JUNE 22, 2020

RULES COMMITTEE PRINT 116–56

TEXT OF H.R. 1425

[Showing the text of the Patient Protection and Affordable Care Enhancement Act.]

1 SECTION 1. SHORT TITLE.

- 2 This Act may be cited as the "Patient Protection and
- 3 Affordable Care Enhancement Act".

4 SEC. 2. TABLE OF CONTENTS.

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

Sec. 1. Short title.

Sec. 2. Table of contents.

TITLE I—LOWERING HEALTH CARE COSTS AND PROTECTING PEOPLE WITH PREEXISTING CONDITIONS

- Sec. 101. Improving affordability by expanding premium assistance for consumers.
- Sec. 102. Improving affordability by reducing out-of-pocket and premium costs for consumers.
- Sec. 103. Expanding affordability for working families to fix the family glitch.
- Sec. 104. Tax credit reconciliation protections for individuals receiving social security lump-sum payments.
- Sec. 105. Preserving State option to implement health care Marketplaces.
- Sec. 106. Establishing a Health Insurance Affordability Fund.
- Sec. 107. Rescinding the short-term limited duration insurance regulation.
- Sec. 108. Revoking section 1332 guidance.
- Sec. 109. Requiring Marketplace outreach, educational activities, and annual enrollment targets.
- Sec. 110. Report on effects of website maintenance during open enrollment.
- Sec. 111. Promoting consumer outreach and education.
- Sec. 112. Improving transparency and accountability in the Marketplace.
- Sec. 113. Improving awareness of health coverage options.
- Sec. 114. Promoting State innovations to expand coverage.
- Sec. 115. Strengthening network adequacy.
- Sec. 116. Protecting consumers from unreasonable rate hikes.

TITLE II—ENCOURAGING MEDICAID EXPANSION AND STRENGTHENING THE MEDICAID PROGRAM

Sec. 201. Incentivizing Medicaid expansion.

- Sec. 202. Providing 12-months of continuous eligibility for Medicaid and CHIP.
- Sec. 203. Mandatory 12-months of postpartum Medicaid eligibility.
- Sec. 204. Reducing the administrative FMAP for nonexpansion States.
- Sec. 205. Enhanced reporting requirements for nonexpansion states.
- Sec. 206. Primary care pay increase.
- Sec. 207. Permanent funding for CHIP.
- Sec. 208. Permanent extension of CHIP enrollment and quality measures.
- Sec. 209. State option to increase children's eligibility for Medicaid and CHIP.
- Sec. 210. Medicaid coverage for citizens of Freely Associated States.
- Sec. 211. Extension of full Federal medical assistance percentage to Indian health care providers.

TITLE III—LOWERING PRICES THROUGH FAIR DRUG PRICE NEGOTIATION

Sec. 301. Establishing a Fair Drug Pricing Program.

Sec. 302. Drug manufacturer excise tax for noncompliance.

Sec. 303. Fair Price Negotiation Implementation Fund.

TITLE I-LOWERING HEALTH 1 CARE COSTS AND PRO-2 **TECTING PEOPLE WITH PRE-**3 **EXISTING CONDITIONS** 4

5 SEC. 101. IMPROVING AFFORDABILITY BY EXPANDING PRE-

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MIUM ASSISTANCE FOR CONSUMERS.

7 (a) IN GENERAL.—Section 36B(b)(3)(A) of the Internal Revenue Code of 1986 is amended to read as fol-8 9 lows:

10 "(A) APPLICABLE PERCENTAGE.—The ap-11 plicable percentage for any taxable year shall be 12 the percentage such that the applicable percent-13 age for any taxpayer whose household income is 14 within an income tier specified in the following 15 table shall increase, on a sliding scale in a lin-16 ear manner, from the initial premium percentage to the final premium percentage specified in such table for such income tier:

"In the case of household income (expressed as a percent of poverty line) within the following income tier:	The initial premium percentage is—	The final premium percentage is—
Up to 150.0 percent	0.0	0.0
150.0 percent up to 200.0 percent	0.0	3.0
200.0 percent up to 250.0 percent	3.0	4.0
250.0 percent up to 300.0 percent	4.0	6.0
300.0 percent up to 400.0 percent	6.0	8.5
400.0 percent and higher	8.5	8.5".

3 (b) CONFORMING AMENDMENT.—Section
4 36B(c)(1)(A) of the Internal Revenue Code of 1986 is
5 amended by striking "but does not exceed 400 percent".
6 (c) EFFECTIVE DATE.—The amendments made by
7 this section shall apply to taxable years beginning after
8 December 31, 2019.

9 SEC. 102. IMPROVING AFFORDABILITY BY REDUCING OUT10 OF-POCKET AND PREMIUM COSTS FOR CON11 SUMERS.

Section 1302(c)(4) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(c)(4)) is amended by striking "calendar year)" and inserting "calendar year, based on estimates and projections for the applicable calendar year of the percentage (if any) by which the average per enrollee premium for eligible employer-sponsored health plans (as defined in section 5000A(f)(2) of the Internal Revenue Code of 1986) exceeds such average per

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enrollee premium for the preceding calendar year, as pub-1 2 lished in the National Health Expenditure Accounts)". 3 SEC. 103. EXPANDING AFFORDABILITY FOR WORKING FAM-4 ILIES TO FIX THE FAMILY GLITCH. 5 (a) IN GENERAL.—Clause (i) of section 36B(c)(2)(C)6 of the Internal Revenue Code of 1986 is amended to read 7 as follows: 8 "(i) COVERAGE MUST BE AFFORD-9 ABLE.— 10 "(I) EMPLOYEES.—An employee 11 shall not be treated as eligible for 12 minimum essential coverage if such 13 coverage consists of an eligible em-14 ployer-sponsored plan (as defined in 15 section 5000A(f)(2)) and the employ-16 ee's required contribution (within the 17 meaning of section 5000A(e)(1)(B)18 with respect to the plan exceeds 9.5 19 percent of the employee's household 20 income. 21 "(II) FAMILY MEMBERS.—An in-22 dividual who is eligible to enroll in an 23 eligible employer-sponsored plan (as 24 defined in section 5000A(f)(2)) by

reason of a relationship the individual

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	bears to the employee shall not be
2	treated as eligible for minimum essen-
3	tial coverage by reason of such eligi-
4	bility to enroll if the employee's re-
5	quired contribution (within the mean-
6	ing of section 5000A(e)(1)(B), deter-
7	mined by substituting 'family' for
8	'self-only') with respect to the plan ex-
9	ceeds 9.5 percent of the employee's
10	household income.".
11	(b) Conforming Amendments.—
12	(1) Clause (ii) of section $36B(c)(2)(C)$ of the
13	Internal Revenue Code of 1986 is amended by strik-
14	ing "Except as provided in clause (iii), an employee"
15	and inserting "An individual".
16	(2) Clause (iii) of section $36B(c)(2)(C)$ of such
17	Code is amended by striking "the last sentence of
18	clause (i)" and inserting "clause (i)(II)".
19	(3) Clause (iv) of section $36B(c)(2)(C)$ of such
19 20	(3) Clause (iv) of section 36B(c)(2)(C) of suchCode is amended by striking "the 9.5 percent under
20	Code is amended by striking "the 9.5 percent under
20 21	Code is amended by striking "the 9.5 percent under clause (i)(II)" and inserting "the 9.5 percent under
20 21 22	Code is amended by striking "the 9.5 percent under clause (i)(II)" and inserting "the 9.5 percent under clauses (i)(I) and (i)(II)".

1	SEC. 104. TAX CREDIT RECONCILIATION PROTECTIONS FOR
2	INDIVIDUALS RECEIVING SOCIAL SECURITY
3	LUMP-SUM PAYMENTS.
4	(a) IN GENERAL.—Section 36B(d)(2) of the Internal
5	Revenue Code of 1986 is amended by adding at the end
6	the following new subparagraph:
7	"(C) EXCLUSION OF PORTION OF LUMP-
8	SUM SOCIAL SECURITY BENEFITS.—
9	"(i) IN GENERAL.—The term 'modi-
10	fied adjusted gross income' shall not in-
11	clude so much of any lump-sum social se-
12	curity benefit payment as is attributable to
13	months ending before the beginning of the
14	taxable year.
15	"(ii) LUMP-SUM SOCIAL SECURITY
16	BENEFIT PAYMENT.—For purposes of this
17	subparagraph, the term 'lump-sum social
18	security benefit payment' means any pay-
19	ment of social security benefits (as defined
20	in section $86(d)(1)$) which constitutes more
21	than 1 month of such benefits.
22	"(iii) Election to include ex-
23	CLUDABLE AMOUNT.—A taxpayer may
24	elect (at such time and in such manner as
25	the Secretary may provide) to have this

subparagraph not apply for any taxable 1 2 year.". 3 (b) EFFECTIVE DATE.—The amendment made by 4 this section shall apply to taxable years beginning after 5 December 31, 2019. 6 SEC. 105. PRESERVING STATE OPTION TO IMPLEMENT 7 HEALTH CARE MARKETPLACES. 8 (a) IN GENERAL.—Section 1311 of the Patient Protection and Affordable Care Act (42 U.S.C. 18031) is 9 10 amended-11 (1) in subsection (a)— 12 (A) in paragraph (4)(B), by striking "under this subsection" and inserting "under 13 14 this paragraph or paragraph (1)"; and 15 (B) by adding at the end the following new 16 paragraph: 17 "(6) Additional planning and establish-18 MENT GRANTS.— 19 "(A) IN GENERAL.—There shall be appro-20 priated to the Secretary, out of any moneys in 21 the Treasury not otherwise appropriated, \$200 22 million to award grants to eligible States for 23 the uses described in paragraph (3).

1	"(B) DURATION AND RENEWABILITY.—A
2	grant awarded under subparagraph (A) shall be
3	for a period of 2 years and may not be renewed.
4	"(C) LIMITATION.—A grant may not be
5	awarded under subparagraph (A) after Decem-
6	ber 31, 2023.
7	"(D) ELIGIBLE STATE DEFINED.—For
8	purposes of this paragraph, the term 'eligible
9	State' means a State that, as of the date of the
10	enactment of this paragraph, is not operating
11	an Exchange (other than an Exchange de-
12	scribed in section 155.200(f) of title 45, Code
13	of Federal Regulations)."; and
14	(2) in subsection $(d)(5)(A)$ —
15	(A) by striking "OPERATIONS.—In estab-
16	lishing an Exchange under this section" and in-
17	serting "OPERATIONS.—
18	"(i) IN GENERAL.—In establishing an
19	Exchange under this section (other than in
20	establishing an Exchange pursuant to a
21	grant awarded under subsection $(a)(6)$)";
22	and
23	(B) by adding at the end the following:
24	"(ii) Additional planning and es-
25	TABLISHMENT GRANTS.—In establishing

1	an Exchange pursuant to a grant awarded
2	under subsection $(a)(6)$, the State shall en-
3	sure that such Exchange is self-sustaining
4	beginning on January 1, 2025, including
5	allowing the Exchange to charge assess-
6	ments or user fees to participating health
7	insurance issuers, or to otherwise generate
8	funding, to support its operations.".
9	(b) Clarification Regarding Failure to Estab-
10	LISH EXCHANGE OR IMPLEMENT REQUIREMENTS.—Sec-
11	tion 1321(c) of the Patient Protection and Affordable
12	Care Act (42 U.S.C. 18041(c)) is amended—
13	(1) in paragraph (1), by striking "If" and in-
14	serting "Subject to paragraph (3), if"; and
15	(2) by adding at the end the following new
16	paragraph:
17	"(3) CLARIFICATION.—This subsection shall
18	not apply in the case of a State that elects to apply
19	the requirements described in subsection (a) and
20	satisfies the requirement described in subsection (b)
21	on or after January 1, 2014.".

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 SEC. 106. ESTABLISHING A HEALTH INSURANCE AFFORD

 2
 ABILITY FUND.

3 Subtitle D of title I of the Patient Protection and
4 Affordable Care Act is amended by inserting after part
5 5 (42 U.S.C. 18061 et seq.) the following new part:

6 **"PART 6—IMPROVE HEALTH INSURANCE**7 **AFFORDABILITY FUND**

8 "SEC. 1351. ESTABLISHMENT OF PROGRAM.

9 "There is hereby established the Improve Health Insurance Affordability Fund' to be administered by the Sec-10 retary of Health and Human Services, acting through the 11 Administrator of the Centers for Medicare & Medicaid 12 Services (in this section referred to as the 'Adminis-13 trator'), to provide funding, in accordance with this part, 14 to the 50 States and the District of Columbia (each re-15 16 ferred to in this section as a 'State') beginning on January 1, 2022, for the purposes described in section 1352. 17

18 "SEC. 1352. USE OF FUNDS.

19 "(a) IN GENERAL.—A State shall use the funds allo20 cated to the State under this part for one of the following
21 purposes:

"(1) To provide reinsurance payments to health
insurance issuers with respect to individuals enrolled
under individual health insurance coverage (other
than through a plan described in subsection (b)) offered by such issuers.

1	"(2) To provide assistance (other than through
2	payments described in paragraph (1)) to reduce out-
3	of-pocket costs, such as copayments, coinsurance,
4	premiums, and deductibles, of individuals enrolled
5	under qualified health plans offered on the indi-
6	vidual market through an Exchange.
7	"(b) Exclusion of Certain Grandfathered and
8	TRANSITIONAL PLANS.—For purposes of subsection (a),
9	a plan described in this subsection is the following:
10	((1) A grandfathered health plan (as defined in
11	section 1251).
12	"(2) A plan (commonly referred to as a 'transi-
13	tional plan') continued under the letter issued by the
14	Centers for Medicare & Medicaid Services on No-
15	vember 14, 2013, to the State Insurance Commis-
16	sioners outlining a transitional policy for coverage in
17	the individual and small group markets to which sec-
18	tion 1251 does not apply, and under the extension
19	of the transitional policy for such coverage set forth
20	in the Insurance Standards Bulletin Series guidance
21	issued by the Centers for Medicare & Medicaid Serv-
22	ices on March 5, 2014, February 29, 2016, Feb-
23	ruary 13, 2017, April 9, 2018, March 25, 2019, and
24	January 31, 2020, or under any subsequent exten-
25	sions thereof.

"(3) Student health insurance coverage (as de fined in section 147.145 of title 45, Code of Federal
 Regulations).

4 "SEC. 1353. STATE ELIGIBILITY AND APPROVAL; DEFAULT 5 SAFEGUARD.

6 "(a) ENCOURAGING STATE OPTIONS FOR ALLOCA-7 TIONS.—

8 "(1) IN GENERAL.—To be eligible for an alloca-9 tion of funds under this part for a year (beginning 10 with 2022), a State shall submit to the Adminis-11 trator an application at such time (but, in the case 12 of allocations for 2022, not later than 90 days after 13 the date of the enactment of this part and, in the 14 case of allocations for a subsequent year, not later 15 than March 1 of the previous year) and in such form 16 and manner as specified by the Administrator con-17 taining-

18 "(A) a description of how the funds will be19 used; and

20 "(B) such other information as the Admin-21 istrator may require.

"(2) AUTOMATIC APPROVAL.—An application so
submitted is approved unless the Administrator notifies the State submitting the application, not later
than 60 days after the date of the submission of

1 such application, that the application has been de-2 nied for not being in compliance with any require-3 ment of this part and of the reason for such denial. 4 "(3) 5-YEAR APPLICATION APPROVAL.—If an 5 application of a State is approved for a purpose de-6 scribed in section 1352 for a year, such application 7 shall be treated as approved for such purpose for 8 each of the subsequent 4 years. 9 "(4) REVOCATION OF APPROVAL.—The ap-10 proval of an application of a State, with respect to 11 a purpose described in section 1352, may be revoked 12 if the State fails to use funds provided to the State 13 under this section for such purpose or otherwise fails 14 to comply with the requirements of this section. 15 "(b) Default Federal Safeguard.— 16 "(1) 2022.—For 2022, in the case of a State 17 that does not submit an application under subsection 18 (a) by the 90-day submission date applicable to such 19 year under subsection (a)(1) and in the case of a 20 State that does submit such an application by such 21 date that is not approved, the Administrator, in con-22 sultation with the State insurance commissioner, 23 shall, from the amount calculated under paragraph 24 (4) for such year, carry out the purpose described in 25 paragraph (3) in such State for such year.

1 (2)2023AND SUBSEQUENT YEARS.—For 2 2023 or a subsequent year, in the case of a State 3 that does not have in effect an approved application 4 under this section for such year, the Administrator, 5 in consultation with the State insurance commis-6 sioner, shall, from the amount calculated under 7 paragraph (4) for such year, carry out the purpose 8 described in paragraph (3) in such State for such 9 year.

10 "(3) Specified USE.—The amount described 11 in paragraph (4), with respect to 2022 or a subse-12 quent year, shall be used to carry out the purpose 13 described in section 1352(a)(1) in each State de-14 scribed in paragraph (1) or (2) for such year, as ap-15 plicable, by providing reinsurance payments to 16 health insurance issuers with respect to attachment 17 range claims (as defined in section 1354(b)(2)), 18 using the dollar amounts specified in subparagraph 19 (B) of such section for such year) in an amount 20 equal to, subject to paragraph (5), the percentage 21 (specified for such year by the Secretary under such 22 subparagraph) of the amount of such claims.

23 "(4) AMOUNT DESCRIBED.—The amount de24 scribed in this paragraph, with respect to 2022 or
25 a subsequent year, is the amount equal to the total

sum of amounts that the Secretary would otherwise
 estimate under section 1354(b)(2)(A)(i) for such
 year for each State described in paragraph (1) or
 (2) for such year, as applicable, if each such State
 were not so described for such year.

6 "(5) ADJUSTMENT.—For purposes of this subsection, the Secretary may apply a percentage under 7 8 paragraph (3) with respect to a year that is less 9 than the percentage otherwise specified in section 10 1354(b)(2)(B) for such year, if the cost of paying 11 the total eligible attachment range claims for States 12 described in this subsection for such year at such 13 percentage otherwise specified would exceed the 14 amount calculated under paragraph (4) for such 15 year.

16 "SEC. 1354. ALLOCATIONS.

"(a) APPROPRIATION.—For the purpose of providing
allocations for States under subsection (b) and payments
under section 1353(b) there is appropriated, out of any
money in the Treasury not otherwise appropriated,
\$10,000,000,000 for 2022 and each subsequent year.

- 22 "(b) Allocations.—
- 23 "(1) PAYMENT.—
- 24 "(A) IN GENERAL.—From amounts appro25 priated under subsection (a) for a year, the

Secretary shall, with respect to a State not de-
scribed in section 1353(b) for such year and
not later than the date specified under subpara-
graph (B) for such year, allocate for such State
the amount determined for such State and year
under paragraph (2).
"(B) Specified date.—For purposes of
subparagraph (A), the date specified in this
subparagraph is—
"(i) for 2022, the date that is 45 days
after the date of the enactment of this
part; and
"(ii) for 2023 or a subsequent year,
January 1 of the respective year.
"(C) NOTIFICATIONS OF ALLOCATION
AMOUNTS.—For 2023 and each subsequent
year, the Secretary shall notify each State of
the amount determined for such State under
paragraph (2) for such year by not later than
January 1 of the previous year.
"(2) Allocation amount determina-
TIONS.—
"(A) IN GENERAL.—For purposes of para-
"(A) IN GENERAL.—For purposes of para- graph (1), the amount determined under this

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paragraph (1)(A) for such year is the amount equal to—

"(i) the amount that the Secretary es-3 4 timates would be expended under this part 5 for such year on attachment range claims 6 of individuals residing in such State if such 7 State used such funds only for the purpose 8 described in paragraph (1) of section 9 1352(a) at the dollar amounts and percentage specified under subparagraph (B) 10 11 for such year; minus 12 "(ii) the amount, if any, by which the 13 Secretary determines— 14 "(I) the estimated amount of 15 premium tax credits under section 36B of the Internal Revenue Code of 16 17 1986 that would be attributable to in-18 dividuals residing in such State for 19 such year without application of this 20 part; exceeds 21 "(II) the estimated amount of 22 premium tax credits under section 23 36B of the Internal Revenue Code of

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1	such year if such State were a State
2	described in section 1353(b) for such
3	year.

For purposes of the previous sentence and section 1353(b)(3), the term 'attachment range claims' means, with respect to an individual, the claims for such individual that exceed a dollar amount specified by the Secretary for a year, but do not exceed a ceiling dollar amount specified by the Secretary for such year, under subparagraph (B).

12 "(B) SPECIFICATIONS.—For purposes of 13 subparagraph (A) and section 1353(b)(3), the 14 Secretary shall determine the dollar amounts 15 and the percentage to be specified under this 16 subparagraph for a year in a manner to ensure 17 that the total amount of expenditures under 18 this part for such year is estimated to equal the 19 total amount appropriated for such year under 20 subsection (a) if such expenditures were used 21 solely for the purpose described in paragraph 22 (1) of section 1352(a) for attachment range 23 claims at the dollar amounts and percentage so 24 specified for such year.

1	"(3) AVAILABILITY.—Funds allocated to a
2	State under this subsection for a year shall remain
3	available through the end of the subsequent year.".
4	SEC. 107. RESCINDING THE SHORT-TERM LIMITED DURA-
5	TION INSURANCE REGULATION.
6	(a) FINDINGS.—Congress finds the following:
7	(1) On August 3, 2018, the Administration
8	issued a final rule entitled "Short-Term, Limited-
9	Duration Insurance' (83 Fed. Reg. 38212).
10	(2) The final rule dramatically expands the sale
11	and marketing of insurance that—
12	(A) may discriminate against individuals
13	living with preexisting health conditions, includ-
14	ing children with complex medical needs and
15	disabilities and their families;
16	(B) lacks important financial protections
17	provided by the Patient Protection and Afford-
18	able Care Act (Public Law 111–148), including
19	the prohibition of annual and lifetime coverage
20	limits and annual out-of-pocket limits, that may
21	increase the cost of treatment and cause finan-
22	cial hardship to those requiring medical care,
23	including children with complex medical needs
24	and disabilities and their families; and

(C) excludes coverage of essential health
 benefits including hospitalization, prescription
 drugs, and other lifesaving care.
 (3) The implementation and enforcement of the

final rule weakens critical protections for up to 130
million Americans living with preexisting health conditions and may place a large financial burden on
those who enroll in short-term limited-duration insurance, which jeopardizes Americans' access to
quality, affordable health insurance.

(b) PROHIBITION.—The Secretary of Health and
Human Services, the Secretary of the Treasury, and the
Secretary of Labor—

(1) may not take any action to implement, enforce, or otherwise give effect to the rule entitled
"Short-Term, Limited Duration Insurance" (83
Fed. Reg. 38212 (August 3, 2018));

18 (2) shall apply any regulation revised by such19 rule as if such rule had not been issued; and

20 (3) may not promulgate any substantially simi-21 lar rule.

22 SEC. 108. REVOKING SECTION 1332 GUIDANCE.

23 (a) FINDINGS.—Congress finds the following:

24 (1) On October 24, 2018, the administration
25 published new guidance to carry out section 1332 of

the Patient Protection and Affordable Care Act (42
 U.S.C. 18052) entitled "State Relief and Empower ment Waivers" (83 Fed. Reg. 53575).

4 (2) The new guidance encourages States to pro5 vide health insurance coverage through insurance
6 plans that may discriminate against individuals with
7 preexisting health conditions, including the one in
8 four Americans living with a disability.

9 (3) The implementation and enforcement of the 10 new guidance weakens protections for the millions of 11 Americans living with preexisting health conditions 12 and jeopardizes Americans' access to quality, afford-13 able health insurance coverage.

14 (b) PROVIDING THAT CERTAIN GUIDANCE RELATED 15 TO WAIVERS FOR STATE INNOVATION UNDER THE PA-16 TIENT PROTECTION AND AFFORDABLE CARE ACT SHALL 17 HAVE NO FORCE OR EFFECT.—Beginning July 1, 2020, 18 the Secretary of Health and Human Services and the Sec-19 retary of the Treasury may not take any action to imple-20 ment, enforce, or otherwise give effect to the guidance en-21 titled "State Relief and Empowerment Waivers" (83 Fed. 22 Reg. 53575 (October 24, 2018)), including any such ac-23 tion that would result in individuals losing health insur-24 ance coverage that includes the essential health benefits package (as defined in subsection (a) of section 1302 of 25

the Patient Protection and Affordable Care Act (42) 1 U.S.C. 18022(a)) without regard to any waiver of any pro-2 3 vision of such package under a waiver under such section 4 1332), including the maternity and newborn care essential health benefit described in subsection (b)(1)(D) of such 5 section, including any such action that would result in a 6 7 decrease in the number of such individuals enrolled in cov-8 erage that is at least as comprehensive as the coverage 9 defined in section 1302(a) of the Patient Protection and 10 Affordable Care Act (42 U.S.C. 18022(a)) compared to the number of such individuals who would have been so 11 12 enrolled in such coverage had such action not been taken, 13 including any such action that would, with respect to individuals with substance use disorders, including opioid use 14 15 disorders, reduce the availability or affordability of coverage that is at least as comprehensive as the coverage 16 defined in section 1302(a) of the Patient Protection and 17 Affordable Care Act (42 U.S.C. 18022(a)) compared to 18 the availability or affordability, respectively, of such cov-19 erage had such action not been taken, including any such 2021 action that would result, with respect to vulnerable popu-22 lations (including low-income individuals, elderly individ-23 uals, and individuals with serious health issues or who 24 have a greater risk of developing serious health issues), 25 in a decrease in the availability of coverage that is at least

as comprehensive as the coverage defined in section 1 2 1302(a) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(a)) with coverage and cost sharing pro-3 4 tections required under section 1332(b)(1)(B) of such Act 5 (42 U.S.C. 18052(b)(1)(B)), including any such action that would, with respect to individuals with preexisting 6 7 conditions, reduce the affordability of coverage that is at 8 least as comprehensive as the coverage defined in section 9 1302(a) of the Patient Protection and Affordable Care Act 10 (42 U.S.C. 18022(a)) compared to the affordability of such coverage had such action not been taken, including 11 12 any such action that would result in higher health insurance premiums for individuals enrolled in health insurance 13 coverage that is at least as comprehensive as the coverage 14 15 defined in section 1302(b) of such Act (42 U.S.C. 18022(b)), and the Secretaries may not promulgate any 16 17 substantially similar guidance or rule. Nothing in the pre-18 vious sentence shall be construed to affect the approval 19 of waivers under section 1332 of the Patient Protection 20 and Affordable Care Act (42 U.S.C. 18052) that establish 21 reinsurance programs that are consistent with the require-22 ments under subsection (b)(1) of such section (42 U.S.C. 23 18052(b)(1), lower health insurance premiums, and pro-24 tect health insurance coverage for people with preexisting conditions. 25

(c) GAO REPORT ON AFFECT OF STATE INNOVATION 1 WAIVERS ON COVERAGE OF INDIVIDUALS AND ON MEN-2 TAL HEALTH HEALTH CARE TREATMENT.-Not later 3 4 than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit 5 to Congress a report on the number of individuals ex-6 7 pected to lose access to health insurance coverage (as de-8 fined in section 2791 of the Public Health Service Act (42) 9 U.S.C. 300gg–91)) if subsection (b) were not enacted and waivers under section 1332 of the Patient Protection and 10 Affordable Care Act (42 U.S.C. 18052) were approved 11 12 under the guidance described in such subsection (b). Such report shall include an analysis of the expected effect such 13 waivers approved under such guidance would have on men-14 tal health care treatment. 15

16 SEC. 109. REQUIRING MARKETPLACE OUTREACH, EDU-17CATIONAL ACTIVITIES, AND ANNUAL EN-18ROLLMENT TARGETS.

(a) IN GENERAL.—Section 1321(c) of the Patient
Protection and Affordable Care Act (42 U.S.C. 18041(c)),
as amended by section 105(b), is further amended by adding at the end the following new paragraphs:

23 "(4) OUTREACH AND EDUCATIONAL ACTIVI24 TIES.—

1 "(A) IN GENERAL.—In the case of an Ex-2 change established or operated by the Secretary 3 within a State pursuant to this subsection, the 4 Secretary shall carry out outreach and edu-5 cational activities for purposes of informing in-6 dividuals about qualified health plans offered 7 through the Exchange, including by informing 8 such individuals of the availability of coverage 9 under such plans and financial assistance for 10 coverage under such plans. Such outreach and 11 educational activities shall be provided in a 12 manner that is culturally and linguistically ap-13 propriate to the needs of the populations being 14 served by the Exchange (including hard-to-15 reach populations, such as racial and sexual mi-16 norities, limited English proficient populations, 17 individuals in rural areas, veterans, and young 18 adults) and shall be provided to populations re-19 siding in high health disparity areas (as defined 20 in subparagraph (E)) served by the Exchange, 21 in addition to other populations served by the 22 Exchange.

23 "(B) LIMITATION ON USE OF FUNDS.—No
24 funds appropriated under this paragraph shall

1	be used for expenditures for promoting non-
2	ACA compliant health insurance coverage.
3	"(C) NON-ACA COMPLIANT HEALTH IN-
4	SURANCE COVERAGE.—For purposes of sub-
5	paragraph (B):
6	"(i) The term 'non-ACA compliant
7	health insurance coverage' means health
8	insurance coverage, or a group health plan,
9	that is not a qualified health plan.
10	"(ii) Such term includes the following:
11	"(I) An association health plan.
12	"(II) Short-term limited duration
13	insurance.
13 14	insurance. "(D) FUNDING.—Out of any funds in the
14	"(D) FUNDING.—Out of any funds in the
14 15	"(D) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are
14 15 16	"(D) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are hereby appropriated for fiscal year 2022 and
14 15 16 17	"(D) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are hereby appropriated for fiscal year 2022 and each subsequent fiscal year, \$100,000,000 to
14 15 16 17 18	"(D) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are hereby appropriated for fiscal year 2022 and each subsequent fiscal year, \$100,000,000 to carry out this paragraph. Funds appropriated
14 15 16 17 18 19	"(D) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are hereby appropriated for fiscal year 2022 and each subsequent fiscal year, \$100,000,000 to carry out this paragraph. Funds appropriated under this subparagraph shall remain available
14 15 16 17 18 19 20	"(D) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are hereby appropriated for fiscal year 2022 and each subsequent fiscal year, \$100,000,000 to carry out this paragraph. Funds appropriated under this subparagraph shall remain available until expended.
 14 15 16 17 18 19 20 21 	"(D) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are hereby appropriated for fiscal year 2022 and each subsequent fiscal year, \$100,000,000 to carry out this paragraph. Funds appropriated under this subparagraph shall remain available until expended. "(E) HIGH HEALTH DISPARITY AREA DE-

1	"(i) is located in one census tract or
2	ZIP code;
3	"(ii) has measurable and documented
4	racial, ethnic, or geographic health dispari-
5	ties;
6	"(iii) has a low-income population, as
7	demonstrated by—
8	"(I) average income below 138
9	percent of the Federal poverty line; or
10	"(II) a rate of participation in
11	the special supplemental nutrition
12	program under section 17 of the Child
13	Nutrition Act of 1966 (42 U.S.C.
14	1786) that is higher than the national
15	average rate of participation in such
16	program;
17	"(iv) has poor health outcomes, as
18	demonstrated by—
19	"(I) lower life expectancy than
20	the national average; or
21	"(II) a higher percentage of in-
22	stances of low birth weight than the
23	national average; and

1	"(v) is part of a Metropolitan Statis-
2	tical Area identified by the Office of Man-
3	agement and Budget.
4	"(5) ANNUAL ENROLLMENT TARGETS.—For

plan year 2021 and each subsequent plan year, in
the case of an Exchange established or operated by
the Secretary within a State pursuant to this subsection, the Secretary shall establish annual enrollment targets for such Exchange for such year.".

10 (b) STUDY AND REPORT.—Not later than 30 days 11 after the date of the enactment of this Act, the Secretary 12 of Health and Human Services shall release to Congress 13 all aggregated documents relating to studies and data sets that were created on or after January 1, 2014, and related 14 15 to marketing and outreach with respect to qualified health plans offered through Exchanges under title I of the Pa-16 tient Protection and Affordable Care Act (42 U.S.C. 17 18 18001 et seq.).

19 SEC. 110. REPORT ON EFFECTS OF WEBSITE MAINTENANCE 20 DURING OPEN ENROLLMENT.

Not later than 1 year after the date of the enactment
of this Act, the Comptroller General of the United States
shall submit to Congress a report examining whether the
Department of Health and Human Services has been conducting maintenance on the website commonly referred to

as "Healthcare.gov" during annual open enrollment peri-1 2 ods (as described in section 1311(c)(6)(B) of the Patient Affordable 3 Protection and Care Act (42)U.S.C. 4 18031(c)(6)(B) in such a manner so as to minimize any 5 disruption to the use of such website resulting from such 6 maintenance.

7 SEC. 111. PROMOTING CONSUMER OUTREACH AND EDU8 CATION.

9 (a) IN GENERAL.—Section 1311(i) of the Patient
10 Protection and Affordable Care Act (42 U.S.C. 18031(i))
11 is amended—

12 (1) in paragraph (2), by adding at the end the13 following new subparagraph:

14 "(C) SELECTION OF RECIPIENTS.—In the
15 case of an Exchange established and operated
16 by the Secretary within a State pursuant to sec17 tion 1321(c), in awarding grants under para18 graph (1), the Exchange shall—

19 "(i) select entities to receive such
20 grants based on an entity's demonstrated
21 capacity to carry out each of the duties
22 specified in paragraph (3);

23 "(ii) not take into account whether or
24 not the entity has demonstrated how the
25 entity will provide information to individ-

1	uals relating to group health plans offered
2	by a group or association of employers de-
3	scribed in section 2510.3–5(b) of title 29,
4	Code of Federal Regulations (or any suc-
5	cessor regulation), or short-term limited
6	duration insurance (as defined by the Sec-
7	retary for purposes of section $2791(b)(5)$
8	of the Public Health Service Act); and
9	"(iii) ensure that, each year, the Ex-
10	change awards such a grant to—
11	"(I) at least one entity described
12	in this paragraph that is a community
13	and consumer-focused nonprofit
14	group; and
15	"(II) at least one entity described
16	in subparagraph (B), which may in-
17	clude another community and con-
18	sumer-focused nonprofit group in ad-
19	dition to any such group awarded a
20	grant pursuant to subclause (I).
21	In awarding such grants, an Exchange may
22	consider an entity's record with respect to
23	waste, fraud, and abuse for purposes of main-
24	taining the integrity of such Exchange.";
25	(2) in paragraph (3)—

1	(A) by amending subparagraph (C) to read
2	as follows:
3	"(C) facilitate enrollment, including with
4	respect to individuals with limited English pro-
5	ficiency and individuals with chronic illnesses,
6	in qualified health plans, State medicaid plans
7	under title XIX of the Social Security Act, and
8	State child health plans under title XXI of such
9	Act;'';
10	(B) in subparagraph (D), by striking
11	"and" at the end;
12	(C) in subparagraph (E), by striking the
13	period at the end and inserting "; and";
14	(D) by inserting after subparagraph (E)
15	the following new subparagraph:
16	"(F) provide referrals to community-based
17	organizations that address social needs related
18	to health outcomes."; and
19	(E) by adding at the end the following
20	flush left sentence:
21	"The duties specified in the preceding sentence may

be carried out by such a navigator at any time during a year.";

24 (3) in paragraph (4)(A)—

1	(A) in the matter preceding clause (i), by
2	striking "not";
3	(B) in clause (i)—
4	(i) by inserting "not" before "be";
5	and
6	(ii) by striking "; or" and inserting a
7	semicolon;
8	(C) in clause (ii)—
9	(i) by inserting "not" before "re-
10	ceive"; and
11	(ii) by striking the period and insert-
12	ing a semicolon; and
13	(D) by adding at the end the following new
14	clauses:
15	"(iii) maintain physical presence in
16	the State of the Exchange so as to allow
17	in-person assistance to consumers; and
18	"(iv) receive opioid specific education
19	and training that ensures the navigator
20	can best educate individuals on qualified
21	health plans offered through an Exchange,
22	specifically coverage under such plans for
23	opioid health care treatment."; and
24	(4) in paragraph (6) —

1	(A) by striking "Funding.—Grants
2	under" and inserting "FUNDING.—
3	"(A) STATE EXCHANGES.—Grants under";
4	and
5	(B) by adding at the end the following new
6	subparagraph:
7	"(B) FEDERAL EXCHANGES.—For pur-
8	poses of carrying out this subsection, with re-
9	spect to an Exchange established and operated
10	by the Secretary within a State pursuant to sec-
11	tion 1321(c), the Secretary shall obligate
12	\$100,000,000 out of amounts collected through
13	the user fees on participating health insurance
14	issuers pursuant to section 156.50 of title 45,
15	Code of Federal Regulations (or any successor
16	regulations), for fiscal year 2022 and each sub-
17	sequent fiscal year. Such amount for a fiscal
18	year shall remain available until expended.".
19	(b) EFFECTIVE DATE.—The amendments made by
20	this section shall apply with respect to plan years begin-
21	ning on or after January 1, 2021.
22	SEC. 112. IMPROVING TRANSPARENCY AND ACCOUNT-
23	ABILITY IN THE MARKETPLACE.
24	(a) Open Enrollment Reports.—For plan year
25	2021 and each subsequent year, the Secretary of Health

1	and Human Services (referred to in this section as the
2	"Secretary"), in coordination with the Secretary of the
3	Treasury and the Secretary of Labor, shall issue biweekly
4	public reports during the annual open enrollment period
5	on the performance of the federally facilitated Exchange
6	operated pursuant to section 1321(c) of the Patient Pro-
7	tection and Affordable Care Act (42 U.S.C. 18041(c)).
8	Each such report shall include a summary, including in-
9	formation on a State-by-State basis where available, of—
10	(1) the number of unique website visits;
11	(2) the number of individuals who create an ac-
12	count;
13	(3) the number of calls to the call center;
14	(4) the average wait time for callers contacting
15	the call center;
16	(5) the number of individuals who enroll in a
17	qualified health plan; and
18	(6) the percentage of individuals who enroll in
19	a qualified health plan through each of—
20	(A) the website;
21	(B) the call center;
22	(C) navigators;
23	(D) agents and brokers;
24	

(F) directly from issuers or web brokers;
 and

3 (G) other means.

4 (b) OPEN ENROLLMENT AFTER ACTION REPORT.— For plan year 2021 and each subsequent year, the Sec-5 retary, in coordination with the Secretary of the Treasury 6 7 and the Secretary of Labor, shall publish an after action 8 report not later than 3 months after the completion of the 9 annual open enrollment period regarding the performance of the Exchange described in subsection (a) for the appli-10 cable plan year. Each such report shall include a sum-11 12 mary, including information on a State-by-State basis where available, of— 13

14 (1) the open enrollment data reported under
15 subsection (a) for the entirety of the enrollment pe16 riod; and

17 (2) activities related to patient navigators de18 scribed in section 1311(i) of the Patient Protection
19 and Affordable Care Act (42 U.S.C. 18031(i)), in20 cluding—

21 (A) the performance objectives established
22 by the Secretary for such patient navigators;
23 (B) the number of consumers enrolled by

such a patient navigator;

1	(C) an assessment of how such patient
2	navigators have met established performance
3	metrics, including a detailed list of all patient
4	navigators, funding received by patient naviga-
5	tors, and whether established performance ob-
6	jectives of patient navigators were met; and
7	(D) with respect to the performance objec-
8	tives described in subparagraph (A)—
9	(i) whether such objectives assess the
10	full scope of patient navigator responsibil-
11	ities, including general education, plan se-
12	lection, and determination of eligibility for
13	tax credits, cost-sharing reductions, or
14	other coverage;
15	(ii) how the Secretary worked with pa-
16	tient navigators to establish such objec-
17	tives; and
18	(iii) how the Secretary adjusted such
19	objectives for case complexity and other
20	contextual factors.
21	(c) Report on Advertising and Consumer Out-
22	REACH.—Not later than 3 months after the completion of
23	the annual open enrollment period for plan year 2021, the
24	Secretary shall issue a report on advertising and outreach
to consumers for the open enrollment period for plan year
 2021. Such report shall include a description of—

3 (1) the division of spending on individual adver4 tising platforms, including television and radio ad5 vertisements and digital media, to raise consumer
6 awareness of open enrollment;

7 (2) the division of spending on individual out8 reach platforms, including email and text messages,
9 to raise consumer awareness of open enrollment; and
10 (3) whether the Secretary conducted targeted
11 outreach to specific demographic groups and geo12 graphic areas.

13 (b) PROMOTING TRANSPARENCY AND ACCOUNT-14 ABILITY IN THE ADMINISTRATION'S EXPENDITURES OF 15 EXCHANGE USER FEES.—For plan year 2021 and each subsequent plan year, not later than the date that is 3 16 months after the end of such plan year, the Secretary of 17 Health and Human Services shall submit to the appro-18 priate committees of Congress and make available to the 19 public an annual report on the expenditures by the De-20 21 partment of Health and Human Services of user fees col-22 lected pursuant to section 156.50 of title 45, Code of Fed-23 eral Regulations (or any successor regulations). Each such 24 report for a plan year shall include a detailed accounting of the amount of such user fees collected during such plan 25

year and of the amount of such expenditures used during
 such plan year for the federally facilitated Exchange oper ated pursuant to section 1321(c) of the Patient Protection
 and Affordable Care Act (42 U.S.C. 18041(c)) on out reach and enrollment activities, navigators, maintenance
 of Healthcare.gov, and operation of call centers.

7 SEC. 113. IMPROVING AWARENESS OF HEALTH COVERAGE 8 OPTIONS.

9 (a) IN GENERAL.—Not later than 90 days after the 10 date of the enactment of this Act, the Secretary of Labor, in consultation with the Secretary of Health and Human 11 12 Services, shall update, and make publicly available in a 13 prominent location on the website of the Department of Labor, the model Consolidated Omnibus Budget Reconcili-14 15 ation Act of 1985 (referred to in this section as "COBRA") continuation coverage general notice and the 16 17 model COBRA continuation coverage election notice devel-18 oped by the Secretary of Labor for purposes of facilitating 19 compliance of group health plans with the notification re-20 quirements under section 606 of the Employee Retirement 21 Income Security Act of 1974 (29 U.S.C. 1166). In updat-22 ing each such notice, the Secretary of Labor shall include 23 information regarding any Exchange established under 24 title I of the Patient Protection and Affordable Care Act (42 U.S.C. 18001 et seq.) through which a qualified bene-25

ficiary may be eligible to enroll in a qualified health plan,
 including—

- 3 (1) the publicly accessible Internet website ad4 dress for such Exchange;
- 5 (2) the publicly accessible Internet website ad6 dress for the Find Local Help directory maintained
 7 by the Department of Health and Human Services
 8 on the healthcare.gov Internet website (or a suc9 cessor website);

10 (3) a clear explanation that—

11 (A) an individual who is eligible for con-12 tinuation coverage may also be eligible to enroll, 13 with financial assistance, in a qualified health 14 plan offered through such Exchange, but, in the 15 case that such individual elects to enroll in such 16 continuation coverage and subsequently elects 17 to terminate such continuation coverage before 18 the period of such continuation coverage ex-19 pires, such individual will not be eligible to en-20 roll in a qualified health plan offered through 21 such Exchange during a special enrollment pe-22 riod; and

(B) an individual who elects to enroll in
continuation coverage will remain eligible to enroll in a qualified health plan offered through

such Exchange during an open enrollment pe riod and may be eligible for financial assistance
 with respect to enrolling in such a qualified
 health plan;

5 (4) information on consumer protections with 6 respect to enrolling in a qualified health plan offered 7 through such Exchange, including the requirement 8 for such a qualified health plan to provide coverage 9 for essential health benefits (as defined in section 10 1302(b) of such Act (42 U.S.C. 18022(b)) and the 11 requirements applicable to such a qualified health 12 plan under part A of title XXVII of the Public 13 Health Service Act (42 U.S.C. 300gg et seq.); and 14 (5) information on the availability of financial 15 assistance with respect to enrolling in a qualified 16 health plan, including the maximum income limit for 17 eligibility for a premium tax credit under section

(b) NAME OF NOTICES.—In addition to updating the
model COBRA continuation coverage general notice and
the model COBRA continuation coverage election notice
under paragraph (1), the Secretary of Labor shall rename
each such notice as the "model COBRA continuation coverage and Affordable Care Act coverage general notice"

36B of the Internal Revenue Code of 1986.

and the "model COBRA continuation coverage and Af-1 2 fordable Care Act coverage election notice", respectively. 3 (c) CONSUMER TESTING.—Prior to making publicly 4 available the model COBRA continuation coverage general 5 notice and the model COBRA continuation coverage elec-6 tion notice updated under paragraph (1), the Secretary 7 of Labor shall provide an opportunity for consumer testing 8 of each such notice, as so updated, to ensure that each 9 such notice is clear and understandable to the average participant or beneficiary of a group health plan. 10

11 (d) DEFINITIONS.—In this subsection:

(1) CONTINUATION COVERAGE.—The term
"continuation coverage", with respect to a group
health plan, has the meaning given such term in section 602 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1162).

17 (2) GROUP HEALTH PLAN.—The term "group
18 health plan" has the meaning given such term in
19 section 607 of such Act (29 U.S.C. 1167).

20 (3) QUALIFIED BENEFICIARY.—The term
21 "qualified beneficiary" has the meaning given such
22 term in such section 607.

23 (4) QUALIFIED HEALTH PLAN.—The term
24 "qualified health plan" has the meaning given such

term in section 1301 of the Patient Protection and
 Affordable Care Act (42 U.S.C. 18021).

3 SEC. 114. PROMOTING STATE INNOVATIONS TO EXPAND 4 COVERAGE.

5 (a) IN GENERAL.—Subject to subsection (d), the Sec-6 retary of Health and Human Services shall award grants 7 to eligible State agencies to enable such States to explore 8 innovative solutions to promote greater enrollment in 9 health insurance coverage in the individual and small 10 group markets, including activities described in subsection 11 (c).

(b) ELIGIBILITY.—For purposes of subsection (a), eligible State agencies are Exchanges established by a State
under title I of the Patient Protection and Affordable Care
Act (42 U.S.C. 18001 et seq.) and State agencies with
primary responsibility over health and human services for
the State involved.

18 (c) USE OF FUNDS.—For purposes of subsection (a), 19 the activities described in this subsection are the following: 20 (1) State efforts to streamline health insurance 21 enrollment procedures in order to reduce burdens on 22 consumers and facilitate greater enrollment in health 23 insurance coverage in the individual and small group 24 markets, including automatic enrollment and re-25 enrollment of, or pre-populated applications for, in-

dividuals without health insurance who are eligible
 for tax credits under section 36B of the Internal
 Revenue Code of 1986, with the ability to opt out
 of such enrollment.

5 (2) State investment in technology to improve 6 data sharing and collection for the purposes of facili-7 tating greater enrollment in health insurance cov-8 erage in such markets.

9 (3) Implementation of a State version of an in10 dividual mandate to be enrolled in health insurance
11 coverage.

12 (4) Feasibility studies to develop comprehensive
13 and coherent State plan for increasing enrollment in
14 the individual and small group market.

(d) FUNDING.—For purposes of carrying out this
section, there is hereby appropriated, out of any funds in
the Treasury not otherwise appropriated, \$200,000,000
for each of the fiscal years 2022 through 2024. Such
amount shall remain available until expended.

20 SEC. 115. STRENGTHENING NETWORK ADEQUACY.

(a) IN GENERAL.—Section 1311(d) of the Patient
Protection and Affordable Care Act (42 U.S.C. 18031(d))
is amended by adding at the end the following new paragraph:

25 "(8) Network adequacy standards.—

1 "(A) CERTAIN EXCHANGES.—In the case 2 of an Exchange operated by the Secretary pursuant section 1321(c)(1) or an Exchange de-3 4 scribed in section 155.200(f) of title 42, Code of Federal Regulations (or a successor regula-5 6 tion), the Exchange shall require each qualified 7 health plan offered through such Exchange to 8 meet such quantitative network adequacy stand-9 ards as the Secretary may prescribe for pur-10 poses of this subparagraph. 11 "(B) STATE EXCHANGES.—In the case of

an Exchange not described in subparagraph (A), the Exchange shall establish quantitative network adequacy standards with respect to qualified health plans offered through such Exchange and require such plans to meet such standards.".

(b) EFFECTIVE DATE.—The amendment made bythis section shall apply with respect to plan years begin-ning on or after January 1, 2022.

21 SEC. 116. PROTECTING CONSUMERS FROM UNREASONABLE
22 RATE HIKES.

(a) PROTECTION FROM EXCESSIVE, UNJUSTIFIED,
OR UNFAIRLY DISCRIMINATORY RATES.—The first section 2794 of the Public Health Service Act (42 U.S.C.)

300gg-94), as added by section 1003 of the Patient Pro tection and Affordable Care Act (Public Law 111-148),
 is amended by adding at the end the following new sub section:

5 "(e) PROTECTION FROM EXCESSIVE, UNJUSTIFIED,
6 OR UNFAIRLY DISCRIMINATORY RATES.—

7 "(1) AUTHORITY OF STATES.—Nothing in this 8 section shall be construed to prohibit a State from 9 imposing requirements (including requirements re-10 lating to rate review standards and procedures and 11 information reporting) on health insurance issuers 12 with respect to rates that are in addition to the requirements of this section and are more protective of 13 14 consumers than such requirements.

15 "(2) CONSULTATION IN RATE REVIEW PROC16 ESS.—In carrying out this section, the Secretary
17 shall consult with the National Association of Insur18 ance Commissioners and consumer groups.

19 "(3) DETERMINATION OF WHO CONDUCTS RE20 VIEWS FOR EACH STATE.—The Secretary shall de21 termine, after the date of enactment of this section
22 and periodically thereafter, the following:

23 "(A) In which markets in each State the
24 State insurance commissioner or relevant State
25 regulator shall undertake the corrective actions

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under paragraph (4), based on the Secretary's determination that the State regulator is adequately undertaking and utilizing such actions in that market.

5 "(B) In which markets in each State the 6 Secretary shall undertake the corrective actions 7 under paragraph (4), in cooperation with the 8 relevant State insurance commissioner or State 9 regulator, based on the Secretary's determina-10 tion that the State is not adequately under-11 taking and utilizing such actions in that mar-12 ket.

13 "(4) CORRECTIVE ACTION FOR EXCESSIVE, UN-14 JUSTIFIED, OR UNFAIRLY DISCRIMINATORY 15 RATES.—In accordance with the process established under this section, the Secretary or the relevant 16 17 State insurance commissioner or State regulator 18 shall take corrective actions to ensure that any ex-19 cessive, unjustified, or unfairly discriminatory rates 20 are corrected prior to implementation, or as soon as 21 possible thereafter, through mechanisms such as— 22 "(A) denying rates;

- 23 "(B) modifying rates; or
- 24 "(C) requiring rebates to consumers.

1	"(5) NONCOMPLIANCE.—Failure to comply with
2	any corrective action taken by the Secretary under
3	this subsection may result in the application of civil
4	monetary penalties under section 2723 and, if the
5	Secretary determines appropriate, make the plan in-
6	volved ineligible for classification as a qualified
7	health plan.".
8	(b) Clarification of Regulatory Authority.—
9	Such section is further amended—
10	(1) in subsection (a)—
11	(A) in the heading, by striking "PRE-
12	MIUM" and inserting "RATE";
13	(B) in paragraph (1), by striking "unrea-
14	sonable increases in premiums" and inserting
15	"potentially excessive, unjustified, or unfairly
16	discriminatory rates, including premiums,"; and
17	(C) in paragraph (2)—
18	(i) by striking "an unreasonable pre-
19	mium increase" and inserting "a poten-
20	tially excessive, unjustified, or unfairly dis-
21	criminatory rate";
22	(ii) by striking "the increase" and in-
23	serting "the rate"; and
24	(iii) by striking "such increases" and
25	inserting "such rates"; and

1	(2) in subsection (b)—
2	(A) by striking "premium increases" each
3	place it appears and inserting "rates"; and
4	(B) in paragraph (2)(B), by striking "pre-
5	mium" and inserting "rate".
6	(c) Conforming Amendments.—Title XXVII of
7	the Public Health Service Act (42 U.S.C. 300gg et seq.)
8	is amended—
9	(1) in section 2723 (42 U.S.C. 300gg–22), as
10	redesignated by the Patient Protection and Afford-
11	able Care Act—
12	(A) in subsection (a)—
13	(i) in paragraph (1), by inserting
14	"and section 2794" after "this part"; and
15	(ii) in paragraph (2), by inserting "or
16	section 2794" after "this part"; and
17	(B) in subsection (b)—
18	(i) in paragraph (1), by inserting
19	"and section 2794" after "this part"; and
20	(ii) in paragraph (2)—
21	(I) in subparagraph (A), by in-
22	serting "or section 2794 that is" after
23	"this part"; and

1	(II) in subparagraph (C)(ii), by
2	inserting "or section 2794" after
3	"this part"; and
4	(2) in section 2761 (42 U.S.C. 300gg-61)—
5	(A) in subsection (a)—
6	(i) in paragraph (1), by inserting
7	"and section 2794" after "this part"; and
8	(ii) in paragraph (2)—
9	(I) by inserting "or section
10	2794" after "set forth in this part";
11	and
12	(II) by inserting "and section
13	2794" after "the requirements of this
14	part"; and
15	(B) in subsection (b)—
16	(i) by inserting "and section 2794"
17	after "this part"; and
18	(ii) by inserting "and section 2794"
19	after "part A".
20	(d) Applicability to Grandfathered Plans.—
21	Section 1251(a)(4)(A) of the Patient Protection and Af-
22	for dable Care Act (Public Law 111–148), as added by sec-
23	tion 2301 of the Health Care and Education Reconcili-
24	ation Act of 2010 (Public Law 111–152), is amended by
25	adding at the end the following:

"(v) Section 2794 (relating to reason ableness of rates with respect to health in surance coverage).".

4 (e) AUTHORIZATION OF APPROPRIATIONS.—There
5 are authorized to be appropriated to carry out this Act
6 such sums as may be necessary.

7 (f) EFFECTIVE DATE.—The amendments made by
8 this section shall take effect on the date of enactment of
9 this Act and shall be implemented with respect to health
10 plans beginning not later than January 1, 2022.

11 TITLE II—ENCOURAGING MED 12 ICAID EXPANSION AND 13 STRENGTHENING THE MED 14 ICAID PROGRAM

15 SEC. 201. INCENTIVIZING MEDICAID EXPANSION.

16 (a) IN GENERAL.—Section 1905(y)(1) of the Social
17 Security Act (42 U.S.C. 1396d(y)(1)) is amended—

(1) in subparagraph (A), by striking "2014,
2015, and 2016" and inserting "each of the first 3
consecutive 12-month periods in which the State
provides medical assistance to newly eligible individuals";

23 (2) in subparagraph (B), by striking "2017"
24 and inserting "the fourth consecutive 12-month pe-

1	riod in which the State provides medical assistance
2	to newly eligible individuals";
2	(2) in order one merch (C) by striking (9010)

3 (3) in subparagraph (C), by striking "2018"
4 and inserting "the fifth consecutive 12-month period
5 in which the State provides medical assistance to
6 newly eligible individuals";

7 (4) in subparagraph (D), by striking "2019"
8 and inserting "the sixth consecutive 12-month period
9 in which the State provides medical assistance to
10 newly eligible individuals"; and

(5) in subparagraph (E), by striking "2020 and
each year thereafter" and inserting "the seventh
consecutive 12-month period in which the State provides medical assistance to newly eligible individuals
and each such period thereafter".

(b) EFFECTIVE DATE.—Beginning on January 1,
2022, the amendments made by subsection (a) shall take
effect as if included in the enactment of the Patient Protection and Affordable Care Act (Public Law 111-148).
SEC. 202. PROVIDING 12-MONTHS OF CONTINUOUS ELIGI-

21

BILITY FOR MEDICAID AND CHIP.

(a) REQUIREMENT OF 12-MONTH CONTINUOUS ENROLLMENT UNDER MEDICAID.—Section 1902(e)(12) of
the Social Security Act (42 U.S.C. 1396a(e)(12)) is
amended to read as follows:

1 "(12) 12-month continuous enrollment.— 2 Notwithstanding any other provision of this title, a 3 State plan approved under this title (or under any 4 waiver of such plan approved pursuant to section 5 1115 or section 1915), shall provide that an indi-6 vidual who is determined to be eligible for benefits 7 under such plan (or waiver) shall remain eligible and 8 enrolled for such benefits through the end of the 9 month in which the 12-month period (beginning on 10 the date of determination of eligibility) ends.".

11 (b) REQUIREMENT OF 12-MONTH CONTINUOUS EN-12 ROLLMENT UNDER CHIP.—

13 (1) IN GENERAL.—Section 2102(b) of the So-14 cial Security Act (42 U.S.C. 1397bb(b)) is amended 15 by adding at the end the following new paragraph: "(6) REQUIREMENT FOR 12-MONTH CONTIN-16 17 UOUS ENROLLMENT.—Notwithstanding any other 18 provision of this title, a State child health plan that 19 provides child health assistance under this title 20 through a means other than described in section 21 2101(a)(2), shall provide that an individual who is 22 determined to be eligible for benefits under such 23 plan shall remain eligible and enrolled for such bene-24 fits through the end of the month in which the 12-

1	month period (beginning on the date of determina-
2	tion of eligibility) ends.".
3	(2) Conforming Amendment.—Section
4	2105(a)(4)(A) of the Social Security Act (42 U.S.C.
5	1397ee(a)(4)(A)) is amended—
6	(A) by striking "has elected the option of"
7	and inserting "is in compliance with the re-
8	quirement for"; and
9	(B) by striking "applying such policy
10	under its State child health plan under this
11	title" and inserting "in compliance with section
12	2102(b)".
13	(c) Effective Date.—
14	(1) IN GENERAL.—Except as provided in para-
15	graph (2) or (3) , the amendments made by sub-
16	sections (a) and (b) shall apply to determinations
17	(and redeterminations) of eligibility made on or after
18	the date that is 12 months after the last day of the
19	emergency period described in section $1135(g)(1)(B)$
20	of the Social Security Act (42 U.S.C. 1320b-
21	5(g)(1)(B)).
22	(2) EXTENSION OF EFFECTIVE DATE FOR
23	STATE LAW AMENDMENT.—In the case of a State
24	plan under title XIX or State child health plan
25	under title XXI of the Social Security Act (42

1 U.S.C. 1396 et seq.; 42 U.S.C. 1397aa et seq.) 2 which the Secretary of Health and Human Services 3 determines requires State legislation (other than leg-4 islation appropriating funds) in order for the respec-5 tive plan to meet the additional requirement imposed 6 by the amendment made by subsection (a) or (b), re-7 spectively, the respective plan shall not be regarded 8 as failing to comply with the requirements of such 9 title solely on the basis of its failure to meet such 10 applicable additional requirement before the first 11 day of the first calendar quarter beginning after the 12 close of the first regular session of the State legisla-13 ture that begins after the date of enactment of this 14 Act. For purposes of the previous sentence, in the 15 case of a State that has a 2-year legislative session, 16 each year of the session is considered to be a sepa-17 rate regular session of the State legislature.

(3) OPTION TO IMPLEMENT 12-MONTH CONTINUOUS ELIGIBILITY PRIOR TO EFFECTIVE DATE.—A
State may elect through a State plan amendment
under title XIX or XXI of the Social Security Act
(42 U.S.C. 1396 et seq.; 42 U.S.C. 1397aa et seq.)
to apply the amendment made by subsection (a) or
(b), respectively, on any date prior to the date speci-

1	fied in paragraph (1), but not sooner than the date
2	of the enactment of this Act.
3	SEC. 203. MANDATORY 12-MONTHS OF POSTPARTUM MED-
4	ICAID ELIGIBILITY.
5	(a) Extending Continuous Medicaid and CHIP
6	Coverage for Pregnant and Postpartum Women.—
7	(1) Medicaid.—Title XIX of the Social Secu-
8	rity Act (42 U.S.C. 1396 et seq.) is amended—
9	(A) in section $1902(l)(1)(A)$, by striking
10	"60-day period" and inserting "365-day pe-
11	riod";
12	(B) in section $1902(e)(6)$, by striking "60-
13	day period" and inserting "365-day period";
14	(C) in section $1903(v)(4)(A)(i)$, by striking
15	"60-day period" and inserting "365-day pe-
16	riod"; and
17	(D) in section 1905(a), in the 4th sentence
18	in the matter following paragraph (30), by
19	striking "60-day period" and inserting "365-
20	day period".
21	(2) CHIP.—Section 2112 of the Social Security
22	Act (42 U.S.C. 1397ll) is amended by striking "60-
23	day period" each place it appears and inserting
24	"365-day period".

(b) REQUIRING FULL BENEFITS FOR PREGNANT
 2 AND POSTPARTUM WOMEN.—

3 (1) MEDICAID.—

4 (A) IN GENERAL.—Paragraph (5) of sec-5 tion 1902(e) of the Social Security Act (24) 6 U.S.C. 1396a(e)) is amended to read as follows: 7 "(5) Any woman who is eligible for medical as-8 sistance under the State plan or a waiver of such 9 plan and who is, or who while so eligible becomes, 10 pregnant, shall continue to be eligible under the plan 11 or waiver for medical assistance through the end of 12 the month in which the 365-day period (beginning 13 on the last day of her pregnancy) ends, regardless 14 of the basis for the woman's eligibility for medical 15 assistance, including if the woman's eligibility for 16 medical assistance is on the basis of being preg-17 nant.".

(B) CONFORMING AMENDMENT.—Section
19 1902(a)(10) of the Social Security Act (42
20 U.S.C. 1396a(a)(10)) is amended in the matter
21 following subparagraph (G) by striking "(VII)
22 the medical assistance" and all that follows
23 through "complicate pregnancy,".

24 (2) CHIP.—Section 2107(e)(1) of the Social
25 Security Act (42 U.S.C. 1397gg(e)(1)) is amended—

1	(A) by redesignating subparagraphs (H)
2	through (S) as subparagraphs (I) through (T),
3	respectively; and
4	(B) by inserting after subparagraph (G),
5	the following:
6	"(H) Section 1902(e)(5) (requiring 365-
7	day continuous coverage for pregnant and
8	postpartum women).".
9	(c) MAINTENANCE OF EFFORT.—
10	(1) Medicaid.—Section 1902 of the Social Se-
11	curity Act (42 U.S.C. 1396a) is amended—
12	(A) in paragraph (74), by striking "sub-
13	section (gg); and" and inserting "subsections
14	(gg) and (qq);"; and
15	(B) by adding at the end the following new
16	subsection:
17	"(qq) Maintenance of Effort Related to Low-
18	INCOME PREGNANT WOMEN.—For calendar quarters be-
19	ginning on or after the effective date described in section
20	203(d) of the Patient Protection and Affordable Care En-
21	hancement Act, and before January 1, 2023, no Federal
22	payment shall be made to a State under section 1903(a)
23	for amounts expended under a State plan under this title
24	or a waiver of such plan if the State—

1 "(1) has in effect under such plan eligibility 2 standards, methodologies, or procedures for individ-3 uals described in subsection (l)(1) who are eligible 4 for medical assistance under the State plan or waiv-5 er under subsection (a)(10)(A)(ii)(IX) that are more 6 restrictive than the eligibility standards, methodolo-7 gies, or procedures, respectively, for such individuals 8 under such plan or waiver that are in effect on the 9 date of the enactment of this subsection; or

10 "(2) provides medical assistance to individuals 11 described in subsection (l)(1) who are eligible for 12 medical assistance under such plan or waiver under 13 subsection (a)(10)(A)(ii)(IX) at a level that is less 14 than the level at which the State provides such as-15 sistance to such individuals under such plan or waiv-16 er on the date of the enactment of this subsection.".

17 (2) CHIP.—Section 2112 of the Social Security
18 Act (42 U.S.C. 1397ll), as amended by subsection
19 (b), is further amended by adding at the end the fol20 lowing subsection:

21 "(g) MAINTENANCE OF EFFORT.—For calendar
22 quarters beginning on or after the effective date described
23 in section 203(d) of the Patient Protection and Affordable
24 Care Enhancement Act, and before January 1, 2023, no

payment may be made under section 2105(a) with respect
 to a State child health plan if the State—

3 "(1) has in effect under such plan eligibility
4 standards, methodologies, or procedures for targeted
5 low-income pregnant women that are more restric6 tive than the eligibility standards, methodologies, or
7 procedures, respectively, under such plan that are in
8 effect on the date of the enactment of this sub9 section; or

10 "(2) provides pregnancy-related assistance to 11 targeted low-income pregnant women under such 12 plan at a level that is less than the level at which 13 the State provides such assistance to such women 14 under such plan on the date of the enactment of this 15 subsection.".

16 (d) Effective Date.—

17 (1) IN GENERAL.—Except as provided under 18 paragraph (2), the amendments made by subsections 19 (a) and (b) shall take effect on (and the effective 20 date described in this subsection shall be) the first 21 day of the calendar quarter during which the last 22 day of the emergency period described in section 23 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 24 1320b-5(g)(1)(B)) occurs.

1 EXTENSION OF (2)EFFECTIVE DATE FOR 2 STATE LAW AMENDMENT.—In the case of a State 3 plan under title XIX or State child health plan 4 under title XXI of the Social Security Act (42) 5 U.S.C. 1396 et seq.; 42 U.S.C. 1397aa et seq.) 6 which the Secretary of Health and Human Services 7 determines requires State legislation (other than leg-8 islation appropriating funds) in order for the respec-9 tive plan to meet the additional requirement imposed 10 by the amendments made by subsection (a) or (b), 11 respectively, the respective plan shall not be re-12 garded as failing to comply with the requirements of 13 such title solely on the basis of its failure to meet 14 such applicable additional requirement before the 15 first day of the first calendar quarter beginning 16 after the close of the first regular session of the 17 State legislature that begins after the date of enact-18 ment of this Act. For purposes of the previous sen-19 tence, in the case of a State that has a 2-year legis-20 lative session, each year of the session is considered 21 to be a separate regular session of the State legisla-22 ture.

1	SEC.	204.	REDUCI	NG T	HE	ADM	INISTRAT	IVE	FMA	Р	FOR
2			NONE	XPAN	SIO	N STA	TES.				
3		Sectio	on 1903	of th	le So	ocial	Security	Act	(42	U.	S.C.

1396b) is amended— 4

(1) in subsection (a)(7), by inserting "sub-5 6 section (bb) and" before "section 1919(g)(3)(B)"; 7 and

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

10 "(bb) Reduction of Federal Payments for CERTAIN ADMINISTRATIVE COSTS OF NONEXPANSION 11 12 STATES.—

13 "(1) IN GENERAL.—In the case of a State that 14 does not provide under the State plan of such State 15 (or waiver of such plan) for making medical assist-16 ance available in accordance with section 1902(k)(1)17 all described to individuals in section 18 1902(a)(10)(i)(VIII) for a calendar quarter begin-19 ning on or after October 1, 2022, the Secretary may 20 reduce the percentage specified in subsection (a)(7)21 for amounts described in such subsection expended 22 during such quarter by such State by the number of 23 percentage points specified in paragraph (2) for such 24 quarter.

25 "(2) Amount of reduction.—For purposes of paragraph (1), the number of percentage points 26 g:\VHLC\062220\062220.023.xml (765570|9)

1	specified in this paragraph for a calendar quarter is
2	the following:
3	"(A) For the calendar quarter beginning
4	on October 1, 2022, 0.5.
5	"(B) For a calendar quarter beginning on
6	or after January 1, 2023, and ending before
7	July 1, 2027, the number of percentage points
8	specified under this paragraph for the previous
9	quarter, plus 0.5.
10	"(C) For a calendar quarter beginning on
11	or after July 1, 2027, 10.
12	"(3) DEFINITION.—For purposes of this sub-
13	section, the term 'State' means a State that is one
14	of the 50 States or the District of Columbia.".
15	SEC. 205. ENHANCED REPORTING REQUIREMENTS FOR
16	NONEXPANSION STATES.
17	Section 1903 of the Social Security Act (42 U.S.C.
18	1396b), as amended by section 204, is further amended—
19	(1) in subsection $(a)(7)$, by striking "subsection
20	(bb)" and inserting "subsections (bb) and (cc)"; and
21	(2) by adding at the end the following new sub-
22	section:
23	"(cc) Reduction of Federal Payments for Cer-
24	TAIN ADMINISTRATIVE COSTS OF NONEXPANSION STATES
25	THAT DO NOT SATISFY REPORTING REQUIREMENTS.—

63

"(1) IN GENERAL.—

2 "(A) REDUCTION.—In the case of a non-3 expansion State, with respect to a fiscal year 4 (beginning with fiscal year 2023) that does not 5 satisfy the reporting requirement under para-6 graph (2) for such fiscal year, the percentage 7 specified in subsection (a)(7) for amounts de-8 scribed in such subsection expended by such 9 State during a calendar quarter described in 10 paragraph (4) with respect to such fiscal year, 11 subject to subparagraph (B), shall be reduced 12 by the number of percentage points specified in 13 paragraph (4) for the respective calendar quar-14 ter.

15 "(B) EXCEPTION.—In the case of a non-16 expansion State that is subject to a reduction 17 under subparagraph (A) for the calendar quar-18 ter described in paragraph (4)(A) with respect 19 to a fiscal year, if the State satisfies the criteria 20 described in subparagraphs (A), (B), and (C) of 21 paragraph (2) (without regard to the dates 22 specified in such subparagraph (A) and (C)) be-23 fore the beginning of a subsequent calendar 24 quarter described in paragraph (4) with respect 25 to such fiscal year, then such State shall not be

1	subject to a reduction under subparagraph (A)
2	for such subsequent calendar quarter.
3	"(2) Reporting requirement.—For pur-
4	poses of paragraph (1), a nonexpansion State satis-
5	fies the reporting requirement under this paragraph
6	for a fiscal year, if the nonexpansion State—
7	"(A) by not later than January 1 of such
8	year, posts on the public website of the State
9	agency administering the State plan, the infor-
10	mation described in paragraph (3) with respect
11	to such State for the previous year;
12	"(B) provides for at least a 30-day period
13	for notice and comment on such information;
14	and
15	"(C) by not later than March 1 of such
16	year, submits to the Secretary a complete re-
17	port including such information, comments sub-
18	mitted pursuant to subparagraph (B), and a re-
19	sponse by the State to each such comment.
20	"(3) INFORMATION DESCRIBED.—The informa-
21	tion described in this paragraph, with respect to a
22	State and year, is the following:
23	"(A) The the estimated number of individ-
24	uals who were uninsured for at least 6 months,
25	shown by age-groups of 0 to 18 years of age

2

3

and of 19 years of age to 64 years of age, as well as a detailed description of the basis for the estimates.

4 "(B) The estimated number of the individ-5 uals estimated under subparagraph (A) in the 6 State who would be eligible for medical assist-7 ance under the State plan if the State were to 8 make medical assistance under the State plan 9 available in accordance with section 1902(k)(1)10 individuals described to all in section 11 1902(a)(10)(i)(VIII), and a detailed description 12 of the basis for the estimates.

"(C) A comprehensive listing of State income eligibility criteria for all mandatory and
optional Medicaid eligibility groups for which
the State plan provides medical assistance
(other than with respect to individuals described
in clause (i)(II), (ii)(VI), or (ii)(XXII) of section 1902(a)(10)(A)).

20 "(D) The total amount of hospital uncom21 pensated-care costs and a breakdown of the
22 source of such costs, as well as a breakdown for
23 rural and non-rural hospitals.

24 "(4) PERCENTAGE DESCRIBED.—For purposes
25 of paragraph (1), a calendar quarter described in

1	this paragraph, with respect to a fiscal year, and the
2	percentage points described in this paragraph for
3	such quarter, with respect to a State, are—
4	"(A) for the calendar quarter beginning on
5	the April 1 occurring during such fiscal year,
6	0.5 percentage points;
7	"(B) for the calendar quarter beginning on
8	the July 1 occurring during such fiscal year,
9	1.0 percentage point; and
10	"(C) for the calendar quarter beginning on
11	the October 1 occurring during the subsequent
12	fiscal year, 1.5 percentage points.
13	"(5) PAYMENT IN CASE OF REPORTING
14	STATE.—The expenses incurred by a non-expansion
15	State, with respect to any calendar quarter with re-
16	spect to a fiscal year (beginning with 2021), for car-
17	rying out subparagraphs (A) through (C) of para-
18	graph (2) shall, for purposes of section $1903(a)(7)$,
19	be considered to be expenses necessary for the prop-
20	er and efficient administration of the State plan
21	under this title.
22	"(6) NONEXPANION STATE DEFINED.—For
23	purposes of this subsection, the term 'nonexpansion
24	State' means, with respect to a fiscal year, a State
25	that as of the first quarter of such fiscal year does

not provide under the State plan of such State (or
 waiver of such plan) for making medical assistance
 available in accordance with section 1902(k)(1) to
 all individuals described in section
 1902(a)(10)(i)(VIII).".

6 SEC. 206. PRIMARY CARE PAY INCREASE.

7 (a) RENEWAL OF PAYMENT FLOOR; ADDITIONAL8 PROVIDERS.—

9 (1) IN GENERAL.—Section 1902(a)(13) of the
10 Social Security Act (42 U.S.C. 1396a(a)(13)) is
11 amended by striking subparagraph (C) and inserting
12 the following:

13 "(C) payment for primary care services (as 14 defined in subsection (ij)) at a rate that is not 15 less than 100 percent of the payment rate that 16 applies to such services and physician under 17 part B of title XVIII (or, if greater, the pay-18 ment rate that would be applicable under such 19 part if the conversion factor under section 20 1848(d) for the year involved were the conver-21 sion factor under such section for 2009), and 22 that is not less than the rate that would other-23 wise apply to such services under this title if 24 the rate were determined without regard to this 25 subparagraph, and that are—

1	"(i) furnished during 2013 and 2014,
2	by a physician with a primary specialty
3	designation of family medicine, general in-
4	ternal medicine, or pediatric medicine; or
5	"(ii) furnished during the period that
6	begins on the first day of the first month
7	that begins one year after the date of en-
8	actment of the Patient Protection and Af-
9	fordable Care Enhancement Act and ends
10	September 30, 2025—
11	"(I) by a physician with a pri-
12	mary specialty designation of family
13	medicine, general internal medicine,
14	or pediatric medicine, but only if the
15	physician self-attests that the physi-
16	cian is Board certified in family medi-
17	cine, general internal medicine, or pe-
18	diatric medicine;
19	"(II) by a physician with a pri-
20	mary specialty designation of obstet-
21	rics and gynecology, but only if the
22	physician self-attests that the physi-
23	cian is Board certified in obstetrics
24	and gynecology;

1	"(III) by an advanced practice
2	clinician, as defined by the Secretary,
3	that works under the supervision of—
4	"(aa) a physician that satis-
5	fies the criteria specified in sub-
6	clause (I) or (II); or
7	"(bb) a nurse practitioner or
8	a physician assistant (as such
9	terms are defined in section
10	1861(aa)(5)(A)) who is working
11	in accordance with State law, or
12	a certified nurse-midwife (as de-
13	fined in section 1861(gg)) who is
14	working in accordance with State
15	law;
16	"(IV) by a rural health clinic,
17	Federally-qualified health center, or
18	other health clinic that receives reim-
19	bursement on a fee schedule applica-
20	ble to a physician, a nurse practi-
21	tioner or a physician assistant (as
22	such terms are defined in section
23	1861(aa)(5)(A)) who is working in ac-
24	cordance with State law, or a certified
25	nurse-midwife (as defined in section

1	1861(gg)) who is working in accord-
2	ance with State law, for services fur-
3	nished by a physician, nurse practi-
4	tioner, physician assistant, or certified
5	nurse-midwife, or services furnished
6	by an advanced practice clinician su-
7	pervised by a physician described in
8	subclause (I)(aa) or (II)(aa), another
9	advanced practice clinician, or a cer-
10	tified nurse-midwife; or
11	"(V) by a nurse practitioner or a
12	physician assistant (as such terms are
13	defined in section $1861(aa)(5)(A))$
14	who is working in accordance with
15	State law, or a certified nurse-midwife
16	(as defined in section $1861(gg)$) who
17	is working in accordance with State
18	law, in accordance with procedures
19	that ensure that the portion of the
20	payment for such services that the
21	nurse practitioner, physician assist-
22	ant, or certified nurse-midwife is paid
23	is not less than the amount that the
24	nurse practitioner, physician assist-
25	ant, or certified nurse-midwife would

1	be paid if the services were provided
2	under part B of title XVIII;".
3	(2) Conforming Amendments.—Section
4	1905(dd) of the Social Security Act (42 U.S.C.
5	1396d(dd)) is amended—
6	(A) by striking "Notwithstanding" and in-
7	serting the following:
8	"(1) IN GENERAL.—Notwithstanding";
9	(B) by inserting "or furnished during the
10	additional period specified in paragraph (2),"
11	after "2015,"; and
12	(C) by adding at the end the following:
13	"(2) Additional period.—For purposes of
14	paragraph (1), the additional period specified in this
15	paragraph is the period that begins on the first day
16	of the first month that begins one year after the
17	date of enactment of the Patient Protection and Af-
18	fordable Care Enhancement Act.".
19	(b) Improved Targeting of Primary Care.—Sec-
20	tion 1902(jj) of the Social Security Act (42 U.S.C.
21	1396a(jj)) is amended—
22	(1) by redesignating paragraphs (1) and (2) as
23	subparagraphs (A) and (B), respectively and realign-
24	ing the left margins accordingly;

1	(2) by striking "For purposes of" and inserting
2	the following:
3	"(1) IN GENERAL.—For purposes of"; and
4	(3) by adding at the end the following:
5	"(2) EXCLUSIONS.—Such term does not include
6	any services described in subparagraph (A) or (B) of
7	paragraph (1) if such services are provided in an
8	emergency department of a hospital.".
9	(c) Ensuring Payment by Managed Care Enti-
10	TIES.—
11	(1) IN GENERAL.—Section $1903(m)(2)(A)$ of
12	the Social Security Act (42 U.S.C. $1396b(m)(2)(A)$)
13	is amended—
14	(A) in clause (xii), by striking "and" after
15	the semicolon;
16	(B) by realigning the left margin of clause
17	(xiii) so as to align with the left margin of
18	clause (xii) and by striking the period at the
19	end of clause (xiii) and inserting "; and"; and
20	(C) by inserting after clause (xiii) the fol-
21	lowing:
22	"(xiv) such contract provides that (I) payments
23	to providers specified in section $1902(a)(13)(C)$ for
24	primary care services defined in section 1902(jj)
25	that are furnished during a year or period specified
1 in section 1902(a)(13)(C) and section 1905(dd) are 2 at least equal to the amounts set forth and required 3 by the Secretary by regulation, (II) the entity shall, 4 upon request, provide documentation to the State, 5 sufficient to enable the State and the Secretary to 6 ensure compliance with subclause (I), and (III) the 7 Secretary shall approve payments described in sub-8 clause (I) that are furnished through an agreed 9 upon capitation, partial capitation, or other value-10 based payment arrangement if the capitation, partial 11 capitation, or other value-based payment arrange-12 ment is based on a reasonable methodology and the entity provides documentation to the State sufficient 13 14 to enable the State and the Secretary to ensure com-15 pliance with subclause (I).". 16 AMENDMENT.—Section (2)Conforming 17 1932(f) of the Social Security Act (42 U.S.C. 18 1396u-2(f) is amended by inserting "and clause 19 (xiv) of section 1903(m)(2)(A)" before the period. 20 SEC. 207. PERMANENT FUNDING FOR CHIP. 21 (a) IN GENERAL.—Section 2104(a) of the Social Se-

22 curity Act (42 U.S.C. 1397dd(a)) is amended—

23 (1) in paragraph (26), by inserting at the end
24 "and";

1	(2) by amending paragraph (27) to read as fol-
2	lows:
3	"(27) for each fiscal year beginning with fiscal
4	year 2024, such sums as are necessary to fund allot-
5	ments to States under subsections (c) and (m).";
6	and
7	(3) by striking paragraph (28).
8	(b) IN GENERAL.—Section 2104(a)(28) of the Social
9	Security Act (42 U.S.C. 1397dd(a)(28)) is amended to
10	read as follows:
11	((28) for fiscal year 2027 and each subsequent
12	year, such sums as are necessary to fund allotments
13	to States under subsections (c) and (m).".
14	(c) Allotments.—
15	(1) IN GENERAL.—Section 2104(m) of the So-
16	cial Security Act (42 U.S.C. 1397dd(m)) is amend-
17	ed—
18	(A) in paragraph (2)(B)(i), by striking ",
19	2023, and 2027" and inserting "and 2023";
20	(B) in paragraph (7)—
21	(i) in subparagraph (A), by striking
22	"and ending with fiscal year 2027,"; and
23	(ii) in the flush left matter at the end,
24	by striking "or fiscal year 2026" and in-

1	serting "fiscal year 2026, or a subsequent
2	even-numbered fiscal year";
3	(C) in paragraph (9)—
4	(i) by striking "(10), or (11)" and in-
5	serting "or (10)"; and
6	(ii) by striking "2023, or 2027," and
7	inserting "or 2023"; and
8	(D) by striking paragraph (11).
9	(2) Conforming Amendment.—Section
10	50101(b)(2) of the Bipartisan Budget Act of 2018
11	(Public Law 115–123) is repealed.
12	SEC. 208. PERMANENT EXTENSION OF CHIP ENROLLMENT
13	AND QUALITY MEASURES.
14	(a) Pediatric Quality Measures Program.—
15	Section 1139A(i)(1) of the Social Security Act (42 U.S.C.
16	1320b–9a(i)(1)) is amended—
17	(1) in subparagraph (C), by striking at the end
18	"and";
19	(2) in subparagraph (D), by striking the period
20	at the end and insert a semicolon; and
21	(3) by adding at the end the following new sub-
22	paragraphs:
23	"(E) for fiscal year 2028, \$15,000,000 for
24	the purpose of carrying out this section (other
25	than subsections (e), (f), and (g)); and

1	"(F) for a subsequent fiscal year, the
2	amount appropriated under this paragraph for
3	the previous fiscal year, increased by the per-
4	centage increase in the consumer price index for
5	all urban consumers (all items; United States
6	city average) over such previous fiscal year, for
7	the purpose of carrying out this section (other
8	than subsections (e), (f), and (g)).".
9	(b) EXPRESS LANE ELIGIBILITY OPTION.—Section
10	1902(e)(13) of the Social Security Act (42 U.S.C.
11	1396a(e)(13)) is amended by striking subparagraph (I).
12	(c) Assurance of Affordability Standard for
13	CHILDREN AND FAMILIES.—
14	(1) IN GENERAL.—Section $2105(d)(3)$ of the
15	Social Security Act $(42 \text{ U.S.C. } 1397ee(d)(3))$ is
16	amended—
17	(A) in the paragraph heading, by striking
18	"THROUGH SEPTEMBER 30, 2027"; and
19	(B) in subparagraph (A), in the matter
20	preceding clause (i)—
21	(i) by striking "During the period
22	that begins on the date of enactment of
23	the Patient Protection and Affordable Care
24	Act and ends on September 30, 2027" and
25	inserting "Beginning on the date of the en-

1	actment of the Patient Protection and Af-
2	fordable Care Act";
3	(ii) by striking "During the period
4	that begins on October 1, 2019, and ends
5	on September 30, 2027" and inserting
6	"Beginning on October 1, 2019"; and
7	(iii) by striking "The preceding sen-
8	tences shall not be construed as preventing
9	a State during any such periods from" and
10	inserting "The preceding sentences shall
11	not be construed as preventing a State
12	from".
13	(2) Conforming Amendments.—Section
14	1902(gg)(2) of the Social Security Act (42 U.S.C.
15	1396a(gg)(2)) is amended—
16	(A) in the paragraph heading, by striking
17	"THROUGH SEPTEMBER 30, 2027"; and
18	(B) by striking "through September 30"
19	and all that follows through "ends on Sep-
20	tember 30, 2027" and inserting "(but begin-
21	ning on October 1, 2019,".
22	(d) QUALIFYING STATES OPTION.—Section
23	2105(g)(4) of the Social Security Act (42 U.S.C.
24	1397ee(g)(4)) is amended—

1	(1) in the paragraph heading, by striking "FOR
2	FISCAL YEARS 2009 THROUGH 2027" and inserting
3	"AFTER FISCAL YEAR 2008"; and
4	(2) in subparagraph (A), by striking "for any
5	of fiscal years 2009 through 2027" and inserting
6	"for any fiscal year after fiscal year 2008".
7	(e) Outreach and Enrollment Program.—Sec-
8	tion 2113 of the Social Security Act (42 U.S.C. 1397mm)
9	is amended—
10	(1) in subsection (a)—
11	(A) in paragraph (1), by striking "during
12	the period of fiscal years 2009 through 2027"
13	and inserting ", beginning with fiscal year
14	2009,";
15	(B) in paragraph (2)—
16	(i) by striking "10 percent of such
17	amounts" and inserting "10 percent of
18	such amounts for the period or the fiscal
19	year for which such amounts are appro-
20	priated"; and
21	(ii) by striking "during such period"
22	and inserting ", during such period or such
23	fiscal year,"; and
24	(C) in paragraph (3), by striking "For the
25	period of fiscal years 2024 through 2027, an

1	amount equal to 10 percent of such amounts"
2	and inserting "Beginning with fiscal year 2024,
3	an amount equal to 10 percent of such amounts
4	for the period or the fiscal year for which such
5	amounts are appropriated"; and
6	(2) in subsection (g) —
7	(A) by striking "2017,," and inserting
8	<i>``2017,''</i> ;
9	(B) by striking "and \$48,000,000" and in-
10	serting "\$48,000,000"; and
11	(C) by inserting after "through 2027" the
12	following: ", \$12,000,000 for fiscal year 2028,
13	and, for each fiscal year after fiscal year 2028,
14	the amount appropriated under this subsection
15	for the previous fiscal year, increased by the
16	percentage increase in the consumer price index
17	for all urban consumers (all items; United
18	States city average) over such previous fiscal
19	year".
20	(f) CHILD ENROLLMENT CONTINGENCY FUND.—
21	Section 2104(n) of the Social Security Act (42 U.S.C.
22	1397dd(n)) is amended—
23	(1) in paragraph (2) —
24	(A) in subparagraph (A)(ii)—

1	(i) by striking "and 2024 through
2	2026" and inserting "beginning with fiscal
3	year 2024"; and
4	(ii) by striking "2023, and 2027" and
5	inserting ", and 2023"; and
6	(B) in subparagraph (B)—
7	(i) by striking "2024 through 2026"
8	and inserting "beginning with fiscal year
9	2024"; and
10	(ii) by striking "2023, and 2027" and
11	inserting ", and 2023"; and
12	(2) in paragraph $(3)(A)$ —
13	(A) by striking "fiscal years 2024 through
14	2026" and inserting "beginning with fiscal year
15	2024"; and
16	(B) by striking "2023, or 2027" and in-
17	serting ", or 2023".
18	SEC. 209. STATE OPTION TO INCREASE CHILDREN'S ELIGI-
19	BILITY FOR MEDICAID AND CHIP.
20	Section 2110(b)(1)(B)(ii) of the Social Security Act
21	(42 U.S.C. 1397jj(b)(1)(B)(ii)) is amended—
22	(1) in subclause (II), by striking "or" at the
23	end;
24	(2) in subclause (III), by striking "and" at the
25	end and inserting "or"; and

1	(3) by inserting after subclause (III) the fol-
2	lowing new subclause:
3	"(IV) at the option of the State,
4	whose family income exceeds the max-
5	imum income level otherwise estab-
6	lished for children under the State
7	child health plan as of the date of the
8	enactment of this subclause; and".
9	SEC. 210. MEDICAID COVERAGE FOR CITIZENS OF FREELY
10	ASSOCIATED STATES.
11	(a) IN GENERAL.—Section 402(b)(2) of the Personal
12	Responsibility and Work Opportunity Reconciliation Act
13	of 1996 (8 U.S.C. $1612(b)(2)$) is amended by adding at
14	the end the following new subparagraph:
15	"(G) Medicaid exception for citizens
16	OF FREELY ASSOCIATED STATES.—With respect
17	to eligibility for benefits for the designated Fed-
18	eral program defined in paragraph $(3)(C)$ (re-
19	lating to the Medicaid program), section 401(a)
20	and paragraph (1) shall not apply to any indi-
21	vidual who lawfully resides in 1 of the 50 States
22	or the District of Columbia in accordance with
23	the Compacts of Free Association between the
24	Government of the United States and the Gov-
25	ernments of the Federated States of Micro-

1	nesia, the Republic of the Marshall Islands, and
2	the Republic of Palau and shall not apply, at
3	the option of the Governor of Puerto Rico, the
4	Virgin Islands, Guam, the Northern Mariana
5	Islands, or American Samoa as communicated
6	to the Secretary of Health and Human Services
7	in writing, to any individual who lawfully re-
8	sides in the respective territory in accordance
9	with such Compacts.".
10	(b) EXCEPTION TO 5-YEAR LIMITED ELIGIBILITY.—
11	Section 403(d) of such Act (8 U.S.C. 1613(d)) is amend-
12	ed—
13	(1) in paragraph (1), by striking "or" at the
13 14	(1) in paragraph (1), by striking "or" at the end;
14	end;
14 15	end; (2) in paragraph (2), by striking the period at
14 15 16	end;(2) in paragraph (2), by striking the period atthe end and inserting "; or"; and
14 15 16 17	 end; (2) in paragraph (2), by striking the period at the end and inserting "; or"; and (3) by adding at the end the following new
14 15 16 17 18	 end; (2) in paragraph (2), by striking the period at the end and inserting "; or"; and (3) by adding at the end the following new paragraph:
14 15 16 17 18 19	 end; (2) in paragraph (2), by striking the period at the end and inserting "; or"; and (3) by adding at the end the following new paragraph: "(3) an individual described in section
 14 15 16 17 18 19 20 	 end; (2) in paragraph (2), by striking the period at the end and inserting "; or"; and (3) by adding at the end the following new paragraph: "(3) an individual described in section 402(b)(2)(G), but only with respect to the des-
 14 15 16 17 18 19 20 21 	 end; (2) in paragraph (2), by striking the period at the end and inserting "; or"; and (3) by adding at the end the following new paragraph: "(3) an individual described in section 402(b)(2)(G), but only with respect to the designated Federal program defined in section

1	(1) in paragraph (6), by striking "; or" at the
2	end and inserting a comma;
3	(2) in paragraph (7) , by striking the period at
4	the end and inserting ", or"; and
5	(3) by adding at the end the following new
6	paragraph:
7	"(8) an individual who lawfully resides in the
8	United States in accordance with a Compact of Free
9	Association referred to in section $402(b)(2)(G)$, but
10	only with respect to the designated Federal program
11	defined in section $402(b)(3)(C)$ (relating to the Med-
12	icaid program).".
13	(d) Application to State Plans.—Section
14	1902(a)(10)(A)(i) of the Social Security Act (42 U.S.C.
15	1396a(a)(10)(A)(i)) is amended by inserting after sub-
16	clause (IX) the following:
17	"(X) who are described in section
18	402(b)(2)(G) of the Personal Respon-
19	sibility and Work Opportunity Rec-
20	onciliation Act of 1996 and eligible
21	for benefits under this title by reason
22	of application of such section;".
23	(e) Conforming Amendments.—Section 1108 of
24	the Social Security Act (42 U.S.C. 1308) is amended—

(1) in subsection (f), in the matter preceding
 paragraph (1), by striking "subsections (g) and (h)
 and section 1935(e)(1)(B)" and inserting "sub sections (g), (h), and (i) and section 1935(e)(1)(B)";
 and

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

7 "(i) EXCLUSION OF MEDICAL ASSISTANCE EXPENDI-8 TURES FOR CITIZENS OF FREELY ASSOCIATED STATES.— 9 Expenditures for medical assistance provided to an individual described in section 431(b)(8) of the Personal Re-10 sponsibility and Work Opportunity Reconciliation Act of 11 12 1996 (8 U.S.C. 1641(b)(8)) shall not be taken into ac-13 count for purposes of applying payment limits under sub-14 sections (f) and (g).".

(f) EFFECTIVE DATE.—The amendments made by
this section shall apply to benefits for items and services
furnished on or after the date of the enactment of this
Act.

19 SEC. 211. EXTENSION OF FULL FEDERAL MEDICAL ASSIST-

20ANCE PERCENTAGE TO INDIAN HEALTH21CARE PROVIDERS.

(a) IN GENERAL.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended—

24 (1) in subsection (a), by amending paragraph25 (9) to read as follows:

"(9) clinic services furnished by or under the
 direction of a physician, without regard to whether
 the clinic itself is administered by a physician, in cluding—

5 "(A) such services furnished outside the 6 clinic by clinic personnel to an eligible indi-7 vidual who does not reside in a permanent 8 dwelling or does not have a fixed home or mail-9 ing address; and

10 "(B) such services provided outside the 11 clinic on the basis of a referral from a clinic ad-12 ministered by an Indian Health Program (as 13 defined in paragraph (12) of section 4 of the 14 Indian Health Care Improvement Act, or an 15 Urban Indian Organization as defined in para-16 graph (29) of section 4 of such Act that has a 17 grant or contract with the Indian Health Serv-18 ice under title V of such Act;".

(2) in subsection (b), by inserting after "(as defined in section 4 of the Indian Health Care Improvement Act)" the following: "; the Federal medical assistance percentage shall also be 100 per centum with respect to amounts expended as medical
assistance for services which are received through an
Urban Indian organization (as defined in section 4

1	of the Indian Health Care Improvement Act) that
2	has a grant or contract with the Indian Health Serv-
3	ice under title V of such Act".
4	(b) EXTENSION OF FULL FEDERAL MEDICAL AS-
5	SISTANCE PERCENTAGE TO SERVICES FURNISHED BY NA-
6	tive Hawahan Health Care Systems.—
7	(1) IN GENERAL.—Beginning on the date of en-
8	actment of this Act—
9	(A) for purposes of section $1905(a)(9)$ of
10	the Social Security Act (42 U.S.C.
11	1396d(a)(9), services described in subsection
12	(b) that are furnished in any location shall be
13	deemed to be clinic services; and
14	(B) notwithstanding section 1905(b) of the
15	Social Security Act (42 U.S.C. 1396d(b)), the
16	Federal medical assistance percentage with re-
17	spect to amounts expended as medical assist-
18	ance for such services shall be 100 percent.
19	(2) SERVICES DESCRIBED.—The services de-
20	scribed in this subsection are services for which pay-
21	ment is available under the State plan under title
22	XIX of the Social Security Act (42 U.S.C. 1396 et
23	seq.) of Hawaii (or any waiver of such plan) that—
24	(A) are furnished on or after the date of
25	enactment of this Act;

1	
1	(B) are furnished to an individual who—
2	(i) is a Native Hawaiian; and
3	(ii) is eligible for medical assistance
4	under such plan; and
5	(C) are furnished by an Indian health care
6	provider (as such term is defined in section
7	1932(h)(4)(A) of the Social Security Act (42)
8	U.S.C. 1396u–2(h)(4)(A)) or a Native Hawai-
9	ian health care system (without regard to
10	whether such services are furnished through an
11	Indian Health Service facility).
12	TITLE III—LOWERING PRICES
13	THROUGH FAIR DRUG PRICE
14	NEGOTIATION
15	SEC. 301. ESTABLISHING A FAIR DRUG PRICING PROGRAM.
16	(a) Program To Lower Prices for Certain
17	HIGH-PRICED SINGLE SOURCE DRUGS.—Title XI of the
1/	
18	Social Security Act (42 U.S.C. 1301 et seq.) is amended
18 19	Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:
18 19 20	Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part: "PART E—FAIR PRICE NEGOTIATION PROGRAM
18 19 20 21	 Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part: "PART E—FAIR PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-
18 19 20 21 22	Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part: "PART E—FAIR PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH- PRICED SINGLE SOURCE DRUGS
 18 19 20 21 22 23 	Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part: "PART E—FAIR PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH- PRICED SINGLE SOURCE DRUGS "SEC. 1191. ESTABLISHMENT OF PROGRAM.

1	as the 'program'). Under the program, with respect to
2	each price applicability period, the Secretary shall—
3	"(1) publish a list of selected drugs in accord-
4	ance with section 1192;
5	"(2) enter into agreements with manufacturers
6	of selected drugs with respect to such period, in ac-
7	cordance with section 1193;
8	"(3) negotiate and, if applicable, renegotiate
9	maximum fair prices for such selected drugs, in ac-
10	cordance with section 1194; and
11	"(4) carry out the administrative duties de-
12	scribed in section 1196.
13	"(b) Definitions Relating to Timing.—For pur-
14	poses of this part:
15	"(1) INITIAL PRICE APPLICABILITY YEAR.—The
16	term 'initial price applicability year' means a plan
17	year (beginning with plan year 2023) or, if agreed
18	to in an agreement under section 1193 by the Sec-
19	retary and manufacturer involved, a period of more
20	than one plan year (beginning on or after January
21	1, 2023).
22	"(2) PRICE APPLICABILITY PERIOD.—The term
23	'price applicability period' means, with respect to a
24	drug, the period beginning with the initial price ap-
25	plicability year with respect to which such drug is a

1	selected drug and ending with the last plan year
2	during which the drug is a selected drug.
3	"(3) Selected drug publication date.—
4	The term 'selected drug publication date' means,
5	with respect to each initial price applicability year,
6	April 15 of the plan year that begins 2 years prior
7	to such year.
8	"(4) Voluntary negotiation period.—The
9	term 'voluntary negotiation period' means, with re-
10	spect to an initial price applicability year with re-
11	spect to a selected drug, the period—
12	"(A) beginning on the sooner of—
13	"(i) the date on which the manufac-
14	turer of the drug and the Secretary enter
15	into an agreement under section 1193 with
16	respect to such drug; or
17	"(ii) June 15 following the selected
18	drug publication date with respect to such
19	selected drug; and
20	"(B) ending on March 31 of the year that
21	begins one year prior to the initial price appli-
22	cability year.
23	"(c) Other Definitions.—For purposes of this
24	part:

1	"(1) FAIR PRICE ELIGIBLE INDIVIDUAL.—The
2	term 'fair price eligible individual' means, with re-
3	spect to a selected drug—
4	"(A) in the case such drug is furnished or
5	dispensed to the individual at a pharmacy or by
6	a mail order service—
7	"(i) an individual who is enrolled
8	under a prescription drug plan under part
9	D of title XVIII or an MA–PD plan under
10	part C of such title if coverage is provided
11	under such plan for such selected drug;
12	and
13	"(ii) an individual who is enrolled
11	under a group health plan or health insur-
14	under a group nearth plan of nearth insur-
14 15	ance coverage offered in the group or indi-
15	ance coverage offered in the group or indi-
15 16	ance coverage offered in the group or indi- vidual market (as such terms are defined
15 16 17	ance coverage offered in the group or indi- vidual market (as such terms are defined in section 2791 of the Public Health Serv-
15 16 17 18	ance coverage offered in the group or indi- vidual market (as such terms are defined in section 2791 of the Public Health Serv- ice Act) with respect to which there is in
15 16 17 18 19	ance coverage offered in the group or indi- vidual market (as such terms are defined in section 2791 of the Public Health Serv- ice Act) with respect to which there is in effect an agreement with the Secretary
15 16 17 18 19 20	ance coverage offered in the group or indi- vidual market (as such terms are defined in section 2791 of the Public Health Serv- ice Act) with respect to which there is in effect an agreement with the Secretary under section 1197 with respect to such se-
 15 16 17 18 19 20 21 	ance coverage offered in the group or indi- vidual market (as such terms are defined in section 2791 of the Public Health Serv- ice Act) with respect to which there is in effect an agreement with the Secretary under section 1197 with respect to such se- lected drug as so furnished or dispensed;

1	physician, or other provider of services or sup-
2	plier—
3	"(i) an individual who is entitled to
4	benefits under part A of title XVIII or en-
5	rolled under part B of such title if such se-
6	lected drug is covered under the respective
7	part; and
8	"(ii) an individual who is enrolled
9	under a group health plan or health insur-
10	ance coverage offered in the group or indi-
11	vidual market (as such terms are defined
12	in section 2791 of the Public Health Serv-
13	ice Act) with respect to which there is in
14	effect an agreement with the Secretary
15	under section 1197 with respect to such se-
16	lected drug as so furnished or adminis-
17	tered.
18	"(2) MAXIMUM FAIR PRICE.—The term 'max-
19	imum fair price' means, with respect to a plan year
20	during a price applicability period and with respect
21	to a selected drug (as defined in section $1192(c)$)
22	with respect to such period, the price published pur-
23	suant to section 1195 in the Federal Register for
24	such drug and year.

"(3) AVERAGE INTERNATIONAL MARKET PRICE
 DEFINED.—

3 "(A) IN GENERAL.—The terms 'average international market price' and 'AIM price' 4 5 mean, with respect to a drug, the average price 6 (which shall be the net average price, if prac-7 ticable, and volume-weighted, if practicable) for 8 a unit (as defined in paragraph (4)) of the drug 9 for sales of such drug (calculated across dif-10 ferent dosage forms and strengths of the drug 11 and not based on the specific formulation or 12 package size or package type), as computed (as 13 of the date of publication of such drug as a se-14 lected drug under section 1192(a)) in all coun-15 tries described in clause (ii) of subparagraph 16 (B) that are applicable countries (as described 17 in clause (i) of such subparagraph) with respect 18 to such drug.

20 "(i) IN GENERAL.—For purposes of
21 subparagraph (A), a country described in
22 clause (ii) is an applicable country de23 scribed in this clause with respect to a
24 drug if there is available an average price

"(B) APPLICABLE COUNTRIES.—

1	for any unit for the drug for sales of such	
2	drug in such country.	
3	"(ii) Countries described.—For	
4	purposes of this paragraph, the following	
5	are countries described in this clause:	
6	"(I) Australia.	
7	"(II) Canada.	
8	"(III) France.	
9	"(IV) Germany.	
10	"(V) Japan.	
11	"(VI) The United Kingdom.	
12	"(4) UNIT.—The term 'unit' means, with re-	
13	spect to a drug, the lowest identifiable quantity	
14	(such as a capsule or tablet, milligram of molecules,	
15	or grams) of the drug that is dispensed.	
16	"SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS	
17	AS SELECTED DRUGS.	
18	"(a) IN GENERAL.—Not later than the selected drug	
19	publication date with respect to an initial price applica-	
20	bility year, subject to subsection (h), the Secretary shall	
21	select and publish in the Federal Register a list of—	
22	((1)(A) with respect to an initial price applica-	
23	bility year during 2023, at least 25 negotiation-eligi-	
24	ble drugs described in subparagraphs (A) and (B),	
25	but not subparagraph (C), of subsection $(d)(1)$ (or,	

with respect to an initial price applicability year dur ing such period beginning after 2023, the maximum
 number (if such number is less than 25) of such ne gotiation-eligible drugs for the year) with respect to
 such year; and

6 "(B) with respect to an initial price applica-7 bility year during 2024 or a subsequent year, at 8 least 50 negotiation-eligible drugs described in sub-9 paragraphs (A) and (B), but not subparagraph (C), 10 of subsection (d)(1) (or, with respect to an initial 11 price applicability year during such period, the max-12 imum number (if such number is less than 50) of 13 such negotiation-eligible drugs for the year) with re-14 spect to such year;

15 "(2) all negotiation-eligible drugs described in
16 subparagraph (C) of such subsection with respect to
17 such year; and

18 "(3) all new-entrant negotiation-eligible drugs
19 (as defined in subsection (g)(1)) with respect to such
20 vear.

21 Each drug published on the list pursuant to the previous
22 sentence shall be subject to the negotiation process under
23 section 1194 for the voluntary negotiation period with re24 spect to such initial price applicability year (and the re25 negotiation process under such section as applicable for

any subsequent year during the applicable price applica-1 2 bility period). In applying this subsection, any negotiationeligible drug that is selected under this subsection for an 3 4 initial price applicability year shall not count toward the required minimum amount of drugs to be selected under 5 paragraph (1) for any subsequent year, including such a 6 7 drug so selected that is subject to renegotiation under sec-8 tion 1194.

9 "(b) SELECTION OF DRUGS.—In carrying out sub-10 section (a)(1) the Secretary shall select for inclusion on the published list described in subsection (a) with respect 11 12 to a price applicability period, the negotiation-eligible drugs that the Secretary projects will result in the greatest 13 savings to the Federal Government or fair price eligible 14 15 individuals during the price applicability period. In making this projection of savings for drugs for which there is an 16 17 AIM price for a price applicability period, the savings shall be projected across different dosage forms and strengths 18 19 of the drugs and not based on the specific formulation or package size or package type of the drugs, taking into con-20 21 sideration both the volume of drugs for which payment 22 is made, to the extent such data is available, and the 23 amount by which the net price for the drugs exceeds the 24 AIM price for the drugs.

1	"(c) Selected Drug.—For purposes of this part,	
2	each drug included on the list published under subsection	
3	(a) with respect to an initial price applicability year shall	
4	be referred to as a 'selected drug' with respect to such	
5	year and each subsequent plan year beginning before the	
6	first plan year beginning after the date on which the Sec-	
7	retary determines two or more drug products—	
8	"(1) are approved or licensed (as applicable)—	
9	"(A) under section $505(j)$ of the Federal	
10	Food, Drug, and Cosmetic Act using such drug	
11	as the listed drug; or	
12	"(B) under section 351(k) of the Public	
13	Health Service Act using such drug as the ref-	
14	erence product; and	
15	"(2) continue to be marketed.	
16	"(d) Negotiation-Eligible Drug.—	
17	"(1) IN GENERAL.—For purposes of this part,	
18	the term 'negotiation-eligible drug' means, with re-	
19	spect to the selected drug publication date with re-	
20	spect to an initial price applicability year, a quali-	
21	fying single source drug, as defined in subsection	
22	(e), that meets any of the following criteria:	
23	"(A) COVERED PART D DRUGS.—The drug	
24	is among the 125 covered part D drugs (as de-	
25	fined in section 1860D–2(e)) for which there	

1 was an estimated greatest net spending under 2 parts C and D of title XVIII, as determined by 3 the Secretary, during the most recent plan year 4 prior to such drug publication date for which 5 data are available. 6 "(B) OTHER DRUGS.—The drug is among 7 the 125 drugs for which there was an estimated 8 greatest net spending in the United States (in-9 cluding the 50 States, the District of Columbia, 10 and the territories of the United States), as de-11 termined by the Secretary, during the most re-12 cent plan year prior to such drug publication 13 date for which data are available. 14 "(C) INSULIN.—The drug is a qualifying 15 single source drug described in subsection 16 (e)(3).17 "(2) CLARIFICATION.—In determining whether 18 a qualifying single source drug satisfies any of the 19 criteria described in paragraph (1), the Secretary 20 shall, to the extent practicable, use data that is ag-21 gregated across dosage forms and strengths of the 22 drug and not based on the specific formulation or 23 package size or package type of the drug.

24 "(3) PUBLICATION.—Not later than the se-25 lected drug publication date with respect to an ini-

1	tial price applicability year, the Secretary shall pub-
2	lish in the Federal Register a list of negotiation-eli-
3	gible drugs with respect to such selected drug publi-
4	cation date.
5	"(e) Qualifying Single Source Drug.—For pur-
6	poses of this part, the term 'qualifying single source drug'
7	means any of the following:
8	"(1) Drug products.—A drug that—
9	"(A) is approved under section 505(c) of
10	the Federal Food, Drug, and Cosmetic Act and
11	continues to be marketed pursuant to such ap-
12	proval; and
13	"(B) is not the listed drug for any drug
14	that is approved and continues to be marketed
15	under section 505(j) of such Act.
16	"(2) BIOLOGICAL PRODUCTS.—A biological
17	product that—
18	"(A) is licensed under section 351(a) of
19	the Public Health Service Act, including any
20	product that has been deemed to be licensed
21	under section 351 of such Act pursuant to sec-
22	tion 7002(e)(4) of the Biologics Price Competi-
23	tion and Innovation Act of 2009, and continues
24	to be marketed under section 351 of such Act;
25	and

"(B) is not the reference product for any
 biological product that is licensed and continues
 to be marketed under section 351(k) of such
 Act.

5 (3)PRODUCT.—Notwithstanding INSULIN 6 paragraphs (1) and (2), any insulin product that is 7 approved under subsection (c) or (j) of section 505 8 of the Federal Food, Drug, and Cosmetic Act or li-9 censed under subsection (a) or (k) of section 351 of 10 the Public Health Service Act and continues to be 11 marketed under such section 505 or 351, including 12 any insulin product that has been deemed to be li-13 censed under section 351(a) of the Public Health 14 Service Act pursuant to section 7002(e)(4) of the 15 Biologics Price Competition and Innovation Act of 16 2009 and continues to be marketed pursuant to such 17 licensure.

18 For purposes of applying paragraphs (1) and (2), a drug 19 or biological product that is marketed by the same sponsor 20 or manufacturer (or an affiliate thereof or a cross-licensed 21 producer or distributor) as the listed drug or reference 22 product described in such respective paragraph shall not 23 be taken into consideration.

24 "(f) INFORMATION ON INTERNATIONAL DRUG25 PRICES.—For purposes of determining which negotiation-

1 eligible drugs to select under subsection (a) and, in the 2 case of such drugs that are selected drugs, to determine the maximum fair price for such a drug and whether such 3 4 maximum fair price should be renegotiated under section 5 1194, the Secretary shall use data relating to the AIM price with respect to such drug as available or provided 6 7 to the Secretary and shall on an ongoing basis request 8 from manufacturers of selected drugs information on the 9 AIM price of such a drug.

10"(g)NEW-ENTRANTNEGOTIATION-ELIGIBLE11DRUGS.—

"(1) IN GENERAL.—For purposes of this part,
the term 'new-entrant negotiation-eligible drug'
means, with respect to the selected drug publication
date with respect to an initial price applicability
year, a qualifying single source drug—

"(A) that is first approved or licensed, as
described in paragraph (1), (2), or (3) of subsection (e), as applicable, during the year preceding such selected drug publication date; and
"(B) that the Secretary determines under
paragraph (2) is likely to be included as a negotiation-eligible drug with respect to the subse-

24 quent selected drug publication date.

1 "(2) DETERMINATION.—In the case of a quali-2 fying single source drug that meets the criteria de-3 scribed in subparagraph (A) of paragraph (1), with 4 respect to an initial price applicability year, if the 5 wholesale acquisition cost at which such drug is first 6 marketed in the United States is equal to or greater 7 than the median household income (as determined 8 according to the most recent data collected by the 9 United States Census Bureau), the Secretary shall 10 determine before the selected drug publication date 11 with respect to the initial price applicability year, if 12 the drug is likely to be included as a negotiation-eli-13 gible drug with respect to the subsequent selected 14 drug publication date, based on the projected spend-15 ing under title XVIII or in the United States on 16 such drug. For purposes of this paragraph the term 17 'United States' includes the 50 States, the District 18 of Columbia, and the territories of the United 19 States.

20 "(h) Conflict of Interest.—

"(1) IN GENERAL.—In the case the Inspector
General of the Department of Health and Human
Services determines the Secretary has a conflict,
with respect to a matter described in paragraph (2),
the individual described in paragraph (3) shall carry

1	out the duties of the Secretary under this part, with
2	respect to a negotiation-eligible drug, that would
3	otherwise be such a conflict.
4	"(2) MATTER DESCRIBED.—A matter described
5	in this paragraph is—
6	"(A) a financial interest (as described in
7	section 2635.402 of title 5, Code of Federal
8	Regulations (except for an interest described in
9	subsection $(b)(2)(iv)$ of such section)) on the
10	date of the selected drug publication date, with
11	respect the price applicability year (as applica-
12	ble);
13	"(B) a personal or business relationship
14	(as described in section 2635.502 of such title)
15	on the date of the selected drug publication
16	date, with respect the price applicability year;
17	"(C) employment by a manufacturer of a
18	negotiation-eligible drug during the preceding
19	10-year period beginning on the date of the se-
20	lected drug publication date, with respect to
21	each price applicability year; and
22	"(D) any other matter the General Counsel
23	determines appropriate.
24	"(3) INDIVIDUAL DESCRIBED.—An individual
25	described in this paragraph is—

1	"(A) the highest-ranking officer or em-
2	ployee of the Department of Health and
3	Human Services (as determined by the organi-
4	zational chart of the Department) that does not
5	have a conflict under this subsection; and
6	"(B) is nominated by the President and
7	confirmed by the Senate with respect to the po-
8	sition.

9 "SEC. 1193. MANUFACTURER AGREEMENTS.

10 IN GENERAL.—For "(a) purposes of section 11 1191(a)(2), the Secretary shall enter into agreements with 12 manufacturers of selected drugs with respect to a price 13 applicability period, by not later than June 15 following the selected drug publication date with respect to such se-14 15 lected drug, under which—

16 "(1) during the voluntary negotiation period for 17 the initial price applicability year for the selected 18 drug, the Secretary and manufacturer, in accordance 19 with section 1194, negotiate to determine (and, by 20 not later than the last date of such period and in ac-21 cordance with subsection (c), agree to) a maximum 22 fair price for such selected drug of the manufacturer 23 in order to provide access to such price—

24 "(A) to fair price eligible individuals who25 with respect to such drug are described in sub-

paragraph (A) of section 1191(c)(1) and are
 furnished or dispensed such drug during, sub ject to subparagraph (2), the price applicability
 period; and

5 "(B) to hospitals, physicians, and other 6 providers of services and suppliers with respect 7 to fair price eligible individuals who with re-8 spect to such drug are described in subpara-9 graph (B) of such section and are furnished or 10 administered such drug during, subject to sub-11 paragraph (2), the price applicability period;

12 "(2) the Secretary and the manufacturer shall, 13 in accordance with a process and during a period 14 specified by the Secretary pursuant to rulemaking, 15 renegotiate (and, by not later than the last date of 16 such period and in accordance with subsection (c), 17 agree to) the maximum fair price for such drug if 18 the Secretary determines that there is a material 19 change in any of the factors described in section 20 1194(d) relating to the drug, including changes in 21 the AIM price for such drug, in order to provide ac-22 cess to such maximum fair price (as so renegoti-23 ated)----

24 "(A) to fair price eligible individuals who25 with respect to such drug are described in sub-

1	paragraph (A) of section $1191(c)(1)$ and are
2	furnished or dispensed such drug during any
3	year during the price applicability period (be-
4	ginning after such renegotiation) with respect
5	to such selected drug; and
6	"(B) to hospitals, physicians, and other
7	providers of services and suppliers with respect
8	to fair price eligible individuals who with re-
9	spect to such drug are described in subpara-
10	graph (B) of such section and are furnished or
11	administered such drug during any year de-
12	scribed in subparagraph (A);
13	"(3) the maximum fair price (including as re-
14	negotiated pursuant to paragraph (2)), with respect
15	to such a selected drug, shall be provided to fair
16	price eligible individuals, who with respect to such
17	drug are described in subparagraph (A) of section
18	1191(c)(1), at the pharmacy or by a mail order serv-
19	ice at the point-of-sale of such drug;
20	((4) the manufacturer, subject to subsection
21	(d), submits to the Secretary, in a form and manner
22	specified by the Secretary—
23	"(A) for the voluntary negotiation period
24	for the price applicability period (and, if appli-
25	cable, before any period of renegotiation speci-

1	fied pursuant to paragraph (2)) with respect to
2	such drug all information that the Secretary re-
3	quires to carry out the negotiation (or renegoti-
4	ation process) under this part, including infor-
5	mation described in section $1192(f)$ and section
6	1194(d)(1); and
_	

"(B) on an ongoing basis, information on
changes in prices for such drug that would affect the AIM price for such drug or otherwise
provide a basis for renegotiation of the maximum fair price for such drug pursuant to
paragraph (2);

13 "(5) the manufacturer agrees that in the case 14 the selected drug of a manufacturer is a drug de-15 scribed in subsection (c), the manufacturer will, in 16 accordance with such subsection, make any payment 17 required under such subsection with respect to such 18 drug; and

"(6) the manufacturer complies with requirements imposed by the Secretary for purposes of administering the program, including with respect to
the duties described in section 1196.

23 "(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO
24 LONGER A SELECTED DRUG.—An agreement entered into
25 under this section shall be effective, with respect to a drug,

until such drug is no longer considered a selected drug
 under section 1192(c).

3 "(c) SPECIAL RULE FOR CERTAIN SELECTED DRUGS
4 WITHOUT AIM PRICE.—

5 "(1) IN GENERAL.—In the case of a selected 6 drug for which there is no AIM price available with 7 respect to the initial price applicability year for such 8 drug and for which an AIM price becomes available 9 beginning with respect to a subsequent plan year 10 during the price applicability period for such drug, 11 if the Secretary determines that the amount de-12 scribed in paragraph (2)(A) for a unit of such drug 13 is greater than the amount described in paragraph 14 (2)(B) for a unit of such drug, then by not later 15 than one year after the date of such determination, 16 the manufacturer of such selected drug shall pay to 17 the Treasury an amount equal to the product of— 18 "(A) the difference between such amount 19

described in paragraph (2)(A) for a unit of such drug and such amount described in paragraph (2)(B) for a unit of such drug; and

22 "(B) the number of units of such drug sold
23 in the United States, including the 50 States,
24 the District of Columbia, and the territories of

20

1	the United States, during the period described
2	in paragraph (2)(B).

3 "(2) Amounts described.—

4 "(A) WEIGHTED AVERAGE PRICE BEFORE 5 AIM PRICE AVAILABLE.—For purposes of para-6 graph (1), the amount described in this sub-7 paragraph for a selected drug described in such 8 paragraph, is the amount equal to the weighted 9 average manufacturer price (as defined in sec-10 tion 1927(k)(1) for such dosage strength and 11 form for the drug during the period beginning 12 with the first plan year for which the drug is 13 included on the list of negotiation-eligible drugs 14 published under section 1192(d) and ending 15 with the last plan year during the price applicability period for such drug with respect to which 16 17 there is no AIM price available for such drug.

18 "(B) AMOUNT MULTIPLIER AFTER AIM
19 PRICE AVAILABLE.—For purposes of paragraph
20 (1), the amount described in this subparagraph
21 for a selected drug described in such paragraph,
22 is the amount equal to 200 percent of the AIM
23 price for such drug with respect to the first
24 plan year during the price applicability period
for such drug with respect to which there is an
 AIM price available for such drug.

3 "(d) CONFIDENTIALITY OF INFORMATION.-Infor-4 mation submitted to the Secretary under this part by a 5 manufacturer of a selected drug that is proprietary infor-6 mation of such manufacturer (as determined by the Sec-7 retary) may be used only by the Secretary or disclosed 8 to and used by the Comptroller General of the United 9 States or the Medicare Payment Advisory Commission for purposes of carrying out this part. 10

11 "(e) REGULATIONS.—

"(1) IN GENERAL.—The Secretary shall, pursuant to rulemaking, specify, in accordance with paragraph (2), the information that must be submitted
under subsection (a)(4).

(2)16 INFORMATION SPECIFIED.—Information 17 described in paragraph (1), with respect to a se-18 lected drug, shall include information on sales of the 19 drug (by the manufacturer of the drug or by another 20 entity under license or other agreement with the 21 manufacturer, with respect to the sales of such drug, 22 regardless of the name under which the drug is sold) 23 in any foreign country that is part of the AIM price. 24 The Secretary shall verify, to the extent practicable,

such sales from appropriate officials of the govern ment of the foreign country involved.

3 "(f) COMPLIANCE WITH REQUIREMENTS FOR AD4 MINISTRATION OF PROGRAM.—Each manufacturer with
5 an agreement in effect under this section shall comply with
6 requirements imposed by the Secretary or a third party
7 with a contract under section 1196(c)(1), as applicable,
8 for purposes of administering the program.

9 "SEC. 1194. NEGOTIATION AND RENEGOTIATION PROCESS.

10 "(a) IN GENERAL.—For purposes of this part, under 11 an agreement under section 1193 between the Secretary 12 and a manufacturer of a selected drug, with respect to 13 the period for which such agreement is in effect and in 14 accordance with subsections (b) and (c), the Secretary and 15 the manufacturer—

"(1) shall during the voluntary negotiation period with respect to the initial price applicability
year for such drug, in accordance with this section,
negotiate a maximum fair price for such drug for
the purpose described in section 1193(a)(1); and

"(2) as applicable pursuant to section
1193(a)(2) and in accordance with the process specified pursuant to such section, renegotiate such maximum fair price for such drug for the purpose described in such section.

1 "(b) Negotiating Methodology and Objec-2 tive.—

3	"(1) IN GENERAL.—The Secretary shall develop
4	and use a consistent methodology for negotiations
5	under subsection (a) that, in accordance with para-
6	graph (2) and subject to paragraph (3), achieves the
7	lowest maximum fair price for each selected drug
8	while appropriately rewarding innovation.
9	"(2) PRIORITIZING FACTORS.—In considering
10	the factors described in subsection (d) in negotiating
11	(and, as applicable, renegotiating) the maximum fair
12	price for a selected drug, the Secretary shall, to the
13	extent practicable, consider all of the available fac-
14	tors listed but shall prioritize the following factors:
15	"(A) RESEARCH AND DEVELOPMENT
16	costs.—The factor described in paragraph
17	(1)(A) of subsection (d).
18	"(B) MARKET DATA.—The factor de-
19	scribed in paragraph (1)(B) of such subsection.
20	"(C) UNIT COSTS OF PRODUCTION AND
21	DISTRIBUTION.—The factor described in para-
22	graph $(1)(C)$ of such subsection.

23 "(D) COMPARISON TO EXISTING THERA24 PEUTIC ALTERNATIVES.—The factor described
25 in paragraph (2)(A) of such subsection.

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"(3) Requirement.—

2 "(A) IN GENERAL.—In negotiating the maximum fair price of a selected drug, with re-3 4 spect to an initial price applicability year for 5 the selected drug, and, as applicable, in renego-6 tiating the maximum fair price for such drug, 7 with respect to a subsequent year during the 8 price applicability period for such drug, in the 9 case that the manufacturer of the selected drug 10 offers under the negotiation or renegotiation, as 11 applicable, a price for such drug that is not 12 more than the target price described in sub-13 paragraph (B) for such drug for the respective 14 vear, the Secretary shall agree under such ne-15 gotiation or renegotiation, respectively, to such 16 offered price as the maximum fair price.

"(B) TARGET PRICE.—

18 "(i) IN GENERAL.—Subject to clause 19 (ii), the target price described in this sub-20 paragraph for a selected drug with respect 21 to a year, is the average price (which shall 22 be the net average price, if practicable, and 23 volume-weighted, if practicable) for a unit 24 of such drug for sales of such drug, as 25 computed (across different dosage forms

1	and strengths of the drug and not based
2	on the specific formulation or package size
3	or package type of the drug) in the appli-
4	cable country described in section
5	1191(c)(3)(B) with respect to such drug
6	that, with respect to such year, has the
7	lowest average price for such drug as com-
8	pared to the average prices (as so com-
9	puted) of such drug with respect to such
10	year in the other applicable countries de-
11	scribed in such section with respect to such
12	drug.
13	"(ii) Selected drugs without aim
14	PRICE.—In applying this paragraph in the
15	case of negotiating the maximum fair price
16	of a selected drug for which there is no
17	AIM price available with respect to the ini-
18	tial price applicability year for such drug,
19	or, as applicable, renegotiating the max-
20	imum fair price for such drug with respect
21	to a subsequent year during the price ap-
22	plicability period for such drug before the
23	first plan year for which there is an AIM
24	price available for such drug, the target
25	price described in this subparagraph for

1	such drug and respective year is the
2	amount that is 80 percent of the average
3	manufacturer price (as defined in section
4	1927(k)(1)) for such drug and year.
5	"(4) ANNUAL REPORT.—After the completion
6	of each voluntary negotiation period, the Secretary
7	shall submit to Congress a report on the maximum
8	fair prices negotiated (or, as applicable, renegoti-
9	ated) for such period. Such report shall include in-
10	formation on how such prices so negotiated (or re-
11	negotiated) meet the requirements of this part, in-
12	cluding the requirements of this subsection.
13	"(c) LIMITATION.—
14	"(1) IN GENERAL.—Subject to paragraph (2),
15	the maximum fair price negotiated (including as re-
16	negotiated) under this section for a selected drug,
17	with respect to each plan year during a price appli-
18	cability period for such drug, shall not exceed 120
19	percent of the AIM price applicable to such drug
20	with respect to such year.
21	"(2) Selected drugs without aim price.—
22	In the case of a selected drug for which there is no
23	AIM price available with respect to the initial price
24	applicability year for such drug, for each plan year
25	during the price applicability period before the first

plan year for which there is an AIM price available
for such drug, the maximum fair price negotiated
(including as renegotiated) under this section for the
selected drug shall not exceed the amount equal to
85 percent of the average manufacturer price for the
drug with respect to such year.

7 "(d) CONSIDERATIONS.—For purposes of negotiating 8 and, as applicable, renegotiating (including for purposes 9 of determining whether to renegotiate) the maximum fair price of a selected drug under this part with the manufac-10 11 turer of the drug, the Secretary, consistent with sub-12 section (b)(2), shall take into consideration the factors described in paragraphs (1), (2), (3), and (5), and may take 13 into consideration the factor described in paragraph (4): 14 **((1)** 15 MANUFACTURER-SPECIFIC INFORMA-16 TION.—The following information, including as sub-17 mitted by the manufacturer:

18 "(A) Research and development costs of
19 the manufacturer for the drug and the extent to
20 which the manufacturer has recouped research
21 and development costs.

"(B) Market data for the drug, including
the distribution of sales across different programs and purchasers and projected future revenues for the drug.

1	"(C) Unit costs of production and distribu-
2	tion of the drug.
3	"(D) Prior Federal financial support for
4	novel therapeutic discovery and development
5	with respect to the drug.
6	"(E) Data on patents and on existing and
7	pending exclusivity for the drug.
8	"(F) National sales data for the drug.
9	"(G) Information on clinical trials for the
10	drug in the United States or in applicable coun-
11	tries described in section $1191(c)(3)(B)$.
12	"(2) INFORMATION ON ALTERNATIVE PROD-
13	UCTS.—The following information:
14	"(A) The extent to which the drug rep-
15	resents a the rapeutic advance as compared to
16	existing the rapeutic alternatives and, to the ex-
17	tent such information is available, the costs of
18	such existing the rapeutic alternatives.
19	"(B) Information on approval by the Food
20	and Drug Administration of alternative drug
21	products.
22	"(C) Information on comparative effective-
23	ness analysis for such products, taking into
24	consideration the effects of such products on
25	specific populations, such as individuals with

disabilities, the elderly, terminally ill, children,
 and other patient populations.

3 In considering information described in subpara-4 graph (C), the Secretary shall not use evidence or 5 findings from comparative clinical effectiveness re-6 search in a manner that treats extending the life of 7 an elderly, disabled, or terminally ill individual as of 8 lower value than extending the life of an individual 9 who is younger, nondisabled, or not terminally ill. 10 Nothing in the previous sentence shall affect the ap-11 plication or consideration of an AIM price for a se-12 lected drug.

13 "(3) FOREIGN SALES INFORMATION.—To the 14 extent available on a timely basis, including as pro-15 vided by a manufacturer of the selected drug or oth-16 erwise, information on sales of the selected drug in 17 section each of the countries described in 18 1191(c)(3)(B).

19 "(4) VA DRUG PRICING INFORMATION.—Infor20 mation disclosed to the Secretary pursuant to sub21 section (f).

22 "(5) ADDITIONAL INFORMATION.—Information
23 submitted to the Secretary, in accordance with a
24 process specified by the Secretary, by other parties

- that are affected by the establishment of a maximum
 fair price for the selected drug.
- 3 "(e) REQUEST FOR INFORMATION.—For purposes of 4 negotiating and, as applicable, renegotiating (including for 5 purposes of determining whether to renegotiate) the max-6 imum fair price of a selected drug under this part with 7 the manufacturer of the drug, with respect to a price ap-8 plicability period, and other relevant data for purposes of 9 this section—
- "(1) the Secretary shall, not later than the selected drug publication date with respect to the initial price applicability year of such period, request
 drug pricing information from the manufacturer of
 such selected drug, including information described
 in subsection (d)(1); and
- "(2) by not later than October 1 following the
 selected drug publication date, the manufacturer of
 such selected drug shall submit to the Secretary
 such requested information in such form and manner as the Secretary may require.

21 The Secretary shall request, from the manufacturer or22 others, such additional information as may be needed to23 carry out the negotiation and renegotiation process under24 this section.

"(f) DISCLOSURE OF INFORMATION.—For purposes
 of this part, the Secretary of Veterans Affairs may disclose
 to the Secretary of Health and Human Services the price
 of any negotiation-eligible drug that is purchased pursuant
 to section 8126 of title 38, United States Code.

6 "SEC. 1195. PUBLICATION OF MAXIMUM FAIR PRICES.

7 "(a) IN GENERAL.—With respect to an initial price 8 applicability year and selected drug with respect to such 9 year, not later than April 1 of the plan year prior to such 10 initial price applicability year, the Secretary shall publish 11 in the Federal Register the maximum fair price for such 12 drug negotiated under this part with the manufacturer of 13 such drug.

14 "(b) UPDATES.—

((1) 15 SUBSEQUENT YEAR MAXIMUM FAIR 16 PRICES.—For a selected drug, for each plan year 17 subsequent to the initial price applicability year for 18 such drug with respect to which an agreement for 19 such drug is in effect under section 1193, the Sec-20 retary shall publish in the Federal Register—

21 "(A) subject to subparagraph (B), the
22 amount equal to the maximum fair price pub23 lished for such drug for the previous year, in24 creased by the annual percentage increase in
25 the consumer price index for all urban con-

1	sumers (all items; U.S. city average) as of Sep-
2	tember of such previous year; or
3	"(B) in the case the maximum fair price
4	for such drug was renegotiated, for the first
5	year for which such price as so renegotiated ap-
6	plies, such renegotiated maximum fair price.
7	"(2) PRICES NEGOTIATED AFTER DEADLINE.—
8	In the case of a selected drug with respect to an ini-
9	tial price applicability year for which the maximum
10	fair price is determined under this part after the
11	date of publication under this section, the Secretary
12	shall publish such maximum fair price in the Fed-
13	eral Register by not later than 30 days after the
14	date such maximum price is so determined.
14 15	date such maximum price is so determined. "SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO-
15	"SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO-
15 16	"SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO- VISIONS.
15 16 17	"SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO- VISIONS. "(a) Administrative Duties.—
15 16 17 18	"SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO- VISIONS. "(a) ADMINISTRATIVE DUTIES.— "(1) IN GENERAL.—For purposes of section
15 16 17 18 19	"SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO- VISIONS. "(a) ADMINISTRATIVE DUTIES.— "(1) IN GENERAL.—For purposes of section 1191, the administrative duties described in this sec-
15 16 17 18 19 20	 *SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO- VISIONS. "(a) ADMINISTRATIVE DUTIES.— "(1) IN GENERAL.—For purposes of section 1191, the administrative duties described in this section are the following:
 15 16 17 18 19 20 21 	 *SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO- VISIONS. "(a) ADMINISTRATIVE DUTIES.— "(1) IN GENERAL.—For purposes of section 1191, the administrative duties described in this sec- tion are the following: "(A) The establishment of procedures (in-
 15 16 17 18 19 20 21 22 	 *SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO- VISIONS. "(a) ADMINISTRATIVE DUTIES.— "(1) IN GENERAL.—For purposes of section 1191, the administrative duties described in this sec- tion are the following: "(A) The establishment of procedures (in- cluding through agreements with manufacturers

1 agreements under section 1197 with group 2 health plans and health insurance issuers of 3 health insurance coverage offered in the indi-4 vidual or group market) under which the max-5 imum fair price for a selected drug is provided 6 to fair price eligible individuals, who with re-7 spect to such drug are described in subpara-8 graph (A) of section 1191(c)(1), at pharmacies 9 or by mail order service at the point-of-sale of 10 the drug for the applicable price period for such 11 drug and providing that such maximum fair 12 price is used for determining cost-sharing under 13 such plans or coverage for the selected drug.

14 "(B) The establishment of procedures (in-15 cluding through agreements with manufacturers 16 under this part and contracts with hospitals, 17 physicians, and other providers of services and 18 suppliers and agreements under section 1197 19 with group health plans and health insurance 20 issuers of health insurance coverage offered in 21 the individual or group market) under which, in 22 the case of a selected drug furnished or admin-23 istered by such a hospital, physician, or other 24 provider of services or supplier to fair price eli-25 gible individuals (who with respect to such drug 1 are described in subparagraph (B) of section 2 1191(c)(1), the maximum fair price for the se-3 lected drug is provided to such hospitals, physi-4 cians, and other providers of services and sup-5 pliers (as applicable) with respect to such individuals and providing that such maximum fair 6 7 price is used for determining cost-sharing under 8 the respective part, plan, or coverage for the se-9 lected drug.

10 "(C) The establishment of procedures (in-11 cluding through agreements and contracts de-12 scribed in subparagraphs (A) and (B)) to en-13 sure that, not later than 90 days after the dis-14 pensing of a selected drug to a fair price eligi-15 ble individual by a pharmacy or mail order serv-16 ice, the pharmacy or mail order service is reim-17 bursed for an amount equal to the difference 18 between-

20 "(I) the wholesale acquisition
21 cost of the drug;

22 "(II) the national average drug
23 acquisition cost of the drug; and
24 "(III) any other similar deter25 mination of pharmacy acquisition

1	costs of the drug, as determined by
2	the Secretary; and
3	"(ii) the maximum fair price for the
4	drug.
5	"(D) The establishment of procedures to
6	ensure that the maximum fair price for a se-
7	lected drug is applied before—
8	"(i) any coverage or financial assist-
9	ance under other health benefit plans or
10	programs that provide coverage or finan-
11	cial assistance for the purchase or provi-
12	sion of prescription drug coverage on be-
13	half of fair price eligible individuals as the
14	Secretary may specify; and
15	"(ii) any other discounts.
16	"(E) The establishment of procedures to
17	enter into appropriate agreements and protocols
18	for the ongoing computation of AIM prices for
19	selected drugs, including, to the extent possible,
20	to compute the AIM price for selected drugs
21	and including by providing that the manufac-
22	turer of such a selected drug should provide in-
23	formation for such computation not later than
24	3 months after the first date of the voluntary
25	negotiation period for such selected drug.

1	"(F) The establishment of procedures to
2	compute and apply the maximum fair price
3	across different strengths and dosage forms of
4	a selected drug and not based on the specific
5	formulation or package size or package type of
6	the drug.
7	"(G) The establishment of procedures to
8	negotiate and apply the maximum fair price in
9	a manner that does not include any dispensing
10	or similar fee.
11	"(H) The establishment of procedures to
12	carry out the provisions of this part, as applica-
13	ble, with respect to—
14	"(i) fair price eligible individuals who
15	are enrolled under a prescription drug plan
16	under part D of title XVIII or an MA–PD
17	plan under part C of such title;
18	"(ii) fair price eligible individuals who
19	are enrolled under a group health plan or
20	health insurance coverage offered by a
21	health insurance issuer in the individual or
22	group market with respect to which there
23	is an agreement in effect under section
24	1197; and

1	"(iii) fair price eligible individuals who
2	are entitled to benefits under part A of
3	title XVIII or enrolled under part B of
4	such title.
5	((I) The establishment of a negotiation
6	process and renegotiation process in accordance
7	with section 1194, including a process for ac-
8	quiring information described in subsection (d)
9	of such section and determining amounts de-
10	scribed in subsection (b) of such section.
11	"(J) The provision of a reasonable dispute
12	resolution mechanism to resolve disagreements
13	between manufacturers, fair price eligible indi-
14	viduals, and the third party with a contract
15	under subsection $(c)(1)$.
16	"(2) Monitoring compliance.—
17	"(A) IN GENERAL.—The Secretary shall
18	monitor compliance by a manufacturer with the
19	terms of an agreement under section 1193, in-
20	cluding by establishing a mechanism through
21	which violations of such terms may be reported.
22	"(B) NOTIFICATION.—If a third party
23	with a contract under subsection $(c)(1)$ deter-
24	mines that the manufacturer is not in compli-
25	ance with such agreement, the third party shall

1	notify the Secretary of such noncompliance for
2	appropriate enforcement under section 4192 of
3	the Internal Revenue Code of 1986 or section
4	1198, as applicable.
5	"(b) Collection of Data.—
6	"(1) FROM PRESCRIPTION DRUG PLANS AND
7	MA-PD PLANS.—The Secretary may collect appro-
8	priate data from prescription drug plans under part
9	D of title XVIII and MA–PD plans under part C of
10	such title in a timeframe that allows for maximum
11	fair prices to be provided under this part for selected
12	drugs.
13	"(2) FROM HEALTH PLANS.—The Secretary
14	may collect appropriate data from group health
15	plans or health insurance issuers offering group or
16	individual health insurance coverage in a timeframe
17	that allows for maximum fair prices to be provided
18	under this part for selected drugs.
19	"(3) Coordination of data collection.—
20	To the extent feasible, as determined by the Sec-
21	retary, the Secretary shall ensure that data collected
22	pursuant to this subsection is coordinated with, and
23	not duplicative of, other Federal data collection ef-
24	forts.
25	

25 "(c) Contract With Third Parties.—

1	"(1) IN GENERAL.—The Secretary may enter
2	into a contract with 1 or more third parties to ad-
3	minister the requirements established by the Sec-
4	retary in order to carry out this part. At a min-
5	imum, the contract with a third party under the pre-
6	ceding sentence shall require that the third party—
7	"(A) receive and transmit information be-
8	tween the Secretary, manufacturers, and other
9	individuals or entities the Secretary determines
10	appropriate;
11	"(B) receive, distribute, or facilitate the
12	distribution of funds of manufacturers to ap-
13	propriate individuals or entities in order to
14	meet the obligations of manufacturers under
15	agreements under this part;
16	"(C) provide adequate and timely informa-
17	tion to manufacturers, consistent with the
18	agreement with the manufacturer under this
19	part, as necessary for the manufacturer to ful-
20	fill its obligations under this part; and
21	"(D) permit manufacturers to conduct
22	periodic audits, directly or through contracts, of
23	the data and information used by the third
24	party to determine discounts for applicable
25	drugs of the manufacturer under the program.

"(2) PERFORMANCE REQUIREMENTS.—The
 Secretary shall establish performance requirements
 for a third party with a contract under paragraph
 (1) and safeguards to protect the independence and
 integrity of the activities carried out by the third
 party under the program under this part.

7 "SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER 8 HEALTH PLANS.

9 "(a) AGREEMENT TO PARTICIPATE UNDER PRO-10 GRAM.—

11 "(1) IN GENERAL.—Subject to paragraph (2), 12 under the program under this part the Secretary 13 shall be treated as having in effect an agreement 14 with a group health plan or health insurance issuer 15 offering group or individual health insurance cov-16 erage (as such terms are defined in section 2791 of 17 the Public Health Service Act), with respect to a 18 price applicability period and a selected drug with 19 respect to such period—

"(A) with respect to such selected drug
furnished or dispensed at a pharmacy or by
mail order service if coverage is provided under
such plan or coverage during such period for
such selected drug as so furnished or dispensed;
and

"(B) with respect to such selected drug
 furnished or administered by a hospital, physi cian, or other provider of services or supplier if
 coverage is provided under such plan or cov erage during such period for such selected drug
 as so furnished or administered.

7 "(2) Opting out of agreement.—The Sec-8 retary shall not be treated as having in effect an 9 agreement under the program under this part with 10 a group health plan or health insurance issuer offer-11 ing group or individual health insurance coverage 12 with respect to a price applicability period and a se-13 lected drug with respect to such period if such a 14 plan or issuer affirmatively elects, through a process 15 specified by the Secretary, not to participate under 16 the program with respect to such period and drug. 17 "(b) PUBLICATION OF ELECTION.—With respect to each price applicability period and each selected drug with 18 19 respect to such period, the Secretary and the Secretary 20 of Labor and the Secretary of the Treasury, as applicable, 21 shall make public a list of each group health plan and each 22 health insurance issuer offering group or individual health 23 insurance coverage, with respect to which coverage is pro-24 vided under such plan or coverage for such drug, that has

elected under subsection (a) not to participate under the
 program with respect to such period and drug.

3 "SEC. 1198. CIVIL MONETARY PENALTY.

4 "(a) VIOLATIONS RELATING TO OFFERING OF MAX-5 IMUM FAIR PRICE.—Any manufacturer of a selected drug 6 that has entered into an agreement under section 1193, 7 with respect to a plan year during the price applicability 8 period for such drug, that does not provide access to a 9 price that is not more than the maximum fair price (or 10 a lesser price) for such drug for such year—

"(1) to a fair price eligible individual who with
respect to such drug is described in subparagraph
(A) of section 1191(c)(1) and who is furnished or
dispensed such drug during such year; or

15 "(2) to a hospital, physician, or other provider 16 of services or supplier with respect to fair price eligi-17 ble individuals who with respect to such drug is de-18 scribed in subparagraph (B) of such section and is 19 furnished or administered such drug by such hos-20 pital, physician, or provider or supplier during such 21 year;

shall be subject to a civil monetary penalty equal to ten
times the amount equal to the difference between the price
for such drug made available for such year by such manufacturer with respect to such individual or hospital, physi-

1 cian, provider, or supplier and the maximum fair price for2 such drug for such year.

3 "(b) VIOLATIONS OF CERTAIN TERMS OF AGREE-4 MENT.—Any manufacturer of a selected drug that has en-5 tered into an agreement under section 1193, with respect to a plan year during the price applicability period for 6 7 such drug, that is in violation of a requirement imposed 8 pursuant to section 1193(a)(6) shall be subject to a civil 9 monetary penalty of not more than \$1,000,000 for each such violation. 10

"(c) APPLICATION.—The provisions of section 1128A
(other than subsections (a) and (b)) shall apply to a civil
monetary penalty under this section in the same manner
as such provisions apply to a penalty or proceeding under
section 1128A(a).

16 "SEC. 1199. MISCELLANEOUS PROVISIONS.

17 "(a) PAPERWORK REDUCTION ACT.—Chapter 35 of
18 title 44, United States Code, shall not apply to data col19 lected under this part.

"(b) NATIONAL ACADEMY OF MEDICINE STUDY.—
Not later than December 31, 2025, the National Academy
of Medicine shall conduct a study, and submit to Congress
a report, on recommendations for improvements to the
program under this part, including the determination of
the limits applied under section 1194(c).

1 "(c) MEDPAC STUDY.—Not later than December 31, 2 2025, the Medicare Payment Advisory Commission shall 3 conduct a study, and submit to Congress a report, on the 4 program under this part with respect to the Medicare pro-5 gram under title XVIII, including with respect to the ef-6 fect of the program on individuals entitled to benefits or 7 enrolled under such title.

8 "(d) LIMITATION ON JUDICIAL REVIEW.—The fol-9 lowing shall not be subject to judicial review:

10 "(1) The selection of drugs for publication11 under section 1192(a).

12 "(2) The determination of whether a drug is a13 negotiation-eligible drug under section 1192(d).

14 "(3) The determination of the maximum fair15 price of a selected drug under section 1194.

16 "(4) The determination of units of a drug for
17 purposes of section 1191(c)(3).

18 "(e) COORDINATION.—In carrying out this part with 19 respect to group health plans or health insurance coverage 20 offered in the group market that are subject to oversight 21 by the Secretary of Labor or the Secretary of the Treas-22 ury, the Secretary of Health and Human Services shall 23 coordinate with such respective Secretary.

24 "(f) DATA SHARING.—The Secretary shall share with25 the Secretary of the Treasury such information as is nec-

essary to determine the tax imposed by section 4192 of
 the Internal Revenue Code of 1986.

3 "(g) GAO STUDY.—Not later than December 31,
4 2025, the Comptroller General of the United States shall
5 conduct a study of, and submit to Congress a report on,
6 the implementation of the Fair Price Negotiation Program
7 under this part.".

8 (b) APPLICATION OF MAXIMUM FAIR PRICES AND9 CONFORMING AMENDMENTS.—

10 (1) UNDER MEDICARE.—

11 (A) APPLICATION TO PAYMENTS UNDER 12 PART B.—Section 1847A(b)(1)(B) of the Social 13 Security Act (42 U.S.C. 1395w-3a(b)(1)(B)) is 14 amended by inserting "or in the case of such a 15 drug or biological that is a selected drug (as defined in section 1192(c), with respect to a 16 17 price applicability period (as defined in section 18 1191(b)(2), 106 percent of the maximum fair 19 price (as defined in section 1191(c)(2) applica-20 ble for such drug and a plan year during such 21 period" after "paragraph (4)".

(B) EXCEPTION TO PART D NON-INTERFERENCE.—Section 1860D–11(i) of the Social
Security Act (42 U.S.C. 1395w–111(i)) is

1	amended by inserting ", except as provided
2	under part E of title XI'' after "the Secretary".
3	(C) Application as negotiated price
4	UNDER PART D.—Section 1860D–2(d)(1) of the
5	Social Security Act (42 U.S.C. 1395w-
6	102(d)(1)) is amended—
7	(i) in subparagraph (B), by inserting
8	", subject to subparagraph (D)," after
9	"negotiated prices"; and
10	(ii) by adding at the end the following
11	new subparagraph:
12	"(D) APPLICATION OF MAXIMUM FAIR
13	PRICE FOR SELECTED DRUGS.—In applying this
14	section, in the case of a covered part D drug
15	that is a selected drug (as defined in section
16	1192(c)), with respect to a price applicability
17	period (as defined in section $1191(b)(2)$), the
18	negotiated prices used for payment (as de-
19	scribed in this subsection) shall be the max-
20	imum fair price (as defined in section
21	1191(c)(2)) for such drug and for each plan
22	year during such period.".
23	(D) INFORMATION FROM PRESCRIPTION
24	DRUG PLANS AND MA-PD PLANS REQUIRED

	100
1	(i) Prescription drug plans.—Sec-
2	tion 1860D–12(b) of the Social Security
3	Act (42 U.S.C. 1395w–112(b)) is amended
4	by adding at the end the following new
5	paragraph:
6	"(8) Provision of information related to
7	MAXIMUM FAIR PRICES.—Each contract entered into
8	with a PDP sponsor under this part with respect to
9	a prescription drug plan offered by such sponsor
10	shall require the sponsor to provide information to
11	the Secretary as requested by the Secretary in ac-
12	cordance with section 1196(b).".
13	(ii) MA-PD PLANS.—Section
14	1857(f)(3) of the Social Security Act (42)
15	U.S.C. $1395w-27(f)(3)$) is amended by
16	adding at the end the following new sub-
17	paragraph:
18	"(E) Provision of information re-
19	LATED TO MAXIMUM FAIR PRICES.—Section
20	1860D–12(b)(8).".
21	(2) UNDER GROUP HEALTH PLANS AND
22	HEALTH INSURANCE COVERAGE.—
23	(A) PHSA.—Part A of title XXVII of the
24	Public Health Service Act is amended by insert-

ing after section 2729 the following new sec tion:

3 "SEC. 2729A. FAIR PRICE NEGOTIATION PROGRAM AND AP4 PLICATION OF MAXIMUM FAIR PRICES.

5 "(a) IN GENERAL.—In the case of a group health plan or health insurance issuer offering group or indi-6 7 vidual health insurance coverage that is treated under sec-8 tion 1197 of the Social Security Act as having in effect 9 an agreement with the Secretary under the Fair Price Negotiation Program under part E of title XI of such Act, 10 11 with respect to a price applicability period (as defined in 12 section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such 13 period with respect to which coverage is provided under 14 15 such plan or coverage—

16 "(1) the provisions of such part shall apply— 17 "(A) if coverage of such selected drug is 18 provided under such plan or coverage if the 19 drug is furnished or dispensed at a pharmacy 20 or by a mail order service, to the plans or cov-21 erage offered by such plan or issuer, and to the 22 individuals enrolled under such plans or cov-23 erage, during such period, with respect to such 24 selected drug, in the same manner as such pro-25 visions apply to prescription drug plans and

MA-PD plans, and to individuals enrolled
 under such prescription drug plans and MA PD plans during such period; and

"(B) if coverage of such selected drug is 4 5 provided under such plan or coverage if the 6 drug is furnished or administered by a hospital, 7 physician, or other provider of services or sup-8 plier, to the plans or coverage offered by such 9 plan or issuers, to the individuals enrolled 10 under such plans or coverage, and to hospitals, 11 physicians, and other providers of services and 12 suppliers during such period, with respect to 13 such drug in the same manner as such provi-14 sions apply to the Secretary, to individuals enti-15 tled to benefits under part A of title XVIII or 16 enrolled under part B of such title, and to hos-17 pitals, physicians, and other providers and sup-18 pliers participating under title XVIII during 19 such period;

"(2) the plan or issuer shall apply any costsharing responsibilities under such plan or coverage,
with respect to such selected drug, by substituting
an amount not more than the maximum fair price
negotiated under such part E of title XI for such
drug in lieu of the drug price upon which the cost-

1 sharing would have otherwise applied, and such cost-2 sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and 3 "(3) the Secretary shall apply the provisions of 4 5 such part E to such plan, issuer, and coverage, such 6 individuals so enrolled in such plans and coverage, 7 and such hospitals, physicians, and other providers 8 and suppliers participating in such plans and cov-9 erage.

10 "(b) NOTIFICATION REGARDING NONPARTICIPATION 11 IN FAIR PRICE NEGOTIATION PROGRAM.—A group health 12 plan or a health insurance issuer offering group or individual health insurance coverage shall publicly disclose in 13 14 a manner and in accordance with a process specified by 15 the Secretary any election made under section 1197 of the 16 Social Security Act by the plan or issuer to not participate 17 in the Fair Price Negotiation Program under part E of 18 title XI of such Act with respect to a selected drug (as 19 defined in section 1192(c) of such Act) for which coverage 20 is provided under such plan or coverage before the begin-21 ning of the plan year for which such election was made.".

- 22 (B) ERISA.—
- 23 (i) IN GENERAL.—Subpart B of part
 24 7 of subtitle B of title I of the Employee
 25 Retirement Income Security Act of 1974

(29 U.S.C. 1181 et. seq.) is amended by
 adding at the end the following new sec tion:

4 "SEC. 716. FAIR PRICE NEGOTIATION PROGRAM AND APPLI-

5

CATION OF MAXIMUM FAIR PRICES.

6 "(a) IN GENERAL.—In the case of a group health 7 plan or health insurance issuer offering group health in-8 surance coverage that is treated under section 1197 of the 9 Social Security Act as having in effect an agreement with the Secretary under the Fair Price Negotiation Program 10 11 under part E of title XI of such Act, with respect to a 12 price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 13 14 1192(c) of such Act) with respect to such period with re-15 spect to which coverage is provided under such plan or 16 coverage-

17 "(1) the provisions of such part shall apply, as18 applicable—

"(A) if coverage of such selected drug is
provided under such plan or coverage if the
drug is furnished or dispensed at a pharmacy
or by a mail order service, to the plans or coverage offered by such plan or issuer, and to the
individuals enrolled under such plans or coverage, during such period, with respect to such

selected drug, in the same manner as such pro visions apply to prescription drug plans and
 MA-PD plans, and to individuals enrolled
 under such prescription drug plans and MA PD plans during such period; and

6 "(B) if coverage of such selected drug is 7 provided under such plan or coverage if the 8 drug is furnished or administered by a hospital, 9 physician, or other provider of services or sup-10 plier, to the plans or coverage offered by such 11 plan or issuers, to the individuals enrolled 12 under such plans or coverage, and to hospitals, 13 physicians, and other providers of services and 14 suppliers during such period, with respect to 15 such drug in the same manner as such provi-16 sions apply to the Secretary, to individuals enti-17 tled to benefits under part A of title XVIII or 18 enrolled under part B of such title, and to hos-19 pitals, physicians, and other providers and sup-20 pliers participating under title XVIII during 21 such period;

"(2) the plan or issuer shall apply any costsharing responsibilities under such plan or coverage,
with respect to such selected drug, by substituting
an amount not more than the maximum fair price

1 negotiated under such part E of title XI for such 2 drug in lieu of the drug price upon which the cost-3 sharing would have otherwise applied, and such cost-4 sharing responsibilities with respect to such selected 5 drug may not exceed such maximum fair price; and 6 "(3) the Secretary shall apply the provisions of 7 such part E to such plan, issuer, and coverage, and 8 such individuals so enrolled in such plans. 9 "(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR PRICE NEGOTIATION PROGRAM.—A group health 10 11 plan or a health insurance issuer offering group health in-

12 surance coverage shall publicly disclose in a manner and 13 in accordance with a process specified by the Secretary any election made under section 1197 of the Social Secu-14 15 rity Act by the plan or issuer to not participate in the Fair Price Negotiation Program under part E of title XI 16 17 of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is pro-18 19 vided under such plan or coverage before the beginning of the plan year for which such election was made.". 20

21 (ii) APPLICATION TO RETIREE AND
22 CERTAIN SMALL GROUP HEALTH PLANS.—
23 Section 732(a) of the Employee Retire24 ment Income Security Act of 1974 (29
25 U.S.C. 1191a(a)) is amended by striking

1	"section 711" and inserting "sections 711
2	and 716''.
3	(iii) CLERICAL AMENDMENT.—The
4	table of sections for subpart B of part 7 of
5	subtitle B of title I of the Employee Re-
6	tirement Income Security Act of 1974 is
7	amended by adding at the end the fol-
8	lowing:
	"Sec. 716. Fair Price Negotiation Program and application of maximum fair prices.".
9	(C) IRC.—
10	(i) IN GENERAL.—Subchapter B of
11	chapter 100 of the Internal Revenue Code
12	of 1986 is amended by adding at the end
13	the following new section:
14	"SEC. 9816. FAIR PRICE NEGOTIATION PROGRAM AND AP-
15	PLICATION OF MAXIMUM FAIR PRICES.
16	"(a) IN GENERAL.—In the case of a group health
17	plan that is treated under section 1197 of the Social Secu-
18	rity Act as having in effect an agreement with the Sec-
19	retary under the Fair Price Negotiation Program under
20	part E of title XI of such Act, with respect to a price
21	applicability period (as defined in section 1191(b) of such
22	Act) and a selected drug (as defined in section 1192(c)
23	of such Act) with respect to such period with respect to
24	which coverage is provided under such plan—

"(1) the provisions of such part shall apply, as
 applicable—

3 "(A) if coverage of such selected drug is 4 provided under such plan if the drug is fur-5 nished or dispensed at a pharmacy or by a mail 6 order service, to the plan, and to the individuals 7 enrolled under such plan during such period, 8 with respect to such selected drug, in the same 9 manner as such provisions apply to prescription 10 drug plans and MA-PD plans, and to individ-11 uals enrolled under such prescription drug plans and MA–PD plans during such period; 12 13 and

14 "(B) if coverage of such selected drug is 15 provided under such plan if the drug is fur-16 nished or administered by a hospital, physician, 17 or other provider of services or supplier, to the 18 plan, to the individuals enrolled under such 19 plan, and to hospitals, physicians, and other 20 providers of services and suppliers during such 21 period, with respect to such drug in the same 22 manner as such provisions apply to the Sec-23 retary, to individuals entitled to benefits under 24 part A of title XVIII or enrolled under part B 25 of such title, and to hospitals, physicians, and

1	other	providers	and	suppliers	participating
2	under	title XVIII	durin	g such peri	od;

3 "(2) the plan shall apply any cost-sharing re-4 sponsibilities under such plan, with respect to such 5 selected drug, by substituting an amount not more 6 than the maximum fair price negotiated under such 7 part E of title XI for such drug in lieu of the drug 8 price upon which the cost-sharing would have other-9 wise applied, and such cost-sharing responsibilities 10 with respect to such selected drug may not exceed 11 such maximum fair price; and

"(3) the Secretary shall apply the provisions of
such part E to such plan and such individuals so enrolled in such plan.

15 "(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR PRICE NEGOTIATION PROGRAM.—A group health 16 plan shall publicly disclose in a manner and in accordance 17 with a process specified by the Secretary any election 18 19 made under section 1197 of the Social Security Act by 20 the plan to not participate in the Fair Price Negotiation 21 Program under part E of title XI of such Act with respect 22 to a selected drug (as defined in section 1192(c) of such 23 Act) for which coverage is provided under such plan before 24 the beginning of the plan year for which such election was made.". 25

1	(ii) Application to retiree and
2	CERTAIN SMALL GROUP HEALTH PLANS.—
3	Section $9831(a)(2)$ of the Internal Revenue
4	Code of 1986 is amended by inserting
5	"other than with respect to section 9816,"
6	before "any group health plan".
7	(iii) CLERICAL AMENDMENT.—The
8	table of sections for subchapter B of chap-
9	ter 100 of such Code is amended by add-
10	ing at the end the following new item:
	"Sec. 9816. Fair Price Negotiation Program and application of maximum fair prices.".
11	(3) FAIR PRICE NEGOTIATION PROGRAM PRICES
12	included in best price and amp.—Section 1927
13	of the Social Security Act (42 U.S.C. 1396r–8) is
14	amended—
15	(A) in subsection $(c)(1)(C)(ii)$ —
16	(i) in subclause (III), by striking at
17	the end "; and";
18	(ii) in subclause (IV), by striking at
19	the end the period and inserting "; and";
20	and
21	(iii) by adding at the end the fol-
22	lowing new subclause:
23	"(V) in the case of a rebate pe-
24	riod and a covered outpatient drug

1	that is a selected drug (as defined in
2	section 1192(c)) during such rebate
3	period, shall be inclusive of the price
4	for such drug made available from the
5	manufacturer during the rebate period
6	by reason of application of part E of
7	title XI to any wholesaler, retailer,
8	provider, health maintenance organi-
9	zation, nonprofit entity, or govern-
10	mental entity within the United
11	States."; and
12	(B) in subsection $(k)(1)(B)$, by adding at
13	the end the following new clause:
14	"(iii) CLARIFICATION.—Notwith-
15	standing clause (i), in the case of a rebate
16	period and a covered outpatient drug that
17	is a selected drug (as defined in section
18	1192(c)) during such rebate period, any
19	reduction in price paid during the rebate
20	period to the manufacturer for the drug by
21	a wholesaler or retail community pharmacy
22	described in subparagraph (A) by reason of
23	application of part E of title XI shall be
24	included in the average manufacturer price
25	for the covered outpatient drug.".

(4) FEHBP.—Section 8902 of title 5, United
 States Code, is amended by adding at the end the
 following:

4 "(p) A contract may not be made or a plan approved
5 under this chapter with any carrier that has affirmatively
6 elected, pursuant to section 1197 of the Social Security
7 Act, not to participate in the Fair Price Negotiation Pro8 gram established under section 1191 of such Act for any
9 selected drug (as that term is defined in section 1192(c)
10 of such Act).".

(5) OPTION OF SECRETARY OF VETERANS AFFAIRS TO PURCHASE COVERED DRUGS AT MAXIMUM
FAIR PRICES.—Section 8126 of title 38, United
States Code, is amended—

15 (A) in subsection (a)(2), by inserting ",
16 subject to subsection (j)," after "may not ex17 ceed";

(B) in subsection (d), in the matter preceding paragraph (1), by inserting ", subject to
subsection (j)" after "for the procurement of
the drug"; and

22 (C) by adding at the end the following new23 subsection:

24 "(j)(1) In the case of a covered drug that is a selected25 drug, for any year during the price applicability period for

such drug, if the Secretary determines that the maximum 1 2 fair price of such drug for such year is less than the price 3 for such drug otherwise in effect pursuant to this section 4 (including after application of any reduction under sub-5 section (a)(2) and any discount under subsection (c)), at 6 the option of the Secretary, in lieu of the maximum price 7 (determined after application of the reduction under sub-8 section (a)(2) and any discount under subsection (c), as 9 applicable) that would be permitted to be charged during such year for such drug pursuant to this section without 10 11 application of this subsection, the maximum price per-12 mitted to be charged during such year for such drug pursuant to this section shall be such maximum fair price for 13 14 such drug and year.

15 "(2) For purposes of this subsection:

- "(A) The term 'maximum fair price' means,
 with respect to a selected drug and year during the
 price applicability period for such drug, the maximum fair price (as defined in section 1191(c)(2) of
 the Social Security Act) for such drug and year.
- 21 "(B) The term 'negotiation eligible drug' has
 22 the meaning given such term in section 1192(d)(1)
 23 of the Social Security Act.

1	"(C) The term 'price applicability period' has,
2	with respect to a selected drug, the meaning given
3	such term in section $1191(b)(2)$ of such Act.
4	"(D) The term 'selected drug' means, with re-
5	spect to a year, a drug that is a selected drug under
6	section 1192(c) of such Act for such year.".
7	SEC. 302. DRUG MANUFACTURER EXCISE TAX FOR NON-
8	COMPLIANCE.
9	(a) IN GENERAL.—Subchapter E of chapter 32 of the
10	Internal Revenue Code of 1986 is amended by adding at
11	the end the following new section:
12	"SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE
13	PERIODS.
13 14	PERIODS. "(a) IN GENERAL.—There is hereby imposed on the
14	"(a) IN GENERAL.—There is hereby imposed on the
14 15	"(a) IN GENERAL.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any
14 15 16	"(a) IN GENERAL.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any selected drug during a day described in subsection (b) a
14 15 16 17	"(a) IN GENERAL.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any selected drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is
14 15 16 17 18	"(a) IN GENERAL.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any selected drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of—
14 15 16 17 18 19	"(a) IN GENERAL.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any selected drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of— "(1) such tax, divided by
 14 15 16 17 18 19 20 	"(a) IN GENERAL.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any selected drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of—
 14 15 16 17 18 19 20 21 	 "(a) IN GENERAL.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any selected drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of— "(1) such tax, divided by "(2) the sum of such tax and the price for which so sold.

1	"(1) The period beginning on the June 16th
2	immediately following the selected drug publication
3	date and ending on the first date during which the
4	manufacturer of the drug has in place an agreement
5	described in subsection (a) of section 1193 of the
6	Social Security Act with respect to such drug.
7	"(2) The period beginning on the April 1st im-
8	mediately following the June 16th described in para-
9	graph (1) and ending on the first date during which
10	the manufacturer of the drug has agreed to a max-
11	imum fair price under such agreement.
12	((3) In the case of a selected drug with respect
13	to which the Secretary of Health and Human Serv-
14	ices has specified a renegotiation period under such
15	agreement, the period beginning on the first date
16	after the last date of such renegotiation period and
17	ending on the first date during which the manufac-
18	turer of the drug has agreed to a renegotiated max-
19	imum fair price under such agreement.
20	"(4) With respect to information that is re-
21	quired to be submitted to the Secretary of Health
22	and Human Services under such agreement, the pe-
23	riod beginning on the date on which such Secretary
24	certifies that such information is overdue and ending
25	on the date that such information is so submitted.

1	((5) In the case of a selected drug with respect
2	to which a payment is due under subsection (c) of
3	such section 1193, the period beginning on the date
4	on which the Secretary of Health and Human Serv-
5	ices certifies that such payment is overdue and end-
6	ing on the date that such payment is made in full.
7	"(c) Applicable Percentage.—For purposes of
8	this section, the term 'applicable percentage' means—
9	((1) in the case of sales of a selected drug dur-
10	ing the first 90 days described in subsection (b) with
11	respect to such drug, 65 percent,
12	((2)) in the case of sales of such drug during
13	the 91st day through the 180th day described in
14	subsection (b) with respect to such drug, 75 percent,
15	"(3) in the case of sales of such drug during
16	the 181st day through the 270th day described in
17	subsection (b) with respect to such drug, 85 percent,
18	and
19	"(4) in the case of sales of such drug during
20	any subsequent day, 95 percent.
21	"(d) Selected Drug.—For purposes of this sec-
22	tion—
23	"(1) IN GENERAL.—The term 'selected drug'
24	means any selected drug (within the meaning of sec-
25	tion 1192 of the Social Security Act) which is manu-

factured or produced in the United States or entered
 into the United States for consumption, use, or
 warehousing.

4 "(2) UNITED STATES.—The term 'United
5 States' has the meaning given such term by section
6 4612(a)(4).

7 "(3) COORDINATION WITH RULES FOR POSSES8 SIONS OF THE UNITED STATES.—Rules similar to
9 the rules of paragraphs (2) and (4) of section
10 4132(c) shall apply for purposes of this section.

"(e) OTHER DEFINITIONS.—For purposes of this
section, the terms 'selected drug publication date' and
'maximum fair price' have the meaning given such terms
in section 1191 of the Social Security Act.

"(f) ANTI-ABUSE RULE.—In the case of a sale which
was timed for the purpose of avoiding the tax imposed by
this section, the Secretary may treat such sale as occurring during a day described in subsection (b).".

(b) NO DEDUCTION FOR EXCISE TAX PAYMENTS.—
20 Section 275 of the Internal Revenue Code of 1986 is
21 amended by adding "or by section 4192" before the period
22 at the end of subsection (a)(6).

23 (c) Conforming Amendments.—

1	(1) Section 4221(a) of the Internal Revenue
2	Code of 1986 is amended by inserting "or 4192"
3	after "section 4191".
4	(2) Section $6416(b)(2)$ of such Code is amend-
5	ed by inserting "or 4192" after "section 4191".
6	(d) Clerical Amendments.—
7	(1) The heading of subchapter E of chapter 32
8	of the Internal Revenue Code of 1986 is amended by
9	striking " Medical Devices " and inserting
10	"Other Medical Products".
11	(2) The table of subchapters for chapter 32 of
12	such Code is amended by striking the item relating
13	to subchapter E and inserting the following new
14	item:
	"SUBCHAPTER E. OTHER MEDICAL PRODUCTS".
15	(3) The table of sections for subchapter E of
16	chapter 32 of such Code is amended by adding at
16 17	chapter 32 of such Code is amended by adding at the end the following new item:
	the end the following new item:
17	the end the following new item: "Sec. 4192. Selected drugs during noncompliance periods.".
17 18	the end the following new item:"Sec. 4192. Selected drugs during noncompliance periods.".(e) EFFECTIVE DATE.—The amendments made by
17 18 19	 the end the following new item: "Sec. 4192. Selected drugs during noncompliance periods.". (e) EFFECTIVE DATE.—The amendments made by this section shall apply to sales after the date of the enact-
17 18 19 20	 the end the following new item: "Sec. 4192. Selected drugs during noncompliance periods.". (e) EFFECTIVE DATE.—The amendments made by this section shall apply to sales after the date of the enactment of this Act.
17 18 19 20 21	 the end the following new item: "Sec. 4192. Selected drugs during noncompliance periods.". (e) EFFECTIVE DATE.—The amendments made by this section shall apply to sales after the date of the enactment of this Act. SEC. 303. FAIR PRICE NEGOTIATION IMPLEMENTATION
 17 18 19 20 21 22 	the end the following new item: "Sec. 4192. Selected drugs during noncompliance periods.". (e) EFFECTIVE DATE.—The amendments made by this section shall apply to sales after the date of the enact- ment of this Act. SEC. 303. FAIR PRICE NEGOTIATION IMPLEMENTATION FUND.

this section as the "Fund"). The Secretary of Health and
 Human Services may obligate and expend amounts in the
 Fund to carry out this title (and the amendments made
 by such title).

5 (b) FUNDING.—There is authorized to be appro6 priated, and there is hereby appropriated, out of any mon7 ies in the Treasury not otherwise appropriated, to the
8 Fund \$3,000,000,000, to remain available until expended,
9 of which—

10 (1) \$600,000,000 shall become available on the
11 date of the enactment of this Act;

12 (2) \$600,000,000 shall become available on Oc13 tober 1, 2020;

14 (3) \$600,000,000 shall become available on Oc15 tober 1, 2021;

16 (4) \$600,000,000 shall become available on Oc17 tober 1, 2022; and

18 (5) \$600,000,000 shall become available on Oc19 tober 1, 2023.

(c) SUPPLEMENT NOT SUPPLANT.—Any amounts
appropriated pursuant to this section shall be in addition
to any other amounts otherwise appropriated pursuant to
any other provision of law.

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