

AMENDMENT TO H.R. 1442
OFFERED BY M____.

Page 1, strike line 6 and all that follows through
page 3, line 10 and insert the following:

1 SEC. 2. TABLE OF CONTENTS.

2 The table of contents for this Act is as follows:

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1 DIVISION A—RECYCLING, 2 WATER, AND ENVIRONMENT 3 RELATED PROVISIONS

4 SEC. 101. RECYCLING AND COMPOSTING ACCOUNTABILITY.

5 (a) SHORT TITLE.—This section may be cited as the
6 “Recycling and Composting Accountability Act”.

7 (b) DEFINITIONS.—

8 (1) IN GENERAL.—In this section:

9 (A) ADMINISTRATOR.—The term “Admin-
10 istrator” means the Administrator of the Envi-
11 ronmental Protection Agency.

12 (B) COMPOST.—The term “compost”
13 means a product that—

14 (i) is manufactured through the con-
15 trolled aerobic, biological decomposition of
16 biodegradable materials;

17 (ii) has been subjected to medium and
18 high temperature organisms, which—

1 (I) significantly reduce the viabil-
2 ity of pathogens and weed seeds; and

3 (II) stabilize carbon in the prod-
4 uct such that the product is beneficial
5 to plant growth; and

6 (iii) is typically used as a soil amend-
7 ment, but may also contribute plant nutri-
8 ents.

9 (C) COMPOSTABLE MATERIAL.—The term
10 “compostable material” means material that is
11 a feedstock for creating compost, including—

12 (i) wood;

13 (ii) agricultural crops;

14 (iii) paper, such as cardboard and
15 other paper products;

16 (iv) certified compostable products as-
17 sociated with organic waste;

18 (v) other organic plant material;

19 (vi) organic waste, including food
20 waste and yard waste; and

21 (vii) such other material that is com-
22 posed of biomass that can be continually
23 replenished or renewed, as determined by
24 the Administrator.

1 (D) INDIAN TRIBE.—The term “Indian
2 Tribe” has the meaning given the term in sec-
3 tion 4 of the Indian Self-Determination and
4 Education Assistance Act (25 U.S.C. 5304).

5 (E) RECYCLABLE MATERIAL.—The term
6 “recyclable material” means a material that is
7 obsolete, previously used, off-specification, sur-
8 plus, or incidentally produced for processing
9 into a specification-grade commodity for which
10 a reuse market currently exists or is being de-
11 veloped.

12 (F) RECYCLING.—The term “recycling”
13 means the series of activities—

14 (i) during which recyclable materials
15 are processed into specification-grade com-
16 modities and consumed as raw-material
17 feedstock, in lieu of virgin materials, in the
18 manufacturing of new products;

19 (ii) that may, with regard to recycla-
20 ble materials and prior to the activities de-
21 scribed in clause (i), include sorting, collec-
22 tion, processing, and brokering; and

23 (iii) that result, subsequent to proc-
24 essing described in clause (i), in consump-

1 tion by a materials manufacturer, includ-
2 ing for the manufacturing of new products.

3 (G) STATE.—The term “State” has the
4 meaning given the term in section 1004 of the
5 Solid Waste Disposal Act (42 U.S.C. 6903).

6 (2) DEFINITION OF PROCESSING.—In subpara-
7 graphs (E) and (F) of paragraph (1), the term
8 “processing” means any mechanical, manual, or
9 other method that—

10 (A) transforms a recyclable material into a
11 specification-grade commodity; and

12 (B) may occur in multiple steps, with dif-
13 ferent phases, including sorting, occurring at
14 different locations.

15 (c) REPORTS ON COMPOSTING AND RECYCLING IN-
16 FRASTRUCTURE CAPABILITIES.—

17 (1) IN GENERAL.—Subtitle D of the Solid
18 Waste Disposal Act (42 U.S.C. 6941 et seq.) is
19 amended by adding at the end the following:

20 **“SEC. 4011. REPORTS ON COMPOSTING AND RECYCLING IN-**
21 **FRASTRUCTURE CAPABILITIES.**

22 “(a) DEFINITIONS.—In this section:

23 “(1) RECYCLING AND COMPOSTING ACCOUNT-
24 ABILITY ACT TERMS.—The terms ‘compost’,
25 ‘compostable material’, ‘recyclable material’, and ‘re-

1 cycling’ have the meanings given the terms in sub-
2 section (b) of the Recycling and Composting Ac-
3 countability Act.

4 “(2) COMPOSTING FACILITY.—The term
5 ‘composting facility’ means a location, structure, or
6 device that transforms compostable materials into
7 compost.

8 “(3) INDIAN TRIBE.—The term ‘Indian Tribe’
9 has the meaning given the term in section 4 of the
10 Indian Self-Determination and Education Assistance
11 Act (25 U.S.C. 5304).

12 “(4) MATERIALS RECOVERY FACILITY.—

13 “(A) IN GENERAL.—The term ‘materials
14 recovery facility’ means a dedicated facility
15 where primarily residential recyclable materials,
16 which are diverted from disposal by the gener-
17 ator and collected separately from municipal
18 solid waste, are mechanically or manually sort-
19 ed into commodities for further processing into
20 specification-grade commodities for sale to end
21 users.

22 “(B) EXCLUSION.—The term ‘materials
23 recovery facility’ does not include a solid waste
24 management facility that may process munic-
25 ipal solid waste to remove recyclable materials.

1 “(C) DEFINITION OF PROCESSING.—For
2 purposes of this paragraph, the term ‘proc-
3 essing’ has the meaning given the term in sub-
4 section (b)(2) of the Recycling and Composting
5 Accountability Act.

6 “(b) REPORT.—

7 “(1) IN GENERAL.—The Administrator shall re-
8 quest information and data from, collaborate with,
9 or contract with, as necessary and appropriate,
10 States, units of local government, and Indian Tribes,
11 for the provision, preparation, and publication of a
12 report, or to expand work under the National Recy-
13 cling Strategy to include information and data, on
14 compostable materials and efforts to reduce contami-
15 nation rates for recycling, including—

16 “(A) an evaluation of existing Federal,
17 State, and local laws that may present barriers
18 to implementation of composting strategies;

19 “(B) a description and evaluation of
20 composting infrastructure and programs within
21 States, units of local government, and Indian
22 Tribes;

23 “(C) an estimate of the costs and approxi-
24 mate land needed to expand composting pro-
25 grams; and

1 “(D) a review of the practices of manufac-
2 turers and companies that are moving to using
3 compostable packaging and food service ware
4 for the purpose of making the composting proc-
5 ess the end-of-life use of those products.

6 “(2) SUBMISSION.—Not later than 2 years
7 after the date of enactment of this section, the Ad-
8 ministrator shall submit to Congress the report pre-
9 pared under paragraph (1).

10 “(c) INVENTORY OF MATERIALS RECOVERY FACILI-
11 TIES.—Not later than 3 years after the date of enactment
12 of this section, and every 4 years thereafter, the Adminis-
13 trator, in consultation with relevant Federal agencies and
14 States, units of local government, and Indian Tribes,
15 shall—

16 “(1) prepare an inventory or estimate of mate-
17 rials recovery facilities in the United States, includ-
18 ing—

19 “(A) the number of materials recovery fa-
20 cilities in each State; and

21 “(B) a general description of the materials
22 that each of those materials recovery facilities
23 can process, including—

24 “(i) in the case of plastic, a descrip-
25 tion of—

1 “(I) the types of accepted resin,
2 if applicable; and

3 “(II) the packaging or product
4 format, such as a jug, a carton, or
5 film;

6 “(ii) food packaging and service ware,
7 such as a bottle, cutlery, or a cup;

8 “(iii) paper;

9 “(iv) aluminum, such as an aluminum
10 beverage can, food can, aerosol can, or foil;

11 “(v) steel, such as a steel food or aer-
12 osol can;

13 “(vi) other scrap metal;

14 “(vii) glass; or

15 “(viii) any other material not de-
16 scribed in any of clauses (i) through (vii)
17 that a materials recovery facility processes;
18 and

19 “(2) submit to Congress the inventory or esti-
20 mate prepared under paragraph (1).

21 “(d) INFORMATION ON RECYCLING AND COMPOSTING
22 SYSTEMS.—The Administrator shall, as necessary and ap-
23 propriate, collaborate or contract with States, units of
24 local government, and Indian Tribes to estimate, with re-
25 spect to the United States—

1 “(1) the number and types of recycling and
2 composting programs;

3 “(2) the types and forms of materials accepted
4 by recycling or composting programs;

5 “(3) the number of individuals—

6 “(A) with access to recycling and
7 composting services to at least the extent of ac-
8 cess to disposal services; and

9 “(B) who use, on a percentage basis, the
10 recycling and composting services described in
11 subparagraph (A);

12 “(4) the number of individuals with barriers to
13 accessing recycling and composting services similar
14 to their access to disposal services and the types of
15 those barriers experienced;

16 “(5) the inbound contamination and capture
17 rates of recycling and composting programs;

18 “(6) if applicable, other available recycling or
19 composting programs; and

20 “(7) the average costs and benefits to States,
21 units of local government, and Indian Tribes of recy-
22 cling and composting programs.

23 “(e) RECYCLING REPORTING RATES.—

24 “(1) COLLECTION OF DATA; DEVELOPMENT OF
25 RATES.—The Administrator may use amounts made

1 available under subsection (f) of the Recycling and
2 Composting Accountability Act—

3 “(A) to biannually collect, in collaboration
4 with States, to the extent practicable, informa-
5 tion supplied on a voluntary basis to develop
6 the estimated rates described in subparagraphs
7 (B) and (C);

8 “(B) to develop a standardized estimated
9 rate of recyclable materials in States that pro-
10 vide information under subparagraph (A) that
11 have been successfully diverted from the waste
12 stream and brought to a materials recovery fa-
13 cility or composting facility; and

14 “(C) to develop an estimated national recy-
15 cling rate based on the information described in
16 subparagraphs (A) and (B).

17 “(2) USE.—Using amounts made available
18 under subsection (f) of the Recycling and
19 Composting Accountability Act, the Administrator
20 may use the information collected and rates devel-
21 oped under paragraph (1) to provide requesting
22 States, units of local government, and Indian Tribes
23 data and technical assistance—

1 “(A) to reduce the overall waste produced
2 by the States, units of local government, and
3 Indian Tribes;

4 “(B) to assist the States, units of local
5 government, and Indian Tribes in under-
6 standing the nuances of the information col-
7 lected relating to diversion activities; and

8 “(C) to increase recycling and composting
9 rates of the States, units of local government,
10 and Indian Tribes.

11 “(f) REPORT ON END MARKETS.—The Adminis-
12 trator, in collaboration or contract with, as necessary and
13 appropriate, relevant Federal agencies, States, units of
14 local government, or Indian Tribes, shall—

15 “(1) provide an update to the report submitted
16 under section 306 of the Save Our Seas 2.0 Act
17 (Public Law 116–224; 134 Stat. 1096) to include an
18 addendum on the end-market sale of all recyclable
19 materials from materials recovery facilities that
20 process recyclable materials, including, to the extent
21 practicable—

22 “(A) the total, in dollars per ton, domestic
23 sales of bales of recyclable materials; and

24 “(B) the total, in dollars per ton, inter-
25 national sales of bales of recyclable materials;

1 “(2) prepare a report on the end-market sale of
2 compost from, to the extent practicable, compostable
3 materials, including the total, in dollars per ton, of
4 domestic sales of compostable materials; and

5 “(3) not later than 3 years after the date of en-
6 actment of this section, submit to Congress the up-
7 date to the report prepared under paragraph (1) and
8 the report prepared under paragraph (2).

9 “(g) PRIVILEGED OR CONFIDENTIAL INFORMA-
10 TION.—

11 “(1) IN GENERAL.—Information collected under
12 subsection (e)(1) or paragraph (1) or (2) of sub-
13 section (f) shall not include any privileged or con-
14 fidential information described in section 552(b)(4)
15 of title 5, United States Code.

16 “(2) NONDISCLOSURE.—Information collected
17 to carry out this section shall not be made public if
18 the information meets the requirements of section
19 552(b) of title 5, United States Code.”.

20 (2) CLERICAL AMENDMENT.—The table of con-
21 tents in section 1001 of the Solid Waste Disposal
22 Act (Public Law 89–272; 90 Stat. 2795; 98 Stat.
23 3268) is amended by inserting after the item relat-
24 ing to section 4010 the following:

“Sec. 4011. Report on composting and recycling infrastructure capabilities.”.

1 (d) FEDERAL AGENCY ACTIVITIES RELATED TO RE-
2 CYCLING.—Not later than 2 years after the date of enact-
3 ment of this Act, and every 2 years thereafter until 2033,
4 the Comptroller General of the United States shall make
5 publicly available a report—

6 (1) detailing or, to the extent practicable, pro-
7 viding an estimate of—

8 (A) the total annual recycling and
9 composting rates reported by all Federal agen-
10 cies; and

11 (B) the total annual percentage of prod-
12 ucts containing recyclable material, compostable
13 material, or recovered materials purchased by
14 all Federal agencies, including—

15 (i) the total quantity of procured
16 products containing recyclable material or
17 recovered materials listed in the com-
18 prehensive procurement guidelines pub-
19 lished under section 6002(e) of the Solid
20 Waste Disposal Act (42 U.S.C. 6962(e));
21 and

22 (ii) the total quantity of compostable
23 material purchased by all Federal agencies;

24 (2) identifying the activities of each Federal
25 agency that promote recycling or composting; and

1 (3) identifying activities that Federal agencies
2 could carry out to further promote recycling or
3 composting.

4 (e) STUDY ON THE DIVERSION OF RECYCLABLE MA-
5 TERIALS FROM A CIRCULAR MARKET.—

6 (1) IN GENERAL.—Not later than 1 year after
7 the date of enactment of this Act, the Administrator
8 shall develop a metric for determining the proportion
9 of recyclable materials in commercial and municipal
10 waste streams that are being diverted from a cir-
11 cular market.

12 (2) STUDY; REPORT.—Not later than 1 year
13 after the development of a metric under paragraph
14 (1), the Administrator shall conduct a study of, and
15 submit to Congress a report on, the proportion of re-
16 cyclable materials in commercial and municipal
17 waste streams that, during each of the 10 calendar
18 years preceding the year of submission of the report,
19 were diverted from a circular market.

20 (3) DATA.—The report under paragraph (2)
21 shall provide data on specific recyclable materials,
22 including aluminum, plastics, paper and paperboard,
23 textiles, and glass, that were prevented from remain-
24 ing in a circular market through disposal or elimi-

1 nation, and to what use those specific recyclable ma-
2 terials were lost.

3 (4) EVALUATION.—The report under paragraph
4 (2) shall include an evaluation of whether the estab-
5 lishment or improvement of recycling programs
6 would—

7 (A) improve recycling rates;

8 (B) reduce the quantity of recyclable mate-
9 rials being unutilized in a circular market; and

10 (C) affect prices paid by consumers for
11 products using materials recycled in the circular
12 market.

13 (f) AUTHORIZATION OF APPROPRIATIONS.—There is
14 authorized to be appropriated to the Administrator to
15 carry out this section and the amendments made by this
16 section \$4,000,000 for each of fiscal years 2025 through
17 2029.

18 (g) ADMINISTRATION.—

19 (1) UNFUNDED MANDATES.—The Adminis-
20 trator or the Secretary of Commerce may not exer-
21 cise any authority under this section or any amend-
22 ment made by this section if exercising that author-
23 ity would require a State, a unit of local govern-
24 ment, or an Indian Tribe to carry out a mandate for
25 which funding is not available.

1 (2) NONDISCLOSURE.—Any information col-
2 lected to carry out this section shall not be made
3 public if the information meets the requirements of
4 section 552(b) of title 5, United States Code.

5 **SEC. 102. RECYCLING INFRASTRUCTURE AND ACCESSI-**
6 **BILITY PROGRAM.**

7 (a) DEFINITIONS.—In this section:

8 (1) ADMINISTRATOR.—The term “Adminis-
9 trator” means the Administrator of the Environ-
10 mental Protection Agency.

11 (2) CURBSIDE RECYCLING.—The term
12 “curbside recycling” means the process by which
13 residential recyclable materials are picked up
14 curbside.

15 (3) ELIGIBLE ENTITY.—The term “eligible enti-
16 ty” means—

17 (A) a State (as defined in section 1004 of
18 the Solid Waste Disposal Act (42 U.S.C.
19 6903));

20 (B) a unit of local government;

21 (C) an Indian Tribe; and

22 (D) a public-private partnership.

23 (4) INDIAN TRIBE.—The term “Indian Tribe”
24 has the meaning given the term in section 4 of the

1 Indian Self-Determination and Education Assistance
2 Act (25 U.S.C. 5304).

3 (5) MATERIALS RECOVERY FACILITY.—

4 (A) IN GENERAL.—The term “materials
5 recovery facility” means a recycling facility
6 where primarily residential recyclables, which
7 are diverted from disposal by a generator and
8 collected separately from municipal solid waste,
9 are mechanically or manually sorted into com-
10 modities for further processing into specifica-
11 tion-grade commodities for sale to end users.

12 (B) EXCLUSION.—The term “materials re-
13 covery facility” does not include a solid waste
14 management facility that may process munic-
15 ipal solid waste to remove recyclable materials.

16 (6) PILOT GRANT PROGRAM.—The term “pilot
17 grant program” means the Recycling Infrastructure
18 and Accessibility Program established under sub-
19 section (b).

20 (7) RECYCLABLE MATERIAL.—The term “recy-
21 clable material” means obsolete, previously used, off-
22 specification, surplus, or incidentally produced mate-
23 rial for processing into a specification-grade com-
24 modity for which a market exists.

1 (8) TRANSFER STATION.—The term “transfer
2 station” means a facility that—

3 (A) receives and consolidates recyclable
4 material from curbside recycling or drop-off fa-
5 cilities; and

6 (B) loads the recyclable material onto trac-
7 tor trailers, railcars, or barges for transport to
8 a distant materials recovery facility or another
9 recycling-related facility.

10 (9) UNDERSERVED COMMUNITY.—The term
11 “underserved community” means a community, in-
12 cluding an unincorporated area, without access to
13 full recycling services because—

14 (A) transportation, distance, or other rea-
15 sons render utilization of available processing
16 capacity at an existing materials recovery facil-
17 ity cost prohibitive; or

18 (B) the processing capacity of an existing
19 materials recovery facility is insufficient to
20 manage the volume of recyclable materials pro-
21 duced by that community.

22 (b) ESTABLISHMENT.—Not later than 18 months
23 after the date of enactment of this Act, the Administrator
24 shall establish a pilot grant program, to be known as the
25 “Recycling Infrastructure and Accessibility Program”, to

1 award grants, on a competitive basis, to eligible entities
2 to improve recycling accessibility in a community or com-
3 munities within the same geographic area.

4 (c) GOAL.—The goal of the pilot grant program is
5 to fund eligible projects that will significantly improve ac-
6 cessibility to recycling systems through investments in in-
7 frastructure in underserved communities through the use
8 of a hub-and-spoke model for recycling infrastructure de-
9 velopment.

10 (d) APPLICATIONS.—To be eligible to receive a grant
11 under the pilot grant program, an eligible entity shall sub-
12 mit to the Administrator an application at such time, in
13 such manner, and containing such information as the Ad-
14 ministrator may require.

15 (e) CONSIDERATIONS.—In selecting eligible entities
16 to receive a grant under the pilot grant program, the Ad-
17 ministrator shall consider—

18 (1) whether the community or communities in
19 which the eligible entity is seeking to carry out a
20 proposed project has curbside recycling;

21 (2) whether the proposed project of the eligible
22 entity will improve accessibility to recycling services
23 in a single underserved community or multiple un-
24 derserved communities; and

1 (3) if the eligible entity is a public-private part-
2 nership, the financial health of the private entity
3 seeking to enter into that public-private partnership.

4 (f) PRIORITY.—In selecting eligible entities to receive
5 a grant under the pilot grant program, the Administrator
6 shall give priority to eligible entities seeking to carry out
7 a proposed project in a community in which there is not
8 more than 1 materials recovery facility within a 75-mile
9 radius of that community.

10 (g) USE OF FUNDS.—An eligible entity awarded a
11 grant under the pilot grant program may use the grant
12 funds for projects to improve recycling accessibility in
13 communities, including in underserved communities, by—

14 (1) increasing the number of transfer stations;

15 (2) expanding curbside recycling collection pro-
16 grams where appropriate; and

17 (3) leveraging public-private partnerships to re-
18 duce the costs associated with collecting and trans-
19 porting recyclable materials in underserved commu-
20 nities.

21 (h) PROHIBITION ON USE OF FUNDS.—An eligible
22 entity awarded a grant under the pilot grant program may
23 not use the grant funds for projects relating to recycling
24 education programs.

1 (i) MINIMUM AND MAXIMUM GRANT AMOUNT.—A
2 grant awarded to an eligible entity under the pilot grant
3 program shall be in an amount—

4 (1) not less than \$500,000; and

5 (2) not more than \$15,000,000.

6 (j) SET-ASIDE.—The Administrator shall set aside
7 not less than 70 percent of the amounts made available
8 to carry out the pilot grant program for each fiscal year
9 to award grants to eligible entities to carry out a proposed
10 project or program in a single underserved community or
11 multiple underserved communities.

12 (k) FEDERAL SHARE.—The Federal share of the cost
13 of a project or program carried out by an eligible entity
14 using grant funds shall be not more than 95 percent.

15 (l) REPORT.—Not later than 2 years after the date
16 on which the first grant is awarded under the pilot grant
17 program, the Administrator shall submit to Congress a re-
18 port describing the implementation of the pilot grant pro-
19 gram, which shall include—

20 (1) a list of eligible entities that have received
21 a grant under the pilot grant program;

22 (2) the actions taken by each eligible entity that
23 received a grant under the pilot grant program to
24 improve recycling accessibility with grant funds; and

1 (3) to the extent information is available, a de-
2 scription of how grant funds received under the pilot
3 grant program improved recycling rates in each com-
4 munity in which a project or program was carried
5 out under the pilot grant program.

6 (m) AUTHORIZATION OF APPROPRIATIONS.—

7 (1) IN GENERAL.—There is authorized to be
8 appropriated to the Administrator to carry out the
9 pilot grant program \$30,000,000 for each of fiscal
10 years 2025 through 2029, to remain available until
11 expended.

12 (2) ADMINISTRATIVE COSTS AND TECHNICAL
13 ASSISTANCE.—Of the amounts made available under
14 paragraph (1), the Administrator may use up to 5
15 percent—

16 (A) for administrative costs relating to car-
17 rying out the pilot grant program; and

18 (B) to provide technical assistance to eligi-
19 ble entities applying for a grant under the pilot
20 grant program.

21 **SEC. 103. DRINKING WATER INFRASTRUCTURE RISK AND**
22 **RESILIENCE.**

23 Section 1433(g) of the Safe Drinking Water Act (42
24 U.S.C. 300i–2(g)) is amended—

1 (1) in paragraph (1), by striking “2020 and
2 2021” and inserting “2026 and 2027”;

3 (2) in paragraph (4), by striking “\$5,000,000”
4 and inserting “\$10,000,000”;

5 (3) in paragraph (5), by striking
6 “\$10,000,000” and inserting “\$20,000,000”; and

7 (4) in paragraph (6)—

8 (A) by striking “\$25,000,000” and insert-
9 ing “\$50,000,000”; and

10 (B) by striking “2020 and 2021” and in-
11 serting “2026 and 2027”.

12 **SEC. 104. REAUTHORIZATION OF DIESEL EMISSIONS RE-**
13 **DUCTION ACT.**

14 Section 797(a) of the Energy Policy Act of 2005 (42
15 U.S.C. 16137(a)) is amended by striking “2024” and in-
16 serting “2029”.

17 **SEC. 105. NATIONWIDE CONSUMER AND FUEL RETAILER**
18 **CHOICE ACT.**

19 (a) **SHORT TITLE.**—This section may be cited as the
20 “Nationwide Consumer and Fuel Retailer Choice Act”.

21 (b) **ETHANOL WAIVER.**—

22 (1) **EXISTING WAIVERS.**—Section 211(f)(4) of
23 the Clean Air Act (42 U.S.C. 7545(f)(4)) is amend-
24 ed—

1 (A) by striking “(4) The Administrator,
2 upon” and inserting the following:

3 “(4) WAIVERS.—

4 “(A) IN GENERAL.—The Administrator,
5 on”;

6 (B) in subparagraph (A) (as so des-
7 ignated)—

8 (i) in the first sentence—

9 (I) by striking “of this sub-
10 section” each place it appears; and

11 (II) by striking “if he deter-
12 mines” and inserting “if the Adminis-
13 trator determines”; and

14 (ii) in the second sentence, by striking
15 “The Administrator” and inserting the fol-
16 lowing:

17 “(B) FINAL ACTION.—The Adminis-
18 trator”; and

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

20 “(C) REID VAPOR PRESSURE.—A fuel or
21 fuel additive may be introduced into commerce
22 if—

23 “(i)(I) the Administrator determines
24 that the fuel or fuel additive is substan-
25 tially similar to a fuel or fuel additive uti-

1 lized in the certification of any model year
2 vehicle pursuant to paragraph (1)(A); or

3 “(II) the fuel or fuel additive has been
4 granted a waiver under subparagraph (A)
5 and meets all of the conditions of that
6 waiver other than any limitation of the
7 waiver with respect to the Reid Vapor
8 Pressure of the fuel or fuel additive; and

9 “(ii) the fuel or fuel additive meets all
10 other applicable Reid Vapor Pressure re-
11 quirements under subsection (h).”.

12 (2) REID VAPOR PRESSURE LIMITATION.—Sec-
13 tion 211(h) of the Clean Air Act (42 U.S.C.
14 7545(h)) is amended—

15 (A) by striking “vapor pressure” each
16 place it appears and inserting “Vapor Pres-
17 sure”;

18 (B) in paragraph (4), in the matter pre-
19 ceding subparagraph (A), by striking “10 per-
20 cent” and inserting “10 to 15 percent”; and

21 (C) in paragraph (5)(A)—

22 (i) by striking “Upon notification, ac-
23 companied by” and inserting “On receipt
24 of a notification that is submitted after the
25 date of enactment of the Nationwide Con-

1 sumer and Fuel Retailer Choice Act, and is
2 accompanied by appropriate”;

3 (ii) by striking “10 percent” and in-
4 serting “10 to 15 percent”; and

5 (iii) by adding at the end the fol-
6 lowing: “Upon the enactment of the Na-
7 tionwide Consumer and Fuel Retailer
8 Choice Act, any State for which the notifi-
9 cation from the Governor of a State was
10 submitted before the date of enactment of
11 the Nationwide Consumer and Fuel Re-
12 tailer Choice Act and to which the Admin-
13 istrator applied the Reid Vapor Pressure
14 limitation established by paragraph (1)
15 shall instead have the Reid Vapor Pressure
16 limitation established by paragraph (4)
17 apply to all fuel blends containing gasoline
18 and 10 to 15 percent denatured anhydrous
19 ethanol that are sold, offered for sale, dis-
20 pensed, supplied, offered for supply, trans-
21 ported, or introduced into commerce in the
22 area during the high ozone season.”.

23 (c) GENERATION OF CREDITS BY SMALL REFIN-
24 ERIES UNDER THE RENEWABLE FUEL PROGRAM.—Sec-
25 tion 211(o)(9) of the Clean Air Act (42 U.S.C.

1 7545(o)(9)) is amended by adding at the end the fol-
2 lowing:

3 “(E) CREDITS GENERATED FOR 2016–2018
4 COMPLIANCE YEARS.—

5 “(i) RULE.—For any small refinery
6 described in clause (ii) or (iii), the credits
7 described in the respective clause shall
8 be—

9 “(I) returned to the small refin-
10 ery and, notwithstanding paragraph
11 (5)(C), deemed eligible for future
12 compliance years; or

13 “(II) applied as a credit in the
14 EPA Moderated Transaction System
15 (EMTS) account of the small refinery.

16 “(ii) COMPLIANCE YEARS 2016 AND
17 2017.—Clause (i) applies with respect to
18 any small refinery that—

19 “(I) retired credits generated for
20 compliance years 2016 or 2017; and

21 “(II) submitted a petition under
22 subparagraph (B)(i) for that compli-
23 ance year that remained outstanding
24 as of December 1, 2022.

1 “(iii) COMPLIANCE YEAR 2018.—In
2 addition to small refineries described in
3 clause (ii), clause (i) applies with respect
4 to any small refinery—

5 “(I) that submitted a petition
6 under subparagraph (B)(i) for compli-
7 ance year 2018 by September 1,
8 2019;

9 “(II) that retired credits gen-
10 erated for compliance year 2018 as
11 part of the compliance demonstration
12 of the small refinery for compliance
13 year 2018 by March 31, 2019; and

14 “(III) for which—

15 “(aa) the petition remained
16 outstanding as of December 1,
17 2022; or

18 “(bb) the Administrator de-
19 nied the petition as of July 1,
20 2022, and has not returned the
21 retired credits as of December 1,
22 2022.”.

23 (d) ADDRESSING RENEWABLE FUEL MARKET MA-
24 nipulation and Transparency.—Not later than 90
25 days after the date of enactment of this Act, the Adminis-

1 trator of the Environmental Protection Agency, in collabo-
2 ration with the Commodity Futures Trading Commission,
3 shall—

4 (1) review all applicable Renewable Identifica-
5 tion Number (as described in section 80.1425 of title
6 40, Code of Federal Regulations (or successor regu-
7 lations)) data collected for the EPA Moderated
8 Transaction System (as defined in section 80.2 of
9 title 40, Code of Federal Regulations (or successor
10 regulations)); and

11 (2) submit to Congress a report that identifies
12 any additional data that should be collected to re-
13 duce renewable fuel market manipulation.

14 **DIVISION B—COMMERCE**
15 **TITLE I—YOUTH POISONING**
16 **PREVENTION**

17 **SEC. 101. SHORT TITLE.**

18 This title may be cited as the “Youth Poisoning Pro-
19 tection Act”.

20 **SEC. 102. BANNING OF PRODUCTS CONTAINING A HIGH**
21 **CONCENTRATION OF SODIUM NITRITE.**

22 (a) IN GENERAL.—Any consumer product containing
23 a high concentration of sodium nitrite shall be considered
24 to be a banned hazardous product under section 8 of the
25 Consumer Product Safety Act (15 U.S.C. 2057).

1 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
2 tion shall be construed to—

3 (1) prohibit any commercial or industrial pur-
4 pose in which high concentration sodium nitrite is
5 not customarily produced or distributed for sale to,
6 or use or consumption by, or enjoyment of, a con-
7 sumer; and

8 (2) apply to high concentration sodium nitrite
9 that meets the definition of a drug, device, or cos-
10 metic (as such terms are defined in sections 201(g),
11 (h), and (i) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 321(g), (h), and (i))), or food
13 (as defined in section 201(f) of such Act (21 U.S.C.
14 321(f))), including poultry and poultry products (as
15 such terms are defined in sections 4(e) and (f) of
16 the Poultry Products Inspection Act (21 U.S.C.
17 453(e) and (f))), meat and meat food products (as
18 such terms are defined in section 1(j) of the Federal
19 Meat Inspection Act (21 U.S.C. 601(j))), and eggs
20 and egg products (as such terms are defined in sec-
21 tion 4 of the Egg Products Inspection Act (21
22 U.S.C. 1033)).

23 (c) DEFINITIONS.—For purposes of this section:

24 (1) CONSUMER PRODUCT.—The term consumer
25 product has the meaning given that term under sec-

tion 3(a)(5) of the Consumer Product Safety Act
(15 U.S.C. 2052(a)(5)).

(2) HIGH CONCENTRATION OF SODIUM NITRITE.—The term high concentration of sodium nitrite means a concentration of 10 or more percent by weight of sodium nitrite.

(d) EFFECTIVE DATE.—This section shall take effect 90 days after the date of enactment of this Act.

TITLE II—CONSUMER PRODUCT SAFETY STANDARD FOR CERTAIN BATTERIES

SEC. 201. CONSUMER PRODUCT SAFETY STANDARD FOR CERTAIN BATTERIES.

(a) CONSUMER PRODUCT SAFETY STANDARD REQUIRED.—Not later than 180 days after the date of the enactment of this Act, the Consumer Product Safety Commission (referred to in this section as the “Commission”) shall promulgate, under section 553 of title 5, United States Code, the provisions of ANSI/CAN/UL 2271–Standard for Batteries for Use in Light Electric Vehicle Applications, ANSI/CAN/UL 2849–Standard for Safety for Electrical Systems for eBikes, and ANSI/CAN/UL 2272–Standard for Electrical Systems for Personal E–Mobility Devices, as in effect on the date of enactment of this Act, as final consumer product safety standards.

1 (b) CONSUMER PRODUCT SAFETY COMMISSION DE-
2 TERMINATION OF SCOPE.—In adopting the standards
3 under subsection (a), the Commission shall limit the appli-
4 cation of such standards to consumer products as defined
5 in section 3(a)(5) of the Consumer Product Safety Act (15
6 U.S.C. 2052(a)(5)).

7 (c) REVISION OF VOLUNTARY STANDARDS.—

8 (1) NOTICE TO COMMISSION.—If the provisions
9 of ANSI/CAN/UL 2271—Standard for Batteries for
10 Use in Light Electric Vehicle Applications, ANSI/
11 CAN/UL 2849—Standard for Safety for Electrical
12 Systems for eBikes, or ANSI/CAN/UL 2272—Stand-
13 ard for Electrical Systems for Personal E—Mobility
14 Devices, are revised following the enactment of this
15 Act, the organization that revised the requirements
16 of such standard shall notify the Commission after
17 the final approval of the revision.

18 (2) TREATMENT OF REVISION.—The revised
19 voluntary standard shall be considered to be a con-
20 sumer product safety standard issued by the Com-
21 mission under section 9 of the Consumer Product
22 Safety Act (15 U.S.C. 2058), effective 180 days
23 after the date on which the organization notifies the
24 Commission (or such later date specified by the
25 Commission in the Federal Register) unless, within

1 90 days after receiving that notice, the Commission
2 notifies the organization that it has determined that
3 the proposed revision, in whole or in part, does not
4 improve the safety of the consumer product covered
5 by the standard and that the Commission is retain-
6 ing the existing consumer product safety standard.

7 (d) TREATMENT OF STANDARD.—A standard pro-
8 mulgated under this section, including a revision of such
9 standard adopted by the Commission, shall be treated as
10 a consumer product safety rule promulgated under section
11 9 of the Consumer Product Safety Act (15 U.S.C. 2058).

12 (e) REPORT TO CONGRESS.—

13 (1) IN GENERAL.—Not later than 5 years after
14 the date of enactment of this Act, the Commission
15 shall submit to the Committee on Commerce,
16 Science, and Transportation of the Senate and the
17 Committee on Energy and Commerce of the House
18 of Representatives, a report regarding fires, explo-
19 sions, and other hazards relating to lithium-ion bat-
20 teries used in micromobility products during the pe-
21 riod beginning on the date of enactment of this Act
22 and ending on the report date.

23 (2) CONTENT.—The report required by para-
24 graph (1) shall describe, at a minimum—

1 (A) the source of the information that was
2 provided to the Commission regarding the fire,
3 explosion, or other hazard;

4 (B) the make and model of the lithium-ion
5 battery and micromobility product that resulted
6 in a fire, explosion, or other hazard, if known;

7 (C) whether a lithium-ion battery involved
8 in a fire, explosion, or other hazard complied
9 with the standard required by this section, if
10 known; and

11 (D) if known, the manufacturer and coun-
12 try of manufacture of a lithium-ion battery that
13 resulted in a fire, explosion, or other hazard.

14 **TITLE III—FOREIGN ADVERSARY**
15 **COMMUNICATIONS TRANSPARENCY**
16 **ACT**

17 **SEC. 301. SHORT TITLE.**

18 This title may be cited as the “Foreign Adversary
19 Communications Transparency Act”.

20 **SEC. 302. LIST OF ENTITIES HOLDING FCC AUTHORIZA-**
21 **TIONS, LICENSES, OR OTHER GRANTS OF AU-**
22 **THORITY AND HAVING CERTAIN FOREIGN**
23 **OWNERSHIP.**

24 (a) IN GENERAL.—Not later than 120 days after the
25 date of the enactment of this Act, the Commission shall

1 publish on the internet website of the Commission a list
2 of each entity—

3 (1) that holds a license issued by the Commis-
4 sion pursuant to—

5 (A) section 309(j) of the Communications
6 Act of 1934 (47 U.S.C. 309(j)); or

7 (B) the Act of May 27, 1921 (47 U.S.C.
8 34 et seq.; commonly known as the “Cable
9 Landing Licensing Act”) and Executive Order
10 10530 (3 U.S.C. 301 note; relating to the per-
11 formance of certain functions vested in or sub-
12 ject to the approval of the President); and

13 (2) with respect to which—

14 (A) a covered entity holds an equity or vot-
15 ing interest that is required to be reported to
16 the Commission under the ownership rules of
17 the Commission; or

18 (B) an appropriate national security agen-
19 cy has determined that a covered entity exerts
20 control, regardless of whether such covered enti-
21 ty holds an equity or voting interest as de-
22 scribed in subparagraph (A).

23 (b) RULEMAKING.—

24 (1) IN GENERAL.—Not later than 18 months
25 after the date of the enactment of this Act, the

1 Commission shall issue rules to obtain information
2 to identify each entity—

3 (A) that holds any authorization, license,
4 or other grant of authority issued by the Com-
5 mission (other than a license described in sub-
6 section (a)(1)); and

7 (B) with respect to which a covered entity
8 holds an equity or voting interest that is re-
9 quired to be reported to the Commission under
10 the ownership rules of the Commission.

11 (2) PLACEMENT ON LIST.—Not later than 1
12 year after the Commission issues the rules required
13 by paragraph (1), the Commission shall place each
14 entity described in such paragraph on the list pub-
15 lished under subsection (a).

16 (c) PAPERWORK REDUCTION ACT EXEMPTION.—A
17 collection of information conducted or sponsored by the
18 Commission to implement this section does not constitute
19 a collection of information for the purposes of subchapter
20 I of chapter 35 of title 44, United States Code (commonly
21 referred to as the “Paperwork Reduction Act”).

22 (d) ANNUAL UPDATES.—The Commission shall, not
23 less frequently than annually, update the list published
24 under subsection (a), including with respect to any entity
25 required to be placed on such list by subsection (b)(2).

1 (e) DEFINITIONS.—In this section:

2 (1) APPROPRIATE NATIONAL SECURITY AGEN-
3 CY.—The term “appropriate national security agen-
4 cy” has the meaning given such term in section 9
5 of the Secure and Trusted Communications Net-
6 works Act of 2019 (47 U.S.C. 1608).

7 (2) COMMISSION.—The term “Commission”
8 means the Federal Communications Commission.

9 (3) COVERED COUNTRY.—The term “covered
10 country” means a country specified in section
11 4872(f)(2) of title 10, United States Code.

12 (4) COVERED ENTITY.—The term “covered en-
13 tity” means—

14 (A) the government of a covered country;

15 (B) an entity organized under the laws of
16 a covered country; and

17 (C) a subsidiary of an entity described in
18 subparagraph (B), regardless of whether the
19 subsidiary is organized under the laws of a cov-
20 ered country.

21 **TITLE IV—PROMOTING** 22 **RESILIENT SUPPLY CHAINS**

23 **SEC. 401. SHORT TITLE.**

24 This title may be cited as the “Promoting Resilient
25 Supply Chains Act”.

1 **SEC. 402. ADDITIONAL RESPONSIBILITIES OF ASSISTANT**
2 **SECRETARY OF COMMERCE FOR INDUSTRY**
3 **AND ANALYSIS.**

4 In addition to the responsibilities of the Assistant
5 Secretary on the day before the date of the enactment of
6 this Act, the Assistant Secretary shall have the following
7 responsibilities:

8 (1) Promote the stability and resilience of crit-
9 ical supply chains and critical and emerging tech-
10 nologies that strengthen the national security of the
11 United States.

12 (2) Lead the Working Group established pursu-
13 ant to section 403 and consult covered nongovern-
14 mental representatives, industry, institutions of
15 higher education, and State and local governments
16 in order to—

17 (A) promote resilient critical supply chains;
18 and

19 (B) identify, prepare for, and respond to
20 supply chain shocks to—

21 (i) critical industries;

22 (ii) critical supply chains; and

23 (iii) critical and emerging tech-
24 nologies.

1 (3) Encourage the growth and competitiveness
2 of United States production and manufacturing in
3 the United States of emerging technologies.

4 (4) Assess the resilience, diversity, and strength
5 of critical supply chains and critical and emerging
6 technologies.

7 (5) In consultation with the Secretary of State
8 and the United States Trade Representative, sup-
9 port the availability of critical goods from domestic
10 manufacturers, domestic enterprises, and manufac-
11 turing operations in countries that are allies or key
12 international partner nations.

13 (6) Assist the Federal Government in preparing
14 for and responding to supply chain shocks to critical
15 supply chains, including by improving flexible manu-
16 facturing capacities and capabilities in the United
17 States.

18 (7) Consistent with United States obligations
19 under international agreements, encourage and
20 incentivize the reduced reliance of domestic enter-
21 prises and domestic manufacturers on critical goods
22 from countries that are described in section
23 407(2)(B).

24 (8) Encourage the relocation of manufacturing
25 facilities that manufacture critical goods from coun-

1 tries that are described in section 407(2)(B) to the
2 United States and countries that are allies or key
3 international partner nations to strengthen the resil-
4 ience, diversity, and strength of critical supply
5 chains.

6 **SEC. 403. CRITICAL SUPPLY CHAIN RESILIENCE WORKING**
7 **GROUP.**

8 (a) ESTABLISHMENT.—Not later than 120 days after
9 the date of the enactment of this Act, the Assistant Sec-
10 retary shall establish a working group to be known as the
11 “Supply Chain Resilience Working Group” (in this title
12 referred to as the “Working Group”) composed of the
13 Federal agencies that rely upon the Industry and Analysis
14 Business unit analysis, including agencies enumerated in
15 subsection (c).

16 (b) ACTIVITIES.—Not later than 1 year after the date
17 of the enactment of this Act, the Assistant Secretary shall
18 carry out the following activities:

19 (1) In consultation with the Working Group—

20 (A) assessing, mapping, and modeling crit-
21 ical supply chains, including for critical and
22 emerging technologies, which may include—

23 (i) modeling the impact of supply
24 chain shocks on critical industries (includ-

1 ing for critical and emerging technologies),
2 and critical supply chains;

3 (ii) assessing the demand for and sup-
4 ply of critical goods, production equipment,
5 and manufacturing technology needed for
6 critical supply chains, including critical
7 goods, production equipment, and manu-
8 facturing technology obtained by or pur-
9 chased from a person outside of the United
10 States or imported into the United States;
11 and

12 (iii) assessing manufacturing,
13 warehousing, transportation, and distribu-
14 tion related to critical supply chains;

15 (B) identifying high priority gaps and
16 vulnerabilities in critical supply chains and crit-
17 ical industries (including critical industries for
18 critical and emerging technologies) that—

19 (i) exist as of the date of the enact-
20 ment of this Act; or

21 (ii) are anticipated to occur after the
22 date of the enactment of this Act;

23 (C) identifying potential supply chain
24 shocks to a critical supply chain that may dis-

1 rupt, strain, or eliminate the critical supply
2 chain;

3 (D) evaluating the capability and capacity
4 of domestic manufacturers or manufacturers lo-
5 cated in countries that are allies or key inter-
6 national partner nations to serve as sources for
7 critical goods, production equipment, or manu-
8 facturing technology needed in critical supply
9 chains;

10 (E) evaluating the effect on market sta-
11 bility that may result from the disruption,
12 strain, or elimination of a critical supply chain;

13 (F) evaluating the state of the manufac-
14 turing workforce, including by—

15 (i) identifying the needs of domestic
16 manufacturers; and

17 (ii) identifying opportunities to create
18 high-quality manufacturing jobs; and

19 (G) identifying and describing necessary
20 tools, including commercially available risk as-
21 sessment tools, that leverage data and industry
22 expertise to provide insights into critical supply
23 chain vulnerabilities, including how such tools
24 fulfill the requirements described in subpara-
25 graphs (A) through (F).

1 (2) In consultation with State and local govern-
2 ments, the Working Group, and (as appropriate)
3 countries that are allies or key international partner
4 nations—

5 (A) identifying opportunities to reduce
6 gaps and vulnerabilities in critical supply chains
7 and critical industries;

8 (B) encouraging consultation between the
9 Federal Government, industry, covered non-
10 governmental representatives, institutions of
11 higher education, and State and local govern-
12 ments to—

13 (i) better respond to supply chain
14 shocks to critical supply chains and critical
15 industries (including critical industries for
16 emerging technologies); and

17 (ii) coordinate response efforts to sup-
18 ply chain shocks;

19 (C) encouraging consultation between the
20 Federal Government and the governments of
21 countries that are allies or key international
22 partner nations;

23 (D) identifying opportunities to build the
24 capacity of the United States in critical supply

1 chains, critical industries, and emerging tech-
2 nologies;

3 (E) identifying opportunities to build the
4 capacity of countries that are allies or key
5 international partner nations in critical indus-
6 tries (including critical industries for emerging
7 technologies) and critical supply chains; and

8 (F) developing and assessing contingency
9 plans and coordination mechanisms to improve
10 the response of critical supply chains and crit-
11 ical industries to supply chain shocks.

12 (c) WORKING GROUP MEMBERSHIP.—The Working
13 Group shall include a representative from each Federal
14 agency that relies on the analysis of the Industry and
15 Analysis business unit, including—

- 16 (1) the Department of State;
17 (2) the Department of Defense;
18 (3) the Department of Homeland Security;
19 (4) the Department of Transportation;
20 (5) the Department of Energy;
21 (6) the Department of Agriculture;
22 (7) the Department of the Interior;
23 (8) the Department of Health and Human
24 Services;

1 (9) the Office of the Director of National Intel-
2 ligence; and

3 (10) the Small Business Administration.

4 (d) DESIGNATIONS.—The Assistant Secretary shall—

5 (1) not later than 120 days after the date of
6 the enactment of this Act, designate—

7 (A) critical industries;

8 (B) critical supply chains; and

9 (C) critical goods;

10 (2) provide for a period of public comment and
11 review in carrying out paragraph (1); and

12 (3) update the designations made pursuant to
13 paragraph (1) not less frequently than once every 4
14 years, including designations for technologies that
15 are not described in section 407(12)(B) that the As-
16 sistant Secretary considers necessary.

17 (e) IMPLEMENTATION REPORT.—Not later than 1
18 year after the date of the enactment of this Act, the As-
19 sistant Secretary shall submit to the relevant committees
20 of Congress a report that—

21 (1) details supply chain activities, including ap-
22 plicable activities described in subsection (b) and re-
23 sponsibilities described in section 402, that the As-
24 sistant Secretary has conducted over the past year;

1 (2) describes supply chain data collected, re-
2 tained, and analyzed by the Assistant Secretary over
3 the past year;

4 (3) identifies and describes necessary tools, in-
5 cluding commercially available risk assessment tools,
6 that leverage data and industry expertise to provide
7 insights into critical supply chain vulnerabilities, in-
8 cluding how such tools fulfill each responsibility de-
9 scribed in subsection (b);

10 (4) identifies and describes all Federal agencies
11 with authorities or responsibilities described in sub-
12 section (b); and

13 (5) identifies Federal agencies, programs, and
14 bureaus with duplicative purposes to fulfill any of
15 the authorities or responsibilities described in sub-
16 section (b).

17 (f) NATIONAL STRATEGY AND REVIEW ON CRITICAL
18 SUPPLY CHAIN RESILIENCY AND MANUFACTURING IN
19 THE UNITED STATES.—

20 (1) IN GENERAL.—Not later than 18 months
21 after the date of the enactment of this Act, and an-
22 nually thereafter, the Assistant Secretary, in con-
23 sultation with the Working Group, covered non-
24 governmental representatives, industries, institutions
25 of higher education, and State and local govern-

1 ments, shall submit to the relevant committees of
2 Congress a report that—

3 (A) identifies—

4 (i) critical infrastructure that may as-
5 sist in fulfilling the responsibilities de-
6 scribed in section 402;

7 (ii) critical and emerging technologies
8 that may assist in fulfilling the responsibil-
9 ities described in section 402, including
10 such technologies that may be critical to
11 addressing preparedness, weaknesses, and
12 vulnerabilities relating to critical supply
13 chains;

14 (iii) critical industries, critical supply
15 chains, and critical goods designated pur-
16 suant to subsection (d);

17 (iv) other supplies and services that
18 are critical to the crisis preparedness of
19 the United States;

20 (v) substitutes for critical goods, pro-
21 duction equipment, and manufacturing
22 technology;

23 (vi) methods and technologies, includ-
24 ing blockchain technology, distributed ledg-
25 er technology, and other critical and

1 emerging technologies, as appropriate, for
2 the authentication and traceability of crit-
3 ical goods; and

4 (vii) countries that are allies or key
5 international partner nations;

6 (B) describes the matters identified and
7 evaluated under subsection (b)(1), including—

8 (i) the manufacturing base, critical
9 supply chains, and emerging technologies
10 in the United States, including the manu-
11 facturing base and critical supply chains
12 for—

13 (I) critical goods;

14 (II) production equipment; and

15 (III) manufacturing technology;

16 and

17 (ii) the ability of the United States
18 to—

19 (I) maintain readiness with re-
20 spect to preparing for and responding
21 to supply chain shocks; and

22 (II) in response to a supply chain
23 shock—

24 (aa) surge production in
25 critical industries;

1 (bb) surge production of
2 critical goods and production
3 equipment; and

4 (cc) maintain access to crit-
5 ical goods, production equipment,
6 and manufacturing technology;

7 (C) assesses and describes—

8 (i) the demand and supply of critical
9 goods, production equipment, and manu-
10 facturing technology;

11 (ii) the production of critical goods,
12 production equipment, and manufacturing
13 technology by domestic manufacturers;

14 (iii) the capability and capacity of do-
15 mestic manufacturers and manufacturers
16 in countries that are allies or key inter-
17 national partner nations to manufacture
18 critical goods, production equipment, and
19 manufacturing technology; and

20 (iv) how supply chain shocks could af-
21 fect rural, Tribal, and underserved commu-
22 nities;

23 (D) identifies threats and supply chain
24 shocks that may disrupt, strain, or eliminate
25 critical supply chains, critical goods, and critical

1 industries (including critical industries for
2 emerging technologies);

3 (E) with regard to any threat identified
4 under subparagraph (D), lists any threat or
5 supply chain shock that may originate from a
6 country, or a company or individual from a
7 country, that is described in section 407(2)(B);

8 (F) assesses—

9 (i) the resilience and capacity of the
10 manufacturing base, critical supply chains,
11 and workforce of the United States and
12 countries that are allies or key inter-
13 national partner nations that can sustain
14 critical industries (including critical indus-
15 tries for emerging technologies) through a
16 supply chain shock; and

17 (ii) the effect innovation has on do-
18 mestic manufacturers;

19 (G) assesses the flexible manufacturing ca-
20 pacity and capability available in the United
21 States in the case of a supply chain shock; and

22 (H) develops a strategy for the Depart-
23 ment of Commerce to support the resilience, di-
24 versity, and strength of critical supply chains
25 and critical and emerging technologies to—

1 (i) support sufficient access to critical
2 goods by mitigating vulnerabilities in crit-
3 ical supply chains, including critical supply
4 chains concentrated in countries that are
5 described in section 407(2)(B);

6 (ii) consult with other relevant agen-
7 cies to assist countries that are allies or
8 key international partner nations in build-
9 ing capacity for manufacturing critical
10 goods;

11 (iii) recover from supply chain shocks;

12 (iv) identify, in consultation with the
13 Working Group and other relevant agen-
14 cies, actions relating to critical supply
15 chains or emerging technologies that the
16 United States may take to improve re-
17 sponses to supply chain shocks;

18 (v) protect against supply chain
19 shocks relating to critical supply chains
20 from countries that are described in sec-
21 tion 407(2)(B); and

22 (vi) make specific recommendations to
23 implement the strategy under this section
24 and improve the security and resiliency of
25 manufacturing capacity and supply chains

1 for critical industries (including critical in-
2 dustries for emerging technologies) by—

3 (I) developing long-term strate-
4 gies;

5 (II) increasing visibility into the
6 networks and capabilities of domestic
7 manufacturers and suppliers of do-
8 mestic manufacturers;

9 (III) identifying and mitigating
10 risks, including—

11 (aa) significant
12 vulnerabilities to supply chain
13 shocks; and

14 (bb) exposure to gaps and
15 vulnerabilities in domestic capac-
16 ity or capabilities and sources of
17 imports needed to sustain critical
18 industries (including critical in-
19 dustries for emerging tech-
20 nologies) or critical supply
21 chains;

22 (IV) identifying opportunities to
23 reuse and recycle critical goods, in-
24 cluding raw materials, to increase re-
25 silient critical supply chains;

1 (V) consulting with countries
2 that are allies or key international
3 partner nations on—

4 (aa) sourcing critical goods,
5 production equipment, and man-
6 ufacturing technology; and

7 (bb) developing, sustaining,
8 and expanding production and
9 availability of critical goods, pro-
10 duction equipment, and manufac-
11 turing technology during a supply
12 chain shock; and

13 (VI) providing guidance to other
14 relevant agencies with respect to crit-
15 ical goods, supply chains, and critical
16 industries (including critical industries
17 for emerging technologies) that should
18 be prioritized to support United
19 States leadership in the deployment of
20 such technologies.

21 (2) PROHIBITION.—The report submitted pur-
22 suant to paragraph (1) may not include—

23 (A) critical supply chain information that
24 is not aggregated;

1 (B) confidential business information of a
2 private sector entity; or

3 (C) classified information.

4 (3) FORM.—The report submitted pursuant to
5 paragraph (1), and any update submitted thereafter,
6 shall be submitted to the relevant committees of
7 Congress in unclassified form and may include a
8 classified annex.

9 (4) PUBLIC COMMENT.—The Assistant Sec-
10 retary shall provide for a period of public comment
11 and review in developing the report submitted pursu-
12 ant to paragraph (1).

13 (g) CONSULTATION.—Not later than 1 year after the
14 date of the enactment of this Act, the Assistant Secretary
15 shall enter into an agreement with the head of any rel-
16 evant agency to obtain any information, data, or assist-
17 ance that the Assistant Secretary determines necessary to
18 conduct the activities described in subsection (b).

19 (h) RULE OF CONSTRUCTION.—Nothing in this sec-
20 tion may be construed to require any private entity—

21 (1) to share information with the Secretary or
22 Assistant Secretary;

23 (2) to request assistance from the Secretary or
24 Assistant Secretary; or

1 (3) to implement any measure or recommenda-
2 tion suggested by the Secretary or Assistant Sec-
3 retary in response to a request by the private entity.

4 (i) PROTECTION OF VOLUNTARILY SHARED CRIT-
5 ICAL SUPPLY CHAIN INFORMATION.—

6 (1) PROTECTION.—

7 (A) IN GENERAL.—Notwithstanding any
8 other provision of law, critical supply chain in-
9 formation (including the identity of the submit-
10 ting person or entity) that is voluntarily sub-
11 mitted under this section to the Department of
12 Commerce for use by the Department for pur-
13 poses of this section, when accompanied by an
14 express statement described in subparagraph

15 (B)—

16 (i) shall be exempt from disclosure
17 under section 552(b)(3) of title 5, United
18 States Code (commonly referred to as the
19 “Freedom of Information Act”);

20 (ii) is not subject to any agency rules
21 or judicial doctrine regarding ex parte
22 communications with a decision-making of-
23 ficial;

24 (iii) may not, without the written con-
25 sent of the person or entity submitting

1 such information, be used directly by the
2 Department of Commerce, any other Fed-
3 eral, State, or local authority, or any third
4 party, in any civil action arising under
5 Federal or State law if such information is
6 submitted in good faith;

7 (iv) may not, without the written con-
8 sent of the person or entity submitting
9 such information, be used or disclosed by
10 any officer or employee of the United
11 States for purposes other than the pur-
12 poses of this section, except—

13 (I) in furtherance of an investiga-
14 tion or the prosecution of a criminal
15 act; or

16 (II) when disclosure of the infor-
17 mation would be—

18 (aa) to either House of Con-
19 gress, or to the extent of matter
20 within its jurisdiction, any com-
21 mittee or subcommittee thereof,
22 any joint committee thereof, or
23 any subcommittee of any such
24 joint committee; or

1 (bb) to the Comptroller Gen-
2 eral of the United States, or any
3 authorized representative of the
4 Comptroller General, in the
5 course of the performance of the
6 duties of the Government Ac-
7 countability Office;

8 (v) may not, if provided to a State or
9 local government or government agency—

10 (I) be made available pursuant to
11 any State or local law requiring dis-
12 closure of information or records;

13 (II) otherwise be disclosed or dis-
14 tributed to any party by such State or
15 local government or government agen-
16 cy without the written consent of the
17 person or entity submitting such in-
18 formation; or

19 (III) be used other than for the
20 purpose of carrying out this section,
21 or in furtherance of an investigation
22 or the prosecution of a criminal act;
23 and

24 (vi) does not constitute a waiver of
25 any applicable privilege or protection pro-

1 vided under law, such as trade secret pro-
2 tection.

3 (B) EXPRESS STATEMENT.—The express
4 statement described in this subparagraph, with
5 respect to information or records, is—

6 (i) in the case of written information
7 or records, a written marking on the infor-
8 mation or records substantially similar to
9 the following: “This information is volun-
10 tarily submitted to the Federal Govern-
11 ment in expectation of protection from dis-
12 closure as provided by the provisions of the
13 Promoting Resilient Supply Chains Act.”;
14 or

15 (ii) in the case of oral information, a
16 written statement similar to the statement
17 described in clause (i) submitted within a
18 reasonable period following the oral com-
19 munication.

20 (2) LIMITATION.—No communication of critical
21 supply chain information to the Department of Com-
22 merce made pursuant to this section may be consid-
23 ered to be an action subject to the requirements of
24 chapter 10 of title 5, United States Code.

1 (3) INDEPENDENTLY OBTAINED INFORMA-
2 TION.—Nothing in this subsection may be construed
3 to limit or otherwise affect the ability of a State,
4 local, or Federal Government entity, agency, or au-
5 thority, or any third party, under applicable law to
6 obtain critical supply chain information in a manner
7 not covered by paragraph (1), including any infor-
8 mation lawfully and properly disclosed generally or
9 broadly to the public and to use such information in
10 any manner permitted by law. For purposes of this
11 subsection, a permissible use of independently ob-
12 tained information includes the disclosure of such in-
13 formation under section 2302(b)(8) of title 5,
14 United States Code.

15 (4) TREATMENT OF VOLUNTARY SUBMITTAL OF
16 INFORMATION.—The voluntary submittal to the De-
17 partment of Commerce of information or records
18 that are protected from disclosure by this section
19 may not be construed to constitute compliance with
20 any requirement to submit such information to an
21 agency under any other provision of law.

22 (5) INAPPLICABILITY TO SEMICONDUCTOR IN-
23 CENTIVE PROGRAM.—This subsection does not apply
24 to the voluntary submission of critical supply chain
25 information in an application for Federal financial

1 assistance under section 9902 of the William M.
2 (Mac) Thornberry National Defense Authorization
3 Act for Fiscal Year 2021 (Public Law 116–283).

4 **SEC. 404. DEPARTMENT OF COMMERCE CAPABILITY AS-**
5 **SESSMENT.**

6 (a) **REPORT REQUIRED.**—The Secretary shall
7 produce a report—

8 (1) identifying the duties, responsibilities, re-
9 sources, programs, and expertise within the offices
10 and bureaus of the Department of Commerce rel-
11 evant to critical supply chain resilience and manu-
12 facturing innovation;

13 (2) identifying and assessing the purpose, legal
14 authority, effectiveness, efficiency, and limitations of
15 each office or bureau identified under paragraph (1);
16 and

17 (3) providing recommendations to enhance the
18 activities related to critical supply chain resilience
19 and manufacturing innovation of the Department of
20 Commerce, including—

21 (A) improving the effectiveness, efficiency,
22 and impact of the offices and bureaus identified
23 under paragraph (1);

24 (B) coordinating across offices and bu-
25 reaus identified under paragraph (1); and

1 (C) consulting with agencies implementing
2 similar activities related to critical supply chain
3 resilience and manufacturing innovation.

4 (b) SUBMISSION OF REPORT.—Not later than 2 years
5 after the date of the enactment of this Act, the Secretary
6 shall submit to the relevant committees of Congress the
7 report required by subsection (a), along with a strategy
8 to implement, as appropriate and as determined by the
9 Secretary, the recommendations contained in the report.

10 **SEC. 405. NO ADDITIONAL FUNDS.**

11 No additional funds are authorized to be appro-
12 priated to carry out this title.

13 **SEC. 406. SUNSET.**

14 This title and all requirements, responsibilities, and
15 obligations under this title shall terminate on the date that
16 is 10 years after the date of the enactment of this Act.

17 **SEC. 407. DEFINITIONS.**

18 In this title:

19 (1) AGENCY.—The term “agency” has the
20 meaning given that term in section 551 of title 5,
21 United States Code.

22 (2) ALLY OR KEY INTERNATIONAL PARTNER
23 NATION.—The term “ally or key international part-
24 ner nation”—

1 (A) means a country that is critical to ad-
2 dressing critical supply chain weaknesses and
3 vulnerabilities; and

4 (B) does not include—

5 (i) a country that poses a significant
6 risk to the national security or economic
7 security of the United States; or

8 (ii) a country that is described in sec-
9 tion 503(b) of the RANSOMWARE Act
10 (title V of division BB of the Consolidated
11 Appropriations Act, 2023; Public Law
12 117–328; 136 Stat. 5564).

13 (3) ASSISTANT SECRETARY.—The term “Assist-
14 ant Secretary” means the Assistant Secretary of
15 Commerce assigned by the Secretary to direct the
16 office of Industry and Analysis.

17 (4) COVERED NONGOVERNMENTAL REPRESENT-
18 ATIVE.—The term “covered nongovernmental rep-
19 resentative” means a representative as specified in
20 the second sentence of section 135(b)(1) of the
21 Trade Act of 1974 (19 U.S.C. 2155(b)(1)), except
22 that such term does not include a representative of
23 a non-Federal government.

24 (5) CRITICAL GOOD.—The term “critical good”
25 means any raw, in process, or manufactured mate-

1 rial (including any mineral, metal, or advanced proc-
2 essed material), article, commodity, supply, product,
3 or item for which an absence of supply would have
4 a debilitating impact on—

5 (A) the national security or economic secu-
6 rity of the United States; and

7 (B) either—

8 (i) critical infrastructure; or

9 (ii) an emerging technology.

10 (6) CRITICAL INDUSTRY.—The term “critical
11 industry” means an industry that—

12 (A) is critical for the national security or
13 economic security of the United States; and

14 (B) produces or procures a critical good.

15 (7) CRITICAL INFRASTRUCTURE.—The term
16 “critical infrastructure” has the meaning given that
17 term in section 1016 of the Critical Infrastructures
18 Protection Act of 2001 (42 U.S.C. 5195c).

19 (8) CRITICAL SUPPLY CHAIN.—The term “crit-
20 ical supply chain” means a supply chain for a crit-
21 ical good.

22 (9) CRITICAL SUPPLY CHAIN INFORMATION.—
23 The term “critical supply chain information” means
24 information that is not customarily in the public do-
25 main and relates to—

1 (A) sustaining and adapting a critical sup-
2 ply chain during a supply chain shock;

3 (B) critical supply chain risk mitigation
4 and recovery planning with respect to a supply
5 chain shock, including any planned or past as-
6 sessment, projection, or estimate of a vulner-
7 ability within the critical supply chain, includ-
8 ing testing, supplier network assessments, pro-
9 duction flexibility, supply chain risk evaluations,
10 supply chain risk management planning, or risk
11 audits; or

12 (C) operational best practices, planning,
13 and supplier partnerships that enable enhanced
14 resilience of a critical supply chain during a
15 supply chain shock, including response, repair,
16 recovery, reconstruction, insurance, or con-
17 tinuity.

18 (10) DOMESTIC ENTERPRISE.—The term “do-
19 mestic enterprise” means an enterprise that con-
20 ducts business in the United States and procures a
21 critical good.

22 (11) DOMESTIC MANUFACTURER.—The term
23 “domestic manufacturer” means a business that
24 conducts in the United States the research and de-

1 velopment, engineering, or production activities nec-
2 essary for manufacturing a critical good.

3 (12) EMERGING TECHNOLOGY.—The term
4 “emerging technology” means a technology that is
5 critical for the national security or economic security
6 of the United States, including the following:

7 (A) Technologies included in the American
8 COMPETE Act (title XV of division FF of the
9 Consolidated Appropriations Act, 2021; Public
10 Law 116–260; 134 Stat. 3276).

11 (B) The following technologies:

12 (i) Artificial intelligence.

13 (ii) Automated vehicles and unmanned
14 delivery systems.

15 (iii) Blockchain and other distributed
16 ledger, data storage, data management,
17 and cybersecurity technologies.

18 (iv) Quantum computing and quan-
19 tum sensing.

20 (v) Additive manufacturing.

21 (vi) Advanced manufacturing and the
22 Internet of Things.

23 (vii) Nano technology.

24 (viii) Robotics.

1 (ix) Microelectronics, optical fiber ray,
2 and high performance and advanced com-
3 puter hardware and software.

4 (x) Semiconductors.

5 (xi) Advanced materials science, in-
6 cluding composition 2D, other next genera-
7 tion materials, and related manufacturing
8 technologies.

9 (13) INSTITUTION OF HIGHER EDUCATION.—

10 The term “institution of higher education” has the
11 meaning given that term in section 101 of the High-
12 er Education Act of 1965 (20 U.S.C. 1001).

13 (14) MANUFACTURE.—The term “manufac-
14 ture”—

15 (A) means any activity that is necessary
16 for the development, production, processing,
17 distribution, or delivery of any raw, in process,
18 or manufactured material (including any min-
19 eral, metal, and advanced processed material),
20 article, commodity, supply, product, critical
21 good, or item of supply; and

22 (B) does not include software unrelated to
23 the manufacturing process.

24 (15) MANUFACTURING TECHNOLOGY.—The
25 term “manufacturing technology” means a tech-

1 nology that is necessary for the manufacturing of a
2 critical good.

3 (16) PRODUCTION EQUIPMENT.—The term
4 “production equipment” means any component, sub-
5 system, system, equipment, tooling, accessory, part,
6 or assembly necessary for the manufacturing of a
7 critical good.

8 (17) RELEVANT COMMITTEES OF CONGRESS.—
9 The term “relevant committees of Congress” means
10 the following:

11 (A) The Committee on Commerce, Science,
12 and Transportation of the Senate.

13 (B) The Committee on Energy and Com-
14 merce of the House of Representatives.

15 (18) RESILIENT CRITICAL SUPPLY CHAIN.—The
16 term “resilient critical supply chain” means a crit-
17 ical supply chain that—

18 (A) ensures that the United States can
19 sustain critical industry, including emerging
20 technologies, production, critical supply chains,
21 services, and access to critical goods, production
22 equipment, and manufacturing technology dur-
23 ing a supply chain shock; and

24 (B) has key components of resilience that
25 include—

- 1 (i) effective private sector risk man-
2 agement and mitigation planning to sus-
3 tain critical supply chains and supplier
4 networks during a supply chain shock; and
5 (ii) minimized or managed exposure to
6 a supply chain shock.

7 (19) SECRETARY.—The term “Secretary”
8 means the Secretary of Commerce.

9 (20) STATE.—The term “State” means each of
10 the several States, the District of Columbia, each
11 commonwealth, territory, or possession of the United
12 States, and each federally recognized Indian Tribe.

13 (21) SUPPLY CHAIN SHOCK.—The term “supply
14 chain shock”—

15 (A) means an event causing severe or seri-
16 ous disruption to normal operations or capacity
17 in a supply chain; and

18 (B) includes—

- 19 (i) a natural disaster;
20 (ii) a pandemic;
21 (iii) a biological threat;
22 (iv) a cyber attack;
23 (v) a geopolitical conflict;
24 (vi) a terrorist or geopolitical attack;
25 (vii) a trade disruption caused by—

1 (I) a country described in para-
2 graph (2)(B); or

3 (II) an entity or an individual
4 subject to the jurisdiction of such a
5 country; and

6 (viii) an event for which the President
7 declares a major disaster or an emergency
8 under section 401 or 501, respectively, of
9 the Robert T. Stafford Disaster Relief and
10 Emergency Assistance Act (42 U.S.C.
11 5170; 42 U.S.C. 5191).

12 **TITLE V—DEPLOYING AMERICAN** 13 **BLOCKCHAINS**

14 **SEC. 501. SHORT TITLE.**

15 This title may be cited as the “Deploying American
16 Blockchains Act”.

17 **SEC. 502. DEFINITIONS.**

18 In this title:

19 (1) **ADVISORY COMMITTEE.**—The term “Advi-
20 sory Committee” means the National Blockchain
21 Deployment Advisory Committee established pursu-
22 ant to section 503(c).

23 (2) **BLOCKCHAIN TECHNOLOGY OR OTHER DIS-**
24 **TRIBUTED LEDGER TECHNOLOGY.**—The term
25 “blockchain technology or other distributed ledger

1 technology” means a distributed digital database
2 where data is—

3 (A) shared across a network of computers
4 to create a ledger of verified information among
5 network participants;

6 (B) linked using cryptography to maintain
7 the integrity of the ledger and to execute other
8 functions; and

9 (C) distributed among network partici-
10 pants in an automated fashion to concurrently
11 update network participants on the state of the
12 ledger and other functions.

13 (3) COVERED NONGOVERNMENTAL REPRESENT-
14 ATIVE.—The term “covered nongovernmental rep-
15 resentative” means a representative as specified in
16 the second sentence of section 135(b)(1) of the
17 Trade Act of 1974 (19 U.S.C. 2155(b)(1)), except
18 that such term does not include a representative of
19 a non-Federal government.

20 (4) SECRETARY.—The term “Secretary” means
21 the Secretary of Commerce.

22 (5) STATE.—The term “State” means each of
23 the several States, the District of Columbia, each
24 commonwealth, territory, or possession of the United
25 States, and each federally recognized Indian Tribe.

1 (6) TOKEN.—The term “token” means a trans-
2 ferable, digital representation of information re-
3 corded on blockchain technology or other distributed
4 ledger technology.

5 (7) TOKENIZATION.—The term “tokenization”
6 means the process of creating a token.

7 **SEC. 503. DEPARTMENT OF COMMERCE LEADERSHIP ON**
8 **BLOCKCHAIN.**

9 (a) FUNCTION OF SECRETARY.—The Secretary shall
10 serve as a principal advisor to the President for policy per-
11 taining to the deployment, use, application, and competi-
12 tiveness of blockchain technology or other distributed ledg-
13 er technology, applications built on blockchain technology
14 or other distributed ledger technology, tokens, and
15 tokenization.

16 (b) ACTIVITIES.—The Secretary shall support the
17 leadership of the United States with respect to the deploy-
18 ment, use, application, and competitiveness of blockchain
19 technology or other distributed ledger technology, applica-
20 tions built on blockchain technology or other distributed
21 ledger technology, tokens, and tokenization by organizing
22 the Advisory Committee—

23 (1) to examine and to provide recommendations
24 on issues and risks relating to the deployment, use,
25 application, and competitiveness of blockchain tech-

1 nology or other distributed ledger technology, appli-
2 cations built on blockchain technology or other dis-
3 tributed ledger technology, tokens, and tokenization,
4 including the issues of decentralized identity, cyber-
5 security, key storage and security systems, artificial
6 intelligence, fraud reduction, regulatory compliance,
7 e-commerce, health care applications, and supply
8 chain resiliency;

9 (2) to support and to promote the improvement
10 and security of blockchain technology or other dis-
11 tributed ledger technology, applications built on
12 blockchain technology or other distributed ledger
13 technology, tokens, and tokenization;

14 (3) to help to promote the leadership of the
15 United States with respect to the deployment, use,
16 application, and competitiveness of blockchain tech-
17 nology or other distributed ledger technology, appli-
18 cations built on blockchain technology or other dis-
19 tributed ledger technology, tokens, and tokenization;

20 (4) to promote the national security of the
21 United States with respect to blockchain technology
22 or other distributed ledger technology, applications
23 built on blockchain technology or other distributed
24 ledger technology, tokens, and tokenization;

1 (5) to support engagement with the public to
2 develop a compendium of proposals for practices as
3 part of the work described in subsection (d);

4 (6) to consider policies to encourage coordina-
5 tion among Federal agencies with respect to the de-
6 ployment of blockchain technology or other distrib-
7 uted ledger technology, applications built on
8 blockchain technology or other distributed ledger
9 technology, tokens, and tokenization;

10 (7) to examine—

11 (A) how Federal agencies can benefit from
12 utilizing blockchain technology or other distrib-
13 uted ledger technology, applications built on
14 blockchain technology or other distributed ledg-
15 er technology, tokens, and tokenization;

16 (B) the current use by Federal agencies of
17 blockchain technology or other distributed ledg-
18 er technology, applications built on blockchain
19 technology or other distributed ledger tech-
20 nology, tokens, and tokenization;

21 (C) the current and future preparedness
22 and ability of Federal agencies to adopt
23 blockchain technology or other distributed ledg-
24 er technology, applications built on blockchain

1 technology or other distributed ledger tech-
2 nology, tokens, and tokenization; and

3 (D) additional security measures Federal
4 agencies may need to take—

5 (i) to securely use blockchain tech-
6 nology or other distributed ledger tech-
7 nology, applications built on blockchain
8 technology or other distributed ledger tech-
9 nology, tokens, and tokenization, including
10 to support the security of critical infra-
11 structure; and

12 (ii) to enhance the resiliency of Fed-
13 eral systems against cyber threats to
14 blockchain technology or other distributed
15 ledger technology, applications built on
16 blockchain technology or other distributed
17 ledger technology, tokens, and
18 tokenization; and

19 (8) to support coordination of the activities of
20 the Federal Government relating to the security of
21 blockchain technology and other distributed ledger
22 technology, applications built on blockchain tech-
23 nology or other distributed ledger technology, to-
24 kens, and tokenization.

1 (c) ESTABLISHMENT OF NATIONAL BLOCKCHAIN
2 DEPLOYMENT ADVISORY COMMITTEE.—

3 (1) ESTABLISHMENT.—

4 (A) IN GENERAL.—Not later than 180
5 days after the date of the enactment of this
6 Act, the Secretary shall, in consultation with
7 the heads of relevant Federal agencies, establish
8 an advisory committee to support the adoption
9 of blockchain technology or other distributed
10 ledger technology, applications built on
11 blockchain technology or other distributed ledger
12 technology, tokens, and tokenization.

13 (B) DESIGNATION.—The advisory com-
14 mittee established pursuant to subparagraph
15 (A) shall be known as the “National Blockchain
16 Deployment Advisory Committee”.

17 (2) MEMBERSHIP COMPOSITION.—The Advisory
18 Committee shall consist of members appointed by
19 the Secretary, which shall include—

20 (A) the Secretary;

21 (B) representatives of Federal agencies (as
22 determined necessary by the Secretary); and

23 (C) covered nongovernmental representa-
24 tives with expertise related to blockchain tech-
25 nology or other distributed ledger technology

1 (as determined necessary by the Secretary),
2 which may include—

3 (i) blockchain technology or other dis-
4 tributed ledger technology infrastructure
5 operators, suppliers, service providers, and
6 vendors;

7 (ii) application developers building on
8 blockchain technology or other distributed
9 ledger technology;

10 (iii) developers and organizations sup-
11 porting the advancement and deployment
12 of public blockchain technology or other
13 distributed ledger technology;

14 (iv) subject matter experts rep-
15 resenting industrial sectors that can ben-
16 efit from blockchain technology or other
17 distributed ledger technology;

18 (v) small, medium, and large busi-
19 nesses;

20 (vi) think tanks and academia;

21 (vii) nonprofit organizations and con-
22 sumer groups;

23 (viii) cybersecurity experts;

24 (ix) rural stakeholders;

1 (x) covered nongovernmental rep-
2 resentatives; and

3 (xi) artists and the content creator
4 community.

5 (3) TERMINATION OF ADVISORY COMMITTEE.—

6 The Advisory Committee shall terminate on the date
7 that is 7 years after the date of the enactment of
8 this Act.

9 (d) BEST PRACTICES.—The Secretary shall, on an
10 ongoing basis, facilitate and support the development of
11 a compendium of identified or recommended guidelines or
12 best practices for the deployment of blockchain technology
13 or other distributed ledger technology, applications built
14 on blockchain technology or other distributed ledger tech-
15 nology, tokens, and tokenization that—

16 (1) support the deployment of technologies
17 needed to advance the capabilities of blockchain
18 technology or other distributed ledger technology,
19 applications built on blockchain technology or other
20 distributed ledger technology, tokens, and
21 tokenization;

22 (2) support the interoperability of blockchain
23 technology or other distributed ledger technology,
24 applications built on blockchain technology or other

1 distributed ledger technology, tokens, and
2 tokenization;

3 (3) support operations, including hashing and
4 key storage and security systems, that form the
5 foundation of blockchain technology or other distrib-
6 uted ledger technology, applications built on
7 blockchain technology or other distributed ledger
8 technology, tokens, and tokenization;

9 (4) reduce cybersecurity risks that may com-
10 promise blockchain technology or other distributed
11 ledger technology, applications built on blockchain
12 technology or other distributed ledger technology, to-
13 kens, and tokenization; and

14 (5) quantify the value and potential cost sav-
15 ings associated with adoption of blockchain tech-
16 nology or other distributed ledger technology, appli-
17 cations built on blockchain technology or other dis-
18 tributed ledger technology, tokens, and tokenization,
19 including through comparative analyses of competing
20 and existing technologies within specific industry ap-
21 plications.

22 (e) ADDITIONAL REQUIREMENTS.—In carrying out
23 this section, the Secretary shall—

1 (1) consult closely and regularly with stake-
2 holders, including private sector individuals and enti-
3 ties, and incorporate industry expertise;

4 (2) collaborate with private sector stakeholders
5 to identify prioritized, flexible, repeatable, perform-
6 ance-based, and cost-effective approaches to the de-
7 ployment of blockchain technology or other distrib-
8 uted ledger technology, applications built on
9 blockchain technology or other distributed ledger
10 technology, tokens, and tokenization;

11 (3) make public research and information per-
12 taining to the use of, and marketplace for,
13 blockchain technology or other distributed ledger
14 technology, applications built on blockchain tech-
15 nology or other distributed ledger technology, to-
16 kens, and tokenization;

17 (4) develop standardized terminology for, and
18 promote common understanding of, blockchain tech-
19 nology or other distributed ledger technology, appli-
20 cations built on blockchain technology or other dis-
21 tributed ledger technology, tokens, and tokenization;

22 (5) align the recommendations of the compen-
23 dium described in subsection (d) with the goal of fa-
24 cilitating the ease of use of blockchain technology or
25 other distributed ledger technology, applications

1 built on blockchain technology or other distributed
2 ledger technology, tokens, and tokenization;

3 (6) support open-source infrastructure, data
4 management, and authentication activities with re-
5 spect to blockchain technology or other distributed
6 ledger technology, applications built on blockchain
7 technology or other distributed ledger technology, to-
8 kens, and tokenization; and

9 (7) consider the needs and interests of both the
10 private and public sector, including small businesses
11 and Federal, State, and local governments.

12 (f) RULES OF CONSTRUCTION.—Nothing in this sec-
13 tion may be construed—

14 (1) to require a private entity to share informa-
15 tion with the Secretary;

16 (2) to require a private entity to request assist-
17 ance from the Secretary;

18 (3) to require a private entity to implement any
19 measure or recommendation suggested by the Sec-
20 retary in response to a request by the private entity;
21 or

22 (4) to require the adoption of the best practices
23 described in subsection (d).

1 (g) CONSULTATION.—In implementing this section,
2 the Secretary may, as appropriate, consult with the heads
3 of relevant Federal agencies.

4 **SEC. 504. REPORTS TO CONGRESS.**

5 (a) INTERIM REPORTS.—Not later than 2 years after
6 the date of the enactment of this Act, and annually there-
7 after, the Secretary shall make public on the website of
8 the Department of Commerce and submit to the Com-
9 mittee on Commerce, Science, and Transportation of the
10 Senate and the Committee on Energy and Commerce of
11 the House of Representatives a report that includes—

12 (1) a description of the activities of the Sec-
13 retary under this title during the preceding year;

14 (2) any recommendations by the Secretary for
15 additional legislation to strengthen the competitive-
16 ness of the United States with respect to blockchain
17 technology or other distributed ledger technology,
18 applications built on blockchain technology or other
19 distributed ledger technology, tokens, and
20 tokenization; and

21 (3) a description of any emerging risks and
22 long-term trends with respect to blockchain tech-
23 nology or other distributed ledger technology, appli-
24 cations built on blockchain technology or other dis-
25 tributed ledger technology, tokens, and tokenization.

1 (b) FINAL REPORT.—Not later than 18 months be-
2 fore the termination of the Advisory Committee pursuant
3 to section 503(c)(3), the Secretary shall make available
4 to the public on the website of the Department of Com-
5 merce and submit to the President, the Committee on
6 Commerce, Science, and Transportation of the Senate,
7 and the Committee on Energy and Commerce of the
8 House of Representatives a final report containing the
9 findings, conclusions, and recommendations of the Advi-
10 sory Committee.

11 **TITLE VI—FUTURE NETWORKS** 12 **ACT**

13 **SEC. 601. SHORT TITLE.**

14 This title may be cited as the “Future Uses of Tech-
15 nology Upholding Reliable and Enhanced Networks Act”
16 or the “FUTURE Networks Act”.

17 **SEC. 602. 6G TASK FORCE.**

18 (a) ESTABLISHMENT.—Not later than 120 days after
19 the date of the enactment of this Act, the Commission
20 shall establish a task force to be known as the “6G Task
21 Force”.

22 (b) MEMBERSHIP.—

23 (1) APPOINTMENT.—The members of the Task
24 Force shall be appointed by the Chair.

1 (2) COMPOSITION.—To the extent practicable,
2 the membership of the Task Force shall be com-
3 posed of the following:

4 (A) Representatives of companies in the
5 communications industry, except companies
6 that are determined by the Chair to be not
7 trusted.

8 (B) Representatives of public interest orga-
9 nizations or academic institutions, except public
10 interest organizations or academic institutions
11 that are determined by the Chair to be not
12 trusted.

13 (C) Representatives of the Federal Govern-
14 ment, State governments, local governments, or
15 Tribal Governments, with at least one member
16 representing each such type of government.

17 (c) REPORT.—

18 (1) IN GENERAL.—Not later than 1 year after
19 the date on which the Task Force is established
20 under subsection (a), the Task Force shall publish
21 in the Federal Register and on the website of the
22 Commission, and submit to the Committee on En-
23 ergy and Commerce of the House of Representatives
24 and the Committee on Commerce, Science, and

1 Transportation of the Senate, a report on sixth-gen-
2 eration wireless technology, including—

3 (A) the status of industry-led standards-
4 setting bodies in setting standards for such
5 technology;

6 (B) possible uses of such technology identi-
7 fied by industry-led standards-setting bodies
8 that are setting standards for such technology;

9 (C) any limitations of such technology (in-
10 cluding any supply chain or cybersecurity limi-
11 tations) identified by industry-led standards-set-
12 ting bodies that are setting standards for such
13 technology;

14 (D) workforce needs to build, maintain,
15 and utilize 6G and advanced wireless commu-
16 nications technologies and networks, and strate-
17 gies to conduct the necessary workforce train-
18 ing;

19 (E) possible uses of emerging technologies
20 and Open RAN networks to bolster 6G and ad-
21 vanced wireless networks; and

22 (F) how to best work with entities across
23 the Federal Government, State governments,
24 local governments, and Tribal Governments to

1 leverage such technology, including with regard
2 to siting, deployment, and adoption.

3 (2) DRAFT REPORT; PUBLIC COMMENT.—The
4 Task Force shall—

5 (A) not later than 180 days after the date
6 on which the Task Force is established under
7 subsection (a), publish in the Federal Register
8 and on the website of the Commission a draft
9 of the report required by paragraph (1); and

10 (B) accept public comments on such draft
11 and take such comments into consideration in
12 preparing the final version of such report.

13 (d) DEFINITIONS.—In this section:

14 (1) CHAIR.—The term “Chair” means the
15 Chair of the Commission.

16 (2) COMMISSION.—The term “Commission”
17 means the Federal Communications Commission.

18 (3) NOT TRUSTED.—

19 (A) IN GENERAL.—The term “not trusted”
20 means, with respect to an entity, that—

21 (i) the Chair has made a public deter-
22 mination that such entity is owned by, con-
23 trolled by, or subject to the influence of a
24 foreign adversary; or

1 (ii) the Chair otherwise determines
2 that such entity poses a threat to the na-
3 tional security of the United States.

4 (B) CRITERIA FOR DETERMINATION.—In
5 making a determination under subparagraph
6 (A)(ii), the Chair shall use the criteria de-
7 scribed in paragraphs (1) through (4) of section
8 2(c) of the Secure and Trusted Communica-
9 tions Networks Act of 2019 (47 U.S.C.
10 1601(c)), as appropriate.

11 (4) STATE.—The term “State” has the mean-
12 ing given such term in section 3 of the Communica-
13 tions Act of 1934 (47 U.S.C. 153).

14 (5) TASK FORCE.—The term “Task Force”
15 means the 6G Task Force established under sub-
16 section (a).

17 **SEC. 603. TERMINATION OF TASK FORCE.**

18 The Task Force shall be terminated 30 days after
19 the date on which the Task Force submits the report re-
20 quired under section 602(c).

21 **TITLE VII—SECURE SPACE ACT**

22 **SEC. 701. SHORT TITLE.**

23 This title may be cited as the “Secure Space Act”.

1 **SEC. 702. PROHIBITION ON GRANT OF CERTAIN SATELLITE**
2 **LICENSES, UNITED STATES MARKET ACCESS,**
3 **OR EARTH STATION AUTHORIZATIONS.**

4 (a) IN GENERAL.—The Secure and Trusted Commu-
5 nications Networks Act of 2019 (47 U.S.C. 1601 et seq.)
6 is amended—

7 (1) by redesignating sections 10 and 11 as sec-
8 tions 11 and 12, respectively; and

9 (2) by inserting after section 9 the following:

10 **“SEC. 10. PROHIBITION ON GRANT OF CERTAIN SATELLITE**
11 **LICENSES, UNITED STATES MARKET ACCESS,**
12 **OR EARTH STATION AUTHORIZATIONS.**

13 “(a) IN GENERAL.—The Commission may not grant
14 a license for, or a petition for a declaratory ruling to ac-
15 cess the United States market using, a geostationary orbit
16 satellite system or a nongeostationary orbit satellite sys-
17 tem, or an authorization to use an individually licensed
18 earth station or a blanket-licensed earth station, if such
19 license, grant of market access, or authorization would be
20 held or controlled by—

21 “(1) an entity that produces or provides any
22 covered communications equipment or service; or

23 “(2) an affiliate (as defined in section 3 of the
24 Communications Act of 1934 (47 U.S.C. 153)) of an
25 entity described in paragraph (1).

26 “(b) DEFINITIONS.—In this section:

1 “(1) BLANKET-LICENSED EARTH STATION.—

2 The term ‘blanket-licensed earth station’ means an
3 earth station that is licensed with a geostationary
4 orbit satellite system or a nongeostationary orbit
5 satellite system.

6 “(2) GATEWAY STATION.—The term ‘gateway
7 station’ means an earth station or a group of earth
8 stations that—

9 “(A) supports the routing and switching
10 functions of a geostationary orbit satellite sys-
11 tem or a nongeostationary orbit satellite sys-
12 tem;

13 “(B) may also be used for telemetry, track-
14 ing, and command transmissions;

15 “(C) does not originate or terminate com-
16 munication traffic; and

17 “(D) is not for the exclusive use of any
18 customer.

19 “(3) INDIVIDUALLY LICENSED EARTH STA-
20 TION.—The term ‘individually licensed earth station’
21 means—

22 “(A) an earth station (other than a blan-
23 ket-licensed earth station) that sends a signal
24 to, and receives a signal from, a geostationary

1 orbit satellite system or a nongeostationary
2 orbit satellite system; or
3 “(B) a gateway station.”.

4 (b) APPLICABILITY.—Section 10 of the Secure and
5 Trusted Communications Networks Act of 2019, as added
6 by subsection (a), shall apply with respect to the grant
7 of a license, petition, or authorization on or after the date
8 of the enactment of this Act.

9 (c) RULES.—Not later than 1 year after the date of
10 the enactment of this Act, the Federal Communications
11 Commission shall issue rules to implement section 10 of
12 the Secure and Trusted Communications Networks Act of
13 2019, as added by subsection (a).

14 **TITLE VIII—TAKE IT DOWN ACT**

15 **SEC. 801. SHORT TITLE.**

16 This title may be cited as the “Tools to Address
17 Known Exploitation by Immobilizing Technological
18 Deepfakes on Websites and Networks Act” or the “TAKE
19 IT DOWN Act”.

20 **SEC. 802. CRIMINAL PROHIBITION ON INTENTIONAL DIS-** 21 **CLOSURE OF NONCONSENSUAL INTIMATE** 22 **VISUAL DEPICTIONS.**

23 (a) IN GENERAL.—Section 223 of the Communica-
24 tions Act of 1934 (47 U.S.C. 223) is amended—

1 (1) by redesignating subsection (h) as sub-
2 section (i); and

3 (2) by inserting after subsection (g) the fol-
4 lowing:

5 “(h) INTENTIONAL DISCLOSURE OF NONCONSEN-
6 SUAL INTIMATE VISUAL DEPICTIONS.—

7 “(1) DEFINITIONS.—In this subsection:

8 “(A) CONSENT.—The term ‘consent’
9 means an affirmative, conscious, and voluntary
10 authorization made by an individual free from
11 force, fraud, duress, misrepresentation, or coer-
12 cion.

13 “(B) DIGITAL FORGERY.—The term ‘dig-
14 ital forgery’ means any intimate visual depic-
15 tion of an identifiable individual created
16 through the use of software, machine learning,
17 artificial intelligence, or any other computer-
18 generated or technological means, including by
19 adapting, modifying, manipulating, or altering
20 an authentic visual depiction, that, when viewed
21 as a whole by a reasonable person, is indistin-
22 guishable from an authentic visual depiction of
23 the individual.

1 “(C) IDENTIFIABLE INDIVIDUAL.—The
2 term ‘identifiable individual’ means an indi-
3 vidual—

4 “(i) who appears in whole or in part
5 in an intimate visual depiction; and

6 “(ii) whose face, likeness, or other dis-
7 tinguishing characteristic (including a
8 unique birthmark or other recognizable
9 feature) is displayed in connection with
10 such intimate visual depiction.

11 “(D) INTERACTIVE COMPUTER SERVICE.—
12 The term ‘interactive computer service’ has the
13 meaning given the term in section 230.

14 “(E) INTIMATE VISUAL DEPICTION.—The
15 term ‘intimate visual depiction’ has the mean-
16 ing given such term in section 1309 of the Con-
17 solidated Appropriations Act, 2022 (15 U.S.C.
18 6851).

19 “(F) MINOR.—The term ‘minor’ means
20 any individual under the age of 18 years.

21 “(2) OFFENSE INVOLVING AUTHENTIC INTI-
22 MATE VISUAL DEPICTIONS.—

23 “(A) INVOLVING ADULTS.—Except as pro-
24 vided in subparagraph (C), it shall be unlawful
25 for any person, in interstate or foreign com-

1 merce, to use an interactive computer service to
2 knowingly publish an intimate visual depiction
3 of an identifiable individual who is not a minor
4 if—

5 “(i) the intimate visual depiction was
6 obtained or created under circumstances in
7 which the person knew or reasonably
8 should have known the identifiable indi-
9 vidual had a reasonable expectation of pri-
10 vacy;

11 “(ii) what is depicted was not volun-
12 tarily exposed by the identifiable individual
13 in a public or commercial setting;

14 “(iii) what is depicted is not a matter
15 of public concern; and

16 “(iv) publication of the intimate visual
17 depiction—

18 “(I) is intended to cause harm;

19 or

20 “(II) causes harm, including psy-
21 chological, financial, or reputational
22 harm, to the identifiable individual.

23 “(B) INVOLVING MINORS.—Except as pro-
24 vided in subparagraph (C), it shall be unlawful
25 for any person, in interstate or foreign com-

1 merce, to use an interactive computer service to
2 knowingly publish an intimate visual depiction
3 of an identifiable individual who is a minor with
4 intent to—

5 “(i) abuse, humiliate, harass, or de-
6 grade the minor; or

7 “(ii) arouse or gratify the sexual de-
8 sire of any person.

9 “(C) EXCEPTIONS.—Subparagraphs (A)
10 and (B) shall not apply to—

11 “(i) a lawfully authorized investiga-
12 tive, protective, or intelligence activity of—

13 “(I) a law enforcement agency of
14 the United States, a State, or a polit-
15 ical subdivision of a State; or

16 “(II) an intelligence agency of
17 the United States;

18 “(ii) a disclosure made reasonably and
19 in good faith—

20 “(I) to a law enforcement officer
21 or agency;

22 “(II) as part of a document pro-
23 duction or filing associated with a
24 legal proceeding;

1 “(III) as part of medical edu-
2 cation, diagnosis, or treatment or for
3 a legitimate medical, scientific, or
4 education purpose;

5 “(IV) in the reporting of unlaw-
6 ful content or unsolicited or unwel-
7 come conduct or in pursuance of a
8 legal, professional, or other lawful ob-
9 ligation; or

10 “(V) to seek support or help with
11 respect to the receipt of an unsolicited
12 intimate visual depiction;

13 “(iii) a disclosure reasonably intended
14 to assist the identifiable individual; or

15 “(iv) a person who possesses or pub-
16 lishes an intimate visual depiction of him-
17 self or herself engaged in nudity or sexu-
18 ally explicit conduct (as that term is de-
19 fined in section 2256(2)(A) of title 18,
20 United States Code).

21 “(3) OFFENSE INVOLVING DIGITAL FOR-
22 GERIES.—

23 “(A) INVOLVING ADULTS.—Except as pro-
24 vided in subparagraph (C), it shall be unlawful
25 for any person, in interstate or foreign com-

1 merce, to use an interactive computer service to
2 knowingly publish a digital forgery of an identi-
3 fiable individual who is not a minor if—

4 “(i) the digital forgery was published
5 without the consent of the identifiable indi-
6 vidual;

7 “(ii) what is depicted was not volun-
8 tarily exposed by the identifiable individual
9 in a public or commercial setting;

10 “(iii) what is depicted is not a matter
11 of public concern; and

12 “(iv) publication of the digital for-
13 gery—

14 “(I) is intended to cause harm;
15 or

16 “(II) causes harm, including psy-
17 chological, financial, or reputational
18 harm, to the identifiable individual.

19 “(B) INVOLVING MINORS.—Except as pro-
20 vided in subparagraph (C), it shall be unlawful
21 for any person, in interstate or foreign com-
22 merce, to use an interactive computer service to
23 knowingly publish a digital forgery of an identi-
24 fiable individual who is a minor with intent
25 to—

1 “(i) abuse, humiliate, harass, or de-
2 grade the minor; or

3 “(ii) arouse or gratify the sexual de-
4 sire of any person.

5 “(C) EXCEPTIONS.—Subparagraphs (A)
6 and (B) shall not apply to—

7 “(i) a lawfully authorized investiga-
8 tive, protective, or intelligence activity of—

9 “(I) a law enforcement agency of
10 the United States, a State, or a polit-
11 ical subdivision of a State; or

12 “(II) an intelligence agency of
13 the United States;

14 “(ii) a disclosure made reasonably and
15 in good faith—

16 “(I) to a law enforcement officer
17 or agency;

18 “(II) as part of a document pro-
19 duction or filing associated with a
20 legal proceeding;

21 “(III) as part of medical edu-
22 cation, diagnosis, or treatment or for
23 a legitimate medical, scientific, or
24 education purpose;

1 “(IV) in the reporting of unlaw-
2 ful content or unsolicited or unwel-
3 come conduct or in pursuance of a
4 legal, professional, or other lawful ob-
5 ligation; or

6 “(V) to seek support or help with
7 respect to the receipt of an unsolicited
8 intimate visual depiction;

9 “(iii) a disclosure reasonably intended
10 to assist the identifiable individual; or

11 “(iv) a person who possesses or pub-
12 lishes a digital forgery of himself or herself
13 engaged in nudity or sexually explicit con-
14 duct (as that term is defined in section
15 2256(2)(A) of title 18, United States
16 Code).

17 “(4) PENALTIES.—

18 “(A) OFFENSES INVOLVING ADULTS.—Any
19 person who violates paragraph (2)(A) or (3)(A)
20 shall be fined under title 18, United States
21 Code, imprisoned not more than 2 years, or
22 both.

23 “(B) OFFENSES INVOLVING MINORS.—Any
24 person who violates paragraph (2)(B) or (3)(B)
25 shall be fined under title 18, United States

1 Code, imprisoned not more than 3 years, or
2 both.

3 “(5) RULES OF CONSTRUCTION.—For purposes
4 of paragraphs (2) and (3)—

5 “(A) the fact that the identifiable indi-
6 vidual provided consent for the creation of the
7 intimate visual depiction shall not establish that
8 the individual provided consent for the publica-
9 tion of the intimate visual depiction; and

10 “(B) the fact that the identifiable indi-
11 vidual disclosed the intimate visual depiction to
12 another individual shall not establish that the
13 identifiable individual provided consent for the
14 publication of the intimate visual depiction by
15 the person alleged to have violated paragraph
16 (2) or (3), respectively.

17 “(6) THREATS.—

18 “(A) THREATS INVOLVING AUTHENTIC IN-
19 TIMATE VISUAL DEPICTIONS.—Any person who
20 intentionally threatens to commit an offense
21 under paragraph (2) for the purpose of intimi-
22 dation, coercion, extortion, or to create mental
23 distress shall be punished as provided in para-
24 graph (4).

1 “(B) THREATS INVOLVING DIGITAL FOR-
2 GERIES.—

3 “(i) THREATS INVOLVING ADULTS.—
4 Any person who intentionally threatens to
5 commit an offense under paragraph (3)(A)
6 for the purpose of intimidation, coercion,
7 extortion, or to create mental distress shall
8 be fined under title 18, United States
9 Code, imprisoned not more than 18
10 months, or both.

11 “(ii) THREATS INVOLVING MINORS.—
12 Any person who intentionally threatens to
13 commit an offense under paragraph (3)(B)
14 for the purpose of intimidation, coercion,
15 extortion, or to create mental distress shall
16 be fined under title 18, United States
17 Code, imprisoned not more than 30
18 months, or both.

19 “(7) FORFEITURE.—

20 “(A) IN GENERAL.—The court, in impos-
21 ing a sentence on any person convicted of a vio-
22 lation of paragraph (2) or (3), shall order, in
23 addition to any other sentence imposed and ir-
24 respective of any provision of State law, that
25 the person forfeit to the United States—

1 “(i) any material distributed in viola-
2 tion of that paragraph;

3 “(ii) the person’s interest in property,
4 real or personal, constituting or derived
5 from any gross proceeds of the violation, or
6 any property traceable to such property,
7 obtained or retained directly or indirectly
8 as a result of the violation; and

9 “(iii) any personal property of the
10 person used, or intended to be used, in any
11 manner or part, to commit or to facilitate
12 the commission of the violation.

13 “(B) PROCEDURES.—Section 413 of the
14 Controlled Substances Act (21 U.S.C. 853),
15 with the exception of subsections (a) and (d),
16 shall apply to the criminal forfeiture of property
17 under subparagraph (A).

18 “(8) RESTITUTION.—The court shall order res-
19 titution for an offense under paragraph (2) or (3) in
20 the same manner as under section 2264 of title 18,
21 United States Code.

22 “(9) RULE OF CONSTRUCTION.—Nothing in
23 this subsection shall be construed to limit the appli-
24 cation of any other relevant law, including section
25 2252 of title 18, United States Code.”.

1 (b) DEFENSES.—Section 223(e)(1) of the Commu-
2 nications Act of 1934 (47 U.S.C. 223(e)(1)) is amended
3 by striking “or (d)” and inserting “, (d), or (h)”.

4 (c) TECHNICAL AND CONFORMING AMENDMENT.—
5 Subsection (i) of section 223 of the Communications Act
6 of 1934 (47 U.S.C. 223), as so redesignated by subsection
7 (a), is amended by inserting “DEFINITIONS.—” before
8 “For purposes of this section”.

9 **SEC. 803. NOTICE AND REMOVAL OF NONCONSENSUAL IN-**
10 **TIMATE VISUAL DEPICTIONS.**

11 (a) IN GENERAL.—

12 (1) NOTICE AND REMOVAL PROCESS.—

13 (A) ESTABLISHMENT.—Not later than 1
14 year after the date of enactment of this Act, a
15 covered platform shall establish a process
16 whereby an identifiable individual (or an au-
17 thorized person acting on behalf of such indi-
18 vidual) may—

19 (i) notify the covered platform of an
20 intimate visual depiction published on the
21 covered platform that—

22 (I) includes a depiction of the
23 identifiable individual; and

1 (II) was published without the
2 consent of the identifiable individual;
3 and

4 (ii) submit a request for the covered
5 platform to remove such intimate visual
6 depiction.

7 (B) REQUIREMENTS.—A notification and
8 request for removal of an intimate visual depic-
9 tion submitted under the process established
10 under subparagraph (A) shall include, in writ-
11 ing—

12 (i) a physical or electronic signature
13 of the identifiable individual (or an author-
14 ized person acting on behalf of such indi-
15 vidual);

16 (ii) an identification of, and informa-
17 tion reasonably sufficient for the covered
18 platform to locate, the intimate visual de-
19 piction of the identifiable individual;

20 (iii) a brief statement that the identi-
21 fiable individual has a good faith belief
22 that any intimate visual depiction identi-
23 fied under clause (ii) is not consensual, in-
24 cluding any relevant information for the
25 covered platform to determine the intimate

1 visual depiction was published without the
2 consent of the identifiable individual; and

3 (iv) information sufficient to enable
4 the covered platform to contact the identi-
5 fiable individual (or an authorized person
6 acting on behalf of such individual).

7 (2) NOTICE OF PROCESS.—A covered platform
8 shall provide on the platform a clear and con-
9 spicuous notice, which may be provided through a
10 clear and conspicuous link to another web page or
11 disclosure, of the notice and removal process estab-
12 lished under paragraph (1)(A) that—

13 (A) is easy to read and in plain language;
14 and

15 (B) provides information regarding the re-
16 sponsibilities of the covered platform under this
17 section, including a description of how an indi-
18 vidual can submit a notification and request for
19 removal.

20 (3) REMOVAL OF NONCONSENSUAL INTIMATE
21 VISUAL DEPICTIONS.—Upon receiving a valid re-
22 moval request from an identifiable individual (or an
23 authorized person acting on behalf of such indi-
24 vidual) using the process described in paragraph
25 (1)(A)(ii), a covered platform shall, as soon as pos-

1 sible, but not later than 48 hours after receiving
2 such request—

3 (A) remove the intimate visual depiction;
4 and

5 (B) make reasonable efforts to identify and
6 remove any known identical copies of such de-
7 piction.

8 (4) LIMITATION ON LIABILITY.—A covered plat-
9 form shall not be liable for any claim based on the
10 covered platform’s good faith disabling of access to,
11 or removal of, material claimed to be a nonconsen-
12 sual intimate visual depiction based on facts or cir-
13 cumstances from which the unlawful publishing of
14 an intimate visual depiction is apparent, regardless
15 of whether the intimate visual depiction is ultimately
16 determined to be unlawful or not.

17 (b) ENFORCEMENT BY THE COMMISSION.—

18 (1) UNFAIR OR DECEPTIVE ACTS OR PRAC-
19 TICES.—A failure to reasonably comply with the no-
20 tice and takedown obligations under subsection (a)
21 shall be treated as a violation of a rule defining an
22 unfair or a deceptive act or practice under section
23 18(a)(1)(B) of the Federal Trade Commission Act
24 (15 U.S.C. 57a(a)(1)(B)).

25 (2) POWERS OF THE COMMISSION.—

1 (A) IN GENERAL.—Except as provided in
2 subparagraph (D), the Commission shall en-
3 force this section in the same manner, by the
4 same means, and with the same jurisdiction,
5 powers, and duties as though all applicable
6 terms and provisions of the Federal Trade
7 Commission Act (15 U.S.C. 41 et seq.) were in-
8 corporated into and made a part of this section.

9 (B) PRIVILEGES AND IMMUNITIES.—Any
10 person who violates this section shall be subject
11 to the penalties and entitled to the privileges
12 and immunities provided in the Federal Trade
13 Commission Act (15 U.S.C. 41 et seq.).

14 (C) AUTHORITY PRESERVED.—Nothing in
15 this title shall be construed to limit the author-
16 ity of the Federal Trade Commission under any
17 other provision of law.

18 (D) SCOPE OF JURISDICTION.—Notwith-
19 standing sections 4, 5(a)(2), or 6 of the Federal
20 Trade Commission Act (15 U.S.C. 44; 45(a)(2);
21 46), or any jurisdictional limitation of the Com-
22 mission, the Commission shall also enforce this
23 section in the same manner provided in sub-
24 paragraph (A), with respect to organizations

1 that are not organized to carry on business for
2 their own profit or that of their members.

3 **SEC. 804. DEFINITIONS.**

4 In this title:

5 (1) COMMISSION.—The term “Commission”
6 means the Federal Trade Commission.

7 (2) CONSENT; DIGITAL FORGERY; IDENTIFI-
8 ABLE INDIVIDUAL; INTIMATE VISUAL DEPICTION.—
9 The terms “consent”, “digital forgery”, “identifiable
10 individual”, “intimate visual depiction”, and
11 “minor” have the meaning given such terms in sec-
12 tion 223(h) of the Communications Act of 1934 (47
13 U.S.C. 223(h)), as added by section 802.

14 (3) COVERED PLATFORM.—

15 (A) IN GENERAL.—The term “covered
16 platform” means a website, online service, on-
17 line application, or mobile application—

18 (i) that serves the public; and

19 (ii)(I) that primarily provides a forum
20 for user-generated content, including mes-
21 sages, videos, images, games, and audio
22 files; or

23 (II) for which it is in the regular
24 course of trade or business of the website,
25 online service, online application, or mobile

1 application to publish, curate, host, or
2 make available content of nonconsensual
3 intimate visual depictions.

4 (B) EXCLUSIONS.—The term “covered
5 platform” shall not include the following:

6 (i) A provider of broadband internet
7 access service (as described in section
8 8.1(b) of title 47, Code of Federal Regula-
9 tions, or successor regulation).

10 (ii) Electronic mail.

11 (iii) Except as provided in subpara-
12 graph (A)(ii)(II), an online service, appli-
13 cation, or website—

14 (I) that consists primarily of con-
15 tent that is not user generated but is
16 preselected by the provider of such on-
17 line service, application, or website;
18 and

19 (II) for which any chat, com-
20 ment, or interactive functionality is
21 incidental to, directly related to, or
22 dependent on the provision of the con-
23 tent described in subparagraph
24 (A)(ii)(I).

1 **SEC. 805. SEVERABILITY.**

2 If any provision of this title, or an amendment made
3 by this title, is determined to be unenforceable or invalid,
4 the remaining provisions of this title and the amendments
5 made by this title shall not be affected.

6 **TITLE IX—RURAL BROADBAND**
7 **PROTECTION ACT**

8 **SEC. 901. SHORT TITLE.**

9 This title may be cited as the “Rural Broadband Pro-
10 tection Act”.

11 **SEC. 902. VETTING PROCESS FOR PROSPECTIVE HIGH-COST**
12 **UNIVERSAL SERVICE FUND APPLICANTS.**

13 Section 254 of the Communications Act of 1934 (47
14 U.S.C. 254) is amended by adding at the end the fol-
15 lowing:

16 “(m) VETTING OF HIGH-COST FUND RECIPIENTS.—

17 “(1) DEFINITIONS.—In this subsection—

18 “(A) the term ‘covered funding’ means any
19 new offer of high-cost universal service program
20 funding, including funding provided through a
21 reverse competitive bidding mechanism provided
22 under this section, for the deployment of a
23 broadband-capable network and the provision of
24 supported services over the network; and

25 “(B) the term ‘new covered funding award’
26 means an award of covered funding that is

1 made based on an application submitted to the
2 Commission on or after the date on which rules
3 are promulgated under paragraph (2).

4 “(2) COMMISSION RULEMAKING.—Not later
5 than 180 days after the date of enactment of this
6 subsection, the Commission shall initiate a rule-
7 making proceeding to establish a vetting process for
8 applicants for, and other recipients of, a new covered
9 funding award.

10 “(3) CONTENTS.—

11 “(A) IN GENERAL.—In promulgating rules
12 under paragraph (2), the Commission shall pro-
13 vide that, consistent with principles of tech-
14 nology neutrality, the Commission will only
15 award covered funding to applicants that can
16 demonstrate that they meet the qualifications in
17 subparagraph (B).

18 “(B) QUALIFICATIONS DESCRIBED.—An
19 applicant for a new covered funding award shall
20 include in the initial application a proposal con-
21 taining sufficient detail and documentation for
22 the Commission to ascertain that the applicant
23 possesses the technical, financial, and oper-
24 ational capabilities, and has a reasonable busi-
25 ness plan, to deploy the proposed network and

1 deliver services with the relevant performance
2 characteristics and requirements defined by the
3 Commission and as pledged by the applicant.

4 “(C) EVALUATION OF PROPOSAL.—The
5 Commission shall evaluate a proposal described
6 in subparagraph (B) against—

7 “(i) reasonable and well-established
8 technical, financial, and operational stand-
9 ards, including the technical standards
10 adopted by the Commission in orders of
11 the Commission relating to Establishing
12 the Digital Opportunity Data Collection
13 (WC Docket No. 19–195) (or orders of the
14 Commission relating to modernizing any
15 successor collection) for purposes of enti-
16 ties that must report broadband avail-
17 ability coverage; and

18 “(ii) the applicant’s history of com-
19 plying with requirements in Commission
20 and other government broadband deploy-
21 ment funding programs.

22 “(D) PENALTIES FOR PRE-AUTHORIZATION
23 DEFAULTS.—In adopting rules for any new cov-
24 ered funding award, the Commission shall set a
25 penalty for pre-authorization defaults of at least

1 \$9,000 per violation and may not limit the base
2 forfeiture to an amount less than 30 percent of
3 the applicant’s total support, unless the Com-
4 mission demonstrates the need for lower pen-
5 alties in a particular instance.”.

6 **TITLE X—AMERICAN MUSIC**
7 **TOURISM**

8 **SEC. 1001. SHORT TITLE.**

9 This title may be cited as the “American Music Tour-
10 ism Act”.

11 **SEC. 1002. RESPONSIBILITIES OF THE ASSISTANT SEC-**
12 **RETARY OF COMMERCE FOR TRAVEL AND**
13 **TOURISM.**

14 (a) DOMESTIC TRAVEL AND TOURISM.—Section
15 605(b) of the Visit America Act (15 U.S.C. 9803(b)) is
16 amended—

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

19 (2) in paragraph (3), by striking the period at
20 the end and inserting “; and”; and

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

22 “(4) identify locations and events in the United
23 States that are important to music tourism and fa-
24 cilitate and promote domestic travel and tourism to
25 those locations and events.”.

1 (b) FACILITATION OF INTERNATIONAL BUSINESS
2 AND LEISURE TRAVEL.—Section 605 of the Visit America
3 Act (15 U.S.C. 9803) is amended by striking subsection
4 (d) and inserting the following:

5 “(d) FACILITATION OF INTERNATIONAL BUSINESS
6 AND LEISURE TRAVEL.—The Assistant Secretary, in co-
7 ordination with relevant Federal agencies, shall strive to
8 increase and facilitate international business and leisure
9 travel to the United States and ensure competitiveness
10 by—

11 “(1) facilitating large meetings, incentives, con-
12 ferences, and exhibitions in the United States;

13 “(2) emphasizing rural and other destinations
14 in the United States that are rich in cultural herit-
15 age or ecological tourism, among other uniquely
16 American destinations, as locations for hosting inter-
17 national meetings, incentives, conferences, and exhi-
18 bitions;

19 “(3) facilitating and promoting international
20 travel and tourism to sports and recreation events
21 and activities in the United States; and

22 “(4) identifying locations and events in the
23 United States that are important to music tourism
24 and facilitating and promoting international travel
25 and tourism to those locations and events.”.

1 (c) REPORTING REQUIREMENTS.—Section 605(f) of
2 the Visit America Act (15 U.S.C. 9803(f)) is amended by
3 adding at the end the following:

4 “(4) REPORT ON GOALS RELATING TO DOMES-
5 TIC AND INTERNATIONAL TRAVEL.—Not later than
6 1 year after the date of enactment of the American
7 Music Tourism Act, and every 2 years thereafter,
8 the Assistant Secretary shall submit to the Sub-
9 committee on Tourism, Trade, and Export Pro-
10 motion of the Committee on Commerce, Science, and
11 Transportation of the Senate and the Subcommittee
12 on Innovation, Data, and Commerce of the Com-
13 mittee on Energy and Commerce of the House of
14 Representatives a report of activities, findings,
15 achievements, and vulnerabilities relating to the
16 goals described in subsections (a) through (d).”.

17 (d) DEFINITION.—Section 600 of title VI of division
18 BB of the Consolidated Appropriations Act, 2023 (15
19 U.S.C. 9801) is amended—

20 (1) by redesignating paragraphs (1) and (2) as
21 subparagraphs (A) and (B), respectively, and adjust-
22 ing the margins accordingly; and

23 (2) by striking “In this title, the term ‘COVID-
24 19 public health emergency’—” and inserting the
25 following:

1 “In this title:

2 “(1) COVID–19 PUBLIC HEALTH EMER-
3 GENCY.—The term ‘COVID–19 public health emer-
4 gency’—”; and

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

6 “(2) MUSIC TOURISM.—The term ‘music tour-
7 ism’ means—

8 “(A) the act of traveling to a State or lo-
9 cality to visit historic or modern day music-re-
10 lated attractions, including museums, studios,
11 venues of all sizes, and other sites related to
12 music; or

13 “(B) the act of traveling to a State or lo-
14 cality to attend a music festival, a concert, or
15 other live musical performance or music-related
16 special event.”.

17 **TITLE XI—INFORMING CON-**
18 **SUMERS ABOUT SMART DE-**
19 **VICES**

20 **SEC. 1101. SHORT TITLE.**

21 This title may be cited as the “Informing Consumers
22 about Smart Devices Act”.

1 **SEC. 1102. REQUIRED DISCLOSURE OF A CAMERA OR RE-**
2 **CORDING CAPABILITY IN CERTAIN INTER-**
3 **NET-CONNECTED DEVICES.**

4 Each manufacturer of a covered device shall disclose,
5 clearly and conspicuously and prior to purchase, whether
6 the covered device manufactured by the manufacturer con-
7 tains a camera or microphone as a component of the cov-
8 ered device.

9 **SEC. 1103. ENFORCEMENT BY THE FEDERAL TRADE COM-**
10 **MISSION.**

11 (a) UNFAIR OR DECEPTIVE ACTS OR PRACTICES.—
12 A violation of section 1102 shall be treated as a violation
13 of a rule defining an unfair or deceptive act or practice
14 prescribed under section 18(a)(1)(B) of the Federal Trade
15 Commission Act (15 U.S.C. 57a(a)(1)(B)).

16 (b) ACTIONS BY THE COMMISSION.—

17 (1) IN GENERAL.—The Federal Trade Commis-
18 sion (in this title referred to as the “Commission”)
19 shall enforce this title in the same manner, by the
20 same means, and with the same jurisdiction, powers,
21 and duties as though all applicable terms and provi-
22 sions of the Federal Trade Commission Act (15
23 U.S.C. 41 et seq.) were incorporated into and made
24 a part of this title.

25 (2) PENALTIES AND PRIVILEGES.—Any person
26 who violates this title or a regulation promulgated

1 under this title shall be subject to the penalties and
2 entitled to the privileges and immunities provided in
3 the Federal Trade Commission Act (15 U.S.C. 41 et
4 seq.).

5 (3) SAVINGS CLAUSE.—Nothing in this title
6 shall be construed to limit the authority of the Com-
7 mission under any other provision of law.

8 (c) COMMISSION GUIDANCE.—Not later than 180
9 days after the date of enactment of this title, the Commis-
10 sion, through outreach to relevant private entities, shall
11 issue guidance to assist manufacturers in complying with
12 the requirements of this title, including guidance about
13 best practices for making the disclosure required by sec-
14 tion 1102 as clear and conspicuous and age appropriate
15 as practicable and about best practices for the use of a
16 pictorial (as defined in section 2(a) of the Consumer Re-
17 view Fairness Act of 2016 (15 U.S.C. 45b(a))) visual rep-
18 resentation of the information to be disclosed.

19 (d) TAILORED GUIDANCE.—A manufacturer of a cov-
20 ered device may petition the Commission for tailored guid-
21 ance as to how to meet the requirements of section 1102
22 consistent with existing rules of practice or any successor
23 rules.

24 (e) LIMITATION ON COMMISSION GUIDANCE.—No
25 guidance issued by the Commission with respect to this

1 title shall confer any rights on any person, State, or local-
2 ity, nor shall operate to bind the Commission or any per-
3 son to the approach recommended in such guidance. In
4 any enforcement action brought pursuant to this title, the
5 Commission shall allege a specific violation of a provision
6 of this title. The Commission may not base an enforce-
7 ment action on, or execute a consent order based on, prac-
8 tices that are alleged to be inconsistent with any such
9 guidelines, unless the practices allegedly violate section
10 1102.

11 **SEC. 1104. DEFINITION OF COVERED DEVICE.**

12 As used in this title, the term “covered device”—

13 (1) means a consumer product, as defined by
14 section 3(a) of the Consumer Product Safety Act
15 (15 U.S.C. 2052(a)) that is capable of connecting to
16 the internet, a component of which is a camera or
17 microphone; and

18 (2) does not include—

19 (A) a telephone (including a mobile phone),
20 a laptop, tablet, or any device that a consumer
21 would reasonably expect to have a microphone
22 or camera;

23 (B) any device that is specifically marketed
24 as a camera, telecommunications device, or
25 microphone; or

1 (C) any device or apparatus described in
2 sections 255, 716, and 718, and subsections
3 (aa) and (bb) of section 303 of the Communica-
4 tions Act of 1934 (47 U.S.C. 255; 617; 619;
5 and 303(aa) and (bb)), and any regulations
6 promulgated thereunder.

7 **SEC. 1105. EFFECTIVE DATE.**

8 This title shall apply to all covered devices manufac-
9 tured after the date that is 180 days after the date on
10 which guidance is issued by the Commission under section
11 1103(c), and shall not apply to covered devices manufac-
12 tured or sold before such date, or otherwise introduced
13 into interstate commerce before such date.

14 **TITLE XII—SECURING SEMICON-**
15 **DUCTOR SUPPLY CHAINS ACT**

16 **SEC. 1201. SHORT TITLE.**

17 This title may be cited as the “Securing Semicon-
18 ductor Supply Chains Act”.

19 **SEC. 1202. SELECTUSA DEFINED.**

20 In this title, the term “SelectUSA” means the
21 SelectUSA program of the Department of Commerce es-
22 tablished by Executive Order 13577 (76 Fed. Reg. 35715;
23 relating to establishment of the SelectUSA Initiative).

24 **SEC. 1203. FINDINGS.**

25 Congress makes the following findings:

1 (1) Semiconductors underpin the United States
2 and global economies, including manufacturing sec-
3 tors. Semiconductors are also essential to the na-
4 tional security of the United States.

5 (2) A shortage of semiconductors, brought
6 about by the COVID–19 pandemic and other com-
7 plex factors impacting the overall supply chain, has
8 threatened the economic recovery of the United
9 States and industries that employ millions of United
10 States citizens.

11 (3) Addressing current challenges and building
12 resilience against future risks requires ensuring a se-
13 cure and stable supply chain for semiconductors that
14 will support the economic and national security
15 needs of the United States and its allies.

16 (4) The supply chain for semiconductors is
17 complex and global. While the United States plays
18 a leading role in certain segments of the semicon-
19 ductor industry, securing the supply chain requires
20 onshoring, reshoring, or diversifying vulnerable seg-
21 ments, such as for—

22 (A) fabrication;

23 (B) advanced packaging; and

24 (C) materials and equipment used to man-
25 ufacture semiconductor products.

1 (5) The Federal Government can leverage for-
2 eign direct investment and private dollars to grow
3 the domestic manufacturing and production capacity
4 of the United States for vulnerable segments of the
5 semiconductor supply chain.

6 (6) The SelectUSA program of the Department
7 of Commerce, in coordination with other Federal
8 agencies and State-level economic development orga-
9 nizations, is positioned to boost foreign direct invest-
10 ment in domestic manufacturing and to help secure
11 the semiconductor supply chain of the United States.

12 **SEC. 1204. COORDINATION WITH STATE-LEVEL ECONOMIC**
13 **DEVELOPMENT ORGANIZATIONS.**

14 Not later than 180 days after the date of the enact-
15 ment of this Act, the Executive Director of SelectUSA
16 shall solicit comments from State-level economic develop-
17 ment organizations—

18 (1) to review—

19 (A) what efforts the Federal Government
20 can take to support increased foreign direct in-
21 vestment in any segment of semiconductor-re-
22 lated production;

23 (B) what barriers to such investment may
24 exist and how to amplify State efforts to attract
25 such investment;

1 (C) public opportunities those organiza-
2 tions have identified to attract foreign direct in-
3 vestment to help increase investment described
4 in subparagraph (A); and

5 (D) resource gaps or other challenges that
6 prevent those organizations from increasing
7 such investment; and

8 (2) to develop recommendations for—

9 (A) how SelectUSA can increase such in-
10 vestment independently or through partnership
11 with those organizations; and

12 (B) working with countries that are allies
13 or partners of the United States to ensure that
14 foreign adversaries (as defined in section
15 8(c)(2) of the Secure and Trusted Communica-
16 tions Networks Act of 2019 (47 U.S.C.
17 1607(c)(2))) do not benefit from United States
18 efforts to increase such investment.

19 **SEC. 1205. REPORT ON INCREASING FOREIGN DIRECT IN-**
20 **VESTMENT IN SEMICONDUCTOR-RELATED**
21 **MANUFACTURING AND PRODUCTION.**

22 Not later than 2 years after the date of the enact-
23 ment of this Act, the Executive Director of SelectUSA,
24 in coordination with the Federal Interagency Investment
25 Working Group established by Executive Order 13577 (76

1 Fed. Reg. 35715; relating to establishment of the
2 SelectUSA Initiative), shall submit to the Committee on
3 Commerce, Science, and Transportation of the Senate and
4 the Committee on Energy and Commerce of the House
5 of Representatives a report that includes—

6 (1) a review of the comments SelectUSA re-
7 ceived from State-level economic development organi-
8 zations under section 1204;

9 (2) a description of activities SelectUSA is en-
10 gaged in to increase foreign direct investment in
11 semiconductor-related manufacturing and produc-
12 tion; and

13 (3) an assessment of strategies SelectUSA may
14 implement to achieve an increase in such investment
15 and to help secure the United States supply chain
16 for semiconductors, including by—

17 (A) working with other relevant Federal
18 agencies; and

19 (B) working with State-level economic de-
20 velopment organizations and implementing any
21 strategies or recommendations SelectUSA re-
22 ceived from those organizations.

23 **SEC. 1206. NO ADDITIONAL FUNDS.**

24 No additional funds are authorized to be appro-
25 priated for the purpose of carrying out this title. The Ex-

1 ecutive Director of SelectUSA shall carry out this title
2 using amounts otherwise available to the Executive Direc-
3 tor for such purposes.

4 **TITLE XIII—HOTEL FEES**
5 **TRANSPARENCY ACT**

6 **SEC. 1301. SHORT TITLE.**

7 This title may be cited as the “Hotel Fees Trans-
8 parency Act”.

9 **SEC. 1302. PROHIBITION ON UNFAIR AND DECEPTIVE AD-**
10 **VERTISING OF HOTEL ROOMS AND OTHER**
11 **SHORT-TERM RENTAL PRICES.**

12 (a) PROHIBITION.—

13 (1) IN GENERAL.—It shall be unlawful for a
14 covered entity to display, advertise, market, or offer
15 in interstate commerce, including through direct of-
16 ferings, third-party distribution, or metasearch refer-
17 rals, a price for covered services that does not clear-
18 ly, conspicuously, and prominently—

19 (A) display the total services price, if a
20 price is displayed, in any advertisement, mar-
21 keting, or price list wherever the covered serv-
22 ices are displayed, advertised, marketed, or of-
23 fered for sale;

24 (B) disclose to any individual who seeks to
25 purchase covered services the total services

1 price at the time the covered services are first
2 displayed to the individual and anytime there-
3 after throughout the covered services pur-
4 chasing process; and

5 (C) disclose, prior to the final purchase,
6 any tax, fee, or assessment imposed by any gov-
7 ernment entity, quasi-government entity, or
8 government-created special district or program
9 on the sale of covered services.

10 (2) INDIVIDUAL COMPONENTS.—Provided that
11 such displays are less prominent than the total serv-
12 ice price required in paragraph (1), nothing in this
13 Act shall be construed to prohibit the display of—

14 (A) individual components of the total
15 price; or

16 (B) details of other items not required by
17 paragraph (1).

18 (3) INDEMNIFICATION PROVISIONS.—Nothing
19 in this section shall be construed to prohibit any cov-
20 ered entity from entering into a contract with any
21 other covered entity that contains an indemnification
22 provision with respect to price or fee information
23 disclosed, exchanged, or shared between the covered
24 entities that are parties to the contract.

25 (b) ENFORCEMENT.—

1 (1) ENFORCEMENT BY THE COMMISSION.—

2 (A) UNFAIR OR DECEPTIVE ACTS OR PRAC-
3 TICES.—A violation of subsection (a) shall be
4 treated as a violation of a rule defining an un-
5 fair or deceptive act or practice prescribed
6 under section 18(a)(1)(B) of the Federal Trade
7 Commission Act (15 U.S.C. 57a(a)(1)(B)).

8 (B) POWERS OF THE COMMISSION.—

9 (i) IN GENERAL.—The Commission
10 shall enforce this section in the same man-
11 ner, by the same means, and with the
12 same jurisdiction, powers, and duties as
13 though all applicable terms and provisions
14 of the Federal Trade Commission Act (15
15 U.S.C. 41 et seq.) were incorporated into
16 and made a part of this Act.

17 (ii) PRIVILEGES AND IMMUNITIES.—
18 Any person who violates this section shall
19 be subject to the penalties and entitled to
20 the privileges and immunities provided in
21 the Federal Trade Commission Act (15
22 U.S.C. 41 et seq.).

23 (iii) AUTHORITY PRESERVED.—Noth-
24 ing in this section shall be construed to

1 limit the authority of the Commission
2 under any other provision of law.

3 (2) ENFORCEMENT BY STATES.—

4 (A) IN GENERAL.—If the attorney general
5 of a State has reason to believe that an interest
6 of the residents of the State has been or is
7 being threatened or adversely affected by a
8 practice that violates subsection (a), the attor-
9 ney general of the State may, as parens patriae,
10 bring a civil action on behalf of the residents of
11 the State in an appropriate district court of the
12 United States to obtain appropriate relief.

13 (B) RIGHTS OF THE COMMISSION.—

14 (i) NOTICE TO THE COMMISSION.—

15 (I) IN GENERAL.—Except as pro-
16 vided in subclause (III), the attorney
17 general of a State, before initiating a
18 civil action under subparagraph (A)
19 shall notify the Commission in writing
20 that the attorney general intends to
21 bring such civil action.

22 (II) CONTENTS.—The notifica-
23 tion required by subclause (I) shall in-
24 clude a copy of the complaint to be
25 filed to initiate the civil action.

1 (III) EXCEPTION.—If it is not
2 feasible for the attorney general of a
3 State to provide the notification re-
4 quired by subclause (I) before initi-
5 ating a civil action under subpara-
6 graph (A), the attorney general shall
7 notify the Commission immediately
8 upon instituting the civil action.

9 (ii) INTERVENTION BY THE COMMIS-
10 SION.—The Commission may—

11 (I) intervene in any civil action
12 brought by the attorney general of a
13 State under subparagraph (A); and

14 (II) upon intervening—
15 (aa) be heard on all matters
16 arising in the civil action; and
17 (bb) file petitions for appeal.

18 (C) INVESTIGATORY POWERS.—Nothing in
19 this paragraph may be construed to prevent the
20 attorney general of a State from exercising the
21 powers conferred on the attorney general by the
22 laws of the State to conduct investigations, to
23 administer oaths or affirmations, or to compel
24 the attendance of witnesses or the production of
25 documentary or other evidence.

1 (D) ACTION BY THE COMMISSION.—When-
2 ever a civil action has been instituted by or on
3 behalf of the Commission for violation of sub-
4 section (a), no attorney general of a State may,
5 during the pendency of that action, institute an
6 action under subparagraph (A) against any de-
7 fendant named in the complaint in that action
8 for a violation of subsection (a) alleged in such
9 complaint.

10 (E) VENUE; SERVICE OF PROCESS.—

11 (i) VENUE.—Any action brought
12 under subparagraph (A) may be brought
13 in—

14 (I) the district court of the
15 United States that meets applicable
16 requirements relating to venue under
17 section 1391 of title 28, United States
18 Code; or

19 (II) another court of competent
20 jurisdiction.

21 (ii) SERVICE OF PROCESS.—In an ac-
22 tion brought under subparagraph (A),
23 process may be served in any district in
24 which—

1 (I) the defendant is an inhab-
2 itant, may be found, or transacts
3 business; or

4 (II) venue is proper under section
5 1391 of title 28, United States Code.

6 (F) ACTIONS BY OTHER STATE OFFI-
7 CIALS.—

8 (i) IN GENERAL.—In addition to civil
9 actions brought by an attorney general
10 under subparagraph (A), any other officer
11 of a State who is authorized by the State
12 to do so may bring a civil action under
13 subparagraph (A), subject to the same re-
14 quirements and limitations that apply
15 under this paragraph to civil actions
16 brought by attorneys general.

17 (ii) SAVINGS PROVISION.—Nothing in
18 this paragraph may be construed to pro-
19 hibit an authorized official of a State from
20 initiating or continuing any proceeding in
21 a court of the State for a violation of any
22 civil or criminal law of the State.

23 (3) AFFIRMATIVE DEFENSE.—In any action
24 pursuant to paragraph (1) or (2), an intermediary
25 or third-party online seller may assert an affirmative

1 defense if such intermediary or third-party online
2 seller—

3 (A) established procedures to receive up-to-
4 date price information from hotels or short-
5 term rentals, or agents acting on behalf of a
6 hotel or short-term rental;

7 (B) relied in good faith on information
8 provided to the intermediary or third-party on-
9 line seller by a hotel or short-term rental, or
10 agent acting on behalf of such hotel or short-
11 term rental, and such information was inac-
12 curate at the time it was provided to the inter-
13 mediary or third-party online seller; and

14 (C) took prompt action to remove or cor-
15 rect any false or inaccurate information about
16 the total services price after receiving notice
17 that such information was false or inaccurate.

18 (c) PREEMPTION.—

19 (1) IN GENERAL.—A State, or political subdivi-
20 sion of a State, may not maintain, enforce, pre-
21 scribe, or continue in effect any law, rule, regulation,
22 requirement, standard, or other provision having the
23 force and effect of law of the State, or political sub-
24 division of the State, that prohibits a covered entity
25 from advertising, displaying, marketing, or otherwise

1 offering, or otherwise affects the manner in which a
2 covered entity may advertise, display, market, or
3 otherwise offer, for sale in interstate commerce, in-
4 cluding through a direct offering, third-party dis-
5 tribution, or metasearch referral, a price of a res-
6 ervation for a covered service, and that requires fee
7 disclosure, unless the law requires the total services
8 price to include each service fee, as defined in sub-
9 section (d)(8), and in accordance with subsection
10 (a)(1).

11 (2) RULE OF CONSTRUCTION.—This section
12 may not be construed to—

13 (A) preempt any law of a State or political
14 subdivision of a State relating to contracts or
15 torts; or

16 (B) preempt any law of a State or political
17 subdivision of a State to the extent that such
18 law relates to an act of fraud, unauthorized ac-
19 cess to personal information, or notification of
20 unauthorized access to personal information.

21 (d) DEFINITIONS.—In this Act:

22 (1) BASE SERVICES PRICE.—The term “base
23 services price” —

24 (A) means, with respect to the covered
25 services provided by a hotel or short-term rent-

1 al, the price in order to obtain the covered serv-
2 ices of the hotel or short-term rental; and

3 (B) does not include—

4 (i) any service fee;

5 (ii) any taxes or fees imposed by a
6 government or quasi-government entity;

7 (iii) assessment fees of a government-
8 created special district or program; or

9 (iv) any charges or fees for an op-
10 tional product or service associated with
11 the covered services that may be selected
12 by a purchaser of covered services.

13 (2) COMMISSION.—The term “Commission”
14 means the Federal Trade Commission.

15 (3) COVERED ENTITY.—The term “covered en-
16 tity” means a person, partnership, or corporation
17 with respect to whom the Commission has jurisdic-
18 tion under section 5(a)(2) of the Federal Trade
19 Commission Act (15 U.S.C. 45(a)(2)), including—

20 (A) a hotel or short-term rental;

21 (B) a third-party online seller; or

22 (C) an intermediary.

23 (4) COVERED SERVICES.—The term “covered
24 services”—

1 (A) means the temporary provision of a
2 room, building, or other lodging facility; and

3 (B) does not include the provision of a
4 meeting room, banquet services, or catering
5 services.

6 (5) HOTEL.—The term “hotel” means an es-
7 tablishment that is—

8 (A) primarily engaged in providing a cov-
9 ered service to the general public; and

10 (B) promoted, advertised, or marketed in
11 interstate commerce or for which such estab-
12 lishment’s services are sold in interstate com-
13 merce.

14 (6) INTERMEDIARY.—The term “intermediary”
15 means an entity that operates either as a business-
16 to-business platform, consumer-facing platform, or
17 both, that displays, including through direct offer-
18 ings, third-party distribution, or metasearch referral,
19 a price for covered services or price comparison tools
20 for consumers seeking covered services.

21 (7) OPTIONAL PRODUCT OR SERVICE.—The
22 term “optional product or service” means a product
23 or service that an individual does not need to pur-
24 chase to use or obtain covered services.

25 (8) SERVICE FEE.—The term “service fee”—

1 (A) means a charge imposed by a covered
2 entity that must be paid in order to obtain cov-
3 ered services; and

4 (B) does not include—

5 (i) any taxes or fees imposed by a
6 government or quasi-government entity;

7 (ii) any assessment fees of a govern-
8 ment-created special district or program;
9 or

10 (iii) any charges or fees for an op-
11 tional product or service associated with
12 the covered services that may be selected
13 by a purchaser of covered services.

14 (9) SHORT-TERM RENTAL.—The term “short-
15 term rental” means a property, including a single-
16 family dwelling or a unit in a condominium, coopera-
17 tive, or time-share, that provides covered services
18 (either with respect to the entire property or a part
19 of the property) to the general public—

20 (A) in exchange for a fee;

21 (B) for periods shorter than 30 consecutive
22 days; and

23 (C) is promoted, advertised, or marketed in
24 interstate commerce or for which such prop-
25 erty’s services are sold in interstate commerce.

1 (10) STATE.—The term “State” means each of
2 the 50 States, the District of Columbia, and any ter-
3 ritory or possession of the United States.

4 (11) THIRD-PARTY ONLINE SELLER.—The term
5 “third-party online seller” means any person other
6 than a hotel or short-term rental that sells covered
7 services or offers for sale covered services with re-
8 spect to a hotel or short-term rental in a transaction
9 facilitated on the internet.

10 (12) TOTAL SERVICES PRICE.—The term “total
11 services”—

12 (A) means, with respect to covered serv-
13 ices, the total cost of the covered services, in-
14 cluding the base services price and any service
15 fees; and

16 (B) does not include—

17 (i) any taxes or fees imposed by a
18 government or quasi-government entity;

19 (ii) any assessment fees of a govern-
20 ment-created special district or program;
21 or

22 (iii) any charges or fees for an op-
23 tional product or service associated with
24 the covered services that may be selected
25 by a purchaser of covered services.

1 (e) EFFECTIVE DATE.—The prohibition under sub-
2 section (a) shall take effect 450 days after the date of
3 the enactment of this Act and shall apply to advertise-
4 ments, displays, marketing, and offers of covered services
5 of a covered entity made on or after such date.

6 **TITLE XIV—TRANSPARENCY IN**
7 **CHARGES FOR KEY EVENTS**
8 **TICKETING**

9 **SEC. 1401. SHORT TITLE.**

10 This title may be cited as the “Transparency In
11 Charges for Key Events Ticketing Act” or the “TICKET
12 Act”.

13 **SEC. 1402. ALL INCLUSIVE TICKET PRICE DISCLOSURE.**

14 Beginning 180 days after the date of the enactment
15 of this Act, it shall be unlawful for a ticket issuer, sec-
16 ondary market ticket issuer, or secondary market ticket
17 exchange to offer for sale an event ticket unless the ticket
18 issuer, secondary market ticket issuer, or secondary mar-
19 ket ticket exchange—

20 (1) clearly and conspicuously displays the total
21 event ticket price, if a price is displayed, in any ad-
22 vertisement, marketing, or price list wherever the
23 ticket is offered for sale;

24 (2) clearly and conspicuously discloses to any
25 individual who seeks to purchase an event ticket the

1 total event ticket price at the time the ticket is first
2 displayed to the individual and anytime thereafter
3 throughout the ticket purchasing process; and

4 (3) provides an itemized list of the base event
5 ticket price and each event ticket fee prior to the
6 completion of the ticket purchasing process.

7 **SEC. 1403. SPECULATIVE TICKETING BAN.**

8 (a) PROHIBITION.—Beginning 180 days after the
9 date of the enactment of this Act, a ticket issuer, sec-
10 ondary market ticket issuer, or secondary market ticket
11 exchange that does not have actual or constructive posses-
12 sion of an event ticket shall not sell, offer for sale, or ad-
13 vertise for sale such event ticket.

14 (b) SERVICES PERMITTED.—Notwithstanding sub-
15 section (a), a secondary market ticket issuer or secondary
16 market ticket exchange may sell, offer for sale, or adver-
17 tise for sale a service to an individual to obtain an event
18 ticket on behalf of such individual if the secondary market
19 ticket issuer or secondary market ticket exchange complies
20 with the following:

21 (1) Does not market or list the service as an
22 event ticket.

23 (2) Maintains a clear, distinct, and easily dis-
24 cernible separation between the service and event

1 tickets that persists throughout the entire service se-
2 lection and purchasing process.

3 (3) Clearly and conspicuously discloses before
4 selection of the service that the service is not an
5 event ticket and that the purchase of the service
6 does not guarantee an event ticket.

7 **SEC. 1404. DISCLOSURES.**

8 A ticket issuer, secondary market ticket issuer, or
9 secondary market ticket exchange—

10 (1) if offering an event ticket for resale, shall
11 provide a clear and conspicuous statement, before a
12 consumer purchases the event ticket from the ticket
13 issuer, secondary market ticket issuer, or secondary
14 market ticket exchange, that the issuer or exchange
15 is engaged in the secondary sale of event tickets; and

16 (2) shall not state that the ticket issuer, sec-
17 ondary market ticket issuer, or secondary market
18 ticket exchange is affiliated with or endorsed by a
19 venue, team, or artist, as applicable, including by
20 using words like “official” in promotional materials,
21 social media promotions, or paid advertising, unless
22 a partnership agreement has been executed or the
23 issuer or exchange has the express written consent
24 of the venue, team, or artist, as applicable.

1 **SEC. 1405. REFUND REQUIREMENTS.**

2 (a) CANCELLATION.—Beginning 180 days after the
3 date of the enactment of this Act, if an event is canceled
4 or postponed (except for a case in which an event is can-
5 celed or postponed due to a cause beyond the reasonable
6 control of the issuer, including a natural disaster, civil dis-
7 turbance, or otherwise unforeseeable impediment), a ticket
8 issuer, secondary market ticket issuer, or secondary mar-
9 ket ticket exchange shall provide the purchaser of an event
10 ticket from the issuer or exchange for the canceled or post-
11 poned event, at a minimum—

12 (1) if the event is cancelled, a full refund for
13 the total event ticket price;

14 (2) subject to availability, if the event is post-
15 poned for not more than 6 months and the original
16 event ticket is no longer valid for entry to the re-
17 scheduled event, a replacement event ticket for the
18 rescheduled event in the same or a comparable loca-
19 tion once the event has been rescheduled; or

20 (3) if the event is postponed for more than 6
21 months, at the option of the purchaser—

22 (A) a full refund for the total event ticket
23 price; or

24 (B) if the original event ticket is no longer
25 valid for entry to the rescheduled event, a re-
26 placement event ticket for the rescheduled event

1 in the same or a comparable location once the
2 event has been rescheduled.

3 (b) DISCLOSURE OF GUARANTEE AND REFUND POL-
4 ICY REQUIRED.—Beginning 180 days after the date of the
5 enactment of this Act, a ticket issuer, secondary market
6 ticket issuer, or secondary market ticket exchange shall
7 disclose clearly and conspicuously to a purchaser before
8 the completion of an event ticket sale the guarantee or
9 refund policy of such ticket issuer, secondary market tick-
10 et issuer, or secondary market ticket exchange, including
11 under what circumstances any refund issued will include
12 a refund of any event ticket fee.

13 (c) DISCLOSURE OF HOW TO OBTAIN A REFUND RE-
14 QUIRED.—Beginning 180 days after the date of the enact-
15 ment of this Act, a ticket issuer, secondary market ticket
16 issuer, or secondary market ticket exchange shall provide
17 a clear and conspicuous explanation of how to obtain a
18 refund of the total event ticket price.

19 **SEC. 1406. REPORT BY THE FEDERAL TRADE COMMISSION**
20 **ON BOTS ACT OF 2016 ENFORCEMENT.**

21 Not later than 6 months after the date of the enact-
22 ment of this Act, the Commission shall submit to Congress
23 a report on enforcement of the Better Online Ticket Sales
24 Act of 2016 (Public Law 114–274; 15 U.S.C. 45c), includ-
25 ing any enforcement action taken, challenges with enforce-

1 ment and coordination with State Attorneys General, and
2 recommendations on how to improve enforcement and in-
3 dustry compliance.

4 **SEC. 1407. ENFORCEMENT.**

5 (a) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A
6 violation of this title shall be treated as a violation of a
7 rule defining an unfair or deceptive act or practice under
8 section 18(a)(1)(B) of the Federal Trade Commission Act
9 (15 U.S.C. 57a(a)(1)(B)).

10 (b) POWERS OF COMMISSION.—

11 (1) IN GENERAL.—The Commission shall en-
12 force this title in the same manner, by the same
13 means, and with the same jurisdiction, powers, and
14 duties as though all applicable terms and provisions
15 of the Federal Trade Commission Act (15 U.S.C. 41
16 et seq.) were incorporated into and made a part of
17 this title.

18 (2) PRIVILEGES AND IMMUNITIES.—Any person
19 who violates this title shall be subject to the pen-
20 alties and entitled to the privileges and immunities
21 provided in the Federal Trade Commission Act (15
22 U.S.C. 41 et seq.).

23 (3) AUTHORITY PRESERVED.—Nothing in this
24 title shall be construed to limit the authority of the
25 Commission under any other provision of law.

1 **SEC. 1408. DEFINITIONS.**

2 In this title:

3 (1) ARTIST.—The term “artist” means any per-
4 former, musician, comedian, producer, ensemble or
5 production entity of a theatrical production, sports
6 team owner, or similar person.

7 (2) BASE EVENT TICKET PRICE.—The term
8 “base event ticket price” means, with respect to an
9 event ticket, the price of the event ticket excluding
10 the cost of any event ticket fees.

11 (3) COMMISSION.—The term “Commission”
12 means the Federal Trade Commission.

13 (4) EVENT.—The term “event” means any live
14 concert, theatrical performance, sporting event,
15 show, or similarly scheduled live activity, that is—

16 (A) taking place in a venue with a seating
17 or attendance capacity exceeding 200 persons;

18 (B) open to the general public; and

19 (C) promoted, advertised, or marketed in
20 interstate commerce, or for which event tickets
21 are generally sold or distributed in interstate
22 commerce.

23 (5) EVENT TICKET; TICKET ISSUER.—The
24 terms “event ticket” and “ticket issuer” have the
25 meaning given those terms in section 3 of the Better

1 Online Ticket Sales Act of 2016 (15 U.S.C. 45c
2 note).

3 (6) EVENT TICKET FEE.—The term “event
4 ticket fee”—

5 (A) means a charge for an event ticket
6 that must be paid in addition to the base event
7 ticket price in order to obtain an event ticket
8 from a ticket issuer, secondary market ticket
9 issuer, or secondary market ticket exchange, in-
10 cluding any service fee, charge and order proc-
11 essing fee, delivery fee, facility charge fee, tax,
12 and any other charge; and

13 (B) does not include any charge or fee for
14 an optional product or service associated with
15 the event that may be selected by a purchaser
16 of an event ticket.

17 (7) OPTIONAL PRODUCT OR SERVICE.—The
18 term “optional product or service” means a product
19 or service that an individual does not need to pur-
20 chase to use or take possession of an event ticket.

21 (8) RESALE; SECONDARY SALE.—The terms
22 “resale” and “secondary sale” mean any sale of an
23 event ticket that occurs after the initial sale of the
24 event ticket by a ticket issuer.

1 (9) SECONDARY MARKET TICKET EXCHANGE.—

2 The term “secondary market ticket exchange”
3 means any person that in the regular course of trade
4 or business of that person operates a platform or ex-
5 change for advertising, listing, or selling resale tick-
6 ets, on behalf of itself, vendors, or a secondary mar-
7 ket ticket issuer.

8 (10) SECONDARY MARKET TICKET ISSUER.—

9 The term “secondary market ticket issuer” means
10 any person, including a ticket issuer, that resells or
11 makes a secondary sale of an event ticket to the gen-
12 eral public in the regular course of the trade or busi-
13 ness of the person.

14 (11) TOTAL EVENT TICKET PRICE.—The term
15 “total event ticket price” means, with respect to an
16 event ticket, the total cost of the event ticket, includ-
17 ing the base event ticket price and any event ticket
18 fee.

19 (12) VENUE.—The term “venue” means a
20 physical space at which an event takes place.

21 **TITLE XV—ROUTERS ACT**

22 **SEC. 1501. SHORT TITLE.**

23 This title may be cited as the “Removing Our Unse-
24 cure Technologies to Ensure Reliability and Security Act”
25 or the “ROUTERS Act”.

1 **SEC. 1502. STUDY OF NATIONAL SECURITY RISKS POSED BY**
2 **CERTAIN ROUTERS AND MODEMS.**

3 (a) IN GENERAL.—The Secretary shall conduct a
4 study of the national security risks posed by consumer
5 routers, modems, and devices that combine a modem and
6 router that are designed, developed, manufactured, or sup-
7 plied by persons owned by, controlled by, or subject to the
8 influence of a covered country.

9 (b) REPORT TO CONGRESS.—Not later than 1 year
10 after the date of the enactment of this Act, the Secretary
11 shall submit to the Committee on Energy and Commerce
12 of the House of Representatives and the Committee on
13 Commerce, Science, and Transportation of the Senate a
14 report on the results of the study conducted under sub-
15 section (a).

16 (c) DEFINITIONS.—In this section:

17 (1) COVERED COUNTRY.—The term “covered
18 country” means a country specified in section
19 4872(f)(2) of title 10, United States Code.

20 (2) SECRETARY.—The term “Secretary” means
21 the Secretary of Commerce, in consultation with the
22 Assistant Secretary of Commerce for Communica-
23 tions and Information.

TITLE XVI—NTIA REAUTHORIZATION

SEC. 1601. SHORT TITLE.

This title may be cited as the “National Telecommunications and Information Administration Reauthorization Act” or the “NTIA Reauthorization Act”.

SEC. 1602. DEFINITIONS.

In this title:

(1) COMMISSION.—The term “Commission” means the Federal Communications Commission.

(2) NTIA.—The term “NTIA” means the National Telecommunications and Information Administration.

(3) UNDER SECRETARY.—The term “Under Secretary” means the Under Secretary of Commerce for Communications and Information.

Subtitle A—Reauthorization

SEC. 1611. REAUTHORIZATION OF THE NATIONAL TELECOMMUNICATIONS AND INFORMATION ADMINISTRATION ORGANIZATION ACT.

(a) AUTHORIZATION OF APPROPRIATIONS.—Section 151 of the National Telecommunications and Information Administration Organization Act is amended by striking “\$17,600,000 for fiscal year 1992 and \$17,900,000 for

1 fiscal year 1993” and inserting “\$57,000,000 for fiscal
2 year 2025 and \$57,000,000 for fiscal year 2026”.

3 (b) UNDER SECRETARY OF COMMERCE FOR COMMU-
4 NICATIONS AND INFORMATION.—

5 (1) UNDER SECRETARY; DEPUTY UNDER SEC-
6 RETARY.—

7 (A) UNDER SECRETARY.—The National
8 Telecommunications and Information Adminis-
9 tration Organization Act (47 U.S.C. 901 et seq)
10 is amended by striking “Assistant Secretary”
11 each place it appears and inserting “Under Sec-
12 retary”.

13 (B) DEPUTY UNDER SECRETARY.—Section
14 103(a) of the National Telecommunications and
15 Information Administration Organization Act
16 (47 U.S.C. 902(a)), as amended by this section,
17 is amended by adding at the end the following:

18 “(3) DEPUTY UNDER SECRETARY.—The Dep-
19 uty Under Secretary of Commerce for Communica-
20 tions and Information shall—

21 “(A) be the principal policy advisor of the
22 Under Secretary;

23 “(B) perform such other functions as the
24 Under Secretary shall from time to time assign
25 or delegate; and

1 “(C) act as Under Secretary during the
2 absence or disability of the Under Secretary or
3 in the event of a vacancy in the office of the
4 Under Secretary.”.

5 (2) CONTINUATION OF CIVIL ACTIONS.—This
6 subsection, and the amendments made by this sub-
7 section, shall not abate any civil action commenced
8 by or against the Assistant Secretary of Commerce
9 for Communications and Information before the date
10 of the enactment of this Act, except that the Under
11 Secretary shall be substituted as a party to the ac-
12 tion on and after such date.

13 (3) CONTINUATION IN OFFICE.—The individual
14 serving as the Assistant Secretary of Commerce for
15 Communications and Information and the individual
16 serving as the Deputy Assistant Secretary of Com-
17 merce for Communications and Information on the
18 day before the date of the enactment of this Act may
19 serve as the Under Secretary and the Deputy Under
20 Secretary of Commerce for Communications and In-
21 formation, respectively, on and after that date with-
22 out the need for renomination or reappointment.

23 (4) REFERENCES.—Any reference in a law, reg-
24 ulation, document, paper, or other record of the
25 United States to the Assistant Secretary of Com-

1 merce for Communications and Information shall, on
2 and after the date of the enactment of this Act, be
3 deemed to be a reference to the Under Secretary.

4 (5) EXECUTIVE SCHEDULE.—

5 (A) IN GENERAL.—Subchapter II of chap-
6 ter 53 of title 5, United States Code, is amend-
7 ed—

8 (i) in section 5314, by adding at the
9 end the following:

10 “Under Secretary of Commerce for Commu-
11 nications and Information.”; and

12 (ii) in section 5315, in the item relat-
13 ing to the Assistant Secretaries of Com-
14 merce, by striking “(11)” and inserting
15 “(10)”.

16 (B) EFFECTIVE DATE.—The amendment
17 made by subparagraph (A) (establishing the an-
18 nual rate of the basic pay of the Under Sec-
19 retary) shall take effect on the first day of the
20 first pay period beginning after the date of the
21 enactment of this Act.

22 (c) AUTHORITIES AND RESPONSIBILITIES.—

23 (1) COORDINATION OF EXECUTIVE BRANCH
24 VIEWS ON MATTERS BEFORE THE FEDERAL COMMU-
25 NICATIONS COMMISSION.—Section 105(a)(1) of the

1 National Telecommunications and Information Ad-
2 ministration Organization Act (47 U.S.C. 904(a)(1))
3 is amended—

4 (A) by striking “to ensure that the con-
5 duct” and inserting the following: “to ensure
6 that—

7 “(A) the conduct”;

8 (B) in subparagraph (A), as so designated,
9 by striking the period at the end and inserting
10 “; and”; and

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

12 “(B) the views of the executive branch on
13 matters presented to the Commission are, con-
14 sistent with section 103(b)(2)(J)—

15 “(i) appropriately coordinated; and

16 “(ii) reflective of executive branch pol-
17 icy.”.

18 (2) ASSIGNED FUNCTIONS.—Section 103(b)(2)
19 of the National Telecommunications and Informa-
20 tion Administration Organization Act (47 U.S.C.
21 902(b)(2)) is amended—

22 (A) in the matter preceding subparagraph
23 (A), by inserting “, some of which were” before
24 “transferred to the Secretary”; and

1 (B) in subparagraph (M), by inserting “,
2 publish reports,” after “studies”.

3 (3) RULE OF CONSTRUCTION.—Nothing in the
4 amendments made by paragraphs (1) and (2) may
5 be construed to expand or contract the authority of
6 the Commission.

7 (d) TECHNICAL AND CONFORMING AMENDMENTS.—

8 (1) PUBLIC TELECOMMUNICATIONS FINANCING
9 ACT OF 1978.—Section 106(c) of the Public Tele-
10 communications Financing Act of 1978 (5 U.S.C.
11 5316 note; Public Law 95–567) is amended by strik-
12 ing “The position of Deputy Assistant Secretary of
13 Commerce for Communications and Information, es-
14 tablished in Department of Commerce Organization
15 Order Numbered 10–10 (effective March 26,
16 1978),” and inserting “The position of Deputy
17 Under Secretary of Commerce for Communications
18 and Information, established under section 103(a) of
19 the National Telecommunications and Information
20 Administration Organization Act (47 U.S.C.
21 902(a)),”.

22 (2) COMMUNICATIONS ACT OF 1934.—Section
23 344(d)(2) of the Communications Act of 1934 (47
24 U.S.C. 344(d)(2)) is amended by striking “Assistant
25 Secretary” and inserting “Under Secretary”.

1 (3) HOMELAND SECURITY ACT OF 2002.—Sec-
2 tion 1805(d)(2) of the Homeland Security Act of
3 2002 (6 U.S.C. 575(d)(2)) is amended by striking
4 “Assistant Secretary for Communications and Infor-
5 mation of the Department of Commerce” and insert-
6 ing “Under Secretary of Commerce for Communica-
7 tions and Information”.

8 (4) AGRICULTURE IMPROVEMENT ACT OF
9 2018.—Section 6212 of the Agriculture Improvement
10 Act of 2018 (7 U.S.C. 950bb–6) is amended—

11 (A) in subsection (d)(1), in the heading, by
12 striking “ASSISTANT SECRETARY” and inserting
13 “UNDER SECRETARY”; and

14 (B) by striking “Assistant Secretary” each
15 place the term appears and inserting “Under
16 Secretary”.

17 (5) TITLE 17, UNITED STATES CODE.—Section
18 1201(a)(1)(C) of title 17, United States Code, is
19 amended by striking “Assistant Secretary for Com-
20 munications and Information of the Department of
21 Commerce” and inserting “Under Secretary of Com-
22 merce for Communications and Information”.

23 (6) UNLOCKING CONSUMER CHOICE AND WIRE-
24 LESS COMPETITION ACT.—Section 2(b) of the
25 Unlocking Consumer Choice and Wireless Competi-

1 tion Act (17 U.S.C. 1201 note; Public Law 113–
2 144) is amended by striking “Assistant Secretary
3 for Communications and Information of the Depart-
4 ment of Commerce” and inserting “Under Secretary
5 of Commerce for Communications and Information”.

6 (7) COMMUNICATIONS SATELLITE ACT OF
7 1962.—Section 625(a)(1) of the Communications
8 Satellite Act of 1962 (47 U.S.C. 763d(a)(1)) is
9 amended, in the matter preceding subparagraph (A),
10 by striking “Assistant Secretary” and inserting
11 “Under Secretary of Commerce”.

12 (8) SPECTRUM PIPELINE ACT OF 2015.—The
13 Spectrum Pipeline Act of 2015 (47 U.S.C. 921 note;
14 title X of Public Law 114–74) is amended—

15 (A) in section 1002(1), in the heading, by
16 striking “ASSISTANT SECRETARY” and inserting
17 “UNDER SECRETARY”; and

18 (B) by striking “Assistant Secretary” each
19 place the term appears and inserting “Under
20 Secretary”.

21 (9) WARNING, ALERT, AND RESPONSE NET-
22 WORK ACT.—Section 606 of the Warning, Alert, and
23 Response Network Act (47 U.S.C. 1205) is amend-
24 ed—

1 (A) by striking “Assistant Secretary” each
2 place the term appears and inserting “Under
3 Secretary”; and

4 (B) in subsection (b), in the first sentence,
5 by striking “for7Communications” and insert-
6 ing “for Communications”.

7 (10) AMERICAN RECOVERY AND REINVESTMENT
8 ACT OF 2009.—Section 6001 of the American Recov-
9 ery and Reinvestment Act of 2009 (47 U.S.C. 1305)
10 is amended by striking “Assistant Secretary” each
11 place the term appears and inserting “Under Sec-
12 retary”.

13 (11) MIDDLE CLASS TAX RELIEF AND JOB CRE-
14 ATION ACT OF 2012.—Title VI of the Middle Class
15 Tax Relief and Job Creation Act of 2012 (47 U.S.C.
16 1401 et seq.) is amended—

17 (A) in section 6001 (47 U.S.C. 1401)—

18 (i) by striking paragraph (4);

19 (ii) by redesignating paragraphs (5)
20 through (32) as paragraphs (4) through
21 (31), respectively; and

22 (iii) by inserting after paragraph (31),
23 as so redesignated, the following:

1 “(32) UNDER SECRETARY.—The term ‘Under
2 Secretary’ means the Under Secretary of Commerce
3 for Communications and Information.”; and

4 (B) by striking “Assistant Secretary” each
5 place the term appears and inserting “Under
6 Secretary”.

7 (12) RAY BAUM’S ACT OF 2018.—The RAY
8 BAUM’S Act of 2018 (division P of Public Law
9 115–141; 132 Stat. 348) is amended by striking
10 “Assistant Secretary” each place the term appears
11 and inserting “Under Secretary”.

12 (13) SECURE AND TRUSTED COMMUNICATIONS
13 NETWORKS ACT OF 2019.—Section 8 of the Secure
14 and Trusted Communications Networks Act of 2019
15 (47 U.S.C. 1607) is amended—

16 (A) in subsection (c)(1), in the heading, by
17 striking “ASSISTANT SECRETARY” and inserting
18 “UNDER SECRETARY”; and

19 (B) by striking “Assistant Secretary” each
20 place the term appears and inserting “Under
21 Secretary”.

22 (14) TITLE 51, UNITED STATES CODE.—Section
23 50112(3) of title 51, United States Code, is amend-
24 ed, in the matter preceding subparagraph (A), by

1 striking “Assistant Secretary” each place the term
2 appears and inserting “Under Secretary”.

3 (15) CONSOLIDATED APPROPRIATIONS ACT,
4 2021.—The Consolidated Appropriations Act, 2021
5 (Public Law 116–260) is amended—

6 (A) in title IX of division N—

7 (i) in section 902(a)(2), in the head-
8 ing, by striking “ASSISTANT SECRETARY”
9 and inserting “UNDER SECRETARY”;

10 (ii) in section 905—

11 (I) in subsection (a)(1), in the
12 heading, by striking “ASSISTANT SEC-
13 RETARY” and inserting “UNDER SEC-
14 RETARY”;

15 (II) in subsection (c)(3)(B), in
16 the heading, by striking “ASSISTANT
17 SECRETARY” and inserting “UNDER
18 SECRETARY”; and

19 (III) in subsection (d)(2)(B), in
20 the heading, by striking “ASSISTANT
21 SECRETARY” and inserting “UNDER
22 SECRETARY”; and

23 (iii) by striking “Assistant Secretary”
24 each place the term appears (except in sec-

1 tion 905(a)(13)(E)) and inserting “Under
2 Secretary”; and

3 (B) in title IX of division FF—

4 (i) in section 903(g)(2), in the head-
5 ing, by striking “ASSISTANT SECRETARY”
6 and inserting “UNDER SECRETARY”; and

7 (ii) by striking “Assistant Secretary”
8 each place the term appears and inserting
9 “Under Secretary”.

10 (16) INFRASTRUCTURE INVESTMENT AND JOBS
11 ACT.—The Infrastructure Investment and Jobs Act
12 (Public Law 117–58) is amended—

13 (A) in section 27003, by striking “Assist-
14 ant Secretary” each place the term appears and
15 inserting “Under Secretary”;

16 (B) in division F—

17 (i) in section 60102—

18 (I) in subsection (a)(2)(A), by
19 striking “ASSISTANT SECRETARY”
20 and inserting “UNDER SECRETARY”;

21 (II) in subsection (d)(1), by
22 striking “ASSISTANT SECRETARY”
23 and inserting “UNDER SECRETARY”;
24 and

25 (III) in subsection (h)—

1 (aa) in paragraph (1)(B), by
2 striking “ASSISTANT SEC-
3 RETARY” and inserting “UNDER
4 SECRETARY”; and

5 (bb) in paragraph
6 (5)(B)(iii), by striking “ASSIST-
7 ANT SECRETARY” and inserting
8 “UNDER SECRETARY”;

9 (ii) in title III—

10 (I) in section 60302(5), by strik-
11 ing “ASSISTANT SECRETARY” and in-
12 serting “UNDER SECRETARY”; and

13 (II) in section
14 60305(d)(2)(B)(ii), by striking “AS-
15 SISTANT SECRETARY” and inserting
16 “UNDER SECRETARY”;

17 (iii) in section 60401(a)(2), by strik-
18 ing “ASSISTANT SECRETARY” and insert-
19 ing “UNDER SECRETARY”; and

20 (iv) by striking “Assistant Secretary”
21 each place the term appears and inserting
22 “Under Secretary”; and

23 (C) in division J, in title I, in the matter
24 under the heading “distance learning, telemedi-
25 cine, and broadband program” under the head-

1 ing “Rural Utilities Service” under the heading
2 “RURAL DEVELOPMENT PROGRAMS”, by
3 striking “Assistant Secretary” and inserting
4 “Under Secretary”.

5 **SEC. 1612. NTIA CONSOLIDATED REPORTING ACT.**

6 (a) ELIMINATION OF CERTAIN OUTDATED OR COM-
7 PLETED REPORTING REQUIREMENTS.—

8 (1) BTOP QUARTERLY REPORT.—Section
9 6001(d) of the American Recovery and Reinvestment
10 Act of 2009 (47 U.S.C. 1305(d)) is amended—

11 (A) in paragraph (2), by striking the semi-
12 colon at the end and inserting “; and”;

13 (B) in paragraph (3), by striking “; and”
14 and inserting a period; and

15 (C) by striking paragraph (4).

16 (2) CERTAIN REPORTS REQUIRED BY NATIONAL
17 TELECOMMUNICATIONS AND INFORMATION ADMINIS-
18 TRATION ORGANIZATION ACT.—Sections 154, 155,
19 and 156 of the National Telecommunications and
20 Information Administration Organization Act are re-
21 pealed.

22 (3) INITIAL REPORT REQUIRED BY SECTION
23 9202(a)(1)(G) OF THE NDAA FOR FISCAL YEAR
24 2021.—Section 9202(a)(1)(G) of the William M.
25 (Mac) Thornberry National Defense Authorization

1 Act for Fiscal Year 2021 (47 U.S.C. 906(a)(1)(G))
2 is amended—

3 (A) in clause (ii), by redesignating sub-
4 clauses (I), (II), and (III) as clauses (i), (ii),
5 and (iii), respectively, and conforming the mar-
6 gins of such clauses accordingly; and

7 (B) by striking “REPORTS TO CONGRESS”
8 and all that follows through “For each fiscal
9 year” and inserting “ANNUAL REPORT TO CON-
10 GRESS.—For each fiscal year”.

11 (4) REPORT TO PRESIDENT.—Section 105(a) of
12 the National Telecommunications and Information
13 Administration Organization Act (47 U.S.C. 904(a))
14 is amended—

15 (A) by striking paragraph (2); and

16 (B) by redesignating paragraph (3) as
17 paragraph (2).

18 (5) EFFECT ON AUTHORITY.—Nothing in this
19 subsection or the amendments made by this sub-
20 section may be construed to expand or contract the
21 authority of the Secretary, the Under Secretary, the
22 NTIA, or the Commission.

23 (6) OTHER REPORTS.—Nothing in this sub-
24 section or the amendments made by this subsection
25 may be construed to prohibit or otherwise prevent

1 the Secretary, the Under Secretary, the NTIA, or
2 the Commission from producing any additional re-
3 ports otherwise within the authority of the Sec-
4 retary, the Under Secretary, the NTIA, or the Com-
5 mission, respectively.

6 (b) CONSOLIDATED ANNUAL REPORT.—

7 (1) IN GENERAL.—In the first quarter of each
8 calendar year, the Under Secretary shall publish on
9 the website of the NTIA and submit to the Com-
10 mittee on Energy and Commerce of the House of
11 Representatives and the Committee on Commerce,
12 Science, and Transportation of the Senate a report
13 that contains the reports described in paragraph (2)
14 for the fiscal year ending most recently before the
15 beginning of such quarter.

16 (2) REPORTS DESCRIBED.—The reports de-
17 scribed in this paragraph are the following:

18 (A) The report required by section
19 903(c)(2)(C) of division FF of the Consolidated
20 Appropriations Act, 2021 (47 U.S.C.
21 1307(c)(2)(C)).

22 (B) If amounts in the Public Wireless Sup-
23 ply Chain Innovation Fund established by sec-
24 tion 9202(a)(1)(A)(i) of the William M. (Mac)
25 Thornberry National Defense Authorization Act

1 for Fiscal Year 2021 (47 U.S.C.
2 906(a)(1)(A)(i)) were available for the fiscal
3 year described in paragraph (1) of this sub-
4 section, the report required by section
5 9202(a)(1)(G) of such Act (47 U.S.C.
6 906(a)(1)(G)).

7 (C) If the Under Secretary awarded grants
8 under section 60304(d)(1) of the Infrastructure
9 Investment and Jobs Act (47 U.S.C.
10 1723(d)(1)) in the fiscal year described in para-
11 graph (1) of this subsection, the report required
12 by section 60306(a)(1)(A) of such Act (47
13 U.S.C. 1725(a)(1)(A)).

14 (3) TIMING OF UNDERLYING REPORTING RE-
15 QUIREMENTS.—

16 (A) REPORT OF OFFICE OF INTERNET
17 CONNECTIVITY AND GROWTH.—Section
18 903(c)(2)(C) of division FF of the Consolidated
19 Appropriations Act, 2021 (47 U.S.C.
20 1307(c)(2)(C)) is amended—

21 (i) in the matter preceding clause
22 (i)—

23 (I) by striking “Not later than 1
24 year after the date of the enactment
25 of this Act, and every year there-

1 after,” and inserting “In the first
2 quarter of each calendar year,”; and

3 (II) by inserting “, for the fiscal
4 year ending most recently before the
5 beginning of such quarter,” after “a
6 report”; and

7 (ii) in clause (i), by striking “for the
8 previous year”.

9 (B) REPORT ON DIGITAL EQUITY GRANT
10 PROGRAMS.—Section 60306(a)(1) of the Infra-
11 structure Investment and Jobs Act (47 U.S.C.
12 1725(a)(1)) is amended—

13 (i) in the matter preceding subpara-
14 graph (A), by striking “Not later than 1
15 year” and all that follows through “shall—
16 ” and inserting the following: “For the
17 first fiscal year in which the Under Sec-
18 retary awards grants under section
19 60304(d)(1), and each fiscal year there-
20 after in which the Under Secretary awards
21 grants under such section, the Under Sec-
22 retary shall—”; and

23 (ii) in subparagraph (A)—

24 (I) by inserting “in the first
25 quarter of the first calendar year that

1 begins after the end of such fiscal
2 year,” before “submit”; and

3 (II) by striking “, for the year
4 covered by the report”.

5 (4) SATISFACTION OF UNDERLYING REPORTING
6 REQUIREMENTS.—

7 (A) IN GENERAL.—Except as provided in
8 subparagraph (B), the publication and submis-
9 sion of a report as required by paragraph (1)
10 in the first quarter of a calendar year shall be
11 treated as satisfying any requirement to publish
12 or otherwise make publicly available or to sub-
13 mit to Congress or to a committee of Congress
14 a report described in paragraph (2) for the fis-
15 cal year ending most recently before the begin-
16 ning of such quarter.

17 (B) CERTAIN SUBMISSION REQUIRE-
18 MENTS.—At the time when the Under Secretary
19 submits a report required by paragraph (1) to
20 the committees described in such paragraph,
21 the Under Secretary shall submit any portion of
22 such report that relates to a report described in
23 paragraph (2)(C) to each committee of Con-
24 gress not described in paragraph (1) to which
25 such report would (without regard to subpara-

1 graph (A) of this paragraph) be required to be
2 submitted.

3 (5) APPLICABILITY.—Paragraph (1), and the
4 amendments made by paragraph (3), shall apply be-
5 ginning on January 1 of the first calendar year that
6 begins after the date of the enactment of this Act.

7 (c) EXTENSION OF CERTAIN AUDIT AND REPORTING
8 REQUIREMENTS.—Section 902(c)(4)(A) of division N of
9 the Consolidated Appropriations Act, 2021 (47 U.S.C.
10 1306(c)(4)(A)) is amended by striking “fiscal years 2021
11 and 2022” and inserting “fiscal years 2021, 2022, 2023,
12 and 2024”.

13 (d) DEFINITION.—In this section, the term “Sec-
14 retary” means the Secretary of Commerce.

15 **Subtitle B—Office of Spectrum** 16 **Management**

17 **SEC. 1621. OFFICE OF SPECTRUM MANAGEMENT.**

18 Part A of the National Telecommunications and In-
19 formation Administration Organization Act (47 U.S.C.
20 901 et seq.) is amended by adding at the end the fol-
21 lowing:

22 **“SEC. 106. OFFICE OF SPECTRUM MANAGEMENT.**

23 “(a) ESTABLISHMENT.—There is established within
24 the NTIA an Office of Spectrum Management (in this sec-
25 tion referred to as the ‘Office’).

1 “(b) HEAD OF OFFICE.—

2 “(1) IN GENERAL.—The head of the Office
3 shall be an Associate Administrator for Spectrum
4 Management (in this section referred to as the ‘As-
5 sociate Administrator’).

6 “(2) REQUIREMENT TO REPORT.—The Asso-
7 ciate Administrator shall report to the Under Sec-
8 retary (or a designee of the Under Secretary).

9 “(c) DUTIES.—The Associate Administrator shall, at
10 the direction of the Under Secretary—

11 “(1) carry out responsibilities under section
12 103(b)(2)(A) (relating to frequency assignments for
13 radio stations belonging to and operated by the
14 United States), make frequency allocations for fre-
15 quencies that will be used by such stations, and de-
16 velop and maintain techniques, databases, measure-
17 ments, files, and procedures necessary for such allo-
18 cations;

19 “(2) carry out responsibilities under section
20 103(b)(2)(K) (relating to establishing policies con-
21 cerning spectrum assignments and use by radio sta-
22 tions belonging to and operated by the United
23 States) and provide Federal agencies with guidance
24 to ensure that the conduct of telecommunications ac-

1 tivities by such agencies is consistent with such poli-
2 cies;

3 “(3) represent the interests of Federal agencies
4 in the process through which the Commission and
5 the NTIA jointly determine the National Table of
6 Frequency Allocations, and coordinate with the
7 Commission in the development of a comprehensive
8 long-range plan for improved management of all
9 electromagnetic spectrum resources;

10 “(4) appoint the chairpersons of and provide
11 secretariat functions for the Interdepartmental
12 Radio Advisory Committee and the Interagency
13 Spectrum Advisory Council;

14 “(5) carry out responsibilities under section
15 103(b)(2)(B) (relating to authorizing a foreign gov-
16 ernment to construct and operate a radio station at
17 the seat of Government of the United States) and
18 assign frequencies for use by such stations;

19 “(6) provide advice and assistance to the Under
20 Secretary and coordinate with the Associate Admin-
21 istrator for International Affairs in carrying out
22 spectrum management aspects of the international
23 policy responsibilities of the NTIA, including spec-
24 trum-related responsibilities under section
25 103(b)(2)(G);

1 “(7) carry out spectrum-related responsibilities
2 under section 103(b)(2)(H) (relating to coordination
3 of the telecommunications activities of the executive
4 branch and assistance in the formulation of policies
5 and standards for such activities);

6 “(8) carry out spectrum-related responsibilities
7 under section 103(b)(2)(Q) (relating to certain ac-
8 tivities with respect to telecommunications re-
9 sources); and

10 “(9) carry out any other duties of the NTIA
11 with respect to spectrum policy that the Under Sec-
12 retary may designate.”.

13 **Subtitle C—Office of International** 14 **Affairs**

15 **SEC. 1631. OFFICE OF INTERNATIONAL AFFAIRS.**

16 Part A of the National Telecommunications and In-
17 formation Administration Organization Act (47 U.S.C.
18 901 et seq.), as amended by the preceding provisions of
19 this title, is further amended by adding at the end the
20 following:

21 **“SEC. 107. OFFICE OF INTERNATIONAL AFFAIRS.**

22 “(a) **ESTABLISHMENT.**—There is established within
23 the NTIA an Office of International Affairs (in this sec-
24 tion referred to as the ‘Office’).

25 “(b) **HEAD OF OFFICE.**—

1 “(1) IN GENERAL.—The head of the Office
2 shall be an Associate Administrator for International
3 Affairs (in this section referred to as the ‘Associate
4 Administrator’).

5 “(2) REQUIREMENT TO REPORT.—The Asso-
6 ciate Administrator shall report to the Under Sec-
7 retary (or a designee of the Under Secretary).

8 “(c) DUTIES.—The Associate Administrator shall, at
9 the direction of the Under Secretary—

10 “(1) in coordination with the Secretary of
11 State, conduct analysis of, review, and formulate
12 international telecommunications and information
13 policy;

14 “(2) present on international telecommuni-
15 cations and information policy—

16 “(A) before the Commission, Congress,
17 and others; and

18 “(B) in coordination with the Secretary of
19 State, before international telecommunications
20 bodies, including the International Tele-
21 communication Union;

22 “(3) conduct or obtain analysis on economic
23 and other aspects of international telecommuni-
24 cations and information policy;

1 “(4) formulate, and recommend to the Under
2 Secretary, policies and plans with respect to prepara-
3 tion for and participation in international tele-
4 communications and information policy activities;

5 “(5) in coordination with the Secretary of
6 State, coordinate NTIA and interdepartmental eco-
7 nomic, technical, operational, and other preparations
8 related to participation by the United States in
9 international telecommunications and information
10 policy conferences and negotiations;

11 “(6) ensure NTIA representation with respect
12 to international telecommunications and information
13 policy meetings and the activities related to prepara-
14 tion for such meetings;

15 “(7) in coordination with the Secretary of
16 State, coordinate with Federal agencies and private
17 organizations engaged in activities involving inter-
18 national telecommunications and information policy
19 matters and maintain cognizance of the activities of
20 United States signatories with respect to related
21 treaties, agreements, and other instruments;

22 “(8) provide advice and assistance related to
23 international telecommunications and information
24 policy to other Federal agencies charged with re-
25 sponsibility for international negotiations, to

1 strengthen the position and serve the best interests
2 of the United States in the conduct of negotiations
3 with foreign nations;

4 “(9) provide advice and assistance to the Under
5 Secretary with respect to evaluating the inter-
6 national impact of matters pending before the Com-
7 mission, other Federal agencies, and Congress;

8 “(10) carry out, at the request of the Secretary,
9 the responsibilities of the Secretary under the Com-
10 munications Satellite Act of 1962 (47 U.S.C. 701 et
11 seq.) and other Federal laws related to international
12 telecommunications and information policy; and

13 “(11) carry out any other duties of the NTIA
14 with respect to international telecommunications and
15 information policy that the Under Secretary may
16 designate.”.

17 **DIVISION C—HEALTH**
18 **TITLE I—MEDICAID**

19 **SEC. 101. STREAMLINED ENROLLMENT PROCESS FOR ELI-**
20 **GIBLE OUT-OF-STATE PROVIDERS UNDER**
21 **MEDICAID AND CHIP.**

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

1 “(10) STREAMLINED ENROLLMENT PROCESS
2 FOR ELIGIBLE OUT-OF-STATE PROVIDERS.—

3 “(A) IN GENERAL.—The State—

4 “(i) adopts and implements a process
5 to allow an eligible out-of-State provider to
6 enroll under the State plan (or a waiver of
7 such plan) to furnish items and services to,
8 or order, prescribe, refer, or certify eligi-
9 bility for items and services for, qualifying
10 individuals without the imposition of
11 screening or enrollment requirements by
12 such State that exceed the minimum nec-
13 essary for such State to provide payment
14 to an eligible out-of-State provider under
15 such State plan (or a waiver of such plan),
16 such as the provider’s name and National
17 Provider Identifier (and such other infor-
18 mation specified by the Secretary); and

19 “(ii) provides that an eligible out-of-
20 State provider that enrolls as a partici-
21 pating provider in the State plan (or a
22 waiver of such plan) through such process
23 shall be so enrolled for a 5-year period, un-
24 less the provider is terminated or excluded
25 from participation during such period.

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

2 “(i) ELIGIBLE OUT-OF-STATE PRO-
3 VIDER.—The term ‘eligible out-of-State
4 provider’ means, with respect to a State, a
5 provider—

6 “(I) that is located in any other
7 State;

8 “(II) that—

9 “(aa) was determined by the
10 Secretary to have a limited risk
11 of fraud, waste, and abuse for
12 purposes of determining the level
13 of screening to be conducted
14 under section 1866(j)(2), has
15 been so screened under such sec-
16 tion 1866(j)(2), and is enrolled in
17 the Medicare program under title
18 XVIII; or

19 “(bb) was determined by the
20 State agency administering or su-
21 pervising the administration of
22 the State plan (or a waiver of
23 such plan) of such other State to
24 have a limited risk of fraud,
25 waste, and abuse for purposes of

1 determining the level of screening
2 to be conducted under paragraph
3 (1) of this subsection, has been
4 so screened under such para-
5 graph (1), and is enrolled under
6 such State plan (or a waiver of
7 such plan); and

8 “(III) that has not been—

9 “(aa) excluded from partici-
10 pation in any Federal health care
11 program pursuant to section
12 1128 or 1128A;

13 “(bb) excluded from partici-
14 pation in the State plan (or a
15 waiver of such plan) pursuant to
16 part 1002 of title 42, Code of
17 Federal Regulations (or any suc-
18 cessor regulation), or State law;
19 or

20 “(cc) terminated from par-
21 ticipating in a Federal health
22 care program or the State plan
23 (or a waiver of such plan) for a
24 reason described in paragraph
25 (8)(A).

1 “(ii) QUALIFYING INDIVIDUAL.—The
2 term ‘qualifying individual’ means an indi-
3 vidual under 21 years of age who is en-
4 rolled under the State plan (or waiver of
5 such plan).

6 “(iii) STATE.—The term ‘State’
7 means 1 of the 50 States or the District
8 of Columbia.”.

9 (b) CONFORMING AMENDMENTS.—

10 (1) Section 1902(a)(77) of the Social Security
11 Act (42 U.S.C. 1396a(a)(77)) is amended by insert-
12 ing “enrollment,” after “screening,”.

13 (2) The subsection heading for section
14 1902(kk) of such Act (42 U.S.C. 1396a(kk)) is
15 amended by inserting “enrollment,” after “screen-
16 ing,”.

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

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

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

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

6 (1) IN GENERAL.—Section 1915(c) of the So-
7 cial Security Act (42 U.S.C. 1396n(c)) is amend-
8 ed—

9 (A) in paragraph (2)—

10 (i) in subparagraph (E)—

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

13 (II) by inserting “(including,
14 with respect to such information pro-
15 vided on or after July 9, 2027, the in-
16 formation specified in paragraph
17 (11))” before the period at the end;
18 and

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

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

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

3 “(11) For purposes of paragraph (2)(E), the
4 information specified in this paragraph is the fol-
5 lowing:

6 “(A) In the case of a State that limits the
7 number of individuals who may be provided
8 home or community-based services under a
9 waiver granted under this subsection and main-
10 tains a list of individuals waiting to enroll in
11 such waiver, a description of how the State
12 maintains such list, including—

13 “(i) information on whether the State
14 screens individuals on such list to deter-
15 mine whether such individuals are eligible
16 to receive such services under such waiver;

17 “(ii) information on whether (and, if
18 applicable, how often) the State periodi-
19 cally re-screens individuals on such list for
20 eligibility;

21 “(iii) the number of people on such
22 list of individuals waiting to enroll in such
23 waiver; and

24 “(iv) the average amount of time that
25 individuals newly enrolled in such waiver

1 within the past 12 months were on such
2 list of individuals waiting to enroll in such
3 waiver.

4 “(B) With respect to homemaker services,
5 home health aide services, personal care serv-
6 ices, and habilitation services furnished under
7 waivers under this subsection, by each such
8 service type—

9 “(i) for individuals newly receiving
10 such services within the past 12 months,
11 the average amount of time (which may be
12 determined using statistically valid random
13 sampling of such individuals) from when
14 such services are initially approved for
15 such an individual to when such individual
16 begins receiving such services; and

17 “(ii) the percentage of authorized
18 hours (which may be determined using sta-
19 tistically valid random sampling of individ-
20 uals authorized to receive such services)
21 that are provided within the past 12
22 months.”.

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

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

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

11 (B) in subsection (j)(2)(E), by inserting
12 after the second sentence the following: “With
13 respect to any homemaker services, home health
14 aide services, personal care services, and habili-
15 tation services provided under this subsection
16 on or after July 9, 2027, the State, not less fre-
17 quently than annually, shall provide to the Sec-
18 retary the same information regarding such
19 services as the State is required to provide
20 under subsection (c)(11)(B).”; and

21 (C) in subsection (k)(3)(E)—

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

24 (ii) by inserting before the period, the
25 following: “, and with respect to home-

1 maker services, home health aide services,
2 personal care services, and habilitation
3 services provided under this subsection on
4 or after July 9, 2027, not less frequently
5 than annually, the same information re-
6 garding such services as the State is re-
7 quired to provide under subsection
8 (c)(11)(B)”.

9 (b) DEMONSTRATION PROGRAM TO EXPAND HCBS
10 COVERAGE UNDER SECTION 1915(c) WAIVERS.—Section
11 1915(c) of the Social Security Act (42 U.S.C. 1396n(c)),
12 as amended by subsection (a), is further amended—

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

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

18 “(12) DEMONSTRATION PROGRAM TO EXPAND
19 COVERAGE FOR HOME OR COMMUNITY-BASED SERV-
20 ICES.—

21 “(A) IN GENERAL.—

22 “(i) APPROVAL.—Not later than 24
23 months after the date on which the plan-
24 ning grants under subparagraph (B) are
25 awarded, notwithstanding paragraph (1),

1 the Secretary may approve a waiver that is
2 standalone from any other waiver approved
3 under this subsection for not more than 5
4 States, selected in accordance with clause
5 (ii), to include as medical assistance under
6 the State plan of such State, for the 3-year
7 period beginning on the date of such ap-
8 proval, payment for part or all of the cost
9 of home or community-based services
10 (other than room and board (as described
11 in paragraph (1))) approved by the Sec-
12 retary which are provided pursuant to a
13 written plan of care to individuals de-
14 scribed in subparagraph (C)(iii).

15 “(ii) SELECTION CRITERIA.—In se-
16 lecting States for purposes of clause (i),
17 the Secretary shall—

18 “(I) only select States that re-
19 ceived a planning grant under sub-
20 paragraph (B);

21 “(II) only select States that meet
22 the requirements specified in subpara-
23 graph (C) and such other require-
24 ments as the Secretary may determine
25 appropriate;

1 “(III) select States in a manner
2 that ensures geographic diversity;

3 “(IV) give preference to States
4 with a higher percentage (relative to
5 other States that apply to be selected
6 for purposes of clause (i)) of the total
7 State population residing in rural
8 areas (as determined by the Sec-
9 retary);

10 “(V) give preference to States
11 that have demonstrated more progress
12 in rebalancing long-term services and
13 supports systems under this title, as
14 determined based on the relative share
15 of individuals who use home or com-
16 munity-based services (as defined by
17 the Secretary) under this title as a
18 percentage of total individuals who
19 use long-term services and supports
20 (as defined by the Secretary) under
21 this title (in the most recent year for
22 which such data is available); and

23 “(VI) give preference to States
24 that pursue a waiver under this para-
25 graph that incorporates the provision

1 of mental health services for adults
2 with serious mental illness, children
3 with serious emotional disturbances,
4 or individuals with substance use dis-
5 order.

6 “(B) PLANNING GRANTS.—

7 “(i) IN GENERAL.—

8 “(I) APPROVAL.—Not later than
9 18 months after the date of the enact-
10 ment of this paragraph, the Secretary
11 shall award planning grants of not
12 more than \$5,000,000 each to not
13 more than 10 States for purposes of
14 preparing to submit a request for a
15 waiver under this subsection (includ-
16 ing for costs to implement the waiver
17 or other activities to expand the provi-
18 sion of home or community-based
19 services under this section) to provide
20 home or community-based services to
21 individuals described in subparagraph
22 (C)(iii).

23 “(II) SELECTION CRITERIA.—In
24 awarding planning grants under sub-
25 clause (I), the Secretary shall use the

1 selection criteria specified in sub-
2 clauses (III) through (VI) of subpara-
3 graph (A)(ii).

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

9 “(I) individuals in need of (and
10 not receiving) home or community-
11 based services, individuals receiving
12 home or community-based services,
13 and the caregivers of such individuals;

14 “(II) providers furnishing home
15 or community-based services; and

16 “(III) such other stakeholders, as
17 the Secretary may specify.

18 “(C) STATE REQUIREMENTS.—In addition
19 to the requirements specified under this sub-
20 section (except for the requirements described
21 in subparagraphs (C) and (D) of paragraph (2)
22 and any other requirement the Secretary deter-
23 mines to be inapplicable in the context of a
24 waiver relation to individuals who do not re-
25 quire the level of care described in paragraph

1 (1)), the requirements specified in this para-
2 graph are, with respect to a State, the fol-
3 lowing:

4 “(i) As of the date that such State re-
5 quests a waiver under this subsection to
6 provide home or community-based services
7 to individuals described in clause (iii), all
8 other waivers (if any) granted under this
9 subsection to such State meet the require-
10 ments of this subsection.

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

22 “(iii) The State establishes needs-
23 based criteria, subject to the approval of
24 the Secretary, to identify individuals for
25 whom a determination described in para-

1 graph (1) is not applicable, who will be eli-
2 gible for home or community-based serv-
3 ices under a waiver approved under this
4 paragraph, and specifies the home or com-
5 munity-based services such individuals so
6 eligible will receive.

7 “(iv) The State established needs-
8 based criteria for determining whether an
9 individual described in clause (iii) requires
10 the level of care provided in a hospital,
11 nursing facility, or an intermediate care fa-
12 cility for individuals with developmental
13 disabilities under the State plan or under
14 any waiver of such plan that are more
15 stringent than the needs-based criteria es-
16 tablished under clause (iii) for determining
17 eligibility for home or community-based
18 services.

19 “(v) The State attests that the State’s
20 average per capita expenditure for medical
21 assistance under the State plan (or waiver
22 of such plan) provided with respect to such
23 individuals enrolled in a waiver under this
24 paragraph will not exceed the State’s aver-
25 age per capita expenditures for medical as-

1 sistance for individuals receiving institu-
2 tional care under the State plan (or waiver
3 of such plan) for the duration that the
4 waiver under this paragraph is in effect.

5 “(vi) The State provides to the Sec-
6 retary data (in such form and manner as
7 the Secretary may specify) regarding the
8 number of individuals described in clause
9 (i) with respect to a State seeking approval
10 of a waiver under this subsection, to whom
11 the State will make such services available
12 under such waiver.

13 “(vii) The State agrees to provide to
14 the Secretary, not less frequently than an-
15 nually, data for purposes of paragraph
16 (2)(E) (in such form and manner as the
17 Secretary may specify) regarding, with re-
18 spect to each preceding year in which a
19 waiver under this subsection to provide
20 home and community-based services to in-
21 dividuals described in clause (iii) was in ef-
22 fect—

23 “(I) the cost (as such term is de-
24 fined by the Secretary) of such serv-
25 ices furnished to individuals described

1 in clause (iii), broken down by type of
2 service;

3 “(II) with respect to each type of
4 home and community-based service
5 provided under the waiver, the length
6 of time that such individuals have re-
7 ceived such service;

8 “(III) a comparison between the
9 data described in subclause (I) and
10 any comparable data available with
11 respect to individuals with respect to
12 whom a determination described in
13 paragraph (1) has been made and
14 with respect to individuals receiving
15 institutional care under this title; and

16 “(IV) the number of individuals
17 who have received home and commu-
18 nity-based services under the waiver
19 during the preceding year.”.

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

1 (d) CMS GUIDANCE TO STATES ON INTERIM COV-
2 ERAGE UNDER SECTION 1915 HOME AND COMMUNITY-
3 BASED SERVICES AUTHORITIES.—Not later than January
4 1, 2027, the Secretary of Health and Human Services
5 shall issue guidance to the States to clarify how a State
6 may provide, with respect to an individual who is eligible
7 for home and community-based services under section
8 1915 of the Social Security Act (42 U.S.C. 1396n), cov-
9 erage of such services pursuant to a provisional written
10 plan of care, pending finalization, with respect to such in-
11 dividual.

12 (e) FUNDING.—

13 (1) IN GENERAL.—There are appropriated, out
14 of any funds in the Treasury not otherwise obli-
15 gated, \$71,000,000 for fiscal year 2025, to remain
16 available until expended, to the Secretary of Health
17 and Human Services for purposes of carrying out
18 subsection (d) and the amendments made by sub-
19 section (b).

20 (2) RESERVATION FOR PLANNING GRANTS.—Of
21 the amount appropriated under paragraph (1), the
22 Secretary of Health and Human Services shall re-
23 serve \$50,000,000 of such amount to award plan-
24 ning grants under the demonstration program estab-
25 lished by the amendments made by subsection (b).

1 **SEC. 103. REMOVING CERTAIN AGE RESTRICTIONS ON MED-**
2 **ICAID ELIGIBILITY FOR WORKING ADULTS**
3 **WITH DISABILITIES.**

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

5 (1) IN GENERAL.—Section
6 1902(a)(10)(A)(ii)(XV) of the Social Security Act
7 (42 U.S.C. 1396a(a)(10)(A)(ii)(XV)) is amended by
8 striking “but less than 65,”.

9 (2) DEFINITION MODIFICATION.—Section
10 1905(v)(1)(A) of the Social Security Act (42 U.S.C.
11 1396d(v)(1)(A)) is amended by striking “, but less
12 than 65,”.

13 (b) APPLICATION TO CERTAIN STATES.—A State
14 that, as of the date of enactment of this Act, provides for
15 making medical assistance available to individuals de-
16 scribed in subclause (XV) or (XVI) of section
17 1902(a)(10)(A)(ii) of the Social Security Act (42 U.S.C.
18 1396a(a)(10)(A)(ii)) shall not be regarded as failing to
19 comply with the requirements of either such subclause (as
20 amended by subsection (a)(1)) or with section
21 1905(v)(1)(A) of the Social Security Act (42 U.S.C.
22 1396d(v)(1)(A)) (as amended by subsection (a)(2)) before
23 January 1, 2027.

1 **SEC. 104. MEDICAID STATE PLAN REQUIREMENT FOR DE-**
2 **TERMINING RESIDENCY AND COVERAGE FOR**
3 **MILITARY FAMILIES.**

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

6 (1) in subsection (a)—

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

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

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

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

16 “(A) that, for purposes of determining eli-
17 gibility for medical assistance under the State
18 plan (or waiver of such plan), such active duty
19 relocated individual is treated as a resident of
20 the State unless such individual voluntarily
21 elects not to be so treated for such purposes;

22 “(B) that if, at the time of relocation (as
23 described in subsection (uu)(1)), such active
24 duty relocated individual is on a home and com-
25 munity-based services waiting list (as defined in

1 subsection (uu)(2)), such individual remains on
2 such list until—

3 “(i) the State completes an assess-
4 ment and renders a decision with respect
5 to the eligibility of such individual to re-
6 ceive the relevant home and community-
7 based services at the time a slot for such
8 services becomes available and, in the case
9 such decision is a denial of such eligibility,
10 such individual has exhausted the individ-
11 ual’s opportunity for a fair hearing; or

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

14 “(C) payment for medical assistance fur-
15 nished under the State plan (or a waiver of the
16 plan) on behalf of such active duty relocated in-
17 dividual in the military service relocation State
18 (as referred to in subsection (uu)(1)(B)(i)), to
19 the extent that such assistance is available in
20 such military service relocation State in accord-
21 ance with such guidance as the Secretary may
22 issue to ensure access to such assistance.”; and
23 (2) by adding at the end the following new sub-
24 section:

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

4 “(1) ACTIVE DUTY RELOCATED INDIVIDUAL.—
5 The term ‘active duty relocated individual’ means an
6 individual—

7 “(A) who—

8 “(i) is enrolled under the State plan
9 (or waiver of such plan); or

10 “(ii) with respect to an individual de-
11 scribed in subparagraph (C)(ii), would be
12 so enrolled pursuant to subsection
13 (a)(10)(A)(ii)(VI) if such individual began
14 receiving home and community-based serv-
15 ices;

16 “(B) who—

17 “(i) is a member of the Armed Forces
18 engaged in active duty service and is relo-
19 cated to another State (in this subsection
20 referred to as the ‘military service reloca-
21 tion State’) by reason of such service;

22 “(ii) would be described in clause (i)
23 except that the individual stopped being
24 engaged in active duty service (including
25 by reason of retirement from such service)

1 and the last day on which the individual
2 was engaged in active duty service oc-
3 curred not more than 12 months ago; or

4 “(iii) is a dependent (as defined by
5 the Secretary) of a member described in
6 clause (i) or (ii) who relocates to the mili-
7 tary service relocation State with such
8 member; and

9 “(C) who—

10 “(i) was receiving home and commu-
11 nity-based services (as defined in section
12 9817(a)(2)(B) of the American Rescue
13 Plan Act of 2021) at the time of such relo-
14 cation; or

15 “(ii) if the State maintains a home
16 and community-based services waiting list,
17 was on such home and community-based
18 services waiting list at the time of such re-
19 location.

20 “(2) HOME AND COMMUNITY-BASED SERVICES
21 WAITING LIST.—The term ‘home and community-
22 based services waiting list’ means, in the case of a
23 State that has a limit on the number of individuals
24 who may receive home and community-based services
25 under section 1115(a), section 1915(c), or section

1 1915(j), a list maintained by such State of individ-
2 uals who are requesting to receive such services
3 under 1 or more such sections but for whom the
4 State has not yet completed an assessment and ren-
5 dered a decision with respect to the eligibility of
6 such individuals to receive the relevant home and
7 community-based services at the time a slot for such
8 services becomes available due to such limit.”.

9 (b) IMPLEMENTATION FUNDING.—There are appro-
10 priated, out of any funds in the Treasury not otherwise
11 obligated, \$1,000,000 for each of fiscal years 2025
12 through 2029, to remain available until expended, to the
13 Secretary of Health and Human Services for purposes of
14 implementing the amendments made by subsection (a).

15 **SEC. 105. ENSURING THE RELIABILITY OF ADDRESS INFOR-**
16 **MATION PROVIDED UNDER THE MEDICAID**
17 **PROGRAM.**

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

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

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

1 (3) by inserting after paragraph (88) the fol-
2 lowing new paragraph:

3 “(89) beginning January 1, 2026, provide for a
4 process to regularly obtain address information for
5 individuals enrolled under such plan (or a waiver of
6 such plan) from reliable data sources (as described
7 in section 435.919(f)(1)(iii) of title 42, Code of Fed-
8 eral Regulations (or a successor regulation)) and act
9 on any changes to such an address based on such in-
10 formation in accordance with such section (or suc-
11 cessor regulation), except that this paragraph shall
12 only apply in the case of the 50 States and the Dis-
13 trict of Columbia.”.

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

17 (1) by redesignating subparagraphs (H)
18 through (U) as subparagraphs (I) through (V), re-
19 spectively; and

20 (2) by inserting after subparagraph (G) the fol-
21 lowing new subparagraph:

22 “(H) Section 1902(a)(89) (relating to reg-
23 ularly obtaining address information for enroll-
24 ees).”.

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

6 “(j) TRANSMISSION OF ADDRESS INFORMATION.—
7 Beginning January 1, 2026, each contract under a State
8 plan with a managed care entity under section 1903(m)
9 shall provide that the entity transmits to the State any
10 address information for an individual enrolled with the en-
11 tity that is provided to such entity directly from, or
12 verified by such entity directly with, such individual.”.

13 **SEC. 106. CODIFYING CERTAIN MEDICAID PROVIDER**
14 **SCREENING REQUIREMENTS RELATED TO**
15 **DECEASED PROVIDERS.**

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

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

19 “(A) IN GENERAL.—The State”; and

20 (2) by adding at the end the following new sub-
21 paragraph:

22 “(B) ADDITIONAL PROVIDER SCREEN-
23 ING.—Beginning January 1, 2027, as part of
24 the enrollment (or reenrollment or revalidation
25 of enrollment) of a provider or supplier under

1 this title, and not less frequently than quarterly
2 during the period that such provider or supplier
3 is so enrolled, the State conducts a check of the
4 Death Master File (as such term is defined in
5 section 203(d) of the Bipartisan Budget Act of
6 2013) to determine whether such provider or
7 supplier is deceased.”.

8 **SEC. 107. MODIFYING CERTAIN STATE REQUIREMENTS FOR**
9 **ENSURING DECEASED INDIVIDUALS DO NOT**
10 **REMAIN ENROLLED.**

11 Section 1902 of the Social Security Act (42 U.S.C.
12 1396a), as previously amended by this title, is amended—

13 (1) in subsection (a)—

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

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

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

20 “(90) provide that the State shall comply with
21 the eligibility verification requirements under sub-
22 section (vv), except that this paragraph shall apply
23 only in the case of the 50 States and the District
24 of Columbia.”; and

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

3 “(vv) VERIFICATION OF CERTAIN ELIGIBILITY CRI-
4 TERIA.—

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

8 “(A) QUARTERLY SCREENING TO VERIFY
9 ENROLLEE STATUS.—The State shall, not less
10 frequently than quarterly, review the Death
11 Master File (as such term is defined in section
12 203(d) of the Bipartisan Budget Act of 2013)
13 to determine whether any individuals enrolled
14 for medical assistance under the State plan (or
15 waiver of such plan) are deceased.

16 “(B) DISENROLLMENT UNDER STATE
17 PLAN.—If the State determines, based on infor-
18 mation obtained from the Death Master File,
19 that an individual enrolled for medical assist-
20 ance under the State plan (or waiver of such
21 plan) is deceased, the State shall—

22 “(i) treat such information as factual
23 information confirming the death of a ben-
24 eficiary for purposes of section 431.213(a)

1 of title 42, Code of Federal Regulations (or
2 any successor regulation);

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

5 “(iii) discontinue any payments for
6 medical assistance under this title made on
7 behalf of such individual (other than pay-
8 ments for any items or services furnished
9 to such individual prior to the death of
10 such individual).

11 “(C) REINSTATEMENT OF COVERAGE IN
12 THE EVENT OF ERROR.—If a State determines
13 that an individual was misidentified as deceased
14 based on information obtained from the Death
15 Master File, and was erroneously disenrolled
16 from medical assistance under the State plan
17 (or waiver of such plan) based on such
18 misidentification, the State shall immediately
19 reenroll such individual under the State plan
20 (or waiver of such plan), retroactive to the date
21 of such disenrollment.

22 “(2) RULE OF CONSTRUCTION.—Nothing under
23 this subsection shall be construed to preclude the
24 ability of a State to use other electronic data sources
25 to timely identify potentially deceased beneficiaries,

1 so long as the State is also in compliance with the
2 requirements of this subsection (and all other re-
3 quirements under this title relating to Medicaid eli-
4 gibility determination and redetermination).”.

5 **SEC. 108. ONE-YEAR DELAY OF MEDICAID AND CHIP RE-**
6 **QUIREMENTS FOR HEALTH SCREENINGS, RE-**
7 **FERRALS, AND CASE MANAGEMENT SERV-**
8 **ICES FOR ELIGIBLE JUVENILES IN PUBLIC**
9 **INSTITUTIONS; STATE INTERIM WORK PLANS.**

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

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

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

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

19 “(2) DELAY OF DATE BY WHICH STATES MUST
20 COMPLY WITH CERTAIN JUVENILE JUSTICE-RE-
21 LATED REQUIREMENTS.—A State shall not be re-
22 garded as failing to comply with the requirements of
23 section 1902(a)(84)(D) or 2102(d)(2) of the Social
24 Security Act (42 U.S.C. 1396a(a)(84)(D),
25 1397bb(d)(2)) before January 1, 2026.”.

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

3 (1) MEDICAID.—

4 (A) Subparagraph (D) of section
5 1902(a)(84) of the Social Security Act (42
6 U.S.C. 1396a(a)(84)), as added by section 5121
7 of subtitle C of title V of division FF of the
8 Consolidated Appropriations Act, 2023 (Public
9 Law 117–328), is amended by striking “an in-
10 dividual who is an eligible juvenile” and insert-
11 ing “an individual (other than an individual
12 who is in Federal custody, including as an in-
13 mate in a Federal prison) who is an eligible ju-
14 venile”.

15 (B) Section 5122(a) of subtitle C of title
16 V of division FF of the Consolidated Appropria-
17 tions Act, 2023 (Public Law 117–328) is
18 amended—

19 (i) by striking “paragraph (31)” each
20 place it appears and inserting “the last
21 numbered paragraph”; and

22 (ii) in paragraph (1), by striking “an
23 individual who is an eligible juvenile” and
24 inserting “an individual (other than an in-
25 dividual who is in Federal custody, includ-

1 ing as an inmate in a Federal prison) who
2 is an eligible juvenile”.

3 (2) CHIP.—

4 (A) Subsection (d)(2) of section 2102 of
5 the Social Security Act (42 U.S.C. 1397bb), as
6 added by section 5121 of subtitle C of title V
7 of division FF of the Consolidated Appropria-
8 tions Act, 2023 (Public Law 117–328), is
9 amended by striking “a targeted low-income
10 child who” and inserting “a targeted low in-
11 come child (other than a child who is in Federal
12 custody, including as an inmate in a Federal
13 prison) who”.

14 (B) Section 5122(b)(2) of subtitle C of
15 title V of division FF of the Consolidated Ap-
16 propriations Act, 2023 (Public Law 117–328)
17 is amended by striking “a child who is” and in-
18 serting “a child (other than a child who is in
19 Federal custody, including as an inmate in a
20 Federal prison) who is”.

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

24 (c) INTERIM WORK PLAN.—Not later than June 30,
25 2025, each State (as such term is defined in section

1 1101(a)(1) of the Social Security Act (42 U.S.C.
2 1301(a)(1)) for purposes of titles XIX and XXI of such
3 Act) shall submit to the Secretary of Health and Human
4 Services an interim work plan, in such form and con-
5 taining such information as the Secretary may specify, de-
6 scribing the State's progress towards implementing, and
7 its plans to come into compliance with, the requirements
8 imposed by the amendments made by section 5121 of sub-
9 title C of title V of division FF of the Consolidated Appro-
10 priations Act, 2023 (Public Law 117–328), consistent
11 with the guidance issued by the Centers for Medicare &
12 Medicaid Services in State Health Official Letter #24–
13 004 on July 23, 2024.

14 **SEC. 109. STATE STUDIES AND HHS REPORT ON COSTS OF**
15 **PROVIDING MATERNITY, LABOR, AND DELIV-**
16 **ERY SERVICES.**

17 (a) STATE STUDY.—

18 (1) IN GENERAL.—Not later than 24 months
19 after the date of enactment of this Act, and every
20 5 years thereafter, each State (as such term is de-
21 fined in section 1101(a)(1) of the Social Security
22 Act (42 U.S.C. 1301(a)(1)) for purposes of titles
23 XIX and XXI of such Act) shall conduct a study on
24 the costs of providing maternity, labor, and delivery
25 services in applicable hospitals (as defined in para-

1 graph (3)) and submit the results of such study to
2 the Secretary of Health and Human Services (re-
3 ferred to in this section as the “Secretary”).

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

9 (A) An estimate of the cost of providing
10 maternity, labor, and delivery services at appli-
11 cable hospitals, based on the expenditures a
12 representative sample of such hospitals incurred
13 for providing such services during the 2 most
14 recent years for which data is available.

15 (B) An estimate of the cost of providing
16 maternity, labor, and delivery services at appli-
17 cable hospitals that ceased providing labor and
18 delivery services within the past 5 years, based
19 on the expenditures a representative sample of
20 such hospitals incurred for providing such serv-
21 ices during the 2 most recent years for which
22 data is available.

23 (C) To the extent data allows, an analysis
24 of the extent to which geographic location, com-
25 munity demographics, and local economic fac-

1 tors (as defined by the Secretary) affect the
2 cost of providing maternity, labor, and delivery
3 services at applicable hospitals, including the
4 cost of services that support the provision of
5 maternity, labor, and delivery services.

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

10 (i) Medicare;

11 (ii) the State Medicaid program, in-
12 cluding payment amounts for such services
13 under fee-for-service payment arrange-
14 ments and under managed care (as appli-
15 cable);

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

20 (iv) private health insurance.

21 (E) A comparative payment rate anal-
22 ysis—

23 (i) comparing payment rates for ma-
24 ternity, labor, and delivery services (inclu-
25 sive of all payments received by applicable

1 hospitals for furnishing maternity, labor,
2 and delivery services) under the State
3 Medicaid fee-for-service program to such
4 payment rates for such services under
5 Medicare (as described in section
6 447.203(b)(3) of title 42, Code of Federal
7 Regulations), other Federally-funded or
8 State-funded programs (including, to the
9 extent data is available, Medicaid managed
10 care rates), and to the payment rates for
11 such services, to the extent data is avail-
12 able, of private health insurers within geo-
13 graphic areas of the State; and

14 (ii) analyzing different payment meth-
15 ods for such services, such as the use of
16 bundled payments, quality incentives, and
17 low-volume adjustments.

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

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

5 (A) The hospital provides labor and deliv-
6 ery services and more than 50 percent of the
7 hospital’s births (in the most recent year for
8 which such data is available) are financed by
9 the Medicaid program or CHIP.

10 (B) The hospital—

11 (i) is located in a rural area (as de-
12 fined by the Federal Office of Rural
13 Health Policy for the purpose of rural
14 health grant programs administered by
15 such Office);

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

20 (iii) provides labor and delivery serv-
21 ices.

22 (4) ASSISTANCE TO SMALL HOSPITALS IN COM-
23 PILING COST INFORMATION.—There are appro-
24 priated to the Secretary for fiscal year 2025,
25 \$10,000,000 for the purpose of providing grants and

1 technical assistance to a hospital described in para-
2 graph (3)(B) to enable such hospital to compile de-
3 tailed information for use in the State studies re-
4 quired under paragraph (1), to remain available
5 until expended.

6 (5) HHS REPORT ON STATE STUDIES.—For
7 each year in which a State is required to conduct a
8 study under paragraph (1), the Secretary shall issue,
9 not later than 12 months after the date on which
10 the State submits to the Secretary the data de-
11 scribed in such paragraph, a publicly available re-
12 port that compiles and details the results of such
13 study and includes the information described in
14 paragraph (2).

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

23 (c) IMPLEMENTATION FUNDING.—In addition to the
24 amount appropriated under subsection (a)(4), there are
25 appropriated, out of any funds in the Treasury not other-

1 wise obligated, \$3,000,000 for fiscal year 2025, to remain
2 available until expended, to the Secretary of Health and
3 Human Services for purposes of implementing this sec-
4 tion.

5 **SEC. 110. MODIFYING CERTAIN DISPROPORTIONATE SHARE**
6 **HOSPITAL ALLOTMENTS.**

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

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

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

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

18 (b) ELIMINATING AND DELAYING DSH ALLOTMENT
19 REDUCTIONS.—Section 1923(f) of the Social Security Act
20 (42 U.S.C. 1396r-4(f)) is amended—

21 (1) in paragraph (7)(A)—

22 (A) in clause (i), in the matter preceding
23 subclause (I), by striking “April 1, 2025,” and
24 all that follows through “2027” and inserting

1 “January 1, 2027, and ending September 30,
2 2027, and for fiscal year 2028”; and

3 (B) in clause (ii), by striking “April 1,
4 2025,” and all that follows through “2027” and
5 inserting “January 1, 2027, and ending Sep-
6 tember 30, 2027, and for fiscal year 2028”;
7 and

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

10 **SEC. 111. MODIFYING CERTAIN LIMITATIONS ON DIS-**
11 **PROPORTIONATE SHARE HOSPITAL PAY-**
12 **MENT ADJUSTMENTS UNDER THE MEDICAID**
13 **PROGRAM.**

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

16 (1) in paragraph (1)—

17 (A) in subparagraph (A)—

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

21 (ii) in clause (i), by inserting “with
22 respect to such hospital and year” after
23 “described in subparagraph (B)”; and

24 (iii) in clause (ii)—

1 (I) in subclause (I), by striking
2 “and” at the end;

3 (II) in subclause (II), by striking
4 the period and inserting “; and”; and

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

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

11 (B) in subparagraph (B)—

12 (i) in the matter preceding clause (i),
13 by striking “in this clause are” and insert-
14 ing “in this subparagraph are, with respect
15 to a hospital and a year,”; and

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

18 “(iii) Individuals who are eligible for
19 medical assistance under the State plan or
20 under a waiver of such plan and for whom
21 the State plan or waiver is a payor for
22 such services after application of benefits
23 under title XVIII or under an applicable
24 plan (as defined in section 1862(b)(8)(F)),
25 but only if the hospital has in the aggre-

1 gate incurred costs exceeding payments
2 under such State plan, waiver, title XVIII,
3 or applicable plan for such services fur-
4 nished to such individuals during such
5 year.”;

6 (2) by striking paragraph (2);

7 (3) by redesignating paragraph (3) as para-
8 graph (2); and

9 (4) in paragraph (2), as so redesignated, by
10 striking “Notwithstanding paragraph (2) of this
11 subsection (as in effect on October 1, 2021), para-
12 graph (2)” and inserting “Paragraph (2)”.

13 (b) EFFECTIVE DATE.—

14 (1) IN GENERAL.—Except as provided in para-
15 graph (2), the amendments made by this section
16 shall apply to payment adjustments made under sec-
17 tion 1923 of the Social Security Act (42 U.S.C.
18 1396r–4) for Medicaid State plan rate years begin-
19 ning on or after the date of enactment of this Act.

20 (2) STATE OPTION TO DISTRIBUTE UNSPENT
21 DSH ALLOTMENTS FROM PRIOR YEARS UP TO MODI-
22 FIED CAP.—

23 (A) IN GENERAL.—If, for any Medicaid
24 State plan rate year that begins on or after Oc-
25 tober 1, 2021, and before the date of enactment

1 of this Act, a State did not spend the full
2 amount of its Federal fiscal year allotment
3 under section 1923 of the Social Security Act
4 (42 U.S.C. 1396r-4) applicable to that State
5 plan rate year, the State may use the unspent
6 portion of such allotment to increase the
7 amount of any payment adjustment made to a
8 hospital for such rate year, provided that—

9 (i) such payment adjustment (as so
10 increased) is consistent with subsection (g)
11 of such section (as amended by this sec-
12 tion); and

13 (ii) the total amount of all payment
14 adjustments for the State plan rate year
15 (as so increased) does not exceed the dis-
16 proportionate share hospital allotment for
17 the State and applicable Federal fiscal
18 year under subsection (f) of such section.

19 (B) NO RECOUPMENT OF PAYMENTS AL-
20 READY MADE TO HOSPITALS.—A State shall not
21 recoup any payment adjustment made by the
22 State to a hospital for a Medicaid State plan
23 rate year described in subparagraph (A) if such
24 payment adjustment is consistent with section

1 1923(g) of such Act (42 U.S.C. 1396r–4(g)) as
2 in effect on October 1, 2021.

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

6 (i) IN GENERAL.—Subject to para-
7 graph (2), solely for the purpose of allow-
8 ing a State to increase the amount of a
9 payment adjustment to a hospital for a
10 Medicaid State plan rate year described in
11 subparagraph (A) pursuant to this para-
12 graph, a State may retroactively modify a
13 provision of the Medicaid State plan, a
14 waiver of such plan, or a State plan
15 amendment that relates to such rate year
16 and the Secretary may approve such modi-
17 fication.

18 (ii) DEADLINE.—A State may not
19 submit a request for approval of a retro-
20 active modification to a provision of the
21 Medicaid State plan, a waiver of such plan,
22 or a State plan amendment for a Medicaid
23 State plan rate year after the date by
24 which the State is required to submit the
25 independent certified audit for that State

1 plan rate year as required under section
2 1923(j)(2) of the Social Security Act (42
3 U.S.C. 1396r-4(j)(2)).

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

12 **SEC. 112. ENSURING ACCURATE PAYMENTS TO PHAR-**
13 **MACIES UNDER MEDICAID.**

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

16 (1) in paragraph (1)(A)—

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

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

22 “(1) DETERMINING PHARMACY ACTUAL ACQUI-
23 SITION COSTS.—The Secretary shall conduct a sur-
24 vey of retail community pharmacy drug prices and
25 applicable non-retail pharmacy drug prices to deter-

1 mine national average drug acquisition cost bench-
2 marks (as such term is defined by the Secretary) as
3 follows:

4 “(A) USE OF VENDOR.—The Secretary
5 may contract services for—

6 “(i) with respect to retail community
7 pharmacies, the determination of retail
8 survey prices of the national average drug
9 acquisition cost for covered outpatient
10 drugs that represent a nationwide average
11 of consumer purchase prices for such
12 drugs, net of all discounts, rebates, and
13 other price concessions (to the extent any
14 information with respect to such discounts,
15 rebates, and other price concessions is
16 available) based on a monthly survey of
17 such pharmacies;

18 “(ii) with respect to applicable non-re-
19 tail pharmacies—

20 “(I) the determination of survey
21 prices, separate from the survey prices
22 described in clause (i), of the non-re-
23 tail national average drug acquisition
24 cost for covered outpatient drugs that
25 represent a nationwide average of con-

1 sumer purchase prices for such drugs,
2 net of all discounts, rebates, and other
3 price concessions (to the extent any
4 information with respect to such dis-
5 counts, rebates, and other price con-
6 cessions is available) based on a
7 monthly survey of such pharmacies;
8 and

9 “(II) at the discretion of the Sec-
10 retary, for each type of applicable
11 non-retail pharmacy, the determina-
12 tion of survey prices, separate from
13 the survey prices described in clause
14 (i) or subclause (I) of this clause, of
15 the national average drug acquisition
16 cost for such type of pharmacy for
17 covered outpatient drugs that rep-
18 resent a nationwide average of con-
19 sumer purchase prices for such drugs,
20 net of all discounts, rebates, and other
21 price concessions (to the extent any
22 information with respect to such dis-
23 counts, rebates, and other price con-
24 cessions is available) based on a

1 monthly survey of such pharmacies;
2 and”;

3 (2) in subparagraph (B) of paragraph (1), by
4 striking “subparagraph (A)(ii)” and inserting “sub-
5 paragraph (A)(iii)”;

6 (3) in subparagraph (D) of paragraph (1), by
7 striking clauses (ii) and (iii) and inserting the fol-
8 lowing:

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

12 “(iii) The vendor must differentiate,
13 in collecting and reporting survey data, for
14 all cost information collected, whether a
15 pharmacy is a retail community pharmacy
16 or an applicable non-retail pharmacy, in-
17 cluding whether such pharmacy is an affil-
18 iate (as defined in subsection (k)(14)),
19 and, in the case of an applicable non-retail
20 pharmacy, which type of applicable non-re-
21 tail pharmacy it is using the relevant phar-
22 macy type indicators included in the guid-
23 ance required by subsection (d)(2) of sec-
24 tion 112 of the Health Improvements, Ex-
25 tenders, and Reauthorizations Act.”;

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

3 “(F) SURVEY REPORTING.—In order to
4 meet the requirement of section 1902(a)(54), a
5 State shall require that any retail community
6 pharmacy or applicable non-retail pharmacy in
7 the State that receives any payment, reimburse-
8 ment, administrative fee, discount, rebate, or
9 other price concession related to the dispensing
10 of covered outpatient drugs to individuals re-
11 ceiving benefits under this title, regardless of
12 whether such payment, reimbursement, admin-
13 istrative fee, discount, rebate, or other price
14 concession is received from the State or a man-
15 aged care entity or other specified entity (as
16 such terms are defined in section
17 1903(m)(9)(D)) directly or from a pharmacy
18 benefit manager or another entity that has a
19 contract with the State or a managed care enti-
20 ty or other specified entity (as so defined), shall
21 respond to surveys conducted under this para-
22 graph.

23 “(G) SURVEY INFORMATION.—Information
24 on national drug acquisition prices obtained
25 under this paragraph shall be made publicly

1 available in a form and manner to be deter-
2 mined by the Secretary and shall include at
3 least the following:

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

7 “(ii) The sampling methodology and
8 number of pharmacies sampled monthly.

9 “(iii) Information on price concessions
10 to pharmacies, including discounts, re-
11 bates, and other price concessions, to the
12 extent that such information may be pub-
13 licly released and has been collected by the
14 Secretary as part of the survey.

15 “(H) PENALTIES.—

16 “(i) IN GENERAL.—Subject to clauses
17 (ii), (iii), and (iv), the Secretary shall en-
18 force the provisions of this paragraph with
19 respect to a pharmacy through the estab-
20 lishment of civil money penalties applicable
21 to a retail community pharmacy or an ap-
22 plicable non-retail pharmacy.

23 “(ii) BASIS FOR PENALTIES.—The
24 Secretary shall impose a civil money pen-
25 alty established under this subparagraph

1 on a retail community pharmacy or appli-
2 cable non-retail pharmacy if—

3 “(I) the retail pharmacy or appli-
4 cable non-retail pharmacy refuses or
5 otherwise fails to respond to a request
6 for information about prices in con-
7 nection with a survey under this sub-
8 section;

9 “(II) knowingly provides false in-
10 formation in response to such a sur-
11 vey; or

12 “(III) otherwise fails to comply
13 with the requirements established
14 under this paragraph.

15 “(iii) PARAMETERS FOR PEN-
16 ALTIES.—

17 “(I) IN GENERAL.—A civil money
18 penalty established under this sub-
19 paragraph may be assessed with re-
20 spect to each violation, and with re-
21 spect to each non-compliant retail
22 community pharmacy (including a
23 pharmacy that is part of a chain) or
24 non-compliant applicable non-retail
25 pharmacy (including a pharmacy that

1 is part of a chain), in an amount not
2 to exceed \$100,000 for each such vio-
3 lation.

4 “(II) CONSIDERATIONS.—In de-
5 termining the amount of a civil money
6 penalty imposed under this subpara-
7 graph, the Secretary may consider the
8 size, business structure, and type of
9 pharmacy involved, as well as the type
10 of violation and other relevant factors,
11 as determined appropriate by the Sec-
12 retary.

13 “(iv) RULE OF APPLICATION.—The
14 provisions of section 1128A (other than
15 subsections (a) and (b)) shall apply to a
16 civil money penalty under this subpara-
17 graph in the same manner as such provi-
18 sions apply to a civil money penalty or pro-
19 ceeding under section 1128A(a).

20 “(I) LIMITATION ON USE OF APPLICABLE
21 NON-RETAIL PHARMACY PRICING INFORMA-
22 TION.—No State shall use pricing information
23 reported by applicable non-retail pharmacies
24 under subparagraph (A)(ii) to develop or inform

1 payment methodologies for retail community
2 pharmacies.”;

3 (5) in paragraph (2)—

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

10 (B) in subparagraph (B), by inserting
11 “and the basis for such dispensing fees” before
12 the semicolon;

13 (6) by redesignating paragraph (4) as para-
14 graph (5);

15 (7) by inserting after paragraph (3) the fol-
16 lowing new paragraph:

17 “(4) OVERSIGHT.—

18 “(A) IN GENERAL.—The Inspector General
19 of the Department of Health and Human Serv-
20 ices shall conduct periodic studies of the survey
21 data reported under this subsection, as appro-
22 priate, including with respect to substantial
23 variations in acquisition costs or other applica-
24 ble costs, as well as with respect to how internal
25 transfer prices and related party transactions

1 may influence the costs reported by pharmacies
2 that are affiliates (as defined in subsection
3 (k)(14)) or are owned by, controlled by, or re-
4 lated under a common ownership structure with
5 a wholesaler, distributor, or other entity that
6 acquires covered outpatient drugs relative to
7 costs reported by pharmacies not affiliated with
8 such entities. The Inspector General shall pro-
9 vide periodic updates to Congress on the results
10 of such studies, as appropriate, in a manner
11 that does not disclose trade secrets or other
12 proprietary information.

13 “(B) APPROPRIATION.—There is appro-
14 priated to the Inspector General of the Depart-
15 ment of Health and Human Services, out of
16 any money in the Treasury not otherwise ap-
17 propriated, \$5,000,000 for fiscal year 2025, to
18 remain available until expended, to carry out
19 this paragraph.”; and
20 (8) in paragraph (5), as so redesignated—

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

24 (B) by inserting “Funds appropriated
25 under this paragraph for fiscal year 2025 and

1 any subsequent fiscal year shall remain avail-
2 able until expended.” after the period.

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

5 (1) in the matter preceding paragraph (1), by
6 striking “In the section” and inserting “In this sec-
7 tion”; and

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

10 “(12) APPLICABLE NON-RETAIL PHARMACY.—
11 The term ‘applicable non-retail pharmacy’ means a
12 pharmacy that is licensed as a pharmacy by the
13 State and that is not a retail community pharmacy,
14 including a pharmacy that dispenses prescription
15 medications to patients primarily through mail and
16 specialty pharmacies. Such term does not include
17 nursing home pharmacies, long-term care facility
18 pharmacies, hospital pharmacies, clinics, charitable
19 or not-for-profit pharmacies, government phar-
20 macies, or low dispensing pharmacies (as defined by
21 the Secretary).

22 “(13) AFFILIATE.—The term ‘affiliate’ means
23 any entity that is owned by, controlled by, or related
24 under a common ownership structure with a phar-
25 macy benefit manager or a managed care entity or

1 other specified entity (as such terms are defined in
2 section 1903(m)(9)(D)).”.

3 (c) EFFECTIVE DATE.—

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

9 (2) DELAYED APPLICATION TO APPLICABLE
10 NON-RETAIL PHARMACIES.—The pharmacy survey
11 requirements established by the amendments to sec-
12 tion 1927(f) of the Social Security Act (42 U.S.C.
13 1396r–8(f)) made by this section shall apply to re-
14 tail community pharmacies beginning on the effec-
15 tive date described in paragraph (1), but shall not
16 apply to applicable non-retail pharmacies until the
17 first day of the first quarter that begins on or after
18 the date that is 18 months after the date of enact-
19 ment of this Act.

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

22 (1) IN GENERAL.—Not later than January 1,
23 2026, the Secretary of Health and Human Services
24 shall, in consultation with stakeholders as appro-
25 priate, publish guidance specifying pharmacies that

1 meet the definition of applicable non-retail phar-
2 macies (as such term is defined in subsection
3 (k)(12) of section 1927 of the Social Security Act
4 (42 U.S.C. 1396r-8), as added by subsection (b)),
5 and that will be subject to the survey requirements
6 under subsection (f)(1) of such section, as amended
7 by subsection (a).

8 (2) INCLUSION OF PHARMACY TYPE INDICA-
9 TORS.—The guidance published under paragraph (1)
10 shall include pharmacy type indicators to distinguish
11 between different types of applicable non-retail phar-
12 macies, such as pharmacies that dispense prescrip-
13 tions primarily through the mail and pharmacies
14 that dispense prescriptions that require special han-
15 dling or distribution. An applicable non-retail phar-
16 macy may be identified through multiple pharmacy
17 type indicators.

18 (e) IMPLEMENTATION.—

19 (1) IN GENERAL.—Notwithstanding any other
20 provision of law, the Secretary of Health and
21 Human Services may implement the amendments
22 made by this section by program instruction or oth-
23 erwise.

24 (2) NONAPPLICATION OF ADMINISTRATIVE PRO-
25 CEDURE ACT.—Implementation of the amendments

1 made by this section shall be exempt from the re-
2 quirements of section 553 of title 5, United States
3 Code.

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

10 **SEC. 113. PREVENTING THE USE OF ABUSIVE SPREAD PRIC-**
11 **ING IN MEDICAID.**

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

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

16 “(6) TRANSPARENT PRESCRIPTION DRUG PASS-
17 THROUGH PRICING REQUIRED.—

18 “(A) IN GENERAL.—A contract between
19 the State and a pharmacy benefit manager (re-
20 ferred to in this paragraph as a ‘PBM’), or a
21 contract between the State and a managed care
22 entity or other specified entity (as such terms
23 are defined in section 1903(m)(9)(D) and col-
24 lectively referred to in this paragraph as the
25 ‘entity’) that includes provisions making the en-

1 tity responsible for coverage of covered out-
2 patient drugs dispensed to individuals enrolled
3 with the entity, shall require that payment for
4 such drugs and related administrative services
5 (as applicable), including payments made by a
6 PBM on behalf of the State or entity, is based
7 on a transparent prescription drug pass-
8 through pricing model under which—

9 “(i) any payment made by the entity
10 or the PBM (as applicable) for such a
11 drug—

12 “(I) is limited to—

13 “(aa) ingredient cost; and

14 “(bb) a professional dis-
15 pensing fee that is not less than
16 the professional dispensing fee
17 that the State would pay if the
18 State were making the payment
19 directly in accordance with the
20 State plan;

21 “(II) is passed through in its en-
22 tirety (except as reduced under Fed-
23 eral or State laws and regulations in
24 response to instances of waste, fraud,
25 or abuse) by the entity or PBM to the

1 pharmacy or provider that dispenses
2 the drug; and

3 “(III) is made in a manner that
4 is consistent with sections 447.502,
5 447.512, 447.514, and 447.518 of
6 title 42, Code of Federal Regulations
7 (or any successor regulation) as if
8 such requirements applied directly to
9 the entity or the PBM, except that
10 any payment by the entity or the
11 PBM for the ingredient cost of such
12 drug purchased by a covered entity
13 (as defined in subsection (a)(5)(B))
14 may exceed the actual acquisition cost
15 (as defined in 447.502 of title 42,
16 Code of Federal Regulations, or any
17 successor regulation) for such drug
18 if—

19 “(aa) such drug was subject
20 to an agreement under section
21 340B of the Public Health Serv-
22 ice Act;

23 “(bb) such payment for the
24 ingredient cost of such drug does
25 not exceed the maximum pay-

1 ment that would have been made
2 by the entity or the PBM for the
3 ingredient cost of such drug if
4 such drug had not been pur-
5 chased by such covered entity;
6 and

7 “(cc) such covered entity re-
8 ports to the Secretary (in a form
9 and manner specified by the Sec-
10 retary), on an annual basis and
11 with respect to payments for the
12 ingredient costs of such drugs so
13 purchased by such covered entity
14 that are in excess of the actual
15 acquisition costs for such drugs,
16 the aggregate amount of such ex-
17 cess;

18 “(ii) payment to the entity or the
19 PBM (as applicable) for administrative
20 services performed by the entity or PBM is
21 limited to an administrative fee that re-
22 flects the fair market value (as defined by
23 the Secretary) of such services;

24 “(iii) the entity or the PBM (as appli-
25 cable) makes available to the State, and

1 the Secretary upon request in a form and
2 manner specified by the Secretary, all costs
3 and payments related to covered outpatient
4 drugs and accompanying administrative
5 services (as described in clause (ii)) in-
6 curred, received, or made by the entity or
7 the PBM, broken down (as specified by the
8 Secretary), to the extent such costs and
9 payments are attributable to an individual
10 covered outpatient drug, by each such
11 drug, including any ingredient costs, pro-
12 fessional dispensing fees, administrative
13 fees (as described in clause (ii)), post-sale
14 and post-invoice fees, discounts, or related
15 adjustments such as direct and indirect re-
16 muneration fees, and any and all other re-
17 muneration, as defined by the Secretary;
18 and

19 “(iv) any form of spread pricing
20 whereby any amount charged or claimed by
21 the entity or the PBM (as applicable) that
22 exceeds the amount paid to the pharmacies
23 or providers on behalf of the State or enti-
24 ty, including any post-sale or post-invoice
25 fees, discounts, or related adjustments

1 such as direct and indirect remuneration
2 fees or assessments, as defined by the Sec-
3 retary, (after allowing for an administra-
4 tive fee as described in clause (ii)) is not
5 allowable for purposes of claiming Federal
6 matching payments under this title.

7 “(B) PUBLICATION OF INFORMATION.—
8 The Secretary shall publish, not less frequently
9 than on an annual basis and in a manner that
10 does not disclose the identity of a particular
11 covered entity or organization, information re-
12 ceived by the Secretary pursuant to subpara-
13 graph (A)(i)(III)(cc) that is broken out by
14 State and by each of the following categories of
15 covered entity within each such State:

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

19 “(ii) Covered entities described in sub-
20 paragraphs (B) through (K) of such sec-
21 tion.

22 “(iii) Covered entities described in
23 subparagraph (L) of such section.

24 “(iv) Covered entities described in
25 subparagraph (M) of such section.

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

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

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

8 “(14) PHARMACY BENEFIT MANAGER.—The
9 term ‘pharmacy benefit manager’ means any person
10 or entity that, either directly or through an inter-
11 mediary, acts as a price negotiator or group pur-
12 chaser on behalf of a State, managed care entity (as
13 defined in section 1903(m)(9)(D)), or other specified
14 entity (as so defined), or manages the prescription
15 drug benefits provided by a State, managed care en-
16 tity, or other specified entity, including the proc-
17 essing and payment of claims for prescription drugs,
18 the performance of drug utilization review, the proc-
19 essing of drug prior authorization requests, the man-
20 aging of appeals or grievances related to the pre-
21 scription drug benefits, contracting with pharmacies,
22 controlling the cost of covered outpatient drugs, or
23 the provision of services related thereto. Such term
24 includes any person or entity that acts as a price ne-
25 gotiator (with regard to payment amounts to phar-

1 macies and providers for a covered outpatient drug
2 or the net cost of the drug) or group purchaser on
3 behalf of a State, managed care entity, or other
4 specified entity or that carries out 1 or more of the
5 other activities described in the preceding sentence,
6 irrespective of whether such person or entity calls
7 itself a pharmacy benefit manager.”.

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

10 (1) in paragraph (2)(A)(xiii)—

11 (A) by striking “and (III)” and inserting
12 “(III)”;

13 (B) by inserting before the period at the
14 end the following: “, and (IV) if the contract in-
15 cludes provisions making the entity responsible
16 for coverage of covered outpatient drugs, the
17 entity shall comply with the requirements of
18 section 1927(e)(6)”;

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

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

23 “(10) No payment shall be made under this
24 title to a State with respect to expenditures incurred
25 by the State for payment for services provided by an

1 other specified entity (as defined in paragraph
2 (9)(D)(iii)) unless such services are provided in ac-
3 cordance with a contract between the State and such
4 entity which satisfies the requirements of paragraph
5 (2)(A)(xiii).”.

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

12 (d) IMPLEMENTATION.—

13 (1) IN GENERAL.—Notwithstanding any other
14 provision of law, the Secretary of Health and
15 Human Services may implement the amendments
16 made by this section by program instruction or oth-
17 erwise.

18 (2) NONAPPLICATION OF ADMINISTRATIVE PRO-
19 CEDURE ACT.—Implementation of the amendments
20 made by this section shall be exempt from the re-
21 quirements of section 553 of title 5, United States
22 Code.

23 (e) NONAPPLICATION OF PAPERWORK REDUCTION
24 ACT.—Chapter 35 of title 44, United States Code, shall
25 not apply to any data collection undertaken by the Sec-

1 retary of Health and Human Services under section
2 1927(e) of the Social Security Act (42 U.S.C. 1396r–
3 8(e)), as amended by this section.

4 **TITLE II—MEDICARE**

5 **SEC. 201. EXTENSION OF INCREASED INPATIENT HOSPITAL** 6 **PAYMENT ADJUSTMENT FOR CERTAIN LOW-** 7 **VOLUME HOSPITALS.**

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

10 (1) in subparagraph (B), in the matter pre-
11 ceding clause (i), by striking “fiscal year 2025 be-
12 ginning on April 1, 2025, and ending on September
13 30, 2025, and in fiscal year 2026” and inserting
14 “fiscal year 2026 beginning on January 1, 2026,
15 and ending on September 30, 2026, and in fiscal
16 year 2027”;

17 (2) in subparagraph (C)(i)—

18 (A) in the matter preceding subclause

19 (I)—

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

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

24 (iii) by striking “October 1, 2024”
25 and inserting “October 1, 2025”; and

1 (iv) by striking “March 31, 2025”
2 and inserting “December 31, 2025”;

3 (B) in subclause (III)—

4 (i) by striking “through 2024” and
5 inserting “through 2025”;

6 (ii) by striking “fiscal year 2025” and
7 inserting “fiscal year 2026”;

8 (iii) by striking “October 1, 2024”
9 and inserting “October 1, 2025”; and

10 (iv) by striking “March 31, 2025”
11 and inserting “December 31, 2025”; and

12 (C) in subclause (IV)—

13 (i) by striking “fiscal year 2025” and
14 inserting “fiscal year 2026”;

15 (ii) by striking “April 1, 2025” and
16 inserting “January 1, 2026”;

17 (iii) by striking “September 30,
18 2025” and inserting “September 30,
19 2026”; and

20 (iv) by striking “fiscal year 2026”
21 and inserting “fiscal year 2027”; and

22 (3) in subparagraph (D)—

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

24 (i) by striking “through 2024” and
25 inserting “through 2025”;

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

3 (iii) by striking “October 1, 2024”
4 and inserting “October 1, 2025”; and

5 (iv) by striking “March 31, 2025”
6 and inserting “December 31, 2025”; and

7 (B) in clause (ii)—

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 “March 31, 2025”
15 and inserting “December 31, 2025”.

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

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

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

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

3 (2) in clause (ii)(II), by striking “April 1,
4 2025” and inserting “January 1, 2026”.

5 (b) CONFORMING AMENDMENTS.—

6 (1) IN GENERAL.—Section 1886(b)(3)(D) of
7 the Social Security Act (42 U.S.C.
8 1395ww(b)(3)(D)) is amended—

9 (A) in the matter preceding clause (i), by
10 striking “April 1, 2025” and inserting “Janu-
11 ary 1, 2026”; and

12 (B) in clause (iv)—

13 (i) by striking “fiscal year 2024” and
14 inserting “fiscal year 2025”;

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

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

19 (iv) by striking “March 31, 2025”
20 and inserting “December 31, 2025”.

21 (2) PERMITTING HOSPITALS TO DECLINE RE-
22 CLASSIFICATION.—Section 13501(e)(2) of the Omni-
23 bus Budget Reconciliation Act of 1993 (42 U.S.C.
24 1395ww note) is amended—

1 (A) by striking “through 2024” and insert-
2 ing “through 2025”;

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

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

7 (D) by striking “March 31, 2025” and in-
8 serting “December 31, 2025”.

9 **SEC. 203. EXTENSION OF ADD-ON PAYMENTS FOR AMBU-**
10 **LANCE SERVICES.**

11 Section 1834(l) of the Social Security Act (42 U.S.C.
12 1395m(l)) is amended—

13 (1) in paragraph (12)(A), by striking “April 1,
14 2025” and inserting “January 1, 2027”; and

15 (2) in paragraph (13), by striking “April 1,
16 2025” each place it appears and inserting “January
17 1, 2027” in each such place.

18 **SEC. 204. EXTENDING INCENTIVE PAYMENTS FOR PARTICI-**
19 **PATION IN ELIGIBLE ALTERNATIVE PAYMENT**
20 **MODELS.**

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

23 (1) in paragraph (1)(A)—

24 (A) by striking “with 2026” and inserting
25 “with 2027”; and

1 (B) by inserting “, or, with respect to
2 2027, 3.53 percent” after “1.88 percent”;

3 (2) in paragraph (2)—

4 (A) in subparagraph (B)—

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

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

9 (B) in subparagraph (C)—

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

12 (ii) in the matter preceding clause (i),
13 by striking “2027” and inserting “2028”;

14 and

15 (C) in subparagraph (D), by striking “and
16 2026” and inserting “2026, and 2027”; and

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

19 (b) CONFORMING AMENDMENTS.—Section
20 1848(q)(1)(C)(iii) of the Social Security Act (42 U.S.C.
21 1395w–4(q)(1)(C)(iii)) is amended—

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

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

1 **SEC. 205. TEMPORARY PAYMENT INCREASE UNDER THE**
2 **MEDICARE PHYSICIAN FEE SCHEDULE TO AC-**
3 **COUNT FOR EXCEPTIONAL CIRCUMSTANCES.**

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

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

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

10 (3) by adding at the end the following new sub-
11 paragraph:

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

15 (b) CONFORMING AMENDMENT.—Section
16 1848(c)(2)(B)(iv)(V) is amended by striking “or 2024”
17 and inserting “2024, or 2025”.

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

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

22 (1) in the first sentence—

23 (A) by striking “\$11,030,000” and insert-
24 ing “\$20,030,000”; and

25 (B) by striking “March 31” and inserting
26 “December 31”; and

1 (2) in the third sentence, by striking “March
2 31” and inserting “December 31”.

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

5 (a) STATE HEALTH INSURANCE ASSISTANCE PRO-
6 GRAMS.—Subsection (a)(1)(B) of section 119 of the Medi-
7 care Improvements for Patients and Providers Act of 2008
8 (42 U.S.C. 1395b–3 note) is amended—

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

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

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

15 “(xv) for the period beginning on
16 April 1, 2025, and ending on December
17 31, 2026, \$30,000,000.”.

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

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

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

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

1 “(xv) for the period beginning on
2 April 1, 2025, and ending on December
3 31, 2026, \$30,000,000.”.

4 (c) AGING AND DISABILITY RESOURCE CENTERS.—

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

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

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

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

12 “(xv) for the period beginning on
13 April 1, 2025, and ending on December
14 31, 2026, \$10,000,000.”.

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

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

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

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

1 “(xv) for the period beginning on
2 April 1, 2025, and ending on December
3 31, 2026, \$30,000,000.”.

4 **SEC. 208. EXTENSION OF THE WORK GEOGRAPHIC INDEX**
5 **FLOOR.**

6 Section 1848(e)(1)(E) of the Social Security Act (42
7 U.S.C. 1395w-4(e)(1)(E)) is amended by striking “April
8 1, 2025” and inserting “January 1, 2026”.

9 **SEC. 209. EXTENSION OF CERTAIN TELEHEALTH FLEXIBILI-**
10 **TIES.**

11 (a) REMOVING GEOGRAPHIC REQUIREMENTS AND
12 EXPANDING ORIGINATING SITES FOR TELEHEALTH
13 SERVICES.—Section 1834(m) of the Social Security Act
14 (42 U.S.C. 1395m(m)) is amended—

15 (1) in paragraph (2)(B)(iii), by striking “end-
16 ing March 31, 2025” and inserting “ending Decem-
17 ber 31, 2026”; and

18 (2) in paragraph (4)(C)(iii), by striking “ending
19 on March 31, 2025” and inserting “ending on De-
20 cember 31, 2026”.

21 (b) EXPANDING PRACTITIONERS ELIGIBLE TO FUR-
22 NISH TELEHEALTH SERVICES.—Section 1834(m)(4)(E)
23 of the Social Security Act (42 U.S.C. 1395m(m)(4)(E))
24 is amended by striking “ending on March 31, 2025” and
25 inserting “ending on December 31, 2026”.

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

5 (1) in subparagraph (A), by striking “ending on
6 March 31, 2025” and inserting “ending on Decem-
7 ber 31, 2026”;

8 (2) in subparagraph (B)—

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

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

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

17 (3) by adding at the end the following new sub-
18 paragraph:

19 “(C) PAYMENT RULE FOR 2025 AND
20 2026.—

21 “(i) IN GENERAL.—A telehealth serv-
22 ice furnished to an eligible telehealth indi-
23 vidual by a Federally qualified health cen-
24 ter or rural health clinic on or after Janu-
25 ary 1, 2025, and before January 1, 2027,

1 shall be paid as a Federally qualified
2 health center service or rural health clinic
3 service (as applicable) under the prospec-
4 tive payment system established under sec-
5 tion 1834(o) or the methodology for all-in-
6 clusive rates established under section
7 1833(a)(3), respectively.

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

19 “(iii) REQUIRING MODIFIERS.—Not
20 later than July 1, 2025, the Secretary
21 shall establish requirements to include 1 or
22 more codes or modifiers, as determined ap-
23 propriate by the Secretary, in the case of
24 claims for telehealth services furnished to
25 an eligible telehealth individual by a Feder-

1 ally qualified health center or rural health
2 clinic.”.

3 (d) DELAYING THE IN-PERSON REQUIREMENTS
4 UNDER MEDICARE FOR MENTAL HEALTH SERVICES
5 FURNISHED THROUGH TELEHEALTH AND TELE-
6 COMMUNICATIONS TECHNOLOGY.—

7 (1) DELAY IN REQUIREMENTS FOR MENTAL
8 HEALTH SERVICES FURNISHED THROUGH TELE-
9 HEALTH.—Section 1834(m)(7)(B)(i) of the Social
10 Security Act (42 U.S.C. 1395m(m)(7)(B)(i)) is
11 amended, in the matter preceding subclause (I), by
12 striking “on or after April 1, 2025” and inserting
13 “on or after January 1, 2027”.

14 (2) MENTAL HEALTH VISITS FURNISHED BY
15 RURAL HEALTH CLINICS.—Section 1834(y)(2) of the
16 Social Security Act (42 U.S.C. 1395m(y)(2)) is
17 amended by striking “April 1, 2025” and inserting
18 “January 1, 2027”.

19 (3) MENTAL HEALTH VISITS FURNISHED BY
20 FEDERALLY QUALIFIED HEALTH CENTERS.—Section
21 1834(o)(4)(B) of the Social Security Act (42 U.S.C.
22 1395m(o)(4)(B)) is amended by striking “April 1,
23 2025” and inserting “January 1, 2027.”.

24 (e) ALLOWING FOR THE FURNISHING OF AUDIO-
25 ONLY TELEHEALTH SERVICES.—Section 1834(m)(9) of

1 the Social Security Act (42 U.S.C. 1395m(m)(9)) is
2 amended by striking “ending on March 31, 2025” and in-
3 serting “ending on December 31, 2026”.

4 (f) EXTENDING USE OF TELEHEALTH TO CONDUCT
5 FACE-TO-FACE ENCOUNTER PRIOR TO RECERTIFICATION
6 OF ELIGIBILITY FOR HOSPICE CARE.—Section
7 1814(a)(7)(D)(i)(II) of the Social Security Act (42 U.S.C.
8 1395f(a)(7)(D)(i)(II)) is amended—

9 (1) by striking “ending on March 31, 2025”
10 and inserting “ending on December 31, 2026”; and

11 (2) by inserting “, except that this subclause
12 shall not apply in the case of such an encounter with
13 an individual occurring on or after January 1, 2025,
14 if such individual is located in an area that is sub-
15 ject to a moratorium on the enrollment of hospice
16 programs under this title pursuant to section
17 1866(j)(7), if such individual is receiving hospice
18 care from a provider that is subject to enhanced
19 oversight under this title pursuant to section
20 1866(j)(3), or if such encounter is performed by a
21 hospice physician or nurse practitioner who is not
22 enrolled under section 1866(j) and is not an opt-out
23 physician or practitioner (as defined in section
24 1802(b)(6)(D))” before the semicolon.

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

5 “(10) REQUIRED USE OF MODIFIERS IN CER-
6 TAIN INSTANCES.—Not later than January 1, 2026,
7 the Secretary shall establish requirements to include
8 1 or more codes or modifiers, as determined appro-
9 priate by the Secretary, in the case of—

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

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

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

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

23 (h) PROGRAM INSTRUCTION AUTHORITY.—The Sec-
24 retary of Health and Human Services may implement the

1 amendments made by this section through program in-
2 struction or otherwise.

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

7 Section 1814(a)(7)(D)(i)(II) of the Social Security
8 Act (42 U.S.C. 1395f(a)(7)(D)(i)(II)), as amended by sec-
9 tion 209(f) of the Health Improvements, Extenders, and
10 Reauthorizations Act, is further amended by inserting “,
11 but only if, in the case of such an encounter occurring
12 on or after January 1, 2026, any hospice claim includes
13 1 or more modifiers or codes (as specified by the Sec-
14 retary) to indicate that such encounter was conducted via
15 telehealth” after “as determined appropriate by the Sec-
16 retary”.

17 **SEC. 211. EXTENDING ACUTE HOSPITAL CARE AT HOME**
18 **WAIVER FLEXIBILITIES.**

19 Section 1866G of the Social Security Act (42 U.S.C.
20 1395cc–7) is amended—

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

25 (2) in subsection (a)—

1 (A) in paragraph (1)—

2 (i) by striking “March 31, 2025” and
3 inserting “December 31, 2029”; and

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

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

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

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

23 (3) in subsection (b)—

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

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

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

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

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

9 “(c) SUBSEQUENT STUDY AND REPORT.—

10 “(1) IN GENERAL.—Not later than September
11 30, 2028, the Secretary shall conduct a study to—

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

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

23 “(i) quality of care furnished to indi-
24 viduals with similar conditions and charac-
25 teristics in the inpatient setting and

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

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

23 “(iii) costs incurred by the hospital
24 for furnishing care in inpatient settings
25 relative to costs incurred by the hospital

1 for furnishing care through the Acute Hos-
2 pital Care at Home initiative, including
3 costs relating to staffing, equipment, food,
4 prescriptions, and other services, as deter-
5 mined by the Secretary;

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

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

22 “(vi) the quality of care, outcomes,
23 costs, quantity and intensity of services,
24 and other relevant metrics between individ-
25 uals who entered into the Acute Hospital

1 Care at Home initiative directly from an
2 emergency department compared with indi-
3 viduals who entered into the Acute Hos-
4 pital Care at Home initiative directly from
5 an existing inpatient stay in a hospital.

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

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

17 “(4) FUNDING.—In addition to amounts other-
18 wise available, there is appropriated to the Centers
19 for Medicare & Medicaid Services Program Manage-
20 ment Account for fiscal year 2025, out of any
21 amounts in the Treasury not otherwise appropriated,
22 \$6,000,000, respectively, to remain available until
23 expended, for purposes of carrying out this section.”.

1 **SEC. 212. ENHANCING CERTAIN PROGRAM INTEGRITY RE-**
2 **QUIREMENTS FOR DME UNDER MEDICARE.**

3 (a) DURABLE MEDICAL EQUIPMENT.—

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

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

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

1 “(B) CLAIM REVIEW.—With respect to
2 items furnished on or after January 1, 2028,
3 that are included on the Master List pursuant
4 to subparagraph (A), if such an item is not sub-
5 ject to a determination of coverage in advance
6 pursuant to paragraph (15)(C), the Secretary
7 may conduct prepayment review of claims for
8 payment for such item.”.

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

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

1 U.S.C. 1395m–1) and effective tools for reducing such
2 fraudulent claims. The report may include information re-
3 garding—

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

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

11 (A) the amount payable under such section
12 1834A with respect to such test;

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

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

22 (D) the frequency with which a claim for
23 payment under such section 1834A included the
24 payment modifier identified by code 59 or 91;
25 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 April
9 1, 2025, and before January 1, 2027, in the home
10 of an individual who is an outpatient of the hos-
11 pital)” 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 April 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 “March 31, 2025” and inserting “December 31, 2025”.

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

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

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

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

3 **SEC. 220. MULTIYEAR CONTRACTING AUTHORITY FOR**
4 **MEDPAC AND MACPAC.**

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

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

17 “(j) THE MEDICAID AND CHIP PAYMENT AND AC-
18 CESS COMMISSION.—The Medicaid and CHIP Payment
19 and Access Commission may use available funds to enter
20 into contracts for the procurement of severable services
21 for a period that begins in one fiscal year and ends in
22 the next fiscal year and may enter into multiyear contracts
23 for the acquisition of property and services to the same
24 extent as executive agencies under the authority of sec-
25 tions 3902 and 3903 of this title.”.

1 **SEC. 221. CONTRACTING PARITY FOR MEDPAC AND**
2 **MACPAC.**

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

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

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

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

18 “(I) for a plan year before
19 2027—

20 “(aa) for a generic drug or a
21 preferred drug that is a multiple
22 source drug (as defined in section
23 1927(k)(7)(A)(i)), \$1 or, if less,
24 the copayment amount applicable
25 to an individual under clause
26 (iii); and

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

5 “(II) for plan year 2027 and
6 each subsequent plan year—

7 “(aa) for a generic drug, \$0;

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

22 “(cc) for a drug not de-
23 scribed in either item (aa) or
24 (bb), the dollar amount applied
25 under this clause for such a drug

1 for the preceding plan year, in-
2 creased in the manner specified
3 in item (bb), or, if less, the co-
4 payment amount applicable to an
5 individual under clause (iii).

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

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

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

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

18 (1) in paragraph (1)(C)—

19 (A) by striking “plan, and any” and insert-
20 ing “plan, any”; and

21 (B) by inserting the following before the
22 period at the end: “, and, in the case of a speci-
23 fied MA plan (as defined in paragraph (3)(C)),
24 for plan year 2027 and subsequent plan years,

1 the information described in paragraph (3)(B)”;

2 and

3 (2) by adding at the end the following new

4 paragraph:

5 “(3) PROVIDER DIRECTORY ACCURACY.—

6 “(A) IN GENERAL.—For plan year 2027

7 and subsequent plan years, each MA organiza-

8 tion offering a specified MA plan (as defined in

9 subparagraph (C)) shall, for each such plan of-

10 fered by the organization—

11 “(i) maintain, on a publicly available

12 internet website, an accurate provider di-

13 rectory that includes the information de-

14 scribed in subparagraph (B);

15 “(ii) not less frequently than once

16 every 90 days (or, in the case of a hospital

17 or any other facility determined appro-

18 priate by the Secretary, at a lesser fre-

19 quency specified by the Secretary but in no

20 case less frequently than once every 12

21 months), verify the provider directory in-

22 formation of each provider listed in such

23 directory and, if applicable, update such

24 provider directory information;

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

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

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

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

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

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

10 (b) ACCOUNTABILITY FOR PROVIDER DIRECTORY
11 ACCURACY.—

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

17 (A) in paragraph (1)(C)—

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

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

23 (iii) by adding at the end the fol-
24 lowing new clause:

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

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

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

1 that the enrollee is only responsible for the less-
2 er of—

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

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

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

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

20 “(ii) include information regarding
21 such cost-sharing protections in the pro-
22 vider directory of each specified MA plan
23 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 (nnn));”; and

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

9 “(nnn) 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 CONSTRU-
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 **TITLE III—OTHER MATTERS**

2 **SEC. 301. SEXUAL RISK AVOIDANCE EDUCATION EXTEN-**
3 **SION.**

4 Section 510 of the Social Security Act (42 U.S.C.
5 710) is amended—

6 (1) in subsection (a)—

7 (A) in paragraph (1)—

8 (i) by striking “and for the period”
9 and inserting “for the period”;

10 (ii) by striking “March 31, 2025” and
11 inserting “September 30, 2025”;

12 (iii) by inserting “and for the period
13 beginning on October 1, 2025, and ending
14 on December 31, 2025,” before “allot to
15 each State”; and

16 (iv) by striking “for fiscal year 2024
17 or 2025” and inserting “for fiscal year
18 2024, 2025, or 2026”; and

19 (B) in paragraph (2), by striking “or
20 2025” each place it appears and inserting “,
21 2025, or 2026”; and

22 (2) in subsection (f)(1)—

23 (A) by striking “and for the period” and
24 inserting “for the period”;

1 (B) by striking “March 31, 2025” and in-
2 serting “September 30, 2025”; and

3 (C) by inserting “, and for the period be-
4 ginning on October 1, 2025, and ending on De-
5 cember 31, 2025, an amount equal to the pro
6 rata portion of the amount appropriated for the
7 corresponding period for fiscal year 2025” after
8 “corresponding period for fiscal year 2024”.

9 **SEC. 302. PERSONAL RESPONSIBILITY EDUCATION EXTEN-**
10 **SION.**

11 Section 513 of the Social Security Act (42 U.S.C.
12 713) is amended—

13 (1) in subsection (a)(1)—

14 (A) in subparagraph (A), in the matter
15 preceding clause (i)—

16 (i) by striking “and for the period”
17 and inserting “for the period”;

18 (ii) by striking “March 31, 2025” and
19 inserting “September 30, 2025”; and

20 (iii) by inserting “and for the period
21 beginning on October 1, 2025, and ending
22 on December 31, 2025,” before “the Sec-
23 retary shall allot”; and

24 (B) in subparagraph (B)(i)—

1 (i) by striking “and for the period”
2 and inserting “for the period”;

3 (ii) by striking “March 31, 2025” and
4 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 period;

8 (2) in subsection (c)(3), by striking “fiscal year
9 2024 or 2025” and inserting “fiscal year 2024,
10 2025, or 2026”; and

11 (3) in subsection (f)—

12 (A) by striking “and for the period” and
13 inserting “for the period”;

14 (B) by striking “March 31, 2025” and in-
15 serting “September 30, 2025”; and

16 (C) by inserting “, and for the period be-
17 ginning on October 1, 2025, and ending on De-
18 cember 31, 2025, an amount equal to the pro
19 rata portion of the amount appropriated for the
20 corresponding period for fiscal year 2025” after
21 “corresponding period for fiscal year 2024”.

22 **SEC. 303. EXTENSION OF FUNDING FOR FAMILY-TO-FAMILY**
23 **HEALTH INFORMATION CENTERS.**

24 Section 501(c)(1)(A)(viii) of the Social Security Act
25 (42 U.S.C. 701(c)(1)(A)(viii)) is amended—

1 (1) by striking “\$3,000,000” and inserting
2 “\$7,500,000”; and

3 (2) by striking “for the portion of fiscal year
4 2025 before April 1, 2025” and inserting “for the
5 period beginning on October 1, 2024, and ending on
6 December 31, 2025”.

7 **TITLE IV—PUBLIC HEALTH**
8 **EXTENDERS**

9 **Subtitle A—Extensions**

10 **SEC. 401. EXTENSION FOR COMMUNITY HEALTH CENTERS,**
11 **NATIONAL HEALTH SERVICE CORPS, AND**
12 **TEACHING HEALTH CENTERS THAT OPERATE**
13 **GME PROGRAMS.**

14 (a) EXTENSION FOR COMMUNITY HEALTH CEN-
15 TERS.—Section 10503(b)(1) of the Patient Protection and
16 Affordable Care Act (42 U.S.C. 254b–2(b)(1)) is amend-
17 ed—

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

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

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

23 “(J) \$2,315,342,466 for the period begin-
24 ning on April 1, 2025, and ending on Sep-
25 tember 30, 2025; and

1 “(K) \$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 (I), by striking “and” at
8 the end;

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

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

12 “(K) \$176,712,329 for the period begin-
13 ning on April 1, 2025, and ending on Sep-
14 tember 30, 2025; and

15 “(L) \$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) 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 a semicolon; and

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

1 “(F) \$112,849,315 for the period begin-
2 ning on April 1, 2025, and ending on Sep-
3 tember 30, 2025;

4 “(G) \$225,000,000 for fiscal year 2026;

5 “(H) \$250,000,000 for fiscal year 2027;

6 “(I) \$275,000,000 for fiscal year 2028;

7 and

8 “(J) \$300,000,000 for fiscal year 2029.”.

9 (d) APPLICATION OF PROVISIONS.—Amounts appro-
10 priated pursuant to the amendments made by this section
11 shall be subject to the requirements contained in Public
12 Law 117–328 for funds for programs authorized under
13 sections 330 through 340 of the Public Health Service Act
14 (42 U.S.C. 254b et seq.).

15 (e) CONFORMING AMENDMENT.—Section 3014(h)(4)
16 of title 18, United States Code, is amended by striking
17 “and section 3101(d) of the Health Extensions and Other
18 Matters Act, 2025” and inserting “section 3101(d) of the
19 Health Extensions and Other Matters Act, 2025, and sec-
20 tion 401 of the Lower Costs for Everyday Americans Act”.

21 **SEC. 402. EXTENSION OF SPECIAL DIABETES PROGRAMS.**

22 (a) EXTENSION OF SPECIAL DIABETES PROGRAMS
23 FOR TYPE I DIABETES.—Section 330B(b)(2) of the Pub-
24 lic Health Service Act (42 U.S.C. 254c–2(b)(2)) is amend-
25 ed—

1 (1) in subparagraph (E), by striking “and” at
2 the end;

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

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

6 “(G) \$110,327,296 for the period begin-
7 ning on April 1, 2025, and ending on Sep-
8 tember 30, 2025, to remain available until ex-
9 pended; and

10 “(H) \$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 (E), by striking “and” at
17 the end;

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

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

21 “(G) \$110,327,296 for the period begin-
22 ning on April 1, 2025, and ending on Sep-
23 tember 30, 2025, to remain available until ex-
24 pended; and

1 “(H) \$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 2025”.

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 2025.”.

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 sserting “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 including, 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 2025” 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 SUPPORT for Patients and Commu-
12 nities Reauthorization Act of 2025”; and

13 (ii) in paragraph (2)(B)(i)—

14 (I) in subclause (I)—

15 (aa) by striking “for cal-
16 endar years 2013 through 2017”;
17 and

18 (bb) by inserting “for cal-
19 endar years 2018 through 2022”
20 after “rates of unemployment”;

21 (II) in subclause (II)—

22 (aa) by striking “for cal-
23 endar years 2013 through 2017”;
24 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)”; and

4 (vi) in the matter being stricken by
5 paragraph (6), by striking “303(g)” and
6 inserting “303(h)”; and

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)”; and

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 “March
10 31, 2025” 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 “March 31,
7 2025” 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: “Not later”.

12 **SEC. 625. STRATEGIC NATIONAL STOCKPILE AND MATE-**
13 **RIAL THREATS.**

14 Section 319F–2 of the Public Health Service Act (42
15 U.S.C. 247d–6b) is amended—

16 (1) in subsection (a)—

17 (A) in paragraph (2)—

18 (i) in subparagraph (A), by inserting
19 “Such review shall include a description of
20 how the Secretary manages and mitigates
21 risks associated with gaps between current
22 inventory levels and stockpiling goals,
23 prioritizes such risks, and tracks progress
24 toward mitigation of such risks.” after the
25 first sentence; and

1 (ii) in subparagraph (B)(i), by amend-
2 ing subclause (IV) to read as follows:

3 “(IV) the emergency health secu-
4 rity threat or threats such counter-
5 measure procurement is intended to
6 address, including—

7 “(aa) whether such procure-
8 ment is consistent with meeting
9 emergency health security needs
10 associated with such threat or
11 threats; and

12 “(bb) in the case of a coun-
13 termeasure that addresses a bio-
14 logical agent, whether such agent
15 has an increased likelihood to be-
16 come resistant to, more resistant
17 to, or evade, such counter-
18 measure relative to other avail-
19 able medical countermeasures;”;

20 (B) in paragraph (3)—

21 (i) in subparagraph (B), by striking
22 “are followed, regularly reviewed, and up-
23 dated with respect to such stockpile” and
24 inserting “with respect to such stockpile

1 are followed, regularly reviewed, and up-
2 dated to reflect best practices”;

3 (ii) in subparagraph (I), by inserting
4 “, through a standard operating proce-
5 dure,” after “ensure”;

6 (iii) by redesignating subparagraphs
7 (H) through (K) as subparagraphs (I)
8 through (L), respectively;

9 (iv) by inserting after subparagraph
10 (G) the following:

11 “(H) utilize tools to enable the timely and
12 accurate tracking of the contents of the stock-
13 pile throughout the deployment of such con-
14 tents, including tracking of the location and ge-
15 ographic distribution and utilization of such
16 contents;”;

17 (v) in subparagraph (K), as so redes-
18 ignated, by striking “; and” at the end and
19 inserting a semicolon;

20 (vi) in subparagraph (L), as so redes-
21 ignated, by striking the period and insert-
22 ing “; and”; and

23 (vii) by adding at the end the fol-
24 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).

1 **Subtitle D—Additional**
2 **Reauthorizations**

3 **SEC. 641. MEDICAL COUNTERMEASURE PRIORITY REVIEW**
4 **VOUCHER.**

5 Section 565A(g) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 360bbb–4a) is amended by striking
7 “October 1, 2023” and inserting “December 31, 2026”.

8 **SEC. 642. EPIDEMIC INTELLIGENCE SERVICE.**

9 Section 317F(c)(2) of the Public Health Service Act
10 (42 U.S.C. 247b–7(c)(2)) is amended by striking “2019
11 through 2023” and inserting “2025 and 2026, to remain
12 available through December 31, 2026”.

13 **SEC. 643. MONITORING AND DISTRIBUTION OF CERTAIN**
14 **MEDICAL COUNTERMEASURES.**

15 Section 319A(e) of the Public Health Service Act (42
16 U.S.C. 247d–1(e)) is amended by striking “2019 through
17 2023” and inserting “2025 and 2026, to remain available
18 through December 31, 2026”.

19 **SEC. 644. REGIONAL HEALTH CARE EMERGENCY PRE-**
20 **PAREDNESS AND RESPONSE SYSTEMS.**

21 Section 319C–3 of the Public Health Service Act (42
22 U.S.C. 247d–3c) is amended—

23 (1) in subsection (b)(3), by striking “under
24 the” and all that follows through “such Act)” and
25 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 “March
6 31, 2025” 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 “March
17 31, 2025” and inserting “December 31, 2026”; and

18 (2) in subsection (g), by striking “\$57,400,000
19 for each of fiscal years 2019 through 2023” and in-
20 serting “\$65,900,000 for each of fiscal years 2025
21 and 2026, to remain available through December 31,
22 2026”.

23 **SEC. 649. VOLUNTEER MEDICAL RESERVE CORPS.**

24 Section 2813(i) of the Public Health Service Act (42
25 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. 650. 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 Lower Costs for Everyday Americans Act, the Secretary
16 of Health and Human Services, in collaboration with other
17 departments, 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. CONFORMING AMENDMENT TO INTERNAL REV-**
14 **ENUE CODE OF 1986.**

15 Section 9008(i)(2) of the Internal Revenue Code of
16 1986 (26 U.S.C. 9008(i)(2)) is amended by striking “10-
17 Year”.

18 **SEC. 709. SCREENS FOR CANCER.**

19 (a) NATIONAL BREAST AND CERVICAL CANCER
20 EARLY DETECTION PROGRAM.—Title XV of the Public
21 Health Service Act (42 U.S.C. 300k et seq.) is amended—
22 (1) in section 1501 (42 U.S.C. 300k)—
23 (A) in subsection (a)—
24 (i) in paragraph (2), by striking “the
25 provision of appropriate follow-up services

1 and support services such as case manage-
2 ment” and inserting “that appropriate fol-
3 low-up services are provided”;

4 (ii) in paragraph (3), by striking
5 “programs for the detection and control”
6 and inserting “for the prevention, detec-
7 tion, and control”;

8 (iii) in paragraph (4), by striking “the
9 detection and control” and inserting “the
10 prevention, detection, and control”;

11 (iv) in paragraph (5)—

12 (I) by striking “monitor” and in-
13 serting “ensure”; and

14 (II) by striking “; and” and in-
15 serting a semicolon;

16 (v) by redesignating paragraph (6) as
17 paragraph (9);

18 (vi) by inserting after paragraph (5)
19 the following:

20 “(6) to enhance appropriate support activities
21 to increase breast and cervical cancer screenings,
22 such as navigation of health care services, implemen-
23 tation of evidence-based or evidence-informed strate-
24 gies to increase breast and cervical cancer screening

1 in health care settings, and facilitation of access to
2 health care settings;

3 “(7) to reduce disparities in breast and cervical
4 cancer incidence, morbidity, and mortality, including
5 in populations with higher than average rates;

6 “(8) to improve access to breast and cervical
7 cancer screening and diagnostic services and reduce
8 related barriers, including factors that relate to neg-
9 ative health outcomes; and”; and

10 (vii) in paragraph (9), as so redesign-
11 nated, by striking “through (5)” and in-
12 serting “through (8)”; and

13 (B) by striking subsection (d);

14 (2) in section 1503 (42 U.S.C. 300m)—

15 (A) in subsection (a)—

16 (i) in paragraph (1), by striking
17 “that, initially” and all that follows
18 through the semicolon and inserting “that
19 appropriate breast and cervical cancer
20 screening and diagnostic services are pro-
21 vided consistent with relevant evidence-
22 based recommendations; and”;

23 (ii) by striking paragraphs (2) and
24 (4);

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

3 (iv) in paragraph (2), as so redesign-
4 nated, by striking “; and” and inserting a
5 period; and

6 (B) by striking subsection (d);

7 (3) in section 1508(b) (42 U.S.C. 300n–4(b))—

8 (A) by striking “1 year after the date of
9 the enactment of the National Breast and Cer-
10 vical Cancer Early Detection Program Reau-
11 thorization of 2007, and annually thereafter,”
12 and inserting “2 years after the date of enact-
13 ment of the Health Improvements, Extenders,
14 and Reauthorizations Act, and every 5 years
15 thereafter,”;

16 (B) by striking “Labor and Human Re-
17 sources” and inserting “Health, Education,
18 Labor, and Pensions”; and

19 (C) by striking “preceding fiscal year” and
20 inserting “preceding 2 fiscal years in the case
21 of the first report after the date of enactment
22 of the Health Improvements, Extenders, and
23 Reauthorizations Act and preceding 5 fiscal
24 years for each report thereafter”; and

25 (4) in section 1510(a) (42 U.S.C. 300n–5(a))—

1 (A) by striking “2011, and” and inserting
2 “2011,”; and

3 (B) by inserting “, and \$235,500,000 for
4 each of fiscal years 2025 through 2029” before
5 the period at the end before the period at the
6 end.

7 (b) GAO STUDY.—Not later than September 30,
8 2027, the Comptroller General of the United States shall
9 report to the Committee on Health, Education, Labor, and
10 Pensions of the Senate and the Committee on Energy and
11 Commerce of the House of Representatives on the work
12 of the National Breast and Cervical Cancer Early Detec-
13 tion Program, including—

14 (1) an estimate of the number of individuals eli-
15 gible for services provided under such program;

16 (2) a summary of trends in the number of indi-
17 viduals served through such program; and

18 (3) an assessment of any factors that may be
19 driving the trends identified under paragraph (2),
20 including any barriers to accessing breast and cer-
21 vical cancer screenings provided by such program.

22 **SEC. 710. DEONDRA DIXON INCLUDE PROJECT.**

23 Part B of title IV of the Public Health Service Act
24 (42 U.S.C. 284 et seq.) is amended by adding at the end
25 the following:

1 **“SEC. 409K. DOWN SYNDROME RESEARCH.**

2 “(a) IN GENERAL.—The Director of NIH shall carry
3 out a program of research, training, and investigation re-
4 lated to Down syndrome to be known as the ‘INvestigation
5 of Co-occurring conditions across the Lifespan to Under-
6 stand Down syndromE Project’ or the ‘INCLUDE
7 Project’.

8 “(b) PROGRAM ELEMENTS.—The program under
9 subsection (a) shall include—

10 “(1) high-risk, high reward research on the ef-
11 fects of trisomy 21 on human development and
12 health;

13 “(2) promoting research for participants with
14 Down syndrome across the lifespan, including cohort
15 studies to facilitate improved understanding of
16 Down syndrome and co-occurring conditions and de-
17 velopment of new interventions;

18 “(3) expanding the number of clinical trials
19 that are inclusive of, or expressly for, participants
20 with Down syndrome, including novel biomedical and
21 pharmacological interventions and other therapies
22 designed to promote or enhance activities of daily
23 living;

24 “(4) research on the biological mechanisms in
25 individuals with Down syndrome pertaining to struc-

1 tural, functional, and behavioral anomalies and dys-
2 function as well as stunted growth;

3 “(5) supporting research to improve diagnosis
4 and treatment of conditions co-occurring with Down
5 syndrome, including the identification of biomarkers
6 related to risk factors, diagnosis, and clinical re-
7 search and therapeutics;

8 “(6) research on the causes of increased preva-
9 lence, and concurrent treatment, of co-occurring con-
10 ditions, such as Alzheimer’s disease and related de-
11 mentias and autoimmunity, in individuals with Down
12 syndrome; and

13 “(7) research, training, and investigation on im-
14 proving the quality of life of individuals with Down
15 syndrome and their families.

16 “(c) COORDINATION; PRIORITIZING NONDUPLICA-
17 TIVE RESEARCH.—The Director of NIH shall ensure
18 that—

19 “(1) the programs and activities of the insti-
20 tutes and centers of the National Institutes of
21 Health relating to Down syndrome and co-occurring
22 conditions are coordinated, including through the
23 Office of the Director of NIH and priority-setting
24 reviews conducted pursuant to section 402(b)(3);
25 and

1 “(2) such institutes and centers, prioritize, as
2 appropriate, Down syndrome research that does not
3 duplicate existing research activities of the National
4 Institutes of Health.

5 “(d) CONSULTATION WITH STAKEHOLDERS.—In
6 carrying out activities under this section, the Director of
7 NIH shall, as appropriate and to the maximum extent fea-
8 sible, consult with relevant stakeholders, including patient
9 advocates, to ensure that such activities take into consid-
10 eration the needs of individuals with Down syndrome.

11 “(e) BIENNIAL REPORTS TO CONGRESS.—

12 “(1) IN GENERAL.—The Director of NIH shall
13 submit, on a biennial basis, to the Committee on
14 Energy and Commerce and the Subcommittee on
15 Labor, Health and Human Services, Education, and
16 Related Agencies of the Committee on Appropria-
17 tions of the House of Representatives and the Com-
18 mittee on Health, Education, Labor, and Pensions
19 and the Subcommittee on Labor, Health and
20 Human Services, Education, and Related Agencies
21 of the Committee on Appropriations of the Senate,
22 a report that catalogs the research conducted or
23 supported under this section.

24 “(2) CONTENTS.—Each report under para-
25 graph (1) shall include—

1 “(A) identification of the institute or cen-
2 ter involved;

3 “(B) a statement of whether the research
4 is or was being carried out directly by such in-
5 stitute or center or by multiple institutes and
6 centers; and

7 “(C) identification of any resulting real-
8 world evidence that is or may be used for clin-
9 ical research and medical care for patients with
10 Down syndrome.”.

11 **SEC. 711. IMPROVE INITIATIVE.**

12 Part B of title IV of the Public Health Service Act
13 (42 U.S.C. 284 et seq.), as amended by section 710, is
14 further amended by adding at the end the following:

15 **“SEC. 409L. IMPROVE INITIATIVE.**

16 “(a) IN GENERAL.—The Director of the National In-
17 stitutes of Health shall carry out a program of research
18 to improve health outcomes to be known as the Imple-
19 menting a Maternal health and PRegnancy Outcomes Vi-
20 sion for Everyone Initiative (referred to in this section as
21 the ‘Initiative’).

22 “(b) OBJECTIVES.—The Initiative shall—

23 “(1) advance research to—

24 “(A) reduce preventable causes of maternal
25 mortality and severe maternal morbidity;

1 “(B) reduce health disparities related to
2 maternal health outcomes, including such dis-
3 parities associated with medically underserved
4 populations; and

5 “(C) improve health for pregnant and
6 postpartum women before, during, and after
7 pregnancy;

8 “(2) use an integrated approach to understand
9 the factors, including biological, behavioral, and
10 other factors, that affect maternal mortality and se-
11 vere maternal morbidity by building an evidence
12 base for improved outcomes in specific regions of the
13 United States; and

14 “(3) target health disparities associated with
15 maternal mortality and severe maternal morbidity
16 by—

17 “(A) implementing and evaluating commu-
18 nity-based interventions for disproportionately
19 affected women; and

20 “(B) identifying risk factors and the un-
21 derlying biological mechanisms associated with
22 leading causes of maternal mortality and severe
23 maternal morbidity in the United States.

24 “(c) SUNSET.—The authority under this section shall
25 expire on September 30, 2029.”.

1 **SEC. 712. ORGAN PROCUREMENT AND TRANSPLANTATION**
2 **NETWORK.**

3 Section 372 of the Public Health Service Act (42
4 U.S.C. 274) is amended—

5 (1) in subsection (b)(2)—

6 (A) by moving the margins of subpara-
7 graphs (M) through (O) 2 ems to the left;

8 (B) in subparagraph (A)—

9 (i) in clause (i), by striking “, and”
10 and inserting “; and”; and

11 (ii) in clause (ii), by striking the
12 comma at the end and inserting a semi-
13 colon;

14 (C) in subparagraph (C), by striking
15 “twenty-four-hour telephone service” and in-
16 serting “24-hour telephone or information tech-
17 nology service”;

18 (D) in each of subparagraphs (B) through
19 (M), by striking the comma at the end and in-
20 serting a semicolon;

21 (E) in subparagraph (N), by striking
22 “transportation, and” and inserting “transport-
23 ation;”;

24 (F) in subparagraph (O), by striking the
25 period and inserting a semicolon; and

26 (G) by adding at the end the following:

1 “(P) encourage the integration of elec-
2 tronic health records systems through applica-
3 tion programming interfaces (or successor tech-
4 nologies) among hospitals, organ procurement
5 organizations, and transplant centers, including
6 the use of automated electronic hospital refer-
7 rals and the grant of remote, electronic access
8 to hospital electronic health records of potential
9 donors by organ procurement organizations, in
10 a manner that complies with the privacy regula-
11 tions promulgated under the Health Insurance
12 Portability and Accountability Act of 1996, at
13 part 160 of title 45, Code of Federal Regula-
14 tions, and subparts A, C, and E of part 164 of
15 such title (or any successor regulations); and

16 “(Q) consider establishing a dashboard to
17 display the number of transplants performed,
18 the types of transplants performed, the number
19 and types of organs that entered the Organ
20 Procurement and Transplantation Network sys-
21 tem and failed to be transplanted, and other
22 appropriate statistics, which should be updated
23 more frequently than annually.”; and

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

25 “(d) REGISTRATION FEES.—

1 “(1) IN GENERAL.—The Secretary may collect
2 registration fees from any member of the Organ
3 Procurement and Transplantation Network for each
4 transplant candidate such member places on the list
5 described in subsection (b)(2)(A)(i). Such registra-
6 tion fees shall be collected and distributed only to
7 support the operation of the Organ Procurement
8 and Transplantation Network. Such registration fees
9 are authorized to remain available until expended.

10 “(2) COLLECTION.—The Secretary may collect
11 the registration fees under paragraph (1) directly or
12 through awards made under subsection (b)(1)(A).

13 “(3) DISTRIBUTION.—Any amounts collected
14 under this subsection shall—

15 “(A) be credited to the currently applicable
16 appropriation, account, or fund of the Depart-
17 ment of Health and Human Services as discre-
18 tionary offsetting collections; and

19 “(B) be available, only to the extent and in
20 the amounts provided in advance in appropria-
21 tions Acts, to distribute such fees among
22 awardees described in subsection (b)(1)(A).

23 “(4) TRANSPARENCY.—The Secretary shall—

1 “(A) promptly post on the website of the
2 Organ Procurement and Transplantation Net-
3 work—

4 “(i) the amount of registration fees
5 collected under this subsection from each
6 member of the Organ Procurement and
7 Transplantation Network; and

8 “(ii) a list of activities such fees are
9 used to support; and

10 “(B) update the information posted pursu-
11 ant to subparagraph (A), as applicable for each
12 calendar quarter for which fees are collected
13 under paragraph (1).

14 “(5) GAO REVIEW.—Not later than 2 years
15 after the date of enactment of this subsection, the
16 Comptroller General of the United States shall, to
17 the extent data are available—

18 “(A) conduct a review concerning the ac-
19 tivities under this subsection; and

20 “(B) submit to the Committee on Health,
21 Education, Labor, and Pensions and the Com-
22 mittee on Finance of the Senate and the Com-
23 mittee on Energy and Commerce of the House
24 of Representatives, a report on such review, in-
25 cluding related recommendations, as applicable.

1 “(6) SUNSET.—The authority to collect reg-
2 istration fees under paragraph (1) shall expire on
3 the date that is 3 years after the date of enactment
4 of the Health Improvements, Extenders, and Reau-
5 thorizations Act.”.

6 **SEC. 713. HONOR OUR LIVING DONORS.**

7 (a) NO CONSIDERATION OF INCOME OF ORGAN RE-
8 CIPIENT.—Section 377 of the Public Health Service Act
9 (42 U.S.C. 274f) is amended—

10 (1) by redesignating subsections (c) through (f)
11 as subsections (d) through (g), respectively;

12 (2) by inserting after subsection (b) the fol-
13 lowing:

14 “(c) NO CONSIDERATION OF INCOME OF ORGAN RE-
15 CIPIENT.—The recipient of a grant under this section, in
16 providing reimbursement to a donating individual through
17 such grant, shall not give any consideration to the income
18 of the organ recipient.”; and

19 (3) in subsection (f), as so redesignated—

20 (A) in paragraph (1), by striking “sub-
21 section (c)(1)” and inserting “subsection
22 (d)(1)”; and

23 (B) in paragraph (2), by striking “sub-
24 section (c)(2)” and inserting “subsection
25 (d)(2)”.

1 (b) REMOVAL OF EXPECTATION OF PAYMENTS BY
2 ORGAN RECIPIENTS.—Section 377(e) of the Public
3 Health Service Act (42 U.S.C. 274f(e)), as redesignated
4 by section 2(1), is amended—

5 (1) in paragraph (1), by adding “or” at the
6 end;

7 (2) in paragraph (2), by striking “; or” and in-
8 serting a period; and

9 (3) by striking paragraph (3).

10 (c) ANNUAL REPORT.—Section 377 of the Public
11 Health Service Act (42 U.S.C. 274f), as amended by sec-
12 tions 2 and 3, is amended by adding at the end the fol-
13 lowing:

14 “(h) ANNUAL REPORT.—Not later than December 31
15 of each year, beginning in Fiscal Year 2026, the Secretary
16 shall—

17 “(1) prepare, submit to the Congress, and make
18 public a report on whether grants under this section
19 provided adequate funding during the preceding fis-
20 cal year to reimburse all donating individuals par-
21 ticipating in the grant program under this section
22 for all qualifying expenses; and

23 “(2) include in each such report—

24 “(A) the estimated number of all donating
25 individuals participating in the grant program

1 under this section who did not receive reim-
2 bursement for all qualifying expenses during
3 the preceding fiscal year; and

4 “(B) the total amount of funding that is
5 estimated to be necessary to fully reimburse all
6 donating individuals participating in the grant
7 program under this section for all qualifying ex-
8 penses.”.

9 **SEC. 714. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

10 Section 409I(d)(1) of the Public Health Service Act
11 (42 U.S.C. 284m(d)(1)) is amended by striking “section,”
12 and all that follows through the period at the end and
13 inserting “section, \$25,000,000 for each of fiscal years
14 2025 through 2027.”.

15 **TITLE VIII—FOOD AND DRUG**
16 **ADMINISTRATION**
17 **Subtitle A—Give Kids a Chance**

18 **SEC. 801. RESEARCH INTO PEDIATRIC USES OF DRUGS; AD-**
19 **DITIONAL AUTHORITIES OF FOOD AND DRUG**
20 **ADMINISTRATION REGARDING MOLECU-**
21 **LARLY TARGETED CANCER DRUGS.**

22 (a) IN GENERAL.—

23 (1) ADDITIONAL ACTIVE INGREDIENT FOR AP-
24 PPLICATION DRUG; LIMITATION REGARDING NOVEL-
25 COMBINATION APPLICATION DRUG.—Section

1 505B(a)(3) of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 355c(a)(3)) is amended—

3 (A) by redesignating subparagraphs (B)
4 and (C) as subparagraphs (C) and (D), respec-
5 tively; and

6 (B) by striking subparagraph (A) and in-
7 serting the following:

8 “(A) IN GENERAL.—For purposes of para-
9 graph (1)(B), the investigation described in this
10 paragraph is a molecularly targeted pediatric
11 cancer investigation of—

12 “(i) the drug or biological product for
13 which the application referred to in such
14 paragraph is submitted; or

15 “(ii) such drug or biological product
16 used in combination with—

17 “(I) an active ingredient of a
18 drug or biological product—

19 “(aa) for which an approved
20 application under section 505(j)
21 under this Act or under section
22 351(k) of the Public Health
23 Service Act is in effect; and

24 “(bb) that is determined by
25 the Secretary, after consultation

1 with the applicant, to be part of
2 the standard of care for treating
3 a pediatric cancer; or

4 “(II) an active ingredient of a
5 drug or biological product—

6 “(aa) for which an approved
7 application under section 505(b)
8 of this Act or section 351(a) of
9 the Public Health Service Act to
10 treat an adult cancer is in effect
11 and is held by the same person
12 submitting the application under
13 paragraph (1)(B); and

14 “(bb) that is directed at a
15 molecular target that the Sec-
16 retary determines to be substan-
17 tially relevant to the growth or
18 progression of a pediatric cancer.

19 “(B) ADDITIONAL REQUIREMENTS.—

20 “(i) DESIGN OF INVESTIGATION.—A
21 molecularly targeted pediatric cancer inves-
22 tigation referred to in subparagraph (A)
23 shall be designed to yield clinically mean-
24 ingful pediatric study data that is gathered
25 using appropriate formulations for each

1 age group for which the study is required,
2 regarding dosing, safety, and preliminary
3 efficacy to inform potential pediatric label-
4 ing.

5 “(ii) LIMITATION.—An investigation
6 described in subparagraph (A)(ii) may be
7 required only if the drug or biological
8 product for which the application referred
9 to in paragraph (1)(B) contains either—

10 “(I) a single new active ingre-
11 dient; or

12 “(II) more than one active ingre-
13 dient, if an application for the com-
14 bination of active ingredients has not
15 previously been approved but each ac-
16 tive ingredient is in a drug product
17 that has been previously approved to
18 treat an adult cancer.

19 “(iii) RESULTS OF ALREADY-COM-
20 PLETED PRECLINICAL STUDIES OF APPLI-
21 CATION DRUG.—With respect to an inves-
22 tigation required pursuant to paragraph
23 (1)(B), the Secretary may require the re-
24 sults of any completed preclinical studies
25 relevant to the initial pediatric study plan

1 be submitted to the Secretary at the same
2 time that the initial pediatric study plan
3 required under subsection (e)(1) is sub-
4 mitted.

5 “(iv) RULE OF CONSTRUCTION RE-
6 GARDING INACTIVE INGREDIENTS.—With
7 respect to a combination of active ingredi-
8 ents referred to in subparagraph (A)(ii),
9 such subparagraph shall not be construed
10 as addressing the use of inactive ingredi-
11 ents with such combination.”.

12 (2) DETERMINATION OF APPLICABLE REQUIRE-
13 MENTS.—Section 505B(e)(1) of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 355c(e)(1)) is
15 amended by adding at the end the following: “The
16 Secretary shall determine whether subparagraph (A)
17 or (B) of subsection (a)(1) applies with respect to an
18 application before the date on which the applicant is
19 required to submit the initial pediatric study plan
20 under paragraph (2)(A).”.

21 (3) CLARIFYING APPLICABILITY.—Section
22 505B(a)(1) of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 355c(a)(1)) is amended by
24 adding at the end the following:

1 “(C) RULE OF CONSTRUCTION.—No appli-
2 cation that is subject to the requirements of
3 subparagraph (B) shall be subject to the re-
4 quirements of subparagraph (A), and no appli-
5 cation (or supplement to an application) that is
6 subject to the requirements of subparagraph
7 (A) shall be subject to the requirements of sub-
8 paragraph (B).”.

9 (4) CONFORMING AMENDMENTS.—Section
10 505B(a) of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 355c(a)) is amended—

12 (A) in paragraph (3)(C), as redesignated
13 by paragraph (1)(A) of this subsection, by
14 striking “investigations described in this para-
15 graph” and inserting “investigations referred to
16 in subparagraph (A)”; and

17 (B) in paragraph (3)(D), as redesignated
18 by paragraph (1)(A) of this subsection, by
19 striking “the assessments under paragraph
20 (2)(B)” and inserting “the assessments re-
21 quired under paragraph (1)(A)”.

22 (b) GUIDANCE.—The Secretary of Health and
23 Human Services, acting through the Commissioner of
24 Food and Drugs, shall—

1 (1) not later than 12 months after the date of
2 enactment of this Act, issue draft guidance on the
3 implementation of the amendments made by sub-
4 section (a); and

5 (2) not later than 12 months after closing the
6 comment period on such draft guidance, finalize
7 such guidance.

8 (c) APPLICABILITY.—The amendments made by this
9 section apply with respect to any application under section
10 505(b) of the Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 355(b)) and any application under section 351(a)
12 of the Public Health Service Act (42 U.S.C. 262(a)), that
13 is submitted on or after the date that is 3 years after the
14 date of enactment of this Act.

15 (d) REPORTS TO CONGRESS.—

16 (1) SECRETARY OF HEALTH AND HUMAN SERV-
17 ICES.—Not later than 6 years after the date of en-
18 actment of this Act, the Secretary of Health and
19 Human Services shall submit to the Committee on
20 Energy and Commerce of the House of Representa-
21 tives and the Committee on Health, Education,
22 Labor, and Pensions of the Senate a report on the
23 Secretary's efforts, in coordination with industry, to
24 ensure implementation of the amendments made by
25 subsection (a).

1 (2) GAO STUDY AND REPORT.—

2 (A) STUDY.—Not later than 8 years after
3 the date of enactment of this Act, the Comp-
4 troller General of the United States shall con-
5 duct a study of the effectiveness of requiring
6 assessments and investigations described in sec-
7 tion 505B of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C.355c), as amended by sub-
9 section (a), in the development of drugs and bi-
10 ological products for pediatric cancer indica-
11 tions, including consideration of any benefits to,
12 or burdens on, pediatric cancer drug develop-
13 ment.

14 (B) FINDINGS.—Not later than 10 years
15 after the date of enactment of this Act, the
16 Comptroller General shall submit to the Com-
17 mittee on Energy and Commerce of the House
18 of Representatives and the Committee on
19 Health, Education, Labor, and Pensions of the
20 Senate a report containing the findings of the
21 study conducted under subparagraph (A).

22 **SEC. 802. ENSURING COMPLETION OF PEDIATRIC STUDY**
23 **REQUIREMENTS.**

24 (a) EQUAL ACCOUNTABILITY FOR PEDIATRIC STUDY
25 REQUIREMENTS.—Section 505B(d) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355c(d)) is amend-
2 ed—

3 (1) in paragraph (1), by striking “Beginning
4 270” and inserting “NONCOMPLIANCE LETTER.—
5 Beginning 270”;

6 (2) in paragraph (2)—

7 (A) by striking “The drug or” and insert-
8 ing “EFFECT OF NONCOMPLIANCE.—The drug
9 or”; and

10 (B) by striking “(except that the drug or
11 biological product shall not be subject to action
12 under section 303)” and inserting “(except that
13 the drug or biological product shall be subject
14 to action under section 303 only if such person
15 demonstrated a lack of due diligence in satis-
16 fying the applicable requirement)”; and

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

18 “(3) LIMITATION.—The Secretary shall not
19 issue enforcement actions under section 303 for fail-
20 ures under this subsection in the case of a drug or
21 biological product that is no longer marketed.”.

22 (b) DUE DILIGENCE.—Section 505B(d) of the Fed-
23 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)),
24 as amended by subsection (a), is further amended by add-
25 ing at the end the following:

1 “(4) DUE DILIGENCE.—Before the Secretary
2 may conclude that a person failed to submit or oth-
3 erwise meet a requirement as described in the mat-
4 ter preceding paragraph (1), the Secretary shall—

5 “(A) issue a noncompliance letter pursuant
6 to paragraph (1);

7 “(B) provide such person with a 45-day
8 period beginning on the date of receipt of such
9 noncompliance letter to respond in writing as
10 set forth in such paragraph; and

11 “(C) after reviewing such written response,
12 determine whether the person demonstrated a
13 lack of due diligence in satisfying such require-
14 ment.”.

15 (c) CONFORMING AMENDMENTS.—Section
16 303(f)(4)(A) of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 333(f)(4)(A)) is amended by striking “or 505–
18 1” and inserting “505–1, or 505B”.

19 (d) TRANSITION RULE.—The Secretary of Health
20 and Human Services may take enforcement action under
21 section 303 of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 333) only for failures described in section
23 505B(d) of such Act (21 U.S.C. 355c(d)) that occur on
24 or after the date that is 180 days after the date of enact-
25 ment of this Act.

1 **SEC. 803. FDA REPORT ON PREA ENFORCEMENT.**

2 Section 508(b) of the Food and Drug Administration
3 Safety and Innovation Act (21 U.S.C. 355c–1(b)) is
4 amended—

5 (1) in paragraph (11), by striking the semicolon
6 at the end and inserting “, including an evaluation
7 of compliance with deadlines provided for in defer-
8 rals and deferral extensions;”;

9 (2) in paragraph (15), by striking “and” at the
10 end;

11 (3) in paragraph (16), by striking the period at
12 the end and inserting “; and”; and

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

14 “(17) a listing of penalties, settlements, or pay-
15 ments under section 303 of the Federal Food, Drug,
16 and Cosmetic Act (21 U.S.C. 353) for failure to
17 comply with requirements under such section 505B,
18 including, for each penalty, settlement, or payment,
19 the name of the drug, the sponsor thereof, and the
20 amount of the penalty, settlement, or payment im-
21 posed; and”.

22 **SEC. 804. EXTENSION OF AUTHORITY TO ISSUE PRIORITY**
23 **REVIEW VOUCHERS TO ENCOURAGE TREAT-**
24 **MENTS FOR RARE PEDIATRIC DISEASES.**

25 (a) EXTENSION.—Paragraph (5) of section 529(b) of
26 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 360ff(b)) is amended by striking “December 20, 2024, un-
2 less” and all that follows through the period at the end
3 and inserting “September 30, 2029.”.

4 (b) USER FEE PAYMENT.—Section 529(c)(4) of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 360ff(c)(4)) is amended by striking subparagraph (A) and
7 inserting the following:

8 “(A) IN GENERAL.—The priority review
9 user fee required by this subsection shall be due
10 upon the submission of a human drug applica-
11 tion under section 505(b)(1) or section 351(a)
12 of the Public Health Service Act for which the
13 priority review voucher is used. All other user
14 fees associated with the human drug application
15 shall be due as required by the Secretary or
16 under applicable law.”.

17 (c) GAO REPORT ON EFFECTIVENESS OF RARE PE-
18 DIATRIC DISEASE PRIORITY VOUCHER AWARDS IN
19 INCENTIVIZING RARE PEDIATRIC DISEASE DRUG DEVEL-
20 OPMENT.—

21 (1) GAO STUDY.—

22 (A) STUDY.—The Comptroller General of
23 the United States shall conduct a study of the
24 effectiveness of awarding rare pediatric disease
25 priority vouchers under section 529 of the Fed-

1 eral Food, Drug, and Cosmetic Act (21 U.S.C.
2 360ff), as amended by subsection (a), in the de-
3 velopment of human drug products that treat or
4 prevent rare pediatric diseases (as defined in
5 such section 529).

6 (B) CONTENTS OF STUDY.—In conducting
7 the study under subparagraph (A), the Comp-
8 troller General shall examine the following:

9 (i) The indications for each drug or
10 biological product that—

11 (I) is the subject of a rare pedi-
12 atric disease product application (as
13 defined in section 529 of the Federal
14 Food, Drug, and Cosmetic Act (21
15 U.S.C. 360ff)) for which a priority re-
16 view voucher was awarded; and

17 (II) was approved under section
18 505 of the Federal Food, Drug, and
19 Cosmetic Act (42 U.S.C. 355) or li-
20 censed under section 351 of the Pub-
21 lic Health Service Act (42 U.S.C.
22 262).

23 (ii) Whether, and to what extent, an
24 unmet need related to the treatment or
25 prevention of a rare pediatric disease was

1 met through the approval or licensure of
2 such a drug or biological product.

3 (iii) The size of the company to which
4 a priority review voucher was awarded
5 under section 529 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 360ff)
7 for such a drug or biological product.

8 (iv) The value of such priority review
9 voucher if transferred.

10 (v) Identification of each drug for
11 which a priority review voucher awarded
12 under such section 529 was used.

13 (vi) The size of the company using
14 each priority review voucher awarded
15 under such section 529.

16 (vii) The length of the period of time
17 between the date on which a priority re-
18 view voucher was awarded under such sec-
19 tion 529 and the date on which it was
20 used.

21 (viii) Whether, and to what extent, an
22 unmet need related to the treatment or
23 prevention of a rare pediatric disease was
24 met through the approval under section
25 505 of the Federal Food, Drug, and Cos-

1 metic Act (42 U.S.C. 355) or licensure
2 under section 351 of the Public Health
3 Service Act (42 U.S.C. 262) of a drug for
4 which a priority review voucher was used.

5 (ix) Whether, and to what extent,
6 companies were motivated by the avail-
7 ability of priority review vouchers under
8 section 529 of the Federal Food, Drug,
9 and Cosmetic Act (21 U.S.C. 360ff) to at-
10 tempt to develop a drug for a rare pedi-
11 atric disease.

12 (x) Whether, and to what extent, pedi-
13 atric review vouchers awarded under such
14 section were successful in stimulating de-
15 velopment and expedited patient access to
16 drug products for treatment or prevention
17 of a rare pediatric disease that wouldn't
18 otherwise take place without the incentive
19 provided by such vouchers.

20 (xi) The impact of such priority re-
21 view vouchers on the workload, review
22 process, and public health prioritization ef-
23 forts of the Food and Drug Administra-
24 tion.

1 (xii) Any other incentives in Federal
2 law that exist for companies developing
3 drugs or biological products described in
4 clause (i).

5 (2) REPORT ON FINDINGS.—Not later than 5
6 years after the date of the enactment of this Act, the
7 Comptroller General of the United States shall sub-
8 mit to the Committee on Energy and Commerce of
9 the House of Representatives and the Committee on
10 Health, Education, Labor, and Pensions of the Sen-
11 ate a report containing the findings of the study
12 conducted under paragraph (1).

13 **SEC. 805. LIMITATIONS ON EXCLUSIVE APPROVAL OR LI-**
14 **CENSURE OF ORPHAN DRUGS.**

15 (a) IN GENERAL.—Section 527 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

17 (1) in subsection (a), in the matter following
18 paragraph (2), by striking “same disease or condi-
19 tion” and inserting “same approved use or indica-
20 tion within such rare disease or condition”;

21 (2) in subsection (b)—

22 (A) in the matter preceding paragraph (1),
23 by striking “same rare disease or condition”
24 and inserting “same approved use or indication

1 for which such 7-year period applies to such al-
2 ready approved or licensed drug”; and

3 (B) in paragraph (1), by inserting “, relat-
4 ing to the approved use or indication,” after
5 “the needs”;

6 (3) in subsection (c)(1), by striking “same rare
7 disease or condition as the already approved drug”
8 and inserting “same use or indication for which the
9 already approved or licensed drug was approved or
10 licensed”; and

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

12 “(f) APPROVED USE OR INDICATION DEFINED.—In
13 this section, the term ‘approved use or indication’ means
14 the use or indication approved under section 505 of this
15 Act or licensed under section 351 of the Public Health
16 Service Act for a drug designated under section 526 for
17 a rare disease or condition.”.

18 (b) APPLICATION OF AMENDMENTS.—The amend-
19 ments made by subsection (a) shall apply with respect to
20 any drug designated under section 526 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regard-
22 less of the date on which the drug was so designated, and
23 regardless of the date on which the drug was approved
24 under section 505 of such Act (21 U.S.C. 355) or licensed

1 under section 351 of the Public Health Service Act (42
2 U.S.C. 262).

3 **Subtitle B—United States-Abraham**
4 **Accords Cooperation and Security**

5 **SEC. 811. ESTABLISHMENT OF ABRAHAM ACCORDS OFFICE**
6 **WITHIN FOOD AND DRUG ADMINISTRATION.**

7 (a) IN GENERAL.—Chapter X of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-
9 ed by adding at the end the following:

10 **“SEC. 1015. ABRAHAM ACCORDS OFFICE.**

11 “(a) IN GENERAL.—The Secretary, acting through
12 the Commissioner of Food and Drugs, shall establish with-
13 in the Food and Drug Administration an office, to be
14 known as the Abraham Accords Office, to be headed by
15 a director.

16 “(b) OFFICE.—Not later than 2 years after the date
17 of enactment of this section, the Secretary shall—

18 “(1) in consultation with the governments of
19 Abraham Accords countries, as well as appropriate
20 United States Government diplomatic and security
21 personnel—

22 “(A) select the location of the Abraham
23 Accords Office in an Abraham Accords country;
24 and

25 “(B) establish such office; and

1 “(2) assign to such office such personnel of the
2 Food and Drug Administration as the Secretary de-
3 termines necessary to carry out the functions of
4 such office.

5 “(c) DUTIES.—The Secretary, acting through the Di-
6 rector of the Abraham Accords Office, shall—

7 “(1) after the Abraham Accords Office is estab-
8 lished—

9 “(A) as part of the Food and Drug Admin-
10 istration’s work to strengthen the international
11 oversight of regulated commodities, provide
12 technical assistance to regulatory partners in
13 Abraham Accords countries on strengthening
14 regulatory oversight and converging regulatory
15 requirements for the oversight of regulated
16 products, including good manufacturing prac-
17 tices and other issues relevant to manufacturing
18 medical products that are regulated by the
19 Food and Drug Administration; and

20 “(B) facilitate interactions between the
21 Food and Drug Administration and interested
22 parties in Abraham Accords countries, including
23 by sharing relevant information regarding
24 United States regulatory pathways with such
25 parties, and facilitate feedback on the research,

1 development, and manufacturing of products
2 regulated in accordance with this Act; and

3 “(2) carry out other functions and activities as
4 the Secretary determines to be necessary to carry
5 out this section.

6 “(d) ABRAHAM ACCORDS COUNTRY DEFINED.—In
7 this section, the term ‘Abraham Accords country’ means
8 a country identified by the Department of State as having
9 signed the Abraham Accords Declaration.

10 “(e) NATIONAL SECURITY.—Nothing in this section
11 shall be construed to require any action inconsistent with
12 a national security recommendation provided by the Fed-
13 eral Government.”.

14 (b) REPORT TO CONGRESS.—

15 (1) IN GENERAL.—Not later than 3 years after
16 the date of enactment of this Act, the Secretary of
17 Health and Human Services shall submit to the
18 Congress a report on the Abraham Accords Office,
19 including—

20 (A) an evaluation of how the Office has ad-
21 vanced progress toward conformance with Food
22 and Drug Administration regulatory require-
23 ments by manufacturers in the Abraham Ac-
24 cords countries;

1 (B) a numerical count of parties that the
2 Office has helped facilitate interactions or feed-
3 back pursuant to section 1015(c)(1)(B) of the
4 Federal Food, Drug, and Cosmetic Act (as
5 added by subsection (a));

6 (C) a summary of technical assistance pro-
7 vided to regulatory partners in Abraham Ac-
8 cords countries pursuant to subparagraph (A)
9 of such section 1015(c)(1); and

10 (D) recommendations for increasing and
11 improving coordination between the Food and
12 Drug Administration and entities in Abraham
13 Accords countries.

14 (2) ABRAHAM ACCORDS COUNTRY DEFINED.—
15 In this subsection, the term “Abraham Accords
16 country” has the meaning given such term in section
17 1015(d) of the Federal Food, Drug, and Cosmetic
18 Act (as added by subsection (a)).

19 **TITLE IX—LOWERING**
20 **PRESCRIPTION DRUG COSTS**

21 **SEC. 901. OVERSIGHT OF PHARMACY BENEFIT MANAGE-**
22 **MENT SERVICES.**

23 (a) PUBLIC HEALTH SERVICE ACT.—Title XXVII of
24 the Public Health Service Act (42 U.S.C. 300gg et seq.)
25 is amended—

1 (1) in part D (42 U.S.C. 300gg–111 et seq.),
2 by adding at the end the following new section:

3 **“SEC. 2799A–11. OVERSIGHT OF ENTITIES THAT PROVIDE**
4 **PHARMACY BENEFIT MANAGEMENT SERV-**
5 **ICES.**

6 “(a) IN GENERAL.—For plan years beginning on or
7 after the date that is 30 months after the date of enact-
8 ment of this section (referred to in this subsection and
9 subsection (b) as the ‘effective date’), a group health plan
10 or a health insurance issuer offering group health insur-
11 ance coverage, or an entity providing pharmacy benefit
12 management services on behalf of such a plan or issuer,
13 shall not enter into a contract, including an extension or
14 renewal of a contract, entered into on or after the effective
15 date, with an applicable entity unless such applicable enti-
16 ty agrees to—

17 “(1) not limit or delay the disclosure of infor-
18 mation to the group health plan (including such a
19 plan offered through a health insurance issuer) in
20 such a manner that prevents an entity providing
21 pharmacy benefit management services on behalf of
22 a group health plan or health insurance issuer offer-
23 ing group health insurance coverage from making
24 the reports described in subsection (b); and

1 “(2) provide the entity providing pharmacy ben-
2 efit management services on behalf of a group health
3 plan or health insurance issuer relevant information
4 necessary to make the reports described in sub-
5 section (b).

6 “(b) REPORTS.—

7 “(1) IN GENERAL.—For plan years beginning
8 on or after the effective date, in the case of any con-
9 tract between a group health plan or a health insur-
10 ance issuer offering group health insurance coverage
11 offered in connection with such a plan and an entity
12 providing pharmacy benefit management services on
13 behalf of such plan or issuer, including an extension
14 or renewal of such a contract, entered into on or
15 after the effective date, the entity providing phar-
16 macy benefit management services on behalf of such
17 a group health plan or health insurance issuer, not
18 less frequently than every 6 months (or, at the re-
19 quest of a group health plan, not less frequently
20 than quarterly, and under the same conditions,
21 terms, and cost of the semiannual report under this
22 subsection), shall submit to the group health plan a
23 report in accordance with this section. Each such re-
24 port shall be made available to such group health
25 plan in plain language, in a machine-readable for-

1 mat, and as the Secretary may determine, other for-
2 mats. Each such report shall include the information
3 described in paragraph (2).

4 “(2) INFORMATION DESCRIBED.—For purposes
5 of paragraph (1), the information described in this
6 paragraph is, with respect to drugs covered by a
7 group health plan or group health insurance cov-
8 erage offered by a health insurance issuer in connec-
9 tion with a group health plan during each reporting
10 period—

11 “(A) in the case of a group health plan
12 that is offered by a specified large employer or
13 that is a specified large plan, and is not offered
14 as health insurance coverage, or in the case of
15 health insurance coverage for which the election
16 under paragraph (3) is made for the applicable
17 reporting period—

18 “(i) a list of drugs for which a claim
19 was filed and, with respect to each such
20 drug on such list—

21 “(I) the contracted compensation
22 paid by the group health plan or
23 health insurance issuer for each cov-
24 ered drug (identified by the National
25 Drug Code) to the entity providing

1 pharmacy benefit management serv-
2 ices or other applicable entity on be-
3 half of the group health plan or health
4 insurance issuer;

5 “(II) the contracted compensa-
6 tion paid to the pharmacy, by any en-
7 tity providing pharmacy benefit man-
8 agement services or other applicable
9 entity on behalf of the group health
10 plan or health insurance issuer, for
11 each covered drug (identified by the
12 National Drug Code);

13 “(III) for each such claim, the
14 difference between the amount paid
15 under subclause (I) and the amount
16 paid under subclause (II);

17 “(IV) the proprietary name, es-
18 tablished name or proper name, and
19 National Drug Code;

20 “(V) for each claim for the drug
21 (including original prescriptions and
22 refills) and for each dosage unit of the
23 drug for which a claim was filed, the
24 type of dispensing channel used to

1 furnish the drug, including retail, mail
2 order, or specialty pharmacy;

3 “(VI) with respect to each drug
4 dispensed, for each type of dispensing
5 channel (including retail, mail order,
6 or specialty pharmacy)—

7 “(aa) whether such drug is a
8 brand name drug or a generic
9 drug, and—

10 “(AA) in the case of a
11 brand name drug, the whole-
12 sale acquisition cost, listed
13 as cost per days supply and
14 cost per dosage unit, on the
15 date such drug was dis-
16 pensed; and

17 “(BB) in the case of a
18 generic drug, the average
19 wholesale price, listed as
20 cost per days supply and
21 cost per dosage unit, on the
22 date such drug was dis-
23 pensed; and

24 “(bb) the total number of—

1 “(AA) prescription
2 claims (including original
3 prescriptions and refills);

4 “(BB) participants and
5 beneficiaries for whom a
6 claim for such drug was
7 filed through the applicable
8 dispensing channel;

9 “(CC) dosage units and
10 dosage units per fill of such
11 drug; and

12 “(DD) days supply of
13 such drug per fill;

14 “(VII) the net price per course of
15 treatment or single fill, such as a 30-
16 day supply or 90-day supply to the
17 plan or coverage after rebates, fees,
18 alternative discounts, or other remun-
19 eration received from applicable enti-
20 ties;

21 “(VIII) the total amount of out-
22 of-pocket spending by participants
23 and beneficiaries on such drug, 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 “(IX) the total net spending on
7 the drug;

8 “(X) the total amount received,
9 or expected to be received, by the plan
10 or issuer from any applicable entity in
11 rebates, fees, alternative discounts, or
12 other remuneration;

13 “(XI) the total amount received,
14 or expected to be received, by the enti-
15 ty providing pharmacy benefit man-
16 agement services, from applicable en-
17 tities, in rebates, fees, alternative dis-
18 counts, or other remuneration from
19 such entities—

20 “(aa) for claims incurred
21 during the reporting period; and

22 “(bb) that is related to utili-
23 zation of such drug or spending
24 on such drug; and

1 “(XII) to the extent feasible, in-
2 formation on the total amount of re-
3 muneration for such drug, including
4 copayment assistance dollars paid, co-
5 payment cards applied, or other dis-
6 counts provided by each drug manu-
7 facturer (or entity administering co-
8 payment assistance on behalf of such
9 drug manufacturer), to the partici-
10 pants and beneficiaries enrolled in
11 such plan or coverage;

12 “(ii) a list of each therapeutic class
13 (as defined by the Secretary) for which a
14 claim was filed under the group health
15 plan or health insurance coverage during
16 the reporting period, and, with respect to
17 each such therapeutic class—

18 “(I) the total gross spending on
19 drugs in such class before rebates,
20 price concessions, alternative dis-
21 counts, or other remuneration from
22 applicable entities;

23 “(II) the net spending in such
24 class after such rebates, price conces-

1 sions, alternative discounts, or other
2 remuneration from applicable entities;

3 “(III) 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 drugs or drug spending;

14 “(IV) the average net spending
15 per 30-day supply and per 90-day
16 supply by the plan or by the issuer
17 with respect to such coverage and its
18 participants and beneficiaries, among
19 all drugs within the therapeutic class
20 for which a claim was filed during the
21 reporting period;

22 “(V) the number of participants
23 and beneficiaries who filled a prescrip-
24 tion for a drug in such class, includ-

1 ing the National Drug Code for each
2 such drug;

3 “(VI) if applicable, a description
4 of the formulary tiers and utilization
5 mechanisms (such as prior authoriza-
6 tion or step therapy) employed for
7 drugs in that class; and

8 “(VII) the total out-of-pocket
9 spending under the plan or coverage
10 by participants and beneficiaries, in-
11 cluding spending through copayments,
12 coinsurance, and deductibles, but not
13 including any amounts spent by par-
14 ticipants and beneficiaries on drugs
15 not covered under the plan or cov-
16 erage or for which no claim is sub-
17 mitted under the plan or coverage;

18 “(iii) with respect to any drug for
19 which gross spending under the group
20 health plan or health insurance coverage
21 exceeded \$10,000 during the reporting pe-
22 riod or, in the case that gross spending
23 under the group health plan or coverage
24 exceeded \$10,000 during the reporting pe-
25 riod with respect to fewer than 50 drugs,

1 with respect to the 50 prescription drugs
2 with the highest spending during the re-
3 porting period—

4 “(I) a list of all other drugs in
5 the same therapeutic class as such
6 drug;

7 “(II) if applicable, the rationale
8 for the formulary placement of such
9 drug in that therapeutic category or
10 class, selected from a list of standard
11 rationales established by the Sec-
12 retary, in consultation with stake-
13 holders; and

14 “(III) any change in formulary
15 placement compared to the prior plan
16 year; and

17 “(iv) in the case that such plan or
18 issuer (or an entity providing pharmacy
19 benefit management services on behalf of
20 such plan or issuer) has an affiliated phar-
21 macy or pharmacy under common owner-
22 ship, including mandatory mail and spe-
23 cialty home delivery programs, retail and
24 mail auto-refill programs, and cost sharing

1 assistance incentives funded by an entity
2 providing pharmacy benefit services—

3 “(I) an explanation of any ben-
4 efit design parameters that encourage
5 or require participants and bene-
6 ficiaries in the plan or coverage to fill
7 prescriptions at mail order, specialty,
8 or retail pharmacies;

9 “(II) the percentage of total pre-
10 scriptions dispensed by such phar-
11 macies to participants or beneficiaries
12 in such plan or coverage; and

13 “(III) a list of all drugs dis-
14 pensed by such pharmacies to partici-
15 pants or beneficiaries enrolled in such
16 plan or coverage, and, with respect to
17 each drug dispensed—

18 “(aa) the amount charged,
19 per dosage unit, per 30-day sup-
20 ply, or per 90-day supply (as ap-
21 plicable) to the plan or issuer,
22 and to participants and bene-
23 ficiaries;

24 “(bb) the median amount
25 charged to such plan or issuer,

1 and the interquartile range of the
2 costs, per dosage unit, per 30-
3 day supply, and per 90-day sup-
4 ply, including amounts paid by
5 the participants and bene-
6 ficiaries, when the same drug is
7 dispensed by other pharmacies
8 that are not affiliated with or
9 under common ownership with
10 the entity and that are included
11 in the pharmacy network of such
12 plan or coverage;

13 “(cc) the lowest cost per
14 dosage unit, per 30-day supply
15 and per 90-day supply, for each
16 such drug, including amounts
17 charged to the plan or coverage
18 and to participants and bene-
19 ficiaries, that is available from
20 any pharmacy included in the
21 network of such plan or coverage;
22 and

23 “(dd) the net acquisition
24 cost per dosage unit, per 30-day
25 supply, and per 90-day supply, if

1 such drug is subject to a max-
2 imum price discount; and

3 “(B) with respect to any group health
4 plan, including group health insurance coverage
5 offered in connection with such a plan, regard-
6 less of whether the plan or coverage is offered
7 by a specified large employer or whether it is a
8 specified large plan—

9 “(i) a summary document for the
10 group health plan that includes such infor-
11 mation described in clauses (i) through (iv)
12 of subparagraph (A), as specified by the
13 Secretary through guidance, program in-
14 struction, or otherwise (with no require-
15 ment of notice and comment rulemaking),
16 that the Secretary determines useful to
17 group health plans for purposes of select-
18 ing pharmacy benefit management serv-
19 ices, such as an estimated net price to
20 group health plan and participant or bene-
21 ficiary, a cost per claim, the fee structure
22 or reimbursement model, and estimated
23 cost per participant or beneficiary;

24 “(ii) a summary document for plans
25 and issuers to provide to participants and

1 beneficiaries, which shall be made available
2 to participants or beneficiaries upon re-
3 quest to their group health plan (including
4 in the case of group health insurance cov-
5 erage offered in connection with such a
6 plan), that—

7 “(I) contains such information
8 described in clauses (iii), (iv), (v), and
9 (vi), as applicable, as specified by the
10 Secretary through guidance, program
11 instruction, or otherwise (with no re-
12 quirement of notice and comment
13 rulemaking) that the Secretary deter-
14 mines useful to participants or bene-
15 ficiaries in better understanding the
16 plan or coverage or benefits under
17 such plan or coverage;

18 “(II) contains only aggregate in-
19 formation; and

20 “(III) states that participants
21 and beneficiaries may request specific,
22 claims-level information required to be
23 furnished under subsection (c) from
24 the group health plan or health insur-
25 ance issuer; and

1 “(iii) with respect to drugs covered by
2 such plan or coverage during such report-
3 ing period—

4 “(I) the total net spending by the
5 plan or coverage for all such drugs;

6 “(II) the total amount received,
7 or expected to be received, by the plan
8 or issuer from any applicable entity in
9 rebates, fees, alternative discounts, or
10 other remuneration; and

11 “(III) to the extent feasible, in-
12 formation on the total amount of re-
13 muneration for such drugs, including
14 copayment assistance dollars paid, co-
15 payment cards applied, or other dis-
16 counts provided by each drug manu-
17 facturer (or entity administering co-
18 payment assistance on behalf of such
19 drug manufacturer) to participants
20 and beneficiaries;

21 “(iv) amounts paid directly or indi-
22 rectly in rebates, fees, or any other type of
23 compensation (as defined in section
24 408(b)(2)(B)(ii)(dd)(AA) of the Employee
25 Retirement Income Security Act) to bro-

1 kerage firms, brokers, consultants, advi-
2 sors, or any other individual or firm, for—

3 “(I) the referral of the group
4 health plan’s or health insurance
5 issuer’s business to an entity pro-
6 viding pharmacy benefit management
7 services, including the identity of the
8 recipient of such amounts;

9 “(II) consideration of the entity
10 providing pharmacy benefit manage-
11 ment services by the group health
12 plan or health insurance issuer; or

13 “(III) the retention of the entity
14 by the group health plan or health in-
15 surance issuer;

16 “(v) an explanation of any benefit de-
17 sign parameters that encourage or require
18 participants and beneficiaries in such plan
19 or coverage to fill prescriptions at mail
20 order, specialty, or retail pharmacies that
21 are affiliated with or under common own-
22 ership with the entity providing pharmacy
23 benefit management services under such
24 plan or coverage, including mandatory mail
25 and specialty home delivery programs, re-

1 tail and mail auto-refill programs, and
2 cost-sharing assistance incentives directly
3 or indirectly funded by such entity; and

4 “(vi) total gross spending on all drugs
5 under the plan or coverage during the re-
6 porting period.

7 “(3) OPT-IN FOR GROUP HEALTH INSURANCE
8 COVERAGE OFFERED BY A SPECIFIED LARGE EM-
9 PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In
10 the case of group health insurance coverage offered
11 in connection with a group health plan that is of-
12 fered by a specified large employer or is a specified
13 large plan, such group health plan may, on an an-
14 nual basis, for plan years beginning on or after the
15 date that is 30 months after the date of enactment
16 of this section, elect to require an entity providing
17 pharmacy benefit management services on behalf of
18 the health insurance issuer to submit to such group
19 health plan a report that includes all of the informa-
20 tion described in paragraph (2)(A), in addition to
21 the information described in paragraph (2)(B).

22 “(4) PRIVACY REQUIREMENTS.—

23 “(A) IN GENERAL.—An entity providing
24 pharmacy benefit management services on be-
25 half of a group health plan or a health insur-

1 ance issuer offering group health insurance cov-
2 erage shall report information under paragraph
3 (1) in a manner consistent with the privacy reg-
4 ulations promulgated under section 13402(a) of
5 the Health Information Technology for Eco-
6 nomic and Clinical Health Act and consistent
7 with the privacy regulations promulgated under
8 the Health Insurance Portability and Account-
9 ability Act of 1996 in part 160 and subparts A
10 and E of part 164 of title 45, Code of Federal
11 Regulations (or successor regulations) (referred
12 to in this paragraph as the ‘HIPAA privacy
13 regulations’) and shall restrict the use and dis-
14 closure of such information according to such
15 privacy regulations and such HIPAA privacy
16 regulations.

17 “(B) ADDITIONAL REQUIREMENTS.—

18 “(i) IN GENERAL.—An entity pro-
19 viding pharmacy benefit management serv-
20 ices on behalf of a group health plan or
21 health insurance issuer offering group
22 health insurance coverage that submits a
23 report under paragraph (1) shall ensure
24 that such report contains only summary
25 health information, as defined in section

1 164.504(a) of title 45, Code of Federal
2 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, including with respect to
9 group health insurance coverage offered in con-
10 nection with a group health plan, shall provide
11 to each participant or beneficiary written notice
12 informing the participant or beneficiary of the
13 requirement for entities providing pharmacy
14 benefit management services on behalf of the
15 group health plan or health insurance issuer of-
16 fering group health insurance coverage to sub-
17 mit reports to group health plans under para-
18 graph (1), as applicable, which may include in-
19 corporating such notification in plan documents
20 provided to the participant or beneficiary, or
21 providing individual notification.

22 “(E) LIMITATION TO BUSINESS ASSOCI-
23 ATES.—A group health plan receiving a report
24 under paragraph (1) may disclose such informa-
25 tion only to the entity from which the report

1 was received or to that entity's business associ-
2 ates as defined in section 160.103 of title 45,
3 Code of Federal Regulations (or successor regu-
4 lations) or as permitted by the HIPAA privacy
5 regulations.

6 “(F) CLARIFICATION REGARDING PUBLIC
7 DISCLOSURE OF INFORMATION.—Nothing in
8 this section shall prevent an entity providing
9 pharmacy benefit management services on be-
10 half of a group health plan or health insurance
11 issuer offering group health insurance coverage,
12 from placing reasonable restrictions on the pub-
13 lic disclosure of the information contained in a
14 report described in paragraph (1), except that
15 such plan, issuer, or entity may not—

16 “(i) restrict disclosure of such report
17 to the Department of Health and Human
18 Services, the Department of Labor, or the
19 Department of the Treasury; or

20 “(ii) prevent disclosure for the pur-
21 poses of subsection (c), or any other public
22 disclosure requirement under this section.

23 “(G) LIMITED FORM OF REPORT.—The
24 Secretary shall define through rulemaking a
25 limited form of the report under paragraph (1)

1 required with respect to any group health plan
2 established by a plan sponsor that is, or is af-
3 filiated with, a drug manufacturer, drug whole-
4 saler, or other direct participant in the drug
5 supply chain, in order to prevent anti-competi-
6 tive behavior.

7 “(5) STANDARD FORMAT AND REGULATIONS.—

8 “(A) IN GENERAL.—Not later than 18
9 months after the date of enactment of this sec-
10 tion, the Secretary shall specify through rule-
11 making a standard format for entities providing
12 pharmacy benefit management services on be-
13 half of group health plans and health insurance
14 issuers offering group health insurance cov-
15 erage, to submit reports required under para-
16 graph (1).

17 “(B) ADDITIONAL REGULATIONS.—Not
18 later than 18 months after the date of enact-
19 ment of this section, the Secretary shall,
20 through rulemaking, promulgate any other final
21 regulations necessary to implement the require-
22 ments of this section. In promulgating such
23 regulations, the Secretary shall, to the extent
24 practicable, align the reporting requirements

1 under this section with the reporting require-
2 ments under section 2799A–10.

3 “(c) REQUIREMENT TO PROVIDE INFORMATION TO
4 PARTICIPANTS OR BENEFICIARIES.—A group health plan,
5 including with respect to group health insurance coverage
6 offered in connection with a group health plan, upon re-
7 quest of a participant or beneficiary, shall provide to such
8 participant or beneficiary—

9 “(1) the summary document described in sub-
10 section (b)(2)(B)(ii); and

11 “(2) the information described in subsection
12 (b)(2)(A)(i)(III) with respect to a claim made by or
13 on behalf of such participant or beneficiary.

14 “(d) ENFORCEMENT.—

15 “(1) IN GENERAL.—The Secretary shall enforce
16 this section. The enforcement authority under this
17 subsection shall apply only with respect to group
18 health plans (including group health insurance cov-
19 erage offered in connection with such a plan) to
20 which the requirements of subparts I and II of part
21 A and part D apply in accordance with section 2722,
22 and with respect to entities providing pharmacy ben-
23 efit management services on behalf of such plans
24 and applicable entities providing services on behalf
25 of such plans.

1 “(2) FAILURE TO PROVIDE INFORMATION.—A
2 group health plan, a health insurance issuer offering
3 group health insurance coverage, an entity providing
4 pharmacy benefit management services on behalf of
5 such a plan or issuer, or an applicable entity pro-
6 viding services on behalf of such a plan or issuer
7 that violates subsection (a); an entity providing
8 pharmacy benefit management services on behalf of
9 such a plan or issuer that fails to provide the infor-
10 mation required under subsection (b); or a group
11 health plan that fails to provide the information re-
12 quired under subsection (c), shall be subject to a
13 civil monetary penalty in the amount of \$10,000 for
14 each day during which such violation continues or
15 such information is not disclosed or reported.

16 “(3) FALSE INFORMATION.—A health insurance
17 issuer, an entity providing pharmacy benefit man-
18 agement services, or a third party administrator pro-
19 viding services on behalf of such issuer offered by a
20 health insurance issuer that knowingly provides false
21 information under this section shall be subject to a
22 civil monetary penalty in an amount not to exceed
23 \$100,000 for each item of false information. Such
24 civil monetary penalty shall be in addition to other
25 penalties as may be prescribed by law.

1 “(4) PROCEDURE.—The provisions of section
2 1128A of the Social Security Act, other than sub-
3 sections (a) and (b) and the first sentence of sub-
4 section (c)(1) of such section shall apply to civil
5 monetary penalties under this subsection in the
6 same manner as such provisions apply to a penalty
7 or proceeding under such section.

8 “(5) WAIVERS.—The Secretary may waive pen-
9 alties under paragraph (2), or extend the period of
10 time for compliance with a requirement of this sec-
11 tion, for an entity in violation of this section that
12 has made a good-faith effort to comply with the re-
13 quirements in this section.

14 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion shall be construed to permit a health insurance issuer,
16 group health plan, entity providing pharmacy benefit man-
17 agement services on behalf of a group health plan or
18 health insurance issuer, or other entity to restrict disclo-
19 sure to, or otherwise limit the access of, the Secretary to
20 a report described in subsection (b)(1) or information re-
21 lated to compliance with subsections (a), (b), (c), or (d)
22 by such issuer, plan, or entity.

23 “(f) DEFINITIONS.—In this section:

24 “(1) APPLICABLE ENTITY.—The term ‘applica-
25 ble entity’ means—

1 “(A) an applicable group purchasing orga-
2 nization, drug manufacturer, distributor, whole-
3 saler, rebate aggregator (or other purchasing
4 entity designed to aggregate rebates), or associ-
5 ated third party;

6 “(B) any subsidiary, parent, affiliate, or
7 subcontractor of a group health plan, health in-
8 surance issuer, entity that provides pharmacy
9 benefit management services on behalf of such
10 a plan or issuer, or any entity described in sub-
11 paragraph (A); or

12 “(C) such other entity as the Secretary
13 may specify through rulemaking.

14 “(2) APPLICABLE GROUP PURCHASING ORGANI-
15 ZATION.—The term ‘applicable group purchasing or-
16 ganization’ means a group purchasing organization
17 that is affiliated with or under common ownership
18 with an entity providing pharmacy benefit manage-
19 ment services.

20 “(3) CONTRACTED COMPENSATION.—The term
21 ‘contracted compensation’ means the sum of any in-
22 gredient cost and dispensing fee for a drug (inclusive
23 of the out-of-pocket costs to the participant or bene-
24 ficiary), or another analogous compensation struc-

1 ture that the Secretary may specify through regula-
2 tions.

3 “(4) GROSS SPENDING.—The term ‘gross
4 spending’, with respect to prescription drug benefits
5 under a group health plan or health insurance cov-
6 erage, means the amount spent by a group health
7 plan or health insurance issuer on prescription drug
8 benefits, calculated before the application of rebates,
9 fees, alternative discounts, or other remuneration.

10 “(5) NET SPENDING.—The term ‘net spending’,
11 with respect to prescription drug benefits under a
12 group health plan or health insurance coverage,
13 means the amount spent by a group health plan or
14 health insurance issuer on prescription drug bene-
15 fits, calculated after the application of rebates, fees,
16 alternative discounts, or other remuneration.

17 “(6) PLAN SPONSOR.—The term ‘plan sponsor’
18 has the meaning given such term in section 3(16)(B)
19 of the Employee Retirement Income Security Act of
20 1974.

21 “(7) REMUNERATION.—The term ‘remunera-
22 tion’ has the meaning given such term by the Sec-
23 retary through rulemaking, which shall be reeval-
24 ated by the Secretary every 5 years.

1 “(8) SPECIFIED LARGE EMPLOYER.—The term
2 ‘specified large employer’ means, in connection with
3 a group health plan (including group health insur-
4 ance coverage offered in connection with such a
5 plan) established or maintained by a single em-
6 ployer, with respect to a calendar year or a plan
7 year, as applicable, an employer who employed an
8 average of at least 100 employees on business days
9 during the preceding calendar year or plan year and
10 who employs at least 1 employee on the first day of
11 the calendar year or plan year.

12 “(9) SPECIFIED LARGE PLAN.—The term ‘spec-
13 ified large plan’ means a group health plan (includ-
14 ing group health insurance coverage offered in con-
15 nection with such a plan) established or maintained
16 by a plan sponsor described in clause (ii) or (iii) of
17 section 3(16)(B) of the Employee Retirement In-
18 come Security Act of 1974 that had an average of
19 at least 100 participants on business days during
20 the preceding calendar year or plan year, as applica-
21 ble.

22 “(10) WHOLESALE ACQUISITION COST.—The
23 term ‘wholesale acquisition cost’ has the meaning
24 given such term in section 1847A(c)(6)(B) of the
25 Social Security Act.”; and

1 (2) in section 2723 (42 U.S.C. 300gg-22)—

2 (A) in subsection (a)—

3 (i) in paragraph (1), by inserting
4 “(other than section 2799A-11)” after
5 “part D”; and

6 (ii) in paragraph (2), by inserting
7 “(other than section 2799A-11)” after
8 “part D”; and

9 (B) in subsection (b)—

10 (i) in paragraph (1), by inserting
11 “(other than section 2799A-11)” after
12 “part D”;

13 (ii) in paragraph (2)(A), by inserting
14 “(other than section 2799A-11)” after
15 “part D”; and

16 (iii) in paragraph (2)(C)(ii), by insert-
17 ing “(other than section 2799A-11)” after
18 “part D”.

19 (b) EMPLOYEE RETIREMENT INCOME SECURITY ACT
20 OF 1974.—

21 (1) IN GENERAL.—Subtitle B of title I of the
22 Employee Retirement Income Security Act of 1974
23 (29 U.S.C. 1021 et seq.) is amended—

1 (A) in subpart B of part 7 (29 U.S.C.
2 1185 et seq.), by adding at the end the fol-
3 lowing:

4 **“SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**
5 **MACY BENEFIT MANAGEMENT SERVICES.**

6 “(a) IN GENERAL.—For plan years beginning on or
7 after the date that is 30 months after the date of enact-
8 ment of this section (referred to in this subsection and
9 subsection (b) as the ‘effective date’), a group health plan
10 or a health insurance issuer offering group health insur-
11 ance coverage, or an entity providing pharmacy benefit
12 management services on behalf of such a plan or issuer,
13 shall not enter into a contract, including an extension or
14 renewal of a contract, entered into on or after the effective
15 date, with an applicable entity unless such applicable enti-
16 ty agrees to—

17 “(1) not limit or delay the disclosure of infor-
18 mation to the group health plan (including such a
19 plan offered through a health insurance issuer) in
20 such a manner that prevents an entity providing
21 pharmacy benefit management services on behalf of
22 a group health plan or health insurance issuer offer-
23 ing group health insurance coverage from making
24 the reports described in subsection (b); and

1 “(2) provide the entity providing pharmacy ben-
2 efit management services on behalf of a group health
3 plan or health insurance issuer relevant information
4 necessary to make the reports described in sub-
5 section (b).

6 “(b) REPORTS.—

7 “(1) IN GENERAL.—For plan years beginning
8 on or after the effective date, in the case of any con-
9 tract between a group health plan or a health insur-
10 ance issuer offering group health insurance coverage
11 offered in connection with such a plan and an entity
12 providing pharmacy benefit management services on
13 behalf of such plan or issuer, including an extension
14 or renewal of such a contract, entered into on or
15 after the effective date, the entity providing phar-
16 macy benefit management services on behalf of such
17 a group health plan or health insurance issuer, not
18 less frequently than every 6 months (or, at the re-
19 quest of a group health plan, not less frequently
20 than quarterly, and under the same conditions,
21 terms, and cost of the semiannual report under this
22 subsection), shall submit to the group health plan a
23 report in accordance with this section. Each such re-
24 port shall be made available to such group health
25 plan in plain language, in a machine-readable for-

1 mat, and as the Secretary may determine, other for-
2 mats. Each such report shall include the information
3 described in paragraph (2).

4 “(2) INFORMATION DESCRIBED.—For purposes
5 of paragraph (1), the information described in this
6 paragraph is, with respect to drugs covered by a
7 group health plan or group health insurance cov-
8 erage offered by a health insurance issuer in connec-
9 tion with a group health plan during each reporting
10 period—

11 “(A) in the case of a group health plan
12 that is offered by a specified large employer or
13 that is a specified large plan, and is not offered
14 as health insurance coverage, or in the case of
15 health insurance coverage for which the election
16 under paragraph (3) is made for the applicable
17 reporting period—

18 “(i) a list of drugs for which a claim
19 was filed and, with respect to each such
20 drug on such list—

21 “(I) the contracted compensation
22 paid by the group health plan or
23 health insurance issuer for each cov-
24 ered drug (identified by the National
25 Drug Code) to the entity providing

1 pharmacy benefit management serv-
2 ices or other applicable entity on be-
3 half of the group health plan or health
4 insurance issuer;

5 “(II) the contracted compensa-
6 tion paid to the pharmacy, by any en-
7 tity providing pharmacy benefit man-
8 agement services or other applicable
9 entity on behalf of the group health
10 plan or health insurance issuer, for
11 each covered drug (identified by the
12 National Drug Code);

13 “(III) for each such claim, the
14 difference between the amount paid
15 under subclause (I) and the amount
16 paid under subclause (II);

17 “(IV) the proprietary name, es-
18 tablished name or proper name, and
19 National Drug Code;

20 “(V) for each claim for the drug
21 (including original prescriptions and
22 refills) and for each dosage unit of the
23 drug for which a claim was filed, the
24 type of dispensing channel used to

1 furnish the drug, including retail, mail
2 order, or specialty pharmacy;

3 “(VI) with respect to each drug
4 dispensed, for each type of dispensing
5 channel (including retail, mail order,
6 or specialty pharmacy)—

7 “(aa) whether such drug is a
8 brand name drug or a generic
9 drug, and—

10 “(AA) in the case of a
11 brand name drug, the whole-
12 sale acquisition cost, listed
13 as cost per days supply and
14 cost per dosage unit, on the
15 date such drug was dis-
16 pensed; and

17 “(BB) in the case of a
18 generic drug, the average
19 wholesale price, listed as
20 cost per days supply and
21 cost per dosage unit, on the
22 date such drug was dis-
23 pensed; and

24 “(bb) the total number of—

1 “(AA) prescription
2 claims (including original
3 prescriptions and refills);

4 “(BB) participants and
5 beneficiaries for whom a
6 claim for such drug was
7 filed through the applicable
8 dispensing channel;

9 “(CC) dosage units and
10 dosage units per fill of such
11 drug; and

12 “(DD) days supply of
13 such drug per fill;

14 “(VII) the net price per course of
15 treatment or single fill, such as a 30-
16 day supply or 90-day supply to the
17 plan or coverage after rebates, fees,
18 alternative discounts, or other remun-
19 eration received from applicable enti-
20 ties;

21 “(VIII) the total amount of out-
22 of-pocket spending by participants
23 and beneficiaries on such drug, 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 “(IX) the total net spending on
7 the drug;

8 “(X) the total amount received,
9 or expected to be received, by the plan
10 or issuer from any applicable entity in
11 rebates, fees, alternative discounts, or
12 other remuneration;

13 “(XI) the total amount received,
14 or expected to be received, by the enti-
15 ty providing pharmacy benefit man-
16 agement services, from applicable en-
17 tities, in rebates, fees, alternative dis-
18 counts, or other remuneration from
19 such entities—

20 “(aa) for claims incurred
21 during the reporting period; and

22 “(bb) that is related to utili-
23 zation of such drug or spending
24 on such drug; and

1 “(XII) to the extent feasible, in-
2 formation on the total amount of re-
3 muneration for such drug, including
4 copayment assistance dollars paid, co-
5 payment cards applied, or other dis-
6 counts provided by each drug manu-
7 facturer (or entity administering co-
8 payment assistance on behalf of such
9 drug manufacturer), to the partici-
10 pants and beneficiaries enrolled in
11 such plan or coverage;

12 “(ii) a list of each therapeutic class
13 (as defined by the Secretary) for which a
14 claim was filed under the group health
15 plan or health insurance coverage during
16 the reporting period, and, with respect to
17 each such therapeutic class—

18 “(I) the total gross spending on
19 drugs in such class before rebates,
20 price concessions, alternative dis-
21 counts, or other remuneration from
22 applicable entities;

23 “(II) the net spending in such
24 class after such rebates, price conces-

1 sions, alternative discounts, or other
2 remuneration from applicable entities;

3 “(III) 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 drugs or drug spending;

14 “(IV) the average net spending
15 per 30-day supply and per 90-day
16 supply by the plan or by the issuer
17 with respect to such coverage and its
18 participants and beneficiaries, among
19 all drugs within the therapeutic class
20 for which a claim was filed during the
21 reporting period;

22 “(V) the number of participants
23 and beneficiaries who filled a prescrip-
24 tion for a drug in such class, includ-

1 ing the National Drug Code for each
2 such drug;

3 “(VI) if applicable, a description
4 of the formulary tiers and utilization
5 mechanisms (such as prior authoriza-
6 tion or step therapy) employed for
7 drugs in that class; and

8 “(VII) the total out-of-pocket
9 spending under the plan or coverage
10 by participants and beneficiaries, in-
11 cluding spending through copayments,
12 coinsurance, and deductibles, but not
13 including any amounts spent by par-
14 ticipants and beneficiaries on drugs
15 not covered under the plan or cov-
16 erage or for which no claim is sub-
17 mitted under the plan or coverage;

18 “(iii) with respect to any drug for
19 which gross spending under the group
20 health plan or health insurance coverage
21 exceeded \$10,000 during the reporting pe-
22 riod or, in the case that gross spending
23 under the group health plan or coverage
24 exceeded \$10,000 during the reporting pe-
25 riod with respect to fewer than 50 drugs,

1 with respect to the 50 prescription drugs
2 with the highest spending during the re-
3 porting period—

4 “(I) a list of all other drugs in
5 the same therapeutic class as such
6 drug;

7 “(II) if applicable, the rationale
8 for the formulary placement of such
9 drug in that therapeutic category or
10 class, selected from a list of standard
11 rationales established by the Sec-
12 retary, in consultation with stake-
13 holders; and

14 “(III) any change in formulary
15 placement compared to the prior plan
16 year; and

17 “(iv) in the case that such plan or
18 issuer (or an entity providing pharmacy
19 benefit management services on behalf of
20 such plan or issuer) has an affiliated phar-
21 macy or pharmacy under common owner-
22 ship, including mandatory mail and spe-
23 cialty home delivery programs, retail and
24 mail auto-refill programs, and cost sharing

1 assistance incentives funded by an entity
2 providing pharmacy benefit services—

3 “(I) an explanation of any ben-
4 efit design parameters that encourage
5 or require participants and bene-
6 ficiaries in the plan or coverage to fill
7 prescriptions at mail order, specialty,
8 or retail pharmacies;

9 “(II) the percentage of total pre-
10 scriptions dispensed by such phar-
11 macies to participants or beneficiaries
12 in such plan or coverage; and

13 “(III) a list of all drugs dis-
14 pensed by such pharmacies to partici-
15 pants or beneficiaries enrolled in such
16 plan or coverage, and, with respect to
17 each drug dispensed—

18 “(aa) the amount charged,
19 per dosage unit, per 30-day sup-
20 ply, or per 90-day supply (as ap-
21 plicable) to the plan or issuer,
22 and to participants and bene-
23 ficiaries;

24 “(bb) the median amount
25 charged to such plan or issuer,

1 and the interquartile range of the
2 costs, per dosage unit, per 30-
3 day supply, and per 90-day sup-
4 ply, including amounts paid by
5 the participants and bene-
6 ficiaries, when the same drug is
7 dispensed by other pharmacies
8 that are not affiliated with or
9 under common ownership with
10 the entity and that are included
11 in the pharmacy network of such
12 plan or coverage;

13 “(cc) the lowest cost per
14 dosage unit, per 30-day supply
15 and per 90-day supply, for each
16 such drug, including amounts
17 charged to the plan or coverage
18 and to participants and bene-
19 ficiaries, that is available from
20 any pharmacy included in the
21 network of such plan or coverage;
22 and

23 “(dd) the net acquisition
24 cost per dosage unit, per 30-day
25 supply, and per 90-day supply, if

1 such drug is subject to a max-
2 imum price discount; and

3 “(B) with respect to any group health
4 plan, including group health insurance coverage
5 offered in connection with such a plan, regard-
6 less of whether the plan or coverage is offered
7 by a specified large employer or whether it is a
8 specified large plan—

9 “(i) a summary document for the
10 group health plan that includes such infor-
11 mation described in clauses (i) through (iv)
12 of subparagraph (A), as specified by the
13 Secretary through guidance, program in-
14 struction, or otherwise (with no require-
15 ment of notice and comment rulemaking),
16 that the Secretary determines useful to
17 group health plans for purposes of select-
18 ing pharmacy benefit management serv-
19 ices, such as an estimated net price to
20 group health plan and participant or bene-
21 ficiary, a cost per claim, the fee structure
22 or reimbursement model, and estimated
23 cost per participant or beneficiary;

24 “(ii) a summary document for plans
25 and issuers to provide to participants and

1 beneficiaries, which shall be made available
2 to participants or beneficiaries upon re-
3 quest to their group health plan (including
4 in the case of group health insurance cov-
5 erage offered in connection with such a
6 plan), that—

7 “(I) contains such information
8 described in clauses (iii), (iv), (v), and
9 (vi), as applicable, as specified by the
10 Secretary through guidance, program
11 instruction, or otherwise (with no re-
12 quirement of notice and comment
13 rulemaking) that the Secretary deter-
14 mines useful to participants or bene-
15 ficiaries in better understanding the
16 plan or coverage or benefits under
17 such plan or coverage;

18 “(II) contains only aggregate in-
19 formation; and

20 “(III) states that participants
21 and beneficiaries may request specific,
22 claims-level information required to be
23 furnished under subsection (c) from
24 the group health plan or health insur-
25 ance issuer; and

1 “(iii) with respect to drugs covered by
2 such plan or coverage during such report-
3 ing period—

4 “(I) the total net spending by the
5 plan or coverage for all such drugs;

6 “(II) the total amount received,
7 or expected to be received, by the plan
8 or issuer from any applicable entity in
9 rebates, fees, alternative discounts, or
10 other remuneration; and

11 “(III) to the extent feasible, in-
12 formation on the total amount of re-
13 muneration for such drugs, including
14 copayment assistance dollars paid, co-
15 payment cards applied, or other dis-
16 counts provided by each drug manu-
17 facturer (or entity administering co-
18 payment assistance on behalf of such
19 drug manufacturer) to participants
20 and beneficiaries;

21 “(iv) amounts paid directly or indi-
22 rectly in rebates, fees, or any other type of
23 compensation (as defined in section
24 408(b)(2)(B)(ii)(dd)(AA)) to brokerage

1 firms, brokers, consultants, advisors, or
2 any other individual or firm, for—

3 “(I) the referral of the group
4 health plan’s or health insurance
5 issuer’s business to an entity pro-
6 viding pharmacy benefit management
7 services, including the identity of the
8 recipient of such amounts;

9 “(II) consideration of the entity
10 providing pharmacy benefit manage-
11 ment services by the group health
12 plan or health insurance issuer; or

13 “(III) the retention of the entity
14 by the group health plan or health in-
15 surance issuer;

16 “(v) an explanation of any benefit de-
17 sign parameters that encourage or require
18 participants and beneficiaries in such plan
19 or coverage to fill prescriptions at mail
20 order, specialty, or retail pharmacies that
21 are affiliated with or under common own-
22 ership with the entity providing pharmacy
23 benefit management services under such
24 plan or coverage, including mandatory mail
25 and specialty home delivery programs, re-

1 tail and mail auto-refill programs, and
2 cost-sharing assistance incentives directly
3 or indirectly funded by such entity; and

4 “(vi) total gross spending on all drugs
5 under the plan or coverage during the re-
6 porting period.

7 “(3) OPT-IN FOR GROUP HEALTH INSURANCE
8 COVERAGE OFFERED BY A SPECIFIED LARGE EM-
9 PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In
10 the case of group health insurance coverage offered
11 in connection with a group health plan that is of-
12 fered by a specified large employer or is a specified
13 large plan, such group health plan may, on an an-
14 nual basis, for plan years beginning on or after the
15 date that is 30 months after the date of enactment
16 of this section, elect to require an entity providing
17 pharmacy benefit management services on behalf of
18 the health insurance issuer to submit to such group
19 health plan a report that includes all of the informa-
20 tion described in paragraph (2)(A), in addition to
21 the information described in paragraph (2)(B).

22 “(4) PRIVACY REQUIREMENTS.—

23 “(A) IN GENERAL.—An entity providing
24 pharmacy benefit management services on be-
25 half of a group health plan or a health insur-

1 ance issuer offering group health insurance cov-
2 erage shall report information under paragraph
3 (1) in a manner consistent with the privacy reg-
4 ulations promulgated under section 13402(a) of
5 the Health Information Technology for Eco-
6 nomic and Clinical Health Act (42 U.S.C.
7 17932(a)) and consistent with the privacy regu-
8 lations promulgated under the Health Insur-
9 ance Portability and Accountability Act of 1996
10 in part 160 and subparts A and E of part 164
11 of title 45, Code of Federal Regulations (or suc-
12 cessor regulations) (referred to in this para-
13 graph as the ‘HIPAA privacy regulations’) and
14 shall restrict the use and disclosure of such in-
15 formation according to such privacy regulations
16 and such HIPAA privacy regulations.

17 “(B) ADDITIONAL REQUIREMENTS.—

18 “(i) IN GENERAL.—An entity pro-
19 viding pharmacy benefit management serv-
20 ices on behalf of a group health plan or
21 health insurance issuer offering group
22 health insurance coverage that submits a
23 report under paragraph (1) shall ensure
24 that such report contains only summary
25 health information, as defined in section

1 164.504(a) of title 45, Code of Federal
2 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, including with respect to
9 group health insurance coverage offered in con-
10 nection with a group health plan, shall provide
11 to each participant or beneficiary written notice
12 informing the participant or beneficiary of the
13 requirement for entities providing pharmacy
14 benefit management services on behalf of the
15 group health plan or health insurance issuer of-
16 fering group health insurance coverage to sub-
17 mit reports to group health plans under para-
18 graph (1), as applicable, which may include in-
19 corporating such notification in plan documents
20 provided to the participant or beneficiary, or
21 providing individual notification.

22 “(E) LIMITATION TO BUSINESS ASSOCI-
23 ATES.—A group health plan receiving a report
24 under paragraph (1) may disclose such informa-
25 tion only to the entity from which the report

1 was received or to that entity's business associ-
2 ates as defined in section 160.103 of title 45,
3 Code of Federal Regulations (or successor regu-
4 lations) or as permitted by the HIPAA privacy
5 regulations.

6 “(F) CLARIFICATION REGARDING PUBLIC
7 DISCLOSURE OF INFORMATION.—Nothing in
8 this section shall prevent an entity providing
9 pharmacy benefit management services on be-
10 half of a group health plan or health insurance
11 issuer offering group health insurance coverage,
12 from placing reasonable restrictions on the pub-
13 lic disclosure of the information contained in a
14 report described in paragraph (1), except that
15 such plan, issuer, or entity may not—

16 “(i) restrict disclosure of such report
17 to the Department of Health and Human
18 Services, the Department of Labor, or the
19 Department of the Treasury; or

20 “(ii) prevent disclosure for the pur-
21 poses of subsection (c), or any other public
22 disclosure requirement under this section.

23 “(G) LIMITED FORM OF REPORT.—The
24 Secretary shall define through rulemaking a
25 limited form of the report under paragraph (1)

1 required with respect to any group health plan
2 established by a plan sponsor that is, or is af-
3 filiated with, a drug manufacturer, drug whole-
4 saler, or other direct participant in the drug
5 supply chain, in order to prevent anti-competi-
6 tive behavior.

7 “(5) STANDARD FORMAT AND REGULATIONS.—

8 “(A) IN GENERAL.—Not later than 18
9 months after the date of enactment of this sec-
10 tion, the Secretary shall specify through rule-
11 making a standard format for entities providing
12 pharmacy benefit management services on be-
13 half of group health plans and health insurance
14 issuers offering group health insurance cov-
15 erage, to submit reports required under para-
16 graph (1).

17 “(B) ADDITIONAL REGULATIONS.—Not
18 later than 18 months after the date of enact-
19 ment of this section, the Secretary shall,
20 through rulemaking, promulgate any other final
21 regulations necessary to implement the require-
22 ments of this section. In promulgating such
23 regulations, the Secretary shall, to the extent
24 practicable, align the reporting requirements

1 under this section with the reporting require-
2 ments under section 725.

3 “(c) REQUIREMENT TO PROVIDE INFORMATION TO
4 PARTICIPANTS OR BENEFICIARIES.—A group health plan,
5 including with respect to group health insurance coverage
6 offered in connection with a group health plan, upon re-
7 quest of a participant or beneficiary, shall provide to such
8 participant or beneficiary—

9 “(1) the summary document described in sub-
10 section (b)(2)(B)(ii); and

11 “(2) the information described in subsection
12 (b)(2)(A)(i)(III) with respect to a claim made by or
13 on behalf of such participant or beneficiary.

14 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion shall be construed to permit a health insurance issuer,
16 group health plan, entity providing pharmacy benefit man-
17 agement services on behalf of a group health plan or
18 health insurance issuer, or other entity to restrict dislo-
19 sure to, or otherwise limit the access of, the Secretary to
20 a report described in subsection (b)(1) or information re-
21 lated to compliance with subsections (a), (b), or (c) of this
22 section or section 502(c)(13) by such issuer, plan, or enti-
23 ty.

24 “(e) DEFINITIONS.—In this section:

1 “(1) APPLICABLE ENTITY.—The term ‘applica-
2 ble entity’ means—

3 “(A) an applicable group purchasing orga-
4 nization, drug manufacturer, distributor, whole-
5 saler, rebate aggregator (or other purchasing
6 entity designed to aggregate rebates), or associ-
7 ated third party;

8 “(B) any subsidiary, parent, affiliate, or
9 subcontractor of a group health plan, health in-
10 surance issuer, entity that provides pharmacy
11 benefit management services on behalf of such
12 a plan or issuer, or any entity described in sub-
13 paragraph (A); or

14 “(C) such other entity as the Secretary
15 may specify through rulemaking.

16 “(2) APPLICABLE GROUP PURCHASING ORGANI-
17 ZATION.—The term ‘applicable group purchasing or-
18 ganization’ means a group purchasing organization
19 that is affiliated with or under common ownership
20 with an entity providing pharmacy benefit manage-
21 ment services.

22 “(3) CONTRACTED COMPENSATION.—The term
23 ‘contracted compensation’ means the sum of any in-
24 gredient cost and dispensing fee for a drug (inclusive
25 of the out-of-pocket costs to the participant or bene-

1 ficiary), or another analogous compensation struc-
2 ture that the Secretary may specify through regula-
3 tions.

4 “(4) GROSS SPENDING.—The term ‘gross
5 spending’, with respect to prescription drug benefits
6 under a group health plan or health insurance cov-
7 erage, means the amount spent by a group health
8 plan or health insurance issuer on prescription drug
9 benefits, calculated before the application of rebates,
10 fees, alternative discounts, or other remuneration.

11 “(5) NET SPENDING.—The term ‘net spending’,
12 with respect to prescription drug benefits under a
13 group health plan or health insurance coverage,
14 means the amount spent by a group health plan or
15 health insurance issuer on prescription drug bene-
16 fits, calculated after the application of rebates, fees,
17 alternative discounts, or other remuneration.

18 “(6) PLAN SPONSOR.—The term ‘plan sponsor’
19 has the meaning given such term in section
20 3(16)(B).

21 “(7) REMUNERATION.—The term ‘remunera-
22 tion’ has the meaning given such term by the Sec-
23 retary through rulemaking, which shall be reeval-
24 ated by the Secretary every 5 years.

1 “(8) SPECIFIED LARGE EMPLOYER.—The term
2 ‘specified large employer’ means, in connection with
3 a group health plan (including group health insur-
4 ance coverage offered in connection with such a
5 plan) established or maintained by a single em-
6 ployer, with respect to a calendar year or a plan
7 year, as applicable, an employer who employed an
8 average of at least 100 employees on business days
9 during the preceding calendar year or plan year and
10 who employs at least 1 employee on the first day of
11 the calendar year or plan year.

12 “(9) SPECIFIED LARGE PLAN.—The term ‘spec-
13 ified large plan’ means a group health plan (includ-
14 ing group health insurance coverage offered in con-
15 nection with such a plan) established or maintained
16 by a plan sponsor described in clause (ii) or (iii) of
17 section 3(16)(B) that had an average of at least 100
18 participants on business days during the preceding
19 calendar year or plan year, as applicable.

20 “(10) WHOLESALE ACQUISITION COST.—The
21 term ‘wholesale acquisition cost’ has the meaning
22 given such term in section 1847A(c)(6)(B) of the
23 Social Security Act (42 U.S.C. 1395w-
24 3a(c)(6)(B)).”;

25 (B) in section 502 (29 U.S.C. 1132)—

1 (i) in subsection (a)(6), by striking
2 “or (9)” and inserting “(9), or (13)”;

3 (ii) in subsection (b)(3), by striking
4 “under subsection (c)(9)” and inserting
5 “under paragraphs (9) and (13) of sub-
6 section (c)”;

7 (iii) in subsection (c), by adding at
8 the end the following:

9 “(13) SECRETARIAL ENFORCEMENT AUTHORITY
10 RELATING TO OVERSIGHT OF PHARMACY BENEFIT
11 MANAGEMENT SERVICES.—

12 “(A) FAILURE TO PROVIDE INFORMA-
13 TION.—The Secretary may impose a penalty
14 against a plan administrator of a group health
15 plan, a health insurance issuer offering group
16 health insurance coverage, or an entity pro-
17 viding pharmacy benefit management services
18 on behalf of such a plan or issuer, or an appli-
19 cable entity (as defined in section 726(f)) that
20 violates section 726(a); an entity providing
21 pharmacy benefit management services on be-
22 half of such a plan or issuer that fails to pro-
23 vide the information required under section
24 726(b); or any person who causes a group
25 health plan to fail to provide the information

1 required under section 726(c), in the amount of
2 \$10,000 for each day during which such viola-
3 tion continues or such information is not dis-
4 closed or reported.

5 “(B) FALSE INFORMATION.—The Sec-
6 retary may impose a penalty against a plan ad-
7 ministrator of a group health plan, a health in-
8 surance issuer offering group health insurance
9 coverage, an entity providing pharmacy benefit
10 management services, or an applicable entity
11 (as defined in section 726(f)) that knowingly
12 provides false information under section 726, in
13 an amount not to exceed \$100,000 for each
14 item of false information. Such penalty shall be
15 in addition to other penalties as may be pre-
16 scribed by law.

17 “(C) WAIVERS.—The Secretary may waive
18 penalties under subparagraph (A), or extend
19 the period of time for compliance with a re-
20 quirement of this section, for an entity in viola-
21 tion of section 726 that has made a good-faith
22 effort to comply with the requirements of sec-
23 tion 726.”; and

1 (C) in section 732(a) (29 U.S.C.
2 1191a(a)), by striking “section 711” and in-
3 serting “sections 711 and 726”.

4 (2) CLERICAL AMENDMENT.—The table of con-
5 tents in section 1 of the Employee Retirement In-
6 come Security Act of 1974 (29 U.S.C. 1001 et seq.)
7 is amended by inserting after the item relating to
8 section 725 the following new item:

“Sec. 726. Oversight of entities that provide pharmacy benefit management
services.”.

9 (c) INTERNAL REVENUE CODE OF 1986.—

10 (1) IN GENERAL.—Chapter 100 of the Internal
11 Revenue Code of 1986 is amended—

12 (A) by adding at the end of subchapter B
13 the following:

14 **“SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**
15 **MACY BENEFIT MANAGEMENT SERVICES.**

16 “(a) IN GENERAL.—For plan years beginning on or
17 after the date that is 30 months after the date of enact-
18 ment of this section (referred to in this subsection and
19 subsection (b) as the ‘effective date’), a group health plan,
20 or an entity providing pharmacy benefit management serv-
21 ices on behalf of such a plan, shall not enter into a con-
22 tract, including an extension or renewal of a contract, en-
23 tered into on or after the effective date, with an applicable
24 entity unless such applicable entity agrees to—

1 “(1) not limit or delay the disclosure of infor-
2 mation to the group health plan in such a manner
3 that prevents an entity providing pharmacy benefit
4 management services on behalf of a group health
5 plan from making the reports described in sub-
6 section (b); and

7 “(2) provide the entity providing pharmacy ben-
8 efit management services on behalf of a group health
9 plan relevant information necessary to make the re-
10 ports described in subsection (b).

11 “(b) REPORTS.—

12 “(1) IN GENERAL.—For plan years beginning
13 on or after the effective date, in the case of any con-
14 tract between a group health plan and an entity pro-
15 viding pharmacy benefit management services on be-
16 half of such plan, including an extension or renewal
17 of such a contract, entered into on or after the effec-
18 tive date, the entity providing pharmacy benefit
19 management services on behalf of such a group
20 health plan, not less frequently than every 6 months
21 (or, at the request of a group health plan, not less
22 frequently than quarterly, and under the same con-
23 ditions, terms, and cost of the semiannual report
24 under this subsection), shall submit to the group
25 health plan a report in accordance with this section.

1 Each such report shall be made available to such
2 group health plan in plain language, in a machine-
3 readable format, and as the Secretary may deter-
4 mine, other formats. Each such report shall include
5 the information described in paragraph (2).

6 “(2) INFORMATION DESCRIBED.—For purposes
7 of paragraph (1), the information described in this
8 paragraph is, with respect to drugs covered by a
9 group health plan during each reporting period—

10 “(A) in the case of a group health plan
11 that is offered by a specified large employer or
12 that is a specified large plan, and is not offered
13 as health insurance coverage, or in the case of
14 health insurance coverage for which the election
15 under paragraph (3) is made for the applicable
16 reporting period—

17 “(i) a list of drugs for which a claim
18 was filed and, with respect to each such
19 drug on such list—

20 “(I) the contracted compensation
21 paid by the group health plan for each
22 covered drug (identified by the Na-
23 tional Drug Code) to the entity pro-
24 viding pharmacy benefit management

1 services or other applicable entity on
2 behalf of the group health plan;

3 “(II) the contracted compensa-
4 tion paid to the pharmacy, by any en-
5 tity providing pharmacy benefit man-
6 agement services or other applicable
7 entity on behalf of the group health
8 plan, for each covered drug (identified
9 by the National Drug Code);

10 “(III) for each such claim, the
11 difference between the amount paid
12 under subclause (I) and the amount
13 paid under subclause (II);

14 “(IV) the proprietary name, es-
15 tablished name or proper name, and
16 National Drug Code;

17 “(V) for each claim for the drug
18 (including original prescriptions and
19 refills) and for each dosage unit of the
20 drug for which a claim was filed, the
21 type of dispensing channel used to
22 furnish the drug, including retail, mail
23 order, or specialty pharmacy;

24 “(VI) with respect to each drug
25 dispensed, for each type of dispensing

1 channel (including retail, mail order,
2 or specialty pharmacy)—

3 “(aa) whether such drug is a
4 brand name drug or a generic
5 drug, and—

6 “(AA) in the case of a
7 brand name drug, the whole-
8 sale acquisition cost, listed
9 as cost per days supply and
10 cost per dosage unit, on the
11 date such drug was dis-
12 pensed; and

13 “(BB) in the case of a
14 generic drug, the average
15 wholesale price, listed as
16 cost per days supply and
17 cost per dosage unit, on the
18 date such drug was dis-
19 pensed; and

20 “(bb) the total number of—

21 “(AA) prescription
22 claims (including original
23 prescriptions and refills);

24 “(BB) participants and
25 beneficiaries for whom a

1 claim for such drug was
2 filed through the applicable
3 dispensing channel;

4 “(CC) dosage units and
5 dosage units per fill of such
6 drug; and

7 “(DD) days supply of
8 such drug per fill;

9 “(VII) the net price per course of
10 treatment or single fill, such as a 30-
11 day supply or 90-day supply to the
12 plan after rebates, fees, alternative
13 discounts, or other remuneration re-
14 ceived from applicable entities;

15 “(VIII) the total amount of out-
16 of-pocket spending by participants
17 and beneficiaries on such drug, in-
18 cluding spending through copayments,
19 coinsurance, and deductibles, but not
20 including any amounts spent by par-
21 ticipants and beneficiaries on drugs
22 not covered under the plan, or for
23 which no claim is submitted under the
24 plan;

1 “(IX) the total net spending on
2 the drug;

3 “(X) the total amount received,
4 or expected to be received, by the plan
5 from any applicable entity in rebates,
6 fees, alternative discounts, or other
7 remuneration;

8 “(XI) the total amount received,
9 or expected to be received, by the enti-
10 ty providing pharmacy benefit man-
11 agement services, from applicable en-
12 tities, in rebates, fees, alternative dis-
13 counts, or other remuneration from
14 such entities—

15 “(aa) for claims incurred
16 during the reporting period; and

17 “(bb) that is related to utili-
18 zation of such drug or spending
19 on such drug; and

20 “(XII) to the extent feasible, in-
21 formation on the total amount of re-
22 muneration for such drug, including
23 copayment assistance dollars paid, co-
24 payment cards applied, or other dis-
25 counts provided by each drug manu-

1 facturer (or entity administering co-
2 payment assistance on behalf of such
3 drug manufacturer), to the partici-
4 pants and beneficiaries enrolled in
5 such plan;

6 “(ii) a list of each therapeutic class
7 (as defined by the Secretary) for which a
8 claim was filed under the group health
9 plan during the reporting period, and, with
10 respect to each such therapeutic class—

11 “(I) the total gross spending on
12 drugs in such class before rebates,
13 price concessions, alternative dis-
14 counts, or other remuneration from
15 applicable entities;

16 “(II) the net spending in such
17 class after such rebates, price conces-
18 sions, alternative discounts, or other
19 remuneration from applicable entities;

20 “(III) the total amount received,
21 or expected to be received, by the enti-
22 ty providing pharmacy benefit man-
23 agement services, from applicable en-
24 tities, in rebates, fees, alternative dis-

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 drugs or drug spending;

7 “(IV) the average net spending
8 per 30-day supply and per 90-day
9 supply by the plan and its partici-
10 pants and beneficiaries, among all
11 drugs within the therapeutic class for
12 which a claim was filed during the re-
13 porting period;

14 “(V) the number of participants
15 and beneficiaries who filled a prescrip-
16 tion for a drug in such class, includ-
17 ing the National Drug Code for each
18 such drug;

19 “(VI) if applicable, a description
20 of the formulary tiers and utilization
21 mechanisms (such as prior authoriza-
22 tion or step therapy) employed for
23 drugs in that class; and

24 “(VII) the total out-of-pocket
25 spending under the plan by partici-

1 pants and beneficiaries, including
2 spending through copayments, coin-
3 surance, and deductibles, but not in-
4 cluding any amounts spent by partici-
5 pants and beneficiaries on drugs not
6 covered under the plan or for which
7 no claim is submitted under the plan;
8 “(iii) with respect to any drug for
9 which gross spending under the group
10 health plan exceeded \$10,000 during the
11 reporting period or, in the case that gross
12 spending under the group health plan ex-
13 ceeded \$10,000 during the reporting pe-
14 riod with respect to fewer than 50 drugs,
15 with respect to the 50 prescription drugs
16 with the highest spending during the re-
17 porting period—
18 “(I) a list of all other drugs in
19 the same therapeutic class as such
20 drug;
21 “(II) if applicable, the rationale
22 for the formulary placement of such
23 drug in that therapeutic category or
24 class, selected from a list of standard
25 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 an
7 entity providing pharmacy benefit manage-
8 ment services on behalf of such plan) has
9 an affiliated pharmacy or pharmacy under
10 common ownership, including mandatory
11 mail and specialty home delivery programs,
12 retail and mail auto-refill programs, and
13 cost sharing assistance incentives funded
14 by an entity providing pharmacy benefit
15 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 to fill prescrip-
20 tions at mail order, specialty, or retail
21 pharmacies;

22 “(II) the percentage of total pre-
23 scriptions dispensed by such phar-
24 macies to participants or beneficiaries
25 in such plan; 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, and, with respect to each drug
5 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, and to par-
10 ticipants and beneficiaries;

11 “(bb) the median amount
12 charged to such plan, and the
13 interquartile range of the costs,
14 per dosage unit, per 30-day sup-
15 ply, and per 90-day supply, in-
16 cluding amounts paid by the par-
17 ticipants and beneficiaries, when
18 the same drug is dispensed by
19 other pharmacies that are not af-
20 filiated with or under common
21 ownership with the entity and
22 that are included in the phar-
23 macy network of such plan;

24 “(cc) the lowest cost per
25 dosage unit, per 30-day supply

1 and per 90-day supply, for each
2 such drug, including amounts
3 charged to the plan and to par-
4 ticipants and beneficiaries, that
5 is available from any pharmacy
6 included in the network of such
7 plan; and

8 “(dd) the net acquisition
9 cost per dosage unit, per 30-day
10 supply, and per 90-day supply, if
11 such drug is subject to a max-
12 imum price discount; and

13 “(B) with respect to any group health
14 plan, regardless of whether the plan is offered
15 by a specified large employer or whether it is a
16 specified large plan—

17 “(i) a summary document for the
18 group health plan that includes such infor-
19 mation described in clauses (i) through (iv)
20 of subparagraph (A), as specified by the
21 Secretary through guidance, program in-
22 struction, or otherwise (with no require-
23 ment of notice and comment rulemaking),
24 that the Secretary determines useful to
25 group health plans for purposes of select-

1 ing pharmacy benefit management serv-
2 ices, such as an estimated net price to
3 group health plan and participant or bene-
4 ficiary, a cost per claim, the fee structure
5 or reimbursement model, and estimated
6 cost per participant or beneficiary;

7 “(ii) a summary document for plans
8 to provide to participants and beneficiaries,
9 which shall be made available to partici-
10 pants or beneficiaries upon request to their
11 group health 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 benefits under such plan;

22 “(II) contains only aggregate in-
23 formation; and

24 “(III) states that participants
25 and beneficiaries may request specific,

1 claims-level information required to be
2 furnished under subsection (c) from
3 the group health plan; and

4 “(iii) with respect to drugs covered by
5 such plan during such reporting period—

6 “(I) the total net spending by the
7 plan for all such drugs;

8 “(II) the total amount received,
9 or expected to be received, by the plan
10 from any applicable entity in rebates,
11 fees, alternative discounts, or other
12 remuneration; and

13 “(III) to the extent feasible, in-
14 formation on the total amount of re-
15 muneration for such drugs, including
16 copayment assistance dollars paid, co-
17 payment cards applied, or other dis-
18 counts provided by each drug manu-
19 facturer (or entity administering co-
20 payment assistance on behalf of such
21 drug manufacturer) to participants
22 and beneficiaries;

23 “(iv) amounts paid directly or indi-
24 rectly in rebates, fees, or any other type of
25 compensation (as defined in section

1 408(b)(2)(B)(ii)(dd)(AA) of the Employee
2 Retirement Income Security Act (29
3 U.S.C. 1108(b)(2)(B)(ii)(dd)(AA))) to bro-
4 kerage firms, brokers, consultants, advi-
5 sors, or any other individual or firm, for—

6 “(I) the referral of the group
7 health plan’s business to an entity
8 providing pharmacy benefit manage-
9 ment services, including the identity
10 of the recipient of such amounts;

11 “(II) consideration of the entity
12 providing pharmacy benefit manage-
13 ment services by the group health
14 plan; or

15 “(III) the retention of the entity
16 by the group health plan;

17 “(v) an explanation of any benefit de-
18 sign parameters that encourage or require
19 participants and beneficiaries in such plan
20 to fill prescriptions at mail order, specialty,
21 or retail pharmacies that are affiliated with
22 or under common ownership with the enti-
23 ty providing pharmacy benefit management
24 services under such plan, including manda-
25 tory mail and specialty home delivery pro-

1 grams, retail and mail auto-refill pro-
2 grams, and cost-sharing assistance incen-
3 tives directly or indirectly funded by such
4 entity; and

5 “(vi) total gross spending on all drugs
6 under the plan during the reporting period.

7 “(3) OPT-IN FOR GROUP HEALTH INSURANCE
8 COVERAGE OFFERED BY A SPECIFIED LARGE EM-
9 PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In
10 the case of group health insurance coverage offered
11 in connection with a group health plan that is of-
12 fered by a specified large employer or is a specified
13 large plan, such group health plan may, on an an-
14 nual basis, for plan years beginning on or after the
15 date that is 30 months after the date of enactment
16 of this section, elect to require an entity providing
17 pharmacy benefit management services on behalf of
18 the health insurance issuer to submit to such group
19 health plan a report that includes all of the informa-
20 tion described in paragraph (2)(A), in addition to
21 the information described in paragraph (2)(B).

22 “(4) PRIVACY REQUIREMENTS.—

23 “(A) IN GENERAL.—An entity providing
24 pharmacy benefit management services on be-
25 half of a group health plan shall report infor-

1 mation under paragraph (1) in a manner con-
2 sistent with the privacy regulations promul-
3 gated under section 13402(a) of the Health In-
4 formation Technology for Economic and Clin-
5 ical Health Act (42 U.S.C. 17932(a)) and con-
6 sistent with the privacy regulations promul-
7 gated under the Health Insurance Portability
8 and Accountability Act of 1996 in part 160 and
9 subparts A and E of part 164 of title 45, Code
10 of Federal Regulations (or successor regula-
11 tions) (referred to in this paragraph as the
12 ‘HIPAA privacy regulations’) and shall restrict
13 the use and disclosure of such information ac-
14 cording to such privacy regulations and such
15 HIPAA privacy regulations.

16 “(B) ADDITIONAL REQUIREMENTS.—

17 “(i) IN GENERAL.—An entity pro-
18 viding pharmacy benefit management serv-
19 ices on behalf of a group health plan that
20 submits a report under paragraph (1) shall
21 ensure that such report contains only sum-
22 mary health information, as defined in sec-
23 tion 164.504(a) of title 45, Code of Fed-
24 eral Regulations (or successor regulations).

1 “(ii) RESTRICTIONS.—In carrying out
2 this subsection, a group health plan shall
3 comply with section 164.504(f) of title 45,
4 Code of Federal Regulations (or a suc-
5 cessor regulation), and a plan sponsor shall
6 act in accordance with the terms of the
7 agreement described in such section.

8 “(C) RULE OF CONSTRUCTION.—

9 “(i) Nothing in this section shall be
10 construed to modify the requirements for
11 the creation, receipt, maintenance, or
12 transmission of protected health informa-
13 tion under the HIPAA privacy regulations.

14 “(ii) Nothing in this section shall be
15 construed to affect the application of any
16 Federal or State privacy or civil rights law,
17 including the HIPAA privacy regulations,
18 the Genetic Information Nondiscrimination
19 Act of 2008 (Public Law 110–233) (in-
20 cluding the amendments made by such
21 Act), the Americans with Disabilities Act
22 of 1990 (42 U.S.C. 12101 et sec), section
23 504 of the Rehabilitation Act of 1973 (29
24 U.S.C. 794), section 1557 of the Patient
25 Protection and Affordable Care Act (42

1 U.S.C. 18116), title VI of the Civil Rights
2 Act of 1964 (42 U.S.C. 2000d), and title
3 VII of the Civil Rights Act of 1964 (42
4 U.S.C. 2000e).

5 “(D) WRITTEN NOTICE.—Each plan year,
6 group health plans shall provide to each partici-
7 pant or beneficiary written notice informing the
8 participant or beneficiary of the requirement for
9 entities providing pharmacy benefit manage-
10 ment services on behalf of the group health
11 plan to submit reports to group health plans
12 under paragraph (1), as applicable, which may
13 include incorporating such notification in plan
14 documents provided to the participant or bene-
15 ficiary, or providing individual notification.

16 “(E) LIMITATION TO BUSINESS ASSOCI-
17 ATES.—A group health plan receiving a report
18 under paragraph (1) may disclose such informa-
19 tion only to the entity from which the report
20 was received or to that entity’s business associ-
21 ates as defined in section 160.103 of title 45,
22 Code of Federal Regulations (or successor regu-
23 lations) or as permitted by the HIPAA privacy
24 regulations.

1 “(F) CLARIFICATION REGARDING PUBLIC
2 DISCLOSURE OF INFORMATION.—Nothing in
3 this section shall prevent an entity providing
4 pharmacy benefit management services on be-
5 half of a group health plan, from placing rea-
6 sonable restrictions on the public disclosure of
7 the information contained in a report described
8 in paragraph (1), except that such plan or enti-
9 ty may not—

10 “(i) restrict disclosure of such report
11 to the Department of Health and Human
12 Services, the Department of Labor, or the
13 Department of the Treasury; or

14 “(ii) prevent disclosure for the pur-
15 poses of subsection (c), or any other public
16 disclosure requirement under this section.

17 “(G) LIMITED FORM OF REPORT.—The
18 Secretary shall define through rulemaking a
19 limited form of the report under paragraph (1)
20 required with respect to any group health plan
21 established by a plan sponsor that is, or is af-
22 filiated with, a drug manufacturer, drug whole-
23 saler, or other direct participant in the drug
24 supply chain, in order to prevent anti-competi-
25 tive behavior.

1 “(5) STANDARD FORMAT AND REGULATIONS.—

2 “(A) IN GENERAL.—Not later than 18
3 months after the date of enactment of this sec-
4 tion, the Secretary shall specify through rule-
5 making a standard format for entities providing
6 pharmacy benefit management services on be-
7 half of group health plans, to submit reports re-
8 quired under paragraph (1).

9 “(B) ADDITIONAL REGULATIONS.—Not
10 later than 18 months after the date of enact-
11 ment of this section, the Secretary shall,
12 through rulemaking, promulgate any other final
13 regulations necessary to implement the require-
14 ments of this section. In promulgating such
15 regulations, the Secretary shall, to the extent
16 practicable, align the reporting requirements
17 under this section with the reporting require-
18 ments under section 9825.

19 “(c) REQUIREMENT TO PROVIDE INFORMATION TO
20 PARTICIPANTS OR BENEFICIARIES.—A group health plan,
21 upon request of a participant or beneficiary, shall provide
22 to such participant or beneficiary—

23 “(1) the summary document described in sub-
24 section (b)(2)(B)(ii); and

1 “(2) the information described in subsection
2 (b)(2)(A)(i)(III) with respect to a claim made by or
3 on behalf of such participant or beneficiary.

4 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
5 tion shall be construed to permit a health insurance issuer,
6 group health plan, entity providing pharmacy benefit man-
7 agement services on behalf of a group health plan or
8 health insurance issuer, or other entity to restrict disclo-
9 sure to, or otherwise limit the access of, the Secretary to
10 a report described in subsection (b)(1) or information re-
11 lated to compliance with subsections (a), (b), or (c) of this
12 section or section 4980D(g) by such issuer, plan, or entity.

13 “(e) DEFINITIONS.—In this section:

14 “(1) APPLICABLE ENTITY.—The term ‘applica-
15 ble entity’ means—

16 “(A) an applicable group purchasing orga-
17 nization, drug manufacturer, distributor, whole-
18 saler, rebate aggregator (or other purchasing
19 entity designed to aggregate rebates), or associ-
20 ated third party;

21 “(B) any subsidiary, parent, affiliate, or
22 subcontractor of a group health plan, health in-
23 surance issuer, entity that provides pharmacy
24 benefit management services on behalf of such

1 a plan or issuer, or any entity described in sub-
2 paragraph (A); or

3 “(C) such other entity as the Secretary
4 may specify through rulemaking.

5 “(2) APPLICABLE GROUP PURCHASING ORGANI-
6 ZATION.—The term ‘applicable group purchasing or-
7 ganization’ means a group purchasing organization
8 that is affiliated with or under common ownership
9 with an entity providing pharmacy benefit manage-
10 ment services.

11 “(3) CONTRACTED COMPENSATION.—The term
12 ‘contracted compensation’ means the sum of any in-
13 gredient cost and dispensing fee for a drug (inclusive
14 of the out-of-pocket costs to the participant or bene-
15 ficiary), or another analogous compensation struc-
16 ture that the Secretary may specify through regula-
17 tions.

18 “(4) GROSS SPENDING.—The term ‘gross
19 spending’, with respect to prescription drug benefits
20 under a group health plan, means the amount spent
21 by a group health plan on prescription drug benefits,
22 calculated before the application of rebates, fees, al-
23 ternative discounts, or other remuneration.

24 “(5) NET SPENDING.—The term ‘net spending’,
25 with respect to prescription drug benefits under a

1 group health plan, means the amount spent by a
2 group health plan on prescription drug benefits, cal-
3 culated after the application of rebates, fees, alter-
4 native discounts, or other remuneration.

5 “(6) PLAN SPONSOR.—The term ‘plan sponsor’
6 has the meaning given such term in section 3(16)(B)
7 of the Employee Retirement Income Security Act of
8 1974 (29 U.S.C. 1002(16)(B)).

9 “(7) REMUNERATION.—The term ‘remunera-
10 tion’ has the meaning given such term by the Sec-
11 retary, through rulemaking, which shall be reevalu-
12 ated by the Secretary every 5 years.

13 “(8) SPECIFIED LARGE EMPLOYER.—The term
14 ‘specified large employer’ means, in connection with
15 a group health plan established or maintained by a
16 single employer, with respect to a calendar year or
17 a plan year, as applicable, an employer who em-
18 ployed an average of at least 100 employees on busi-
19 ness days during the preceding calendar year or plan
20 year and who employs at least 1 employee on the
21 first day of the calendar year or plan year.

22 “(9) SPECIFIED LARGE PLAN.—The term ‘spec-
23 ified large plan’ means a group health plan estab-
24 lished or maintained by a plan sponsor described in
25 clause (ii) or (iii) of section 3(16)(B) of the Em-

1 ployee Retirement Income Security Act of 1974 (29
2 U.S.C. 1002(16)(B)) that had an average of at least
3 100 participants on business days during the pre-
4 ceding calendar year or plan year, as applicable.

5 “(10) WHOLESALE ACQUISITION COST.—The
6 term ‘wholesale acquisition cost’ has the meaning
7 given such term in section 1847A(c)(6)(B) of the
8 Social Security Act (42 U.S.C. 1395w–
9 3a(c)(6)(B)).”;

10 (2) EXCEPTION FOR CERTAIN GROUP HEALTH
11 PLANS.—Section 9831(a)(2) of the Internal Revenue
12 Code of 1986 is amended by inserting “other than
13 with respect to section 9826,” before “any group
14 health plan”.

15 (3) ENFORCEMENT.—Section 4980D of the In-
16 ternal Revenue Code of 1986 is amended by adding
17 at the end the following new subsection:

18 “(g) APPLICATION TO REQUIREMENTS IMPOSED ON
19 CERTAIN ENTITIES PROVIDING PHARMACY BENEFIT
20 MANAGEMENT SERVICES.—In the case of any requirement
21 under section 9826 that applies with respect to an entity
22 providing pharmacy benefit management services on be-
23 half of a group health plan, any reference in this section
24 to such group health plan (and the reference in subsection

1 (e)(1) to the employer) shall be treated as including a ref-
2 erence to such entity.”.

3 (4) CLERICAL AMENDMENT.—The table of sec-
4 tions for subchapter B of chapter 100 of the Inter-
5 nal Revenue Code of 1986 is amended by adding at
6 the end the following new item:

“Sec. 9826. Oversight of entities that provide pharmacy benefit management
services.”.

7 **SEC. 902. FULL REBATE PASS THROUGH TO PLAN; EXCEP-**
8 **TION FOR INNOCENT PLAN FIDUCIARIES.**

9 (a) IN GENERAL.—Section 408(b)(2) of the Em-
10 ployee Retirement Income Security Act of 1974 (29
11 U.S.C. 1108(b)(2)) is amended—

12 (1) in subparagraph (B)(viii)—

13 (A) by redesignating subclauses (II)
14 through (IV) as subclauses (III) through (V),
15 respectively;

16 (B) in subclause (I)—

17 (i) by striking “subclause (II)” and
18 inserting “subclause (III)”; and

19 (ii) by striking “subclauses (II) and
20 (III)” and inserting “subclauses (III) and
21 (IV)”; and

22 (C) by inserting after subclause (I) the fol-
23 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 ceived 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.

Amend the title so as to read: “A bill to provide for
lower costs for everyday Americans, and for other pur-
poses.”.

