

119TH CONGRESS  
1ST SESSION

# H. R. 1768

To provide for lower costs for everyday Americans, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 3, 2025

Mr. PALLONE introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, the Budget, the Judiciary, and Education and Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To provide for lower costs for everyday Americans, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Lower Costs for Every-  
5 day Americans Act”.

6 **SEC. 2. TABLE OF CONTENTS.**

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

Sec. 1. Short title.

Sec. 2. Table of contents.

## DIVISION A—RECYCLING, WATER, AND ENVIRONMENT RELATED PROVISIONS

- Sec. 101. Recycling and composting accountability.
- Sec. 102. Recycling Infrastructure and Accessibility Program.
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- Sec. 105. Nationwide Consumer and Fuel Retailer Choice Act.

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### TITLE I—YOUTH POISONING PREVENTION

- Sec. 101. Short title.
- Sec. 102. Banning of products containing a high concentration of sodium nitrite.

### TITLE II—CONSUMER PRODUCT SAFETY STANDARD FOR CERTAIN BATTERIES

- Sec. 201. Consumer product safety standard for certain batteries.

### TITLE III—FOREIGN ADVERSARY COMMUNICATIONS TRANSPARENCY ACT

- Sec. 301. Short title.
- Sec. 302. List of entities holding FCC authorizations, licenses, or other grants of authority and having certain foreign ownership.

### TITLE IV—PROMOTING RESILIENT SUPPLY CHAINS

- Sec. 401. Short title.
- Sec. 402. Additional responsibilities of Assistant Secretary of Commerce for Industry and Analysis.
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- Sec. 405. No additional funds.
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- Sec. 407. Definitions.

### TITLE V—DEPLOYING AMERICAN BLOCKCHAINS

- Sec. 501. Short title.
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- Sec. 503. Department of Commerce leadership on blockchain.
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### TITLE VI—FUTURE NETWORKS ACT

- Sec. 601. Short title.
- Sec. 602. 6G task force.
- Sec. 603. Termination of Task Force.

### TITLE VII—SECURE SPACE ACT

- Sec. 701. Short title.
- Sec. 702. Prohibition on grant of certain satellite licenses, United States market access, or earth station authorizations.

## TITLE VIII—TAKE IT DOWN ACT

- Sec. 801. Short title.
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## TITLE XI—INFORMING CONSUMERS ABOUT SMART DEVICES

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## TITLE IX—LOWERING PRESCRIPTION DRUG COSTS

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

# 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”.



1 (b) DEFINITIONS.—

2 (1) IN GENERAL.—In this section:

3 (A) ADMINISTRATOR.—The term “Admin-  
4 istrator” means the Administrator of the Envi-  
5 ronmental Protection Agency.

6 (B) COMPOST.—The term “compost”  
7 means a product that—

8 (i) is manufactured through the con-  
9 trolled aerobic, biological decomposition of  
10 biodegradable materials;

11 (ii) has been subjected to medium and  
12 high temperature organisms, which—

13 (I) significantly reduce the viabil-  
14 ity of pathogens and weed seeds; and

15 (II) stabilize carbon in the prod-  
16 uct such that the product is beneficial  
17 to plant growth; and

18 (iii) is typically used as a soil amend-  
19 ment, but may also contribute plant nutri-  
20 ents.

21 (C) COMPOSTABLE MATERIAL.—The term  
22 “compostable material” means material that is  
23 a feedstock for creating compost, including—

24 (i) wood;

25 (ii) agricultural crops;

- 1 (iii) paper, such as cardboard and  
2 other paper products;  
3 (iv) certified compostable products as-  
4 sociated with organic waste;  
5 (v) other organic plant material;  
6 (vi) organic waste, including food  
7 waste and yard waste; and  
8 (vii) such other material that is com-  
9 posed of biomass that can be continually  
10 replenished or renewed, as determined by  
11 the Administrator.

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

16 (E) RECYCLABLE MATERIAL.—The term  
17 “recyclable material” means a material that is  
18 obsolete, previously used, off-specification, sur-  
19 plus, or incidentally produced for processing  
20 into a specification-grade commodity for which  
21 a reuse market currently exists or is being de-  
22 veloped.

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

1 (i) during which recyclable materials  
2 are processed into specification-grade com-  
3 modities and consumed as raw-material  
4 feedstock, in lieu of virgin materials, in the  
5 manufacturing of new products;

6 (ii) that may, with regard to recycla-  
7 ble materials and prior to the activities de-  
8 scribed in clause (i), include sorting, collec-  
9 tion, processing, and brokering; and

10 (iii) that result, subsequent to proc-  
11 essing described in clause (i), in consump-  
12 tion by a materials manufacturer, includ-  
13 ing for the manufacturing of new products.

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

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

21 (A) transforms a recyclable material into a  
22 specification-grade commodity; and

23 (B) may occur in multiple steps, with dif-  
24 ferent phases, including sorting, occurring at  
25 different locations.

1 (c) REPORTS ON COMPOSTING AND RECYCLING IN-  
 2 FRASTRUCTURE CAPABILITIES.—

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

6 **“SEC. 4011. REPORTS ON COMPOSTING AND RECYCLING IN-**  
 7 **FRASTRUCTURE CAPABILITIES.**

8 “(a) DEFINITIONS.—In this section:

9 “(1) RECYCLING AND COMPOSTING ACCOUNT-  
 10 ABILITY ACT TERMS.—The terms ‘compost’,  
 11 ‘compostable material’, ‘recyclable material’, and ‘re-  
 12 cycling’ have the meanings given the terms in sub-  
 13 section (b) of the Recycling and Composting Ac-  
 14 countability Act.

15 “(2) COMPOSTING FACILITY.—The term  
 16 ‘composting facility’ means a location, structure, or  
 17 device that transforms compostable materials into  
 18 compost.

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

23 “(4) MATERIALS RECOVERY FACILITY.—

24 “(A) IN GENERAL.—The term ‘materials  
 25 recovery facility’ means a dedicated facility

1 where primarily residential recyclable materials,  
2 which are diverted from disposal by the gener-  
3 ator and collected separately from municipal  
4 solid waste, are mechanically or manually sort-  
5 ed into commodities for further processing into  
6 specification-grade commodities for sale to end  
7 users.

8 “(B) EXCLUSION.—The term ‘materials  
9 recovery facility’ does not include a solid waste  
10 management facility that may process munic-  
11 ipal solid waste to remove recyclable materials.

12 “(C) DEFINITION OF PROCESSING.—For  
13 purposes of this paragraph, the term ‘proc-  
14 essing’ has the meaning given the term in sub-  
15 section (b)(2) of the Recycling and Composting  
16 Accountability Act.

17 “(b) REPORT.—

18 “(1) IN GENERAL.—The Administrator shall re-  
19 quest information and data from, collaborate with,  
20 or contract with, as necessary and appropriate,  
21 States, units of local government, and Indian Tribes,  
22 for the provision, preparation, and publication of a  
23 report, or to expand work under the National Recy-  
24 cling Strategy to include information and data, on

1 compostable materials and efforts to reduce contami-  
2 nation rates for recycling, including—

3 “(A) an evaluation of existing Federal,  
4 State, and local laws that may present barriers  
5 to implementation of composting strategies;

6 “(B) a description and evaluation of  
7 composting infrastructure and programs within  
8 States, units of local government, and Indian  
9 Tribes;

10 “(C) an estimate of the costs and approxi-  
11 mate land needed to expand composting pro-  
12 grams; and

13 “(D) a review of the practices of manufac-  
14 turers and companies that are moving to using  
15 compostable packaging and food service ware  
16 for the purpose of making the composting proc-  
17 ess the end-of-life use of those products.

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

22 “(c) INVENTORY OF MATERIALS RECOVERY FACILI-  
23 TIES.—Not later than 3 years after the date of enactment  
24 of this section, and every 4 years thereafter, the Adminis-  
25 trator, in consultation with relevant Federal agencies and

1 States, units of local government, and Indian Tribes,  
2 shall—

3 “(1) prepare an inventory or estimate of mate-  
4 rials recovery facilities in the United States, includ-  
5 ing—

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

8 “(B) a general description of the materials  
9 that each of those materials recovery facilities  
10 can process, including—

11 “(i) in the case of plastic, a descrip-  
12 tion of—

13 “(I) the types of accepted resin,  
14 if applicable; and

15 “(II) the packaging or product  
16 format, such as a jug, a carton, or  
17 film;

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

20 “(iii) paper;

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

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

25 “(vi) other scrap metal;

1 “(vii) glass; or

2 “(viii) any other material not de-  
3 scribed in any of clauses (i) through (vii)  
4 that a materials recovery facility processes;  
5 and

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

8 “(d) INFORMATION ON RECYCLING AND COMPOSTING  
9 SYSTEMS.—The Administrator shall, as necessary and ap-  
10 propriate, collaborate or contract with States, units of  
11 local government, and Indian Tribes to estimate, with re-  
12 spect to the United States—

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

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

17 “(3) the number of individuals—

18 “(A) with access to recycling and  
19 composting services to at least the extent of ac-  
20 cess to disposal services; and

21 “(B) who use, on a percentage basis, the  
22 recycling and composting services described in  
23 subparagraph (A);

24 “(4) the number of individuals with barriers to  
25 accessing recycling and composting services similar



1 to their access to disposal services and the types of  
2 those barriers experienced;

3 “(5) the inbound contamination and capture  
4 rates of recycling and composting programs;

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

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

10 “(e) RECYCLING REPORTING RATES.—

11 “(1) COLLECTION OF DATA; DEVELOPMENT OF  
12 RATES.—The Administrator may use amounts made  
13 available under subsection (f) of the Recycling and  
14 Composting Accountability Act—

15 “(A) to biannually collect, in collaboration  
16 with States, to the extent practicable, informa-  
17 tion supplied on a voluntary basis to develop  
18 the estimated rates described in subparagraphs  
19 (B) and (C);

20 “(B) to develop a standardized estimated  
21 rate of recyclable materials in States that pro-  
22 vide information under subparagraph (A) that  
23 have been successfully diverted from the waste  
24 stream and brought to a materials recovery fa-  
25 cility or composting facility; and

1           “(C) to develop an estimated national recycling rate based on the information described in  
2           subparagraphs (A) and (B).

3           “(2) USE.—Using amounts made available  
4           under subsection (f) of the Recycling and  
5           Composting Accountability Act, the Administrator  
6           may use the information collected and rates developed under paragraph (1) to provide requesting  
7           States, units of local government, and Indian Tribes  
8           data and technical assistance—

9           “(A) to reduce the overall waste produced  
10           by the States, units of local government, and  
11           Indian Tribes;

12           “(B) to assist the States, units of local  
13           government, and Indian Tribes in understanding the nuances of the information collected relating to diversion activities; and

14           “(C) to increase recycling and composting  
15           rates of the States, units of local government,  
16           and Indian Tribes.

17           “(f) REPORT ON END MARKETS.—The Administrator, in collaboration or contract with, as necessary and  
18           appropriate, relevant Federal agencies, States, units of  
19           local government, or Indian Tribes, shall—

1           “(1) provide an update to the report submitted  
2           under section 306 of the Save Our Seas 2.0 Act  
3           (Public Law 116–224; 134 Stat. 1096) to include an  
4           addendum on the end-market sale of all recyclable  
5           materials from materials recovery facilities that  
6           process recyclable materials, including, to the extent  
7           practicable—

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

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

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

16           “(3) not later than 3 years after the date of en-  
17           actment of this section, submit to Congress the up-  
18           date to the report prepared under paragraph (1) and  
19           the report prepared under paragraph (2).

20           “(g) PRIVILEGED OR CONFIDENTIAL INFORMA-  
21           TION.—

22           “(1) IN GENERAL.—Information collected under  
23           subsection (e)(1) or paragraph (1) or (2) of sub-  
24           section (f) shall not include any privileged or con-

1        confidential information described in section 552(b)(4)  
 2        of title 5, United States Code.

3                “(2) NONDISCLOSURE.—Information collected  
 4        to carry out this section shall not be made public if  
 5        the information meets the requirements of section  
 6        552(b) of title 5, United States Code.”.

7                (2) CLERICAL AMENDMENT.—The table of con-  
 8        tents in section 1001 of the Solid Waste Disposal  
 9        Act (Public Law 89–272; 90 Stat. 2795; 98 Stat.  
 10       3268) is amended by inserting after the item relat-  
 11       ing to section 4010 the following:

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

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

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

19                        (A) the total annual recycling and  
 20       composting rates reported by all Federal agen-  
 21       cies; and

22                        (B) the total annual percentage of prod-  
 23       ucts containing recyclable material, compostable  
 24       material, or recovered materials purchased by  
 25       all Federal agencies, including—

1 (i) the total quantity of procured  
2 products containing recyclable material or  
3 recovered materials listed in the com-  
4 prehensive procurement guidelines pub-  
5 lished under section 6002(e) of the Solid  
6 Waste Disposal Act (42 U.S.C. 6962(e));  
7 and

8 (ii) the total quantity of compostable  
9 material purchased by all Federal agencies;

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

12 (3) identifying activities that Federal agencies  
13 could carry out to further promote recycling or  
14 composting.

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

17 (1) IN GENERAL.—Not later than 1 year after  
18 the date of enactment of this Act, the Administrator  
19 shall develop a metric for determining the proportion  
20 of recyclable materials in commercial and municipal  
21 waste streams that are being diverted from a cir-  
22 cular market.

23 (2) STUDY; REPORT.—Not later than 1 year  
24 after the development of a metric under paragraph  
25 (1), the Administrator shall conduct a study of, and

1 submit to Congress a report on, the proportion of re-  
2 cyclable materials in commercial and municipal  
3 waste streams that, during each of the 10 calendar  
4 years preceding the year of submission of the report,  
5 were diverted from a circular market.

6 (3) DATA.—The report under paragraph (2)  
7 shall provide data on specific recyclable materials,  
8 including aluminum, plastics, paper and paperboard,  
9 textiles, and glass, that were prevented from remain-  
10 ing in a circular market through disposal or elimi-  
11 nation, and to what use those specific recyclable ma-  
12 terials were lost.

13 (4) EVALUATION.—The report under paragraph  
14 (2) shall include an evaluation of whether the estab-  
15 lishment or improvement of recycling programs  
16 would—

17 (A) improve recycling rates;

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

20 (C) affect prices paid by consumers for  
21 products using materials recycled in the circular  
22 market.

23 (f) AUTHORIZATION OF APPROPRIATIONS.—There is  
24 authorized to be appropriated to the Administrator to  
25 carry out this section and the amendments made by this

1 section \$4,000,000 for each of fiscal years 2025 through  
2 2029.

3 (g) ADMINISTRATION.—

4 (1) UNFUNDED MANDATES.—The Adminis-  
5 trator or the Secretary of Commerce may not exer-  
6 cise any authority under this section or any amend-  
7 ment made by this section if exercising that author-  
8 ity would require a State, a unit of local govern-  
9 ment, or an Indian Tribe to carry out a mandate for  
10 which funding is not available.

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

15 **SEC. 102. RECYCLING INFRASTRUCTURE AND ACCESSI-**  
16 **BILITY PROGRAM.**

17 (a) DEFINITIONS.—In this section:

18 (1) ADMINISTRATOR.—The term “Adminis-  
19 trator” means the Administrator of the Environ-  
20 mental Protection Agency.

21 (2) CURBSIDE RECYCLING.—The term  
22 “curbside recycling” means the process by which  
23 residential recyclable materials are picked up  
24 curbside.

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

3           (A) a State (as defined in section 1004 of  
4       the Solid Waste Disposal Act (42 U.S.C.  
5       6903));

6           (B) a unit of local government;

7           (C) an Indian Tribe; and

8           (D) a public-private partnership.

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

13          (5) MATERIALS RECOVERY FACILITY.—

14           (A) IN GENERAL.—The term “materials  
15       recovery facility” means a recycling facility  
16       where primarily residential recyclables, which  
17       are diverted from disposal by a generator and  
18       collected separately from municipal solid waste,  
19       are mechanically or manually sorted into com-  
20       modities for further processing into specifica-  
21       tion-grade commodities for sale to end users.

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



1           (6) PILOT GRANT PROGRAM.—The term “pilot  
2       grant program” means the Recycling Infrastructure  
3       and Accessibility Program established under sub-  
4       section (b).

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

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

12               (A) receives and consolidates recyclable  
13       material from curbside recycling or drop-off fa-  
14       cilities; and

15               (B) loads the recyclable material onto trac-  
16       tor trailers, railcars, or barges for transport to  
17       a distant materials recovery facility or another  
18       recycling-related facility.

19          (9) UNDERSERVED COMMUNITY.—The term  
20       “underserved community” means a community, in-  
21       cluding an unincorporated area, without access to  
22       full recycling services because—

23               (A) transportation, distance, or other rea-  
24       sons render utilization of available processing

1 capacity at an existing materials recovery facil-  
2 ity cost prohibitive; or

3 (B) the processing capacity of an existing  
4 materials recovery facility is insufficient to  
5 manage the volume of recyclable materials pro-  
6 duced by that community.

7 (b) ESTABLISHMENT.—Not later than 18 months  
8 after the date of enactment of this Act, the Administrator  
9 shall establish a pilot grant program, to be known as the  
10 “Recycling Infrastructure and Accessibility Program”, to  
11 award grants, on a competitive basis, to eligible entities  
12 to improve recycling accessibility in a community or com-  
13 munities within the same geographic area.

14 (c) GOAL.—The goal of the pilot grant program is  
15 to fund eligible projects that will significantly improve ac-  
16 cessibility to recycling systems through investments in in-  
17 frastructure in underserved communities through the use  
18 of a hub-and-spoke model for recycling infrastructure de-  
19 velopment.

20 (d) APPLICATIONS.—To be eligible to receive a grant  
21 under the pilot grant program, an eligible entity shall sub-  
22 mit to the Administrator an application at such time, in  
23 such manner, and containing such information as the Ad-  
24 ministrator may require.

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

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

7 (2) whether the proposed project of the eligible  
8 entity will improve accessibility to recycling services  
9 in a single underserved community or multiple un-  
10 derserved communities; and

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

14 (f) PRIORITY.—In selecting eligible entities to receive  
15 a grant under the pilot grant program, the Administrator  
16 shall give priority to eligible entities seeking to carry out  
17 a proposed project in a community in which there is not  
18 more than 1 materials recovery facility within a 75-mile  
19 radius of that community.

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

24 (1) increasing the number of transfer stations;

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

3           (3) leveraging public-private partnerships to re-  
4       duce the costs associated with collecting and trans-  
5       porting recyclable materials in underserved commu-  
6       nities.

7       (h) PROHIBITION ON USE OF FUNDS.—An eligible  
8       entity awarded a grant under the pilot grant program may  
9       not use the grant funds for projects relating to recycling  
10      education programs.

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

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

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

16      (j) SET-ASIDE.—The Administrator shall set aside  
17      not less than 70 percent of the amounts made available  
18      to carry out the pilot grant program for each fiscal year  
19      to award grants to eligible entities to carry out a proposed  
20      project or program in a single underserved community or  
21      multiple underserved communities.

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

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

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

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

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

16       (m) AUTHORIZATION OF APPROPRIATIONS.—

17           (1) IN GENERAL.—There is authorized to be  
18 appropriated to the Administrator to carry out the  
19 pilot grant program \$30,000,000 for each of fiscal  
20 years 2025 through 2029, to remain available until  
21 expended.

22           (2) ADMINISTRATIVE COSTS AND TECHNICAL  
23 ASSISTANCE.—Of the amounts made available under  
24 paragraph (1), the Administrator may use up to 5  
25 percent—

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

3 (B) to provide technical assistance to eligi-  
 4 ble entities applying for a grant under the pilot  
 5 grant program.

6 **SEC. 103. DRINKING WATER INFRASTRUCTURE RISK AND**  
 7 **RESILIENCE.**

8 Section 1433(g) of the Safe Drinking Water Act (42  
 9 U.S.C. 300i-2(g)) is amended—

10 (1) in paragraph (1), by striking “2020 and  
 11 2021” and inserting “2026 and 2027”;

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

14 (3) in paragraph (5), by striking  
 15 “\$10,000,000” and inserting “\$20,000,000”; and

16 (4) in paragraph (6)—

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

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

21 **SEC. 104. REAUTHORIZATION OF DIESEL EMISSIONS RE-**  
 22 **DUCTION ACT.**

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

1 **SEC. 105. NATIONWIDE CONSUMER AND FUEL RETAILER**  
 2 **CHOICE ACT.**

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

5 (b) **ETHANOL WAIVER.**—

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

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

11 “(4) **WAIVERS.**—

12 “(A) **IN GENERAL.**—The Administrator,  
 13 on”;

14 (B) in subparagraph (A) (as so des-  
 15 ignated)—

16 (i) in the first sentence—

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

19 (II) by striking “if he deter-  
 20 mines” and inserting “if the Adminis-  
 21 trator determines”; and

22 (ii) in the second sentence, by striking  
 23 “The Administrator” and inserting the fol-  
 24 lowing:

25 “(B) **FINAL ACTION.**—The Adminis-  
 26 trator”; and

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

2 “(C) REID VAPOR PRESSURE.—A fuel or  
3 fuel additive may be introduced into commerce  
4 if—

5 “(i)(I) the Administrator determines  
6 that the fuel or fuel additive is substan-  
7 tially similar to a fuel or fuel additive uti-  
8 lized in the certification of any model year  
9 vehicle pursuant to paragraph (1)(A); or

10 “(II) the fuel or fuel additive has been  
11 granted a waiver under subparagraph (A)  
12 and meets all of the conditions of that  
13 waiver other than any limitation of the  
14 waiver with respect to the Reid Vapor  
15 Pressure of the fuel or fuel additive; and

16 “(ii) the fuel or fuel additive meets all  
17 other applicable Reid Vapor Pressure re-  
18 quirements under subsection (h).”.

19 (2) REID VAPOR PRESSURE LIMITATION.—Sec-  
20 tion 211(h) of the Clean Air Act (42 U.S.C.  
21 7545(h)) is amended—

22 (A) by striking “vapor pressure” each  
23 place it appears and inserting “Vapor Pres-  
24 sure”;



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

4 (C) in paragraph (5)(A)—

5 (i) by striking “Upon notification, ac-  
6 companied by” and inserting “On receipt  
7 of a notification that is submitted after the  
8 date of enactment of the Nationwide Con-  
9 sumer and Fuel Retailer Choice Act, and is  
10 accompanied by appropriate”;

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

13 (iii) by adding at the end the fol-  
14 lowing: “Upon the enactment of the Na-  
15 tionwide Consumer and Fuel Retailer  
16 Choice Act, any State for which the notifi-  
17 cation from the Governor of a State was  
18 submitted before the date of enactment of  
19 the Nationwide Consumer and Fuel Re-  
20 tailer Choice Act and to which the Admin-  
21 istrator applied the Reid Vapor Pressure  
22 limitation established by paragraph (1)  
23 shall instead have the Reid Vapor Pressure  
24 limitation established by paragraph (4)  
25 apply to all fuel blends containing gasoline

1 and 10 to 15 percent denatured anhydrous  
 2 ethanol that are sold, offered for sale, dis-  
 3 pensed, supplied, offered for supply, trans-  
 4 ported, or introduced into commerce in the  
 5 area during the high ozone season.”.

6 (c) GENERATION OF CREDITS BY SMALL REFIN-  
 7 ERIES UNDER THE RENEWABLE FUEL PROGRAM.—Sec-  
 8 tion 211(o)(9) of the Clean Air Act (42 U.S.C.  
 9 7545(o)(9)) is amended by adding at the end the fol-  
 10 lowing:

11 “(E) CREDITS GENERATED FOR 2016–2018  
 12 COMPLIANCE YEARS.—

13 “(i) RULE.—For any small refinery  
 14 described in clause (ii) or (iii), the credits  
 15 described in the respective clause shall  
 16 be—

17 “(I) returned to the small refin-  
 18 ery and, notwithstanding paragraph  
 19 (5)(C), deemed eligible for future  
 20 compliance years; or

21 “(II) applied as a credit in the  
 22 EPA Moderated Transaction System  
 23 (EMTS) account of the small refinery.

1 “(ii) COMPLIANCE YEARS 2016 AND  
2 2017.—Clause (i) applies with respect to  
3 any small refinery that—

4 “(I) retired credits generated for  
5 compliance years 2016 or 2017; and

6 “(II) submitted a petition under  
7 subparagraph (B)(i) for that compli-  
8 ance year that remained outstanding  
9 as of December 1, 2022.

10 “(iii) COMPLIANCE YEAR 2018.—In  
11 addition to small refineries described in  
12 clause (ii), clause (i) applies with respect  
13 to any small refinery—

14 “(I) that submitted a petition  
15 under subparagraph (B)(i) for compli-  
16 ance year 2018 by September 1,  
17 2019;

18 “(II) that retired credits gen-  
19 erated for compliance year 2018 as  
20 part of the compliance demonstration  
21 of the small refinery for compliance  
22 year 2018 by March 31, 2019; and

23 “(III) for which—

1                   “(aa) the petition remained  
2                   outstanding as of December 1,  
3                   2022; or

4                   “(bb) the Administrator de-  
5                   nied the petition as of July 1,  
6                   2022, and has not returned the  
7                   retired credits as of December 1,  
8                   2022.”.

9           (d) ADDRESSING RENEWABLE FUEL MARKET MA-  
10   NIPULATION AND TRANSPARENCY.—Not later than 90  
11   days after the date of enactment of this Act, the Adminis-  
12   trator of the Environmental Protection Agency, in collabo-  
13   ration with the Commodity Futures Trading Commission,  
14   shall—

15           (1) review all applicable Renewable Identifica-  
16           tion Number (as described in section 80.1425 of title  
17           40, Code of Federal Regulations (or successor regu-  
18           lations)) data collected for the EPA Moderated  
19           Transaction System (as defined in section 80.2 of  
20           title 40, Code of Federal Regulations (or successor  
21           regulations)); and

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

**DIVISION B—COMMERCE**  
**TITLE I—YOUTH POISONING**  
**PREVENTION**

**SEC. 101. SHORT TITLE.**

This title may be cited as the “Youth Poisoning Protection Act”.

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

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

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

(1) prohibit any commercial or industrial purpose in which high concentration sodium nitrite is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer; and

(2) apply to high concentration sodium nitrite that meets the definition of a drug, device, or cosmetic (as such terms are defined in sections 201(g), (h), and (i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g), (h), and (i))), or food (as defined in section 201(f) of such Act (21 U.S.C.

1        321(f))), including poultry and poultry products (as  
2        such terms are defined in sections 4(e) and (f) of  
3        the Poultry Products Inspection Act (21 U.S.C.  
4        453(e) and (f))), meat and meat food products (as  
5        such terms are defined in section 1(j) of the Federal  
6        Meat Inspection Act (21 U.S.C. 601(j))), and eggs  
7        and egg products (as such terms are defined in sec-  
8        tion 4 of the Egg Products Inspection Act (21  
9        U.S.C. 1033)).

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

11                (1) CONSUMER PRODUCT.—The term consumer  
12        product has the meaning given that term under sec-  
13        tion 3(a)(5) of the Consumer Product Safety Act  
14        (15 U.S.C. 2052(a)(5)).

15                (2) HIGH CONCENTRATION OF SODIUM NI-  
16        TRITE.—The term high concentration of sodium ni-  
17        trite means a concentration of 10 or more percent  
18        by weight of sodium nitrite.

19        (d) EFFECTIVE DATE.—This section shall take effect  
20        90 days after the date of enactment of this Act.

1 **TITLE II—CONSUMER PRODUCT**  
2 **SAFETY STANDARD FOR CER-**  
3 **TAIN BATTERIES**

4 **SEC. 201. CONSUMER PRODUCT SAFETY STANDARD FOR**  
5 **CERTAIN BATTERIES.**

6 (a) CONSUMER PRODUCT SAFETY STANDARD RE-  
7 QUIRED.—Not later than 180 days after the date of the  
8 enactment of this Act, the Consumer Product Safety Com-  
9 mission (referred to in this section as the “Commission”)  
10 shall promulgate, under section 553 of title 5, United  
11 States Code, the provisions of ANSI/CAN/UL 2271–  
12 Standard for Batteries for Use in Light Electric Vehicle  
13 Applications, ANSI/CAN/UL 2849–Standard for Safety  
14 for Electrical Systems for eBikes, and ANSI/CAN/UL  
15 2272–Standard for Electrical Systems for Personal E-  
16 Mobility Devices, as in effect on the date of enactment  
17 of this Act, as final consumer product safety standards.

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

24 (c) REVISION OF VOLUNTARY STANDARDS.—

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

11          (2) TREATMENT OF REVISION.—The revised  
12      voluntary standard shall be considered to be a con-  
13      sumer product safety standard issued by the Com-  
14      mission under section 9 of the Consumer Product  
15      Safety Act (15 U.S.C. 2058), effective 180 days  
16      after the date on which the organization notifies the  
17      Commission (or such later date specified by the  
18      Commission in the Federal Register) unless, within  
19      90 days after receiving that notice, the Commission  
20      notifies the organization that it has determined that  
21      the proposed revision, in whole or in part, does not  
22      improve the safety of the consumer product covered  
23      by the standard and that the Commission is retain-  
24      ing the existing consumer product safety standard.



1 (d) TREATMENT OF STANDARD.—A standard pro-  
2 mulgated under this section, including a revision of such  
3 standard adopted by the Commission, shall be treated as  
4 a consumer product safety rule promulgated under section  
5 9 of the Consumer Product Safety Act (15 U.S.C. 2058).

6 (e) REPORT TO CONGRESS.—

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

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

19 (A) the source of the information that was  
20 provided to the Commission regarding the fire,  
21 explosion, or other hazard;

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

1 (C) whether a lithium-ion battery involved  
 2 in a fire, explosion, or other hazard complied  
 3 with the standard required by this section, if  
 4 known; and

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

8 **TITLE III—FOREIGN ADVERSARY**  
 9 **COMMUNICATIONS TRANSPARENCY**  
 10 **ACT**

11 **SEC. 301. SHORT TITLE.**

12 This title may be cited as the “Foreign Adversary  
 13 Communications Transparency Act”.

14 **SEC. 302. LIST OF ENTITIES HOLDING FCC AUTHORIZA-**  
 15 **TIONS, LICENSES, OR OTHER GRANTS OF AU-**  
 16 **THORITY AND HAVING CERTAIN FOREIGN**  
 17 **OWNERSHIP.**

18 (a) IN GENERAL.—Not later than 120 days after the  
 19 date of the enactment of this Act, the Commission shall  
 20 publish on the internet website of the Commission a list  
 21 of each entity—

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

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

(B) the Act of May 27, 1921 (47 U.S.C. 34 et seq.; commonly known as the “Cable Landing Licensing Act”) and Executive Order 10530 (3 U.S.C. 301 note; relating to the performance of certain functions vested in or subject to the approval of the President); and

(2) with respect to which—

(A) a covered entity holds an equity or voting interest that is required to be reported to the Commission under the ownership rules of the Commission; or

(B) an appropriate national security agency has determined that a covered entity exerts control, regardless of whether such covered entity holds an equity or voting interest as described in subparagraph (A).

(b) RULEMAKING.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Commission shall issue rules to obtain information to identify each entity—

(A) that holds any authorization, license, or other grant of authority issued by the Commission (other than a license described in subsection (a)(1)); and

1 (B) with respect to which a covered entity  
2 holds an equity or voting interest that is re-  
3 quired to be reported to the Commission under  
4 the ownership rules of the Commission.

5 (2) PLACEMENT ON LIST.—Not later than 1  
6 year after the Commission issues the rules required  
7 by paragraph (1), the Commission shall place each  
8 entity described in such paragraph on the list pub-  
9 lished under subsection (a).

10 (c) PAPERWORK REDUCTION ACT EXEMPTION.—A  
11 collection of information conducted or sponsored by the  
12 Commission to implement this section does not constitute  
13 a collection of information for the purposes of subchapter  
14 I of chapter 35 of title 44, United States Code (commonly  
15 referred to as the “Paperwork Reduction Act”).

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

20 (e) DEFINITIONS.—In this section:

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

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

3           (3) COVERED COUNTRY.—The term “covered  
4 country” means a country specified in section  
5 4872(f)(2) of title 10, United States Code.

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

8                   (A) the government of a covered country;

9                   (B) an entity organized under the laws of  
10 a covered country; and

11                   (C) a subsidiary of an entity described in  
12 subparagraph (B), regardless of whether the  
13 subsidiary is organized under the laws of a cov-  
14 ered country.

## 15           **TITLE IV—PROMOTING** 16           **RESILIENT SUPPLY CHAINS**

### 17   **SEC. 401. SHORT TITLE.**

18           This title may be cited as the “Promoting Resilient  
19 Supply Chains Act”.

### 20   **SEC. 402. ADDITIONAL RESPONSIBILITIES OF ASSISTANT** 21                   **SECRETARY OF COMMERCE FOR INDUSTRY** 22                   **AND ANALYSIS.**

23           In addition to the responsibilities of the Assistant  
24 Secretary on the day before the date of the enactment of

1 this Act, the Assistant Secretary shall have the following  
2 responsibilities:

3 (1) Promote the stability and resilience of crit-  
4 ical supply chains and critical and emerging tech-  
5 nologies that strengthen the national security of the  
6 United States.

7 (2) Lead the Working Group established pursu-  
8 ant to section 403 and consult covered nongovern-  
9 mental representatives, industry, institutions of  
10 higher education, and State and local governments  
11 in order to—

12 (A) promote resilient critical supply chains;

13 and

14 (B) identify, prepare for, and respond to  
15 supply chain shocks to—

16 (i) critical industries;

17 (ii) critical supply chains; and

18 (iii) critical and emerging tech-  
19 nologies.

20 (3) Encourage the growth and competitiveness  
21 of United States production and manufacturing in  
22 the United States of emerging technologies.

23 (4) Assess the resilience, diversity, and strength  
24 of critical supply chains and critical and emerging  
25 technologies.

1           (5) In consultation with the Secretary of State  
2           and the United States Trade Representative, sup-  
3           port the availability of critical goods from domestic  
4           manufacturers, domestic enterprises, and manufac-  
5           turing operations in countries that are allies or key  
6           international partner nations.

7           (6) Assist the Federal Government in preparing  
8           for and responding to supply chain shocks to critical  
9           supply chains, including by improving flexible manu-  
10          facturing capacities and capabilities in the United  
11          States.

12          (7) Consistent with United States obligations  
13          under international agreements, encourage and  
14          incentivize the reduced reliance of domestic enter-  
15          prises and domestic manufacturers on critical goods  
16          from countries that are described in section  
17          407(2)(B).

18          (8) Encourage the relocation of manufacturing  
19          facilities that manufacture critical goods from coun-  
20          tries that are described in section 407(2)(B) to the  
21          United States and countries that are allies or key  
22          international partner nations to strengthen the resil-  
23          ience, diversity, and strength of critical supply  
24          chains.

1 **SEC. 403. CRITICAL SUPPLY CHAIN RESILIENCE WORKING**  
2 **GROUP.**

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

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

14 (1) In consultation with the Working Group—

15 (A) assessing, mapping, and modeling crit-  
16 ical supply chains, including for critical and  
17 emerging technologies, which may include—

18 (i) modeling the impact of supply  
19 chain shocks on critical industries (includ-  
20 ing for critical and emerging technologies),  
21 and critical supply chains;

22 (ii) assessing the demand for and sup-  
23 ply of critical goods, production equipment,  
24 and manufacturing technology needed for  
25 critical supply chains, including critical  
26 goods, production equipment, and manu-



1           facturing technology obtained by or pur-  
2           chased from a person outside of the United  
3           States or imported into the United States;  
4           and

5                   (iii)        assessing        manufacturing,  
6           warehousing, transportation, and distribu-  
7           tion related to critical supply chains;

8           (B) identifying high priority gaps and  
9           vulnerabilities in critical supply chains and crit-  
10          ical industries (including critical industries for  
11          critical and emerging technologies) that—

12                   (i) exist as of the date of the enact-  
13          ment of this Act; or

14                   (ii) are anticipated to occur after the  
15          date of the enactment of this Act;

16          (C) identifying potential supply chain  
17          shocks to a critical supply chain that may dis-  
18          rupt, strain, or eliminate the critical supply  
19          chain;

20          (D) evaluating the capability and capacity  
21          of domestic manufacturers or manufacturers lo-  
22          cated in countries that are allies or key inter-  
23          national partner nations to serve as sources for  
24          critical goods, production equipment, or manu-

1           facturing technology needed in critical supply  
2           chains;

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

6           (F) evaluating the state of the manufac-  
7           turing workforce, including by—

8                   (i) identifying the needs of domestic  
9                   manufacturers; and

10                   (ii) identifying opportunities to create  
11                   high-quality manufacturing jobs; and

12           (G) identifying and describing necessary  
13           tools, including commercially available risk as-  
14           sessment tools, that leverage data and industry  
15           expertise to provide insights into critical supply  
16           chain vulnerabilities, including how such tools  
17           fulfill the requirements described in subpara-  
18           graphs (A) through (F).

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

23                   (A) identifying opportunities to reduce  
24                   gaps and vulnerabilities in critical supply chains  
25                   and critical industries;

1 (B) encouraging consultation between the  
2 Federal Government, industry, covered non-  
3 governmental representatives, institutions of  
4 higher education, and State and local govern-  
5 ments to—

6 (i) better respond to supply chain  
7 shocks to critical supply chains and critical  
8 industries (including critical industries for  
9 emerging technologies); and

10 (ii) coordinate response efforts to sup-  
11 ply chain shocks;

12 (C) encouraging consultation between the  
13 Federal Government and the governments of  
14 countries that are allies or key international  
15 partner nations;

16 (D) identifying opportunities to build the  
17 capacity of the United States in critical supply  
18 chains, critical industries, and emerging tech-  
19 nologies;

20 (E) identifying opportunities to build the  
21 capacity of countries that are allies or key  
22 international partner nations in critical indus-  
23 tries (including critical industries for emerging  
24 technologies) and critical supply chains; and

1 (F) developing and assessing contingency  
2 plans and coordination mechanisms to improve  
3 the response of critical supply chains and crit-  
4 ical industries to supply chain shocks.

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

- 9 (1) the Department of State;
- 10 (2) the Department of Defense;
- 11 (3) the Department of Homeland Security;
- 12 (4) the Department of Transportation;
- 13 (5) the Department of Energy;
- 14 (6) the Department of Agriculture;
- 15 (7) the Department of the Interior;
- 16 (8) the Department of Health and Human  
17 Services;
- 18 (9) the Office of the Director of National Intel-  
19 ligence; and
- 20 (10) the Small Business Administration.

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

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

- 24 (A) critical industries;
- 25 (B) critical supply chains; and

1 (C) critical goods;

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

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

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

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

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

20 (3) identifies and describes necessary tools, in-  
21 cluding commercially available risk assessment tools,  
22 that leverage data and industry expertise to provide  
23 insights into critical supply chain vulnerabilities, in-  
24 cluding how such tools fulfill each responsibility de-  
25 scribed in subsection (b);

1           (4) identifies and describes all Federal agencies  
2           with authorities or responsibilities described in sub-  
3           section (b); and

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

8           (f) NATIONAL STRATEGY AND REVIEW ON CRITICAL  
9           SUPPLY CHAIN RESILIENCY AND MANUFACTURING IN  
10          THE UNITED STATES.—

11           (1) IN GENERAL.—Not later than 18 months  
12           after the date of the enactment of this Act, and an-  
13           nually thereafter, the Assistant Secretary, in con-  
14           sultation with the Working Group, covered non-  
15           governmental representatives, industries, institutions  
16           of higher education, and State and local govern-  
17           ments, shall submit to the relevant committees of  
18           Congress a report that—

19                   (A) identifies—

20                           (i) critical infrastructure that may as-  
21                           sist in fulfilling the responsibilities de-  
22                           scribed in section 402;

23                           (ii) critical and emerging technologies  
24                           that may assist in fulfilling the responsibil-  
25                           ities described in section 402, including

1 such technologies that may be critical to  
2 addressing preparedness, weaknesses, and  
3 vulnerabilities relating to critical supply  
4 chains;

5 (iii) critical industries, critical supply  
6 chains, and critical goods designated pur-  
7 suant to subsection (d);

8 (iv) other supplies and services that  
9 are critical to the crisis preparedness of  
10 the United States;

11 (v) substitutes for critical goods, pro-  
12 duction equipment, and manufacturing  
13 technology;

14 (vi) methods and technologies, includ-  
15 ing blockchain technology, distributed ledg-  
16 er technology, and other critical and  
17 emerging technologies, as appropriate, for  
18 the authentication and traceability of crit-  
19 ical goods; and

20 (vii) countries that are allies or key  
21 international partner nations;

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

24 (i) the manufacturing base, critical  
25 supply chains, and emerging technologies

1 in the United States, including the manu-  
2 facturing base and critical supply chains  
3 for—

4 (I) critical goods;

5 (II) production equipment; and

6 (III) manufacturing technology;

7 and

8 (ii) the ability of the United States  
9 to—

10 (I) maintain readiness with re-  
11 spect to preparing for and responding  
12 to supply chain shocks; and

13 (II) in response to a supply chain  
14 shock—

15 (aa) surge production in  
16 critical industries;

17 (bb) surge production of  
18 critical goods and production  
19 equipment; and

20 (cc) maintain access to crit-  
21 ical goods, production equipment,  
22 and manufacturing technology;

23 (C) assesses and describes—



1 (i) the demand and supply of critical  
2 goods, production equipment, and manu-  
3 facturing technology;

4 (ii) the production of critical goods,  
5 production equipment, and manufacturing  
6 technology by domestic manufacturers;

7 (iii) the capability and capacity of do-  
8 mestic manufacturers and manufacturers  
9 in countries that are allies or key inter-  
10 national partner nations to manufacture  
11 critical goods, production equipment, and  
12 manufacturing technology; and

13 (iv) how supply chain shocks could af-  
14 fect rural, Tribal, and underserved commu-  
15 nities;

16 (D) identifies threats and supply chain  
17 shocks that may disrupt, strain, or eliminate  
18 critical supply chains, critical goods, and critical  
19 industries (including critical industries for  
20 emerging technologies);

21 (E) with regard to any threat identified  
22 under subparagraph (D), lists any threat or  
23 supply chain shock that may originate from a  
24 country, or a company or individual from a  
25 country, that is described in section 407(2)(B);

1 (F) assesses—

2 (i) the resilience and capacity of the  
3 manufacturing base, critical supply chains,  
4 and workforce of the United States and  
5 countries that are allies or key inter-  
6 national partner nations that can sustain  
7 critical industries (including critical indus-  
8 tries for emerging technologies) through a  
9 supply chain shock; and

10 (ii) the effect innovation has on do-  
11 mestic manufacturers;

12 (G) assesses the flexible manufacturing ca-  
13 pacity and capability available in the United  
14 States in the case of a supply chain shock; and

15 (H) develops a strategy for the Depart-  
16 ment of Commerce to support the resilience, di-  
17 versity, and strength of critical supply chains  
18 and critical and emerging technologies to—

19 (i) support sufficient access to critical  
20 goods by mitigating vulnerabilities in crit-  
21 ical supply chains, including critical supply  
22 chains concentrated in countries that are  
23 described in section 407(2)(B);

24 (ii) consult with other relevant agen-  
25 cies to assist countries that are allies or

1 key international partner nations in build-  
2 ing capacity for manufacturing critical  
3 goods;

4 (iii) recover from supply chain shocks;

5 (iv) identify, in consultation with the  
6 Working Group and other relevant agen-  
7 cies, actions relating to critical supply  
8 chains or emerging technologies that the  
9 United States may take to improve re-  
10 sponses to supply chain shocks;

11 (v) protect against supply chain  
12 shocks relating to critical supply chains  
13 from countries that are described in sec-  
14 tion 407(2)(B); and

15 (vi) make specific recommendations to  
16 implement the strategy under this section  
17 and improve the security and resiliency of  
18 manufacturing capacity and supply chains  
19 for critical industries (including critical in-  
20 dustries for emerging technologies) by—

21 (I) developing long-term strate-

22 gies;

23 (II) increasing visibility into the

24 networks and capabilities of domestic

1 manufacturers and suppliers of do-  
2 mestic manufacturers;

3 (III) identifying and mitigating  
4 risks, including—

5 (aa) significant  
6 vulnerabilities to supply chain  
7 shocks; and

8 (bb) exposure to gaps and  
9 vulnerabilities in domestic capac-  
10 ity or capabilities and sources of  
11 imports needed to sustain critical  
12 industries (including critical in-  
13 dustries for emerging tech-  
14 nologies) or critical supply  
15 chains;

16 (IV) identifying opportunities to  
17 reuse and recycle critical goods, in-  
18 cluding raw materials, to increase re-  
19 silient critical supply chains;

20 (V) consulting with countries  
21 that are allies or key international  
22 partner nations on—

23 (aa) sourcing critical goods,  
24 production equipment, and man-  
25 ufacturing technology; and

1 (bb) developing, sustaining,  
2 and expanding production and  
3 availability of critical goods, pro-  
4 duction equipment, and manufac-  
5 turing technology during a supply  
6 chain shock; and

7 (VI) providing guidance to other  
8 relevant agencies with respect to crit-  
9 ical goods, supply chains, and critical  
10 industries (including critical industries  
11 for emerging technologies) that should  
12 be prioritized to support United  
13 States leadership in the deployment of  
14 such technologies.

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

17 (A) critical supply chain information that  
18 is not aggregated;

19 (B) confidential business information of a  
20 private sector entity; or

21 (C) classified information.

22 (3) FORM.—The report submitted pursuant to  
23 paragraph (1), and any update submitted thereafter,  
24 shall be submitted to the relevant committees of

1 Congress in unclassified form and may include a  
2 classified annex.

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

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

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

15 (1) to share information with the Secretary or  
16 Assistant Secretary;

17 (2) to request assistance from the Secretary or  
18 Assistant Secretary; or

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

22 (i) PROTECTION OF VOLUNTARILY SHARED CRIT-  
23 ICAL SUPPLY CHAIN INFORMATION.—

24 (1) PROTECTION.—

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

10 (i) shall be exempt from disclosure  
11 under section 552(b)(3) of title 5, United  
12 States Code (commonly referred to as the  
13 “Freedom of Information Act”);

14 (ii) is not subject to any agency rules  
15 or judicial doctrine regarding ex parte  
16 communications with a decision-making of-  
17 ficial;

18 (iii) may not, without the written con-  
19 sent of the person or entity submitting  
20 such information, be used directly by the  
21 Department of Commerce, any other Fed-  
22 eral, State, or local authority, or any third  
23 party, in any civil action arising under  
24 Federal or State law if such information is  
25 submitted in good faith;

1 (iv) may not, without the written con-  
2 sent of the person or entity submitting  
3 such information, be used or disclosed by  
4 any officer or employee of the United  
5 States for purposes other than the pur-  
6 poses of this section, except—

7 (I) in furtherance of an investiga-  
8 tion or the prosecution of a criminal  
9 act; or

10 (II) when disclosure of the infor-  
11 mation would be—

12 (aa) to either House of Con-  
13 gress, or to the extent of matter  
14 within its jurisdiction, any com-  
15 mittee or subcommittee thereof,  
16 any joint committee thereof, or  
17 any subcommittee of any such  
18 joint committee; or

19 (bb) to the Comptroller Gen-  
20 eral of the United States, or any  
21 authorized representative of the  
22 Comptroller General, in the  
23 course of the performance of the  
24 duties of the Government Ac-  
25 countability Office;



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

3 (I) be made available pursuant to  
4 any State or local law requiring dis-  
5 closure of information or records;

6 (II) otherwise be disclosed or dis-  
7 tributed to any party by such State or  
8 local government or government agen-  
9 cy without the written consent of the  
10 person or entity submitting such in-  
11 formation; or

12 (III) be used other than for the  
13 purpose of carrying out this section,  
14 or in furtherance of an investigation  
15 or the prosecution of a criminal act;  
16 and

17 (vi) does not constitute a waiver of  
18 any applicable privilege or protection pro-  
19 vided under law, such as trade secret pro-  
20 tection.

21 (B) EXPRESS STATEMENT.—The express  
22 statement described in this subparagraph, with  
23 respect to information or records, is—

24 (i) in the case of written information  
25 or records, a written marking on the infor-

1           mation or records substantially similar to  
2           the following: “This information is volun-  
3           tarily submitted to the Federal Govern-  
4           ment in expectation of protection from dis-  
5           closure as provided by the provisions of the  
6           Promoting Resilient Supply Chains Act.”;  
7           or

8           (ii) in the case of oral information, a  
9           written statement similar to the statement  
10          described in clause (i) submitted within a  
11          reasonable period following the oral com-  
12          munication.

13          (2) LIMITATION.—No communication of critical  
14          supply chain information to the Department of Com-  
15          merce made pursuant to this section may be consid-  
16          ered to be an action subject to the requirements of  
17          chapter 10 of title 5, United States Code.

18          (3) INDEPENDENTLY OBTAINED INFORMA-  
19          TION.—Nothing in this subsection may be construed  
20          to limit or otherwise affect the ability of a State,  
21          local, or Federal Government entity, agency, or au-  
22          thority, or any third party, under applicable law to  
23          obtain critical supply chain information in a manner  
24          not covered by paragraph (1), including any infor-  
25          mation lawfully and properly disclosed generally or

1 broadly to the public and to use such information in  
2 any manner permitted by law. For purposes of this  
3 subsection, a permissible use of independently ob-  
4 tained information includes the disclosure of such in-  
5 formation under section 2302(b)(8) of title 5,  
6 United States Code.

7 (4) TREATMENT OF VOLUNTARY SUBMITTAL OF  
8 INFORMATION.—The voluntary submittal to the De-  
9 partment of Commerce of information or records  
10 that are protected from disclosure by this section  
11 may not be construed to constitute compliance with  
12 any requirement to submit such information to an  
13 agency under any other provision of law.

14 (5) INAPPLICABILITY TO SEMICONDUCTOR IN-  
15 CENTIVE PROGRAM.—This subsection does not apply  
16 to the voluntary submission of critical supply chain  
17 information in an application for Federal financial  
18 assistance under section 9902 of the William M.  
19 (Mac) Thornberry National Defense Authorization  
20 Act for Fiscal Year 2021 (Public Law 116–283).

21 **SEC. 404. DEPARTMENT OF COMMERCE CAPABILITY AS-**  
22 **SESSMENT.**

23 (a) REPORT REQUIRED.—The Secretary shall  
24 produce a report—

1           (1) identifying the duties, responsibilities, re-  
2           sources, programs, and expertise within the offices  
3           and bureaus of the Department of Commerce rel-  
4           evant to critical supply chain resilience and manu-  
5           facturing innovation;

6           (2) identifying and assessing the purpose, legal  
7           authority, effectiveness, efficiency, and limitations of  
8           each office or bureau identified under paragraph (1);  
9           and

10          (3) providing recommendations to enhance the  
11          activities related to critical supply chain resilience  
12          and manufacturing innovation of the Department of  
13          Commerce, including—

14                (A) improving the effectiveness, efficiency,  
15                and impact of the offices and bureaus identified  
16                under paragraph (1);

17                (B) coordinating across offices and bu-  
18                reaus identified under paragraph (1); and

19                (C) consulting with agencies implementing  
20                similar activities related to critical supply chain  
21                resilience and manufacturing innovation.

22          (b) SUBMISSION OF REPORT.—Not later than 2 years  
23          after the date of the enactment of this Act, the Secretary  
24          shall submit to the relevant committees of Congress the  
25          report required by subsection (a), along with a strategy

1 to implement, as appropriate and as determined by the  
2 Secretary, the recommendations contained in the report.

3 **SEC. 405. NO ADDITIONAL FUNDS.**

4 No additional funds are authorized to be appro-  
5 priated to carry out this title.

6 **SEC. 406. SUNSET.**

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

10 **SEC. 407. DEFINITIONS.**

11 In this title:

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

15 (2) ALLY OR KEY INTERNATIONAL PARTNER  
16 NATION.—The term “ally or key international part-  
17 ner nation”—

18 (A) means a country that is critical to ad-  
19 dressing critical supply chain weaknesses and  
20 vulnerabilities; and

21 (B) does not include—

22 (i) a country that poses a significant  
23 risk to the national security or economic  
24 security of the United States; or

1 (ii) a country that is described in sec-  
2 tion 503(b) of the RANSOMWARE Act  
3 (title V of division BB of the Consolidated  
4 Appropriations Act, 2023; Public Law  
5 117–328; 136 Stat. 5564).

6 (3) ASSISTANT SECRETARY.—The term “Assist-  
7 ant Secretary” means the Assistant Secretary of  
8 Commerce assigned by the Secretary to direct the  
9 office of Industry and Analysis.

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

17 (5) CRITICAL GOOD.—The term “critical good”  
18 means any raw, in process, or manufactured mate-  
19 rial (including any mineral, metal, or advanced proc-  
20 essed material), article, commodity, supply, product,  
21 or item for which an absence of supply would have  
22 a debilitating impact on—

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

25 (B) either—

- 1 (i) critical infrastructure; or
- 2 (ii) an emerging technology.

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

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

7 (B) produces or procures a critical good.

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

12 (8) CRITICAL SUPPLY CHAIN.—The term “crit-  
13 ical supply chain” means a supply chain for a crit-  
14 ical good.

15 (9) CRITICAL SUPPLY CHAIN INFORMATION.—  
16 The term “critical supply chain information” means  
17 information that is not customarily in the public do-  
18 main and relates to—

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

21 (B) critical supply chain risk mitigation  
22 and recovery planning with respect to a supply  
23 chain shock, including any planned or past as-  
24 sessment, projection, or estimate of a vulner-  
25 ability within the critical supply chain, includ-

ing testing, supplier network assessments, production flexibility, supply chain risk evaluations, supply chain risk management planning, or risk audits; or

(C) operational best practices, planning, and supplier partnerships that enable enhanced resilience of a critical supply chain during a supply chain shock, including response, repair, recovery, reconstruction, insurance, or continuity.

(10) DOMESTIC ENTERPRISE.—The term “domestic enterprise” means an enterprise that conducts business in the United States and procures a critical good.

(11) DOMESTIC MANUFACTURER.—The term “domestic manufacturer” means a business that conducts in the United States the research and development, engineering, or production activities necessary for manufacturing a critical good.

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

(A) Technologies included in the American COMPETE Act (title XV of division FF of the



1 Consolidated Appropriations Act, 2021; Public  
2 Law 116–260; 134 Stat. 3276).

3 (B) The following technologies:

4 (i) Artificial intelligence.

5 (ii) Automated vehicles and unmanned  
6 delivery systems.

7 (iii) Blockchain and other distributed  
8 ledger, data storage, data management,  
9 and cybersecurity technologies.

10 (iv) Quantum computing and quan-  
11 tum sensing.

12 (v) Additive manufacturing.

13 (vi) Advanced manufacturing and the  
14 Internet of Things.

15 (vii) Nano technology.

16 (viii) Robotics.

17 (ix) Microelectronics, optical fiber ray,  
18 and high performance and advanced com-  
19 puter hardware and software.

20 (x) Semiconductors.

21 (xi) Advanced materials science, in-  
22 cluding composition 2D, other next genera-  
23 tion materials, and related manufacturing  
24 technologies.

1 (13) INSTITUTION OF HIGHER EDUCATION.—

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

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

7 (A) means any activity that is necessary  
8 for the development, production, processing,  
9 distribution, or delivery of any raw, in process,  
10 or manufactured material (including any min-  
11 eral, metal, and advanced processed material),  
12 article, commodity, supply, product, critical  
13 good, or item of supply; and

14 (B) does not include software unrelated to  
15 the manufacturing process.

16 (15) MANUFACTURING TECHNOLOGY.—The  
17 term “manufacturing technology” means a tech-  
18 nology that is necessary for the manufacturing of a  
19 critical good.

20 (16) PRODUCTION EQUIPMENT.—The term  
21 “production equipment” means any component, sub-  
22 system, system, equipment, tooling, accessory, part,  
23 or assembly necessary for the manufacturing of a  
24 critical good.

1 (17) RELEVANT COMMITTEES OF CONGRESS.—

2 The term “relevant committees of Congress” means  
3 the following:

4 (A) The Committee on Commerce, Science,  
5 and Transportation of the Senate.

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

8 (18) RESILIENT CRITICAL SUPPLY CHAIN.—The  
9 term “resilient critical supply chain” means a crit-  
10 ical supply chain that—

11 (A) ensures that the United States can  
12 sustain critical industry, including emerging  
13 technologies, production, critical supply chains,  
14 services, and access to critical goods, production  
15 equipment, and manufacturing technology dur-  
16 ing a supply chain shock; and

17 (B) has key components of resilience that  
18 include—

19 (i) effective private sector risk man-  
20 agement and mitigation planning to sus-  
21 tain critical supply chains and supplier  
22 networks during a supply chain shock; and

23 (ii) minimized or managed exposure to  
24 a supply chain shock.

1           (19) SECRETARY.—The term “Secretary”  
2 means the Secretary of Commerce.

3           (20) STATE.—The term “State” means each of  
4 the several States, the District of Columbia, each  
5 commonwealth, territory, or possession of the United  
6 States, and each federally recognized Indian Tribe.

7           (21) SUPPLY CHAIN SHOCK.—The term “supply  
8 chain shock”—

9                   (A) means an event causing severe or seri-  
10 ous disruption to normal operations or capacity  
11 in a supply chain; and

12                   (B) includes—

- 13                           (i) a natural disaster;  
14                           (ii) a pandemic;  
15                           (iii) a biological threat;  
16                           (iv) a cyber attack;  
17                           (v) a geopolitical conflict;  
18                           (vi) a terrorist or geopolitical attack;  
19                           (vii) a trade disruption caused by—

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

22                                   (II) an entity or an individual  
23 subject to the jurisdiction of such a  
24 country; and

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

## 7 **TITLE V—DEPLOYING AMERICAN** 8 **BLOCKCHAINS**

### 9 **SEC. 501. SHORT TITLE.**

10 This title may be cited as the “Deploying American  
11 Blockchains Act”.

### 12 **SEC. 502. DEFINITIONS.**

13 In this title:

14 (1) **ADVISORY COMMITTEE.**—The term “Advi-  
15 sory Committee” means the National Blockchain  
16 Deployment Advisory Committee established pursu-  
17 ant to section 503(c).

18 (2) **BLOCKCHAIN TECHNOLOGY OR OTHER DIS-**  
19 **TRIBUTED LEDGER TECHNOLOGY.**—The term  
20 “blockchain technology or other distributed ledger  
21 technology” means a distributed digital database  
22 where data is—

23 (A) shared across a network of computers  
24 to create a ledger of verified information among  
25 network participants;

1 (B) linked using cryptography to maintain  
2 the integrity of the ledger and to execute other  
3 functions; and

4 (C) distributed among network partici-  
5 pants in an automated fashion to concurrently  
6 update network participants on the state of the  
7 ledger and other functions.

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

15 (4) SECRETARY.—The term “Secretary” means  
16 the Secretary of Commerce.

17 (5) STATE.—The term “State” means each of  
18 the several States, the District of Columbia, each  
19 commonwealth, territory, or possession of the United  
20 States, and each federally recognized Indian Tribe.

21 (6) TOKEN.—The term “token” means a trans-  
22 ferable, digital representation of information re-  
23 corded on blockchain technology or other distributed  
24 ledger technology.

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

3   **SEC. 503. DEPARTMENT OF COMMERCE LEADERSHIP ON**  
4           **BLOCKCHAIN.**

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

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

19           (1) to examine and to provide recommendations  
20      on issues and risks relating to the deployment, use,  
21      application, and competitiveness of blockchain tech-  
22      nology or other distributed ledger technology, applica-  
23      tions built on blockchain technology or other dis-  
24      tributed ledger technology, tokens, and tokenization,  
25      including the issues of decentralized identity, cyber-

1 security, key storage and security systems, artificial  
2 intelligence, fraud reduction, regulatory compliance,  
3 e-commerce, health care applications, and supply  
4 chain resiliency;

5 (2) to support and to promote the improvement  
6 and security of blockchain technology or other dis-  
7 tributed ledger technology, applications built on  
8 blockchain technology or other distributed ledger  
9 technology, tokens, and tokenization;

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

16 (4) to promote the national security of the  
17 United States with respect to blockchain technology  
18 or other distributed ledger technology, applications  
19 built on blockchain technology or other distributed  
20 ledger technology, tokens, and tokenization;

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

24 (6) to consider policies to encourage coordina-  
25 tion among Federal agencies with respect to the de-



1       ployment of blockchain technology or other distrib-  
2       uted ledger technology, applications built on  
3       blockchain technology or other distributed ledger  
4       technology, tokens, and tokenization;

5           (7) to examine—

6               (A) how Federal agencies can benefit from  
7               utilizing blockchain technology or other distrib-  
8               uted ledger technology, applications built on  
9               blockchain technology or other distributed ledg-  
10              er technology, tokens, and tokenization;

11              (B) the current use by Federal agencies of  
12              blockchain technology or other distributed ledg-  
13              er technology, applications built on blockchain  
14              technology or other distributed ledger tech-  
15              nology, tokens, and tokenization;

16              (C) the current and future preparedness  
17              and ability of Federal agencies to adopt  
18              blockchain technology or other distributed ledg-  
19              er technology, applications built on blockchain  
20              technology or other distributed ledger tech-  
21              nology, tokens, and tokenization; and

22              (D) additional security measures Federal  
23              agencies may need to take—

24                   (i) to securely use blockchain tech-  
25                   nology or other distributed ledger tech-

nology, applications built on blockchain technology or other distributed ledger technology, tokens, and tokenization, including to support the security of critical infrastructure; and

(ii) to enhance the resiliency of Federal systems against cyber threats to blockchain technology or other distributed ledger technology, applications built on blockchain technology or other distributed ledger technology, tokens, and tokenization; and

(8) to support coordination of the activities of the Federal Government relating to the security of blockchain technology and other distributed ledger technology, applications built on blockchain technology or other distributed ledger technology, tokens, and tokenization.

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

(1) ESTABLISHMENT.—

(A) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall, in consultation with the heads of relevant Federal agencies, establish

1 an advisory committee to support the adoption  
2 of blockchain technology or other distributed  
3 ledger technology, applications built on  
4 blockchain technology or other distributed ledger  
5 technology, tokens, and tokenization.

6 (B) DESIGNATION.—The advisory com-  
7 mittee established pursuant to subparagraph  
8 (A) shall be known as the “National Blockchain  
9 Deployment Advisory Committee”.

10 (2) MEMBERSHIP COMPOSITION.—The Advisory  
11 Committee shall consist of members appointed by  
12 the Secretary, which shall include—

13 (A) the Secretary;

14 (B) representatives of Federal agencies (as  
15 determined necessary by the Secretary); and

16 (C) covered nongovernmental representa-  
17 tives with expertise related to blockchain tech-  
18 nology or other distributed ledger technology  
19 (as determined necessary by the Secretary),  
20 which may include—

21 (i) blockchain technology or other dis-  
22 tributed ledger technology infrastructure  
23 operators, suppliers, service providers, and  
24 vendors;

1 (ii) application developers building on  
2 blockchain technology or other distributed  
3 ledger technology;

4 (iii) developers and organizations sup-  
5 porting the advancement and deployment  
6 of public blockchain technology or other  
7 distributed ledger technology;

8 (iv) subject matter experts rep-  
9 resenting industrial sectors that can ben-  
10 efit from blockchain technology or other  
11 distributed ledger technology;

12 (v) small, medium, and large busi-  
13 nesses;

14 (vi) think tanks and academia;

15 (vii) nonprofit organizations and con-  
16 sumer groups;

17 (viii) cybersecurity experts;

18 (ix) rural stakeholders;

19 (x) covered nongovernmental rep-  
20 resentatives; and

21 (xi) artists and the content creator  
22 community.

23 (3) TERMINATION OF ADVISORY COMMITTEE.—

24 The Advisory Committee shall terminate on the date

1       that is 7 years after the date of the enactment of  
2       this Act.

3       (d) BEST PRACTICES.—The Secretary shall, on an  
4 ongoing basis, facilitate and support the development of  
5 a compendium of identified or recommended guidelines or  
6 best practices for the deployment of blockchain technology  
7 or other distributed ledger technology, applications built  
8 on blockchain technology or other distributed ledger tech-  
9 nology, tokens, and tokenization that—

10           (1) support the deployment of technologies  
11 needed to advance the capabilities of blockchain  
12 technology or other distributed ledger technology,  
13 applications built on blockchain technology or other  
14 distributed ledger technology, tokens, and  
15 tokenization;

16           (2) support the interoperability of blockchain  
17 technology or other distributed ledger technology,  
18 applications built on blockchain technology or other  
19 distributed ledger technology, tokens, and  
20 tokenization;

21           (3) support operations, including hashing and  
22 key storage and security systems, that form the  
23 foundation of blockchain technology or other distrib-  
24 uted ledger technology, applications built on

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

3 (4) reduce cybersecurity risks that may com-  
4 promise blockchain technology or other distributed  
5 ledger technology, applications built on blockchain  
6 technology or other distributed ledger technology, to-  
7 kens, and tokenization; and

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

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

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

21 (2) collaborate with private sector stakeholders  
22 to identify prioritized, flexible, repeatable, perform-  
23 ance-based, and cost-effective approaches to the de-  
24 ployment of blockchain technology or other distrib-  
25 uted ledger technology, applications built on

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

3 (3) make public research and information per-  
4 taining to the use of, and marketplace for,  
5 blockchain technology or other distributed ledger  
6 technology, applications built on blockchain tech-  
7 nology or other distributed ledger technology, to-  
8 kens, and tokenization;

9 (4) develop standardized terminology for, and  
10 promote common understanding of, blockchain tech-  
11 nology or other distributed ledger technology, appli-  
12 cations built on blockchain technology or other dis-  
13 tributed ledger technology, tokens, and tokenization;

14 (5) align the recommendations of the compen-  
15 dium described in subsection (d) with the goal of fa-  
16 cilitating the ease of use of blockchain technology or  
17 other distributed ledger technology, applications  
18 built on blockchain technology or other distributed  
19 ledger technology, tokens, and tokenization;

20 (6) support open-source infrastructure, data  
21 management, and authentication activities with re-  
22 spect to blockchain technology or other distributed  
23 ledger technology, applications built on blockchain  
24 technology or other distributed ledger technology, to-  
25 kens, and tokenization; and

1           (7) consider the needs and interests of both the  
2       private and public sector, including small businesses  
3       and Federal, State, and local governments.

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

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

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

10          (3) to require a private entity to implement any  
11       measure or recommendation suggested by the Sec-  
12       retary in response to a request by the private entity;  
13       or

14          (4) to require the adoption of the best practices  
15       described in subsection (d).

16       (g) CONSULTATION.—In implementing this section,  
17       the Secretary may, as appropriate, consult with the heads  
18       of relevant Federal agencies.

19       **SEC. 504. REPORTS TO CONGRESS.**

20       (a) INTERIM REPORTS.—Not later than 2 years after  
21       the date of the enactment of this Act, and annually there-  
22       after, the Secretary shall make public on the website of  
23       the Department of Commerce and submit to the Com-  
24       mittee on Commerce, Science, and Transportation of the



1 Senate and the Committee on Energy and Commerce of  
2 the House of Representatives a report that includes—

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

5 (2) any recommendations by the Secretary for  
6 additional legislation to strengthen the competitive-  
7 ness of the United States with respect to blockchain  
8 technology or other distributed ledger technology,  
9 applications built on blockchain technology or other  
10 distributed ledger technology, tokens, and  
11 tokenization; and

12 (3) a description of any emerging risks and  
13 long-term trends with respect to blockchain tech-  
14 nology or other distributed ledger technology, appli-  
15 cations built on blockchain technology or other dis-  
16 tributed ledger technology, tokens, and tokenization.

17 (b) FINAL REPORT.—Not later than 18 months be-  
18 fore the termination of the Advisory Committee pursuant  
19 to section 503(c)(3), the Secretary shall make available  
20 to the public on the website of the Department of Com-  
21 merce and submit to the President, the Committee on  
22 Commerce, Science, and Transportation of the Senate,  
23 and the Committee on Energy and Commerce of the  
24 House of Representatives a final report containing the

1 findings, conclusions, and recommendations of the Advi-  
2 sory Committee.

3 **TITLE VI—FUTURE NETWORKS**  
4 **ACT**

5 **SEC. 601. SHORT TITLE.**

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

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

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

14 (b) MEMBERSHIP.—

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

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

20 (A) Representatives of companies in the  
21 communications industry, except companies  
22 that are determined by the Chair to be not  
23 trusted.

24 (B) Representatives of public interest orga-  
25 nizations or academic institutions, except public

1 interest organizations or academic institutions  
2 that are determined by the Chair to be not  
3 trusted.

4 (C) Representatives of the Federal Govern-  
5 ment, State governments, local governments, or  
6 Tribal Governments, with at least one member  
7 representing each such type of government.

8 (c) REPORT.—

9 (1) IN GENERAL.—Not later than 1 year after  
10 the date on which the Task Force is established  
11 under subsection (a), the Task Force shall publish  
12 in the Federal Register and on the website of the  
13 Commission, and submit to the Committee on En-  
14 ergy and Commerce of the House of Representatives  
15 and the Committee on Commerce, Science, and  
16 Transportation of the Senate, a report on sixth-gen-  
17 eration wireless technology, including—

18 (A) the status of industry-led standards-  
19 setting bodies in setting standards for such  
20 technology;

21 (B) possible uses of such technology identi-  
22 fied by industry-led standards-setting bodies  
23 that are setting standards for such technology;

24 (C) any limitations of such technology (in-  
25 cluding any supply chain or cybersecurity limi-

tations) identified by industry-led standards-setting bodies that are setting standards for such technology;

(D) workforce needs to build, maintain, and utilize 6G and advanced wireless communications technologies and networks, and strategies to conduct the necessary workforce training;

(E) possible uses of emerging technologies and Open RAN networks to bolster 6G and advanced wireless networks; and

(F) how to best work with entities across the Federal Government, State governments, local governments, and Tribal Governments to leverage such technology, including with regard to siting, deployment, and adoption.

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

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

1 (B) accept public comments on such draft  
2 and take such comments into consideration in  
3 preparing the final version of such report.

4 (d) DEFINITIONS.—In this section:

5 (1) CHAIR.—The term “Chair” means the  
6 Chair of the Commission.

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

9 (3) NOT TRUSTED.—

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

12 (i) the Chair has made a public deter-  
13 mination that such entity is owned by, con-  
14 trolled by, or subject to the influence of a  
15 foreign adversary; or

16 (ii) the Chair otherwise determines  
17 that such entity poses a threat to the na-  
18 tional security of the United States.

19 (B) CRITERIA FOR DETERMINATION.—In  
20 making a determination under subparagraph  
21 (A)(ii), the Chair shall use the criteria de-  
22 scribed in paragraphs (1) through (4) of section  
23 2(c) of the Secure and Trusted Communica-  
24 tions Networks Act of 2019 (47 U.S.C.  
25 1601(c)), as appropriate.

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

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

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

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

11 **TITLE VII—SECURE SPACE ACT**

12 **SEC. 701. SHORT TITLE.**

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

14 **SEC. 702. PROHIBITION ON GRANT OF CERTAIN SATELLITE**  
 15 **LICENSES, UNITED STATES MARKET ACCESS,**  
 16 **OR EARTH STATION AUTHORIZATIONS.**

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

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

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

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

4 “(a) IN GENERAL.—The Commission may not grant  
5 a license for, or a petition for a declaratory ruling to ac-  
6 cess the United States market using, a geostationary orbit  
7 satellite system or a nongeostationary orbit satellite sys-  
8 tem, or an authorization to use an individually licensed  
9 earth station or a blanket-licensed earth station, if such  
10 license, grant of market access, or authorization would be  
11 held or controlled by—

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

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

17 “(b) DEFINITIONS.—In this section:

18 “(1) BLANKET-LICENSED EARTH STATION.—  
19 The term ‘blanket-licensed earth station’ means an  
20 earth station that is licensed with a geostationary  
21 orbit satellite system or a nongeostationary orbit  
22 satellite system.

23 “(2) GATEWAY STATION.—The term ‘gateway  
24 station’ means an earth station or a group of earth  
25 stations that—

1           “(A) supports the routing and switching  
2           functions of a geostationary orbit satellite sys-  
3           tem or a nongeostationary orbit satellite sys-  
4           tem;

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

7           “(C) does not originate or terminate com-  
8           munication traffic; and

9           “(D) is not for the exclusive use of any  
10          customer.

11          “(3) INDIVIDUALLY LICENSED EARTH STA-  
12          TION.—The term ‘individually licensed earth station’  
13          means—

14               “(A) an earth station (other than a blan-  
15               ket-licensed earth station) that sends a signal  
16               to, and receives a signal from, a geostationary  
17               orbit satellite system or a nongeostationary  
18               orbit satellite system; or

19               “(B) a gateway station.”.

20          (b) APPLICABILITY.—Section 10 of the Secure and  
21          Trusted Communications Networks Act of 2019, as added  
22          by subsection (a), shall apply with respect to the grant  
23          of a license, petition, or authorization on or after the date  
24          of the enactment of this Act.



1 (c) RULES.—Not later than 1 year after the date of  
 2 the enactment of this Act, the Federal Communications  
 3 Commission shall issue rules to implement section 10 of  
 4 the Secure and Trusted Communications Networks Act of  
 5 2019, as added by subsection (a).

## 6 **TITLE VIII—TAKE IT DOWN ACT**

### 7 **SEC. 801. SHORT TITLE.**

8 This title may be cited as the “Tools to Address  
 9 Known Exploitation by Immobilizing Technological  
 10 Deepfakes on Websites and Networks Act” or the “TAKE  
 11 IT DOWN Act”.

### 12 **SEC. 802. CRIMINAL PROHIBITION ON INTENTIONAL DIS-** 13 **CLOSURE OF NONCONSENSUAL INTIMATE** 14 **VISUAL DEPICTIONS.**

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

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

19 (2) by inserting after subsection (g) the fol-  
 20 lowing:

21 “(h) INTENTIONAL DISCLOSURE OF NONCONSEN-  
 22 SUAL INTIMATE VISUAL DEPICTIONS.—

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

24 “(A) CONSENT.—The term ‘consent’  
 25 means an affirmative, conscious, and voluntary

1 authorization made by an individual free from  
2 force, fraud, duress, misrepresentation, or coer-  
3 cion.

4 “(B) DIGITAL FORGERY.—The term ‘dig-  
5 ital forgery’ means any intimate visual depic-  
6 tion of an identifiable individual created  
7 through the use of software, machine learning,  
8 artificial intelligence, or any other computer-  
9 generated or technological means, including by  
10 adapting, modifying, manipulating, or altering  
11 an authentic visual depiction, that, when viewed  
12 as a whole by a reasonable person, is indistin-  
13 guishable from an authentic visual depiction of  
14 the individual.

15 “(C) IDENTIFIABLE INDIVIDUAL.—The  
16 term ‘identifiable individual’ means an indi-  
17 vidual—

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

20 “(ii) whose face, likeness, or other dis-  
21 tinguishing characteristic (including a  
22 unique birthmark or other recognizable  
23 feature) is displayed in connection with  
24 such intimate visual depiction.

1 “(D) INTERACTIVE COMPUTER SERVICE.—

2 The term ‘interactive computer service’ has the  
3 meaning given the term in section 230.

4 “(E) INTIMATE VISUAL DEPICTION.—The  
5 term ‘intimate visual depiction’ has the mean-  
6 ing given such term in section 1309 of the Con-  
7 solidated Appropriations Act, 2022 (15 U.S.C.  
8 6851).

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

11 “(2) OFFENSE INVOLVING AUTHENTIC INTI-  
12 MATE VISUAL DEPICTIONS.—

13 “(A) INVOLVING ADULTS.—Except as pro-  
14 vided in subparagraph (C), it shall be unlawful  
15 for any person, in interstate or foreign com-  
16 merce, to use an interactive computer service to  
17 knowingly publish an intimate visual depiction  
18 of an identifiable individual who is not a minor  
19 if—

20 “(i) the intimate visual depiction was  
21 obtained or created under circumstances in  
22 which the person knew or reasonably  
23 should have known the identifiable indi-  
24 vidual had a reasonable expectation of pri-  
25 vacy;

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

4 “(iii) what is depicted is not a matter  
5 of public concern; and

6 “(iv) publication of the intimate visual  
7 depiction—

8 “(I) is intended to cause harm;  
9 or

10 “(II) causes harm, including psy-  
11 chological, financial, or reputational  
12 harm, to the identifiable individual.

13 “(B) INVOLVING MINORS.—Except as pro-  
14 vided in subparagraph (C), it shall be unlawful  
15 for any person, in interstate or foreign com-  
16 merce, to use an interactive computer service to  
17 knowingly publish an intimate visual depiction  
18 of an identifiable individual who is a minor with  
19 intent to—

20 “(i) abuse, humiliate, harass, or de-  
21 grade the minor; or

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

24 “(C) EXCEPTIONS.—Subparagraphs (A)  
25 and (B) shall not apply to—

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

3 “(I) a law enforcement agency of  
4 the United States, a State, or a polit-  
5 ical subdivision of a State; or

6 “(II) an intelligence agency of  
7 the United States;

8 “(ii) a disclosure made reasonably and  
9 in good faith—

10 “(I) to a law enforcement officer  
11 or agency;

12 “(II) as part of a document pro-  
13 duction or filing associated with a  
14 legal proceeding;

15 “(III) as part of medical edu-  
16 cation, diagnosis, or treatment or for  
17 a legitimate medical, scientific, or  
18 education purpose;

19 “(IV) in the reporting of unlaw-  
20 ful content or unsolicited or unwel-  
21 come conduct or in pursuance of a  
22 legal, professional, or other lawful ob-  
23 ligation; or

1 “(V) to seek support or help with  
2 respect to the receipt of an unsolicited  
3 intimate visual depiction;

4 “(iii) a disclosure reasonably intended  
5 to assist the identifiable individual; or

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

12 “(3) OFFENSE INVOLVING DIGITAL FOR-  
13 GERIES.—

14 “(A) INVOLVING ADULTS.—Except as pro-  
15 vided in subparagraph (C), it shall be unlawful  
16 for any person, in interstate or foreign com-  
17 merce, to use an interactive computer service to  
18 knowingly publish a digital forgery of an identi-  
19 fiable individual who is not a minor if—

20 “(i) the digital forgery was published  
21 without the consent of the identifiable indi-  
22 vidual;

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

1 “(iii) what is depicted is not a matter  
2 of public concern; and

3 “(iv) publication of the digital for-  
4 gery—

5 “(I) is intended to cause harm;  
6 or

7 “(II) causes harm, including psy-  
8 chological, financial, or reputational  
9 harm, to the identifiable individual.

10 “(B) INVOLVING MINORS.—Except as pro-  
11 vided in subparagraph (C), it shall be unlawful  
12 for any person, in interstate or foreign com-  
13 merce, to use an interactive computer service to  
14 knowingly publish a digital forgery of an identi-  
15 fiable individual who is a minor with intent  
16 to—

17 “(i) abuse, humiliate, harass, or de-  
18 grade the minor; or

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

21 “(C) EXCEPTIONS.—Subparagraphs (A)  
22 and (B) shall not apply to—

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

1 “(I) a law enforcement agency of  
2 the United States, a State, or a polit-  
3 ical subdivision of a State; or

4 “(II) an intelligence agency of  
5 the United States;

6 “(ii) a disclosure made reasonably and  
7 in good faith—

8 “(I) to a law enforcement officer  
9 or agency;

10 “(II) as part of a document pro-  
11 duction or filing associated with a  
12 legal proceeding;

13 “(III) as part of medical edu-  
14 cation, diagnosis, or treatment or for  
15 a legitimate medical, scientific, or  
16 education purpose;

17 “(IV) in the reporting of unlaw-  
18 ful content or unsolicited or unwel-  
19 come conduct or in pursuance of a  
20 legal, professional, or other lawful ob-  
21 ligation; or

22 “(V) to seek support or help with  
23 respect to the receipt of an unsolicited  
24 intimate visual depiction;



1 “(iii) a disclosure reasonably intended  
2 to assist the identifiable individual; or

3 “(iv) a person who possesses or pub-  
4 lishes a digital forgery of himself or herself  
5 engaged in nudity or sexually explicit con-  
6 duct (as that term is defined in section  
7 2256(2)(A) of title 18, United States  
8 Code).

9 “(4) PENALTIES.—

10 “(A) OFFENSES INVOLVING ADULTS.—Any  
11 person who violates paragraph (2)(A) or (3)(A)  
12 shall be fined under title 18, United States  
13 Code, imprisoned not more than 2 years, or  
14 both.

15 “(B) OFFENSES INVOLVING MINORS.—Any  
16 person who violates paragraph (2)(B) or (3)(B)  
17 shall be fined under title 18, United States  
18 Code, imprisoned not more than 3 years, or  
19 both.

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

22 “(A) the fact that the identifiable indi-  
23 vidual provided consent for the creation of the  
24 intimate visual depiction shall not establish that

1 the individual provided consent for the publica-  
2 tion of the intimate visual depiction; and

3 “(B) the fact that the identifiable indi-  
4 vidual disclosed the intimate visual depiction to  
5 another individual shall not establish that the  
6 identifiable individual provided consent for the  
7 publication of the intimate visual depiction by  
8 the person alleged to have violated paragraph  
9 (2) or (3), respectively.

10 “(6) THREATS.—

11 “(A) THREATS INVOLVING AUTHENTIC IN-  
12 TIMATE VISUAL DEPICTIONS.—Any person who  
13 intentionally threatens to commit an offense  
14 under paragraph (2) for the purpose of intimi-  
15 dation, coercion, extortion, or to create mental  
16 distress shall be punished as provided in para-  
17 graph (4).

18 “(B) THREATS INVOLVING DIGITAL FOR-  
19 GERIES.—

20 “(i) THREATS INVOLVING ADULTS.—

21 Any person who intentionally threatens to  
22 commit an offense under paragraph (3)(A)  
23 for the purpose of intimidation, coercion,  
24 extortion, or to create mental distress shall  
25 be fined under title 18, United States

1 Code, imprisoned not more than 18  
2 months, or both.

3 “(ii) THREATS INVOLVING MINORS.—  
4 Any person who intentionally threatens to  
5 commit an offense under paragraph (3)(B)  
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 30  
10 months, or both.

11 “(7) FORFEITURE.—

12 “(A) IN GENERAL.—The court, in impos-  
13 ing a sentence on any person convicted of a vio-  
14 lation of paragraph (2) or (3), shall order, in  
15 addition to any other sentence imposed and ir-  
16 respective of any provision of State law, that  
17 the person forfeit to the United States—

18 “(i) any material distributed in viola-  
19 tion of that paragraph;

20 “(ii) the person’s interest in property,  
21 real or personal, constituting or derived  
22 from any gross proceeds of the violation, or  
23 any property traceable to such property,  
24 obtained or retained directly or indirectly  
25 as a result of the violation; and

1                   “(iii) any personal property of the  
2                   person used, or intended to be used, in any  
3                   manner or part, to commit or to facilitate  
4                   the commission of the violation.

5                   “(B) PROCEDURES.—Section 413 of the  
6                   Controlled Substances Act (21 U.S.C. 853),  
7                   with the exception of subsections (a) and (d),  
8                   shall apply to the criminal forfeiture of property  
9                   under subparagraph (A).

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

14                  “(9) RULE OF CONSTRUCTION.—Nothing in  
15                  this subsection shall be construed to limit the appli-  
16                  cation of any other relevant law, including section  
17                  2252 of title 18, United States Code.”.

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

21                  (c) TECHNICAL AND CONFORMING AMENDMENT.—  
22                  Subsection (i) of section 223 of the Communications Act  
23                  of 1934 (47 U.S.C. 223), as so redesignated by subsection  
24                  (a), is amended by inserting “DEFINITIONS.—” before  
25                  “For purposes of this section”.

1 **SEC. 803. NOTICE AND REMOVAL OF NONCONSENSUAL IN-**  
2 **TIMATE VISUAL DEPICTIONS.**

3 (a) IN GENERAL.—

4 (1) NOTICE AND REMOVAL PROCESS.—

5 (A) ESTABLISHMENT.—Not later than 1  
6 year after the date of enactment of this Act, a  
7 covered platform shall establish a process  
8 whereby an identifiable individual (or an au-  
9 thorized person acting on behalf of such indi-  
10 vidual) may—

11 (i) notify the covered platform of an  
12 intimate visual depiction published on the  
13 covered platform that—

14 (I) includes a depiction of the  
15 identifiable individual; and

16 (II) was published without the  
17 consent of the identifiable individual;  
18 and

19 (ii) submit a request for the covered  
20 platform to remove such intimate visual  
21 depiction.

22 (B) REQUIREMENTS.—A notification and  
23 request for removal of an intimate visual depic-  
24 tion submitted under the process established  
25 under subparagraph (A) shall include, in writ-  
26 ing—

1 (i) a physical or electronic signature  
2 of the identifiable individual (or an author-  
3 ized person acting on behalf of such indi-  
4 vidual);

5 (ii) an identification of, and informa-  
6 tion reasonably sufficient for the covered  
7 platform to locate, the intimate visual de-  
8 piction of the identifiable individual;

9 (iii) a brief statement that the identi-  
10 fiable individual has a good faith belief  
11 that any intimate visual depiction identi-  
12 fied under clause (ii) is not consensual, in-  
13 cluding any relevant information for the  
14 covered platform to determine the intimate  
15 visual depiction was published without the  
16 consent of the identifiable individual; and

17 (iv) information sufficient to enable  
18 the covered platform to contact the identi-  
19 fiable individual (or an authorized person  
20 acting on behalf of such individual).

21 (2) NOTICE OF PROCESS.—A covered platform  
22 shall provide on the platform a clear and con-  
23 spicuous notice, which may be provided through a  
24 clear and conspicuous link to another web page or

1 disclosure, of the notice and removal process estab-  
2 lished under paragraph (1)(A) that—

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

4 and

5 (B) provides information regarding the re-  
6 sponsibilities of the covered platform under this  
7 section, including a description of how an indi-  
8 vidual can submit a notification and request for  
9 removal.

10 (3) REMOVAL OF NONCONSENSUAL INTIMATE  
11 VISUAL DEPICTIONS.—Upon receiving a valid re-  
12 moval request from an identifiable individual (or an  
13 authorized person acting on behalf of such indi-  
14 vidual) using the process described in paragraph  
15 (1)(A)(ii), a covered platform shall, as soon as pos-  
16 sible, but not later than 48 hours after receiving  
17 such request—

18 (A) remove the intimate visual depiction;

19 and

20 (B) make reasonable efforts to identify and  
21 remove any known identical copies of such de-  
22 piction.

23 (4) LIMITATION ON LIABILITY.—A covered plat-  
24 form shall not be liable for any claim based on the  
25 covered platform’s good faith disabling of access to,

1 or removal of, material claimed to be a nonconsen-  
2 sual intimate visual depiction based on facts or cir-  
3 cumstances from which the unlawful publishing of  
4 an intimate visual depiction is apparent, regardless  
5 of whether the intimate visual depiction is ultimately  
6 determined to be unlawful or not.

7 (b) ENFORCEMENT BY THE COMMISSION.—

8 (1) UNFAIR OR DECEPTIVE ACTS OR PRAC-  
9 TICES.—A failure to reasonably comply with the no-  
10 tice and takedown obligations under subsection (a)  
11 shall be treated as a violation of a rule defining an  
12 unfair or a deceptive act or practice under section  
13 18(a)(1)(B) of the Federal Trade Commission Act  
14 (15 U.S.C. 57a(a)(1)(B)).

15 (2) POWERS OF THE COMMISSION.—

16 (A) IN GENERAL.—Except as provided in  
17 subparagraph (D), the Commission shall en-  
18 force this section in the same manner, by the  
19 same means, and with the same jurisdiction,  
20 powers, and duties as though all applicable  
21 terms and provisions of the Federal Trade  
22 Commission Act (15 U.S.C. 41 et seq.) were in-  
23 corporated into and made a part of this section.

24 (B) PRIVILEGES AND IMMUNITIES.—Any  
25 person who violates this section shall be subject



1 to the penalties and entitled to the privileges  
2 and immunities provided in the Federal Trade  
3 Commission Act (15 U.S.C. 41 et seq.).

4 (C) AUTHORITY PRESERVED.—Nothing in  
5 this title shall be construed to limit the author-  
6 ity of the Federal Trade Commission under any  
7 other provision of law.

8 (D) SCOPE OF JURISDICTION.—Notwith-  
9 standing sections 4, 5(a)(2), or 6 of the Federal  
10 Trade Commission Act (15 U.S.C. 44; 45(a)(2);  
11 46), or any jurisdictional limitation of the Com-  
12 mission, the Commission shall also enforce this  
13 section in the same manner provided in sub-  
14 paragraph (A), with respect to organizations  
15 that are not organized to carry on business for  
16 their own profit or that of their members.

17 **SEC. 804. DEFINITIONS.**

18 In this title:

19 (1) COMMISSION.—The term “Commission”  
20 means the Federal Trade Commission.

21 (2) CONSENT; DIGITAL FORGERY; IDENTIFI-  
22 ABLE INDIVIDUAL; INTIMATE VISUAL DEPICTION.—  
23 The terms “consent”, “digital forgery”, “identifiable  
24 individual”, “intimate visual depiction”, and  
25 “minor” have the meaning given such terms in sec-

tion 223(h) of the Communications Act of 1934 (47 U.S.C. 223(h)), as added by section 802.

(3) COVERED PLATFORM.—

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

(i) that serves the public; and

(ii)(I) that primarily provides a forum for user-generated content, including messages, videos, images, games, and audio files; or

(II) for which it is in the regular course of trade or business of the website, online service, online application, or mobile application to publish, curate, host, or make available content of nonconsensual intimate visual depictions.

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

(i) A provider of broadband internet access service (as described in section 8.1(b) of title 47, Code of Federal Regulations, or successor regulation).

(ii) Electronic mail.

(iii) Except as provided in subparagraph (A)(ii)(II), an online service, application, or website—

(I) that consists primarily of content that is not user generated but is preselected by the provider of such online service, application, or website; and

(II) for which any chat, comment, or interactive functionality is incidental to, directly related to, or dependent on the provision of the content described in subparagraph (A)(ii)(I).

**SEC. 805. SEVERABILITY.**

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

**TITLE IX—RURAL BROADBAND  
PROTECTION ACT**

**SEC. 901. SHORT TITLE.**

This title may be cited as the “Rural Broadband Protection Act”.

1 **SEC. 902. VETTING PROCESS FOR PROSPECTIVE HIGH-COST**  
2 **UNIVERSAL SERVICE FUND APPLICANTS.**

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

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

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

8 “(A) the term ‘covered funding’ means any  
9 new offer of high-cost universal service program  
10 funding, including funding provided through a  
11 reverse competitive bidding mechanism provided  
12 under this section, for the deployment of a  
13 broadband-capable network and the provision of  
14 supported services over the network; and

15 “(B) the term ‘new covered funding award’  
16 means an award of covered funding that is  
17 made based on an application submitted to the  
18 Commission on or after the date on which rules  
19 are promulgated under paragraph (2).

20 “(2) COMMISSION RULEMAKING.—Not later  
21 than 180 days after the date of enactment of this  
22 subsection, the Commission shall initiate a rule-  
23 making proceeding to establish a vetting process for  
24 applicants for, and other recipients of, a new covered  
25 funding award.

26 “(3) CONTENTS.—

1           “(A) IN GENERAL.—In promulgating rules  
2           under paragraph (2), the Commission shall pro-  
3           vide that, consistent with principles of tech-  
4           nology neutrality, the Commission will only  
5           award covered funding to applicants that can  
6           demonstrate that they meet the qualifications in  
7           subparagraph (B).

8           “(B) QUALIFICATIONS DESCRIBED.—An  
9           applicant for a new covered funding award shall  
10          include in the initial application a proposal con-  
11          taining sufficient detail and documentation for  
12          the Commission to ascertain that the applicant  
13          possesses the technical, financial, and oper-  
14          ational capabilities, and has a reasonable busi-  
15          ness plan, to deploy the proposed network and  
16          deliver services with the relevant performance  
17          characteristics and requirements defined by the  
18          Commission and as pledged by the applicant.

19          “(C) EVALUATION OF PROPOSAL.—The  
20          Commission shall evaluate a proposal described  
21          in subparagraph (B) against—

22                 “(i) reasonable and well-established  
23                 technical, financial, and operational stand-  
24                 ards, including the technical standards  
25                 adopted by the Commission in orders of

1 the Commission relating to Establishing  
2 the Digital Opportunity Data Collection  
3 (WC Docket No. 19–195) (or orders of the  
4 Commission relating to modernizing any  
5 successor collection) for purposes of enti-  
6 ties that must report broadband avail-  
7 ability coverage; and

8 “(ii) the applicant’s history of com-  
9 plying with requirements in Commission  
10 and other government broadband deploy-  
11 ment funding programs.

12 “(D) PENALTIES FOR PRE-AUTHORIZATION  
13 DEFAULTS.—In adopting rules for any new cov-  
14 ered funding award, the Commission shall set a  
15 penalty for pre-authorization defaults of at least  
16 \$9,000 per violation and may not limit the base  
17 forfeiture to an amount less than 30 percent of  
18 the applicant’s total support, unless the Com-  
19 mission demonstrates the need for lower pen-  
20 alties in a particular instance.”.

## 21 **TITLE X—AMERICAN MUSIC** 22 **TOURISM**

### 23 **SEC. 1001. SHORT TITLE.**

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

1 **SEC. 1002. RESPONSIBILITIES OF THE ASSISTANT SEC-**  
2 **RETARY OF COMMERCE FOR TRAVEL AND**  
3 **TOURISM.**

4 (a) DOMESTIC TRAVEL AND TOURISM.—Section  
5 605(b) of the Visit America Act (15 U.S.C. 9803(b)) is  
6 amended—

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

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

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

12 “(4) identify locations and events in the United  
13 States that are important to music tourism and fa-  
14 cilitate and promote domestic travel and tourism to  
15 those locations and events.”.

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

20 “(d) FACILITATION OF INTERNATIONAL BUSINESS  
21 AND LEISURE TRAVEL.—The Assistant Secretary, in co-  
22 ordination with relevant Federal agencies, shall strive to  
23 increase and facilitate international business and leisure  
24 travel to the United States and ensure competitiveness  
25 by—

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

3           “(2) emphasizing rural and other destinations  
4           in the United States that are rich in cultural herit-  
5           age or ecological tourism, among other uniquely  
6           American destinations, as locations for hosting inter-  
7           national meetings, incentives, conferences, and exhi-  
8           bitions;

9           “(3) facilitating and promoting international  
10          travel and tourism to sports and recreation events  
11          and activities in the United States; and

12          “(4) identifying locations and events in the  
13          United States that are important to music tourism  
14          and facilitating and promoting international travel  
15          and tourism to those locations and events.”.

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

19                 “(4) REPORT ON GOALS RELATING TO DOMES-  
20                 TIC AND INTERNATIONAL TRAVEL.—Not later than  
21                 1 year after the date of enactment of the American  
22                 Music Tourism Act, and every 2 years thereafter,  
23                 the Assistant Secretary shall submit to the Sub-  
24                 committee on Tourism, Trade, and Export Pro-  
25                 motion of the Committee on Commerce, Science, and



1 Transportation of the Senate and the Subcommittee  
2 on Innovation, Data, and Commerce of the Com-  
3 mittee on Energy and Commerce of the House of  
4 Representatives a report of activities, findings,  
5 achievements, and vulnerabilities relating to the  
6 goals described in subsections (a) through (d).”.

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

10 (1) by redesignating paragraphs (1) and (2) as  
11 subparagraphs (A) and (B), respectively, and adjust-  
12 ing the margins accordingly; and

13 (2) by striking “In this title, the term ‘COVID–  
14 19 public health emergency’—” and inserting the  
15 following:

16 “In this title:

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

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

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

23 “(A) the act of traveling to a State or lo-  
24 cality to visit historic or modern day music-re-  
25 lated attractions, including museums, studios,

1 venues of all sizes, and other sites related to  
2 music; or

3 “(B) the act of traveling to a State or lo-  
4 cality to attend a music festival, a concert, or  
5 other live musical performance or music-related  
6 special event.”.

7 **TITLE XI—INFORMING CON-**  
8 **SUMERS ABOUT SMART DE-**  
9 **VICES**

10 **SEC. 1101. SHORT TITLE.**

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

13 **SEC. 1102. REQUIRED DISCLOSURE OF A CAMERA OR RE-**  
14 **CORDING CAPABILITY IN CERTAIN INTER-**  
15 **NET-CONNECTED DEVICES.**

16 Each manufacturer of a covered device shall disclose,  
17 clearly and conspicuously and prior to purchase, whether  
18 the covered device manufactured by the manufacturer con-  
19 tains a camera or microphone as a component of the cov-  
20 ered device.

21 **SEC. 1103. ENFORCEMENT BY THE FEDERAL TRADE COM-**  
22 **MISSION.**

23 (a) UNFAIR OR DECEPTIVE ACTS OR PRACTICES.—  
24 A violation of section 1102 shall be treated as a violation  
25 of a rule defining an unfair or deceptive act or practice

1 prescribed under section 18(a)(1)(B) of the Federal Trade  
2 Commission Act (15 U.S.C. 57a(a)(1)(B)).

3 (b) ACTIONS BY THE COMMISSION.—

4 (1) IN GENERAL.—The Federal Trade Commis-  
5 sion (in this title referred to as the “Commission”)  
6 shall enforce this title in the same manner, by the  
7 same means, and with the same jurisdiction, powers,  
8 and duties as though all applicable terms and provi-  
9 sions of the Federal Trade Commission Act (15  
10 U.S.C. 41 et seq.) were incorporated into and made  
11 a part of this title.

12 (2) PENALTIES AND PRIVILEGES.—Any person  
13 who violates this title or a regulation promulgated  
14 under this title shall be subject to the penalties and  
15 entitled to the privileges and immunities provided in  
16 the Federal Trade Commission Act (15 U.S.C. 41 et  
17 seq.).

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

21 (c) COMMISSION GUIDANCE.—Not later than 180  
22 days after the date of enactment of this title, the Commis-  
23 sion, through outreach to relevant private entities, shall  
24 issue guidance to assist manufacturers in complying with  
25 the requirements of this title, including guidance about

1 best practices for making the disclosure required by sec-  
2 tion 1102 as clear and conspicuous and age appropriate  
3 as practicable and about best practices for the use of a  
4 pictorial (as defined in section 2(a) of the Consumer Re-  
5 view Fairness Act of 2016 (15 U.S.C. 45b(a))) visual rep-  
6 resentation of the information to be disclosed.

7 (d) TAILORED GUIDANCE.—A manufacturer of a cov-  
8 ered device may petition the Commission for tailored guid-  
9 ance as to how to meet the requirements of section 1102  
10 consistent with existing rules of practice or any successor  
11 rules.

12 (e) LIMITATION ON COMMISSION GUIDANCE.—No  
13 guidance issued by the Commission with respect to this  
14 title shall confer any rights on any person, State, or local-  
15 ity, nor shall operate to bind the Commission or any per-  
16 son to the approach recommended in such guidance. In  
17 any enforcement action brought pursuant to this title, the  
18 Commission shall allege a specific violation of a provision  
19 of this title. The Commission may not base an enforce-  
20 ment action on, or execute a consent order based on, prac-  
21 tices that are alleged to be inconsistent with any such  
22 guidelines, unless the practices allegedly violate section  
23 1102.

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

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

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

6           (2) does not include—

7                   (A) a telephone (including a mobile phone),  
8                   a laptop, tablet, or any device that a consumer  
9                   would reasonably expect to have a microphone  
10                  or camera;

11                  (B) any device that is specifically marketed  
12                  as a camera, telecommunications device, or  
13                  microphone; or

14                  (C) any device or apparatus described in  
15                  sections 255, 716, and 718, and subsections  
16                  (aa) and (bb) of section 303 of the Communica-  
17                  tions Act of 1934 (47 U.S.C. 255; 617; 619;  
18                  and 303(aa) and (bb)), and any regulations  
19                  promulgated thereunder.

20   **SEC. 1105. EFFECTIVE DATE.**

21           This title shall apply to all covered devices manufac-  
22           tured after the date that is 180 days after the date on  
23           which guidance is issued by the Commission under section  
24           1103(c), and shall not apply to covered devices manufac-

1 tured or sold before such date, or otherwise introduced  
2 into interstate commerce before such date.

## 3 **TITLE XII—SECURING SEMICON-** 4 **DUCTOR SUPPLY CHAINS ACT**

### 5 **SEC. 1201. SHORT TITLE.**

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

### 8 **SEC. 1202. SELECTUSA DEFINED.**

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

### 13 **SEC. 1203. FINDINGS.**

14 Congress makes the following findings:

15 (1) Semiconductors underpin the United States  
16 and global economies, including manufacturing sec-  
17 tors. Semiconductors are also essential to the na-  
18 tional security of the United States.

19 (2) A shortage of semiconductors, brought  
20 about by the COVID–19 pandemic and other com-  
21 plex factors impacting the overall supply chain, has  
22 threatened the economic recovery of the United  
23 States and industries that employ millions of United  
24 States citizens.

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

6           (4) The supply chain for semiconductors is  
7           complex and global. While the United States plays  
8           a leading role in certain segments of the semicon-  
9           ductor industry, securing the supply chain requires  
10          onshoring, reshoring, or diversifying vulnerable seg-  
11          ments, such as for—

12                   (A) fabrication;

13                   (B) advanced packaging; and

14                   (C) materials and equipment used to man-  
15          ufacture semiconductor products.

16          (5) The Federal Government can leverage for-  
17          eign direct investment and private dollars to grow  
18          the domestic manufacturing and production capacity  
19          of the United States for vulnerable segments of the  
20          semiconductor supply chain.

21          (6) The SelectUSA program of the Department  
22          of Commerce, in coordination with other Federal  
23          agencies and State-level economic development orga-  
24          nizations, is positioned to boost foreign direct invest-

1       ment in domestic manufacturing and to help secure  
2       the semiconductor supply chain of the United States.

3   **SEC. 1204. COORDINATION WITH STATE-LEVEL ECONOMIC**  
4       **DEVELOPMENT ORGANIZATIONS.**

5       Not later than 180 days after the date of the enact-  
6   ment of this Act, the Executive Director of SelectUSA  
7   shall solicit comments from State-level economic develop-  
8   ment organizations—

9           (1) to review—

10                (A) what efforts the Federal Government  
11                can take to support increased foreign direct in-  
12                vestment in any segment of semiconductor-re-  
13                lated production;

14                (B) what barriers to such investment may  
15                exist and how to amplify State efforts to attract  
16                such investment;

17                (C) public opportunities those organiza-  
18                tions have identified to attract foreign direct in-  
19                vestment to help increase investment described  
20                in subparagraph (A); and

21                (D) resource gaps or other challenges that  
22                prevent those organizations from increasing  
23                such investment; and

24           (2) to develop recommendations for—



1 (A) how SelectUSA can increase such in-  
2 vestment independently or through partnership  
3 with those organizations; and

4 (B) working with countries that are allies  
5 or partners of the United States to ensure that  
6 foreign adversaries (as defined in section  
7 8(c)(2) of the Secure and Trusted Communica-  
8 tions Networks Act of 2019 (47 U.S.C.  
9 1607(c)(2))) do not benefit from United States  
10 efforts to increase such investment.

11 **SEC. 1205. REPORT ON INCREASING FOREIGN DIRECT IN-**  
12 **VESTMENT IN SEMICONDUCTOR-RELATED**  
13 **MANUFACTURING AND PRODUCTION.**

14 Not later than 2 years after the date of the enact-  
15 ment of this Act, the Executive Director of SelectUSA,  
16 in coordination with the Federal Interagency Investment  
17 Working Group established by Executive Order 13577 (76  
18 Fed. Reg. 35715; relating to establishment of the  
19 SelectUSA Initiative), shall submit to the Committee on  
20 Commerce, Science, and Transportation of the Senate and  
21 the Committee on Energy and Commerce of the House  
22 of Representatives a report that includes—

23 (1) a review of the comments SelectUSA re-  
24 ceived from State-level economic development organi-  
25 zations under section 1204;

1           (2) a description of activities SelectUSA is en-  
2           gaged in to increase foreign direct investment in  
3           semiconductor-related manufacturing and produc-  
4           tion; and

5           (3) an assessment of strategies SelectUSA may  
6           implement to achieve an increase in such investment  
7           and to help secure the United States supply chain  
8           for semiconductors, including by—

9                   (A) working with other relevant Federal  
10                  agencies; and

11                  (B) working with State-level economic de-  
12                  velopment organizations and implementing any  
13                  strategies or recommendations SelectUSA re-  
14                  ceived from those organizations.

15 **SEC. 1206. NO ADDITIONAL FUNDS.**

16       No additional funds are authorized to be appro-  
17       priated for the purpose of carrying out this title. The Ex-  
18       ecutive Director of SelectUSA shall carry out this title  
19       using amounts otherwise available to the Executive Direc-  
20       tor for such purposes.

21                   **TITLE XIII—HOTEL FEES**  
22                   **TRANSPARENCY ACT**

23 **SEC. 1301. SHORT TITLE.**

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

1 **SEC. 1302. PROHIBITION ON UNFAIR AND DECEPTIVE AD-**  
2 **VERTISING OF HOTEL ROOMS AND OTHER**  
3 **SHORT-TERM RENTAL PRICES.**

4 (a) PROHIBITION.—

5 (1) IN GENERAL.—It shall be unlawful for a  
6 covered entity to display, advertise, market, or offer  
7 in interstate commerce, including through direct of-  
8 ferings, third-party distribution, or metasearch refer-  
9 rals, a price for covered services that does not clear-  
10 ly, conspicuously, and prominently—

11 (A) display the total services price, if a  
12 price is displayed, in any advertisement, mar-  
13 keting, or price list wherever the covered serv-  
14 ices are displayed, advertised, marketed, or of-  
15 fered for sale;

16 (B) disclose to any individual who seeks to  
17 purchase covered services the total services  
18 price at the time the covered services are first  
19 displayed to the individual and anytime there-  
20 after throughout the covered services pur-  
21 chasing process; and

22 (C) disclose, prior to the final purchase,  
23 any tax, fee, or assessment imposed by any gov-  
24 ernment entity, quasi-government entity, or  
25 government-created special district or program  
26 on the sale of covered services.

1           (2) INDIVIDUAL COMPONENTS.—Provided that  
2           such displays are less prominent than the total serv-  
3           ice price required in paragraph (1), nothing in this  
4           Act shall be construed to prohibit the display of—

5                   (A) individual components of the total  
6           price; or

7                   (B) details of other items not required by  
8           paragraph (1).

9           (3) INDEMNIFICATION PROVISIONS.—Nothing  
10          in this section shall be construed to prohibit any cov-  
11          ered entity from entering into a contract with any  
12          other covered entity that contains an indemnification  
13          provision with respect to price or fee information  
14          disclosed, exchanged, or shared between the covered  
15          entities that are parties to the contract.

16       (b) ENFORCEMENT.—

17           (1) ENFORCEMENT BY THE COMMISSION.—

18                   (A) UNFAIR OR DECEPTIVE ACTS OR PRAC-  
19           TICES.—A violation of subsection (a) shall be  
20           treated as a violation of a rule defining an un-  
21           fair or deceptive act or practice prescribed  
22           under section 18(a)(1)(B) of the Federal Trade  
23           Commission Act (15 U.S.C. 57a(a)(1)(B)).

24                   (B) POWERS OF THE COMMISSION.—

1 (i) IN GENERAL.—The Commission  
2 shall enforce this section in the same man-  
3 ner, by the same means, and with the  
4 same jurisdiction, powers, and duties as  
5 though all applicable terms and provisions  
6 of the Federal Trade Commission Act (15  
7 U.S.C. 41 et seq.) were incorporated into  
8 and made a part of this Act.

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

15 (iii) AUTHORITY PRESERVED.—Noth-  
16 ing in this section shall be construed to  
17 limit the authority of the Commission  
18 under any other provision of law.

19 (2) ENFORCEMENT BY STATES.—

20 (A) IN GENERAL.—If the attorney general  
21 of a State has reason to believe that an interest  
22 of the residents of the State has been or is  
23 being threatened or adversely affected by a  
24 practice that violates subsection (a), the attor-  
25 ney general of the State may, as *parens patriae*,

1 bring a civil action on behalf of the residents of  
2 the State in an appropriate district court of the  
3 United States to obtain appropriate relief.

4 (B) RIGHTS OF THE COMMISSION.—

5 (i) NOTICE TO THE COMMISSION.—

6 (I) IN GENERAL.—Except as pro-  
7 vided in subclause (III), the attorney  
8 general of a State, before initiating a  
9 civil action under subparagraph (A)  
10 shall notify the Commission in writing  
11 that the attorney general intends to  
12 bring such civil action.

13 (II) CONTENTS.—The notifica-  
14 tion required by subclause (I) shall in-  
15 clude a copy of the complaint to be  
16 filed to initiate the civil action.

17 (III) EXCEPTION.—If it is not  
18 feasible for the attorney general of a  
19 State to provide the notification re-  
20 quired by subclause (I) before initi-  
21 ating a civil action under subpara-  
22 graph (A), the attorney general shall  
23 notify the Commission immediately  
24 upon instituting the civil action.

1 (ii) INTERVENTION BY THE COMMIS-  
2 SION.—The Commission may—

3 (I) intervene in any civil action  
4 brought by the attorney general of a  
5 State under subparagraph (A); and

6 (II) upon intervening—

7 (aa) be heard on all matters  
8 arising in the civil action; and

9 (bb) file petitions for appeal.

10 (C) INVESTIGATORY POWERS.—Nothing in  
11 this paragraph may be construed to prevent the  
12 attorney general of a State from exercising the  
13 powers conferred on the attorney general by the  
14 laws of the State to conduct investigations, to  
15 administer oaths or affirmations, or to compel  
16 the attendance of witnesses or the production of  
17 documentary or other evidence.

18 (D) ACTION BY THE COMMISSION.—When-  
19 ever a civil action has been instituted by or on  
20 behalf of the Commission for violation of sub-  
21 section (a), no attorney general of a State may,  
22 during the pendency of that action, institute an  
23 action under subparagraph (A) against any de-  
24 fendant named in the complaint in that action

1 for a violation of subsection (a) alleged in such  
2 complaint.

3 (E) VENUE; SERVICE OF PROCESS.—

4 (i) VENUE.—Any action brought  
5 under subparagraph (A) may be brought  
6 in—

7 (I) the district court of the  
8 United States that meets applicable  
9 requirements relating to venue under  
10 section 1391 of title 28, United States  
11 Code; or

12 (II) another court of competent  
13 jurisdiction.

14 (ii) SERVICE OF PROCESS.—In an ac-  
15 tion brought under subparagraph (A),  
16 process may be served in any district in  
17 which—

18 (I) the defendant is an inhab-  
19 itant, may be found, or transacts  
20 business; or

21 (II) venue is proper under section  
22 1391 of title 28, United States Code.

23 (F) ACTIONS BY OTHER STATE OFFI-  
24 CIALS.—



1 (i) IN GENERAL.—In addition to civil  
2 actions brought by an attorney general  
3 under subparagraph (A), any other officer  
4 of a State who is authorized by the State  
5 to do so may bring a civil action under  
6 subparagraph (A), subject to the same re-  
7 quirements and limitations that apply  
8 under this paragraph to civil actions  
9 brought by attorneys general.

10 (ii) SAVINGS PROVISION.—Nothing in  
11 this paragraph may be construed to pro-  
12 hibit an authorized official of a State from  
13 initiating or continuing any proceeding in  
14 a court of the State for a violation of any  
15 civil or criminal law of the State.

16 (3) AFFIRMATIVE DEFENSE.—In any action  
17 pursuant to paragraph (1) or (2), an intermediary  
18 or third-party online seller may assert an affirmative  
19 defense if such intermediary or third-party online  
20 seller—

21 (A) established procedures to receive up-to-  
22 date price information from hotels or short-  
23 term rentals, or agents acting on behalf of a  
24 hotel or short-term rental;

1 (B) relied in good faith on information  
2 provided to the intermediary or third-party on-  
3 line seller by a hotel or short-term rental, or  
4 agent acting on behalf of such hotel or short-  
5 term rental, and such information was inac-  
6 curate at the time it was provided to the inter-  
7 mediary or third-party online seller; and

8 (C) took prompt action to remove or cor-  
9 rect any false or inaccurate information about  
10 the total services price after receiving notice  
11 that such information was false or inaccurate.

12 (c) PREEMPTION.—

13 (1) IN GENERAL.—A State, or political subdivi-  
14 sion of a State, may not maintain, enforce, pre-  
15 scribe, or continue in effect any law, rule, regulation,  
16 requirement, standard, or other provision having the  
17 force and effect of law of the State, or political sub-  
18 division of the State, that prohibits a covered entity  
19 from advertising, displaying, marketing, or otherwise  
20 offering, or otherwise affects the manner in which a  
21 covered entity may advertise, display, market, or  
22 otherwise offer, for sale in interstate commerce, in-  
23 cluding through a direct offering, third-party dis-  
24 tribution, or metasearch referral, a price of a res-  
25 ervation for a covered service, and that requires fee

1 disclosure, unless the law requires the total services  
2 price to include each service fee, as defined in sub-  
3 section (d)(8), and in accordance with subsection  
4 (a)(1).

5 (2) RULE OF CONSTRUCTION.—This section  
6 may not be construed to—

7 (A) preempt any law of a State or political  
8 subdivision of a State relating to contracts or  
9 torts; or

10 (B) preempt any law of a State or political  
11 subdivision of a State to the extent that such  
12 law relates to an act of fraud, unauthorized ac-  
13 cess to personal information, or notification of  
14 unauthorized access to personal information.

15 (d) DEFINITIONS.—In this Act:

16 (1) BASE SERVICES PRICE.—The term “base  
17 services price” —

18 (A) means, with respect to the covered  
19 services provided by a hotel or short-term rent-  
20 al, the price in order to obtain the covered serv-  
21 ices of the hotel or short-term rental; and

22 (B) does not include—

23 (i) any service fee;

24 (ii) any taxes or fees imposed by a  
25 government or quasi-government entity;

1 (iii) assessment fees of a government-  
2 created special district or program; or

3 (iv) any charges or fees for an op-  
4 tional product or service associated with  
5 the covered services that may be selected  
6 by a purchaser of covered services.

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

9 (3) COVERED ENTITY.—The term “covered en-  
10 tity” means a person, partnership, or corporation  
11 with respect to whom the Commission has jurisdic-  
12 tion under section 5(a)(2) of the Federal Trade  
13 Commission Act (15 U.S.C. 45(a)(2)), including—

- 14 (A) a hotel or short-term rental;  
15 (B) a third-party online seller; or  
16 (C) an intermediary.

17 (4) COVERED SERVICES.—The term “covered  
18 services”—

19 (A) means the temporary provision of a  
20 room, building, or other lodging facility; and

21 (B) does not include the provision of a  
22 meeting room, banquet services, or catering  
23 services.

24 (5) HOTEL.—The term “hotel” means an es-  
25 tablishment that is—

1 (A) primarily engaged in providing a cov-  
2 ered service to the general public; and

3 (B) promoted, advertised, or marketed in  
4 interstate commerce or for which such estab-  
5 lishment's services are sold in interstate com-  
6 merce.

7 (6) INTERMEDIARY.—The term “intermediary”  
8 means an entity that operates either as a business-  
9 to-business platform, consumer-facing platform, or  
10 both, that displays, including through direct offer-  
11 ings, third-party distribution, or metasearch referral,  
12 a price for covered services or price comparison tools  
13 for consumers seeking covered services.

14 (7) OPTIONAL PRODUCT OR SERVICE.—The  
15 term “optional product or service” means a product  
16 or service that an individual does not need to pur-  
17 chase to use or obtain covered services.

18 (8) SERVICE FEE.—The term “service fee”—

19 (A) means a charge imposed by a covered  
20 entity that must be paid in order to obtain cov-  
21 ered services; and

22 (B) does not include—

23 (i) any taxes or fees imposed by a  
24 government or quasi-government entity;

1 (ii) any assessment fees of a govern-  
2 ment-created special district or program;  
3 or

4 (iii) any charges or fees for an op-  
5 tional product or service associated with  
6 the covered services that may be selected  
7 by a purchaser of covered services.

8 (9) SHORT-TERM RENTAL.—The term “short-  
9 term rental” means a property, including a single-  
10 family dwelling or a unit in a condominium, coopera-  
11 tive, or time-share, that provides covered services  
12 (either with respect to the entire property or a part  
13 of the property) to the general public—

14 (A) in exchange for a fee;

15 (B) for periods shorter than 30 consecutive  
16 days; and

17 (C) is promoted, advertised, or marketed in  
18 interstate commerce or for which such prop-  
19 erty’s services are sold in interstate commerce.

20 (10) STATE.—The term “State” means each of  
21 the 50 States, the District of Columbia, and any ter-  
22 ritory or possession of the United States.

23 (11) THIRD-PARTY ONLINE SELLER.—The term  
24 “third-party online seller” means any person other  
25 than a hotel or short-term rental that sells covered

1 services or offers for sale covered services with re-  
2 spect to a hotel or short-term rental in a transaction  
3 facilitated on the internet.

4 (12) TOTAL SERVICES PRICE.—The term “total  
5 services”—

6 (A) means, with respect to covered serv-  
7 ices, the total cost of the covered services, in-  
8 cluding the base services price and any service  
9 fees; and

10 (B) does not include—

11 (i) any taxes or fees imposed by a  
12 government or quasi-government entity;

13 (ii) any assessment fees of a govern-  
14 ment-created special district or program;  
15 or

16 (iii) any charges or fees for an op-  
17 tional product or service associated with  
18 the covered services that may be selected  
19 by a purchaser of covered services.

20 (e) EFFECTIVE DATE.—The prohibition under sub-  
21 section (a) shall take effect 450 days after the date of  
22 the enactment of this Act and shall apply to advertise-  
23 ments, displays, marketing, and offers of covered services  
24 of a covered entity made on or after such date.

1 **TITLE XIV—TRANSPARENCY IN**  
2 **CHARGES FOR KEY EVENTS**  
3 **TICKETING**

4 **SEC. 1401. SHORT TITLE.**

5 This title may be cited as the “Transparency In  
6 Charges for Key Events Ticketing Act” or the “TICKET  
7 Act”.

8 **SEC. 1402. ALL INCLUSIVE TICKET PRICE DISCLOSURE.**

9 Beginning 180 days after the date of the enactment  
10 of this Act, it shall be unlawful for a ticket issuer, sec-  
11 ondary market ticket issuer, or secondary market ticket  
12 exchange to offer for sale an event ticket unless the ticket  
13 issuer, secondary market ticket issuer, or secondary mar-  
14 ket ticket exchange—

15 (1) clearly and conspicuously displays the total  
16 event ticket price, if a price is displayed, in any ad-  
17 vertisement, marketing, or price list wherever the  
18 ticket is offered for sale;

19 (2) clearly and conspicuously discloses to any  
20 individual who seeks to purchase an event ticket the  
21 total event ticket price at the time the ticket is first  
22 displayed to the individual and anytime thereafter  
23 throughout the ticket purchasing process; and



1           (3) provides an itemized list of the base event  
2           ticket price and each event ticket fee prior to the  
3           completion of the ticket purchasing process.

4 **SEC. 1403. SPECULATIVE TICKETING BAN.**

5           (a) PROHIBITION.—Beginning 180 days after the  
6           date of the enactment of this Act, a ticket issuer, sec-  
7           ondary market ticket issuer, or secondary market ticket  
8           exchange that does not have actual or constructive posses-  
9           sion of an event ticket shall not sell, offer for sale, or ad-  
10          vertise for sale such event ticket.

11          (b) SERVICES PERMITTED.—Notwithstanding sub-  
12          section (a), a secondary market ticket issuer or secondary  
13          market ticket exchange may sell, offer for sale, or adver-  
14          tise for sale a service to an individual to obtain an event  
15          ticket on behalf of such individual if the secondary market  
16          ticket issuer or secondary market ticket exchange complies  
17          with the following:

18               (1) Does not market or list the service as an  
19               event ticket.

20               (2) Maintains a clear, distinct, and easily dis-  
21               cernible separation between the service and event  
22               tickets that persists throughout the entire service se-  
23               lection and purchasing process.

24               (3) Clearly and conspicuously discloses before  
25               selection of the service that the service is not an

1 event ticket and that the purchase of the service  
2 does not guarantee an event ticket.

3 **SEC. 1404. DISCLOSURES.**

4 A ticket issuer, secondary market ticket issuer, or  
5 secondary market ticket exchange—

6 (1) if offering an event ticket for resale, shall  
7 provide a clear and conspicuous statement, before a  
8 consumer purchases the event ticket from the ticket  
9 issuer, secondary market ticket issuer, or secondary  
10 market ticket exchange, that the issuer or exchange  
11 is engaged in the secondary sale of event tickets; and

12 (2) shall not state that the ticket issuer, sec-  
13 ondary market ticket issuer, or secondary market  
14 ticket exchange is affiliated with or endorsed by a  
15 venue, team, or artist, as applicable, including by  
16 using words like “official” in promotional materials,  
17 social media promotions, or paid advertising, unless  
18 a partnership agreement has been executed or the  
19 issuer or exchange has the express written consent  
20 of the venue, team, or artist, as applicable.

21 **SEC. 1405. REFUND REQUIREMENTS.**

22 (a) CANCELLATION.—Beginning 180 days after the  
23 date of the enactment of this Act, if an event is canceled  
24 or postponed (except for a case in which an event is can-  
25 celed or postponed due to a cause beyond the reasonable

1 control of the issuer, including a natural disaster, civil dis-  
2 turbance, or otherwise unforeseeable impediment), a ticket  
3 issuer, secondary market ticket issuer, or secondary mar-  
4 ket ticket exchange shall provide the purchaser of an event  
5 ticket from the issuer or exchange for the canceled or post-  
6 poned event, at a minimum—

7 (1) if the event is cancelled, a full refund for  
8 the total event ticket price;

9 (2) subject to availability, if the event is post-  
10 poned for not more than 6 months and the original  
11 event ticket is no longer valid for entry to the re-  
12 scheduled event, a replacement event ticket for the  
13 rescheduled event in the same or a comparable loca-  
14 tion once the event has been rescheduled; or

15 (3) if the event is postponed for more than 6  
16 months, at the option of the purchaser—

17 (A) a full refund for the total event ticket  
18 price; or

19 (B) if the original event ticket is no longer  
20 valid for entry to the rescheduled event, a re-  
21 placement event ticket for the rescheduled event  
22 in the same or a comparable location once the  
23 event has been rescheduled.

24 (b) DISCLOSURE OF GUARANTEE AND REFUND POL-  
25 ICY REQUIRED.—Beginning 180 days after the date of the

1 enactment of this Act, a ticket issuer, secondary market  
2 ticket issuer, or secondary market ticket exchange shall  
3 disclose clearly and conspicuously to a purchaser before  
4 the completion of an event ticket sale the guarantee or  
5 refund policy of such ticket issuer, secondary market tick-  
6 et issuer, or secondary market ticket exchange, including  
7 under what circumstances any refund issued will include  
8 a refund of any event ticket fee.

9 (c) DISCLOSURE OF HOW TO OBTAIN A REFUND RE-  
10 QUIRED.—Beginning 180 days after the date of the enact-  
11 ment of this Act, a ticket issuer, secondary market ticket  
12 issuer, or secondary market ticket exchange shall provide  
13 a clear and conspicuous explanation of how to obtain a  
14 refund of the total event ticket price.

15 **SEC. 1406. REPORT BY THE FEDERAL TRADE COMMISSION**  
16 **ON BOTS ACT OF 2016 ENFORCEMENT.**

17 Not later than 6 months after the date of the enact-  
18 ment of this Act, the Commission shall submit to Congress  
19 a report on enforcement of the Better Online Ticket Sales  
20 Act of 2016 (Public Law 114–274; 15 U.S.C. 45c), includ-  
21 ing any enforcement action taken, challenges with enforce-  
22 ment and coordination with State Attorneys General, and  
23 recommendations on how to improve enforcement and in-  
24 dustry compliance.

1 **SEC. 1407. ENFORCEMENT.**

2 (a) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A  
3 violation of this title shall be treated as a violation of a  
4 rule defining an unfair or deceptive act or practice under  
5 section 18(a)(1)(B) of the Federal Trade Commission Act  
6 (15 U.S.C. 57a(a)(1)(B)).

7 (b) POWERS OF COMMISSION.—

8 (1) IN GENERAL.—The Commission shall en-  
9 force this title in the same manner, by the same  
10 means, and with the same jurisdiction, powers, and  
11 duties as though all applicable terms and provisions  
12 of the Federal Trade Commission Act (15 U.S.C. 41  
13 et seq.) were incorporated into and made a part of  
14 this title.

15 (2) PRIVILEGES AND IMMUNITIES.—Any person  
16 who violates this title shall be subject to the pen-  
17 alties and entitled to the privileges and immunities  
18 provided in the Federal Trade Commission Act (15  
19 U.S.C. 41 et seq.).

20 (3) AUTHORITY PRESERVED.—Nothing in this  
21 title shall be construed to limit the authority of the  
22 Commission under any other provision of law.

23 **SEC. 1408. DEFINITIONS.**

24 In this title:

25 (1) ARTIST.—The term “artist” means any per-  
26 former, musician, comedian, producer, ensemble or

1 production entity of a theatrical production, sports  
2 team owner, or similar person.

3 (2) BASE EVENT TICKET PRICE.—The term  
4 “base event ticket price” means, with respect to an  
5 event ticket, the price of the event ticket excluding  
6 the cost of any event ticket fees.

7 (3) COMMISSION.—The term “Commission”  
8 means the Federal Trade Commission.

9 (4) EVENT.—The term “event” means any live  
10 concert, theatrical performance, sporting event,  
11 show, or similarly scheduled live activity, that is—

12 (A) taking place in a venue with a seating  
13 or attendance capacity exceeding 200 persons;

14 (B) open to the general public; and

15 (C) promoted, advertised, or marketed in  
16 interstate commerce, or for which event tickets  
17 are generally sold or distributed in interstate  
18 commerce.

19 (5) EVENT TICKET; TICKET ISSUER.—The  
20 terms “event ticket” and “ticket issuer” have the  
21 meaning given those terms in section 3 of the Better  
22 Online Ticket Sales Act of 2016 (15 U.S.C. 45c  
23 note).

24 (6) EVENT TICKET FEE.—The term “event  
25 ticket fee”—

1 (A) means a charge for an event ticket  
2 that must be paid in addition to the base event  
3 ticket price in order to obtain an event ticket  
4 from a ticket issuer, secondary market ticket  
5 issuer, or secondary market ticket exchange, in-  
6 cluding any service fee, charge and order proc-  
7 essing fee, delivery fee, facility charge fee, tax,  
8 and any other charge; and

9 (B) does not include any charge or fee for  
10 an optional product or service associated with  
11 the event that may be selected by a purchaser  
12 of an event ticket.

13 (7) OPTIONAL PRODUCT OR SERVICE.—The  
14 term “optional product or service” means a product  
15 or service that an individual does not need to pur-  
16 chase to use or take possession of an event ticket.

17 (8) RESALE; SECONDARY SALE.—The terms  
18 “resale” and “secondary sale” mean any sale of an  
19 event ticket that occurs after the initial sale of the  
20 event ticket by a ticket issuer.

21 (9) SECONDARY MARKET TICKET EXCHANGE.—  
22 The term “secondary market ticket exchange”  
23 means any person that in the regular course of trade  
24 or business of that person operates a platform or ex-  
25 change for advertising, listing, or selling resale tick-

1       ets, on behalf of itself, vendors, or a secondary mar-  
 2       ket ticket issuer.

3           (10) SECONDARY MARKET TICKET ISSUER.—

4       The term “secondary market ticket issuer” means  
 5       any person, including a ticket issuer, that resells or  
 6       makes a secondary sale of an event ticket to the gen-  
 7       eral public in the regular course of the trade or busi-  
 8       ness of the person.

9           (11) TOTAL EVENT TICKET PRICE.—The term

10      “total event ticket price” means, with respect to an  
 11      event ticket, the total cost of the event ticket, includ-  
 12      ing the base event ticket price and any event ticket  
 13      fee.

14           (12) VENUE.—The term “venue” means a  
 15      physical space at which an event takes place.

## 16           **TITLE XV—ROUTERS ACT**

### 17   **SEC. 1501. SHORT TITLE.**

18      This title may be cited as the “Removing Our Unse-  
 19      cure Technologies to Ensure Reliability and Security Act”  
 20      or the “ROUTERS Act”.

### 21   **SEC. 1502. STUDY OF NATIONAL SECURITY RISKS POSED BY** 22           **CERTAIN ROUTERS AND MODEMS.**

23      (a) IN GENERAL.—The Secretary shall conduct a  
 24      study of the national security risks posed by consumer  
 25      routers, modems, and devices that combine a modem and



1 router that are designed, developed, manufactured, or sup-  
 2 plied by persons owned by, controlled by, or subject to the  
 3 influence of a covered country.

4 (b) REPORT TO CONGRESS.—Not later than 1 year  
 5 after the date of the enactment of this Act, the Secretary  
 6 shall submit to the Committee on Energy and Commerce  
 7 of the House of Representatives and the Committee on  
 8 Commerce, Science, and Transportation of the Senate a  
 9 report on the results of the study conducted under sub-  
 10 section (a).

11 (c) DEFINITIONS.—In this section:

12 (1) COVERED COUNTRY.—The term “covered  
 13 country” means a country specified in section  
 14 4872(f)(2) of title 10, United States Code.

15 (2) SECRETARY.—The term “Secretary” means  
 16 the Secretary of Commerce, in consultation with the  
 17 Assistant Secretary of Commerce for Communica-  
 18 tions and Information.

## 19 **TITLE XVI—NTIA** 20 **REAUTHORIZATION**

### 21 **SEC. 1601. SHORT TITLE.**

22 This title may be cited as the “National Tele-  
 23 communications and Information Administration Reau-  
 24 thorization Act” or the “NTIA Reauthorization Act”.

1 **SEC. 1602. DEFINITIONS.**

2 In this title:

3 (1) COMMISSION.—The term “Commission”  
4 means the Federal Communications Commission.

5 (2) NTIA.—The term “NTIA” means the Na-  
6 tional Telecommunications and Information Admin-  
7 istration.

8 (3) UNDER SECRETARY.—The term “Under  
9 Secretary” means the Under Secretary of Commerce  
10 for Communications and Information.

11 **Subtitle A—Reauthorization**

12 **SEC. 1611. REAUTHORIZATION OF THE NATIONAL TELE-**  
13 **COMMUNICATIONS AND INFORMATION AD-**  
14 **MINISTRATION ORGANIZATION ACT.**

15 (a) AUTHORIZATION OF APPROPRIATIONS.—Section  
16 151 of the National Telecommunications and Information  
17 Administration Organization Act is amended by striking  
18 “\$17,600,000 for fiscal year 1992 and \$17,900,000 for  
19 fiscal year 1993” and inserting “\$57,000,000 for fiscal  
20 year 2025 and \$57,000,000 for fiscal year 2026”.

21 (b) UNDER SECRETARY OF COMMERCE FOR COMMU-  
22 NICATIONS AND INFORMATION.—

23 (1) UNDER SECRETARY; DEPUTY UNDER SEC-  
24 RETARY.—

25 (A) UNDER SECRETARY.—The National  
26 Telecommunications and Information Adminis-

1           tration Organization Act (47 U.S.C. 901 et  
2           seq.) is amended by striking “Assistant Sec-  
3           retary” each place it appears and inserting  
4           “Under Secretary”.

5                   (B) DEPUTY UNDER SECRETARY.—Section  
6           103(a) of the National Telecommunications and  
7           Information Administration Organization Act  
8           (47 U.S.C. 902(a)), as amended by this section,  
9           is amended by adding at the end the following:

10           “(3) DEPUTY UNDER SECRETARY.—The Dep-  
11          uty Under Secretary of Commerce for Communica-  
12          tions and Information shall—

13                   “(A) be the principal policy advisor of the  
14          Under Secretary;

15                   “(B) perform such other functions as the  
16          Under Secretary shall from time to time assign  
17          or delegate; and

18                   “(C) act as Under Secretary during the  
19          absence or disability of the Under Secretary or  
20          in the event of a vacancy in the office of the  
21          Under Secretary.”.

22           (2) CONTINUATION OF CIVIL ACTIONS.—This  
23          subsection, and the amendments made by this sub-  
24          section, shall not abate any civil action commenced  
25          by or against the Assistant Secretary of Commerce

1 for Communications and Information before the date  
2 of the enactment of this Act, except that the Under  
3 Secretary shall be substituted as a party to the ac-  
4 tion on and after such date.

5 (3) CONTINUATION IN OFFICE.—The individual  
6 serving as the Assistant Secretary of Commerce for  
7 Communications and Information and the individual  
8 serving as the Deputy Assistant Secretary of Com-  
9 merce for Communications and Information on the  
10 day before the date of the enactment of this Act may  
11 serve as the Under Secretary and the Deputy Under  
12 Secretary of Commerce for Communications and In-  
13 formation, respectively, on and after that date with-  
14 out the need for renomination or reappointment.

15 (4) REFERENCES.—Any reference in a law, reg-  
16 ulation, document, paper, or other record of the  
17 United States to the Assistant Secretary of Com-  
18 merce for Communications and Information shall, on  
19 and after the date of the enactment of this Act, be  
20 deemed to be a reference to the Under Secretary.

21 (5) EXECUTIVE SCHEDULE.—

22 (A) IN GENERAL.—Subchapter II of chap-  
23 ter 53 of title 5, United States Code, is amend-  
24 ed—

1 (i) in section 5314, by adding at the  
2 end the following:

3 “Under Secretary of Commerce for Commu-  
4 nications and Information.”; and

5 (ii) in section 5315, in the item relat-  
6 ing to the Assistant Secretaries of Com-  
7 merce, by striking “(11)” and inserting  
8 “(10)”.

9 (B) EFFECTIVE DATE.—The amendment  
10 made by subparagraph (A) (establishing the an-  
11 nual rate of the basic pay of the Under Sec-  
12 retary) shall take effect on the first day of the  
13 first pay period beginning after the date of the  
14 enactment of this Act.

15 (c) AUTHORITIES AND RESPONSIBILITIES.—

16 (1) COORDINATION OF EXECUTIVE BRANCH  
17 VIEWS ON MATTERS BEFORE THE FEDERAL COMMU-  
18 NICATIONS COMMISSION.—Section 105(a)(1) of the  
19 National Telecommunications and Information Ad-  
20 ministration Organization Act (47 U.S.C. 904(a)(1))  
21 is amended—

22 (A) by striking “to ensure that the con-  
23 duct” and inserting the following: “to ensure  
24 that—

25 “(A) the conduct”;

1 (B) in subparagraph (A), as so designated,  
 2 by striking the period at the end and inserting  
 3 “; and”; and

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

5 “(B) the views of the executive branch on  
 6 matters presented to the Commission are, con-  
 7 sistent with section 103(b)(2)(J)—

8 “(i) appropriately coordinated; and

9 “(ii) reflective of executive branch pol-  
 10 icy.”.

11 (2) ASSIGNED FUNCTIONS.—Section 103(b)(2)  
 12 of the National Telecommunications and Informa-  
 13 tion Administration Organization Act (47 U.S.C.  
 14 902(b)(2)) is amended—

15 (A) in the matter preceding subparagraph  
 16 (A), by inserting “, some of which were” before  
 17 “transferred to the Secretary”; and

18 (B) in subparagraph (M), by inserting “,  
 19 publish reports,” after “studies”.

20 (3) RULE OF CONSTRUCTION.—Nothing in the  
 21 amendments made by paragraphs (1) and (2) may  
 22 be construed to expand or contract the authority of  
 23 the Commission.

24 (d) TECHNICAL AND CONFORMING AMENDMENTS.—

1           (1) PUBLIC TELECOMMUNICATIONS FINANCING  
2     ACT OF 1978.—Section 106(c) of the Public Tele-  
3     communications Financing Act of 1978 (5 U.S.C.  
4     5316 note; Public Law 95–567) is amended by strik-  
5     ing “The position of Deputy Assistant Secretary of  
6     Commerce for Communications and Information, es-  
7     tablished in Department of Commerce Organization  
8     Order Numbered 10–10 (effective March 26,  
9     1978),” and inserting “The position of Deputy  
10    Under Secretary of Commerce for Communications  
11    and Information, established under section 103(a) of  
12    the National Telecommunications and Information  
13    Administration Organization Act (47 U.S.C.  
14    902(a)),”.

15           (2) COMMUNICATIONS ACT OF 1934.—Section  
16    344(d)(2) of the Communications Act of 1934 (47  
17    U.S.C. 344(d)(2)) is amended by striking “Assistant  
18    Secretary” and inserting “Under Secretary”.

19           (3) HOMELAND SECURITY ACT OF 2002.—Sec-  
20    tion 1805(d)(2) of the Homeland Security Act of  
21    2002 (6 U.S.C. 575(d)(2)) is amended by striking  
22    “Assistant Secretary for Communications and Infor-  
23    mation of the Department of Commerce” and insert-  
24    ing “Under Secretary of Commerce for Communica-  
25    tions and Information”.

1           (4) AGRICULTURE IMPROVEMENT ACT OF  
2           2018.—Section 6212 of the Agriculture Improvement  
3           Act of 2018 (7 U.S.C. 950bb–6) is amended—

4                   (A) in subsection (d)(1), in the heading, by  
5                   striking “ASSISTANT SECRETARY” and inserting  
6                   “UNDER SECRETARY”; and

7                   (B) by striking “Assistant Secretary” each  
8                   place the term appears and inserting “Under  
9                   Secretary”.

10          (5) TITLE 17, UNITED STATES CODE.—Section  
11          1201(a)(1)(C) of title 17, United States Code, is  
12          amended by striking “Assistant Secretary for Com-  
13          munications and Information of the Department of  
14          Commerce” and inserting “Under Secretary of Com-  
15          merce for Communications and Information”.

16          (6) UNLOCKING CONSUMER CHOICE AND WIRE-  
17          LESS COMPETITION ACT.—Section 2(b) of the  
18          Unlocking Consumer Choice and Wireless Competi-  
19          tion Act (17 U.S.C. 1201 note; Public Law 113–  
20          144) is amended by striking “Assistant Secretary  
21          for Communications and Information of the Depart-  
22          ment of Commerce” and inserting “Under Secretary  
23          of Commerce for Communications and Information”.

24          (7) COMMUNICATIONS SATELLITE ACT OF  
25          1962.—Section 625(a)(1) of the Communications



1 Satellite Act of 1962 (47 U.S.C. 763d(a)(1)) is  
2 amended, in the matter preceding subparagraph (A),  
3 by striking “Assistant Secretary” and inserting  
4 “Under Secretary of Commerce”.

5 (8) SPECTRUM PIPELINE ACT OF 2015.—The  
6 Spectrum Pipeline Act of 2015 (47 U.S.C. 921 note;  
7 title X of Public Law 114–74) is amended—

8 (A) in section 1002(1), in the heading, by  
9 striking “ASSISTANT SECRETARY” and inserting  
10 “UNDER SECRETARY”; and

11 (B) by striking “Assistant Secretary” each  
12 place the term appears and inserting “Under  
13 Secretary”.

14 (9) WARNING, ALERT, AND RESPONSE NET-  
15 WORK ACT.—Section 606 of the Warning, Alert, and  
16 Response Network Act (47 U.S.C. 1205) is amend-  
17 ed—

18 (A) by striking “Assistant Secretary” each  
19 place the term appears and inserting “Under  
20 Secretary”; and

21 (B) in subsection (b), in the first sentence,  
22 by striking “for7Communications” and insert-  
23 ing “for Communications”.

24 (10) AMERICAN RECOVERY AND REINVESTMENT  
25 ACT OF 2009.—Section 6001 of the American Recov-

1       ery and Reinvestment Act of 2009 (47 U.S.C. 1305)  
2       is amended by striking “Assistant Secretary” each  
3       place the term appears and inserting “Under Sec-  
4       retary”.

5               (11) MIDDLE CLASS TAX RELIEF AND JOB CRE-  
6       ATION ACT OF 2012.—Title VI of the Middle Class  
7       Tax Relief and Job Creation Act of 2012 (47 U.S.C.  
8       1401 et seq.) is amended—

9               (A) in section 6001 (47 U.S.C. 1401)—

10                       (i) by striking paragraph (4);

11                       (ii) by redesignating paragraphs (5)  
12                       through (32) as paragraphs (4) through  
13                       (31), respectively; and

14                       (iii) by inserting after paragraph (31),  
15                       as so redesignated, the following:

16               “(32) UNDER SECRETARY.—The term ‘Under  
17       Secretary’ means the Under Secretary of Commerce  
18       for Communications and Information.”; and

19               (B) by striking “Assistant Secretary” each  
20       place the term appears and inserting “Under  
21       Secretary”.

22               (12) RAY BAUM’S ACT OF 2018.—The RAY  
23       BAUM’S Act of 2018 (division P of Public Law  
24       115–141; 132 Stat. 348) is amended by striking

1 “Assistant Secretary” each place the term appears  
2 and inserting “Under Secretary”.

3 (13) SECURE AND TRUSTED COMMUNICATIONS  
4 NETWORKS ACT OF 2019.—Section 8 of the Secure  
5 and Trusted Communications Networks Act of 2019  
6 (47 U.S.C. 1607) is amended—

7 (A) in subsection (c)(1), in the heading, by  
8 striking “ASSISTANT SECRETARY” and inserting  
9 “UNDER SECRETARY”; and

10 (B) by striking “Assistant Secretary” each  
11 place the term appears and inserting “Under  
12 Secretary”.

13 (14) TITLE 51, UNITED STATES CODE.—Section  
14 50112(3) of title 51, United States Code, is amend-  
15 ed, in the matter preceding subparagraph (A), by  
16 striking “Assistant Secretary” each place the term  
17 appears and inserting “Under Secretary”.

18 (15) CONSOLIDATED APPROPRIATIONS ACT,  
19 2021.—The Consolidated Appropriations Act, 2021  
20 (Public Law 116–260) is amended—

21 (A) in title IX of division N—

22 (i) in section 902(a)(2), in the head-  
23 ing, by striking “ASSISTANT SECRETARY”  
24 and inserting “UNDER SECRETARY”;

25 (ii) in section 905—

1 (I) in subsection (a)(1), in the  
2 heading, by striking “ASSISTANT SEC-  
3 RETARY” and inserting “UNDER SEC-  
4 RETARY”;

5 (II) in subsection (c)(3)(B), in  
6 the heading, by striking “ASSISTANT  
7 SECRETARY” and inserting “UNDER  
8 SECRETARY”;

9 (III) in subsection (d)(2)(B), in  
10 the heading, by striking “ASSISTANT  
11 SECRETARY” and inserting “UNDER  
12 SECRETARY”; and

13 (iii) by striking “Assistant Secretary”  
14 each place the term appears (except in sec-  
15 tion 905(a)(13)(E)) and inserting “Under  
16 Secretary”; and

17 (B) in title IX of division FF—

18 (i) in section 903(g)(2), in the head-  
19 ing, by striking “ASSISTANT SECRETARY”  
20 and inserting “UNDER SECRETARY”; and

21 (ii) by striking “Assistant Secretary”  
22 each place the term appears and inserting  
23 “Under Secretary”.

1           (16) INFRASTRUCTURE INVESTMENT AND JOBS  
2       ACT.—The Infrastructure Investment and Jobs Act  
3       (Public Law 117–58) is amended—

4           (A) in section 27003, by striking “Assist-  
5       ant Secretary” each place the term appears and  
6       inserting “Under Secretary”;

7           (B) in division F—

8           (i) in section 60102—

9           (I) in subsection (a)(2)(A), by  
10       striking “ASSISTANT SECRETARY”  
11       and inserting “UNDER SECRETARY”;

12          (II) in subsection (d)(1), by  
13       striking “ASSISTANT SECRETARY”  
14       and inserting “UNDER SECRETARY”;  
15       and

16          (III) in subsection (h)—

17           (aa) in paragraph (1)(B), by  
18       striking “ASSISTANT SEC-  
19       RETARY” and inserting “UNDER  
20       SECRETARY”; and

21           (bb) in paragraph  
22       (5)(B)(iii), by striking “ASSIST-  
23       ANT SECRETARY” and inserting  
24       “UNDER SECRETARY”;

25          (ii) in title III—

1 (I) in section 60302(5), by strik-  
 2 ing “ASSISTANT SECRETARY” and in-  
 3 serting “UNDER SECRETARY”; and

4 (II) in section  
 5 60305(d)(2)(B)(ii), by striking “AS-  
 6 SISTANT SECRETARY” and inserting  
 7 “UNDER SECRETARY”;

8 (iii) in section 60401(a)(2), by strik-  
 9 ing “ASSISTANT SECRETARY” and insert-  
 10 ing “UNDER SECRETARY”;

11 (iv) by striking “Assistant Secretary”  
 12 each place the term appears and inserting  
 13 “Under Secretary”; and

14 (C) in division J, in title I, in the matter  
 15 under the heading “distance learning, telemedi-  
 16 cine, and broadband program” under the head-  
 17 ing “Rural Utilities Service” under the heading  
 18 “RURAL DEVELOPMENT PROGRAMS”, by  
 19 striking “Assistant Secretary” and inserting  
 20 “Under Secretary”.

21 **SEC. 1612. NTIA CONSOLIDATED REPORTING ACT.**

22 (a) ELIMINATION OF CERTAIN OUTDATED OR COM-  
 23 PLETED REPORTING REQUIREMENTS.—

1           (1) BTOP QUARTERLY REPORT.—Section  
2           6001(d) of the American Recovery and Reinvestment  
3           Act of 2009 (47 U.S.C. 1305(d)) is amended—

4                   (A) in paragraph (2), by striking the semi-  
5                   colon at the end and inserting “; and”;

6                   (B) in paragraph (3), by striking “; and”  
7                   and inserting a period; and

8                   (C) by striking paragraph (4).

9           (2) CERTAIN REPORTS REQUIRED BY NATIONAL  
10          TELECOMMUNICATIONS AND INFORMATION ADMINIS-  
11          TRATION ORGANIZATION ACT.—Sections 154, 155,  
12          and 156 of the National Telecommunications and  
13          Information Administration Organization Act are re-  
14          pealed.

15          (3) INITIAL REPORT REQUIRED BY SECTION  
16          9202(a)(1)(G) OF THE NDAA FOR FISCAL YEAR  
17          2021.—Section 9202(a)(1)(G) of the William M.  
18          (Mac) Thornberry National Defense Authorization  
19          Act for Fiscal Year 2021 (47 U.S.C. 906(a)(1)(G))  
20          is amended—

21                   (A) in clause (ii), by redesignating sub-  
22                   clauses (I), (II), and (III) as clauses (i), (ii),  
23                   and (iii), respectively, and conforming the mar-  
24                   gins of such clauses accordingly; and

1 (B) by striking “REPORTS TO CONGRESS”  
2 and all that follows through “For each fiscal  
3 year” and inserting “ANNUAL REPORT TO CON-  
4 GRESS.—For each fiscal year”.

5 (4) REPORT TO PRESIDENT.—Section 105(a) of  
6 the National Telecommunications and Information  
7 Administration Organization Act (47 U.S.C. 904(a))  
8 is amended—

9 (A) by striking paragraph (2); and

10 (B) by redesignating paragraph (3) as  
11 paragraph (2).

12 (5) EFFECT ON AUTHORITY.—Nothing in this  
13 subsection or the amendments made by this sub-  
14 section may be construed to expand or contract the  
15 authority of the Secretary, the Under Secretary, the  
16 NTIA, or the Commission.

17 (6) OTHER REPORTS.—Nothing in this sub-  
18 section or the amendments made by this subsection  
19 may be construed to prohibit or otherwise prevent  
20 the Secretary, the Under Secretary, the NTIA, or  
21 the Commission from producing any additional re-  
22 ports otherwise within the authority of the Sec-  
23 retary, the Under Secretary, the NTIA, or the Com-  
24 mission, respectively.

25 (b) CONSOLIDATED ANNUAL REPORT.—



1           (1) IN GENERAL.—In the first quarter of each  
2           calendar year, the Under Secretary shall publish on  
3           the website of the NTIA and submit to the Com-  
4           mittee on Energy and Commerce of the House of  
5           Representatives and the Committee on Commerce,  
6           Science, and Transportation of the Senate a report  
7           that contains the reports described in paragraph (2)  
8           for the fiscal year ending most recently before the  
9           beginning of such quarter.

10          (2) REPORTS DESCRIBED.—The reports de-  
11          scribed in this paragraph are the following:

12                (A) The report required by section  
13                903(c)(2)(C) of division FF of the Consolidated  
14                Appropriations Act, 2021 (47 U.S.C.  
15                1307(c)(2)(C)).

16                (B) If amounts in the Public Wireless Sup-  
17                ply Chain Innovation Fund established by sec-  
18                tion 9202(a)(1)(A)(i) of the William M. (Mac)  
19                Thornberry National Defense Authorization Act  
20                for Fiscal Year 2021 (47 U.S.C.  
21                906(a)(1)(A)(i)) were available for the fiscal  
22                year described in paragraph (1) of this sub-  
23                section, the report required by section  
24                9202(a)(1)(G) of such Act (47 U.S.C.  
25                906(a)(1)(G)).

1 (C) If the Under Secretary awarded grants  
2 under section 60304(d)(1) of the Infrastructure  
3 Investment and Jobs Act (47 U.S.C.  
4 1723(d)(1)) in the fiscal year described in para-  
5 graph (1) of this subsection, the report required  
6 by section 60306(a)(1)(A) of such Act (47  
7 U.S.C. 1725(a)(1)(A)).

8 (3) TIMING OF UNDERLYING REPORTING RE-  
9 QUIREMENTS.—

10 (A) REPORT OF OFFICE OF INTERNET  
11 CONNECTIVITY AND GROWTH.—Section  
12 903(c)(2)(C) of division FF of the Consolidated  
13 Appropriations Act, 2021 (47 U.S.C.  
14 1307(c)(2)(C)) is amended—

15 (i) in the matter preceding clause  
16 (i)—

17 (I) by striking “Not later than 1  
18 year after the date of the enactment  
19 of this Act, and every year there-  
20 after,” and inserting “In the first  
21 quarter of each calendar year,”;

22 (II) by inserting “, for the fiscal  
23 year ending most recently before the  
24 beginning of such quarter,” after “a  
25 report”; and

(ii) in clause (i), by striking “for the previous year”.

(B) REPORT ON DIGITAL EQUITY GRANT PROGRAMS.—Section 60306(a)(1) of the Infrastructure Investment and Jobs Act (47 U.S.C. 1725(a)(1)) is amended—

(i) in the matter preceding subparagraph (A), by striking “Not later than 1 year” and all that follows through “shall—” and inserting the following: “For the first fiscal year in which the Under Secretary awards grants under section 60304(d)(1), and each fiscal year thereafter in which the Under Secretary awards grants under such section, the Under Secretary shall—”; and

(ii) in subparagraph (A)—

(I) by inserting “in the first quarter of the first calendar year that begins after the end of such fiscal year,” before “submit”; and

(II) by striking “, for the year covered by the report”.

(4) SATISFACTION OF UNDERLYING REPORTING REQUIREMENTS.—

1           (A) IN GENERAL.—Except as provided in  
2           subparagraph (B), the publication and submis-  
3           sion of a report as required by paragraph (1)  
4           in the first quarter of a calendar year shall be  
5           treated as satisfying any requirement to publish  
6           or otherwise make publicly available or to sub-  
7           mit to Congress or to a committee of Congress  
8           a report described in paragraph (2) for the fis-  
9           cal year ending most recently before the begin-  
10          ning of such quarter.

11          (B) CERTAIN SUBMISSION REQUIRE-  
12          MENTS.—At the time when the Under Secretary  
13          submits a report required by paragraph (1) to  
14          the committees described in such paragraph,  
15          the Under Secretary shall submit any portion of  
16          such report that relates to a report described in  
17          paragraph (2)(C) to each committee of Con-  
18          gress not described in paragraph (1) to which  
19          such report would (without regard to subpara-  
20          graph (A) of this paragraph) be required to be  
21          submitted.

22          (5) APPLICABILITY.—Paragraph (1), and the  
23          amendments made by paragraph (3), shall apply be-  
24          ginning on January 1 of the first calendar year that  
25          begins after the date of the enactment of this Act.

1 (c) EXTENSION OF CERTAIN AUDIT AND REPORTING  
 2 REQUIREMENTS.—Section 902(c)(4)(A) of division N of  
 3 the Consolidated Appropriations Act, 2021 (47 U.S.C.  
 4 1306(c)(4)(A)) is amended by striking “fiscal years 2021  
 5 and 2022” and inserting “fiscal years 2021, 2022, 2023,  
 6 and 2024”.

7 (d) DEFINITION.—In this section, the term “Sec-  
 8 retary” means the Secretary of Commerce.

## 9 **Subtitle B—Office of Spectrum** 10 **Management**

### 11 **SEC. 1621. OFFICE OF SPECTRUM MANAGEMENT.**

12 Part A of the National Telecommunications and In-  
 13 formation Administration Organization Act (47 U.S.C.  
 14 901 et seq.) is amended by adding at the end the fol-  
 15 lowing:

#### 16 **“SEC. 106. OFFICE OF SPECTRUM MANAGEMENT.**

17 “(a) ESTABLISHMENT.—There is established within  
 18 the NTIA an Office of Spectrum Management (in this sec-  
 19 tion referred to as the ‘Office’).

20 “(b) HEAD OF OFFICE.—

21 “(1) IN GENERAL.—The head of the Office  
 22 shall be an Associate Administrator for Spectrum  
 23 Management (in this section referred to as the ‘As-  
 24 sociate Administrator’).

1           “(2) REQUIREMENT TO REPORT.—The Asso-  
2       ciate Administrator shall report to the Under Sec-  
3       retary (or a designee of the Under Secretary).

4           “(c) DUTIES.—The Associate Administrator shall, at  
5       the direction of the Under Secretary—

6           “(1) carry out responsibilities under section  
7       103(b)(2)(A) (relating to frequency assignments for  
8       radio stations belonging to and operated by the  
9       United States), make frequency allocations for fre-  
10      quencies that will be used by such stations, and de-  
11      velop and maintain techniques, databases, measure-  
12      ments, files, and procedures necessary for such allo-  
13      cations;

14          “(2) carry out responsibilities under section  
15      103(b)(2)(K) (relating to establishing policies con-  
16      cerning spectrum assignments and use by radio sta-  
17      tions belonging to and operated by the United  
18      States) and provide Federal agencies with guidance  
19      to ensure that the conduct of telecommunications ac-  
20      tivities by such agencies is consistent with such poli-  
21      cies;

22          “(3) represent the interests of Federal agencies  
23      in the process through which the Commission and  
24      the NTIA jointly determine the National Table of  
25      Frequency Allocations, and coordinate with the

1 Commission in the development of a comprehensive  
2 long-range plan for improved management of all  
3 electromagnetic spectrum resources;

4 “(4) appoint the chairpersons of and provide  
5 secretariat functions for the Interdepartmental  
6 Radio Advisory Committee and the Interagency  
7 Spectrum Advisory Council;

8 “(5) carry out responsibilities under section  
9 103(b)(2)(B) (relating to authorizing a foreign gov-  
10 ernment to construct and operate a radio station at  
11 the seat of Government of the United States) and  
12 assign frequencies for use by such stations;

13 “(6) provide advice and assistance to the Under  
14 Secretary and coordinate with the Associate Admin-  
15 istrator for International Affairs in carrying out  
16 spectrum management aspects of the international  
17 policy responsibilities of the NTIA, including spec-  
18 trum-related responsibilities under section  
19 103(b)(2)(G);

20 “(7) carry out spectrum-related responsibilities  
21 under section 103(b)(2)(H) (relating to coordination  
22 of the telecommunications activities of the executive  
23 branch and assistance in the formulation of policies  
24 and standards for such activities);

1 “(8) carry out spectrum-related responsibilities  
 2 under section 103(b)(2)(Q) (relating to certain ac-  
 3 tivities with respect to telecommunications re-  
 4 sources); and

5 “(9) carry out any other duties of the NTIA  
 6 with respect to spectrum policy that the Under Sec-  
 7 retary may designate.”.

## 8 **Subtitle C—Office of International** 9 **Affairs**

### 10 **SEC. 1631. OFFICE OF INTERNATIONAL AFFAIRS.**

11 Part A of the National Telecommunications and In-  
 12 formation Administration Organization Act (47 U.S.C.  
 13 901 et seq.), as amended by the preceding provisions of  
 14 this title, is further amended by adding at the end the  
 15 following:

#### 16 **“SEC. 107. OFFICE OF INTERNATIONAL AFFAIRS.**

17 “(a) ESTABLISHMENT.—There is established within  
 18 the NTIA an Office of International Affairs (in this sec-  
 19 tion referred to as the ‘Office’).

20 “(b) HEAD OF OFFICE.—

21 “(1) IN GENERAL.—The head of the Office  
 22 shall be an Associate Administrator for International  
 23 Affairs (in this section referred to as the ‘Associate  
 24 Administrator’).



1           “(2) REQUIREMENT TO REPORT.—The Asso-  
2       ciate Administrator shall report to the Under Sec-  
3       retary (or a designee of the Under Secretary).

4           “(c) DUTIES.—The Associate Administrator shall, at  
5       the direction of the Under Secretary—

6           “(1) in coordination with the Secretary of  
7       State, conduct analysis of, review, and formulate  
8       international telecommunications and information  
9       policy;

10          “(2) present on international telecommuni-  
11       cations and information policy—

12               “(A) before the Commission, Congress,  
13       and others; and

14               “(B) in coordination with the Secretary of  
15       State, before international telecommunications  
16       bodies, including the International Tele-  
17       communication Union;

18          “(3) conduct or obtain analysis on economic  
19       and other aspects of international telecommuni-  
20       cations and information policy;

21          “(4) formulate, and recommend to the Under  
22       Secretary, policies and plans with respect to prepara-  
23       tion for and participation in international tele-  
24       communications and information policy activities;

1           “(5) in coordination with the Secretary of  
2           State, coordinate NTIA and interdepartmental eco-  
3           nomic, technical, operational, and other preparations  
4           related to participation by the United States in  
5           international telecommunications and information  
6           policy conferences and negotiations;

7           “(6) ensure NTIA representation with respect  
8           to international telecommunications and information  
9           policy meetings and the activities related to prepara-  
10          tion for such meetings;

11          “(7) in coordination with the Secretary of  
12          State, coordinate with Federal agencies and private  
13          organizations engaged in activities involving inter-  
14          national telecommunications and information policy  
15          matters and maintain cognizance of the activities of  
16          United States signatories with respect to related  
17          treaties, agreements, and other instruments;

18          “(8) provide advice and assistance related to  
19          international telecommunications and information  
20          policy to other Federal agencies charged with re-  
21          sponsibility for international negotiations, to  
22          strengthen the position and serve the best interests  
23          of the United States in the conduct of negotiations  
24          with foreign nations;

1 “(9) provide advice and assistance to the Under  
 2 Secretary with respect to evaluating the inter-  
 3 national impact of matters pending before the Com-  
 4 mission, other Federal agencies, and Congress;

5 “(10) carry out, at the request of the Secretary,  
 6 the responsibilities of the Secretary under the Com-  
 7 munications Satellite Act of 1962 (47 U.S.C. 701 et  
 8 seq.) and other Federal laws related to international  
 9 telecommunications and information policy; and

10 “(11) carry out any other duties of the NTIA  
 11 with respect to international telecommunications and  
 12 information policy that the Under Secretary may  
 13 designate.”.

## 14 **DIVISION C—HEALTH**

### 15 **TITLE I—MEDICAID**

#### 16 **SEC. 101. STREAMLINED ENROLLMENT PROCESS FOR ELI-**

#### 17 **GIBLE OUT-OF-STATE PROVIDERS UNDER**

#### 18 **MEDICAID AND CHIP.**

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

22 “(10) STREAMLINED ENROLLMENT PROCESS  
 23 FOR ELIGIBLE OUT-OF-STATE PROVIDERS.—

24 “(A) IN GENERAL.—The State—

1 “(i) adopts and implements a process  
2 to allow an eligible out-of-State provider to  
3 enroll under the State plan (or a waiver of  
4 such plan) to furnish items and services to,  
5 or order, prescribe, refer, or certify eligi-  
6 bility for items and services for, qualifying  
7 individuals without the imposition of  
8 screening or enrollment requirements by  
9 such State that exceed the minimum nec-  
10 essary for such State to provide payment  
11 to an eligible out-of-State provider under  
12 such State plan (or a waiver of such plan),  
13 such as the provider’s name and National  
14 Provider Identifier (and such other infor-  
15 mation specified by the Secretary); and

16 “(ii) provides that an eligible out-of-  
17 State provider that enrolls as a partici-  
18 pating provider in the State plan (or a  
19 waiver of such plan) through such process  
20 shall be so enrolled for a 5-year period, un-  
21 less the provider is terminated or excluded  
22 from participation during such period.

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

24 “(i) ELIGIBLE OUT-OF-STATE PRO-  
25 VIDER.—The term ‘eligible out-of-State

1 provider’ means, with respect to a State, a  
2 provider—

3 “(I) that is located in any other  
4 State;

5 “(II) that—

6 “(aa) was determined by the  
7 Secretary to have a limited risk  
8 of fraud, waste, and abuse for  
9 purposes of determining the level  
10 of screening to be conducted  
11 under section 1866(j)(2), has  
12 been so screened under such sec-  
13 tion 1866(j)(2), and is enrolled in  
14 the Medicare program under title  
15 XVIII; or

16 “(bb) was determined by the  
17 State agency administering or su-  
18 pervising the administration of  
19 the State plan (or a waiver of  
20 such plan) of such other State to  
21 have a limited risk of fraud,  
22 waste, and abuse for purposes of  
23 determining the level of screening  
24 to be conducted under paragraph  
25 (1) of this subsection, has been

1 so screened under such para-  
2 graph (1), and is enrolled under  
3 such State plan (or a waiver of  
4 such plan); and

5 “(III) that has not been—

6 “(aa) excluded from partici-  
7 pation in any Federal health care  
8 program pursuant to section  
9 1128 or 1128A;

10 “(bb) excluded from partici-  
11 pation in the State plan (or a  
12 waiver of such plan) pursuant to  
13 part 1002 of title 42, Code of  
14 Federal Regulations (or any suc-  
15 cessor regulation), or State law;  
16 or

17 “(cc) terminated from par-  
18 ticipating in a Federal health  
19 care program or the State plan  
20 (or a waiver of such plan) for a  
21 reason described in paragraph  
22 (8)(A).

23 “(ii) QUALIFYING INDIVIDUAL.—The  
24 term ‘qualifying individual’ means an indi-  
25 vidual under 21 years of age who is en-

1 rolled under the State plan (or waiver of  
2 such plan).

3 “(iii) STATE.—The term ‘State’  
4 means 1 of the 50 States or the District  
5 of Columbia.”.

6 (b) CONFORMING AMENDMENTS.—

7 (1) Section 1902(a)(77) of the Social Security  
8 Act (42 U.S.C. 1396a(a)(77)) is amended by insert-  
9 ing “enrollment,” after “screening,”.

10 (2) The subsection heading for section  
11 1902(kk) of such Act (42 U.S.C. 1396a(kk)) is  
12 amended by inserting “enrollment,” after “screen-  
13 ing,”.

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

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

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

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

1           (1) IN GENERAL.—Section 1915(c) of the So-  
2       cial Security Act (42 U.S.C. 1396n(c)) is amend-  
3       ed—

4                   (A) in paragraph (2)—

5                           (i) in subparagraph (E)—

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

8                                   (II) by inserting “(including,  
9                                   with respect to such information pro-  
10                                  vided on or after July 9, 2027, the in-  
11                                  formation specified in paragraph  
12                                  (11))” before the period at the end;  
13                                  and

14                           (ii) by adding at the end the following

15                                  flush sentence:

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

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

23                                  “(11) For purposes of paragraph (2)(E), the  
24                                  information specified in this paragraph is the fol-  
25                                  lowing:



1           “(A) In the case of a State that limits the  
2           number of individuals who may be provided  
3           home or community-based services under a  
4           waiver granted under this subsection and main-  
5           tains a list of individuals waiting to enroll in  
6           such waiver, a description of how the State  
7           maintains such list, including—

8                   “(i) information on whether the State  
9                   screens individuals on such list to deter-  
10                  mine whether such individuals are eligible  
11                  to receive such services under such waiver;

12                  “(ii) information on whether (and, if  
13                  applicable, how often) the State periodi-  
14                  cally re-screens individuals on such list for  
15                  eligibility;

16                  “(iii) the number of people on such  
17                  list of individuals waiting to enroll in such  
18                  waiver; and

19                  “(iv) the average amount of time that  
20                  individuals newly enrolled in such waiver  
21                  within the past 12 months were on such  
22                  list of individuals waiting to enroll in such  
23                  waiver.

24           “(B) With respect to homemaker services,  
25           home health aide services, personal care serv-

ices, and habilitation services furnished under  
waivers under this subsection, by each such  
service type—

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

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

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

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

“(8) REPORTING REQUIREMENT.—With respect  
to homemaker services, home health aide services,  
personal care services, and habilitation services pro-

1 vided under this subsection on or after July 9, 2027,  
2 the State, not less frequently than annually, shall  
3 provide to the Secretary the same information re-  
4 garding such services as the State is required to pro-  
5 vide under subsection (c)(11)(B).”;

6 (B) in subsection (j)(2)(E), by inserting  
7 after the second sentence the following: “With  
8 respect to any homemaker services, home health  
9 aide services, personal care services, and habili-  
10 tation services provided under this subsection  
11 on or after July 9, 2027, the State, not less fre-  
12 quently than annually, shall provide to the Sec-  
13 retary the same information regarding such  
14 services as the State is required to provide  
15 under subsection (c)(11)(B).”; and

16 (C) in subsection (k)(3)(E)—

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

19 (ii) by inserting before the period, the  
20 following: “, and with respect to home-  
21 maker services, home health aide services,  
22 personal care services, and habilitation  
23 services provided under this subsection on  
24 or after July 9, 2027, not less frequently  
25 than annually, the same information re-

1           garding such services as the State is re-  
 2           quired to provide under subsection  
 3           (c)(11)(B)”.

4           (b) DEMONSTRATION PROGRAM TO EXPAND HCBS  
 5 COVERAGE UNDER SECTION 1915(c) WAIVERS.—Section  
 6 1915(c) of the Social Security Act (42 U.S.C. 1396n(c)),  
 7 as amended by subsection (a), is further amended—

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

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

13               “(12) DEMONSTRATION PROGRAM TO EXPAND  
 14               COVERAGE FOR HOME OR COMMUNITY-BASED SERV-  
 15               ICES.—

16               “(A) IN GENERAL.—

17                       “(i) APPROVAL.—Not later than 24  
 18                       months after the date on which the plan-  
 19                       ning grants under subparagraph (B) are  
 20                       awarded, notwithstanding paragraph (1),  
 21                       the Secretary may approve a waiver that is  
 22                       standalone from any other waiver approved  
 23                       under this subsection for not more than 5  
 24                       States, selected in accordance with clause  
 25                       (ii), to include as medical assistance under

1 the State plan of such State, for the 3-year  
2 period beginning on the date of such ap-  
3 proval, payment for part or all of the cost  
4 of home or community-based services  
5 (other than room and board (as described  
6 in paragraph (1))) approved by the Sec-  
7 retary which are provided pursuant to a  
8 written plan of care to individuals de-  
9 scribed in subparagraph (C)(iii).

10 “(ii) SELECTION CRITERIA.—In se-  
11 lecting States for purposes of clause (i),  
12 the Secretary shall—

13 “(I) only select States that re-  
14 ceived a planning grant under sub-  
15 paragraph (B);

16 “(II) only select States that meet  
17 the requirements specified in subpara-  
18 graph (C) and such other require-  
19 ments as the Secretary may determine  
20 appropriate;

21 “(III) select States in a manner  
22 that ensures geographic diversity;

23 “(IV) give preference to States  
24 with a higher percentage (relative to  
25 other States that apply to be selected

1 for purposes of clause (i)) of the total  
2 State population residing in rural  
3 areas (as determined by the Sec-  
4 retary);

5 “(V) give preference to States  
6 that have demonstrated more progress  
7 in rebalancing long-term services and  
8 supports systems under this title, as  
9 determined based on the relative share  
10 of individuals who use home or com-  
11 munity-based services (as defined by  
12 the Secretary) under this title as a  
13 percentage of total individuals who  
14 use long-term services and supports  
15 (as defined by the Secretary) under  
16 this title (in the most recent year for  
17 which such data is available); and

18 “(VI) give preference to States  
19 that pursue a waiver under this para-  
20 graph that incorporates the provision  
21 of mental health services for adults  
22 with serious mental illness, children  
23 with serious emotional disturbances,  
24 or individuals with substance use dis-  
25 order.

1 “(B) PLANNING GRANTS.—

2 “(i) IN GENERAL.—

3 “(I) APPROVAL.—Not later than  
4 18 months after the date of the enact-  
5 ment of this paragraph, the Secretary  
6 shall award planning grants of not  
7 more than \$5,000,000 each to not  
8 more than 10 States for purposes of  
9 preparing to submit a request for a  
10 waiver under this subsection (includ-  
11 ing for costs to implement the waiver  
12 or other activities to expand the provi-  
13 sion of home or community-based  
14 services under this section) to provide  
15 home or community-based services to  
16 individuals described in subparagraph  
17 (C)(iii).

18 “(II) SELECTION CRITERIA.—In  
19 awarding planning grants under sub-  
20 clause (I), the Secretary shall use the  
21 selection criteria specified in sub-  
22 clauses (III) through (VI) of subpara-  
23 graph (A)(ii).

24 “(ii) CONSULTATION.—A State that is  
25 awarded a planning grant under clause (i)

1 shall, in preparing to submit a request for  
2 a waiver described in such clause, consult  
3 with—

4 “(I) individuals in need of (and  
5 not receiving) home or community-  
6 based services, individuals receiving  
7 home or community-based services,  
8 and the caregivers of such individuals;

9 “(II) providers furnishing home  
10 or community-based services; and

11 “(III) such other stakeholders, as  
12 the Secretary may specify.

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

24 “(i) As of the date that such State re-  
25 quests a waiver under this subsection to



1 provide home or community-based services  
2 to individuals described in clause (iii), all  
3 other waivers (if any) granted under this  
4 subsection to such State meet the require-  
5 ments of this subsection.

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

17 “(iii) The State establishes needs-  
18 based criteria, subject to the approval of  
19 the Secretary, to identify individuals for  
20 whom a determination described in para-  
21 graph (1) is not applicable, who will be eli-  
22 gible for home or community-based serv-  
23 ices under a waiver approved under this  
24 paragraph, and specifies the home or com-

1 community-based services such individuals so  
2 eligible will receive.

3 “(iv) The State established needs-  
4 based criteria for determining whether an  
5 individual described in clause (iii) requires  
6 the level of care provided in a hospital,  
7 nursing facility, or an intermediate care fa-  
8 cility for individuals with developmental  
9 disabilities under the State plan or under  
10 any waiver of such plan that are more  
11 stringent than the needs-based criteria es-  
12 tablished under clause (iii) for determining  
13 eligibility for home or community-based  
14 services.

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

1 “(vi) The State provides to the Sec-  
2 retary data (in such form and manner as  
3 the Secretary may specify) regarding the  
4 number of individuals described in clause  
5 (i) with respect to a State seeking approval  
6 of a waiver under this subsection, to whom  
7 the State will make such services available  
8 under such waiver.

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

19 “(I) the cost (as such term is de-  
20 fined by the Secretary) of such serv-  
21 ices furnished to individuals described  
22 in clause (iii), broken down by type of  
23 service;

24 “(II) with respect to each type of  
25 home and community-based service

1 provided under the waiver, the length  
2 of time that such individuals have re-  
3 ceived such service;

4 “(III) a comparison between the  
5 data described in subclause (I) and  
6 any comparable data available with  
7 respect to individuals with respect to  
8 whom a determination described in  
9 paragraph (1) has been made and  
10 with respect to individuals receiving  
11 institutional care under this title; and

12 “(IV) the number of individuals  
13 who have received home and commu-  
14 nity-based services under the waiver  
15 during the preceding year.”.

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

21 (d) CMS GUIDANCE TO STATES ON INTERIM COV-  
22 ERAGE UNDER SECTION 1915 HOME AND COMMUNITY-  
23 BASED SERVICES AUTHORITIES.—Not later than January  
24 1, 2027, the Secretary of Health and Human Services  
25 shall issue guidance to the States to clarify how a State

1 may provide, with respect to an individual who is eligible  
2 for home and community-based services under section  
3 1915 of the Social Security Act (42 U.S.C. 1396n), cov-  
4 erage of such services pursuant to a provisional written  
5 plan of care, pending finalization, with respect to such in-  
6 dividual.

7 (e) FUNDING.—

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

15 (2) RESERVATION FOR PLANNING GRANTS.—Of  
16 the amount appropriated under paragraph (1), the  
17 Secretary of Health and Human Services shall re-  
18 serve \$50,000,000 of such amount to award plan-  
19 ning grants under the demonstration program estab-  
20 lished by the amendments made by subsection (b).

21 **SEC. 103. REMOVING CERTAIN AGE RESTRICTIONS ON MED-**  
22 **ICAID ELIGIBILITY FOR WORKING ADULTS**  
23 **WITH DISABILITIES.**

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

1           (1)           IN           GENERAL.—Section  
2       1902(a)(10)(A)(ii)(XV) of the Social Security Act  
3       (42 U.S.C. 1396a(a)(10)(A)(ii)(XV)) is amended by  
4       striking “but less than 65,”.

5           (2)       DEFINITION       MODIFICATION.—Section  
6       1905(v)(1)(A) of the Social Security Act (42 U.S.C.  
7       1396d(v)(1)(A)) is amended by striking “, but less  
8       than 65,”.

9       (b) APPLICATION TO CERTAIN STATES.—A State  
10   that, as of the date of enactment of this Act, provides for  
11   making medical assistance available to individuals de-  
12   scribed in subclause (XV) or (XVI) of section  
13   1902(a)(10)(A)(ii) of the Social Security Act (42 U.S.C.  
14   1396a(a)(10)(A)(ii)) shall not be regarded as failing to  
15   comply with the requirements of either such subclause (as  
16   amended by subsection (a)(1)) or with section  
17   1905(v)(1)(A) of the Social Security Act (42 U.S.C.  
18   1396d(v)(1)(A)) (as amended by subsection (a)(2)) before  
19   January 1, 2027.

20   **SEC. 104. MEDICAID STATE PLAN REQUIREMENT FOR DE-**  
21                           **TERMINING RESIDENCY AND COVERAGE FOR**  
22                           **MILITARY FAMILIES.**

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

25           (1) in subsection (a)—

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

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

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

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

10 “(A) that, for purposes of determining eli-  
11 gibility for medical assistance under the State  
12 plan (or waiver of such plan), such active duty  
13 relocated individual is treated as a resident of  
14 the State unless such individual voluntarily  
15 elects not to be so treated for such purposes;

16 “(B) that if, at the time of relocation (as  
17 described in subsection (uu)(1)), such active  
18 duty relocated individual is on a home and com-  
19 munity-based services waiting list (as defined in  
20 subsection (uu)(2)), such individual remains on  
21 such list until—

22 “(i) the State completes an assess-  
23 ment and renders a decision with respect  
24 to the eligibility of such individual to re-  
25 ceive the relevant home and community-

1           based services at the time a slot for such  
 2           services becomes available and, in the case  
 3           such decision is a denial of such eligibility,  
 4           such individual has exhausted the individ-  
 5           ual’s opportunity for a fair hearing; or

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

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

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

22                 “(1) ACTIVE DUTY RELOCATED INDIVIDUAL.—  
 23          The term ‘active duty relocated individual’ means an  
 24          individual—

25                 “(A) who—



1 “(i) is enrolled under the State plan  
2 (or waiver of such plan); or

3 “(ii) with respect to an individual de-  
4 scribed in subparagraph (C)(ii), would be  
5 so enrolled pursuant to subsection  
6 (a)(10)(A)(ii)(VI) if such individual began  
7 receiving home and community-based serv-  
8 ices;

9 “(B) who—

10 “(i) is a member of the Armed Forces  
11 engaged in active duty service and is relo-  
12 cated to another State (in this subsection  
13 referred to as the ‘military service reloca-  
14 tion State’) by reason of such service;

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

22 “(iii) is a dependent (as defined by  
23 the Secretary) of a member described in  
24 clause (i) or (ii) who relocates to the mili-

tary service relocation State with such member; and

“(C) who—

“(i) was receiving home and community-based services (as defined in section 9817(a)(2)(B) of the American Rescue Plan Act of 2021) at the time of such relocation; or

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

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

1 community-based services at the time a slot for such  
2 services becomes available due to such limit.”.

3 (b) IMPLEMENTATION FUNDING.—There are appro-  
4 priated, out of any funds in the Treasury not otherwise  
5 obligated, \$1,000,000 for each of fiscal years 2025  
6 through 2029, to remain available until expended, to the  
7 Secretary of Health and Human Services for purposes of  
8 implementing the amendments made by subsection (a).

9 **SEC. 105. ENSURING THE RELIABILITY OF ADDRESS INFOR-**  
10 **MATION PROVIDED UNDER THE MEDICAID**  
11 **PROGRAM.**

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

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

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

19 (3) by inserting after paragraph (88) the fol-  
20 lowing new paragraph:

21 “(89) beginning January 1, 2026, provide for a  
22 process to regularly obtain address information for  
23 individuals enrolled under such plan (or a waiver of  
24 such plan) from reliable data sources (as described  
25 in section 435.919(f)(1)(iii) of title 42, Code of Fed-

1       eral Regulations (or a successor regulation)) and act  
 2       on any changes to such an address based on such in-  
 3       formation in accordance with such section (or suc-  
 4       cessor regulation), except that this paragraph shall  
 5       only apply in the case of the 50 States and the Dis-  
 6       trict of Columbia.”.

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

10           (1) by redesignating subparagraphs (H)  
 11           through (U) as subparagraphs (I) through (V), re-  
 12           spectively; and

13           (2) by inserting after subparagraph (G) the fol-  
 14           lowing new subparagraph:

15                   “(H) Section 1902(a)(89) (relating to reg-  
 16                   ularly obtaining address information for enroll-  
 17                   ees).”.

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

23           “(j) TRANSMISSION OF ADDRESS INFORMATION.—  
 24       Beginning January 1, 2026, each contract under a State  
 25       plan with a managed care entity under section 1903(m)

1 shall provide that the entity transmits to the State any  
2 address information for an individual enrolled with the en-  
3 tity that is provided to such entity directly from, or  
4 verified by such entity directly with, such individual.”.

5 **SEC. 106. CODIFYING CERTAIN MEDICAID PROVIDER**  
6 **SCREENING REQUIREMENTS RELATED TO**  
7 **DECEASED PROVIDERS.**

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

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

11 “(A) IN GENERAL.—The State”; and

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

14 “(B) ADDITIONAL PROVIDER SCREEN-  
15 ING.—Beginning January 1, 2027, as part of  
16 the enrollment (or reenrollment or revalidation  
17 of enrollment) of a provider or supplier under  
18 this title, and not less frequently than quarterly  
19 during the period that such provider or supplier  
20 is so enrolled, the State conducts a check of the  
21 Death Master File (as such term is defined in  
22 section 203(d) of the Bipartisan Budget Act of  
23 2013) to determine whether such provider or  
24 supplier is deceased.”.

1 **SEC. 107. MODIFYING CERTAIN STATE REQUIREMENTS FOR**  
2 **ENSURING DECEASED INDIVIDUALS DO NOT**  
3 **REMAIN ENROLLED.**

4 Section 1902 of the Social Security Act (42 U.S.C.  
5 1396a), as previously amended by this title, is amended—

6 (1) in subsection (a)—

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

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

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

13 “(90) provide that the State shall comply with  
14 the eligibility verification requirements under sub-  
15 section (vv), except that this paragraph shall apply  
16 only in the case of the 50 States and the District  
17 of Columbia.”; and

18 (2) by adding at the end the following new sub-  
19 section:

20 “(vv) VERIFICATION OF CERTAIN ELIGIBILITY CRI-  
21 TERIA.—

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

25 “(A) QUARTERLY SCREENING TO VERIFY  
26 ENROLLEE STATUS.—The State shall, not less

1 frequently than quarterly, review the Death  
2 Master File (as such term is defined in section  
3 203(d) of the Bipartisan Budget Act of 2013)  
4 to determine whether any individuals enrolled  
5 for medical assistance under the State plan (or  
6 waiver of such plan) are deceased.

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

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

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

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

1                   “(C) REINSTATEMENT OF COVERAGE IN  
2                   THE EVENT OF ERROR.—If a State determines  
3                   that an individual was misidentified as deceased  
4                   based on information obtained from the Death  
5                   Master File, and was erroneously disenrolled  
6                   from medical assistance under the State plan  
7                   (or waiver of such plan) based on such  
8                   misidentification, the State shall immediately  
9                   reenroll such individual under the State plan  
10                  (or waiver of such plan), retroactive to the date  
11                  of such disenrollment.

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



1 **SEC. 108. ONE-YEAR DELAY OF MEDICAID AND CHIP RE-**  
2 **QUIREMENTS FOR HEALTH SCREENINGS, RE-**  
3 **FERRALS, AND CASE MANAGEMENT SERV-**  
4 **ICES FOR ELIGIBLE JUVENILES IN PUBLIC**  
5 **INSTITUTIONS; STATE INTERIM WORK PLANS.**

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

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

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

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

15 “(2) DELAY OF DATE BY WHICH STATES MUST  
16 COMPLY WITH CERTAIN JUVENILE JUSTICE-RE-  
17 LATED REQUIREMENTS.—A State shall not be re-  
18 garded as failing to comply with the requirements of  
19 section 1902(a)(84)(D) or 2102(d)(2) of the Social  
20 Security Act (42 U.S.C. 1396a(a)(84)(D),  
21 1397bb(d)(2)) before January 1, 2026.”.

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

24 (1) MEDICAID.—

25 (A) Subparagraph (D) of section  
26 1902(a)(84) of the Social Security Act (42

1 U.S.C. 1396a(a)(84)), as added by section 5121  
2 of subtitle C of title V of division FF of the  
3 Consolidated Appropriations Act, 2023 (Public  
4 Law 117–328), is amended by striking “an in-  
5 dividual who is an eligible juvenile” and insert-  
6 ing “an individual (other than an individual  
7 who is in Federal custody, including as an in-  
8 mate in a Federal prison) who is an eligible ju-  
9 venile”.

10 (B) Section 5122(a) of subtitle C of title  
11 V of division FF of the Consolidated Appropria-  
12 tions Act, 2023 (Public Law 117–328) is  
13 amended—

14 (i) by striking “paragraph (31)” each  
15 place it appears and inserting “the last  
16 numbered paragraph”; and

17 (ii) in paragraph (1), by striking “an  
18 individual who is an eligible juvenile” and  
19 inserting “an individual (other than an in-  
20 dividual who is in Federal custody, includ-  
21 ing as an inmate in a Federal prison) who  
22 is an eligible juvenile”.

23 (2) CHIP.—

24 (A) Subsection (d)(2) of section 2102 of  
25 the Social Security Act (42 U.S.C. 1397bb), as

1 added by section 5121 of subtitle C of title V  
2 of division FF of the Consolidated Appropria-  
3 tions Act, 2023 (Public Law 117–328), is  
4 amended by striking “a targeted low-income  
5 child who” and inserting “a targeted low in-  
6 come child (other than a child who is in Federal  
7 custody, including as an inmate in a Federal  
8 prison) who”.

9 (B) Section 5122(b)(2) of subtitle C of  
10 title V of division FF of the Consolidated Ap-  
11 propriations Act, 2023 (Public Law 117–328)  
12 is amended by striking “a child who is” and in-  
13 serting “a child (other than a child who is in  
14 Federal custody, including as an inmate in a  
15 Federal prison) who is”.

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

19 (c) INTERIM WORK PLAN.—Not later than June 30,  
20 2025, each State (as such term is defined in section  
21 1101(a)(1) of the Social Security Act (42 U.S.C.  
22 1301(a)(1)) for purposes of titles XIX and XXI of such  
23 Act) shall submit to the Secretary of Health and Human  
24 Services an interim work plan, in such form and con-  
25 taining such information as the Secretary may specify, de-

1 scribing the State’s progress towards implementing, and  
2 its plans to come into compliance with, the requirements  
3 imposed by the amendments made by section 5121 of sub-  
4 title C of title V of division FF of the Consolidated Appro-  
5 priations Act, 2023 (Public Law 117–328), consistent  
6 with the guidance issued by the Centers for Medicare &  
7 Medicaid Services in State Health Official Letter #24–  
8 004 on July 23, 2024.

9 **SEC. 109. STATE STUDIES AND HHS REPORT ON COSTS OF**  
10 **PROVIDING MATERNITY, LABOR, AND DELIV-**  
11 **ERY SERVICES.**

12 (a) STATE STUDY.—

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

24 (2) CONTENT OF STUDY.—A State study re-  
25 quired under paragraph (1) shall include the fol-

1       lowing information (to the extent practicable) with  
2       respect to maternity, labor, and delivery services fur-  
3       nished by applicable hospitals located in the State:

4               (A) An estimate of the cost of providing  
5       maternity, labor, and delivery services at appli-  
6       cable hospitals, based on the expenditures a  
7       representative sample of such hospitals incurred  
8       for providing such services during the 2 most  
9       recent years for which data is available.

10              (B) An estimate of the cost of providing  
11       maternity, labor, and delivery services at appli-  
12       cable hospitals that ceased providing labor and  
13       delivery services within the past 5 years, based  
14       on the expenditures a representative sample of  
15       such hospitals incurred for providing such serv-  
16       ices during the 2 most recent years for which  
17       data is available.

18              (C) To the extent data allows, an analysis  
19       of the extent to which geographic location, com-  
20       munity demographics, and local economic fac-  
21       tors (as defined by the Secretary) affect the  
22       cost of providing maternity, labor, and delivery  
23       services at applicable hospitals, including the  
24       cost of services that support the provision of  
25       maternity, labor, and delivery services.

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

5 (i) Medicare;

6 (ii) the State Medicaid program, in-  
7 cluding payment amounts for such services  
8 under fee-for-service payment arrange-  
9 ments and under managed care (as appli-  
10 cable);

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

15 (iv) private health insurance.

16 (E) A comparative payment rate anal-  
17 ysis—

18 (i) comparing payment rates for ma-  
19 ternity, labor, and delivery services (inclu-  
20 sive of all payments received by applicable  
21 hospitals for furnishing maternity, labor,  
22 and delivery services) under the State  
23 Medicaid fee-for-service program to such  
24 payment rates for such services under  
25 Medicare (as described in section

1 447.203(b)(3) of title 42, Code of Federal  
2 Regulations), other Federally-funded or  
3 State-funded programs (including, to the  
4 extent data is available, Medicaid managed  
5 care rates), and to the payment rates for  
6 such services, to the extent data is avail-  
7 able, of private health insurers within geo-  
8 graphic areas of the State; and

9 (ii) analyzing different payment meth-  
10 ods for such services, such as the use of  
11 bundled payments, quality incentives, and  
12 low-volume adjustments.

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

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

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

6           (B) The hospital—

7                 (i) is located in a rural area (as de-  
8                 fined by the Federal Office of Rural  
9                 Health Policy for the purpose of rural  
10                health grant programs administered by  
11                such Office);

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

16               (iii) provides labor and delivery serv-  
17               ices.

18           (4) ASSISTANCE TO SMALL HOSPITALS IN COM-  
19           PILING COST INFORMATION.—There are appro-  
20           priated to the Secretary for fiscal year 2025,  
21           \$10,000,000 for the purpose of providing grants and  
22           technical assistance to a hospital described in para-  
23           graph (3)(B) to enable such hospital to compile de-  
24           tailed information for use in the State studies re-



1       quired under paragraph (1), to remain available  
2       until expended.

3           (5) HHS REPORT ON STATE STUDIES.—For  
4       each year in which a State is required to conduct a  
5       study under paragraph (1), the Secretary shall issue,  
6       not later than 12 months after the date on which  
7       the State submits to the Secretary the data de-  
8       scribed in such paragraph, a publicly available re-  
9       port that compiles and details the results of such  
10      study and includes the information described in  
11      paragraph (2).

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

20       (c) IMPLEMENTATION FUNDING.—In addition to the  
21      amount appropriated under subsection (a)(4), there are  
22      appropriated, out of any funds in the Treasury not other-  
23      wise obligated, \$3,000,000 for fiscal year 2025, to remain  
24      available until expended, to the Secretary of Health and

1 Human Services for purposes of implementing this sec-  
2 tion.

3 **SEC. 110. MODIFYING CERTAIN DISPROPORTIONATE SHARE**  
4 **HOSPITAL ALLOTMENTS.**

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

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

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

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

16 (b) ELIMINATING AND DELAYING DSH ALLOTMENT  
17 REDUCTIONS.—Section 1923(f) of the Social Security Act  
18 (42 U.S.C. 1396r-4(f)) is amended—

19 (1) in paragraph (7)(A)—

20 (A) in clause (i), in the matter preceding  
21 subclause (I), by striking “April 1, 2025,” and  
22 all that follows through “2027” and inserting  
23 “January 1, 2027, and ending September 30,  
24 2027, and for fiscal year 2028”; and

1 (B) in clause (ii), by striking “April 1,  
 2 2025,” and all that follows through “2027” and  
 3 inserting “January 1, 2027, and ending Sep-  
 4 tember 30, 2027, and for fiscal year 2028”;  
 5 and

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

8 **SEC. 111. MODIFYING CERTAIN LIMITATIONS ON DIS-**  
 9 **PROPORTIONATE SHARE HOSPITAL PAY-**  
 10 **MENT ADJUSTMENTS UNDER THE MEDICAID**  
 11 **PROGRAM.**

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

14 (1) in paragraph (1)—

15 (A) in subparagraph (A)—

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

19 (ii) in clause (i), by inserting “with  
 20 respect to such hospital and year” after  
 21 “described in subparagraph (B)”; and

22 (iii) in clause (ii)—

23 (I) in subclause (I), by striking  
 24 “and” at the end;

1 (II) in subclause (II), by striking  
2 the period and inserting “; and”; and

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

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

9 (B) in subparagraph (B)—

10 (i) in the matter preceding clause (i),  
11 by striking “in this clause are” and insert-  
12 ing “in this subparagraph are, with respect  
13 to a hospital and a year,”; and

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

16 “(iii) Individuals who are eligible for  
17 medical assistance under the State plan or  
18 under a waiver of such plan and for whom  
19 the State plan or waiver is a payor for  
20 such services after application of benefits  
21 under title XVIII or under an applicable  
22 plan (as defined in section 1862(b)(8)(F)),  
23 but only if the hospital has in the aggre-  
24 gate incurred costs exceeding payments  
25 under such State plan, waiver, title XVIII,

1 or applicable plan for such services fur-  
2 nished to such individuals during such  
3 year.”;

4 (2) by striking paragraph (2);

5 (3) by redesignating paragraph (3) as para-  
6 graph (2); and

7 (4) in paragraph (2), as so redesignated, by  
8 striking “Notwithstanding paragraph (2) of this  
9 subsection (as in effect on October 1, 2021), para-  
10 graph (2)” and inserting “Paragraph (2)”.

11 (b) EFFECTIVE DATE.—

12 (1) IN GENERAL.—Except as provided in para-  
13 graph (2), the amendments made by this section  
14 shall apply to payment adjustments made under sec-  
15 tion 1923 of the Social Security Act (42 U.S.C.  
16 1396r–4) for Medicaid State plan rate years begin-  
17 ning on or after the date of enactment of this Act.

18 (2) STATE OPTION TO DISTRIBUTE UNSPENT  
19 DSH ALLOTMENTS FROM PRIOR YEARS UP TO MODI-  
20 FIED CAP.—

21 (A) IN GENERAL.—If, for any Medicaid  
22 State plan rate year that begins on or after Oc-  
23 tober 1, 2021, and before the date of enactment  
24 of this Act, a State did not spend the full  
25 amount of its Federal fiscal year allotment

1 under section 1923 of the Social Security Act  
2 (42 U.S.C. 1396r–4) applicable to that State  
3 plan rate year, the State may use the unspent  
4 portion of such allotment to increase the  
5 amount of any payment adjustment made to a  
6 hospital for such rate year, provided that—

7 (i) such payment adjustment (as so  
8 increased) is consistent with subsection (g)  
9 of such section (as amended by this sec-  
10 tion); and

11 (ii) the total amount of all payment  
12 adjustments for the State plan rate year  
13 (as so increased) does not exceed the dis-  
14 proportionate share hospital allotment for  
15 the State and applicable Federal fiscal  
16 year under subsection (f) of such section.

17 (B) NO RECOUPMENT OF PAYMENTS AL-  
18 READY MADE TO HOSPITALS.—A State shall not  
19 recoup any payment adjustment made by the  
20 State to a hospital for a Medicaid State plan  
21 rate year described in subparagraph (A) if such  
22 payment adjustment is consistent with section  
23 1923(g) of such Act (42 U.S.C. 1396r–4(g)) as  
24 in effect on October 1, 2021.

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

4 (i) IN GENERAL.—Subject to para-  
5 graph (2), solely for the purpose of allow-  
6 ing a State to increase the amount of a  
7 payment adjustment to a hospital for a  
8 Medicaid State plan rate year described in  
9 subparagraph (A) pursuant to this para-  
10 graph, a State may retroactively modify a  
11 provision of the Medicaid State plan, a  
12 waiver of such plan, or a State plan  
13 amendment that relates to such rate year  
14 and the Secretary may approve such modi-  
15 fication.

16 (ii) DEADLINE.—A State may not  
17 submit a request for approval of a retro-  
18 active modification to a provision of the  
19 Medicaid State plan, a waiver of such plan,  
20 or a State plan amendment for a Medicaid  
21 State plan rate year after the date by  
22 which the State is required to submit the  
23 independent certified audit for that State  
24 plan rate year as required under section

1                   1923(j)(2) of the Social Security Act (42  
2                   U.S.C. 1396r-4(j)(2)).

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

11 **SEC. 112. ENSURING ACCURATE PAYMENTS TO PHAR-**  
12 **MACIES UNDER MEDICAID.**

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

15                       (1) in paragraph (1)(A)—

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

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

21                       “(1) DETERMINING PHARMACY ACTUAL ACQUI-  
22                       SITION COSTS.—The Secretary shall conduct a sur-  
23                       vey of retail community pharmacy drug prices and  
24                       applicable non-retail pharmacy drug prices to deter-  
25                       mine national average drug acquisition cost bench-



1 marks (as such term is defined by the Secretary) as  
2 follows:

3 “(A) USE OF VENDOR.—The Secretary  
4 may contract services for—

5 “(i) with respect to retail community  
6 pharmacies, the determination of retail  
7 survey prices of the national average drug  
8 acquisition cost for covered outpatient  
9 drugs that represent a nationwide average  
10 of consumer purchase prices for such  
11 drugs, net of all discounts, rebates, and  
12 other price concessions (to the extent any  
13 information with respect to such discounts,  
14 rebates, and other price concessions is  
15 available) based on a monthly survey of  
16 such pharmacies; and

17 “(ii) with respect to applicable non-re-  
18 tail pharmacies—

19 “(I) the determination of survey  
20 prices, separate from the survey prices  
21 described in clause (i), of the non-re-  
22 tail national average drug acquisition  
23 cost for covered outpatient drugs that  
24 represent a nationwide average of con-  
25 sumer purchase prices for such drugs,

1 net of all discounts, rebates, and other  
2 price concessions (to the extent any  
3 information with respect to such dis-  
4 counts, rebates, and other price con-  
5 cessions is available) based on a  
6 monthly survey of such pharmacies;  
7 and

8 “(II) at the discretion of the Sec-  
9 retary, for each type of applicable  
10 non-retail pharmacy, the determina-  
11 tion of survey prices, separate from  
12 the survey prices described in clause  
13 (i) or subclause (I) of this clause, of  
14 the national average drug acquisition  
15 cost for such type of pharmacy for  
16 covered outpatient drugs that rep-  
17 resent a nationwide average of con-  
18 sumer purchase prices for such drugs,  
19 net of all discounts, rebates, and other  
20 price concessions (to the extent any  
21 information with respect to such dis-  
22 counts, rebates, and other price con-  
23 cessions is available) based on a  
24 monthly survey of such pharmacies;  
25 and”;

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

4           (3) in subparagraph (D) of paragraph (1), by  
5       striking clauses (ii) and (iii) and inserting the fol-  
6       lowing:

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

10                      “(iii) The vendor must differentiate,  
11                      in collecting and reporting survey data, for  
12                      all cost information collected, whether a  
13                      pharmacy is a retail community pharmacy  
14                      or an applicable non-retail pharmacy, in-  
15                      cluding whether such pharmacy is an affil-  
16                      iate (as defined in subsection (k)(14)),  
17                      and, in the case of an applicable non-retail  
18                      pharmacy, which type of applicable non-re-  
19                      tail pharmacy it is using the relevant phar-  
20                      macy type indicators included in the guid-  
21                      ance required by subsection (d)(2) of sec-  
22                      tion 112 of the Health Improvements, Ex-  
23                      tenders, and Reauthorizations Act.”;

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

“(F) SURVEY REPORTING.—In order to meet the requirement of section 1902(a)(54), a State shall require that any retail community pharmacy or applicable non-retail pharmacy in the State that receives any payment, reimbursement, administrative fee, discount, rebate, or other price concession related to the dispensing of covered outpatient drugs to individuals receiving benefits under this title, regardless of whether such payment, reimbursement, administrative fee, discount, rebate, or other price concession is received from the State or a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D)) directly or from a pharmacy benefit manager or another entity that has a contract with the State or a managed care entity or other specified entity (as so defined), shall respond to surveys conducted under this paragraph.

“(G) SURVEY INFORMATION.—Information on national drug acquisition prices obtained under this paragraph shall be made publicly available in a form and manner to be deter-

1           mined by the Secretary and shall include at  
2           least the following:

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

6                   “(ii) The sampling methodology and  
7                   number of pharmacies sampled monthly.

8                   “(iii) Information on price concessions  
9                   to pharmacies, including discounts, re-  
10                  bates, and other price concessions, to the  
11                  extent that such information may be pub-  
12                  licly released and has been collected by the  
13                  Secretary as part of the survey.

14                  “(H) PENALTIES.—

15                   “(i) IN GENERAL.—Subject to clauses  
16                   (ii), (iii), and (iv), the Secretary shall en-  
17                   force the provisions of this paragraph with  
18                   respect to a pharmacy through the estab-  
19                   lishment of civil money penalties applicable  
20                   to a retail community pharmacy or an ap-  
21                   plicable non-retail pharmacy.

22                   “(ii) BASIS FOR PENALTIES.—The  
23                   Secretary shall impose a civil money pen-  
24                   alty established under this subparagraph

on a retail community pharmacy or applicable non-retail pharmacy if—

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

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

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

“(iii) PARAMETERS FOR PENALTIES.—

“(I) IN GENERAL.—A civil money penalty established under this subparagraph may be assessed with respect to each violation, and with respect to each non-compliant retail community pharmacy (including a pharmacy that is part of a chain) or non-compliant applicable non-retail pharmacy (including a pharmacy that

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 munerations fees, and any and all other re-  
17 munerations, 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—

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

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

(b) ACCOUNTABILITY FOR PROVIDER DIRECTORY ACCURACY.—

(1) COST SHARING FOR SERVICES FURNISHED BASED ON RELIANCE ON INCORRECT PROVIDER DIRECTORY INFORMATION.—Section 1852(d) of the Social Security Act (42 U.S.C. 1395w-22(d)) is amended—

(A) in paragraph (1)(C)—

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

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

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

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



evidence for such an allegation  
under this clause.

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

“(V) PREVENTING FRIVOLOUS ALLEGATIONS.—In the case where the Secretary determines that a pharmacy has submitted frivolous allegations under this clause on a routine basis, the Secretary may temporarily prohibit such pharmacy from using the allegation submission process under this clause, as determined appropriate by the Secretary.

“(VI) EXEMPTION FROM FREEDOM OF INFORMATION ACT.—Allega-

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

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

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

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

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

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

5 “(iii) ENFORCEMENT.—

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

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

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

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

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

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

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

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

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

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

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

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

3 “(9) ACCOUNTABILITY OF PHARMACY BENEFIT  
4 MANAGERS FOR VIOLATIONS OF REASONABLE AND  
5 RELEVANT CONTRACT TERMS AND CONDITIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

7 (a) IN GENERAL.—

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

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

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

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

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

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



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

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

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

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

3            “(v) DISGORGEMENT.—The pharmacy  
4            benefit manager shall disgorge any remu-  
5            nation 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-

ees, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply for each drug dispensed by pharmacies that are an affiliate of the pharmacy benefit manager and that are included in the pharmacy network of such plan.

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

“(ee) The difference between the average acquisition cost of the affiliate, such as a pharmacy or other entity that acquires prescription drugs, that initially acquires the drug and the amount reported under subclause (I)(jj) for each drug.

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);

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  
23 shall, as appropriate, collaborate with other such  
24 grantees, the NCTSI coordinating center, and the



1 Secretary in carrying out subsections (a)(2) and  
2 (d)(2).”;

3 (6) by amending subsection (h) to read as fol-  
4 lows:

5 “(h) APPLICATION AND EVALUATION.—To be eligible  
6 to receive a grant, contract, or cooperative agreement  
7 under subsection (a), a public or nonprofit private entity  
8 or an Indian Tribe or Tribal organization shall submit to  
9 the Secretary an application at such time, in such manner,  
10 and containing such information and assurances as the  
11 Secretary may require, including—

12 “(1) a plan for the evaluation of the activities  
13 funded under the grant, contract, or agreement, in-  
14 cluding both process and outcomes evaluation, and  
15 the submission of an evaluation at the end of the  
16 project period; and

17 “(2) a description of how such entity, Indian  
18 Tribe, or Tribal organization will support efforts led  
19 by the Secretary or the NCTSI coordinating center,  
20 as applicable, to evaluate activities carried out under  
21 this section.”; and

22 (7) by amending subsection (j) to read as fol-  
23 lows:

24 “(j) AUTHORIZATION OF APPROPRIATIONS.—There  
25 is authorized to be appropriated to carry out this section—

- 1 “(1) \$93,887,000 for fiscal year 2025;  
2 “(2) \$95,000,000 for fiscal year 2026;  
3 “(3) \$97,000,000 for fiscal year 2027;  
4 “(4) \$100,000,000 for fiscal year 2028; and  
5 “(5) \$100,000,000 for fiscal year 2029.”.

6 **SEC. 518. PROTECTING SUICIDE PREVENTION LIFELINE**  
7 **FROM CYBERSECURITY INCIDENTS.**

8 (a) NATIONAL SUICIDE PREVENTION LIFELINE PRO-  
9 GRAM.—Section 520E–3(b) of the Public Health Service  
10 Act (42 U.S.C. 290bb–36c(b)) is amended—

11 (1) in paragraph (4), by striking “and” at the  
12 end;

13 (2) in paragraph (5), by striking the period at  
14 the end and inserting “; and”; and

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

16 “(6) taking such steps as may be necessary to  
17 ensure the suicide prevention hotline is protected  
18 from cybersecurity incidents and eliminates known  
19 cybersecurity vulnerabilities.”.

20 (b) REPORTING.—Section 520E–3 of the Public  
21 Health Service Act (42 U.S.C. 290bb–36c) is amended—

22 (1) by redesignating subsection (f) as sub-  
23 section (g); and

24 (2) by inserting after subsection (e) the fol-  
25 lowing:

1 “(f) CYBERSECURITY REPORTING.—

2 “(1) NOTIFICATION.—

3 “(A) IN GENERAL.—The program’s net-  
4 work administrator receiving Federal funding  
5 pursuant to subsection (a) shall report to the  
6 Assistant Secretary, in a manner that protects  
7 personal privacy, consistent with applicable  
8 Federal and State privacy laws—

9 “(i) any identified cybersecurity  
10 vulnerabilities to the program within a rea-  
11 sonable amount of time after identification  
12 of such a vulnerability; and

13 “(ii) any identified cybersecurity inci-  
14 dents to the program within a reasonable  
15 amount of time after identification of such  
16 incident.

17 “(B) LOCAL AND REGIONAL CRISIS CEN-  
18 TERS.—Local and regional crisis centers par-  
19 ticipating in the program shall report to the  
20 program’s network administrator identified  
21 under subparagraph (A), in a manner that pro-  
22 tects personal privacy, consistent with applica-  
23 ble Federal and State privacy laws—

24 “(i) any identified cybersecurity  
25 vulnerabilities to the program within a rea-

sonable amount of time after identification  
of such vulnerability; and

“(ii) any identified cybersecurity incidents to the program within a reasonable amount of time after identification of such incident.

“(2) NOTIFICATION.—If the program’s network administrator receiving funding pursuant to subsection (a) discovers, or is informed by a local or regional crisis center pursuant to paragraph (1)(B) of, a cybersecurity vulnerability or incident, within a reasonable amount of time after such discovery or receipt of information, such entity shall report the vulnerability or incident to the Assistant Secretary.

“(3) CLARIFICATION.—

“(A) OVERSIGHT.—

“(i) LOCAL AND REGIONAL CRISIS CENTERS.—Except as provided in clause (ii), local and regional crisis centers participating in the program shall oversee all technology each center employs in the provision of services as a participant in the program.

“(ii) NETWORK ADMINISTRATOR.—  
The program’s network administrator re-

1           ceiving Federal funding pursuant to sub-  
2           section (a) shall oversee the technology  
3           each crisis center employs in the provision  
4           of services as a participant in the program  
5           if such oversight responsibilities are estab-  
6           lished in the applicable network participa-  
7           tion agreement.

8           “(B) SUPPLEMENT, NOT SUPPLANT.—The  
9           cybersecurity incident reporting requirements  
10          under this subsection shall supplement, and not  
11          supplant, cybersecurity incident reporting re-  
12          quirements under other provisions of applicable  
13          Federal law that are in effect on the date of the  
14          enactment of the SUPPORT for Patients and  
15          Communities Reauthorization Act of 2025.”.

16          (c) STUDY.—Not later than 180 days after the date  
17          of the enactment of this Act, the Comptroller General of  
18          the United States shall—

19               (1) conduct and complete a study that evaluates  
20               cybersecurity risks and vulnerabilities associated  
21               with the 9–8–8 National Suicide Prevention Lifeline;  
22               and

23               (2) submit a report on the findings of such  
24               study to the Committee on Health, Education,  
25               Labor, and Pensions of the Senate and the Com-

1        mittee on Energy and Commerce of the House of  
2        Representatives.

3    **SEC. 519. BRUCE’S LAW.**

4        (a) YOUTH PREVENTION AND RECOVERY.—Section  
5    7102(c) of the SUPPORT for Patients and Communities  
6    Act (42 U.S.C. 290bb–7a(c)) is amended—

7            (1) in paragraph (3)(A)(i), by inserting “,  
8        which may include strategies to increase education  
9        and awareness of the potency and dangers of syn-  
10        thetic opioids (including drugs contaminated with  
11        fentanyl) and, as appropriate, other emerging drug  
12        use or misuse issues” before the semicolon; and

13            (2) in paragraph (4)(A), by inserting “and  
14        strategies to increase education and awareness of  
15        the potency and dangers of synthetic opioids (includ-  
16        ing drugs contaminated with fentanyl) and, as ap-  
17        propriate, emerging drug use or misuse issues” be-  
18        fore the semicolon.

19        (b) INTERDEPARTMENTAL SUBSTANCE USE DIS-  
20    ORDERS COORDINATING COMMITTEE.—Section 7022 of  
21    the SUPPORT for Patients and Communities Act (42  
22    U.S.C. 290aa note) is amended—

23            (1) by striking subsection (g) and inserting the  
24        following:

25        “(g) WORKING GROUPS.—

1           “(1) IN GENERAL.—The Committee may estab-  
2       lish working groups for purposes of carrying out the  
3       duties described in subsection (e). Any such working  
4       group shall be composed of members of the Com-  
5       mittee (or the designees of such members) and may  
6       hold such meetings as are necessary to carry out the  
7       duties delegated to the working group.

8           “(2)    ADDITIONAL    FEDERAL    INTERAGENCY  
9       WORK GROUP ON FENTANYL CONTAMINATION OF IL-  
10      LEGAL DRUGS.—

11           “(A)   ESTABLISHMENT.—The   Secretary,  
12       acting through the Committee, shall establish a  
13       Federal Interagency Work Group on Fentanyl  
14       Contamination of Illegal Drugs (referred to in  
15       this paragraph as the ‘Work Group’) consisting  
16       of representatives from relevant Federal depart-  
17       ments and agencies on the Committee.

18           “(B)   CONSULTATION.—The   Work   Group  
19       shall consult with relevant stakeholders and  
20       subject matter experts, including—

21           “(i)   State, Tribal, and local subject  
22       matter experts in reducing, preventing, and  
23       responding to drug overdose caused by  
24       fentanyl contamination of illicit drugs; and

1 “(ii) family members of both adults  
2 and youth who have overdosed by fentanyl-  
3 contaminated illicit drugs.

4 “(C) DUTIES.—The Work Group shall—

5 “(i) examine Federal efforts to reduce  
6 and prevent drug overdose by fentanyl-con-  
7 taminated illicit drugs;

8 “(ii) identify strategies to improve  
9 State, Tribal, and local responses to over-  
10 dose by fentanyl-contaminated illicit drugs;

11 “(iii) coordinate with the Secretary, as  
12 appropriate, in carrying out activities to  
13 raise public awareness of synthetic opioids  
14 and other emerging drug use and misuse  
15 issues;

16 “(iv) make recommendations to Con-  
17 gress for improving Federal programs, in-  
18 cluding with respect to the coordination of  
19 efforts across such programs; and

20 “(v) make recommendations for edu-  
21 cating youth on the potency and dangers of  
22 drugs contaminated by fentanyl.

23 “(D) ANNUAL REPORT TO SECRETARY.—

24 The Work Group shall annually prepare and  
25 submit to the Secretary, the Committee on



1 Health, Education, Labor, and Pensions of the  
2 Senate, and the Committee on Energy and  
3 Commerce and the Committee on Education  
4 and the Workforce of the House of Representa-  
5 tives, a report on the activities carried out by  
6 the Work Group under subparagraph (C), in-  
7 cluding recommendations to reduce and prevent  
8 drug overdose by fentanyl contamination of ille-  
9 gal drugs, in all populations, and specifically  
10 among youth at risk for substance misuse.”;  
11 and

12 (2) by striking subsection (i) and inserting the  
13 following:

14 “(i) SUNSET.—The Committee shall  
15 terminate on September 30, 2029.”.

16 **SEC. 520. GUIDANCE ON AT-HOME DRUG DISPOSAL SYS-**  
17 **TEMS.**

18 (a) IN GENERAL.—Not later than one year after the  
19 date of enactment of this Act, the Secretary of Health and  
20 Human Services, in consultation with the Administrator  
21 of the Drug Enforcement Administration, shall publish  
22 guidance to facilitate the use of at-home safe disposal sys-  
23 tems for applicable drugs.

24 (b) CONTENTS.—The guidance under subsection (a)  
25 shall include—

1           (1) recommended standards for effective at-  
2           home drug disposal systems to meet applicable re-  
3           quirements enforced by the Food and Drug Adminis-  
4           tration;

5           (2) recommended information to include as in-  
6           structions for use to disseminate with at-home drug  
7           disposal systems;

8           (3) best practices and educational tools to sup-  
9           port the use of an at-home drug disposal system, as  
10          appropriate; and

11          (4) recommended use of licensed health pro-  
12          viders for the dissemination of education, instruc-  
13          tion, and at-home drug disposal systems, as appro-  
14          priate.

15 **SEC. 521. ASSESSMENT OF OPIOID DRUGS AND ACTIONS.**

16          (a) IN GENERAL.—Not later than one year after the  
17          date of enactment of this Act, the Secretary of Health and  
18          Human Services (referred to in this section as the “Sec-  
19          retary”) shall publish on the website of the Food and  
20          Drug Administration (referred to in this section as the  
21          “FDA”) a report that outlines a plan for assessing opioid  
22          analgesic drugs that are approved under section 505 of  
23          the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
24          355) that addresses the public health effects of such opioid  
25          analgesic drugs as part of the benefit-risk assessment and

1 the activities of the FDA that relate to facilitating the de-  
2 velopment of nonaddictive medical products intended to  
3 treat pain or addiction. Such report shall include—

4 (1) an update on the actions taken by the FDA  
5 to consider the effectiveness, safety, benefit-risk pro-  
6 file, and use of approved opioid analgesic drugs;

7 (2) a timeline for an assessment of the potential  
8 need, as appropriate, for labeling changes, revised or  
9 additional postmarketing requirements, enforcement  
10 actions, or withdrawals for opioid analgesic drugs;

11 (3) an overview of the steps that the FDA has  
12 taken to support the development and approval of  
13 nonaddictive medical products intended to treat pain  
14 or addiction, and actions planned to further support  
15 the development and approval of such products; and

16 (4) an overview of the consideration by the  
17 FDA of clinical trial methodologies for analgesic  
18 drugs, including the enriched enrollment randomized  
19 withdrawal methodology, and the benefits and draw-  
20 backs associated with different trial methodologies  
21 for such drugs, incorporating any public input re-  
22 ceived under subsection (b).

23 (b) PUBLIC INPUT.—In carrying out subsection (a),  
24 the Secretary shall provide an opportunity for public input  
25 concerning the regulation by the FDA of opioid analgesic

1 drugs, including scientific evidence that relates to condi-  
 2 tions of use, safety, or benefit-risk assessment (including  
 3 consideration of the public health effects) of such opioid  
 4 analgesic drugs.

5 **SEC. 522. GRANT PROGRAM FOR STATE AND TRIBAL RE-**  
 6 **SPONSE TO OPIOID USE DISORDERS.**

7 The activities carried out pursuant to section  
 8 1003(b)(4)(A) of the 21st Century Cures Act (42 U.S.C.  
 9 290ee–3a(b)(4)(A)) may include facilitating access to  
 10 products used to prevent overdose deaths by detecting the  
 11 presence of one or more substances, such as fentanyl and  
 12 xylazine test strips, to the extent the purchase and posses-  
 13 sion of such products is consistent with Federal and State  
 14 law.

15 **Subtitle B—Treatment**

16 **SEC. 531. RESIDENTIAL TREATMENT PROGRAM FOR PREG-**  
 17 **NANT AND POSTPARTUM WOMEN.**

18 Section 508 of the Public Health Service Act (42  
 19 U.S.C. 290bb–1) is amended—

20 (1) in subsection (d)(11)(C), by striking “pro-  
 21 viding health services” and inserting “providing  
 22 health care services”;

23 (2) in subsection (g)—

24 (A) by inserting “a plan describing” after  
 25 “will provide”; and

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

2 “Such plan may include a description of how  
3 such applicant will target outreach to women  
4 disproportionately impacted by maternal sub-  
5 stance use disorder.”; and

6 (3) in subsection (s), by striking “\$29,931,000  
7 for each of fiscal years 2019 through 2023” and in-  
8 serting “\$38,931,000 for each of fiscal years 2025  
9 through 2029”.

10 **SEC. 532. IMPROVING ACCESS TO ADDICTION MEDICINE**  
11 **PROVIDERS.**

12 Section 597 of the Public Health Service Act (42  
13 U.S.C. 290ll) is amended—

14 (1) in subsection (a)(1), by inserting “diag-  
15 nosis,” after “related to”; and

16 (2) in subsection (b), by inserting “addiction  
17 medicine,” after “psychiatry,”.

18 **SEC. 533. MENTAL AND BEHAVIORAL HEALTH EDUCATION**  
19 **AND TRAINING GRANTS.**

20 Section 756(f) of the Public Health Service Act (42  
21 U.S.C. 294e–1(f)) is amended by striking “fiscal years  
22 2023 through 2027” and inserting “fiscal years 2025  
23 through 2029”.

1 **SEC. 534. LOAN REPAYMENT PROGRAM FOR SUBSTANCE**  
2 **USE DISORDER TREATMENT WORKFORCE.**

3 Section 781(j) of the Public Health Service Act (42  
4 U.S.C. 295h(j)) is amended by striking “\$25,000,000 for  
5 each of fiscal years 2019 through 2023” and inserting  
6 “\$40,000,000 for each of fiscal years 2025 through  
7 2029”.

8 **SEC. 535. DEVELOPMENT AND DISSEMINATION OF MODEL**  
9 **TRAINING PROGRAMS FOR SUBSTANCE USE**  
10 **DISORDER PATIENT RECORDS.**

11 Section 7053 of the SUPPORT for Patients and  
12 Communities Act (42 U.S.C. 290dd–2 note) is amended  
13 by striking subsection (e).

14 **SEC. 536. TASK FORCE ON BEST PRACTICES FOR TRAUMA-**  
15 **INFORMED IDENTIFICATION, REFERRAL, AND**  
16 **SUPPORT.**

17 Section 7132 of the SUPPORT for Patients and  
18 Communities Act (Public Law 115–271; 132 Stat. 4046)  
19 is amended—

20 (1) in subsection (b)(1)—

21 (A) by redesignating subparagraph (CC) as  
22 subparagraph (DD); and

23 (B) by inserting after subparagraph (BB)  
24 the following:

25 “(CC) The Administration for Community  
26 Living.”;

1           (2) in subsection (d)(1), in the matter pre-  
 2           ceding subparagraph (A), by inserting “, develop-  
 3           mental disability service providers” before “, individ-  
 4           uals who are”; and

5           (3) in subsection (i), by striking “2023” and in-  
 6           serting “2029”.

7   **SEC. 537. GRANTS TO ENHANCE ACCESS TO SUBSTANCE**  
 8           **USE DISORDER TREATMENT.**

9           Section 3203 of the SUPPORT for Patients and  
 10          Communities Act (21 U.S.C. 823 note) is amended—

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

12           (2) by striking “(a) IN GENERAL.—The Sec-  
 13          retary” and inserting the following: “The Sec-  
 14          retary”.

15   **SEC. 538. STATE GUIDANCE RELATED TO INDIVIDUALS**  
 16           **WITH SERIOUS MENTAL ILLNESS AND CHIL-**  
 17           **DREN WITH SERIOUS EMOTIONAL DISTURB-**  
 18           **ANCE.**

19          (a) REVIEW OF USE OF CERTAIN FUNDING.—Not  
 20          later than 1 year after the date of enactment of this Act,  
 21          the Secretary of Health and Human Services (referred to  
 22          in this section as the “Secretary”), acting through the As-  
 23          sistant Secretary for Mental Health and Substance Use,  
 24          shall conduct a review of State use of funds made available  
 25          under the Community Mental Health Services Block

1 Grant program under subpart I of part B of title XIX  
2 of the Public Health Service Act (42 U.S.C. 300x et seq.)  
3 (referred to in this section as the “block grant program”)  
4 for first episode psychosis activities. Such review shall con-  
5 sider the following:

6 (1) How States use funds for evidence-based  
7 treatments and services according to the standard of  
8 care for individuals with early serious mental illness  
9 and children with a serious emotional disturbance.

10 (2) The percentages of the State funding under  
11 the block grant program expended on early serious  
12 mental illness and first episode psychosis, and the  
13 number of individuals served under such funds.

14 (b) REPORT AND GUIDANCE.—

15 (1) REPORT.—Not later than 180 days after  
16 the completion of the review under subsection (a),  
17 the Secretary shall submit to the Committee on  
18 Health, Education, Labor, and Pensions and the  
19 Committee on Appropriations of the Senate and the  
20 Committee on Energy and Commerce and the Com-  
21 mittee on Appropriations of the House of Represent-  
22 atives a report describing—

23 (A) the findings of the review under sub-  
24 section (a); and



1 (B) any recommendations for changes to  
2 the block grant program that would facilitate  
3 improved outcomes for individuals with serious  
4 mental illness and children with serious emo-  
5 tional disturbance.

6 (2) GUIDANCE.—Not later than 1 year after  
7 the date on which the report is submitted under  
8 paragraph (1), the Secretary shall update the guid-  
9 ance provided to States under the block grant pro-  
10 gram on coordinated specialty care and other evi-  
11 dence-based mental health care services for individ-  
12 uals with serious mental illness and children with a  
13 serious emotional disturbance, based on the findings  
14 and recommendations of such report.

15 **SEC. 539. REVIEWING THE SCHEDULING OF APPROVED**  
16 **PRODUCTS CONTAINING A COMBINATION OF**  
17 **BUPRENORPHINE AND NALOXONE.**

18 (a) SECRETARY OF HHS.—The Secretary of Health  
19 and Human Services shall, consistent with the require-  
20 ments and procedures set forth in sections 201 and 202  
21 of the Controlled Substances Act (21 U.S.C. 811, 812)—

22 (1) review the relevant data pertaining to the  
23 scheduling of products containing a combination of  
24 buprenorphine and naloxone that have been ap-

1 proved under section 505 of the Federal Food,  
2 Drug, and Cosmetic Act (21 U.S.C. 355); and

3 (2) if appropriate, request that the Attorney  
4 General initiate rulemaking proceedings to revise the  
5 schedules accordingly with respect to such products.

6 (b) ATTORNEY GENERAL.—The Attorney General  
7 shall review any request made by the Secretary of Health  
8 and Human Services under subsection (a)(2) and deter-  
9 mine whether to initiate proceedings to revise the sched-  
10 ules in accordance with the criteria set forth in sections  
11 201 and 202 of the Controlled Substances Act (21 U.S.C.  
12 811, 812).

## 13 **Subtitle C—Recovery**

### 14 **SEC. 541. BUILDING COMMUNITIES OF RECOVERY.**

15 Section 547(f) of the Public Health Service Act (42  
16 U.S.C. 290ee–2(f)) is amended by striking “\$5,000,000  
17 for each of fiscal years 2019 through 2023” and inserting  
18 “\$16,000,000 for each of fiscal years 2025 through  
19 2029”.

### 20 **SEC. 542. PEER SUPPORT TECHNICAL ASSISTANCE CEN-** 21 **TER.**

22 Section 547A of the Public Health Service Act (42  
23 U.S.C. 290ee–2a) is amended—

1           (1) in subsection (b)(4), by striking “building;  
2           and” and inserting the following: “building, such  
3           as—

4                   “(A) professional development of peer sup-  
5           port specialists; and

6                   “(B) making recovery support services  
7           available in nonclinical settings; and”;

8           (2) by redesignating subsections (d) and (e) as  
9           subsections (e) and (f), respectively;

10          (3) by inserting after subsection (c) the fol-  
11          lowing:

12          “(d) REGIONAL CENTERS.—

13               “(1) IN GENERAL.—The Secretary may estab-  
14          lish one regional technical assistance center (referred  
15          to in this subsection as the ‘Regional Center’), with  
16          existing resources, to assist the Center in carrying  
17          out activities described in subsection (b) within the  
18          geographic region of such Regional Center in a man-  
19          ner that is tailored to the needs of such region.

20               “(2) EVALUATION.—Not later than 4 years  
21          after the date of enactment of the SUPPORT for  
22          Patients and Communities Reauthorization Act of  
23          2024, the Secretary shall evaluate the activities of  
24          the Regional Center and submit to the Committee  
25          on Health, Education, Labor, and Pensions of the

1 Senate and the Committee on Energy and Com-  
2 merce of the House of Representatives a report on  
3 the findings of such evaluation, including—

4 “(A) a description of the distinct roles and  
5 responsibilities of the Regional Center and the  
6 Center;

7 “(B) available information relating to the  
8 outcomes of the Regional Center under this  
9 subsection, such as any impact on the oper-  
10 ations and efficiency of the Center relating to  
11 requests for technical assistance and support  
12 within the region of such Regional Center;

13 “(C) a description of any gaps or areas of  
14 duplication relating to the activities of the Re-  
15 gional Center and the Center within such re-  
16 gion; and

17 “(D) recommendations relating to the  
18 modification, expansion, or termination of the  
19 Regional Center under this subsection.

20 “(3) TERMINATION.—This subsection shall ter-  
21minate on September 30, 2029.”; and

22 (4) in subsection (f), as so redesignated, by  
23 striking “\$1,000,000 for each of fiscal years 2019  
24 through 2023” and inserting “\$2,000,000 for each  
25 of fiscal years 2025 through 2029”.

1 **SEC. 543. COMPREHENSIVE OPIOID RECOVERY CENTERS.**

2 Section 552 of the Public Health Service Act (42  
3 U.S.C. 290ee–7) is amended—

4 (1) in subsection (d)(2)—

5 (A) in the matter preceding subparagraph  
6 (A), by striking “and in such manner” and in-  
7 serting “, in such manner, and containing such  
8 information and assurances, including relevant  
9 documentation,”; and

10 (B) in subparagraph (A), by striking “is  
11 capable of coordinating with other entities to  
12 carry out” and inserting “has the demonstrated  
13 capability to carry out, through referral or con-  
14 tractual arrangements”;

15 (2) in subsection (h)—

16 (A) by redesignating paragraphs (1)  
17 through (4) as subparagraphs (A) through (D),  
18 respectively, and adjusting the margins accord-  
19 ingly;

20 (B) by striking “With respect to” and in-  
21 serting the following:

22 “(1) IN GENERAL.—With respect to”; and

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

24 “(2) ADDITIONAL REPORTING FOR CERTAIN EL-  
25 IGIBLE ENTITIES.—An entity carrying out activities  
26 described in subsection (g) through referral or con-

1       tractual arrangements shall include in the submis-  
 2       sions required under paragraph (1) information re-  
 3       lated to the status of such referrals or contractual  
 4       arrangements, including an assessment of whether  
 5       such referrals or contractual arrangements are sup-  
 6       porting the ability of such entity to carry out such  
 7       activities.”; and

8               (3) in subsection (j), by striking “2019 through  
 9       2023” and inserting “2025 through 2029”.

10 **SEC. 544. YOUTH PREVENTION AND RECOVERY.**

11       Section 7102(c) of the SUPPORT for Patients and  
 12       Communities Act (42 U.S.C. 290bb–7a(c)) (as amended  
 13       by section 110(a)) is amended—

14               (1) in paragraph (2)—

15                       (A) in subparagraph (A)—

16                               (i) in clause (i)—

17                                       (I) by inserting “, or a consor-  
 18                                       tium of local educational agencies,”  
 19                                       after “a local educational agency”;  
 20                                       and

21                                       (II) by striking “high schools”  
 22                                       and inserting “secondary schools”;  
 23                                       and

24                               (ii) in clause (vi), by striking “tribe,  
 25       or tribal” and inserting “Tribe, or Tribal”;

1 (B) by amending subparagraph (E) to read  
2 as follows:

3 “(E) INDIAN TRIBE; TRIBAL ORGANIZA-  
4 TION.—The terms ‘Indian Tribe’ and ‘Tribal  
5 organization’ have the meanings given such  
6 terms in section 4 of the Indian Self-Deter-  
7 mination and Education Assistance Act (25  
8 U.S.C. 5304).”;

9 (C) by redesignating subparagraph (K) as  
10 subparagraph (L); and

11 (D) by inserting after subparagraph (J)  
12 the following:

13 “(K) SECONDARY SCHOOL.—The term  
14 ‘secondary school’ has the meaning given such  
15 term in section 8101 of the Elementary and  
16 Secondary Education Act of 1965 (20 U.S.C.  
17 7801).”;

18 (2) in paragraph (3)(A), in the matter pre-  
19 ceding clause (i)—

20 (A) by striking “and abuse”; and

21 (B) by inserting “at increased risk for sub-  
22 stance misuse” after “specific populations”;

23 (3) in paragraph (4)—

1 (A) in the matter preceding subparagraph  
2 (A), by striking “Indian tribes” and inserting  
3 “Indian Tribes”;

4 (B) in subparagraph (A), by striking “and  
5 abuse”; and

6 (C) in subparagraph (B), by striking “peer  
7 mentoring” and inserting “peer-to-peer sup-  
8 port”;

9 (4) in paragraph (5), by striking “tribal” and  
10 inserting “Tribal”;

11 (5) in paragraph (6)(A)—

12 (A) in clause (iv), by striking “; and” and  
13 inserting a semicolon; and

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

15 “(vi) a plan to sustain the activities  
16 carried out under the grant program, after  
17 the grant program has ended; and”;

18 (6) in paragraph (8), by striking “2022” and  
19 inserting “2027”; and

20 (7) by amending paragraph (9) to read as fol-  
21 lows:

22 “(9) AUTHORIZATION OF APPROPRIATIONS.—  
23 To carry out this subsection, there are authorized to  
24 be appropriated—

25 “(A) \$10,000,000 for fiscal year 2025;



1 “(B) \$12,000,000 for fiscal year 2026;  
 2 “(C) \$13,000,000 for fiscal year 2027;  
 3 “(D) \$14,000,000 for fiscal year 2028;  
 4 and  
 5 “(E) \$15,000,000 for fiscal year 2029.”.

6 **SEC. 545. CAREER ACT.**

7 (a) IN GENERAL.—Section 7183 of the SUPPORT  
 8 for Patients and Communities Act (42 U.S.C. 290ee–8)  
 9 is amended—

10 (1) in the section heading, by inserting “;  
 11 **TREATMENT, RECOVERY, AND WORKFORCE**  
 12 **SUPPORT GRANTS**” after “**CAREER ACT**”;

13 (2) in subsection (b), by inserting “each” before  
 14 “for a period”;

15 (3) in subsection (c)—

16 (A) in paragraph (1), by striking “the  
 17 rates described in paragraph (2)” and inserting  
 18 “the average rates for calendar years 2018  
 19 through 2022 described in paragraph (2)”; and

20 (B) by amending paragraph (2) to read as  
 21 follows:

22 “(2) RATES.—The rates described in this para-  
 23 graph are the following:

24 “(A) The highest age-adjusted average  
 25 rates of drug overdose deaths for calendar years

1           2018 through 2022 based on data from the  
2           Centers for Disease Control and Prevention, in-  
3           cluding, if necessary, provisional data for cal-  
4           endar year 2022.

5           “(B) The highest average rates of unem-  
6           ployment for calendar years 2018 through 2022  
7           based on data provided by the Bureau of Labor  
8           Statistics.

9           “(C) The lowest average labor force par-  
10          ticipation rates for calendar years 2018 through  
11          2022 based on data provided by the Bureau of  
12          Labor Statistics.”;

13         (4) in subsection (g)—

14                 (A) in each of paragraphs (1) and (3), by  
15                 redesignating subparagraphs (A) and (B) as  
16                 clauses (i) and (ii), respectively, and adjusting  
17                 the margins accordingly;

18                 (B) by redesignating paragraphs (1)  
19                 through (3) as subparagraphs (A) through (C),  
20                 respectively, and adjusting the margins accord-  
21                 ingly;

22                 (C) in the matter preceding subparagraph  
23                 (A) (as so redesignated), by striking “An enti-  
24                 ty” and inserting the following:

25                 “(1) IN GENERAL.—An entity”; and

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

2 “(2) TRANSPORTATION SERVICES.—An entity  
3 receiving a grant under this section may use not  
4 more than 5 percent of the funds for providing  
5 transportation for individuals to participate in an ac-  
6 tivity supported by a grant under this section, which  
7 transportation shall be to or from a place of work  
8 or a place where the individual is receiving voca-  
9 tional education or job training services or receiving  
10 services directly linked to treatment of or recovery  
11 from a substance use disorder.

12 “(3) LIMITATION.—The Secretary may not re-  
13 quire an entity to, or give priority to an entity that  
14 plans to, use the funds of a grant under this section  
15 for activities that are not specified in this sub-  
16 section.”;

17 (5) in subsection (i)(2), by inserting “, which  
18 shall include employment and earnings outcomes de-  
19 scribed in subclauses (I) and (III) of section  
20 116(b)(2)(A)(i) of the Workforce Innovation and  
21 Opportunity Act (29 U.S.C. 3141(b)(2)(A)(i)) with  
22 respect to the participation of such individuals with  
23 a substance use disorder in programs and activities  
24 funded by the grant under this section” after “sub-  
25 section (g)”;

1 (6) in subsection (j)—

2 (A) in paragraph (1), by inserting “for  
3 grants awarded prior to the date of enactment  
4 of the SUPPORT for Patients and Commu-  
5 nities Reauthorization Act of 2025” after  
6 “grant period under this section”; and

7 (B) in paragraph (2)—

8 (i) in the matter preceding subpara-  
9 graph (A), by striking “2 years after sub-  
10 mitting the preliminary report required  
11 under paragraph (1)” and inserting “Sep-  
12 tember 30, 2029”; and

13 (ii) in subparagraph (A), by striking  
14 “(g)(3)” and inserting “(g)(1)(C)”; and

15 (7) in subsection (k), by striking “\$5,000,000  
16 for each of fiscal years 2019 through 2023” and in-  
17 serting “\$12,000,000 for each of fiscal years 2025  
18 through 2029”.

19 (b) REAUTHORIZATION OF THE CAREER ACT; RE-  
20 COVERY HOUSING PILOT PROGRAM.—

21 (1) IN GENERAL.—Section 8071 of the SUP-  
22 PORT for Patients and Communities Act (42  
23 U.S.C. 5301 note; Public Law 115–271) is amend-  
24 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”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if enacted on December 29, 2022.

**SEC. 554. EXTENSION OF TEMPORARY ORDER FOR FENTANYL-RELATED SUBSTANCES.**

Effective as if included in the enactment of the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (Public Law 116–114), section 2 of such Act is amended by striking “March 31, 2025” and inserting “September 30, 2026”.

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

**SEC. 601. SHORT TITLE.**

This title may be cited as the “Pandemic and All-Hazards Preparedness and Response Act”.

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

**SEC. 611. TEMPORARY REASSIGNMENT OF STATE AND  
LOCAL PERSONNEL DURING A PUBLIC  
HEALTH EMERGENCY.**

Section 319(e) of the Public Health Service Act (42 U.S.C. 247d(e)) is amended—

(1) in paragraph (1), by striking “tribal organization or such Governor or tribal organization’s des-

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-

nents, testing kits, reagents, and other testing supplies)” after “supply needs”; and

(C) in paragraph (7)—

(i) in the matter preceding subparagraph (A), by inserting “and the requirements developed pursuant to paragraph (3)(B)” after “subsection (d)”;

(ii) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively; and

(iii) by inserting after subparagraph (D) the following:

“(E) include a professional judgment of anticipated budget needs for each future fiscal year accounted for in such plan to account for the full range of anticipated medical countermeasure needs and life-cycle costs to address such priorities and requirements;”;

(2) in subsection (d)—

(A) by amending paragraph (1) to read as follows:

“(1) IN GENERAL.—Not later than March 15, 2020, and biennially thereafter, the Assistant Secretary for Preparedness and Response shall develop



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-

ing such agents that are an emerging infectious disease” after “become a pandemic”; and

(B) in paragraph (2)(A), by striking “\$250,000,000 for each of fiscal years 2019 through 2023” and inserting “\$335,000,000 for each of fiscal years 2025 and 2026, to remain available through December 31, 2026”.

**SEC. 622. NATIONAL HEALTH SECURITY STRATEGY.**

Section 2802 of the Public Health Service Act (42 U.S.C. 300hh–1) is amended—

(1) in subsection (a)(3)—

(A) by striking “In 2022, the” and inserting “The”; and

(B) by inserting “, maintaining, and sustaining” after “establishing”; and

(2) in subsection (b)—

(A) in paragraph (2)—

(i) in subparagraph (A), by inserting “that support interagency coordination and availability of information, as appropriate” before the period; and

(ii) in subparagraph (B), by inserting “rapid testing,” after “and supplies,”;

(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); and

3 (E) by inserting after paragraph (3) the  
4 following:

5 “(4) ACTION PLAN.—Not later than October 1,  
6 2026, and every 5 years thereafter, the task force  
7 described in paragraph (1) shall develop and submit  
8 to the Committee on Health, Education, Labor, and  
9 Pensions and the Committee on Appropriations of  
10 the Senate and the Committee on Energy and Com-  
11 merce and the Committee on Appropriations of the  
12 House of Representatives a plan regarding Federal  
13 programs and activities to combat antimicrobial re-  
14 sistance, including measurable outcomes, as appro-  
15 priate, informed by—

16 “(A) the agenda described in paragraph  
17 (3);

18 “(B) input provided by the Advisory Coun-  
19 cil described in subsection (b); and

20 “(C) input from other relevant stake-  
21 holders provided pursuant to paragraph (2).”;

22 (2) by redesignating subsections (b) through (o)  
23 as subsections (c) through (p), respectively;

24 (3) by inserting after subsection (a) the fol-  
25 lowing:

1 “(b) ADVISORY COUNCIL.—

2 “(1) IN GENERAL.—The Secretary may con-  
3 tinue the Presidential Advisory Council on Com-  
4 bating Antibiotic-Resistant Bacteria, referred to in  
5 this subsection as the ‘Advisory Council’.

6 “(2) DUTIES.—The Advisory Council shall ad-  
7 vise and provide information and recommendations  
8 to the Secretary, acting through the Task Force es-  
9 tablished under subsection (a), regarding Federal  
10 programs and activities intended to reduce or com-  
11 bat antimicrobial-resistant bacteria or fungi that  
12 may present a public health threat and improve ca-  
13 pabilities to prevent, diagnose, mitigate, or treat  
14 such resistance. Such advice, information, and rec-  
15 ommendations may be related to improving Federal  
16 efforts related to factors described in subsection  
17 (a)(3) and other topics related to antimicrobial re-  
18 sistance, as appropriate.

19 “(3) MEETINGS AND COORDINATION.—

20 “(A) MEETINGS.—The Advisory Council  
21 shall meet not less frequently than biannually  
22 and, to the extent practicable, in coordination  
23 with meetings of the task force established  
24 under subsection (a).

1           “(B) COORDINATION.—The Advisory  
2           Council shall, to the greatest extent practicable,  
3           coordinate activities carried out by the Council  
4           with the task force established under subsection  
5           (a).

6           “(4) FACA.—Chapter 10 of title 5, United  
7           States Code, shall apply to the activities and duties  
8           of the Advisory Council.

9           “(5) SUNSET.—

10           “(A) IN GENERAL.—The Advisory Council  
11           under this subsection shall terminate on De-  
12           cember 31, 2026.

13           “(B) EXTENSION OF ADVISORY COUN-  
14           CIL.—Not later than October 1, 2026, the Sec-  
15           retary shall submit to the Committee on  
16           Health, Education, Labor, and Pensions of the  
17           Senate and the Committee on Energy and Com-  
18           merce of the House of Representatives a report  
19           that includes a recommendation on whether the  
20           Advisory Council should be extended, and iden-  
21           tifying whether there are other committees,  
22           councils, or task forces that have overlapping or  
23           similar duties to that of the Advisory Council,  
24           and whether such committees, councils, or task  
25           forces should be combined, restructured, or

1 eliminated, including with respect to the task  
2 force established under subsection (a).”; and  
3 (4) in subsection (n), as so redesignated, by  
4 striking “(f) through (j)” and inserting “(g) through  
5 (k)”.

6 (b) CONFORMING AMENDMENT.—Section 505 of the  
7 Pandemic and All-Hazards Preparedness and Advancing  
8 Innovation Act of 2019 (42 U.S.C. 247d–5 note; Public  
9 Law 116–22) is amended by striking subsection (a) and  
10 all that follows through “Not later” in subsection (e) and  
11 inserting the following:

12 “Not later”.

13 **SEC. 625. STRATEGIC NATIONAL STOCKPILE AND MATE-**  
14 **RIAL THREATS.**

15 Section 319F–2 of the Public Health Service Act (42  
16 U.S.C. 247d–6b) is amended—

17 (1) in subsection (a)—

18 (A) in paragraph (2)—

19 (i) in subparagraph (A), by inserting  
20 “Such review shall include a description of  
21 how the Secretary manages and mitigates  
22 risks associated with gaps between current  
23 inventory levels and stockpiling goals,  
24 prioritizes such risks, and tracks progress

1 toward mitigation of such risks.” after the  
2 first sentence; and

3 (ii) in subparagraph (B)(i), by amend-  
4 ing subclause (IV) to read as follows:

5 “(IV) the emergency health secu-  
6 rity threat or threats such counter-  
7 measure procurement is intended to  
8 address, including—

9 “(aa) whether such procure-  
10 ment is consistent with meeting  
11 emergency health security needs  
12 associated with such threat or  
13 threats; and

14 “(bb) in the case of a coun-  
15 termeasure that addresses a bio-  
16 logical agent, whether such agent  
17 has an increased likelihood to be-  
18 come resistant to, more resistant  
19 to, or evade, such counter-  
20 measure relative to other avail-  
21 able medical countermeasures;”;

22 (B) in paragraph (3)—

23 (i) in subparagraph (B), by striking  
24 “are followed, regularly reviewed, and up-  
25 dated with respect to such stockpile” and

1 inserting “with respect to such stockpile  
2 are followed, regularly reviewed, and up-  
3 dated to reflect best practices”;

4 (ii) in subparagraph (I), by inserting  
5 “, through a standard operating proce-  
6 dure,” after “ensure”;

7 (iii) by redesignating subparagraphs  
8 (H) through (K) as subparagraphs (I)  
9 through (L), respectively;

10 (iv) by inserting after subparagraph  
11 (G) the following:

12 “(H) utilize tools to enable the timely and  
13 accurate tracking of the contents of the stock-  
14 pile throughout the deployment of such con-  
15 tents, including tracking of the location and ge-  
16 ographic distribution and utilization of such  
17 contents;”;

18 (v) in subparagraph (K), as so redes-  
19 ignated, by striking “; and” at the end and  
20 inserting a semicolon;

21 (vi) in subparagraph (L), as so redes-  
22 ignated, by striking the period and insert-  
23 ing “; and”; and

24 (vii) by adding at the end the fol-  
25 lowing:

1           “(M) communicate to relevant vendors re-  
2           garding modifications, renewals, extensions, or  
3           terminations of contracts, or the intent to exer-  
4           cise options for such contracts, within 30 days,  
5           as practicable, of such determination, including  
6           through the development of a contract notifica-  
7           tion process.”;

8           (C) in paragraph (5)(B), in the matter  
9           preceding clause (i), by inserting “, which may  
10          accompany the review required under paragraph  
11          (2),” after “Representatives a report”; and

12          (D) in paragraph (6)(A)—

13               (i) by redesignating clauses (viii)  
14               through (x) as clauses (ix) through (xi), re-  
15               spectively; and

16               (ii) by inserting after clause (vii) the  
17               following:

18               “(viii) with respect to any change in  
19               the Federal organizational management of  
20               the stockpile, an assessment and compari-  
21               son of any differences in the processes and  
22               operations resulting from such change, in-  
23               cluding—



1 “(I) planning for potential coun-  
2 termeasure deployment, distribution,  
3 or dispensing capabilities;

4 “(II) organizational structure;

5 “(III) communication with rel-  
6 evant stakeholders related to procure-  
7 ment decisions;

8 “(IV) processes related to pro-  
9 curement, deployment, and use of  
10 stockpiled countermeasures;

11 “(V) communication and coordi-  
12 nation with the Public Health Emer-  
13 gency Medical Countermeasures En-  
14 terprise and other related Federal en-  
15 tities;

16 “(VI) inventory management;  
17 and

18 “(VII) availability and use of re-  
19 sources for such activities;” and

20 (2) in subsection (c)(2)(C), by striking  
21 “promptly” and inserting “, not later than 60 days  
22 after each such determination,”;

23 (3) in subsection (f)(1), by striking  
24 “\$610,000,000 for each of fiscal years 2019 through  
25 2021, and \$750,000,000 for each of fiscal years

1       2022 and 2023” and inserting “\$1,100,000,000 for  
 2       fiscal year 2025, and \$1,210,000,000 for fiscal year  
 3       2026”; and

4               (4) in subsection (g)(1), by striking “2019  
 5       through 2028” and inserting “2025 through 2034”.

6   **SEC. 626. MEDICAL COUNTERMEASURES FOR VIRAL**  
 7               **THREATS WITH PANDEMIC POTENTIAL.**

8       Section 319L of the Public Health Service Act (42  
 9   U.S.C. 247d–7e) is amended—

10           (1) in subsection (c)—

11                   (A) in paragraph (4)—

12                           (i) in subparagraph (D)—

13                                   (I) in clause (ii), by striking “;  
 14                                   and” and inserting a semicolon;

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-  
8plementary to the work carried out by other such fa-  
9cilities 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-  
22demic 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-  
25eign 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

individual may be eligible for compensation under this section with respect to a vaccine that, at the time it was administered, was included in the Vaccine Injury Table under section 2114.”; and

(ii) in subsection (d)(3)—

(I) by striking “This section”

and inserting the following:

“(A) IN GENERAL.—This section”; and

(II) by adding at the end the fol-

lowing:

“(B) EXHAUSTION OF REMEDIES.—A covered individual shall not be considered to have exhausted remedies as described in paragraph (1), nor be eligible to seek remedy under section 319F–3(d), unless such individual has provided to the Secretary all supporting documentation necessary to facilitate the determinations required under subsection (b)(4).”.

(B) TITLE XXI.—Title XXI of the Public Health Service Act (42 U.S.C. 300aa–1 et seq.) is amended—

(i) in section 2111(a)(2)(A) (42 U.S.C. 300aa–11(a)(2)(A)), in the matter preceding clause (i), by inserting “con-

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 such sec-  
20 tion 319F–4 only if the administration of such  
21 vaccine occurred prior to the addition of the  
22 vaccine to the Vaccine Injury Table under sec-  
23 tion 2114 of the Public Health Service Act (42  
24 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 appropriate, in the implementation of such evidence-  
5           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-

priate, shall appoint to the Advisory Committee under paragraph (1) at least 13 individuals, including the following:

“(i) At least 3 non-Federal health care providers with expertise in geriatric medical disaster planning, preparedness, response, or recovery.

“(ii) At least 3 representatives of State, local, territorial, or Tribal agencies with expertise in geriatric disaster planning, preparedness, response, or recovery.

“(iii) At least 2 non-Federal professionals with training in gerontology, such as social workers, scientists, human services specialists, or other non-medical professionals, with experience in disaster planning, preparedness, response, or recovery among other adults.”; and

(2) by amending subsection (g) to read as follows:

“(g) SUNSET.—The Advisory Committee shall terminate on December 31, 2026.”.

(c) NATIONAL ADVISORY COMMITTEE ON INDIVIDUALS WITH DISABILITIES AND DISASTERS.—Section

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-

paredness, response, or recovery for individuals with disabilities.

“(iii) At least 4 individuals with a disability with expertise in disaster planning, preparedness, response, or recovery for individuals with disabilities.

“(iv) Other members as the Secretary determines appropriate, of whom—

“(I) at least one such member shall represent a local, State, or national organization with expertise in individuals with disabilities;

“(II) at least one such member shall be an individual with a disability; and

“(III) at least one such member shall be an individual with expertise in the needs of housing services, including during the response to, and recovery from, disasters.”; and

(C) by adding at the end the following:

“(3) CONSIDERATION.—In appointing members, including the Chair, to the Committee under this subsection, the Secretary may give consideration to disability status.”; and

1           (4) by amending subsection (h), as so redesign-  
2       nated, to read as follows:

3       “(h) SUNSET.—The Advisory Committee shall termi-  
4       nate on December 31, 2026.”.

5       **SEC. 634. NATIONAL ACADEMIES STUDY ON PRIZES.**

6       (a) IN GENERAL.—Not later than 90 days after the  
7       date of enactment of this Act, the Secretary of Health and  
8       Human Services shall seek to enter into an agreement  
9       with the National Academies of Sciences, Engineering,  
10      and Medicine (referred to in this section as the “National  
11      Academies”) to conduct a study to examine—

12           (1) alternative models for directly funding, or  
13      stimulating investment in, biomedical research and  
14      development that delink research and development  
15      costs from the prices of drugs, including the pro-  
16      gressive replacement of patents and regulatory  
17      exclusivities on new drugs with a combination of ex-  
18      panded support for research and innovation prizes to  
19      reward the successful development of drugs or  
20      achievement of related milestones;

21           (2) the dollar amount of innovation prizes for  
22      different stages of research and development of dif-  
23      ferent classes or types of drugs, and total annual  
24      funding, that would be necessary to stimulate invest-

1       ment sufficient to achieve such successful drug de-  
2       velopment and related milestones;

3           (3) the relative effectiveness and efficiency of  
4       such alternative models in stimulating innovation,  
5       compared to the status quo that includes patents  
6       and regulatory exclusivities;

7           (4) strategies to implement such alternative  
8       models described in paragraph (1), including a  
9       phased transition; and

10          (5) the anticipated economic and societal im-  
11       pacts of such alternative models, including an as-  
12       sessment of impact on—

13           (A) the number and variety of new drugs  
14       that would be developed, approved, and mar-  
15       keted in the United States, including such new  
16       drugs intended to prevent, diagnose, or treat a  
17       rare disease or condition;

18           (B) the rate at which new drugs would be  
19       developed, approved, and marketed in the  
20       United States;

21           (C) access to medication;

22           (D) health outcomes;

23           (E) average lifespan and disease burden in  
24       the United States;



1 (F) the number of manufacturers that  
2 would be seeking approval for a drug or bring-  
3 ing a drug to market for the first time;

4 (G) Federal discretionary and mandatory  
5 spending; and

6 (H) public and private insurance markets.

7 (b) REQUIREMENTS.—In conducting the study pursu-  
8 ant to subsection (a), the National Academies shall hold  
9 not fewer than 2 public listening sessions to solicit feed-  
10 back from interested parties, including representatives of  
11 academia, professional societies, patient advocates, public  
12 health organizations, relevant Federal departments and  
13 agencies, drug developers, representatives of other rel-  
14 evant industries, and subject matter experts.

15 (c) REPORT.—Not later than 2 years after the agree-  
16 ment under subsection (a), the National Academies shall  
17 submit to the Committee on Health, Education, Labor,  
18 and Pensions and the Committee on Appropriations of the  
19 Senate and the Committee on Energy and Commerce and  
20 the Committee on Appropriations of the House of Rep-  
21 resentatives a report on the study conducted pursuant to  
22 subsection (a).

## **Subtitle D—Additional Reauthorizations**

### **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 “transpor-  
23 tation;”;

24 (F) in subparagraph (O), by striking the  
25 period and inserting a semicolon; and

26 (G) by adding at the end the following:

“(P) encourage the integration of electronic health records systems through application programming interfaces (or successor technologies) among hospitals, organ procurement organizations, and transplant centers, including the use of automated electronic hospital referrals and the grant of remote, electronic access to hospital electronic health records of potential donors by organ procurement organizations, in a manner that complies with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, at part 160 of title 45, Code of Federal Regulations, and subparts A, C, and E of part 164 of such title (or any successor regulations); and

“(Q) consider establishing a dashboard to display the number of transplants performed, the types of transplants performed, the number and types of organs that entered the Organ Procurement and Transplantation Network system and failed to be transplanted, and other appropriate statistics, which should be updated more frequently than annually.”; and

(2) by adding at the end the following:

“(d) REGISTRATION FEES.—

1           “(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

under this section who did not receive reimbursement for all qualifying expenses during the preceding fiscal year; and

“(B) the total amount of funding that is estimated to be necessary to fully reimburse all donating individuals participating in the grant program under this section for all qualifying expenses.”.

**SEC. 714. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

Section 409I(d)(1) of the Public Health Service Act (42 U.S.C. 284m(d)(1)) is amended by striking “section,” and all that follows through the period at the end and inserting “section, \$25,000,000 for each of fiscal years 2025 through 2027.”.

**TITLE VIII—FOOD AND DRUG  
ADMINISTRATION  
Subtitle A—Give Kids a Chance**

**SEC. 801. RESEARCH INTO PEDIATRIC USES OF DRUGS; ADDITIONAL AUTHORITIES OF FOOD AND DRUG ADMINISTRATION REGARDING MOLECULARLY TARGETED CANCER DRUGS.**

(a) IN GENERAL.—

(1) ADDITIONAL ACTIVE INGREDIENT FOR APPLICATION DRUG; LIMITATION REGARDING NOVEL-COMBINATION APPLICATION DRUG.—Section



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).

(2) GAO STUDY AND REPORT.—

(A) STUDY.—Not later than 8 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study of the effectiveness of requiring assessments and investigations described in section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.355c), as amended by subsection (a), in the development of drugs and biological products for pediatric cancer indications, including consideration of any benefits to, or burdens on, pediatric cancer drug development.

(B) FINDINGS.—Not later than 10 years after the date of enactment of this Act, the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing the findings of the study conducted under subparagraph (A).

**SEC. 802. ENSURING COMPLETION OF PEDIATRIC STUDY REQUIREMENTS.**

(a) EQUAL ACCOUNTABILITY FOR PEDIATRIC STUDY REQUIREMENTS.—Section 505B(d) of the Federal Food,

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 the 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 seq.), 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 seq.), 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-

grams, retail and mail auto-refill programs, and cost-sharing assistance incentives directly or indirectly funded by such entity; and

“(vi) total gross spending on all drugs under the plan during the reporting period.

“(3) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE OFFERED BY A SPECIFIED LARGE EMPLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In the case of group health insurance coverage offered in connection with a group health plan that is offered by a specified large employer or is a specified large plan, such group health plan may, on an annual basis, for plan years beginning on or after the date that is 30 months after the date of enactment of this section, elect to require an entity providing pharmacy benefit management services on behalf of the health insurance issuer to submit to such group health plan a report that includes all of the information described in paragraph (2)(A), in addition to the information described in paragraph (2)(B).

“(4) PRIVACY REQUIREMENTS.—

“(A) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan shall report infor-



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 seq.), 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 reeval-  
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       metec 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 under 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.

