paragraph (B).”.

22          (4) CONFORMING AMENDMENTS.—Section  
23          505B(a) of the Federal Food, Drug, and Cosmetic  
24          Act (21 U.S.C. 355c(a)) is amended—



1 (A) in paragraph (3)(C), as redesignated  
2 by paragraph (1)(A) of this subsection, by  
3 striking “investigations described in this para-  
4 graph” and inserting “investigations referred to  
5 in subparagraph (A)”; and

6 (B) in paragraph (3)(D), as redesignated  
7 by paragraph (1)(A) of this subsection, by  
8 striking “the assessments under paragraph  
9 (2)(B)” and inserting “the assessments re-  
10 quired under paragraph (1)(A)”.

11 (b) GUIDANCE.—The Secretary of Health and  
12 Human Services, acting through the Commissioner of  
13 Food and Drugs, shall—

14 (1) not later than 12 months after the date of  
15 enactment of this Act, issue draft guidance on the  
16 implementation of the amendments made by sub-  
17 section (a); and

18 (2) not later than 12 months after closing the  
19 comment period on such draft guidance, finalize  
20 such guidance.

21 (c) APPLICABILITY.—The amendments made by this  
22 section apply with respect to any application under section  
23 505(b) of the Federal Food, Drug, and Cosmetic Act (21  
24 U.S.C. 355(b)) and any application under section 351(a)  
25 of the Public Health Service Act (42 U.S.C. 262(a)), that

1 is submitted on or after the date that is 3 years after the  
2 date of enactment of this Act.

3 (d) REPORTS TO CONGRESS.—

4 (1) SECRETARY OF HEALTH AND HUMAN SERV-  
5 ICES.—Not later than 6 years after the date of en-  
6 actment of this Act, the Secretary of Health and  
7 Human Services shall submit to the Committee on  
8 Energy and Commerce of the House of Representa-  
9 tives and the Committee on Health, Education,  
10 Labor, and Pensions of the Senate a report on the  
11 Secretary's efforts, in coordination with industry, to  
12 ensure implementation of the amendments made by  
13 subsection (a).

14 (2) GAO STUDY AND REPORT.—

15 (A) STUDY.—Not later than 8 years after  
16 the date of enactment of this Act, the Comp-  
17 troller General of the United States shall con-  
18 duct a study of the effectiveness of requiring  
19 assessments and investigations described in sec-  
20 tion 505B of the Federal Food, Drug, and Cos-  
21 metic Act (21 U.S.C.355c), as amended by sub-  
22 section (a), in the development of drugs and bi-  
23 ological products for pediatric cancer indica-  
24 tions, including consideration of any benefits to,

1 or burdens on, pediatric cancer drug develop-  
2 ment.

3 (B) FINDINGS.—Not later than 10 years  
4 after the date of enactment of this Act, the  
5 Comptroller General shall submit to the Com-  
6 mittee on Energy and Commerce of the House  
7 of Representatives and the Committee on  
8 Health, Education, Labor, and Pensions of the  
9 Senate a report containing the findings of the  
10 study conducted under subparagraph (A).

11 **SEC. 802. ENSURING COMPLETION OF PEDIATRIC STUDY**  
12 **REQUIREMENTS.**

13 (a) EQUAL ACCOUNTABILITY FOR PEDIATRIC STUDY  
14 REQUIREMENTS.—Section 505B(d) of the Federal Food,  
15 Drug, and Cosmetic Act (21 U.S.C. 355c(d)) is amend-  
16 ed—

17 (1) in paragraph (1), by striking “Beginning  
18 270” and inserting “NONCOMPLIANCE LETTER.—  
19 Beginning 270”;

20 (2) in paragraph (2)—

21 (A) by striking “The drug or” and insert-  
22 ing “EFFECT OF NONCOMPLIANCE.—The drug  
23 or”; and

24 (B) by striking “(except that the drug or  
25 biological product shall not be subject to action

1 under section 303)” and inserting “(except that  
2 the drug or biological product shall be subject  
3 to action under section 303 only if such person  
4 demonstrated a lack of due diligence in satis-  
5 fying the applicable requirement)”;

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

7 “(3) LIMITATION.—The Secretary shall not  
8 issue enforcement actions under section 303 for fail-  
9 ures under this subsection in the case of a drug or  
10 biological product that is no longer marketed.”.

11 (b) DUE DILIGENCE.—Section 505B(d) of the Fed-  
12 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)),  
13 as amended by subsection (a), is further amended by add-  
14 ing at the end the following:

15 “(4) DUE DILIGENCE.—Before the Secretary  
16 may conclude that a person failed to submit or oth-  
17 erwise meet a requirement as described in the mat-  
18 ter preceding paragraph (1), the Secretary shall—

19 “(A) issue a noncompliance letter pursuant  
20 to paragraph (1);

21 “(B) provide such person with a 45-day  
22 period beginning on the date of receipt of such  
23 noncompliance letter to respond in writing as  
24 set forth in such paragraph; and

1                   “(C) after reviewing such written response,  
2                   determine whether the person demonstrated a  
3                   lack of due diligence in satisfying such require-  
4                   ment.”.

5           (c)       CONFORMING        AMENDMENTS.—Section  
6   303(f)(4)(A) of the Federal Food, Drug, and Cosmetic Act  
7   (21 U.S.C. 333(f)(4)(A)) is amended by striking “or 505–  
8   1” and inserting “505–1, or 505B”.

9           (d) TRANSITION RULE.—The Secretary of Health  
10 and Human Services may take enforcement action under  
11 section 303 of the Federal Food, Drug, and Cosmetic Act  
12 (21 U.S.C. 333) only for failures described in section  
13 505B(d) of such Act (21 U.S.C. 355c(d)) that occur on  
14 or after the date that is 180 days after the date of enact-  
15 ment of this Act.

16 **SEC. 803. FDA REPORT ON PREA ENFORCEMENT.**

17       Section 508(b) of the Food and Drug Administration  
18 Safety and Innovation Act (21 U.S.C. 355c–1(b)) is  
19 amended—

20           (1) in paragraph (11), by striking the semicolon  
21       at the end and inserting “, including an evaluation  
22       of compliance with deadlines provided for in defer-  
23       rals and deferral extensions;”;

24           (2) in paragraph (15), by striking “and” at the  
25       end;

1           (3) in paragraph (16), by striking the period at  
2           the end and inserting “; and”; and

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

4           “(17) a listing of penalties, settlements, or pay-  
5           ments under section 303 of the Federal Food, Drug,  
6           and Cosmetic Act (21 U.S.C. 353) for failure to  
7           comply with requirements under such section 505B,  
8           including, for each penalty, settlement, or payment,  
9           the name of the drug, the sponsor thereof, and the  
10          amount of the penalty, settlement, or payment im-  
11          posed; and”.

12 **SEC. 804. EXTENSION OF AUTHORITY TO ISSUE PRIORITY**  
13 **REVIEW VOUCHERS TO ENCOURAGE TREAT-**  
14 **MENTS FOR RARE PEDIATRIC DISEASES.**

15          (a) EXTENSION.—Paragraph (5) of section 529(b) of  
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
17 360ff(b)) is amended by striking “December 20, 2024, un-  
18 less” and all that follows through the period at the end  
19 and inserting “September 30, 2029.”.

20          (b) USER FEE PAYMENT.—Section 529(c)(4) of the  
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22 360ff(c)(4)) is amended by striking subparagraph (A) and  
23 inserting the following:

24                 “(A) IN GENERAL.—The priority review  
25                 user fee required by this subsection shall be due

1           upon the submission of a human drug applica-  
2           tion under section 505(b)(1) or section 351(a)  
3           of the Public Health Service Act for which the  
4           priority review voucher is used. All other user  
5           fees associated with the human drug application  
6           shall be due as required by the Secretary or  
7           under applicable law.”.

8           (c) GAO REPORT ON EFFECTIVENESS OF RARE PE-  
9           DIATRIC DISEASE PRIORITY VOUCHER AWARDS IN  
10          INCENTIVIZING RARE PEDIATRIC DISEASE DRUG DEVEL-  
11          OPMENT.—

12           (1) GAO STUDY.—

13           (A) STUDY.—The Comptroller General of  
14           the United States shall conduct a study of the  
15           effectiveness of awarding rare pediatric disease  
16           priority vouchers under section 529 of the Fed-  
17           eral Food, Drug, and Cosmetic Act (21 U.S.C.  
18           360ff), as amended by subsection (a), in the de-  
19           velopment of human drug products that treat or  
20           prevent rare pediatric diseases (as defined in  
21           such section 529).

22           (B) CONTENTS OF STUDY.—In conducting  
23           the study under subparagraph (A), the Comp-  
24           troller General shall examine the following:

1 (i) The indications for each drug or  
2 biological product that—

3 (I) is the subject of a rare pedi-  
4 atric disease product application (as  
5 defined in section 529 of the Federal  
6 Food, Drug, and Cosmetic Act (21  
7 U.S.C. 360ff)) for which a priority re-  
8 view voucher was awarded; and

9 (II) was approved under section  
10 505 of the Federal Food, Drug, and  
11 Cosmetic Act (42 U.S.C. 355) or li-  
12 censed under section 351 of the Pub-  
13 lic Health Service Act (42 U.S.C.  
14 262).

15 (ii) Whether, and to what extent, an  
16 unmet need related to the treatment or  
17 prevention of a rare pediatric disease was  
18 met through the approval or licensure of  
19 such a drug or biological product.

20 (iii) The size of the company to which  
21 a priority review voucher was awarded  
22 under section 529 of the Federal Food,  
23 Drug, and Cosmetic Act (21 U.S.C. 360ff)  
24 for such a drug or biological product.



1 (iv) The value of such priority review  
2 voucher if transferred.

3 (v) Identification of each drug for  
4 which a priority review voucher awarded  
5 under such section 529 was used.

6 (vi) The size of the company using  
7 each priority review voucher awarded  
8 under such section 529.

9 (vii) The length of the period of time  
10 between the date on which a priority re-  
11 view voucher was awarded under such sec-  
12 tion 529 and the date on which it was  
13 used.

14 (viii) Whether, and to what extent, an  
15 unmet need related to the treatment or  
16 prevention of a rare pediatric disease was  
17 met through the approval under section  
18 505 of the Federal Food, Drug, and Cos-  
19 metic Act (42 U.S.C. 355) or licensure  
20 under section 351 of the Public Health  
21 Service Act (42 U.S.C. 262) of a drug for  
22 which a priority review voucher was used.

23 (ix) Whether, and to what extent,  
24 companies were motivated by the avail-  
25 ability of priority review vouchers under

1 section 529 of the Federal Food, Drug,  
2 and Cosmetic Act (21 U.S.C. 360ff) to at-  
3 tempt to develop a drug for a rare pedi-  
4 atric disease.

5 (x) Whether, and to what extent, pedi-  
6 atric review vouchers awarded under such  
7 section were successful in stimulating de-  
8 velopment and expedited patient access to  
9 drug products for treatment or prevention  
10 of a rare pediatric disease that wouldn't  
11 otherwise take place without the incentive  
12 provided by such vouchers.

13 (xi) The impact of such priority re-  
14 view vouchers on the workload, review  
15 process, and public health prioritization ef-  
16 forts of the Food and Drug Administra-  
17 tion.

18 (xii) Any other incentives in Federal  
19 law that exist for companies developing  
20 drugs or biological products described in  
21 clause (i).

22 (2) REPORT ON FINDINGS.—Not later than 5  
23 years after the date of the enactment of this Act, the  
24 Comptroller General of the United States shall sub-  
25 mit to the Committee on Energy and Commerce of

1 the House of Representatives and the Committee on  
2 Health, Education, Labor, and Pensions of the Sen-  
3 ate a report containing the findings of the study  
4 conducted under paragraph (1).

5 **SEC. 805. LIMITATIONS ON EXCLUSIVE APPROVAL OR LI-**  
6 **CENSURE OF ORPHAN DRUGS.**

7 (a) IN GENERAL.—Section 527 of the Federal Food,  
8 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

9 (1) in subsection (a), in the matter following  
10 paragraph (2), by striking “same disease or condi-  
11 tion” and inserting “same approved use or indica-  
12 tion within such rare disease or condition”;

13 (2) in subsection (b)—

14 (A) in the matter preceding paragraph (1),  
15 by striking “same rare disease or condition”  
16 and inserting “same approved use or indication  
17 for which such 7-year period applies to such al-  
18 ready approved or licensed drug”; and

19 (B) in paragraph (1), by inserting “, relat-  
20 ing to the approved use or indication,” after  
21 “the needs”;

22 (3) in subsection (c)(1), by striking “same rare  
23 disease or condition as the already approved drug”  
24 and inserting “same use or indication for which the

1 already approved or licensed drug was approved or  
2 licensed”; and

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

4 “(f) APPROVED USE OR INDICATION DEFINED.—In  
5 this section, the term ‘approved use or indication’ means  
6 the use or indication approved under section 505 of this  
7 Act or licensed under section 351 of the Public Health  
8 Service Act for a drug designated under section 526 for  
9 a rare disease or condition.”.

10 (b) APPLICATION OF AMENDMENTS.—The amend-  
11 ments made by subsection (a) shall apply with respect to  
12 any drug designated under section 526 of the Federal  
13 Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regard-  
14 less of the date on which the drug was so designated, and  
15 regardless of the date on which the drug was approved  
16 under section 505 of such Act (21 U.S.C. 355) or licensed  
17 under section 351 of the Public Health Service Act (42  
18 U.S.C. 262).

19 **Subtitle B—United States-Abraham**  
20 **Accords Cooperation and Security**

21 **SEC. 811. ESTABLISHMENT OF ABRAHAM ACCORDS OFFICE**

22 **WITHIN FOOD AND DRUG ADMINISTRATION.**

23 (a) IN GENERAL.—Chapter X of the Federal Food,  
24 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-  
25 ed by adding at the end the following:

1   **“SEC. 1015. ABRAHAM ACCORDS OFFICE.**

2           “(a) IN GENERAL.—The Secretary, acting through  
3 the Commissioner of Food and Drugs, shall establish with-  
4 in the Food and Drug Administration an office, to be  
5 known as the Abraham Accords Office, to be headed by  
6 a director.

7           “(b) OFFICE.—Not later than 2 years after the date  
8 of enactment of this section, the Secretary shall—

9                   “(1) in consultation with the governments of  
10 Abraham Accords countries, as well as appropriate  
11 United States Government diplomatic and security  
12 personnel—

13                           “(A) select the location of the Abraham  
14 Accords Office in an Abraham Accords country;  
15 and

16                           “(B) establish such office; and

17           “(2) assign to such office such personnel of the  
18 Food and Drug Administration as the Secretary de-  
19 termines necessary to carry out the functions of  
20 such office.

21           “(c) DUTIES.—The Secretary, acting through the Di-  
22 rector of the Abraham Accords Office, shall—

23                   “(1) after the Abraham Accords Office is estab-  
24 lished—

25                           “(A) as part of the Food and Drug Admin-  
26 istration’s work to strengthen the international

1 oversight of regulated commodities, provide  
2 technical assistance to regulatory partners in  
3 Abraham Accords countries on strengthening  
4 regulatory oversight and converging regulatory  
5 requirements for the oversight of regulated  
6 products, including good manufacturing prac-  
7 tices and other issues relevant to manufacturing  
8 medical products that are regulated by the  
9 Food and Drug Administration; and

10 “(B) facilitate interactions between the  
11 Food and Drug Administration and interested  
12 parties in Abraham Accords countries, including  
13 by sharing relevant information regarding  
14 United States regulatory pathways with such  
15 parties, and facilitate feedback on the research,  
16 development, and manufacturing of products  
17 regulated in accordance with this Act; and

18 “(2) carry out other functions and activities as  
19 the Secretary determines to be necessary to carry  
20 out this section.

21 “(d) ABRAHAM ACCORDS COUNTRY DEFINED.—In  
22 this section, the term ‘Abraham Accords country’ means  
23 a country identified by the Department of State as having  
24 signed the Abraham Accords Declaration.

1       “(e) NATIONAL SECURITY.—Nothing in this section  
2 shall be construed to require any action inconsistent with  
3 a national security recommendation provided by the Fed-  
4 eral Government.”.

5       (b) REPORT TO CONGRESS.—

6           (1) IN GENERAL.—Not later than 3 years after  
7 the date of enactment of this Act, the Secretary of  
8 Health and Human Services shall submit to the  
9 Congress a report on the Abraham Accords Office,  
10 including—

11           (A) an evaluation of how the Office has ad-  
12 vanced progress toward conformance with Food  
13 and Drug Administration regulatory require-  
14 ments by manufacturers in the Abraham Ac-  
15 cords countries;

16           (B) a numerical count of parties that the  
17 Office has helped facilitate interactions or feed-  
18 back pursuant to section 1015(c)(1)(B) of the  
19 Federal Food, Drug, and Cosmetic Act (as  
20 added by subsection (a));

21           (C) a summary of technical assistance pro-  
22 vided to regulatory partners in Abraham Ac-  
23 cords countries pursuant to subparagraph (A)  
24 of such section 1015(c)(1); and

1 (D) recommendations for increasing and  
2 improving coordination between the Food and  
3 Drug Administration and entities in Abraham  
4 Accords countries.

5 (2) ABRAHAM ACCORDS COUNTRY DEFINED.—  
6 In this subsection, the term “Abraham Accords  
7 country” has the meaning given such term in section  
8 1015(d) of the Federal Food, Drug, and Cosmetic  
9 Act (as added by subsection (a)).

10 **TITLE IX—LOWERING**  
11 **PRESCRIPTION DRUG COSTS**

12 **SEC. 901. OVERSIGHT OF PHARMACY BENEFIT MANAGE-**  
13 **MENT SERVICES.**

14 (a) PUBLIC HEALTH SERVICE ACT.—Title XXVII of  
15 the Public Health Service Act (42 U.S.C. 300gg et seq.)  
16 is amended—

17 (1) in part D (42 U.S.C. 300gg–111 et seq.),  
18 by adding at the end the following new section:

19 **“SEC. 2799A–11. OVERSIGHT OF ENTITIES THAT PROVIDE**  
20 **PHARMACY BENEFIT MANAGEMENT SERV-**  
21 **ICES.**

22 “(a) IN GENERAL.—For plan years beginning on or  
23 after the date that is 30 months after the date of enact-  
24 ment of this section (referred to in this subsection and  
25 subsection (b) as the ‘effective date’), a group health plan



1 or a health insurance issuer offering group health insur-  
2 ance coverage, or an entity providing pharmacy benefit  
3 management services on behalf of such a plan or issuer,  
4 shall not enter into a contract, including an extension or  
5 renewal of a contract, entered into on or after the effective  
6 date, with an applicable entity unless such applicable enti-  
7 ty agrees to—

8           “(1) not limit or delay the disclosure of infor-  
9 mation to the group health plan (including such a  
10 plan offered through a health insurance issuer) in  
11 such a manner that prevents an entity providing  
12 pharmacy benefit management services on behalf of  
13 a group health plan or health insurance issuer offer-  
14 ing group health insurance coverage from making  
15 the reports described in subsection (b); and

16           “(2) provide the entity providing pharmacy ben-  
17 efit management services on behalf of a group health  
18 plan or health insurance issuer relevant information  
19 necessary to make the reports described in sub-  
20 section (b).

21           “(b) REPORTS.—

22           “(1) IN GENERAL.—For plan years beginning  
23 on or after the effective date, in the case of any con-  
24 tract between a group health plan or a health insur-  
25 ance issuer offering group health insurance coverage

1        offered in connection with such a plan and an entity  
2        providing pharmacy benefit management services on  
3        behalf of such plan or issuer, including an extension  
4        or renewal of such a contract, entered into on or  
5        after the effective date, the entity providing pharmacy  
6        benefit management services on behalf of such  
7        a group health plan or health insurance issuer, not  
8        less frequently than every 6 months (or, at the request  
9        of a group health plan, not less frequently  
10       than quarterly, and under the same conditions,  
11       terms, and cost of the semiannual report under this  
12       subsection), shall submit to the group health plan a  
13       report in accordance with this section. Each such report  
14       shall be made available to such group health  
15       plan in plain language, in a machine-readable format,  
16       and as the Secretary may determine, other formats.  
17       Each such report shall include the information  
18       described in paragraph (2).

19            “(2) INFORMATION DESCRIBED.—For purposes  
20       of paragraph (1), the information described in this  
21       paragraph is, with respect to drugs covered by a  
22       group health plan or group health insurance coverage  
23       offered by a health insurance issuer in connection  
24       with a group health plan during each reporting  
25       period—

1           “(A) in the case of a group health plan  
2           that is offered by a specified large employer or  
3           that is a specified large plan, and is not offered  
4           as health insurance coverage, or in the case of  
5           health insurance coverage for which the election  
6           under paragraph (3) is made for the applicable  
7           reporting period—

8           “(i) a list of drugs for which a claim  
9           was filed and, with respect to each such  
10          drug on such list—

11           “(I) the contracted compensation  
12           paid by the group health plan or  
13           health insurance issuer for each cov-  
14           ered drug (identified by the National  
15           Drug Code) to the entity providing  
16           pharmacy benefit management serv-  
17           ices or other applicable entity on be-  
18           half of the group health plan or health  
19           insurance issuer;

20           “(II) the contracted compensa-  
21           tion paid to the pharmacy, by any en-  
22           tity providing pharmacy benefit man-  
23           agement services or other applicable  
24           entity on behalf of the group health  
25           plan or health insurance issuer, for

1 each covered drug (identified by the  
2 National Drug Code);

3 “(III) for each such claim, the  
4 difference between the amount paid  
5 under subclause (I) and the amount  
6 paid under subclause (II);

7 “(IV) the proprietary name, es-  
8 tablished name or proper name, and  
9 National Drug Code;

10 “(V) for each claim for the drug  
11 (including original prescriptions and  
12 refills) and for each dosage unit of the  
13 drug for which a claim was filed, the  
14 type of dispensing channel used to  
15 furnish the drug, including retail, mail  
16 order, or specialty pharmacy;

17 “(VI) with respect to each drug  
18 dispensed, for each type of dispensing  
19 channel (including retail, mail order,  
20 or specialty pharmacy)—

21 “(aa) whether such drug is a  
22 brand name drug or a generic  
23 drug, and—

24 “(AA) in the case of a  
25 brand name drug, the whole-

1 sale acquisition cost, listed  
2 as cost per days supply and  
3 cost per dosage unit, on the  
4 date such drug was dis-  
5 pensed; and

6 “(BB) in the case of a  
7 generic drug, the average  
8 wholesale price, listed as  
9 cost per days supply and  
10 cost per dosage unit, on the  
11 date such drug was dis-  
12 pensed; and

13 “(bb) the total number of—

14 “(AA) prescription  
15 claims (including original  
16 prescriptions and refills);

17 “(BB) participants and  
18 beneficiaries for whom a  
19 claim for such drug was  
20 filed through the applicable  
21 dispensing channel;

22 “(CC) dosage units and  
23 dosage units per fill of such  
24 drug; and

1 “(DD) days supply of  
2 such drug per fill;

3 “(VII) the net price per course of  
4 treatment or single fill, such as a 30-  
5 day supply or 90-day supply to the  
6 plan or coverage after rebates, fees,  
7 alternative discounts, or other remun-  
8 eration received from applicable enti-  
9 ties;

10 “(VIII) the total amount of out-  
11 of-pocket spending by participants  
12 and beneficiaries on such drug, in-  
13 cluding spending through copayments,  
14 coinsurance, and deductibles, but not  
15 including any amounts spent by par-  
16 ticipants and beneficiaries on drugs  
17 not covered under the plan or cov-  
18 erage, or for which no claim is sub-  
19 mitted under the plan or coverage;

20 “(IX) the total net spending on  
21 the drug;

22 “(X) the total amount received,  
23 or expected to be received, by the plan  
24 or issuer from any applicable entity in

1 rebates, fees, alternative discounts, or  
2 other remuneration;

3 “(XI) the total amount received,  
4 or expected to be received, by the enti-  
5 ty providing pharmacy benefit man-  
6 agement services, from applicable en-  
7 tities, in rebates, fees, alternative dis-  
8 counts, or other remuneration from  
9 such entities—

10 “(aa) for claims incurred  
11 during the reporting period; and

12 “(bb) that is related to utili-  
13 zation of such drug or spending  
14 on such drug; and

15 “(XII) to the extent feasible, in-  
16 formation on the total amount of re-  
17 munerated for such drug, including  
18 copayment assistance dollars paid, co-  
19 payment cards applied, or other dis-  
20 counts provided by each drug manu-  
21 facturer (or entity administering co-  
22 payment assistance on behalf of such  
23 drug manufacturer), to the partici-  
24 pants and beneficiaries enrolled in  
25 such plan or coverage;

1                   “(ii) a list of each therapeutic class  
2                   (as defined by the Secretary) for which a  
3                   claim was filed under the group health  
4                   plan or health insurance coverage during  
5                   the reporting period, and, with respect to  
6                   each such therapeutic class—

7                   “(I) the total gross spending on  
8                   drugs in such class before rebates,  
9                   price concessions, alternative dis-  
10                  counts, or other remuneration from  
11                  applicable entities;

12                  “(II) the net spending in such  
13                  class after such rebates, price conces-  
14                  sions, alternative discounts, or other  
15                  remuneration from applicable entities;

16                  “(III) the total amount received,  
17                  or expected to be received, by the enti-  
18                  ty providing pharmacy benefit man-  
19                  agement services, from applicable en-  
20                  tities, in rebates, fees, alternative dis-  
21                  counts, or other remuneration from  
22                  such entities—

23                  “(aa) for claims incurred  
24                  during the reporting period; and



1 “(bb) that is related to utili-  
2 zation of drugs or drug spending;

3 “(IV) the average net spending  
4 per 30-day supply and per 90-day  
5 supply by the plan or by the issuer  
6 with respect to such coverage and its  
7 participants and beneficiaries, among  
8 all drugs within the therapeutic class  
9 for which a claim was filed during the  
10 reporting period;

11 “(V) the number of participants  
12 and beneficiaries who filled a prescrip-  
13 tion for a drug in such class, includ-  
14 ing the National Drug Code for each  
15 such drug;

16 “(VI) if applicable, a description  
17 of the formulary tiers and utilization  
18 mechanisms (such as prior authoriza-  
19 tion or step therapy) employed for  
20 drugs in that class; and

21 “(VII) the total out-of-pocket  
22 spending under the plan or coverage  
23 by participants and beneficiaries, in-  
24 cluding spending through copayments,  
25 coinsurance, and deductibles, but not

1 including any amounts spent by par-  
2 ticipants and beneficiaries on drugs  
3 not covered under the plan or cov-  
4 erage or for which no claim is sub-  
5 mitted under the plan or coverage;

6 “(iii) with respect to any drug for  
7 which gross spending under the group  
8 health plan or health insurance coverage  
9 exceeded \$10,000 during the reporting pe-  
10 riod or, in the case that gross spending  
11 under the group health plan or coverage  
12 exceeded \$10,000 during the reporting pe-  
13 riod with respect to fewer than 50 drugs,  
14 with respect to the 50 prescription drugs  
15 with the highest spending during the re-  
16 porting period—

17 “(I) a list of all other drugs in  
18 the same therapeutic class as such  
19 drug;

20 “(II) if applicable, the rationale  
21 for the formulary placement of such  
22 drug in that therapeutic category or  
23 class, selected from a list of standard  
24 rationales established by the Sec-

1                   retary, in consultation with stake-  
2                   holders; and

3                   “(III) any change in formulary  
4                   placement compared to the prior plan  
5                   year; and

6                   “(iv) in the case that such plan or  
7                   issuer (or an entity providing pharmacy  
8                   benefit management services on behalf of  
9                   such plan or issuer) has an affiliated phar-  
10                  macy or pharmacy under common owner-  
11                  ship, including mandatory mail and spe-  
12                  cialty home delivery programs, retail and  
13                  mail auto-refill programs, and cost sharing  
14                  assistance incentives funded by an entity  
15                  providing pharmacy benefit services—

16                  “(I) an explanation of any ben-  
17                  efit design parameters that encourage  
18                  or require participants and bene-  
19                  ficiaries in the plan or coverage to fill  
20                  prescriptions at mail order, specialty,  
21                  or retail pharmacies;

22                  “(II) the percentage of total pre-  
23                  scriptions dispensed by such phar-  
24                  macies to participants or beneficiaries  
25                  in such plan or coverage; and

1                   “(III) a list of all drugs dis-  
2                   pensed by such pharmacies to partici-  
3                   pants or beneficiaries enrolled in such  
4                   plan or coverage, and, with respect to  
5                   each drug dispensed—

6                   “(aa) the amount charged,  
7                   per dosage unit, per 30-day sup-  
8                   ply, or per 90-day supply (as ap-  
9                   plicable) to the plan or issuer,  
10                  and to participants and bene-  
11                  ficiaries;

12                  “(bb) the median amount  
13                  charged to such plan or issuer,  
14                  and the interquartile range of the  
15                  costs, per dosage unit, per 30-  
16                  day supply, and per 90-day sup-  
17                  ply, including amounts paid by  
18                  the participants and bene-  
19                  ficiaries, when the same drug is  
20                  dispensed by other pharmacies  
21                  that are not affiliated with or  
22                  under common ownership with  
23                  the entity and that are included  
24                  in the pharmacy network of such  
25                  plan or coverage;

1                   “(cc) the lowest cost per  
2                   dosage unit, per 30-day supply  
3                   and per 90-day supply, for each  
4                   such drug, including amounts  
5                   charged to the plan or coverage  
6                   and to participants and bene-  
7                   ficiaries, that is available from  
8                   any pharmacy included in the  
9                   network of such plan or coverage;  
10                  and

11                  “(dd) the net acquisition  
12                  cost per dosage unit, per 30-day  
13                  supply, and per 90-day supply, if  
14                  such drug is subject to a max-  
15                  imum price discount; and

16                  “(B) with respect to any group health  
17                  plan, including group health insurance coverage  
18                  offered in connection with such a plan, regard-  
19                  less of whether the plan or coverage is offered  
20                  by a specified large employer or whether it is a  
21                  specified large plan—

22                  “(i) a summary document for the  
23                  group health plan that includes such infor-  
24                  mation described in clauses (i) through (iv)  
25                  of subparagraph (A), as specified by the

1 Secretary through guidance, program in-  
2 struction, or otherwise (with no require-  
3 ment of notice and comment rulemaking),  
4 that the Secretary determines useful to  
5 group health plans for purposes of select-  
6 ing pharmacy benefit management serv-  
7 ices, such as an estimated net price to  
8 group health plan and participant or bene-  
9 ficiary, a cost per claim, the fee structure  
10 or reimbursement model, and estimated  
11 cost per participant or beneficiary;

12 “(ii) a summary document for plans  
13 and issuers to provide to participants and  
14 beneficiaries, which shall be made available  
15 to participants or beneficiaries upon re-  
16 quest to their group health plan (including  
17 in the case of group health insurance cov-  
18 erage offered in connection with such a  
19 plan), that—

20 “(I) contains such information  
21 described in clauses (iii), (iv), (v), and  
22 (vi), as applicable, as specified by the  
23 Secretary through guidance, program  
24 instruction, or otherwise (with no re-  
25 quirement of notice and comment

1 rulemaking) that the Secretary deter-  
2 mines useful to participants or bene-  
3 ficiaries in better understanding the  
4 plan or coverage or benefits under  
5 such plan or coverage;

6 “(II) contains only aggregate in-  
7 formation; and

8 “(III) states that participants  
9 and beneficiaries may request specific,  
10 claims-level information required to be  
11 furnished under subsection (c) from  
12 the group health plan or health insur-  
13 ance issuer; and

14 “(iii) with respect to drugs covered by  
15 such plan or coverage during such report-  
16 ing period—

17 “(I) the total net spending by the  
18 plan or coverage for all such drugs;

19 “(II) the total amount received,  
20 or expected to be received, by the plan  
21 or issuer from any applicable entity in  
22 rebates, fees, alternative discounts, or  
23 other remuneration; and

24 “(III) to the extent feasible, in-  
25 formation on the total amount of re-

1                   muneration for such drugs, including  
2                   copayment assistance dollars paid, co-  
3                   payment cards applied, or other dis-  
4                   counts provided by each drug manu-  
5                   facturer (or entity administering co-  
6                   payment assistance on behalf of such  
7                   drug manufacturer) to participants  
8                   and beneficiaries;

9                   “(iv) amounts paid directly or indi-  
10                  rectly in rebates, fees, or any other type of  
11                  compensation (as defined in section  
12                  408(b)(2)(B)(ii)(dd)(AA) of the Employee  
13                  Retirement Income Security Act) to bro-  
14                  kerage firms, brokers, consultants, advi-  
15                  sors, or any other individual or firm, for—

16                  “(I) the referral of the group  
17                  health plan’s or health insurance  
18                  issuer’s business to an entity pro-  
19                  viding pharmacy benefit management  
20                  services, including the identity of the  
21                  recipient of such amounts;

22                  “(II) consideration of the entity  
23                  providing pharmacy benefit manage-  
24                  ment services by the group health  
25                  plan or health insurance issuer; or



1                   “(III) the retention of the entity  
2                   by the group health plan or health in-  
3                   surance issuer;

4                   “(v) an explanation of any benefit de-  
5                   sign parameters that encourage or require  
6                   participants and beneficiaries in such plan  
7                   or coverage to fill prescriptions at mail  
8                   order, specialty, or retail pharmacies that  
9                   are affiliated with or under common own-  
10                  ership with the entity providing pharmacy  
11                  benefit management services under such  
12                  plan or coverage, including mandatory mail  
13                  and specialty home delivery programs, re-  
14                  tail and mail auto-refill programs, and  
15                  cost-sharing assistance incentives directly  
16                  or indirectly funded by such entity; and

17                  “(vi) total gross spending on all drugs  
18                  under the plan or coverage during the re-  
19                  porting period.

20                  “(3) OPT-IN FOR GROUP HEALTH INSURANCE  
21                  COVERAGE OFFERED BY A SPECIFIED LARGE EM-  
22                  PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In  
23                  the case of group health insurance coverage offered  
24                  in connection with a group health plan that is of-  
25                  fered by a specified large employer or is a specified

1 large plan, such group health plan may, on an an-  
2 nual basis, for plan years beginning on or after the  
3 date that is 30 months after the date of enactment  
4 of this section, elect to require an entity providing  
5 pharmacy benefit management services on behalf of  
6 the health insurance issuer to submit to such group  
7 health plan a report that includes all of the informa-  
8 tion described in paragraph (2)(A), in addition to  
9 the information described in paragraph (2)(B).

10 “(4) PRIVACY REQUIREMENTS.—

11 “(A) IN GENERAL.—An entity providing  
12 pharmacy benefit management services on be-  
13 half of a group health plan or a health insur-  
14 ance issuer offering group health insurance cov-  
15 erage shall report information under paragraph  
16 (1) in a manner consistent with the privacy reg-  
17 ulations promulgated under section 13402(a) of  
18 the Health Information Technology for Eco-  
19 nomic and Clinical Health Act and consistent  
20 with the privacy regulations promulgated under  
21 the Health Insurance Portability and Account-  
22 ability Act of 1996 in part 160 and subparts A  
23 and E of part 164 of title 45, Code of Federal  
24 Regulations (or successor regulations) (referred  
25 to in this paragraph as the ‘HIPAA privacy

1 regulations’) and shall restrict the use and dis-  
2 closure of such information according to such  
3 privacy regulations and such HIPAA privacy  
4 regulations.

5 “(B) ADDITIONAL REQUIREMENTS.—

6 “(i) IN GENERAL.—An entity pro-  
7 viding pharmacy benefit management serv-  
8 ices on behalf of a group health plan or  
9 health insurance issuer offering group  
10 health insurance coverage that submits a  
11 report under paragraph (1) shall ensure  
12 that such report contains only summary  
13 health information, as defined in section  
14 164.504(a) of title 45, Code of Federal  
15 Regulations (or successor regulations).

16 “(ii) RESTRICTIONS.—In carrying out  
17 this subsection, a group health plan shall  
18 comply with section 164.504(f) of title 45,  
19 Code of Federal Regulations (or a suc-  
20 cessor regulation), and a plan sponsor shall  
21 act in accordance with the terms of the  
22 agreement described in such section.

23 “(C) RULE OF CONSTRUCTION.—

24 “(i) Nothing in this section shall be  
25 construed to modify the requirements for

1           the creation, receipt, maintenance, or  
2           transmission of protected health informa-  
3           tion under the HIPAA privacy regulations.

4           “(ii) Nothing in this section shall be  
5           construed to affect the application of any  
6           Federal or State privacy or civil rights law,  
7           including the HIPAA privacy regulations,  
8           the Genetic Information Nondiscrimination  
9           Act of 2008 (Public Law 110–233) (in-  
10          cluding the amendments made by such  
11          Act), the Americans with Disabilities Act  
12          of 1990 (42 U.S.C. 12101 et sec), section  
13          504 of the Rehabilitation Act of 1973 (29  
14          U.S.C. 794), section 1557 of the Patient  
15          Protection and Affordable Care Act (42  
16          U.S.C. 18116), title VI of the Civil Rights  
17          Act of 1964 (42 U.S.C. 2000d), and title  
18          VII of the Civil Rights Act of 1964 (42  
19          U.S.C. 2000e).

20          “(D) WRITTEN NOTICE.—Each plan year,  
21          group health plans, including with respect to  
22          group health insurance coverage offered in con-  
23          nection with a group health plan, shall provide  
24          to each participant or beneficiary written notice  
25          informing the participant or beneficiary of the

1 requirement for entities providing pharmacy  
2 benefit management services on behalf of the  
3 group health plan or health insurance issuer of-  
4 fering group health insurance coverage to sub-  
5 mit reports to group health plans under para-  
6 graph (1), as applicable, which may include in-  
7 corporating such notification in plan documents  
8 provided to the participant or beneficiary, or  
9 providing individual notification.

10 “(E) LIMITATION TO BUSINESS ASSOCI-  
11 ATES.—A group health plan receiving a report  
12 under paragraph (1) may disclose such informa-  
13 tion only to the entity from which the report  
14 was received or to that entity’s business associ-  
15 ates as defined in section 160.103 of title 45,  
16 Code of Federal Regulations (or successor regu-  
17 lations) or as permitted by the HIPAA privacy  
18 regulations.

19 “(F) CLARIFICATION REGARDING PUBLIC  
20 DISCLOSURE OF INFORMATION.—Nothing in  
21 this section shall prevent an entity providing  
22 pharmacy benefit management services on be-  
23 half of a group health plan or health insurance  
24 issuer offering group health insurance coverage,  
25 from placing reasonable restrictions on the pub-

1           lic disclosure of the information contained in a  
2           report described in paragraph (1), except that  
3           such plan, issuer, or entity may not—

4                   “(i) restrict disclosure of such report  
5                   to the Department of Health and Human  
6                   Services, the Department of Labor, or the  
7                   Department of the Treasury; or

8                   “(ii) prevent disclosure for the pur-  
9                   poses of subsection (c), or any other public  
10                  disclosure requirement under this section.

11               “(G) LIMITED FORM OF REPORT.—The  
12               Secretary shall define through rulemaking a  
13               limited form of the report under paragraph (1)  
14               required with respect to any group health plan  
15               established by a plan sponsor that is, or is af-  
16               filiated with, a drug manufacturer, drug whole-  
17               saler, or other direct participant in the drug  
18               supply chain, in order to prevent anti-competi-  
19               tive behavior.

20               “(5) STANDARD FORMAT AND REGULATIONS.—

21                   “(A) IN GENERAL.—Not later than 18  
22                   months after the date of enactment of this sec-  
23                   tion, the Secretary shall specify through rule-  
24                   making a standard format for entities providing  
25                   pharmacy benefit management services on be-

1 half of group health plans and health insurance  
2 issuers offering group health insurance cov-  
3 erage, to submit reports required under para-  
4 graph (1).

5 “(B) ADDITIONAL REGULATIONS.—Not  
6 later than 18 months after the date of enact-  
7 ment of this section, the Secretary shall,  
8 through rulemaking, promulgate any other final  
9 regulations necessary to implement the require-  
10 ments of this section. In promulgating such  
11 regulations, the Secretary shall, to the extent  
12 practicable, align the reporting requirements  
13 under this section with the reporting require-  
14 ments under section 2799A–10.

15 “(c) REQUIREMENT TO PROVIDE INFORMATION TO  
16 PARTICIPANTS OR BENEFICIARIES.—A group health plan,  
17 including with respect to group health insurance coverage  
18 offered in connection with a group health plan, upon re-  
19 quest of a participant or beneficiary, shall provide to such  
20 participant or beneficiary—

21 “(1) the summary document described in sub-  
22 section (b)(2)(B)(ii); and

23 “(2) the information described in subsection  
24 (b)(2)(A)(i)(III) with respect to a claim made by or  
25 on behalf of such participant or beneficiary.

1 “(d) ENFORCEMENT.—

2 “(1) IN GENERAL.—The Secretary shall enforce  
3 this section. The enforcement authority under this  
4 subsection shall apply only with respect to group  
5 health plans (including group health insurance cov-  
6 erage offered in connection with such a plan) to  
7 which the requirements of subparts I and II of part  
8 A and part D apply in accordance with section 2722,  
9 and with respect to entities providing pharmacy ben-  
10 efit management services on behalf of such plans  
11 and applicable entities providing services on behalf  
12 of such plans.

13 “(2) FAILURE TO PROVIDE INFORMATION.—A  
14 group health plan, a health insurance issuer offering  
15 group health insurance coverage, an entity providing  
16 pharmacy benefit management services on behalf of  
17 such a plan or issuer, or an applicable entity pro-  
18 viding services on behalf of such a plan or issuer  
19 that violates subsection (a); an entity providing  
20 pharmacy benefit management services on behalf of  
21 such a plan or issuer that fails to provide the infor-  
22 mation required under subsection (b); or a group  
23 health plan that fails to provide the information re-  
24 quired under subsection (c), shall be subject to a  
25 civil monetary penalty in the amount of \$10,000 for



1 each day during which such violation continues or  
2 such information is not disclosed or reported.

3 “(3) FALSE INFORMATION.—A health insurance  
4 issuer, an entity providing pharmacy benefit man-  
5 agement services, or a third party administrator pro-  
6 viding services on behalf of such issuer offered by a  
7 health insurance issuer that knowingly provides false  
8 information under this section shall be subject to a  
9 civil monetary penalty in an amount not to exceed  
10 \$100,000 for each item of false information. Such  
11 civil monetary penalty shall be in addition to other  
12 penalties as may be prescribed by law.

13 “(4) PROCEDURE.—The provisions of section  
14 1128A of the Social Security Act, other than sub-  
15 sections (a) and (b) and the first sentence of sub-  
16 section (c)(1) of such section shall apply to civil  
17 monetary penalties under this subsection in the  
18 same manner as such provisions apply to a penalty  
19 or proceeding under such section.

20 “(5) WAIVERS.—The Secretary may waive pen-  
21 alties under paragraph (2), or extend the period of  
22 time for compliance with a requirement of this sec-  
23 tion, for an entity in violation of this section that  
24 has made a good-faith effort to comply with the re-  
25 quirements in this section.

1       “(e) RULE OF CONSTRUCTION.—Nothing in this sec-  
2       tion shall be construed to permit a health insurance issuer,  
3       group health plan, entity providing pharmacy benefit man-  
4       agement services on behalf of a group health plan or  
5       health insurance issuer, or other entity to restrict disclo-  
6       sure to, or otherwise limit the access of, the Secretary to  
7       a report described in subsection (b)(1) or information re-  
8       lated to compliance with subsections (a), (b), (c), or (d)  
9       by such issuer, plan, or entity.

10       “(f) DEFINITIONS.—In this section:

11               “(1) APPLICABLE ENTITY.—The term ‘applica-  
12       ble entity’ means—

13                       “(A) an applicable group purchasing orga-  
14                       nization, drug manufacturer, distributor, whole-  
15                       saler, rebate aggregator (or other purchasing  
16                       entity designed to aggregate rebates), or associ-  
17                       ated third party;

18                       “(B) any subsidiary, parent, affiliate, or  
19                       subcontractor of a group health plan, health in-  
20                       surance issuer, entity that provides pharmacy  
21                       benefit management services on behalf of such  
22                       a plan or issuer, or any entity described in sub-  
23                       paragraph (A); or

24                       “(C) such other entity as the Secretary  
25                       may specify through rulemaking.

1           “(2) APPLICABLE GROUP PURCHASING ORGANI-  
2           ZATION.—The term ‘applicable group purchasing or-  
3           ganization’ means a group purchasing organization  
4           that is affiliated with or under common ownership  
5           with an entity providing pharmacy benefit manage-  
6           ment services.

7           “(3) CONTRACTED COMPENSATION.—The term  
8           ‘contracted compensation’ means the sum of any in-  
9           gredient cost and dispensing fee for a drug (inclusive  
10          of the out-of-pocket costs to the participant or bene-  
11          ficiary), or another analogous compensation struc-  
12          ture that the Secretary may specify through regula-  
13          tions.

14          “(4) GROSS SPENDING.—The term ‘gross  
15          spending’, with respect to prescription drug benefits  
16          under a group health plan or health insurance cov-  
17          erage, means the amount spent by a group health  
18          plan or health insurance issuer on prescription drug  
19          benefits, calculated before the application of rebates,  
20          fees, alternative discounts, or other remuneration.

21          “(5) NET SPENDING.—The term ‘net spending’,  
22          with respect to prescription drug benefits under a  
23          group health plan or health insurance coverage,  
24          means the amount spent by a group health plan or  
25          health insurance issuer on prescription drug bene-

1 fits, calculated after the application of rebates, fees,  
2 alternative discounts, or other remuneration.

3 “(6) PLAN SPONSOR.—The term ‘plan sponsor’  
4 has the meaning given such term in section 3(16)(B)  
5 of the Employee Retirement Income Security Act of  
6 1974.

7 “(7) REMUNERATION.—The term ‘remunera-  
8 tion’ has the meaning given such term by the Sec-  
9 retary through rulemaking, which shall be reeval-  
10 ated by the Secretary every 5 years.

11 “(8) SPECIFIED LARGE EMPLOYER.—The term  
12 ‘specified large employer’ means, in connection with  
13 a group health plan (including group health insur-  
14 ance coverage offered in connection with such a  
15 plan) established or maintained by a single em-  
16 ployer, with respect to a calendar year or a plan  
17 year, as applicable, an employer who employed an  
18 average of at least 100 employees on business days  
19 during the preceding calendar year or plan year and  
20 who employs at least 1 employee on the first day of  
21 the calendar year or plan year.

22 “(9) SPECIFIED LARGE PLAN.—The term ‘spec-  
23 ified large plan’ means a group health plan (includ-  
24 ing group health insurance coverage offered in con-  
25 nection with such a plan) established or maintained

1 by a plan sponsor described in clause (ii) or (iii) of  
2 section 3(16)(B) of the Employee Retirement In-  
3 come Security Act of 1974 that had an average of  
4 at least 100 participants on business days during  
5 the preceding calendar year or plan year, as applica-  
6 ble.

7 “(10) WHOLESALE ACQUISITION COST.—The  
8 term ‘wholesale acquisition cost’ has the meaning  
9 given such term in section 1847A(c)(6)(B) of the  
10 Social Security Act.”; and

11 (2) in section 2723 (42 U.S.C. 300gg–22)—

12 (A) in subsection (a)—

13 (i) in paragraph (1), by inserting  
14 “(other than section 2799A–11)” after  
15 “part D”; and

16 (ii) in paragraph (2), by inserting  
17 “(other than section 2799A–11)” after  
18 “part D”; and

19 (B) in subsection (b)—

20 (i) in paragraph (1), by inserting  
21 “(other than section 2799A–11)” after  
22 “part D”;

23 (ii) in paragraph (2)(A), by inserting  
24 “(other than section 2799A–11)” after  
25 “part D”; and

1 (iii) in paragraph (2)(C)(ii), by insert-  
2 ing “(other than section 2799A–11)” after  
3 “part D”.

4 (b) EMPLOYEE RETIREMENT INCOME SECURITY ACT  
5 OF 1974.—

6 (1) IN GENERAL.—Subtitle B of title I of the  
7 Employee Retirement Income Security Act of 1974  
8 (29 U.S.C. 1021 et seq.) is amended—

9 (A) in subpart B of part 7 (29 U.S.C.  
10 1185 et seq.), by adding at the end the fol-  
11 lowing:

12 **“SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**  
13 **MACY BENEFIT MANAGEMENT SERVICES.**

14 “(a) IN GENERAL.—For plan years beginning on or  
15 after the date that is 30 months after the date of enact-  
16 ment of this section (referred to in this subsection and  
17 subsection (b) as the ‘effective date’), a group health plan  
18 or a health insurance issuer offering group health insur-  
19 ance coverage, or an entity providing pharmacy benefit  
20 management services on behalf of such a plan or issuer,  
21 shall not enter into a contract, including an extension or  
22 renewal of a contract, entered into on or after the effective  
23 date, with an applicable entity unless such applicable enti-  
24 ty agrees to—

1           “(1) not limit or delay the disclosure of infor-  
2           mation to the group health plan (including such a  
3           plan offered through a health insurance issuer) in  
4           such a manner that prevents an entity providing  
5           pharmacy benefit management services on behalf of  
6           a group health plan or health insurance issuer offer-  
7           ing group health insurance coverage from making  
8           the reports described in subsection (b); and

9           “(2) provide the entity providing pharmacy ben-  
10          efit management services on behalf of a group health  
11          plan or health insurance issuer relevant information  
12          necessary to make the reports described in sub-  
13          section (b).

14         “(b) REPORTS.—

15                 “(1) IN GENERAL.—For plan years beginning  
16                 on or after the effective date, in the case of any con-  
17                 tract between a group health plan or a health insur-  
18                 ance issuer offering group health insurance coverage  
19                 offered in connection with such a plan and an entity  
20                 providing pharmacy benefit management services on  
21                 behalf of such plan or issuer, including an extension  
22                 or renewal of such a contract, entered into on or  
23                 after the effective date, the entity providing phar-  
24                 macy benefit management services on behalf of such  
25                 a group health plan or health insurance issuer, not

1 less frequently than every 6 months (or, at the re-  
2 quest of a group health plan, not less frequently  
3 than quarterly, and under the same conditions,  
4 terms, and cost of the semiannual report under this  
5 subsection), shall submit to the group health plan a  
6 report in accordance with this section. Each such re-  
7 port shall be made available to such group health  
8 plan in plain language, in a machine-readable for-  
9 mat, and as the Secretary may determine, other for-  
10 mats. Each such report shall include the information  
11 described in paragraph (2).

12 “(2) INFORMATION DESCRIBED.—For purposes  
13 of paragraph (1), the information described in this  
14 paragraph is, with respect to drugs covered by a  
15 group health plan or group health insurance cov-  
16 erage offered by a health insurance issuer in connec-  
17 tion with a group health plan during each reporting  
18 period—

19 “(A) in the case of a group health plan  
20 that is offered by a specified large employer or  
21 that is a specified large plan, and is not offered  
22 as health insurance coverage, or in the case of  
23 health insurance coverage for which the election  
24 under paragraph (3) is made for the applicable  
25 reporting period—



1 “(i) a list of drugs for which a claim  
2 was filed and, with respect to each such  
3 drug on such list—

4 “(I) the contracted compensation  
5 paid by the group health plan or  
6 health insurance issuer for each cov-  
7 ered drug (identified by the National  
8 Drug Code) to the entity providing  
9 pharmacy benefit management serv-  
10 ices or other applicable entity on be-  
11 half of the group health plan or health  
12 insurance issuer;

13 “(II) the contracted compensa-  
14 tion paid to the pharmacy, by any en-  
15 tity providing pharmacy benefit man-  
16 agement services or other applicable  
17 entity on behalf of the group health  
18 plan or health insurance issuer, for  
19 each covered drug (identified by the  
20 National Drug Code);

21 “(III) for each such claim, the  
22 difference between the amount paid  
23 under subclause (I) and the amount  
24 paid under subclause (II);

1                   “(IV) the proprietary name, es-  
2                   tablished name or proper name, and  
3                   National Drug Code;

4                   “(V) for each claim for the drug  
5                   (including original prescriptions and  
6                   refills) and for each dosage unit of the  
7                   drug for which a claim was filed, the  
8                   type of dispensing channel used to  
9                   furnish the drug, including retail, mail  
10                  order, or specialty pharmacy;

11                  “(VI) with respect to each drug  
12                  dispensed, for each type of dispensing  
13                  channel (including retail, mail order,  
14                  or specialty pharmacy)—

15                  “(aa) whether such drug is a  
16                  brand name drug or a generic  
17                  drug, and—

18                  “(AA) in the case of a  
19                  brand name drug, the whole-  
20                  sale acquisition cost, listed  
21                  as cost per days supply and  
22                  cost per dosage unit, on the  
23                  date such drug was dis-  
24                  pensed; and

1 “(BB) in the case of a  
2 generic drug, the average  
3 wholesale price, listed as  
4 cost per days supply and  
5 cost per dosage unit, on the  
6 date such drug was dis-  
7 pensed; and

8 “(bb) the total number of—

9 “(AA) prescription  
10 claims (including original  
11 prescriptions and refills);

12 “(BB) participants and  
13 beneficiaries for whom a  
14 claim for such drug was  
15 filed through the applicable  
16 dispensing channel;

17 “(CC) dosage units and  
18 dosage units per fill of such  
19 drug; and

20 “(DD) days supply of  
21 such drug per fill;

22 “(VII) the net price per course of  
23 treatment or single fill, such as a 30-  
24 day supply or 90-day supply to the  
25 plan or coverage after rebates, fees,

1 alternative discounts, or other remuneration received from applicable entities;  
2  
3

4 “(VIII) the total amount of out-of-pocket spending by participants  
5 and beneficiaries on such drug, including spending through copayments,  
6 coinsurance, and deductibles, but not  
7 including any amounts spent by participants and beneficiaries on drugs  
8 not covered under the plan or coverage, or for which no claim is submitted under the plan or coverage;  
9  
10  
11  
12  
13

14 “(IX) the total net spending on the drug;  
15

16 “(X) the total amount received, or expected to be received, by the plan  
17 or issuer from any applicable entity in rebates, fees, alternative discounts, or  
18 other remuneration;  
19  
20

21 “(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,  
22  
23  
24  
25

1 counts, or other remuneration from  
2 such entities—

3 “(aa) for claims incurred  
4 during the reporting period; and

5 “(bb) that is related to utili-  
6 zation of such drug or spending  
7 on such drug; and

8 “(XII) to the extent feasible, in-  
9 formation on the total amount of re-  
10 muneration for such drug, including  
11 copayment assistance dollars paid, co-  
12 payment cards applied, or other dis-  
13 counts provided by each drug manu-  
14 facturer (or entity administering co-  
15 payment assistance on behalf of such  
16 drug manufacturer), to the partici-  
17 pants and beneficiaries enrolled in  
18 such plan or coverage;

19 “(ii) a list of each therapeutic class  
20 (as defined by the Secretary) for which a  
21 claim was filed under the group health  
22 plan or health insurance coverage during  
23 the reporting period, and, with respect to  
24 each such therapeutic class—

1 “(I) the total gross spending on  
2 drugs in such class before rebates,  
3 price concessions, alternative dis-  
4 counts, or other remuneration from  
5 applicable entities;

6 “(II) the net spending in such  
7 class after such rebates, price conces-  
8 sions, alternative discounts, or other  
9 remuneration from applicable entities;

10 “(III) the total amount received,  
11 or expected to be received, by the enti-  
12 ty providing pharmacy benefit man-  
13 agement services, from applicable en-  
14 tities, in rebates, fees, alternative dis-  
15 counts, or other remuneration from  
16 such entities—

17 “(aa) for claims incurred  
18 during the reporting period; and

19 “(bb) that is related to utili-  
20 zation of drugs or drug spending;

21 “(IV) the average net spending  
22 per 30-day supply and per 90-day  
23 supply by the plan or by the issuer  
24 with respect to such coverage and its  
25 participants and beneficiaries, among

1 all drugs within the therapeutic class  
2 for which a claim was filed during the  
3 reporting period;

4 “(V) the number of participants  
5 and beneficiaries who filled a prescrip-  
6 tion for a drug in such class, includ-  
7 ing the National Drug Code for each  
8 such drug;

9 “(VI) if applicable, a description  
10 of the formulary tiers and utilization  
11 mechanisms (such as prior authoriza-  
12 tion or step therapy) employed for  
13 drugs in that class; and

14 “(VII) the total out-of-pocket  
15 spending under the plan or coverage  
16 by participants and beneficiaries, in-  
17 cluding spending through copayments,  
18 coinsurance, and deductibles, but not  
19 including any amounts spent by par-  
20 ticipants and beneficiaries on drugs  
21 not covered under the plan or cov-  
22 erage or for which no claim is sub-  
23 mitted under the plan or coverage;

24 “(iii) with respect to any drug for  
25 which gross spending under the group

1 health plan or health insurance coverage  
2 exceeded \$10,000 during the reporting pe-  
3 riod or, in the case that gross spending  
4 under the group health plan or coverage  
5 exceeded \$10,000 during the reporting pe-  
6 riod with respect to fewer than 50 drugs,  
7 with respect to the 50 prescription drugs  
8 with the highest spending during the re-  
9 porting period—

10 “(I) a list of all other drugs in  
11 the same therapeutic class as such  
12 drug;

13 “(II) if applicable, the rationale  
14 for the formulary placement of such  
15 drug in that therapeutic category or  
16 class, selected from a list of standard  
17 rationales established by the Sec-  
18 retary, in consultation with stake-  
19 holders; and

20 “(III) any change in formulary  
21 placement compared to the prior plan  
22 year; and

23 “(iv) in the case that such plan or  
24 issuer (or an entity providing pharmacy  
25 benefit management services on behalf of



1           such plan or issuer) has an affiliated phar-  
2           macy or pharmacy under common owner-  
3           ship, including mandatory mail and spe-  
4           cialty home delivery programs, retail and  
5           mail auto-refill programs, and cost sharing  
6           assistance incentives funded by an entity  
7           providing pharmacy benefit services—

8                   “(I) an explanation of any ben-  
9                   efit design parameters that encourage  
10                  or require participants and bene-  
11                  ficiaries in the plan or coverage to fill  
12                  prescriptions at mail order, specialty,  
13                  or retail pharmacies;

14                  “(II) the percentage of total pre-  
15                  scriptions dispensed by such phar-  
16                  macies to participants or beneficiaries  
17                  in such plan or coverage; and

18                  “(III) a list of all drugs dis-  
19                  pensed by such pharmacies to partici-  
20                  pants or beneficiaries enrolled in such  
21                  plan or coverage, and, with respect to  
22                  each drug dispensed—

23                          “(aa) the amount charged,  
24                          per dosage unit, per 30-day sup-  
25                          ply, or per 90-day supply (as ap-

1 plicable) to the plan or issuer,  
2 and to participants and bene-  
3 ficiaries;

4 “(bb) the median amount  
5 charged to such plan or issuer,  
6 and the interquartile range of the  
7 costs, per dosage unit, per 30-  
8 day supply, and per 90-day sup-  
9 ply, including amounts paid by  
10 the participants and bene-  
11 ficiaries, when the same drug is  
12 dispensed by other pharmacies  
13 that are not affiliated with or  
14 under common ownership with  
15 the entity and that are included  
16 in the pharmacy network of such  
17 plan or coverage;

18 “(cc) the lowest cost per  
19 dosage unit, per 30-day supply  
20 and per 90-day supply, for each  
21 such drug, including amounts  
22 charged to the plan or coverage  
23 and to participants and bene-  
24 ficiaries, that is available from  
25 any pharmacy included in the

1 network of such plan or coverage;

2 and

3 “(dd) the net acquisition

4 cost per dosage unit, per 30-day

5 supply, and per 90-day supply, if

6 such drug is subject to a max-

7 imum price discount; and

8 “(B) with respect to any group health

9 plan, including group health insurance coverage

10 offered in connection with such a plan, regard-

11 less of whether the plan or coverage is offered

12 by a specified large employer or whether it is a

13 specified large plan—

14 “(i) a summary document for the

15 group health plan that includes such infor-

16 mation described in clauses (i) through (iv)

17 of subparagraph (A), as specified by the

18 Secretary through guidance, program in-

19 struction, or otherwise (with no require-

20 ment of notice and comment rulemaking),

21 that the Secretary determines useful to

22 group health plans for purposes of select-

23 ing pharmacy benefit management serv-

24 ices, such as an estimated net price to

25 group health plan and participant or bene-

1           ficiary, a cost per claim, the fee structure  
2           or reimbursement model, and estimated  
3           cost per participant or beneficiary;

4           “(ii) a summary document for plans  
5           and issuers to provide to participants and  
6           beneficiaries, which shall be made available  
7           to participants or beneficiaries upon re-  
8           quest to their group health plan (including  
9           in the case of group health insurance cov-  
10          erage offered in connection with such a  
11          plan), that—

12                   “(I) contains such information  
13                   described in clauses (iii), (iv), (v), and  
14                   (vi), as applicable, as specified by the  
15                   Secretary through guidance, program  
16                   instruction, or otherwise (with no re-  
17                   quirement of notice and comment  
18                   rulemaking) that the Secretary deter-  
19                   mines useful to participants or bene-  
20                   ficiaries in better understanding the  
21                   plan or coverage or benefits under  
22                   such plan or coverage;

23                   “(II) contains only aggregate in-  
24                   formation; and

1                   “(III) states that participants  
2                   and beneficiaries may request specific,  
3                   claims-level information required to be  
4                   furnished under subsection (c) from  
5                   the group health plan or health insur-  
6                   ance issuer; and

7                   “(iii) with respect to drugs covered by  
8                   such plan or coverage during such report-  
9                   ing period—

10                   “(I) the total net spending by the  
11                   plan or coverage for all such drugs;

12                   “(II) the total amount received,  
13                   or expected to be received, by the plan  
14                   or issuer from any applicable entity in  
15                   rebates, fees, alternative discounts, or  
16                   other remuneration; and

17                   “(III) to the extent feasible, in-  
18                   formation on the total amount of re-  
19                   muneration for such drugs, including  
20                   copayment assistance dollars paid, co-  
21                   payment cards applied, or other dis-  
22                   counts provided by each drug manu-  
23                   facturer (or entity administering co-  
24                   payment assistance on behalf of such

1 drug manufacturer) to participants  
2 and beneficiaries;

3 “(iv) amounts paid directly or indi-  
4 rectly in rebates, fees, or any other type of  
5 compensation (as defined in section  
6 408(b)(2)(B)(ii)(dd)(AA)) to brokerage  
7 firms, brokers, consultants, advisors, or  
8 any other individual or firm, for—

9 “(I) the referral of the group  
10 health plan’s or health insurance  
11 issuer’s business to an entity pro-  
12 viding pharmacy benefit management  
13 services, including the identity of the  
14 recipient of such amounts;

15 “(II) consideration of the entity  
16 providing pharmacy benefit manage-  
17 ment services by the group health  
18 plan or health insurance issuer; or

19 “(III) the retention of the entity  
20 by the group health plan or health in-  
21 surance issuer;

22 “(v) an explanation of any benefit de-  
23 sign parameters that encourage or require  
24 participants and beneficiaries in such plan  
25 or coverage to fill prescriptions at mail

1 order, specialty, or retail pharmacies that  
2 are affiliated with or under common own-  
3 ership with the entity providing pharmacy  
4 benefit management services under such  
5 plan or coverage, including mandatory mail  
6 and specialty home delivery programs, re-  
7 tail and mail auto-refill programs, and  
8 cost-sharing assistance incentives directly  
9 or indirectly funded by such entity; and

10 “(vi) total gross spending on all drugs  
11 under the plan or coverage during the re-  
12 porting period.

13 “(3) OPT-IN FOR GROUP HEALTH INSURANCE  
14 COVERAGE OFFERED BY A SPECIFIED LARGE EM-  
15 PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In  
16 the case of group health insurance coverage offered  
17 in connection with a group health plan that is of-  
18 fered by a specified large employer or is a specified  
19 large plan, such group health plan may, on an an-  
20 nual basis, for plan years beginning on or after the  
21 date that is 30 months after the date of enactment  
22 of this section, elect to require an entity providing  
23 pharmacy benefit management services on behalf of  
24 the health insurance issuer to submit to such group  
25 health plan a report that includes all of the informa-

1       tion described in paragraph (2)(A), in addition to  
2       the information described in paragraph (2)(B).

3           “(4) PRIVACY REQUIREMENTS.—

4               “(A) IN GENERAL.—An entity providing  
5       pharmacy benefit management services on be-  
6       half of a group health plan or a health insur-  
7       ance issuer offering group health insurance cov-  
8       erage shall report information under paragraph  
9       (1) in a manner consistent with the privacy reg-  
10      ulations promulgated under section 13402(a) of  
11      the Health Information Technology for Eco-  
12      nomic and Clinical Health Act (42 U.S.C.  
13      17932(a)) and consistent with the privacy regu-  
14      lations promulgated under the Health Insur-  
15      ance Portability and Accountability Act of 1996  
16      in part 160 and subparts A and E of part 164  
17      of title 45, Code of Federal Regulations (or suc-  
18      cessor regulations) (referred to in this para-  
19      graph as the ‘HIPAA privacy regulations’) and  
20      shall restrict the use and disclosure of such in-  
21      formation according to such privacy regulations  
22      and such HIPAA privacy regulations.

23           “(B) ADDITIONAL REQUIREMENTS.—

24               “(i) IN GENERAL.—An entity pro-  
25      viding pharmacy benefit management serv-



1           ices on behalf of a group health plan or  
2           health insurance issuer offering group  
3           health insurance coverage that submits a  
4           report under paragraph (1) shall ensure  
5           that such report contains only summary  
6           health information, as defined in section  
7           164.504(a) of title 45, Code of Federal  
8           Regulations (or successor regulations).

9           “(ii) RESTRICTIONS.—In carrying out  
10          this subsection, a group health plan shall  
11          comply with section 164.504(f) of title 45,  
12          Code of Federal Regulations (or a suc-  
13          cessor regulation), and a plan sponsor shall  
14          act in accordance with the terms of the  
15          agreement described in such section.

16          “(C) RULE OF CONSTRUCTION.—

17               “(i) Nothing in this section shall be  
18               construed to modify the requirements for  
19               the creation, receipt, maintenance, or  
20               transmission of protected health informa-  
21               tion under the HIPAA privacy regulations.

22               “(ii) Nothing in this section shall be  
23               construed to affect the application of any  
24               Federal or State privacy or civil rights law,  
25               including the HIPAA privacy regulations,

1 the Genetic Information Nondiscrimination  
2 Act of 2008 (Public Law 110–233) (in-  
3 cluding the amendments made by such  
4 Act), the Americans with Disabilities Act  
5 of 1990 (42 U.S.C. 12101 et seq), section  
6 504 of the Rehabilitation Act of 1973 (29  
7 U.S.C. 794), section 1557 of the Patient  
8 Protection and Affordable Care Act (42  
9 U.S.C. 18116), title VI of the Civil Rights  
10 Act of 1964 (42 U.S.C. 2000d), and title  
11 VII of the Civil Rights Act of 1964 (42  
12 U.S.C. 2000e).

13 “(D) WRITTEN NOTICE.—Each plan year,  
14 group health plans, including with respect to  
15 group health insurance coverage offered in con-  
16 nection with a group health plan, shall provide  
17 to each participant or beneficiary written notice  
18 informing the participant or beneficiary of the  
19 requirement for entities providing pharmacy  
20 benefit management services on behalf of the  
21 group health plan or health insurance issuer of-  
22 fering group health insurance coverage to sub-  
23 mit reports to group health plans under para-  
24 graph (1), as applicable, which may include in-  
25 corporating such notification in plan documents

1 provided to the participant or beneficiary, or  
2 providing individual notification.

3 “(E) LIMITATION TO BUSINESS ASSOCI-  
4 ATES.—A group health plan receiving a report  
5 under paragraph (1) may disclose such informa-  
6 tion only to the entity from which the report  
7 was received or to that entity’s business associ-  
8 ates as defined in section 160.103 of title 45,  
9 Code of Federal Regulations (or successor regu-  
10 lations) or as permitted by the HIPAA privacy  
11 regulations.

12 “(F) CLARIFICATION REGARDING PUBLIC  
13 DISCLOSURE OF INFORMATION.—Nothing in  
14 this section shall prevent an entity providing  
15 pharmacy benefit management services on be-  
16 half of a group health plan or health insurance  
17 issuer offering group health insurance coverage,  
18 from placing reasonable restrictions on the pub-  
19 lic disclosure of the information contained in a  
20 report described in paragraph (1), except that  
21 such plan, issuer, or entity may not—

22 “(i) restrict disclosure of such report  
23 to the Department of Health and Human  
24 Services, the Department of Labor, or the  
25 Department of the Treasury; or

1 “(ii) prevent disclosure for the pur-  
2 poses of subsection (c), or any other public  
3 disclosure requirement under this section.

4 “(G) LIMITED FORM OF REPORT.—The  
5 Secretary shall define through rulemaking a  
6 limited form of the report under paragraph (1)  
7 required with respect to any group health plan  
8 established by a plan sponsor that is, or is af-  
9 filiated with, a drug manufacturer, drug whole-  
10 saler, or other direct participant in the drug  
11 supply chain, in order to prevent anti-competi-  
12 tive behavior.

13 “(5) STANDARD FORMAT AND REGULATIONS.—

14 “(A) IN GENERAL.—Not later than 18  
15 months after the date of enactment of this sec-  
16 tion, the Secretary shall specify through rule-  
17 making a standard format for entities providing  
18 pharmacy benefit management services on be-  
19 half of group health plans and health insurance  
20 issuers offering group health insurance cov-  
21 erage, to submit reports required under para-  
22 graph (1).

23 “(B) ADDITIONAL REGULATIONS.—Not  
24 later than 18 months after the date of enact-  
25 ment of this section, the Secretary shall,

1 through rulemaking, promulgate any other final  
2 regulations necessary to implement the require-  
3 ments of this section. In promulgating such  
4 regulations, the Secretary shall, to the extent  
5 practicable, align the reporting requirements  
6 under this section with the reporting require-  
7 ments under section 725.

8 “(c) REQUIREMENT TO PROVIDE INFORMATION TO  
9 PARTICIPANTS OR BENEFICIARIES.—A group health plan,  
10 including with respect to group health insurance coverage  
11 offered in connection with a group health plan, upon re-  
12 quest of a participant or beneficiary, shall provide to such  
13 participant or beneficiary—

14 “(1) the summary document described in sub-  
15 section (b)(2)(B)(ii); and

16 “(2) the information described in subsection  
17 (b)(2)(A)(i)(III) with respect to a claim made by or  
18 on behalf of such participant or beneficiary.

19 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-  
20 tion shall be construed to permit a health insurance issuer,  
21 group health plan, entity providing pharmacy benefit man-  
22 agement services on behalf of a group health plan or  
23 health insurance issuer, or other entity to restrict disclo-  
24 sure to, or otherwise limit the access of, the Secretary to  
25 a report described in subsection (b)(1) or information re-

1 lated to compliance with subsections (a), (b), or (c) of this  
2 section or section 502(c)(13) by such issuer, plan, or enti-  
3 ty.

4 “(e) DEFINITIONS.—In this section:

5 “(1) APPLICABLE ENTITY.—The term ‘applica-  
6 ble entity’ means—

7 “(A) an applicable group purchasing orga-  
8 nization, drug manufacturer, distributor, whole-  
9 saler, rebate aggregator (or other purchasing  
10 entity designed to aggregate rebates), or associ-  
11 ated third party;

12 “(B) any subsidiary, parent, affiliate, or  
13 subcontractor of a group health plan, health in-  
14 surance issuer, entity that provides pharmacy  
15 benefit management services on behalf of such  
16 a plan or issuer, or any entity described in sub-  
17 paragraph (A); or

18 “(C) such other entity as the Secretary  
19 may specify through rulemaking.

20 “(2) APPLICABLE GROUP PURCHASING ORGANI-  
21 ZATION.—The term ‘applicable group purchasing or-  
22 ganization’ means a group purchasing organization  
23 that is affiliated with or under common ownership  
24 with an entity providing pharmacy benefit manage-  
25 ment services.

1           “(3) CONTRACTED COMPENSATION.—The term  
2           ‘contracted compensation’ means the sum of any in-  
3           gredient cost and dispensing fee for a drug (inclusive  
4           of the out-of-pocket costs to the participant or bene-  
5           ficiary), or another analogous compensation struc-  
6           ture that the Secretary may specify through regula-  
7           tions.

8           “(4) GROSS SPENDING.—The term ‘gross  
9           spending’, with respect to prescription drug benefits  
10          under a group health plan or health insurance cov-  
11          erage, means the amount spent by a group health  
12          plan or health insurance issuer on prescription drug  
13          benefits, calculated before the application of rebates,  
14          fees, alternative discounts, or other remuneration.

15          “(5) NET SPENDING.—The term ‘net spending’,  
16          with respect to prescription drug benefits under a  
17          group health plan or health insurance coverage,  
18          means the amount spent by a group health plan or  
19          health insurance issuer on prescription drug bene-  
20          fits, calculated after the application of rebates, fees,  
21          alternative discounts, or other remuneration.

22          “(6) PLAN SPONSOR.—The term ‘plan sponsor’  
23          has the meaning given such term in section  
24          3(16)(B).

1           “(7) REMUNERATION.—The term ‘remunera-  
2           tion’ has the meaning given such term by the Sec-  
3           retary through rulemaking, which shall be reevaluated by the Secretary every 5 years.

5           “(8) SPECIFIED LARGE EMPLOYER.—The term  
6           ‘specified large employer’ means, in connection with  
7           a group health plan (including group health insurance coverage offered in connection with such a  
8           plan) established or maintained by a single employer, with respect to a calendar year or a plan  
9           year, as applicable, an employer who employed an  
10          average of at least 100 employees on business days  
11          during the preceding calendar year or plan year and  
12          who employs at least 1 employee on the first day of  
13          the calendar year or plan year.

16          “(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  
17          by a plan sponsor described in clause (ii) or (iii) of  
18          section 3(16)(B) that had an average of at least 100  
19          participants on business days during the preceding  
20          calendar year or plan year, as applicable.

24          “(10) WHOLESALE ACQUISITION COST.—The  
25          term ‘wholesale acquisition cost’ has the meaning



1 given such term in section 1847A(c)(6)(B) of the  
2 Social Security Act (42 U.S.C. 1395w–  
3 3a(c)(6)(B)).”;

4 (B) in section 502 (29 U.S.C. 1132)—

5 (i) in subsection (a)(6), by striking  
6 “or (9)” and inserting “(9), or (13)”;

7 (ii) in subsection (b)(3), by striking  
8 “under subsection (c)(9)” and inserting  
9 “under paragraphs (9) and (13) of sub-  
10 section (c)”;

11 (iii) in subsection (c), by adding at  
12 the end the following:

13 “(13) SECRETARIAL ENFORCEMENT AUTHORITY  
14 RELATING TO OVERSIGHT OF PHARMACY BENEFIT  
15 MANAGEMENT SERVICES.—

16 “(A) FAILURE TO PROVIDE INFORMA-  
17 TION.—The Secretary may impose a penalty  
18 against a plan administrator of a group health  
19 plan, a health insurance issuer offering group  
20 health insurance coverage, or an entity pro-  
21 viding pharmacy benefit management services  
22 on behalf of such a plan or issuer, or an appli-  
23 cable entity (as defined in section 726(f)) that  
24 violates section 726(a); an entity providing  
25 pharmacy benefit management services on be-

1 half of such a plan or issuer that fails to pro-  
2 vide the information required under section  
3 726(b); or any person who causes a group  
4 health plan to fail to provide the information  
5 required under section 726(e), in the amount of  
6 \$10,000 for each day during which such viola-  
7 tion continues or such information is not dis-  
8 closed or reported.

9 “(B) FALSE INFORMATION.—The Sec-  
10 retary may impose a penalty against a plan ad-  
11 ministrator of a group health plan, a health in-  
12 surance issuer offering group health insurance  
13 coverage, an entity providing pharmacy benefit  
14 management services, or an applicable entity  
15 (as defined in section 726(f)) that knowingly  
16 provides false information under section 726, in  
17 an amount not to exceed \$100,000 for each  
18 item of false information. Such penalty shall be  
19 in addition to other penalties as may be pre-  
20 scribed by law.

21 “(C) WAIVERS.—The Secretary may waive  
22 penalties under subparagraph (A), or extend  
23 the period of time for compliance with a re-  
24 quirement of this section, for an entity in viola-  
25 tion of section 726 that has made a good-faith

1 effort to comply with the requirements of sec-  
2 tion 726.”; and

3 (C) in section 732(a) (29 U.S.C.  
4 1191a(a)), by striking “section 711” and in-  
5 serting “sections 711 and 726”.

6 (2) CLERICAL AMENDMENT.—The table of con-  
7 tents in section 1 of the Employee Retirement In-  
8 come Security Act of 1974 (29 U.S.C. 1001 et seq.)  
9 is amended by inserting after the item relating to  
10 section 725 the following new item:

“Sec. 726. Oversight of entities that provide pharmacy benefit management  
services.”.

11 (c) INTERNAL REVENUE CODE OF 1986.—

12 (1) IN GENERAL.—Chapter 100 of the Internal  
13 Revenue Code of 1986 is amended—

14 (A) by adding at the end of subchapter B  
15 the following:

16 **“SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**  
17 **MACY BENEFIT MANAGEMENT SERVICES.**

18 “(a) IN GENERAL.—For plan years beginning on or  
19 after the date that is 30 months after the date of enact-  
20 ment of this section (referred to in this subsection and  
21 subsection (b) as the ‘effective date’), a group health plan,  
22 or an entity providing pharmacy benefit management serv-  
23 ices on behalf of such a plan, shall not enter into a con-  
24 tract, including an extension or renewal of a contract, en-

1 tered into on or after the effective date, with an applicable  
2 entity unless such applicable entity agrees to—

3 “(1) not limit or delay the disclosure of infor-  
4 mation to the group health plan in such a manner  
5 that prevents an entity providing pharmacy benefit  
6 management services on behalf of a group health  
7 plan from making the reports described in sub-  
8 section (b); and

9 “(2) provide the entity providing pharmacy ben-  
10 efit management services on behalf of a group health  
11 plan relevant information necessary to make the re-  
12 ports described in subsection (b).

13 “(b) REPORTS.—

14 “(1) IN GENERAL.—For plan years beginning  
15 on or after the effective date, in the case of any con-  
16 tract between a group health plan and an entity pro-  
17 viding pharmacy benefit management services on be-  
18 half of such plan, including an extension or renewal  
19 of such a contract, entered into on or after the effec-  
20 tive date, the entity providing pharmacy benefit  
21 management services on behalf of such a group  
22 health plan, not less frequently than every 6 months  
23 (or, at the request of a group health plan, not less  
24 frequently than quarterly, and under the same con-  
25 ditions, terms, and cost of the semiannual report

1 under this subsection), shall submit to the group  
2 health plan a report in accordance with this section.  
3 Each such report shall be made available to such  
4 group health plan in plain language, in a machine-  
5 readable format, and as the Secretary may deter-  
6 mine, other formats. Each such report shall include  
7 the information described in paragraph (2).

8 “(2) INFORMATION DESCRIBED.—For purposes  
9 of paragraph (1), the information described in this  
10 paragraph is, with respect to drugs covered by a  
11 group health plan during each reporting period—

12 “(A) in the case of a group health plan  
13 that is offered by a specified large employer or  
14 that is a specified large plan, and is not offered  
15 as health insurance coverage, or in the case of  
16 health insurance coverage for which the election  
17 under paragraph (3) is made for the applicable  
18 reporting period—

19 “(i) a list of drugs for which a claim  
20 was filed and, with respect to each such  
21 drug on such list—

22 “(I) the contracted compensation  
23 paid by the group health plan for each  
24 covered drug (identified by the Na-  
25 tional Drug Code) to the entity pro-

1           viding pharmacy benefit management  
2           services or other applicable entity on  
3           behalf of the group health plan;

4           “(II) the contracted compensa-  
5           tion paid to the pharmacy, by any en-  
6           tity providing pharmacy benefit man-  
7           agement services or other applicable  
8           entity on behalf of the group health  
9           plan, for each covered drug (identified  
10          by the National Drug Code);

11          “(III) for each such claim, the  
12          difference between the amount paid  
13          under subclause (I) and the amount  
14          paid under subclause (II);

15          “(IV) the proprietary name, es-  
16          tablished name or proper name, and  
17          National Drug Code;

18          “(V) for each claim for the drug  
19          (including original prescriptions and  
20          refills) and for each dosage unit of the  
21          drug for which a claim was filed, the  
22          type of dispensing channel used to  
23          furnish the drug, including retail, mail  
24          order, or specialty pharmacy;

1 “(VI) with respect to each drug  
2 dispensed, for each type of dispensing  
3 channel (including retail, mail order,  
4 or specialty pharmacy)—

5 “(aa) whether such drug is a  
6 brand name drug or a generic  
7 drug, and—

8 “(AA) in the case of a  
9 brand name drug, the whole-  
10 sale acquisition cost, listed  
11 as cost per days supply and  
12 cost per dosage unit, on the  
13 date such drug was dis-  
14 pensed; and

15 “(BB) in the case of a  
16 generic drug, the average  
17 wholesale price, listed as  
18 cost per days supply and  
19 cost per dosage unit, on the  
20 date such drug was dis-  
21 pensed; and

22 “(bb) the total number of—

23 “(AA) prescription  
24 claims (including original  
25 prescriptions and refills);

1 “(BB) participants and  
2 beneficiaries for whom a  
3 claim for such drug was  
4 filed through the applicable  
5 dispensing channel;

6 “(CC) dosage units and  
7 dosage units per fill of such  
8 drug; and

9 “(DD) days supply of  
10 such drug per fill;

11 “(VII) the net price per course of  
12 treatment or single fill, such as a 30-  
13 day supply or 90-day supply to the  
14 plan after rebates, fees, alternative  
15 discounts, or other remuneration re-  
16 ceived from applicable entities;

17 “(VIII) the total amount of out-  
18 of-pocket spending by participants  
19 and beneficiaries on such drug, in-  
20 cluding spending through copayments,  
21 coinsurance, and deductibles, but not  
22 including any amounts spent by par-  
23 ticipants and beneficiaries on drugs  
24 not covered under the plan, or for



1 which no claim is submitted under the  
2 plan;

3 “(IX) the total net spending on  
4 the drug;

5 “(X) the total amount received,  
6 or expected to be received, by the plan  
7 from any applicable entity in rebates,  
8 fees, alternative discounts, or other  
9 remuneration;

10 “(XI) the total amount received,  
11 or expected to be received, by the enti-  
12 ty providing pharmacy benefit man-  
13 agement services, from applicable en-  
14 tities, in rebates, fees, alternative dis-  
15 counts, or other remuneration from  
16 such entities—

17 “(aa) for claims incurred  
18 during the reporting period; and

19 “(bb) that is related to utili-  
20 zation of such drug or spending  
21 on such drug; and

22 “(XII) to the extent feasible, in-  
23 formation on the total amount of re-  
24 muneration for such drug, including  
25 copayment assistance dollars paid, co-

1 payment cards applied, or other dis-  
2 counts provided by each drug manu-  
3 facturer (or entity administering co-  
4 payment assistance on behalf of such  
5 drug manufacturer), to the partici-  
6 pants and beneficiaries enrolled in  
7 such plan;

8 “(ii) a list of each therapeutic class  
9 (as defined by the Secretary) for which a  
10 claim was filed under the group health  
11 plan during the reporting period, and, with  
12 respect to each such therapeutic class—

13 “(I) the total gross spending on  
14 drugs in such class before rebates,  
15 price concessions, alternative dis-  
16 counts, or other remuneration from  
17 applicable entities;

18 “(II) the net spending in such  
19 class after such rebates, price conces-  
20 sions, alternative discounts, or other  
21 remuneration from applicable entities;

22 “(III) the total amount received,  
23 or expected to be received, by the enti-  
24 ty providing pharmacy benefit man-  
25 agement services, from applicable en-

1                   tities, in rebates, fees, alternative dis-  
2                   counts, or other remuneration from  
3                   such entities—

4                   “(aa) for claims incurred  
5                   during the reporting period; and

6                   “(bb) that is related to utili-  
7                   zation of drugs or drug spending;

8                   “(IV) the average net spending  
9                   per 30-day supply and per 90-day  
10                  supply by the plan and its partici-  
11                  pants and beneficiaries, among all  
12                  drugs within the therapeutic class for  
13                  which a claim was filed during the re-  
14                  porting period;

15                  “(V) the number of participants  
16                  and beneficiaries who filled a prescrip-  
17                  tion for a drug in such class, includ-  
18                  ing the National Drug Code for each  
19                  such drug;

20                  “(VI) if applicable, a description  
21                  of the formulary tiers and utilization  
22                  mechanisms (such as prior authoriza-  
23                  tion or step therapy) employed for  
24                  drugs in that class; and

1                   “(VII) the total out-of-pocket  
2                   spending under the plan by partici-  
3                   pants and beneficiaries, including  
4                   spending through copayments, coin-  
5                   surance, and deductibles, but not in-  
6                   cluding any amounts spent by partici-  
7                   pants and beneficiaries on drugs not  
8                   covered under the plan or for which  
9                   no claim is submitted under the plan;  
10                  “(iii) with respect to any drug for  
11                  which gross spending under the group  
12                  health plan exceeded \$10,000 during the  
13                  reporting period or, in the case that gross  
14                  spending under the group health plan ex-  
15                  ceeded \$10,000 during the reporting pe-  
16                  riod with respect to fewer than 50 drugs,  
17                  with respect to the 50 prescription drugs  
18                  with the highest spending during the re-  
19                  porting period—  
20                  “(I) a list of all other drugs in  
21                  the same therapeutic class as such  
22                  drug;  
23                  “(II) if applicable, the rationale  
24                  for the formulary placement of such  
25                  drug in that therapeutic category or

1 class, selected from a list of standard  
2 rationales established by the Sec-  
3 retary, in consultation with stake-  
4 holders; and

5 “(III) any change in formulary  
6 placement compared to the prior plan  
7 year; and

8 “(iv) in the case that such plan (or an  
9 entity providing pharmacy benefit manage-  
10 ment services on behalf of such plan) has  
11 an affiliated pharmacy or pharmacy under  
12 common ownership, including mandatory  
13 mail and specialty home delivery programs,  
14 retail and mail auto-refill programs, and  
15 cost sharing assistance incentives funded  
16 by an entity providing pharmacy benefit  
17 services—

18 “(I) an explanation of any ben-  
19 efit design parameters that encourage  
20 or require participants and bene-  
21 ficiaries in the plan to fill prescrip-  
22 tions at mail order, specialty, or retail  
23 pharmacies;

24 “(II) the percentage of total pre-  
25 scriptions dispensed by such phar-

1                   macies to participants or beneficiaries  
2                   in such plan; and

3                   “(III) a list of all drugs dis-  
4                   pensed by such pharmacies to partici-  
5                   pants or beneficiaries enrolled in such  
6                   plan, and, with respect to each drug  
7                   dispensed—

8                   “(aa) the amount charged,  
9                   per dosage unit, per 30-day sup-  
10                  ply, or per 90-day supply (as ap-  
11                  plicable) to the plan, and to par-  
12                  ticipants and beneficiaries;

13                  “(bb) the median amount  
14                  charged to such plan, and the  
15                  interquartile range of the costs,  
16                  per dosage unit, per 30-day sup-  
17                  ply, and per 90-day supply, in-  
18                  cluding amounts paid by the par-  
19                  ticipants and beneficiaries, when  
20                  the same drug is dispensed by  
21                  other pharmacies that are not af-  
22                  filiated with or under common  
23                  ownership with the entity and  
24                  that are included in the phar-  
25                  macy network of such plan;

1                   “(cc) the lowest cost per  
2                   dosage unit, per 30-day supply  
3                   and per 90-day supply, for each  
4                   such drug, including amounts  
5                   charged to the plan and to par-  
6                   ticipants and beneficiaries, that  
7                   is available from any pharmacy  
8                   included in the network of such  
9                   plan; and

10                   “(dd) the net acquisition  
11                   cost per dosage unit, per 30-day  
12                   supply, and per 90-day supply, if  
13                   such drug is subject to a max-  
14                   imum price discount; and

15                   “(B) with respect to any group health  
16                   plan, regardless of whether the plan is offered  
17                   by a specified large employer or whether it is a  
18                   specified large plan—

19                   “(i) a summary document for the  
20                   group health plan that includes such infor-  
21                   mation described in clauses (i) through (iv)  
22                   of subparagraph (A), as specified by the  
23                   Secretary through guidance, program in-  
24                   struction, or otherwise (with no require-  
25                   ment of notice and comment rulemaking),

1           that the Secretary determines useful to  
2           group health plans for purposes of select-  
3           ing pharmacy benefit management serv-  
4           ices, such as an estimated net price to  
5           group health plan and participant or bene-  
6           ficiary, a cost per claim, the fee structure  
7           or reimbursement model, and estimated  
8           cost per participant or beneficiary;

9           “(ii) a summary document for plans  
10          to provide to participants and beneficiaries,  
11          which shall be made available to partici-  
12          pants or beneficiaries upon request to their  
13          group health plan, that—

14               “(I) contains such information  
15               described in clauses (iii), (iv), (v), and  
16               (vi), as applicable, as specified by the  
17               Secretary through guidance, program  
18               instruction, or otherwise (with no re-  
19               quirement of notice and comment  
20               rulemaking) that the Secretary deter-  
21               mines useful to participants or bene-  
22               ficiaries in better understanding the  
23               plan or benefits under such plan;

24               “(II) contains only aggregate in-  
25               formation; and



1                   “(III) states that participants  
2                   and beneficiaries may request specific,  
3                   claims-level information required to be  
4                   furnished under subsection (c) from  
5                   the group health plan; and

6                   “(iii) with respect to drugs covered by  
7                   such plan during such reporting period—

8                   “(I) the total net spending by the  
9                   plan for all such drugs;

10                  “(II) the total amount received,  
11                  or expected to be received, by the plan  
12                  from any applicable entity in rebates,  
13                  fees, alternative discounts, or other  
14                  remuneration; and

15                  “(III) to the extent feasible, in-  
16                  formation on the total amount of re-  
17                  muneration for such drugs, including  
18                  copayment assistance dollars paid, co-  
19                  payment cards applied, or other dis-  
20                  counts provided by each drug manu-  
21                  facturer (or entity administering co-  
22                  payment assistance on behalf of such  
23                  drug manufacturer) to participants  
24                  and beneficiaries;

1 “(iv) amounts paid directly or indi-  
2 rectly in rebates, fees, or any other type of  
3 compensation (as defined in section  
4 408(b)(2)(B)(ii)(dd)(AA) of the Employee  
5 Retirement Income Security Act (29  
6 U.S.C. 1108(b)(2)(B)(ii)(dd)(AA))) to bro-  
7 kerage firms, brokers, consultants, advi-  
8 sors, or any other individual or firm, for—

9 “(I) the referral of the group  
10 health plan’s business to an entity  
11 providing pharmacy benefit manage-  
12 ment services, including the identity  
13 of the recipient of such amounts;

14 “(II) consideration of the entity  
15 providing pharmacy benefit manage-  
16 ment services by the group health  
17 plan; or

18 “(III) the retention of the entity  
19 by the group health plan;

20 “(v) an explanation of any benefit de-  
21 sign parameters that encourage or require  
22 participants and beneficiaries in such plan  
23 to fill prescriptions at mail order, specialty,  
24 or retail pharmacies that are affiliated with  
25 or under common ownership with the enti-

1                   ty providing pharmacy benefit management  
2                   services under such plan, including manda-  
3                   tory mail and specialty home delivery pro-  
4                   grams, retail and mail auto-refill pro-  
5                   grams, and cost-sharing assistance incen-  
6                   tives directly or indirectly funded by such  
7                   entity; and

8                   “(vi) total gross spending on all drugs  
9                   under the plan during the reporting period.

10               “(3) OPT-IN FOR GROUP HEALTH INSURANCE  
11               COVERAGE OFFERED BY A SPECIFIED LARGE EM-  
12               PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In  
13               the case of group health insurance coverage offered  
14               in connection with a group health plan that is of-  
15               fered by a specified large employer or is a specified  
16               large plan, such group health plan may, on an an-  
17               nual basis, for plan years beginning on or after the  
18               date that is 30 months after the date of enactment  
19               of this section, elect to require an entity providing  
20               pharmacy benefit management services on behalf of  
21               the health insurance issuer to submit to such group  
22               health plan a report that includes all of the informa-  
23               tion described in paragraph (2)(A), in addition to  
24               the information described in paragraph (2)(B).

25               “(4) PRIVACY REQUIREMENTS.—

1           “(A) IN GENERAL.—An entity providing  
2           pharmacy benefit management services on be-  
3           half of a group health plan shall report infor-  
4           mation under paragraph (1) in a manner con-  
5           sistent with the privacy regulations promul-  
6           gated under section 13402(a) of the Health In-  
7           formation Technology for Economic and Clin-  
8           ical Health Act (42 U.S.C. 17932(a)) and con-  
9           sistent with the privacy regulations promul-  
10          gated under the Health Insurance Portability  
11          and Accountability Act of 1996 in part 160 and  
12          subparts A and E of part 164 of title 45, Code  
13          of Federal Regulations (or successor regula-  
14          tions) (referred to in this paragraph as the  
15          ‘HIPAA privacy regulations’) and shall restrict  
16          the use and disclosure of such information ac-  
17          cording to such privacy regulations and such  
18          HIPAA privacy regulations.

19           “(B) ADDITIONAL REQUIREMENTS.—

20           “(i) IN GENERAL.—An entity pro-  
21           viding pharmacy benefit management serv-  
22           ices on behalf of a group health plan that  
23           submits a report under paragraph (1) shall  
24           ensure that such report contains only sum-  
25           mary health information, as defined in sec-

1                   tion 164.504(a) of title 45, Code of Fed-  
2                   eral Regulations (or successor regulations).

3                   “(ii) RESTRICTIONS.—In carrying out  
4                   this subsection, a group health plan shall  
5                   comply with section 164.504(f) of title 45,  
6                   Code of Federal Regulations (or a suc-  
7                   cessor regulation), and a plan sponsor shall  
8                   act in accordance with the terms of the  
9                   agreement described in such section.

10                  “(C) RULE OF CONSTRUCTION.—

11                   “(i) Nothing in this section shall be  
12                   construed to modify the requirements for  
13                   the creation, receipt, maintenance, or  
14                   transmission of protected health informa-  
15                   tion under the HIPAA privacy regulations.

16                   “(ii) Nothing in this section shall be  
17                   construed to affect the application of any  
18                   Federal or State privacy or civil rights law,  
19                   including the HIPAA privacy regulations,  
20                   the Genetic Information Nondiscrimination  
21                   Act of 2008 (Public Law 110–233) (in-  
22                   cluding the amendments made by such  
23                   Act), the Americans with Disabilities Act  
24                   of 1990 (42 U.S.C. 12101 et sec), section  
25                   504 of the Rehabilitation Act of 1973 (29

1 U.S.C. 794), section 1557 of the Patient  
2 Protection and Affordable Care Act (42  
3 U.S.C. 18116), title VI of the Civil Rights  
4 Act of 1964 (42 U.S.C. 2000d), and title  
5 VII of the Civil Rights Act of 1964 (42  
6 U.S.C. 2000e).

7 “(D) WRITTEN NOTICE.—Each plan year,  
8 group health plans shall provide to each partici-  
9 pant or beneficiary written notice informing the  
10 participant or beneficiary of the requirement for  
11 entities providing pharmacy benefit manage-  
12 ment services on behalf of the group health  
13 plan to submit reports to group health plans  
14 under paragraph (1), as applicable, which may  
15 include incorporating such notification in plan  
16 documents provided to the participant or bene-  
17 ficiary, or providing individual notification.

18 “(E) LIMITATION TO BUSINESS ASSOCI-  
19 ATES.—A group health plan receiving a report  
20 under paragraph (1) may disclose such informa-  
21 tion only to the entity from which the report  
22 was received or to that entity’s business associ-  
23 ates as defined in section 160.103 of title 45,  
24 Code of Federal Regulations (or successor regu-

1           lations) or as permitted by the HIPAA privacy  
2           regulations.

3           “(F) CLARIFICATION REGARDING PUBLIC  
4           DISCLOSURE OF INFORMATION.—Nothing in  
5           this section shall prevent an entity providing  
6           pharmacy benefit management services on be-  
7           half of a group health plan, from placing rea-  
8           sonable restrictions on the public disclosure of  
9           the information contained in a report described  
10          in paragraph (1), except that such plan or enti-  
11          ty may not—

12                 “(i) restrict disclosure of such report  
13                 to the Department of Health and Human  
14                 Services, the Department of Labor, or the  
15                 Department of the Treasury; or

16                 “(ii) prevent disclosure for the pur-  
17                 poses of subsection (c), or any other public  
18                 disclosure requirement under this section.

19           “(G) LIMITED FORM OF REPORT.—The  
20           Secretary shall define through rulemaking a  
21           limited form of the report under paragraph (1)  
22           required with respect to any group health plan  
23           established by a plan sponsor that is, or is af-  
24           filiated with, a drug manufacturer, drug whole-  
25           saler, or other direct participant in the drug

1 supply chain, in order to prevent anti-competi-  
2 tive behavior.

3 “(5) STANDARD FORMAT AND REGULATIONS.—

4 “(A) IN GENERAL.—Not later than 18  
5 months after the date of enactment of this sec-  
6 tion, the Secretary shall specify through rule-  
7 making a standard format for entities providing  
8 pharmacy benefit management services on be-  
9 half of group health plans, to submit reports re-  
10 quired under paragraph (1).

11 “(B) ADDITIONAL REGULATIONS.—Not  
12 later than 18 months after the date of enact-  
13 ment of this section, the Secretary shall,  
14 through rulemaking, promulgate any other final  
15 regulations necessary to implement the require-  
16 ments of this section. In promulgating such  
17 regulations, the Secretary shall, to the extent  
18 practicable, align the reporting requirements  
19 under this section with the reporting require-  
20 ments under section 9825.

21 “(c) REQUIREMENT TO PROVIDE INFORMATION TO  
22 PARTICIPANTS OR BENEFICIARIES.—A group health plan,  
23 upon request of a participant or beneficiary, shall provide  
24 to such participant or beneficiary—



1           “(1) the summary document described in sub-  
2           section (b)(2)(B)(ii); and

3           “(2) the information described in subsection  
4           (b)(2)(A)(i)(III) with respect to a claim made by or  
5           on behalf of such participant or beneficiary.

6           “(d) RULE OF CONSTRUCTION.—Nothing in this sec-  
7           tion shall be construed to permit a health insurance issuer,  
8           group health plan, entity providing pharmacy benefit man-  
9           agement services on behalf of a group health plan or  
10          health insurance issuer, or other entity to restrict disclo-  
11          sure to, or otherwise limit the access of, the Secretary to  
12          a report described in subsection (b)(1) or information re-  
13          lated to compliance with subsections (a), (b), or (c) of this  
14          section or section 4980D(g) by such issuer, plan, or entity.

15          “(e) DEFINITIONS.—In this section:

16                 “(1) APPLICABLE ENTITY.—The term ‘applica-  
17                 ble entity’ means—

18                         “(A) an applicable group purchasing orga-  
19                         nization, drug manufacturer, distributor, whole-  
20                         saler, rebate aggregator (or other purchasing  
21                         entity designed to aggregate rebates), or associ-  
22                         ated third party;

23                         “(B) any subsidiary, parent, affiliate, or  
24                         subcontractor of a group health plan, health in-  
25                         surance issuer, entity that provides pharmacy

1 benefit management services on behalf of such  
2 a plan or issuer, or any entity described in sub-  
3 paragraph (A); or

4 “(C) such other entity as the Secretary  
5 may specify through rulemaking.

6 “(2) APPLICABLE GROUP PURCHASING ORGANI-  
7 ZATION.—The term ‘applicable group purchasing or-  
8 ganization’ means a group purchasing organization  
9 that is affiliated with or under common ownership  
10 with an entity providing pharmacy benefit manage-  
11 ment services.

12 “(3) CONTRACTED COMPENSATION.—The term  
13 ‘contracted compensation’ means the sum of any in-  
14 gredient cost and dispensing fee for a drug (inclusive  
15 of the out-of-pocket costs to the participant or bene-  
16 ficiary), or another analogous compensation struc-  
17 ture that the Secretary may specify through regula-  
18 tions.

19 “(4) GROSS SPENDING.—The term ‘gross  
20 spending’, with respect to prescription drug benefits  
21 under a group health plan, means the amount spent  
22 by a group health plan on prescription drug benefits,  
23 calculated before the application of rebates, fees, al-  
24 ternative discounts, or other remuneration.

1           “(5) NET SPENDING.—The term ‘net spending’,  
2           with respect to prescription drug benefits under a  
3           group health plan, means the amount spent by a  
4           group health plan on prescription drug benefits, cal-  
5           culated after the application of rebates, fees, alter-  
6           native discounts, or other remuneration.

7           “(6) PLAN SPONSOR.—The term ‘plan sponsor’  
8           has the meaning given such term in section 3(16)(B)  
9           of the Employee Retirement Income Security Act of  
10          1974 (29 U.S.C. 1002(16)(B)).

11          “(7) REMUNERATION.—The term ‘remunera-  
12          tion’ has the meaning given such term by the Sec-  
13          retary, through rulemaking, which shall be reevalu-  
14          ated by the Secretary every 5 years.

15          “(8) SPECIFIED LARGE EMPLOYER.—The term  
16          ‘specified large employer’ means, in connection with  
17          a group health plan established or maintained by a  
18          single employer, with respect to a calendar year or  
19          a plan year, as applicable, an employer who em-  
20          ployed an average of at least 100 employees on busi-  
21          ness days during the preceding calendar year or plan  
22          year and who employs at least 1 employee on the  
23          first day of the calendar year or plan year.

24          “(9) SPECIFIED LARGE PLAN.—The term ‘spec-  
25          ified large plan’ means a group health plan estab-

lished 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 (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

1 to such group health plan (and the reference in subsection  
2 (e)(1) to the employer) shall be treated as including a ref-  
3 erence to such entity.”.

4 (4) CLERICAL AMENDMENT.—The table of sec-  
5 tions for subchapter B of chapter 100 of the Inter-  
6 nal Revenue Code of 1986 is amended by adding at  
7 the end the following new item:

“Sec. 9826. Oversight of entities that provide pharmacy benefit management  
services.”.

8 **SEC. 902. FULL REBATE PASS THROUGH TO PLAN; EXCEP-**  
9 **TION FOR INNOCENT PLAN FIDUCIARIES.**

10 (a) IN GENERAL.—Section 408(b)(2) of the Em-  
11 ployee Retirement Income Security Act of 1974 (29  
12 U.S.C. 1108(b)(2)) is amended—

13 (1) in subparagraph (B)(viii)—

14 (A) by redesignating subclauses (II)  
15 through (IV) as subclauses (III) through (V),  
16 respectively;

17 (B) in subclause (I)—

18 (i) by striking “subclause (II)” and  
19 inserting “subclause (III)”; and

20 (ii) by striking “subclauses (II) and  
21 (III)” and inserting “subclauses (III) and  
22 (IV)”; and

23 (C) by inserting after subclause (I) the fol-  
24 lowing:

1           “(II) Pursuant to subsection (a), subpara-  
2           graphs (C) and (D) of section 406(a)(1) shall not  
3           apply to a responsible plan fiduciary, notwith-  
4           standing any failure to remit required amounts  
5           under subparagraph (C)(i), if the following condi-  
6           tions are met:

7                   “(aa) The responsible plan fiduciary did  
8                   not know that the covered service provider  
9                   failed or would fail to make required remit-  
10                  tances and reasonably believed that the covered  
11                  service provider remitted such required  
12                  amounts.

13                  “(bb) The responsible plan fiduciary, upon  
14                  discovering that the covered service provider  
15                  failed to remit the required amounts, requests  
16                  in writing that the covered service provider  
17                  remit such amounts.

18                  “(cc) If the covered service provider fails  
19                  to comply with a written request described in  
20                  subclause (III) within 90 days of the request,  
21                  the responsible plan fiduciary notifies the Sec-  
22                  retary of the covered service provider’s failure,  
23                  in accordance with subclauses (III) and (IV).”;  
24                  and

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

1           “(C)(i)(I) For plan years beginning on or after  
2           the date that is 30 months after the date of enact-  
3           ment of this subparagraph (referred to in this clause  
4           as the ‘effective date’), no contract or arrangement  
5           or renewal or extension of a contract or arrange-  
6           ment, entered into on or after the effective date, for  
7           services between a covered plan and a covered serv-  
8           ice provider, through a health insurance issuer offer-  
9           ing group health insurance coverage, a third party  
10          administrator, an entity providing pharmacy benefit  
11          management services, or other entity, for pharmacy  
12          benefit management services, is reasonable within  
13          the meaning of this paragraph unless such entity  
14          providing pharmacy benefit management services—

15               “(aa) remits 100 percent of rebates, fees,  
16               alternative discounts, and other remuneration  
17               received from any applicable entity that are re-  
18               lated to utilization of drugs or drug spending  
19               under such health plan or health insurance cov-  
20               erage, to the group health plan or health insur-  
21               ance issuer offering group health insurance cov-  
22               erage; and

23               “(bb) does not enter into any contract for  
24               pharmacy benefit management services on be-  
25               half of such a plan or coverage, with an applica-

1           ble entity unless 100 percent of rebates, fees,  
2           alternative discounts, and other remuneration  
3           received under such contract that are related to  
4           the utilization of drugs or drug spending under  
5           such group health plan or health insurance cov-  
6           erage are remitted to the group health plan or  
7           health insurance issuer by the entity providing  
8           pharmacy benefit management services.

9           “(II) Nothing in subclause (I) shall be con-  
10          strued to affect the term of a contract or arrange-  
11          ment, as in effect on the effective date (as described  
12          in such subclause), except that such subclause shall  
13          apply to any renewal or extension of such a contract  
14          or arrangement entered into on or after such effec-  
15          tive date, as so described.

16          “(ii) With respect to such rebates, fees, alter-  
17          native discounts, and other remuneration—

18                 “(I) the rebates, fees, alternative dis-  
19                 counts, and other remuneration under clause  
20                 (i)(I) shall be—

21                         “(aa) remitted—

22                                 “(AA) on a quarterly basis, to  
23                                 the group health plan or the group  
24                                 health insurance issuer, not later than



1 90 days after the end of each quarter;

2 or

3 “(BB) in the case of an under-

4 payment in a remittance for a prior

5 quarter, as soon as practicable, but

6 not later than 90 days after notice of

7 the underpayment is first given;

8 “(bb) fully disclosed and enumerated

9 to the group health plan or health insur-

10 ance issuer; and

11 “(cc) returned to the covered service

12 provider for pharmacy benefit management

13 services on behalf of the group health plan

14 if any audit by a plan sponsor, issuer or a

15 third party designated by a plan sponsor,

16 indicates that the amounts received are in-

17 correct after such amounts have been paid

18 to the group health plan or health insur-

19 ance issuer;

20 “(II) the Secretary may establish proce-

21 dures for the remittance of rebates fees, alter-

22 native discounts, and other remuneration under

23 subclause (I)(aa) and the disclosure of rebates,

24 fees, alternative discounts, and other remunera-

25 tion under subclause (I)(bb); and

1           “(III) the records of such rebates, fees, al-  
2           ternative discounts, and other remuneration  
3           shall be available for audit by the plan sponsor,  
4           issuer, or a third party designated by a plan  
5           sponsor, not less than once per plan year.

6           “(iii) To ensure that an entity providing phar-  
7           macy benefit management services is able to meet  
8           the requirements of clause (ii)(I), a rebate  
9           aggregator (or other purchasing entity designed to  
10          aggregate rebates) and an applicable group pur-  
11          chasing organization shall remit such rebates to the  
12          entity providing pharmacy benefit management serv-  
13          ices not later than 45 days after the end of each  
14          quarter.

15          “(iv) A third-party administrator of a group  
16          health plan, a health insurance issuer offering group  
17          health insurance coverage, or a covered service pro-  
18          vider for pharmacy benefit management services  
19          under such health plan or health insurance coverage  
20          shall make rebate contracts with rebate aggregators  
21          or drug manufacturers available for audit by such  
22          plan sponsor or designated third party, subject to  
23          reasonable restrictions (as determined by the Sec-  
24          retary) on confidentiality to prevent re-disclosure of

1       such contracts or use of such information in audits  
2       for purposes unrelated to this section.

3           “(v) Audits carried out under clauses (ii)(III)  
4       and (iv) shall be performed by an auditor selected by  
5       the responsible plan fiduciary. Payment for such au-  
6       dits shall not be made, whether directly or indirectly,  
7       by the entity providing pharmacy benefit manage-  
8       ment services.

9           “(vi) Nothing in this subparagraph shall be  
10       construed to—

11           “(I) prohibit reasonable payments to enti-  
12       ties offering pharmacy benefit management  
13       services for bona fide services using a fee struc-  
14       ture not described in this subparagraph, pro-  
15       vided that such fees are transparent and quan-  
16       tifiable to group health plans and health insur-  
17       ance issuers;

18           “(II) require a third-party administrator of  
19       a group health plan or covered service provider  
20       for pharmacy benefit management services  
21       under such health plan or health insurance cov-  
22       erage to remit bona fide service fees to the  
23       group health plan;

24           “(III) limit the ability of a group health  
25       plan or health insurance issuer to pass through

1 rebates, fees, alternative discounts, and other  
2 remuneration to the participant or beneficiary;  
3 or

4 “(IV) modify the requirements for the cre-  
5 ation, receipt, maintenance, or transmission of  
6 protected health information under the privacy  
7 regulations promulgated under the Health In-  
8 surance Portability and Accountability Act of  
9 1996 in part 160 and subparts A and E of part  
10 164 of title 45, Code of Federal Regulations (or  
11 successor regulations).

12 “(vii) For purposes of this subparagraph—

13 “(I) the terms ‘applicable entity’ and ‘ap-  
14 plicable group purchasing organization’ have  
15 the meanings given such terms in section  
16 726(e);

17 “(II) the terms ‘covered plan’, ‘covered  
18 service provider’, and ‘responsible plan fidu-  
19 ciary’ have the meanings given such terms in  
20 subparagraph (B); and

21 “(III) the terms ‘group health insurance  
22 coverage’, ‘health insurance coverage’, and  
23 ‘health insurance issuer’ have the meanings  
24 given such terms in section 733.”.

1 (b) RULE OF CONSTRUCTION.—Subclause (II)(aa) of  
2 section 408(b)(2)(B)(viii) of the Employee Retirement In-  
3 come Security Act of 1974 (29 U.S.C.  
4 1108(b)(2)(B)(viii)), as amended by subsection (a), shall  
5 not be construed to relieve or limit a responsible plan fidu-  
6 ciary from the duty to monitor the practices of any covered  
7 service provider that contracts with the applicable covered  
8 plan, including for the purposes of ensuring the reason-  
9 ableness of compensation. For purposes of this subsection,  
10 the terms “covered plan”, “covered service provider”, and  
11 “responsible plan fiduciary” have the meanings given such  
12 terms in section 408(b)(2)(B)(ii) of the Employee Retire-  
13 ment Income Security Act of 1974 (29 U.S.C.  
14 1108(b)(2)(B)(ii)).

15 (c) CLARIFICATION OF COVERED SERVICE PRO-  
16 VIDER.—

17 (1) SERVICES.—

18 (A) IN GENERAL.—Section  
19 408(b)(2)(B)(ii)(I)(bb) of the Employee Retire-  
20 ment Income Security Act of 1974 (29 U.S.C.  
21 1108(b)(2)(B)(ii)(I)(bb)) is amended—

22 (i) in subitem (AA) by striking “Bro-  
23 kerage services,” and inserting “Services  
24 (including brokerage services),”; and

25 (ii) in subitem (BB)—

1 (I) by striking “Consulting,” and  
2 inserting “Other services,”; and

3 (II) by striking “related to the  
4 development or implementation of  
5 plan design” and all that follows  
6 through the period at the end and in-  
7 serting “including any of the fol-  
8 lowing: plan design, insurance or in-  
9 surance product selection (including  
10 vision and dental), recordkeeping,  
11 medical management, benefits admin-  
12 istration selection (including vision  
13 and dental), stop-loss insurance, phar-  
14 macy benefit management services,  
15 wellness design and management serv-  
16 ices, transparency tools, group pur-  
17 chasing organization agreements and  
18 services, participation in and services  
19 from preferred vendor panels, disease  
20 management, compliance services, em-  
21 ployee assistance programs, or third  
22 party administration services, or con-  
23 sulting services related to any such  
24 services.”.

1 (B) SENSE OF CONGRESS.—It is the sense  
2 of Congress that the amendment made by sub-  
3 paragraph (A) clarifies the existing requirement  
4 of covered service providers with respect to  
5 services described in section  
6 408(b)(2)(B)(ii)(I)(bb)(BB) of the Employee  
7 Retirement Income Security Act of 1974 (29  
8 U.S.C. 1108(b)(2)(B)(ii)(I)(bb)(BB)) that were  
9 in effect since the application date described in  
10 section 202(e) of the No Surprises Act (Public  
11 Law 116–260; 29 U.S.C. 1108 note), and does  
12 not impose any additional requirement under  
13 section 408(b)(2)(B) of such Act.

14 (2) CERTAIN ARRANGEMENTS FOR PHARMACY  
15 BENEFIT MANAGEMENT SERVICES CONSIDERED AS  
16 INDIRECT.—

17 (A) IN GENERAL.—Section 408(b)(2)(B)(i)  
18 of the Employee Retirement Income Security  
19 Act of 1974 (29 U.S.C. 1108(b)(2)(B)(i)) is  
20 amended—

21 (i) by striking “requirements of this  
22 clause” and inserting “requirements of this  
23 subparagraph”; and

24 (ii) by adding at the end the fol-  
25 lowing: “For purposes of applying section

1                   406(a)(1)(C) with respect to a transaction  
2                   described under this subparagraph or sub-  
3                   paragraph (C), a contract or arrangement  
4                   for services between a covered plan and an  
5                   entity providing services to the plan, in-  
6                   cluding a health insurance issuer providing  
7                   health insurance coverage in connection  
8                   with the covered plan, in which such entity  
9                   contracts, in connection with such plan,  
10                  with a service provider for pharmacy ben-  
11                  efit management services, shall be consid-  
12                  ered an indirect furnishing of goods, serv-  
13                  ices, or facilities between the covered plan  
14                  and the service provider for pharmacy ben-  
15                  efit management services acting as the  
16                  party in interest.”.

17                  (B) HEALTH INSURANCE ISSUER AND  
18                  HEALTH INSURANCE COVERAGE DEFINED.—  
19                  Section 408(b)(2)(B)(ii)(I)(aa) of such Act (29  
20                  U.S.C. 1108(b)(2)(B)(ii)(I)(aa)) is amended by  
21                  inserting before the period at the end “and the  
22                  terms ‘health insurance coverage’ and ‘health  
23                  insurance issuer’ have the meanings given such  
24                  terms in section 733(b)”.



1 (C) TECHNICAL AMENDMENT.—Section  
2 408(b)(2)(B)(ii)(I)(aa) of the Employee Retirement  
3 Income Security Act of 1974 (29 U.S.C.  
4 1108(b)(2)(B)(ii)(I)(aa)) is amended by inserting  
5 “in” after “defined”.

6 **SEC. 903. INCREASING TRANSPARENCY IN GENERIC DRUG**  
7 **APPLICATIONS.**

8 (a) IN GENERAL.—Section 505(j)(3) of the Federal  
9 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)) is  
10 amended by adding at the end the following:

11 “(H)(i) Upon request (in controlled correspondence  
12 or an analogous process) by a person that has submitted  
13 or intends to submit an abbreviated application under this  
14 subsection for a drug that is required by regulation to contain  
15 one or more of the same inactive ingredients in the  
16 same concentrations as the listed drug referred to, or for  
17 which the Secretary determines there is a scientific justification  
18 for an approach that is in vitro, in whole or in  
19 part, to be used to demonstrate bioequivalence for a drug  
20 if such a drug contains one or more of the same inactive  
21 ingredients in the same concentrations as the listed drug  
22 referred to, the Secretary shall inform the person whether  
23 such drug is qualitatively and quantitatively the same as  
24 the listed drug. The Secretary may also provide such information  
25 to such a person on the Secretary’s own initiative

1 during the review of an abbreviated application under this  
2 subsection for such drug.

3 “(ii) Notwithstanding section 301(j), if the Secretary  
4 determines that such drug is not qualitatively or quan-  
5 titatively the same as the listed drug, the Secretary shall  
6 identify and disclose to the person—

7 “(I) the ingredient or ingredients that cause  
8 such drug not to be qualitatively or quantitatively  
9 the same as the listed drug; and

10 “(II) for any ingredient for which there is an  
11 identified quantitative deviation, the amount of such  
12 deviation.

13 “(iii) If the Secretary determines that such drug is  
14 qualitatively and quantitatively the same as the listed  
15 drug, the Secretary shall not change or rescind such deter-  
16 mination after the submission of an abbreviated applica-  
17 tion for such drug under this subsection unless—

18 “(I) the formulation of the listed drug has been  
19 changed and the Secretary has determined that the  
20 prior listed drug formulation was withdrawn for rea-  
21 sons of safety or effectiveness; or

22 “(II) the Secretary makes a written determina-  
23 tion that the prior determination must be changed  
24 because an error has been identified.

1       “(iv) If the Secretary makes a written determination  
2 described in clause (iii)(II), the Secretary shall provide no-  
3 tice and a copy of the written determination to the person  
4 making the request under clause (i).

5       “(v) The disclosures authorized under clauses (i) and  
6 (ii) are disclosures authorized by law, including for pur-  
7 poses of section 1905 of title 18, United States Code. This  
8 subparagraph shall not otherwise be construed to author-  
9 ize the disclosure of nonpublic qualitative or quantitative  
10 information about the ingredients in a listed drug, or to  
11 affect the status, if any, of such information as trade se-  
12 cret or confidential commercial information for purposes  
13 of section 301(j) of this Act, section 552 of title 5, United  
14 States Code, or section 1905 of title 18, United States  
15 Code.”.

16       (b) GUIDANCE.—

17           (1) IN GENERAL.—Not later than one year  
18 after the date of enactment of this Act, the Sec-  
19 retary of Health and Human Services shall issue  
20 draft guidance, or update guidance, describing how  
21 the Secretary will determine whether a drug is quali-  
22 tatively and quantitatively the same as the listed  
23 drug (as such terms are used in section  
24 505(j)(3)(H) of the Federal Food, Drug, and Cos-

1        metric Act, as added by subsection (a)), including  
2        with respect to assessing pH adjusters.

3            (2) PROCESS.—In issuing guidance under this  
4        subsection, the Secretary of Health and Human  
5        Services shall—

6            (A) publish draft guidance;

7            (B) provide a period of at least 60 days for  
8        comment on the draft guidance; and

9            (C) after considering any comments re-  
10       received and not later than one year after the  
11       close of the comment period on the draft guid-  
12       ance, publish final guidance.

13        (c) APPLICABILITY.—Section 505(j)(3)(H) of the  
14       Federal Food, Drug, and Cosmetic Act, as added by sub-  
15       section (a), applies beginning on the date of enactment  
16       of this Act, irrespective of the date on which the guidance  
17       required by subsection (b) is finalized.

18       **SEC. 904. TITLE 35 AMENDMENTS.**

19        (a) IN GENERAL.—Section 271(e) of title 35, United  
20       States Code, is amended—

21            (1) in paragraph (2)(C), in the flush text fol-  
22       lowing clause (ii), by adding at the end the fol-  
23       lowing: “With respect to a submission described in  
24       clause (ii), the act of infringement shall extend to  
25       any patent that claims the biological product, a

1 method of using the biological product, or a method  
2 or product used to manufacture the biological prod-  
3 uct.”; and

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

5 “(7)(A) Subject to subparagraphs (C), (D), and (E),  
6 if the sponsor of an approved application for a reference  
7 product, as defined in section 351(i) of the Public Health  
8 Service Act (42 U.S.C. 262(i)) (referred to in this para-  
9 graph as the ‘reference product sponsor’), brings an action  
10 for infringement under this section against an applicant  
11 for approval of a biological product under section 351(k)  
12 of such Act that references that reference product (re-  
13 ferred to in this paragraph as the ‘subsection (k) appli-  
14 cant’), the reference product sponsor may assert in the  
15 action a total of not more than 20 patents of the type  
16 described in subparagraph (B), not more than 10 of which  
17 shall have issued after the date specified in section  
18 351(l)(7)(A) of such Act.

19 “(B) The patents described in this subparagraph are  
20 patents that satisfy each of the following requirements:

21 “(i) Patents that claim the biological product  
22 that is the subject of an application under section  
23 351(k) of the Public Health Service Act (42 U.S.C.  
24 262(k)) (or a use of that product) or a method or

1 product used in the manufacture of such biological  
2 product.

3 “(ii) Patents that are included on the list of  
4 patents described in paragraph (3)(A) of section  
5 351(l) of the Public Health Service Act (42 U.S.C.  
6 262(l)), including as provided under paragraph (7)  
7 of such section 351(l).

8 “(iii) Patents that—

9 “(I) have an actual filing date of more  
10 than 4 years after the date on which the ref-  
11 erence product is approved; or

12 “(II) include a claim to a method in a  
13 manufacturing process that is not used by the  
14 reference product sponsor.

15 “(C) The court in which an action described in sub-  
16 paragraph (A) is brought may increase the number of pat-  
17 ents limited under that subparagraph—

18 “(i) if the request to increase that number is  
19 made without undue delay; and

20 “(ii)(I) if the interest of justice so requires; or

21 “(II) for good cause shown, which—

22 “(aa) shall be established if the subsection  
23 (k) applicant fails to provide information re-  
24 quired section 351(k)(2)(A) of the Public  
25 Health Service Act (42 U.S.C. 262(k)(2)(A))

1           that would enable the reference product sponsor  
2           to form a reasonable belief with respect to  
3           whether a claim of infringement under this sec-  
4           tion could reasonably be asserted; and

5           “(bb) may be established—

6                   “(AA) if there is a material change to  
7                   the biological product (or process with re-  
8                   spect to the biological product) of the sub-  
9                   section (k) applicant that is the subject of  
10                  the application;

11                  “(BB) if, with respect to a patent on  
12                  the supplemental list described in section  
13                  351(l)(7)(A) of Public Health Service Act  
14                  (42 U.S.C. 262(l)(7)(A)), the patent would  
15                  have issued before the date specified in  
16                  such section 351(l)(7)(A) but for the fail-  
17                  ure of the Office to issue the patent or a  
18                  delay in the issuance of the patent, as de-  
19                  scribed in paragraph (1) of section 154(b)  
20                  and subject to the limitations under para-  
21                  graph (2) of such section 154(b); or

22                  “(CC) for another reason that shows  
23                  good cause, as determined appropriate by  
24                  the court.

1       “(D) In determining whether good cause has been  
2 shown for the purposes of subparagraph (C)(ii)(II), a  
3 court may consider whether the reference product sponsor  
4 has provided a reasonable description of the identity and  
5 relevance of any information beyond the subsection (k) ap-  
6 plication that the court believes is necessary to enable the  
7 court to form a belief with respect to whether a claim of  
8 infringement under this section could reasonably be as-  
9 serted.

10       “(E) The limitation imposed under subparagraph  
11 (A)—

12               “(i) shall apply only if the subsection (k) appli-  
13 cant completes all actions required under paragraphs  
14 (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of  
15 section 351(l) of the Public Health Service Act (42  
16 U.S.C. 262(l)); and

17               “(ii) shall not apply with respect to any patent  
18 that claims, with respect to a biological product, a  
19 method for using that product in therapy, diagnosis,  
20 or prophylaxis, such as an indication or method of  
21 treatment or other condition of use.”.

22       (b) APPLICABILITY.—The amendments made by sub-  
23 section (a) shall apply with respect to an application sub-  
24 mitted under section 351(k) of the Public Health Service



1 Act (42 U.S.C. 262(k)) on or after the date of enactment  
2 of this Act.

3 **TITLE X—MISCELLANEOUS**

4 **SEC. 1001. TWO-YEAR EXTENSION OF SAFE HARBOR FOR**  
5 **ABSENCE OF DEDUCTIBLE FOR TELEHEALTH.**

6 (a) IN GENERAL.—Section 223(c)(2)(E)(ii) of the In-  
7 ternal Revenue Code of 1986 is amended by striking “Jan-  
8 uary 1, 2025” and inserting “January 1, 2027”.

9 (b) EFFECTIVE DATE.—The amendments made by  
10 this section shall apply to plan years beginning after De-  
11 cember 31, 2024.