

AMENDMENT NO.III Calendar No.III Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—117th Cong., 1st Sess. **H. R. 5376**

To provide for reconciliation pursuant to title II of S.
Con. Res. 14.

Referred to the Committee on IIIIIIIII and ordered to be
printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to
be proposed by IIIIIII

Viz:

1 Strike all after the enacting clause and insert the fol 2
lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Inflation Reduction 5 Act
of 2022”.

6 **TITLE I—COMMITTEE ON** 7
FINANCE

8 **Subtitle A—Deficit Reduction** 9 SEC. 10001.

AMENDMENT OF 1986 CODE.

10 Except as otherwise expressly provided, whenever in
11 this subtitle an amendment or repeal is expressed in
terms 12 of an amendment to, or repeal of, a section or

other provi-

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1 sion, the reference shall be considered to be made to
a 2 section or other provision of the Internal Revenue
Code 3 of 1986.

4 **PART 1—CORPORATE TAX REFORM** 5 SEC. 10101.

CORPORATE ALTERNATIVE MINIMUM TAX. 6 (a) IMPOSITION OF
TAX.—

7 (1) IN GENERAL.—Paragraph (2) of section 8 55(b) is
amended to read as follows:

9 “(2) CORPORATIONS.—

10 “(A) APPLICABLE CORPORATIONS.—In the 11 case of an
applicable corporation, the tentative 12 minimum tax for
the taxable year shall be the 13 excess of—

14 “(i) 15 percent of the adjusted finan 15 cial statement
income for the taxable year 16 (as determined under
section 56A), over 17 “(ii) the corporate AMT foreign tax
18 credit for the taxable year.

19 “(B) OTHER CORPORATIONS.—In the case 20 of any
corporation which is not an applicable 21 corporation, the
tentative minimum tax for the 22 taxable year shall be
zero.”.

23 (2) APPLICABLE CORPORATION.—Section 59 is 24
amended by adding at the end the following new 25
subsection:

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1 “(k) APPLICABLE CORPORATION.—For purposes of 2 this part—

3 “(1) APPLICABLE CORPORATION DEFINED.— 4 “(A) IN GENERAL.—The term ‘applicable 5 corporation’ means, with respect to any taxable 6 year, any corporation (other than an S corpora 7 tion, a regulated investment company, or a real 8 estate investment trust) which meets the aver 9 age annual adjusted financial statement income

10 test of subparagraph (B) for one or more tax 11 able years which—

12 “(i) are prior to such taxable year, 13 and

14 “(ii) end after December 31, 2021. 15 “(B) AVERAGE

ANNUAL ADJUSTED FINAN 16 CIAL STATEMENT INCOME

TEST.—For purposes 17 of this subsection—

18 “(i) a corporation meets the average 19 annual adjusted financial statement income 20 test for a taxable year if the average an 21 nual adjusted financial statement income 22 of such corporation for the 3-taxable-year 23 period ending with such taxable year ex 24 ceeds \$1,000,000,000, and

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1 “(ii) in the case of a corporation de 2 scribed in paragraph (2), such corporation 3 meets the average annual adjusted finan 4 cial statement income test for a taxable 5 year if—

6 “(I) the corporation meets the re 7 quirements of clause
(i) for such tax 8 able year (determined after the appli 9
cation of paragraph (2)), and

10 “(II) the average annual adjusted 11 financial
statement income of such 12 corporation (determined
without re 13 gard to the application of paragraph 14 (2))
for the 3-taxable-year-period end 15 ing with such taxable
year is 16 \$100,000,000 or more.

17 “(C) EXCEPTION.—Notwithstanding sub 18 paragraph
(A), the term ‘applicable corporation’ 19 shall not include
any corporation which other 20 wise meets the
requirements of subparagraph 21 (A) if—

22 “(i) such corporation— 23 “(I) has a change in
ownership, 24 or

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1 “(II) has a specified number (to 2 be determined by the
Secretary and 3 which shall, as appropriate, take into 4
account the facts and circumstances 5 of the taxpayer)
of consecutive taxable 6 years, including the most recent
tax 7 able year, in which the corporation 8 does not meet
the average annual ad 9 justed financial statement
income test

10 of subparagraph (B), and 11 “(ii) the Secretary
determines that it 12 would not be appropriate to continue
to 13 treat such corporation as an applicable cor 14
poration.

15 The preceding sentence shall not apply to any 16
corporation if, after the Secretary makes the 17
determination described in clause (ii), such cor 18 poration
meets the average annual adjusted fi 19 nancial statement
income test of subparagraph 20 (B) for any taxable year
beginning after the 21 first taxable year for which such
determination 22 applies.

23 “(D) SPECIAL RULES FOR DETERMINING 24 APPLICABLE
CORPORATION STATUS.—Solely for 25 purposes of
determining whether a corporation

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1 is an applicable corporation under paragraph 2 (1), all
adjusted financial statement income of 3 persons treated
as a single employer with such 4 corporation under
subsection (a) or (b) of sec 5 tion 52 shall be treated as
adjusted financial 6 statement of income of such
corporation, and 7 adjusted financial statement income of
such 8 corporation shall be determined without regard 9 to
paragraphs (2)(D)(i) and (11) of section 10 56A(c).

11 “(E) OTHER SPECIAL RULES.— 12 “(i) CORPORATIONS IN
EXISTENCE 13 FOR LESS THAN 3 YEARS.—If the corpora 14
tion was in existence for less than 3-tax 15 able years,
subparagraph (B) shall be ap 16 plied on the basis of the
period during 17 which such corporation was in existence.

18 “(ii) SHORT TAXABLE YEARS.—Ad 19 justed financial
statement income for any 20 taxable year of less than 12

months shall be annualized by multiplying the adjusted financial statement income for the short period by 12 and dividing the result by the number of months in the short period.

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“(iii) TREATMENT OF PREDECESSORS.—Any reference in this subparagraph to a corporation shall include a reference to any predecessor of such corporation.

“(2) SPECIAL RULE FOR FOREIGN-PARENTED CORPORATIONS.—

“(A) IN GENERAL.—Solely for purposes of determining whether a corporation meets the average annual adjusted financial statement income test under paragraph (1)(B)(ii)(I), in the case of any corporation which for any taxable year is a member of an international financial reporting group the common parent of which is a foreign corporation, such corporation shall include in the adjusted financial statement income of such corporation for such taxable year the adjusted financial statement income of all foreign members of such group. Solely for purposes of this subparagraph, adjusted financial statement income shall be determined without regard to paragraphs (2)(D)(i), (3), (4), and (11) of section 56A(c).

“(B) INTERNATIONAL FINANCIAL REPORTING GROUP.—For purposes of subparagraph

1 (A), the term ‘international financial reporting 2 group’ shall have the meaning given such term 3 by section 163(n)(3).

4 “(C) COMMON PARENT.—For purposes of 5 subparagraph (A), the term ‘common parent’ 6 has the meaning given such term under section 7 163(n)(5).

8 “(3) REGULATIONS OR OTHER GUIDANCE.— 9 The Secretary shall provide regulations or other 10 guidance for the purposes of carrying out this sub

11 section, including regulations or other guidance— 12

“(A) providing a simplified method for de 13 termining whether a corporation meets the re 14 quirements of paragraph (1), and 15 “(B) addressing the application of this 16 subsection to a corporation that experiences a 17 change in ownership.”.

18 (3) REDUCTION FOR BASE EROSION AND ANTI 19 ABUSE TAX.—Section 55(a)(2) is amended by insert 20 ing “plus, in the case of an applicable corporation, 21 the tax imposed by section 59A” before the period 22 at the end.

23 (4) CONFORMING AMENDMENTS.—

1 (A) Section 55(a) is amended by striking 2 “In the case of a taxpayer other than a cor 3 poration, there” and inserting “There”. 4 (B)(i) Section 55(b)(1) is amended— 5 (l) by striking so much as precedes 6 subparagraph (A)

and inserting the following:

“(1) NONCORPORATE TAXPAYERS.—In the case of a taxpayer other than a corporation—”, and (II) by adding at the end the following new subparagraph:

“(D) ALTERNATIVE MINIMUM TAXABLE INCOME.—The term ‘alternative minimum taxable income’ means the taxable income of the taxpayer for the taxable year—

“(i) determined with the adjustments provided in section 56 and section 58, and “(ii) increased by the amount of the items of tax preference described in section 57.

If a taxpayer is subject to the regular tax, such taxpayer shall be subject to the tax imposed by this section (and, if the regular tax is determined by reference to an amount other than taxable income, such amount shall be treated as

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the taxable income of such taxpayer for purposes of the preceding sentence).” (ii) Section 860E(a)(4) is amended by striking “55(b)(2)” and inserting “55(b)(1)(D)”.

(iii) Section 897(a)(2)(A)(i) is amended by striking “55(b)(2)” and inserting “55(b)(1)(D)”.

(C) Section 11(d) is amended by striking “the tax imposed by subsection (a)” and inserting “the taxes imposed by subsection (a) and section 55”.

13 (D) Section 12 is amended by adding at 14 the end the following new paragraph: 15 “(5) For alternative minimum tax, see section 16 55.”.

17 (E) Section 882(a)(1) is amended by in 18 serting “, 55,” after “section 11”. 19 (F) Section 6425(c)(1)(A) is amended to 20 read as follows:

21 “(A) the sum of—

22 “(i) the tax imposed by section 11 or 23 subchapter L of chapter 1, whichever is 24 applicable, plus

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1 “(ii) the tax imposed by section 55, 2 plus

3 “(iii) the tax imposed by section 59A, 4 over”.

5 (G) Section 6655(e)(2) is amended by in 6 serting “, adjusted financial statement income 7 (as defined in section 56A),” before “and modi 8 fied taxable income” each place it appears in 9 subparagraphs (A)(i) and (B)(i).

10 (H) Section 6655(g)(1)(A) is amended by 11 redesignating clauses (ii) and (iii) as clauses 12 (iii) and (iv), respectively, and by inserting 13 after clause (i) the following new clause:

14 “(ii) the tax imposed by section 55,”. 15 (b) ADJUSTED FINANCIAL STATEMENT INCOME.— 16 (1) IN GENERAL.—Part VI of subchapter A of 17 chapter 1 is amended by inserting after section 56 18 the following new section:

19 “SEC. 56A. ADJUSTED FINANCIAL STATEMENT INCOME. 20 “(a) IN

GENERAL.—For purposes of this part, the 21 term
'adjusted financial statement income' means, with re 22
spect to any corporation for any taxable year, the net in 23
come or loss of the taxpayer set forth on the taxpayer's 24
applicable financial statement for such taxable year, ad 25
justed as provided in this section.

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1 "(b) APPLICABLE FINANCIAL STATEMENT.—For 2 purposes
of this section, the term 'applicable financial 3 statement'
means, with respect to any taxable year, an ap 4 plicable
financial statement (as defined in section 5 451(b)(3) or
as specified by the Secretary in regulations 6 or other
guidance) which covers such taxable year.

7 "(c) GENERAL ADJUSTMENTS.—

8 "(1) STATEMENTS COVERING DIFFERENT TAX 9 ABLE
YEARS.—Appropriate adjustments shall be 10 made in
adjusted financial statement income in any
11 case in which an applicable financial statement cov 12
ers a period other than the taxable year. 13 "(2) SPECIAL
RULES FOR RELATED ENTI 14 TIES.—

15 "(A) CONSOLIDATED FINANCIAL STATE 16 MENTS.—If the
financial results of a taxpayer 17 are reported on the
applicable financial state 18 ment for a group of entities,
rules similar to the 19 rules of section 451(b)(5) shall
apply.

20 "(B) CONSOLIDATED RETURNS.—Except 21 as provided in

regulations prescribed by the 22 Secretary, if the taxpayer is part of an affili 23 ated group of corporations filing a consolidated 24 return for any taxable year, adjusted financial 25 statement income for such group for such tax-

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1 able year shall take into account items on the 2 group's applicable financial statement which are 3 properly allocable to members of such group. 4 “(C) TREATMENT OF DIVIDENDS AND 5 OTHER AMOUNTS.—In the case of any corpora 6 tion which is not included on a consolidated re 7 turn with the taxpayer, adjusted financial state 8 ment income of the taxpayer with respect to 9 such other corporation shall be determined by

10 only taking into account the dividends received 11 from such other corporation (reduced to the ex 12 tent provided by the Secretary in regulations or 13 other guidance) and other amounts which are 14 includible in gross income or deductible as a 15 loss under this chapter (other than amounts re 16 quired to be included under sections 951 and 17 951A or such other amounts as provided by the 18 Secretary) with respect to such other corpora 19 tion.

20 “(D) TREATMENT OF PARTNERSHIPS.— 21 “(i) IN GENERAL.—Except as pro 22 vided by the Secretary, if the taxpayer is 23 a partner in a partnership, adjusted finan 24 cial statement income of the taxpayer shall 25 be adjusted to only take into account the

1 taxpayer's distributive share of adjusted fi 2 nancial
statement income of such partner 3 ship.

4 “(ii) ADJUSTED FINANCIAL STATE 5 MENT INCOME OF
PARTNERSHIPS.—For 6 the purposes of this part, the
adjusted fi 7 nancial statement income of a partnership 8
shall be the partnership's net income or 9 loss set forth
on such partnership's appli

10 cable financial statement (adjusted under 11 rules
similar to the rules of this section). 12 “(3) ADJUSTMENTS
TO TAKE INTO ACCOUNT 13 CERTAIN ITEMS OF FOREIGN
INCOME.—

14 “(A) IN GENERAL.—If, for any taxable 15 year, a taxpayer
is a United States shareholder 16 of one or more
controlled foreign corporations, 17 the adjusted financial
statement income of such 18 taxpayer shall be adjusted to
take into account 19 such taxpayer's pro rata share
(determined 20 under rules similar to the rules under
section 21 951(a)(2)) of items taken into account in com
22 puting the net income or loss set forth on the 23
applicable financial statement (as adjusted 24 under rules
similar to those that apply in deter 25 mining adjusted
financial statement income) of

1 each such controlled foreign corporation with 2 respect
to which such taxpayer is a United 3 States shareholder.

4 “(B) NEGATIVE ADJUSTMENTS.—In any 5 case in which
the adjustment determined under 6 subparagraph (A)
would result in a negative ad 7 justment for such taxable
year—

8 “(i) no adjustment shall be made 9 under this
paragraph for such taxable 10 year, and

11 “(ii) the amount of the adjustment 12 determined under
this paragraph for the 13 succeeding taxable year
(determined with 14 out regard to this paragraph) shall be
re 15 duced by an amount equal to the negative 16
adjustment for such taxable year.

17 “(4) EFFECTIVELY CONNECTED INCOME.—In 18 the case of
a foreign corporation, to determine ad 19 justed financial
statement income, the principles of 20 section 882 shall
apply.

21 “(5) ADJUSTMENTS FOR CERTAIN TAXES.—Ad 22 justed
financial statement income shall be appro 23 priately
adjusted to disregard any Federal income 24 taxes, or
income, war profits, or excess profits taxes 25 (within the
meaning of section 901) with respect to

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1 a foreign country or possession of the United States, 2
which are taken into account on the taxpayer’s ap 3
plicable financial statement. To the extent provided 4 by
the Secretary, the preceding sentence shall not 5 apply
to income, war profits, or excess profits taxes 6 (within

the meaning of section 901) that are imposed by a foreign country or possession of the United States and taken into account on the taxpayer's applicable financial statement if the taxpayer

does not choose to have the benefits of subpart A of part III of subchapter N for the taxable year. The Secretary shall prescribe such regulations or other guidance as may be necessary and appropriate to provide for the proper treatment of current and deferred taxes for purposes of this paragraph, including the time at which such taxes are properly taken into account.

“(6) ADJUSTMENT WITH RESPECT TO DISREGARDED ENTITIES.—Adjusted financial statement income shall be adjusted to take into account any adjusted financial statement income of a disregarded entity owned by the taxpayer.

“(7) SPECIAL RULE FOR COOPERATIVES.—In the case of a cooperative to which section 1381 applies, the adjusted financial statement income (deter-

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mined without regard to this paragraph) shall be reduced by the amounts referred to in section 1382(b) (relating to patronage dividends and per-unit retained allocations) to the extent such amounts were not otherwise taken into account in determining adjusted

financial statement income.

7 “(8) RULES FOR ALASKA NATIVE CORPORA 8
TIONS.—Adjusted financial statement income shall 9 be
appropriately adjusted to allow—

10 “(A) cost recovery and depletion attrib 11 utable to
property the basis of which is deter 12 mined under
section 21(c) of the Alaska Native 13 Claims Settlement
Act (43 U.S.C. 1620(c)), 14 and

15 “(B) deductions for amounts payable made 16
pursuant to section 7(i) or section 7(j) of such 17 Act (43
U.S.C. 1606(i) and 1606(j)) only at 18 such time as the
deductions are allowed for tax 19 purposes.

20 “(9) AMOUNTS ATTRIBUTABLE TO ELECTIONS 21 FOR DIRECT
PAYMENT OF CERTAIN CREDITS.—Ad 22 justed financial
statement income shall be appro 23 priately adjusted to
disregard any amount treated as 24 a payment against
the tax imposed by subtitle A 25 pursuant to an election
under section 6417, to the

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1 extent such amount was not otherwise taken into ac 2
count under paragraph (5).

3 “(10) CONSISTENT TREATMENT OF MORTGAGE 4 SERVICING
INCOME OF TAXPAYER OTHER THAN A 5 REGULATED

INVESTMENT COMPANY.— 6 “(A) IN GENERAL.—Adjusted
financial 7 statement income shall be adjusted so as not
to 8 include any item of income in connection with 9 a

mortgage servicing contract any earlier than
10 when such income is included in gross income 11
under any other provision of this chapter. 12 “(B) RULES
FOR AMOUNTS NOT REPRESENTING REASONABLE
COMPENSATION.— 14 The Secretary shall provide
regulations to prevent the avoidance of taxes imposed
by this 16 chapter with respect to amounts not representing
reasonable compensation (as determined
by the Secretary) with respect to a mortgage servicing
contract.

20 “(11) ADJUSTMENT WITH RESPECT TO DEFINED BENEFIT
PENSIONS.—

22 “(A) IN GENERAL.—Except as otherwise 23 provided in
rules prescribed by the Secretary in 24 regulations or
other guidance, adjusted financial statement income
shall be—

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1 “(i) adjusted to disregard any amount 2 of income,
cost, or expense that would otherwise be included on
the applicable financial statement in connection with
any covered benefit plan,

6 “(ii) increased by any amount of income in 7
connection with any such covered 8 benefit plan that is
included in the gross 9 income of the corporation under
any other

10 provision of this chapter, and 11 “(iii) reduced by

deductions allowed 12 under any other provision of this chapter 13 with respect to any such covered benefit 14 plan.

15 “(B) COVERED BENEFIT PLAN.—For pur 16 poses of this paragraph, the term ‘covered ben 17 efit plan’ means—

18 “(i) a defined benefit plan (other than 19 a multiemployer plan described in section 20 414(f)) if the trust which is part of such 21 plan is an employees’ trust described in 22 section 401(a) which is exempt from tax 23 under section 501(a),

24 “(ii) any qualified foreign plan (as de 25 fined in section 404A(e)), or

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1 “(iii) any other defined benefit plan 2 which provides post-employment benefits 3 other than pension benefits.

4 “(12) TAX-EXEMPT ENTITIES.—In the case of 5 an organization subject to tax under section 511, ad 6 justed financial statement income shall be appro 7 priately adjusted to only take into account any ad 8 justed financial statement income—

9 “(A) of an unrelated trade or business (as 10 defined in section 513) of such organization, or 11 “(B) derived from debt-financed property 12 (as defined in section 514) to the extent that 13 income from such property is treated as unre 14 lated business taxable income.

15 “(13) SECRETARIAL AUTHORITY TO ADJUST 16 ITEMS.—The

Secretary shall issue regulations or 17 other guidance to provide for such adjustments to 18 adjusted financial statement income as the Secretary 19 determines necessary to carry out the purposes of 20 this section, including adjustments—

21 “(A) to prevent the omission or duplication 22 of any item, and

23 “(B) to carry out the principles of part II 24 of subchapter C of this chapter (relating to cor 25 porate liquidations), part III of subchapter C of

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1 this chapter (relating to corporate organizations 2 and reorganizations), and part II of subchapter 3 K of this chapter (relating to partnership con 4 tributions and distributions).

5 “(d) DEDUCTION FOR FINANCIAL STATEMENT NET 6 OPERATING LOSS.—

7 “(1) IN GENERAL.—Adjusted financial state 8 ment income (determined after application of sub 9 section (c) and without regard to this subsection)

10 shall be reduced by an amount equal to the lesser 11 of—

12 “(A) the aggregate amount of financial 13 statement net operating loss carryovers to the 14 taxable year, or

15 “(B) 80 percent of adjusted financial 16 statement income computed without regard to 17 the deduction

allowable under this subsection. 18 “(2) FINANCIAL STATEMENT NET OPERATING 19 LOSS CARRYOVER.—A financial statement net operating loss for any taxable year shall be a financial 21 statement net operating loss carryover to each tax 22 able year following the taxable year of the loss. The 23 portion of such loss which shall be carried to subsequent taxable years shall be the amount of such loss

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1 remaining (if any) after the application of paragraph 2 (1).

3 “(3) FINANCIAL STATEMENT NET OPERATING 4 LOSS DEFINED.—For purposes of this subsection, 5 the term ‘financial statement net operating loss’ 6 means the amount of the net loss (if any) set forth 7 on the corporation’s applicable financial statement 8 (determined after application of subsection (c) and 9 without regard to this subsection) for taxable years 10 ending after December 31, 2019.

11 “(e) REGULATIONS AND OTHER GUIDANCE.—The 12 Secretary shall provide for such regulations and other 13 guidance as necessary to carry out the purposes of this 14 section, including regulations and other guidance relating 15 to the effect of the rules of this section on partnerships 16 with income taken into account by an applicable corporation 17 tion.”.

18 (2) CLERICAL AMENDMENT.—The table of sec 19 tions for
part VI of subchapter A of chapter 1 is 20 amended by
inserting after the item relating to sec 21 tion 56 the
following new item:

“Sec. 56A. Adjusted financial statement income.”.

22 (c) CORPORATE AMT FOREIGN TAX CREDIT.—Sec 23 tion
59, as amended by this section, is amended by adding 24
at the end the following new subsection:

25 “(l) CORPORATE AMT FOREIGN TAX CREDIT.—

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1 “(1) IN GENERAL.—For purposes of this part, 2 if an
applicable corporation chooses to have the ben 3 efits of
subpart A of part III of subchapter N for 4 any taxable
year, the corporate AMT foreign tax 5 credit for the
taxable year of the applicable corpora 6 tion is an
amount equal to sum of—

7 “(A) the lesser of—

8 “(i) the aggregate of the applicable 9 corporation’s pro
rata share (as deter 10 mined under section 56A(c)(3)) of
the

11 amount of income, war profits, and excess 12 profits
taxes (within the meaning of sec 13 tion 901) imposed by
any foreign country 14 or possession of the United States
which 15 are—

16 “(l) taken into account on the 17 applicable financial
statement of each 18 controlled foreign corporation with re

19 spect to which the applicable corpora 20 tion is a
United States shareholder, 21 and

22 “(II) paid or accrued (for Fed 23 eral income tax
purposes) by each 24 such controlled foreign corporation,
or

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1 “(ii) the product of the amount of the 2 adjustment
under section 56A(c)(3) and 3 the percentage specified
in section 4 55(b)(2)(A)(i), and

5 “(B) in the case of an applicable corpora 6 tion that is a
domestic corporation, the amount 7 of income, war
profits, and excess profits taxes 8 (within the meaning of
section 901) imposed by 9 any foreign country or
possession of the United

10 States to the extent such taxes are— 11 “(i) taken into
account on the applica 12 ble corporation’s applicable
financial state 13 ment, and

14 “(ii) paid or accrued (for Federal in 15 come tax
purposes) by the applicable cor 16 poration.

17 “(2) CARRYOVER OF EXCESS TAX PAID.—For 18 any
taxable year for which an applicable corporation 19
chooses to have the benefits of subpart A of part III 20 of
subchapter N, the excess of the amount described 21 in
paragraph (1)(A)(i) over the amount described in 22
paragraph (1)(A)(ii) shall increase the amount de 23
scribed in paragraph (1)(A)(i) in any of the first 5 24

succeeding taxable years to the extent not taken into 25 account in a prior taxable year.

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1 “(3) REGULATIONS OR OTHER GUIDANCE.— 2 The Secretary shall provide for such regulations or 3 other guidance as is necessary to carry out the pur 4 poses of this subsection.”.

5 (d) TREATMENT OF GENERAL BUSINESS CREDIT.— 6

Section 38(c)(6)(E) is amended to read as follows: 7 “(E)

CORPORATIONS.—In the case of a 8 corporation—

9 “(i) the first sentence of paragraph 10 (1) shall be applied by substituting ‘25 11 percent of the taxpayer’s net income tax as 12 exceeds \$25,000’ for ‘the greater of’ and 13 all that follows,

14 “(ii) paragraph (2)(A) shall be applied 15 without regard to clause (ii)(I) thereof, 16 and

17 “(iii) paragraph (4)(A) shall be ap 18 plied without regard to clause (ii)(I) there 19 of.”.

20 (e) CREDIT FOR PRIOR YEAR MINIMUM TAX LIABIL 21 ITY.—

22 (1) IN GENERAL.—Section 53(e) is amended to 23 read as follows:

24 “(e) APPLICATION TO APPLICABLE CORPORA 25 TIONS.—In the case of a corporation—

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1 “(1) subsection (b)(1) shall be applied by sub 2 stituting ‘the net minimum tax for all prior taxable 3 years

beginning after 2022’ for ‘the adjusted net 4 minimum tax imposed for all prior taxable years be 5 ginning after 1986’, and

6 “(2) the amount determined under subsection 7 (c)(1) shall be increased by the amount of tax im 8 posed under section 59A for the taxable year.”. 9 (2) CONFORMING AMENDMENTS.—Section 10 53(d) is amended—

11 (A) in paragraph (2), by striking “, except 12 that in the case” and all that follows through 13 “treated as zero”, and

14 (B) by striking paragraph (3). 15 (f) EFFECTIVE DATE.—The amendments made by 16 this section shall apply to taxable years beginning after 17 December 31, 2022.

18 **PART 2—CLOSING THE CARRIED INTEREST** 19 **LOOPHOLE**

20 **SEC. 10201. MODIFICATION OF RULES FOR PARTNERSHIP** 21
INTERESTS HELD IN CONNECTION WITH THE 22 **PERFORMANCE OF**
SERVICES.

23 (a) **IN GENERAL.**—Section 1061 is amended by strik 24
ing subsections (a) and (b) and inserting the following
new 25 subsections:

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1 “(a) **IN GENERAL.**—If one or more applicable part 2
nership interests are held by a taxpayer at any time
during 3 the taxable year, the taxpayer’s net applicable

partnership 4 gain for such taxable year shall be treated
as short-term 5 capital gain.

6 “(b) NET APPLICABLE PARTNERSHIP GAIN.—For 7
purposes of this section—

8 “(1) IN GENERAL.—The term ‘net applicable 9
partnership gain’ means—

10 “(A) the taxpayer’s net long-term capital 11 gain
determined by only taking into account 12 gains and
losses with respect to one or more ap 13 plicable
partnership interests described in sub 14 section (a), and

15 “(B) any other amounts which are— 16 “(i) includible in
the gross income of 17 the taxpayer with respect to one or
more 18 such applicable partnership interests, and 19 “(ii)
treated as capital gain or subject 20 to tax at the rate
applicable to capital 21 gain.

22 “(2) HOLDING PERIOD EXCEPTION.— 23 “(A) IN
GENERAL.—Net applicable part 24 nership gain shall be
determined without regard

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1 to any amount which is realized after the date 2 that is
5 years after the latest of:

3 “(i) The date on which the taxpayer 4 acquired
substantially all of the applicable 5 partnership interest
with respect to which 6 the amount is realized.

7 “(ii) The date on which the partner 8 ship in which such
applicable partnership 9 interest is held acquired

substantially all of

10 the assets held by such partnership. 11 “(iii) If the
partnership described in 12 clause (i) owns, directly or
indirectly, inter 13 ests in one or more other partnerships,
the 14 dates determined by applying rules similar 15 to the
rules in clauses (i) and (ii) in the 16 case of each such
other partnership. 17 “(B) SHORTER HOLDING PERIOD IN CER
18 TAIN CIRCUMSTANCES.—Subparagraph (A) 19 shall be
applied by substituting ‘3 years’ for ‘5 20 years’ in the case
of—

21 “(i) a taxpayer (other than a trust or 22 estate) with an
adjusted gross income (de 23 termined without regard to
sections 911, 24 931 and 933) of less than \$400,000, and

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1 “(ii) any income with respect to any 2 applicable
partnership interest that is at 3 tributable to a real
property trade or busi 4 ness within the meaning of
section 5 469(c)(7)(C).

6 “(iii) The Secretary is directed to pro 7 vide guidance
regarding determination of 8 the amount described in
subsection (a) as 9 applied in paragraph (1) hereof, and
any

10 necessary and appropriate reporting by any 11
partnership to carry out the purposes of 12 this section. —

13 “(3) SECTION 83 TO NOT APPLY.—This section 14 shall be
applied without regard to section 83 and 15 any election in

effect under section 83(b). 16 “(4) SPECIAL RULE.—To the extent provided 17 by the Secretary, subsection (a) shall not apply to 18 income or gain attributable to any asset not held for 19 portfolio investment on behalf of third party inves 20 tors.”.

21 (b) MODIFICATIONS RELATED TO DEFINITION OF 22 APPLICABLE PARTNERSHIP INTEREST.—Section 1061(c) 23 is amended—

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1 (1) in paragraph (1), by striking “to such other 2 entity” and inserting “with respect to a trade or 3 business that is not an applicable trade or business”, 4 (2) in paragraph (3), by striking “an interest in 5 a partnership to the extent of the partnership’s pro 6 portionate interest in any of the foregoing” and in 7 serting “except as otherwise provided by the Sec 8 retary, an interest in a partnership if such partner 9 ship has a direct or indirect interest in any of the 10 foregoing”, and

11 (3) in paragraph (4)—

12 (A) by striking “The term” and inserting 13 “Except as otherwise provided by the Secretary, 14 the term”, and

15 (B) in subparagraph (A), by striking “cor 16 poration” and inserting “C corporation”. 17 (c) RECOGNITION OF GAIN ON TRANSFERS OF AP 18 PLICABLE PARTNERSHIP INTERESTS TO UNRELATED 19 PARTIES.—Section 1061(d) is amended to read as follows: 20 “(d) TRANSFER OF APPLICABLE

PARTNERSHIP IN 21 TEREST.—If a taxpayer transfers any applicable partner 22 ship interest, gain shall be recognized notwithstanding any 23 other provision of this subtitle.”.

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1 (d) REGULATIONS.—Section 1061(e) is amended by 2 striking the period at the end and inserting the following:
3 “, including regulations or other guidance to— 4 “(1) to prevent the avoidance of the purposes of 5 this section, including through the distribution of 6 property by a partnership and through carry waiv 7 ers, and
8 “(2) to provide for the application of this sec 9 tion to financial instruments, contracts or interests 10 in entities other than partnerships to the extent nec 11 essary or appropriate to carry out the purposes of 12 this section.”.

13 (e) EFFECTIVE DATE.—The amendments made by 14 this section shall apply to taxable years beginning after 15 December 31, 2022.

16 **PART 3—FUNDING THE INTERNAL REVENUE 17 SERVICE** **AND IMPROVING TAXPAYER COM 18 PLIANCE**

19 **SEC. 10301. ENHANCEMENT OF INTERNAL REVENUE SERV 20 ICE**
RESOURCES.

21 (a) APPROPRIATIONS.—

22 (1) IN GENERAL.—The following sums are ap 23 propriated, out of any money in the Treasury not 24 otherwise appropriated, for the fiscal year ending 25

September 30, 2022:

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1 (A) INTERNAL REVENUE SERVICE.— 2 (i) IN
GENERAL.—

3 (I) TAXPAYER SERVICES.—For 4 necessary expenses of
the Internal 5 Revenue Service to provide taxpayer 6
services, including pre-filing assistance 7 and education,
filing and account 8 services, taxpayer advocacy
services, 9 and other services as authorized by 5
10 U.S.C. 3109, at such rates as may be 11 determined
by the Commissioner, 12 \$3,181,500,000, to remain
available 13 until September 30, 2031: *Provided*, 14 That
these amounts shall be in addi 15 tion to amounts
otherwise available 16 for such purposes.

17 (II) ENFORCEMENT.—For nec 18 essary expenses for
tax enforcement 19 activities of the Internal Revenue 20
Service to determine and collect owed 21 taxes, to
provide legal and litigation 22 support, to conduct criminal
investiga 23 tions (including investigative tech 24 nology),
to provide digital asset moni 25 toring and compliance
activities, to

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1 enforce criminal statutes related to 2 violations of
internal revenue laws and 3 other financial crimes, to
purchase 4 and hire passenger motor vehicles (31 5
U.S.C. 1343(b)), and to provide other 6 services as

authorized by 5 U.S.C. 7 3109, at such rates as may be
deter 8 mined by the Commissioner, 9 \$45,637,400,000,
to remain available

10 until September 30, 2031: *Provided*, 11 That these
amounts shall be in addi 12 tion to amounts otherwise
available 13 for such purposes.

14 (III) OPERATIONS SUPPORT.— 15 For necessary
expenses of the Inter 16 nal Revenue Service to support
tax 17 payer services and enforcement pro 18 grams,
including rent payments; fa 19 cilities services; printing;
postage; 20 physical security; headquarters and 21 other
IRS-wide administration activi 22 ties; research and
statistics of income; 23 telecommunications; information
tech 24 nology development, enhancement, op 25
erations, maintenance, and security;

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1 the hire of passenger motor vehicles 2 (31 U.S.C.
1343(b)); the operations of 3 the Internal Revenue
Service Over 4 sight Board; and other services as au 5
thorized by 5 U.S.C. 3109, at such 6 rates as may be
determined by the 7 Commissioner, \$25,326,400,000, to
8 remain available until September 30, 9 2031: *Provided*,
That these amounts

10 shall be in addition to amounts other 11 wise available
for such purposes. 12 (IV) BUSINESS SYSTEMS MOD 13
ERNIZATION.—For necessary expenses 14 of the Internal

Revenue Service's 15 business systems modernization program, including development of call back technology and other technology 18 to provide a more personalized customer service but not including the 20 operation and maintenance of legacy 21 systems, \$4,750,700,000, to remain 22 available until September 30, 2031: 23 *Provided*, That these amounts shall be 24 in addition to amounts otherwise 25 available for such purposes.

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1 (ii) TASK FORCE TO DESIGN AN IRS 2 RUN FREE "DIRECT EFILE" TAX RETURN 3 SYSTEM.—For necessary expenses of the 4 Internal Revenue Service to deliver to Congress, within nine months following the 6 date of the enactment of this Act, a report 7 on (I) the cost (including options for differential coverage based on taxpayer adjusted gross income and return complexity) 10 of developing and running a free direct 11 efile tax return system, including costs to 12 build and administer each release, with a 13 focus on multi-lingual and mobile-friendly 14 features and safeguards for taxpayer data; 15 (II) taxpayer opinions, expectations, and 16 level of trust, based on surveys, for such a 17 free direct efile system; and (III) the opinions 18 of an independent third-party on the 19 overall feasibility, approach, schedule, cost, 20 organizational design, and Internal Rev

21 enue Service capacity to deliver such a di 22 rect efile
tax return system, \$15,000,000, 23 to remain available
until September 30, 24 2023: *Provided*, That these
amounts shall

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1 be in addition to amounts otherwise avail 2 able for
such purposes.

3 (B) TREASURY INSPECTOR GENERAL FOR 4 TAX
ADMINISTRATION.—For necessary expenses 5 of the
Treasury Inspector General for Tax Ad 6 ministration in
carrying out the Inspector Gen 7 eral Act of 1978, as
amended, including pur 8 chase and hire of passenger
motor vehicles (31 9 U.S.C. 1343(b)); and services
authorized by 5

10 U.S.C. 3109, at such rates as may be deter 11 mined
by the Inspector General for Tax Admin 12 istration,
\$403,000,000, to remain available 13 until September 30,
2031: *Provided*, That these 14 amounts shall be in
addition to amounts other 15 wise available for such
purposes.

16 (C) OFFICE OF TAX POLICY.—For nec 17 essary
expenses of the Office of Tax Policy of 18 the Department
of the Treasury to carry out 19 functions related to
promulgating regulations 20 under the Internal Revenue
Code of 1986, 21 \$104,533,803, to remain available until
Sep 22 tember 30, 2031: *Provided*, That these amounts 23

shall be in addition to amounts otherwise available for such purposes.

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1 (D) UNITED STATES TAX COURT.—For 2 necessary expenses of the United States Tax 3 Court, including contract reporting and other 4 services as authorized by 5 U.S.C. 3109; 5 \$153,000,000, to remain available until Sep 6 tember 30, 2031: *Provided*, That these amounts 7 shall be in addition to amounts otherwise avail 8 able for such purposes.

9 (E) TREASURY DEPARTMENTAL OF 10 FICES.—For necessary expenses of the Depart 11 mental Offices of the Department of the Treas 12 ury to provide for oversight and implementation 13 support for actions by the Internal Revenue 14 Service to implement this Act and the amend 15 ments made by this Act, \$50,000,000, to re 16 main available until September 30, 2031: *Pro 17 vided*, That these amounts shall be in addition 18 to amounts otherwise available for such pur 19 poses.

20 (2) MULTI-YEAR OPERATIONAL PLAN.— 21 (A) IN GENERAL.—Not later than 6 22 months after the date of the enactment of this 23 Act, the Commissioner of Internal Revenue 24 shall submit to Congress a plan detailing how 25 the funds appropriated under paragraph

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1 (1)(A)(i) will be spent over the ten-year period 2 ending

with fiscal year 2031.

3 (B) QUARTERLY UPDATES.— 4 (i) IN GENERAL.—Not later than the 5 last day of each calendar quarter beginning 6 during the applicable period, the Commis 7 sioner of Internal Revenue shall submit to 8 Congress a report on the plan established 9 under subparagraph (A), including—

10 (I) any updates to the plan; 11 (II) progress made in imple 12 menting the plan; and

13 (III) any changes in cir 14 cumstances or challenges in imple 15 menting the plan.

16 (ii) APPLICABLE PERIOD.—For pur 17 poses of clause (i), the applicable period is 18 the period beginning 1 year after the date 19 the report under subparagraph (A) is due 20 and ending on September 30, 2031.

21 (C) REDUCTION IN APPROPRIATION.— 22 (i) IN GENERAL.—In the case of any 23 failure to submit a plan required under 24 subparagraph (A) or a report required 25 under subparagraph (B) by the required

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1 date, the amounts made available under 2 paragraph (1)(A)(i) shall be reduced by 3 \$100,000 for each day after such required 4 date that report has not been submitted to 5 Congress.

6 (ii) REQUIRED DATE.—For purposes 7 of clause (i), the required date is the date 8 that is 60 days after the date

the plan or report is required to be submitted under
subparagraph (A) or (B), as the case may be.

(3) NO TAX INCREASES ON CERTAIN TAX
PAYERS.—Nothing in this subsection is intended to
increase taxes on any taxpayer with a taxable income
below \$400,000.

(b) PERSONNEL FLEXIBILITIES.—The Secretary of the
Treasury (or the Secretary's delegate) may use the
funds made available under subsection (a)(1)(A), subject
to such policies as the Secretary (or the Secretary's
delegate) may establish, to take such personnel
actions as the Secretary (or the Secretary's delegate)
determines necessary to administer the Internal
Revenue Code of 1986, including—

(1) utilizing direct hire authority to recruit and
appoint qualified applicants, without regard to any

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notice or preference requirements, directly to positions
in the competitive service;

(2) in addition to the authority under section 7812(1)
of the Internal Revenue Code of 1986, appointing not
more than 200 individuals to positions in the Internal
Revenue Service under streamlined critical pay
authority, except that—

(A) the authority to offer streamlined critical pay
under this paragraph shall expire on September 30,

2031; and

11 (B) the positions for which streamlined 12 critical pay is
authorized under this paragraph 13 may include positions
critical to the purposes 14 described in subclauses (I), (II),
and (III) of 15 subsection (a)(1)(A)(i); and

16 (3) appointing not more than 300 individuals to 17
positions in the Internal Revenue Service for 18 which—

19 (A) the rate of basic pay may be estab 20 lished by the
Secretary of the Treasury (or the 21 Secretary's delegate)
at a rate that does not ex 22 ceed the salary set in
accordance with section 23 104 of title 3, United States
Code; and

24 (B) the total annual compensation paid to 25 an
employee in such a position, including allow-

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1 ances, differentials, bonuses, awards, and simi 2 lar
cash payments, may not exceed the max 3 imum
amount of total annual compensation 4 payable at the
salary set in accordance with 5 section 104 of title 3,
United States Code.

6 **Subtitle B—Prescription Drug 7 Pricing** **Reform**

8 **PART 1—LOWERING PRICES THROUGH DRUG 9 PRICE** **NEGOTIATION**

10 **SEC. 11001. PROVIDING FOR LOWER PRICES FOR CERTAIN 11**

HIGH-PRICED SINGLE SOURCE DRUGS. 12 (a) PROGRAM TO LOWER

PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE

DRUGS.—Title XI of the Social Security Act is amended by adding after section 1184 (42 U.S.C. 1320e–3) the following new part: **“PART E—PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS**

“SEC. 1191. ESTABLISHMENT OF PROGRAM.

“(a) IN GENERAL.—The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the ‘program’). Under the program, with respect to each price applicability period, the Secretary shall—

“(1) publish a list of selected drugs in accordance with section 1192;

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“(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1193;

“(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1194;

“(4) carry out the publication and administrative duties and compliance monitoring in accordance with sections 1195 and 1196.

“(b) DEFINITIONS RELATING TO TIMING.—For purposes of this part:

“(1) INITIAL PRICE APPLICABILITY YEAR.—The term

‘initial price applicability year’ means a year 14 (beginning with 2026).

15 “(2) PRICE APPLICABILITY PERIOD.—The term 16 ‘price applicability period’ means, with respect to a 17 qualifying single source drug, the period beginning 18 with the first initial price applicability year with re 19 spect to which such drug is a selected drug and end 20 ing with the last year during which the drug is a se 21 lected drug.

22 “(3) SELECTED DRUG PUBLICATION DATE.— 23 The term ‘selected drug publication date’ means, 24 with respect to each initial price applicability year,

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1 February 1 of the year that begins 2 years prior to 2 such year.

3 “(4) NEGOTIATION PERIOD.—The term ‘nego 4 tiation period’ means, with respect to an initial price 5 applicability year with respect to a selected drug, the 6 period—

7 “(A) beginning on the sooner of— 8 “(i) the date on which the manufac 9 turer of the drug and the Secretary enter

10 into an agreement under section 1193 with 11 respect to such drug; or

12 “(ii) February 28 following the se 13 lected drug publication date with respect to 14 such selected drug; and

15 “(B) ending on November 1 of the year 16 that begins
2 years prior to the initial price ap 17 plicability year.

18 “(c) OTHER DEFINITIONS.—For purposes of this 19 part:

20 “(1) MAXIMUM FAIR PRICE ELIGIBLE INDI 21 VIDUAL.—The
term ‘maximum fair price eligible in 22 dividual’ means,
with respect to a selected drug— 23 “(A) in the case such
drug is dispensed to 24 the individual at a pharmacy, by a
mail order 25 service, or by another dispenser, an
individual

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1 who is enrolled under a prescription drug plan 2 under
part D of title XVIII or an MA–PD plan 3 under part C of
such title if coverage is pro 4 vided under such plan for
such selected drug; 5 and

6 “(B) in the case such drug is furnished or 7
administered to the individual by a hospital, 8 physician,
or other provider of services or sup 9 plier, an individual
who is enrolled under part

10 B of title XVIII, including an individual who is 11
enrolled under an MA plan under part C of 12 such title, if
such selected drug is covered under 13 such part.

14 “(2) MAXIMUM FAIR PRICE.—The term ‘max 15 imum fair
price’ means, with respect to a year dur 16 ing a price
applicability period and with respect to 17 a selected drug
(as defined in section 1192(c)) with 18 respect to such
period, the price negotiated pursuant 19 to section 1194,

and updated pursuant to section 20 1195(b), as applicable, for such drug and year.

21 “(3) REFERENCE PRODUCT.—The term ‘reference
product’ has the meaning given such term in 23 section
351(i) of the Public Health Service Act. 24 “(4) UNIT.—The
term ‘unit’ means, with re 25 spect to a drug or biological
product, the lowest

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1 identifiable amount (such as a capsule or tablet, mil 2
ligram of molecules, or grams) of the drug or bio 3 logical
product that is dispensed or furnished. The 4
determination of a unit, with respect to a drug or 5
biological product, pursuant to this paragraph shall 6 not
be subject to administrative or judicial review.

7 “(5) TOTAL EXPENDITURES.—The term ‘total 8
expenditures’ includes, in the case of expenditures 9 with
respect to part D of title XVIII, the total gross
10 covered prescription drug costs (as defined in section
11 1860D–15(b)(3)). The term ‘total expenditures’ ex 12
cludes, in the case of expenditures with respect to 13 part
B of such title, expenditures for a drug or bio 14 logical
product that are bundled or packaged into 15 the payment
for another service.

16 “(d) TIMING FOR INITIAL PRICE APPLICABILITY 17 YEAR
2026.—Notwithstanding the provisions of this part, 18 in
the case of initial price applicability year 2026, the fol 19

lowing rules shall apply for purposes of implementing the
20 program:

21 “(1) Subsection (b)(3) shall be applied by sub 22
stituting ‘September 1, 2023’ for ‘, with respect to 23 each
initial price applicability year, February 1 of 24 the year
that begins 2 years prior to such year’.

25 “(2) Subsection (b)(4) shall be applied—

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1 “(A) in subparagraph (A)(ii), by sub 2 stituting ‘October
1, 2023’ for ‘February 28 3 following the selected drug
publication date 4 with respect to such selected drug’;
and

5 “(B) in subparagraph (B), by substituting 6 ‘August 1,
2024’ for ‘November 1 of the year 7 that begins 2 years
prior to the initial price ap 8 plicability year’.

9 “(3) Section 1192 shall be applied— 10 “(A) in
subsection (b)(1)(A), by sub 11 stituting ‘during the period
beginning on June 12 1, 2022, and ending on May 31,
2023’ for ‘dur 13 ing the most recent period of 12 months
prior 14 to the selected drug publication date (but end 15
ing not later than October 31 of the year prior 16 to the
year of such drug publication date), with 17 respect to
such year’;

18 “(B) in subsection (d)(1)(A), by sub 19 stituting ‘during
the period beginning on June 20 1, 2022, and ending on
May 31, 2023’ for ‘dur 21 ing the most recent period for

which data are 22 available of at least 12 months prior to the se 23 lected drug publication date (but ending no 24 later than October 31 of the year prior to the

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1 year of such drug publication date), with re 2 spect to such year'; and

3 "(C) in subsection (e)(3)(B), by sub 4 stituting 'during the period beginning on June 5 1, 2022, and ending on May 31, 2023' for 'dur 6 ing the most recent period for which data are 7 available of at least 12 months prior to the se 8 lected drug publication date (but ending no 9 later than October 31 of the year prior to the

10 year of such drug publication date), with re 11 spect to such year'.

12 "(4) Section 1193(a) shall be applied by sub 13 stituting 'October 1, 2023' for 'February 28 fol 14 lowing the selected drug publication date with re 15 spect to such selected drug '.

16 "(5) Section 1194(b)(2) shall be applied— 17 "(A) in subparagraph (A), by substituting 18 'October 2, 2023' for 'March 1 of the year of 19 the selected drug publication date, with respect 20 to the selected drug';

21 "(B) in subparagraph (B), by substituting 22 'February 1, 2024' for 'the June 1 following 23 the selected drug publication date'; and 24 "(C) in subparagraph (E), by substituting 25 'August 1, 2024' for 'the first day of

1 following the selected drug publication date, 2 with
respect to the initial price applicability 3 year ’.

4 “(6) Section 1195(a) shall be applied— 5 “(A) in
paragraph (1), by substituting 6 ‘September 1, 2024’ for
‘November 30 of the 7 year that is 2 years prior to such
initial price 8 applicability year’; and

9 “(B) in paragraph (2), by substituting 10 ‘March 1, 2025’
for ‘March 1 of the year prior 11 to such initial price
applicability year’. 12 “SEC. 1192. SELECTION OF

NEGOTIATION-ELIGIBLE DRUGS 13 AS SELECTED DRUGS.

14 “(a) IN GENERAL.—Not later than the selected drug 15
publication date with respect to an initial price applica 16
bility year, in accordance with subsection (b), the Sec 17
retary shall select and publish a list of—

18 “(1) with respect to the initial price applica 19 bility year
2026, 10 negotiation-eligible drugs de 20 scribed in
subparagraph (A) of subsection (d)(1), 21 but not
subparagraph (B) of such subsection, with 22 respect to
such year (or, all (if such number is less 23 than 10) such
negotiation-eligible drugs with respect 24 to such year);

1 “(2) with respect to the initial price applica 2 bility year
2027, 15 negotiation-eligible drugs de 3 scribed in
subparagraph (A) of subsection (d)(1), 4 but not

subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year);

“(3) with respect to the initial price applicability year 2028, 15 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1) with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year); and

“(4) with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1), with respect to such year (or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year); and Subject to subsection (c)(2) and section 1194(f)(5), each drug published on the list pursuant to the previous sentence shall be subject to the negotiation process under section 1194 for the negotiation period with respect to such initial price applicability year (and the renegotiation proc-

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less under such section as applicable for any subsequent year during the applicable price applicability period). “(b) SELECTION OF DRUGS.—

“(1) IN GENERAL.—In carrying out subsection (a)(1),

subject to paragraph (2), the Secretary shall, 6 with respect to an initial price applicability year, do 7 the following:

8 “(A) Rank negotiation-eligible drugs de 9 scribed in subsection (d)(1) according to the 10 total expenditures for such drugs under parts B 11 and D of title XVIII, as determined by the Sec 12 retary, during the most recent period of 12 13 months prior to the selected drug publication 14 date (but ending not later than October 31 of 15 the year prior to the year of such drug publica 16 tion date), with respect to such year, for which 17 data are available, with the negotiation-eligible 18 drugs with the highest total expenditures being 19 ranked the highest.

20 “(B) Select from such ranked drugs with 21 respect to such year the negotiation-eligible 22 drugs with the highest such rankings. 23 “(2) HIGH SPEND PART D DRUGS FOR 2026 AND 24 2027.—With respect to the initial price applicability 25 year 2026 and with respect to the initial price appli-

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1 cability year 2027, the Secretary shall apply para 2 graph (1) as if the reference to ‘negotiation-eligible 3 drugs described in subsection (d)(1)’ were a ref 4 erence to ‘negotiation-eligible drugs described in sub 5 section (d)(1)(A)’ and as if the reference to ‘total ex 6 penditures

for such drugs under parts B and D of 7 title XVIII' were a reference to 'total expenditures 8 for such drugs under part D of title XVIII'.

9 "(c) SELECTED DRUG.—

10 "(1) IN GENERAL.—For purposes of this part, 11 in accordance with subsection (e)(2) and subject to 12 paragraph (2), each negotiation-eligible drug in 13 cluded on the list published under subsection (a) 14 with respect to an initial price applicability year 15 shall be referred to as a 'selected drug' with respect 16 to such year and each subsequent year beginning be 17 fore the first year that begins at least 9 months 18 after the date on which the Secretary determines at 19 least one drug or biological product—

20 "(A) is approved or licensed (as applica 21 ble)—

22 "(i) under section 505(j) of the Fed 23 eral Food, Drug, and Cosmetic Act using 24 such drug as the listed drug; or

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1 "(ii) under section 351(k) of the Pub 2 lic Health Service Act using such drug as 3 the reference product; and

4 "(B) is marketed pursuant to such ap 5 proval or licensure.

6 "(2) CLARIFICATION.—A negotiation-eligible 7 drug—

8 "(A) that is included on the list published 9 under

subsection (a) with respect to an initial 10 price
applicability year; and

11 “(B) for which the Secretary makes a de 12 termination
described in paragraph (1) before 13 or during the
negotiation period with respect to 14 such initial price
applicability year;

15 shall not be subject to the negotiation process under
16 section 1194 with respect to such negotiation period 17
and shall continue to be considered a selected drug 18
under this part with respect to the number of nego 19
tiation-eligible drugs published on the list under sub 20
section (a) with respect to such initial price applica 21
bility year.

22 “(d) NEGOTIATION-ELIGIBLE DRUG.— 23 “(1) IN
GENERAL.—For purposes of this part, 24 subject to
paragraph (2), the term ‘negotiation-eligi 25 ble drug’
means, with respect to the selected drug

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1 publication date with respect to an initial price ap 2
plicability year, a qualifying single source drug, as 3
defined in subsection (e), that is described in either 4 of
the following subparagraphs (or, with respect to 5 the
initial price applicability year 2026 or 2027, that 6 is
described in subparagraph (A)):

7 “(A) PART D HIGH SPEND DRUGS.—The 8 qualifying single
source drug is, determined in 9 accordance with

subsection (e)(2), among the

10 50 qualifying single source drugs with the high 11 est
total expenditures under part D of title 12 XVIII, as
determined by the Secretary in ac 13 cordance with
paragraph (3), during the most 14 recent period for which
data are available of at 15 least 12 months prior to the
selected drug pub 16 lication date (but ending no later
than October 17 31 of the year prior to the year of such
drug 18 publication date), with respect to such year.

19 “(B) PART B HIGH SPEND DRUGS.—The 20 qualifying
single source drug is, determined in 21 accordance with
subsection (e)(2), among the 22 50 qualifying single
source drugs with the high 23 est total expenditures under
part B of title 24 XVIII, as determined by the Secretary in
ac-

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1 cordance with paragraph (3), during such most 2
recent period, as described in clause (i). 3 “(2)

EXCEPTION FOR SMALL BIOTECH 4 DRUGS.—

5 “(A) IN GENERAL.—Subject to subpara 6 graph (C), the
term ‘negotiation-eligible drug’ 7 shall not include, with
respect to the initial 8 price applicability years 2026, 2027,
and 2028, 9 a qualifying single source drug that meets ei
10 ther of the following:

11 “(i) PART D DRUGS.—The total ex 12 penditures for the
qualifying single source 13 drug under part D of title XVIII,

as determined by the Secretary in accordance with paragraph (3)(B), during 2021—

“(I) are equal to or less than 17 percent of the total expenditures under such part D, as so determined, for all covered part D drugs (as determined in section 1860D–2(e)) during such year; and

“(II) are equal to at least 80 percent of the total expenditures under such part D, as so determined, for all covered part D drugs for which the

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1 manufacturer of the drug has an agreement in effect under section 1860D–14A during such year. 4 “(ii)

PART B DRUGS.—The total expenditures for the qualifying single source drug under part B of title XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021— 9 “(I) are equal to or less than 1

10 percent of the total expenditures under such part B, as so determined, 12 for all qualifying single source drugs 13 covered under such part B during 14 such year; and

15 “(II) are equal to at least 80 percent of the total expenditures under 17 such part B, as so determined, for all 18 qualifying single source drugs of the 19 manufacturer that are covered under 20 such part B during such year.

21 “(B) CLARIFICATIONS RELATING TO MANUFACTURERS.—

23 “(i) AGGREGATION RULE.—All per 24 sons treated as a
single employer under 25 subsection (a) or (b) of section
52 of the

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1 Internal Revenue Code of 1986 shall be 2 treated as
one manufacturer for purposes 3 of this paragraph.

4 “(ii) LIMITATION.—A drug shall not 5 be considered to be
a qualifying single 6 source drug described in clause (i)
or (ii) 7 of subparagraph (A) if the manufacturer 8 of such
drug is acquired after 2021 by an 9 other manufacturer
that does not meet the

10 definition of a specified manufacturer 11 under section
1860D–14C(g)(4)(B)(ii), ef 12 fective at the beginning of
the plan year 13 immediately following such acquisition or,
14 in the case of an acquisition before 2025, 15 effective
January 1, 2025.

16 “(C) DRUGS NOT INCLUDED AS SMALL 17 BIOTECH
DRUGS.—The following shall not be 18 considered a
qualifying single source drug de 19 scribed in
subparagraph (A):

20 “(i) A vaccine that is licensed under 21 section 351 of
the Public Health Service 22 Act and is marketed pursuant
to such sec 23 tion.

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1 “(ii) A new formulation, such as an 2 extended release
formulation, of a quali 3 fying single source drug.

4 “(3) CLARIFICATIONS AND DETERMINATIONS.— 5 “(A)
PREVIOUSLY SELECTED DRUGS AND 6 SMALL BIOTECH DRUGS
EXCLUDED.—In apply 7 ing subparagraphs (A) and (B) of
paragraph 8 (1), the Secretary shall not consider or
count— 9 “(i) drugs that are already selected 10 drugs;
and

11 “(ii) for initial price applicability 12 years 2026, 2027,
and 2028, qualifying 13 single source drugs described in
paragraph 14 (2)(A).

15 “(B) USE OF DATA.—In determining 16 whether a
qualifying single source drug satisfies 17 any of the criteria
described in paragraph (1) 18 or (2), the Secretary shall
use data that is ag 19 gregated across dosage forms and
strengths of 20 the drug, including new formulations of the
21 drug, such as an extended release formulation, 22 and
not based on the specific formulation or 23 package size
or package type of the drug.

24 “(e) QUALIFYING SINGLE SOURCE DRUG.—

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1 “(1) IN GENERAL.—For purposes of this part, 2 the term
‘qualifying single source drug’ means, with 3 respect to
an initial price applicability year, subject 4 to paragraphs
(2) and (3), a covered part D drug 5 (as defined in
section 1860D–2(e)) that is described 6 in any of the
following or a drug or biological prod 7 uct covered under
part B of title XVIII that is de 8 scribed in any of the

following:

9 “(A) DRUG PRODUCTS.—A drug— 10 “(i) that is approved under section 11 505(c) of the Federal Food, Drug, and 12 Cosmetic Act and is marketed pursuant to 13 such approval;

14 “(ii) for which, as of the selected drug 15 publication date with respect to such initial 16 price applicability year, at least 7 years 17 will have elapsed since the date of such ap 18 proval; and

19 “(iii) that is not the listed drug for 20 any drug that is approved and marketed 21 under section 505(j) of such Act. 22 “(B) BIOLOGICAL PRODUCTS.—A biologi 23 cal product—

24 “(i) that is licensed under section 25 351(a) of the Public Health Service Act

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1 and is marketed under section 351 of such 2 Act;

3 “(ii) for which, as of the selected drug 4 publication date with respect to such initial 5 price applicability year, at least 11 years 6 will have elapsed since the date of such li 7 censure; and

8 “(iii) that is not the reference product 9 for any biological product that is licensed 10 and marketed under section 351(k) of such 11 Act.

12 “(2) TREATMENT OF AUTHORIZED GENERIC 13 DRUGS.—

14 “(A) IN GENERAL.—In the case of a quali 15 fying single

source drug described in subpara 16 graph (A) or (B) of paragraph (1) that is the 17 listed drug (as such term is used in section 18 505(j) of the Federal Food, Drug, and Cos 19 metic Act) or a product described in clause (ii) 20 of subparagraph (B), with respect to an author 21 ized generic drug, in applying the provisions of 22 this part, such authorized generic drug and 23 such listed drug or such product shall be treat 24 ed as the same qualifying single source drug.

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1 “(B) AUTHORIZED GENERIC DRUG DEFINED.—For purposes of this paragraph, the 3 term ‘authorized generic drug’ means— 4 “(i) in the case of a drug, an author 5 ized generic drug (as such term is defined 6 in section 505(t)(3) of the Federal Food, 7 Drug, and Cosmetic Act); and 8 “(ii) in the case of a biological prod 9 uct, a product that—

10 “(I) has been licensed under sec 11 tion 351(a) of such Act; and 12 “(II) is marketed, sold, or dis 13 tributed directly or indirectly to retail 14 class of trade under a different label 15 ing, packaging (other than repack 16 aging as the reference product in blis 17 ter packs, unit doses, or similar pack 18 aging for use in institutions), product 19 code, labeler code, trade name, or 20 trade mark than the reference prod 21 uct.

22 “(3) EXCLUSIONS.—In this part, the term 23 ‘qualifying

single source drug' does not include any 24 of the following:

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1 “(A) CERTAIN ORPHAN DRUGS.—A drug 2 that is designated as a drug for only one rare 3 disease or condition under section 526 of the 4 Federal Food, Drug, and Cosmetic Act and for 5 which the only approved indication (or indica 6 tions) is for such disease or condition.

7 “(B) LOW SPEND MEDICARE DRUGS.—A 8 drug or biological product with respect to which 9 the total expenditures under parts B and D of

10 title XVIII, as determined by the Secretary, 11 during the most recent period for which data 12 are available of at least 12 months prior to the 13 selected drug publication date (but ending no 14 later than October 31 of the year prior to the 15 year of such drug publication date), with re 16 spect to such year, is less than—

17 “(i) with respect to 2021, 18 \$200,000,000; or

19 “(ii) with respect to a subsequent 20 year, the dollar amount specified in this 21 subparagraph for the previous year in 22 creased by the annual percentage increase 23 in the consumer price index for all urban 24 consumers (all items; United States city

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1 average) for the 12-month period ending 2 with

September of such previous year. 3 “(C) PLASMA-DERIVED
PRODUCTS.—A bio 4 logical product that is derived from
human 5 whole blood or plasma.

6 “(f) NO ADMINISTRATIVE OR JUDICIAL REVIEW.— 7 The
determination of negotiation-eligible drugs under sub 8
section (d), the determination of qualifying single source
9 drugs under subsection (e), and the selection of drugs
10 under this section are not subject to administrative or
ju 11 dicial review.

12 “SEC. 1193. MANUFACTURER AGREEMENTS.

13 “(a) IN GENERAL.—For purposes of section 14
1191(a)(2), the Secretary shall enter into agreements with
15 manufacturers of selected drugs with respect to a price
16 applicability period, by not later than February 28 fol 17
lowing the selected drug publication date with respect to
18 such selected drug, under which—

19 “(1) during the negotiation period for the initial 20 price
applicability year for the selected drug, the 21 Secretary
and the manufacturer, in accordance with 22 section 1194,
negotiate to determine (and, by not 23 later than the last
date of such period, agree to) a 24 maximum fair price for
such selected drug of the

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1 manufacturer in order for the manufacturer to pro 2
vide access to such price—

3 “(A) to maximum fair price eligible indi 4 viduals who

with respect to such drug are described in subparagraph (A) of section 1191(c)(1) and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such

drugs) during, subject to paragraph (2), the price applicability period; and

“(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to paragraph (2), the price applicability period;

“(2) the Secretary and the manufacturer shall, in accordance with section 1194, renegotiate (and, by not later than the last date of such period, agree to) the maximum fair price for such drug, in order for the manufacturer to provide access to such maximum fair price (as so renegotiated)—

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“(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(1) and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such

maximum fair price eligible individuals who are dispensed such drugs) during any year during the price applicability period (beginning after such renegotiation) with respect to such selected drug; and “(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in sub paragraph (B) of such section and are furnished or administered such drug during any year described in subparagraph (A);

“(3) subject to subsection (d), access to the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided by the manufacturer to—
“(A) maximum fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section

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1191(c)(1), at the pharmacy, mail order service, or other dispenser at the point-of-sale of such drug (and shall be provided by the manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed such drugs), as described in paragraph (1)(A) or (2)(A), as applicable; and
“(B) hospitals, physicians, and other providers of

services and suppliers with respect to 11 maximum fair price eligible individuals who 12 with respect to such drug are described in sub 13 paragraph (B) of such section and are furnished or administered such drug, as described 15 in paragraph (1)(B) or (2)(B), as applicable;

16 “(4) the manufacturer submits to the Secretary, in a form and manner specified by the Secretary, for the negotiation period for the price applicability period (and, if applicable, before any period 20 of renegotiation pursuant to section 1194(f)) with 21 respect to such drug—

22 “(A) information on the non-Federal average manufacturer price (as defined in section 24 8126(h)(5) of title 38, United States Code) for 25 the drug for the applicable year or period; and

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1 “(B) information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part; and 4 “(5) the manufacturer complies with requirements determined by the Secretary to be necessary 6 for purposes of administering the program and monitoring compliance with the program.

8 “(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO 9 LONGER A SELECTED DRUG.—An agreement entered into 10 under this section shall be effective, with respect to a selected 11 drug, until such drug is no longer considered a se

12 lected drug under section 1192(c).

13 “(c) CONFIDENTIALITY OF INFORMATION.—Informa 14 tion
submitted to the Secretary under this part by a man 15
ufacturer of a selected drug that is proprietary informa 16
tion of such manufacturer (as determined by the Sec 17
retary) shall be used only by the Secretary or disclosed
18 to and used by the Comptroller General of the United
19 States for purposes of carrying out this part.

20 “(d) NONDUPLICATION WITH 340B CEILING 21
PRICE.—Under an agreement entered into under this sec
22 tion, the manufacturer of a selected drug shall not be
re 23 quired to provide access to the maximum fair price
under 24 subsection (a)(3), with respect to such selected
drug and 25 maximum fair price eligible individuals who
are eligible to

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1 be furnished, administered, or dispensed such
selected 2 drug at a covered entity described in section
340B(a)(4) 3 of the Public Health Service Act, to such
covered entity 4 if such selected drug is subject to an
agreement described 5 in section 340B(a)(1) of such Act
and the ceiling price 6 (defined in section 340B(a)(1) of
such Act) is lower than 7 the maximum fair price for such
selected drug, except that 8 the manufacturer shall
provide for the maximum fair price 9 to such covered
entity with respect to maximum fair price

10 eligible individuals who are eligible to be furnished,
admin 11 istered, or dispensed such selected drug at
such entity at 12 such ceiling price in a nonduplicated
amount to the ceiling 13 price if the maximum fair price is
below the ceiling price 14 for such selected drug.

15 “SEC. 1194. NEGOTIATION AND RENEGOTIATION PROCESS. 16 “(a) IN
GENERAL.—For purposes of this part, under 17 an
agreement under section 1193 between the Secretary 18
and a manufacturer of a selected drug (or selected
drugs), 19 with respect to the period for which such
agreement is 20 in effect and in accordance with
subsections (b), (c), and 21 (d), the Secretary and the
manufacturer—

22 “(1) shall during the negotiation period with re 23 spect
to such drug, in accordance with this section, 24 negotiate
a maximum fair price for such drug for 25 the purpose
described in section 1193(a)(1); and

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1 “(2) renegotiate, in accordance with the process 2
specified pursuant to subsection (f), such maximum 3 fair
price for such drug for the purpose described in 4 section
1193(a)(2) if such drug is a renegotiation-el 5 igible drug
under such subsection.

6 “(b) NEGOTIATION PROCESS REQUIREMENTS.— 7 “(1)
METHODOLOGY AND PROCESS.—The Sec 8 retary shall
develop and use a consistent method 9 ology and

process, in accordance with paragraph (2),
10 for negotiations under subsection (a) that aims to 11
achieve the lowest maximum fair price for each se 12
lected drug.

13 “(2) SPECIFIC ELEMENTS OF NEGOTIATION 14
PROCESS.—As part of the negotiation process under 15
this section, with respect to a selected drug and the 16
negotiation period with respect to the initial price 17
applicability year with respect to such drug, the fol 18
lowing shall apply:

19 “(A) SUBMISSION OF INFORMATION.—Not 20 later than
March 1 of the year of the selected 21 drug publication
date, with respect to the se 22 lected drug, the
manufacturer of the drug shall 23 submit to the Secretary,
in accordance with sec 24 tion 1193(a)(4), the information
described in 25 such section.

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1 “(B) INITIAL OFFER BY SECRETARY.—Not 2 later than the
June 1 following the selected 3 drug publication date, the
Secretary shall pro 4 vide the manufacturer of a selected
drug with 5 a written initial offer that contains the Sec 6
retary’s proposal for the maximum fair price of 7 the drug
and a list of the factors described in 8 section 1194(e)
that were used in developing 9 such offer.

10 “(C) RESPONSE TO INITIAL OFFER.— 11 “(i) IN
GENERAL.—Not later than 30 12 days after the date of

receipt of an initial 13 offer under subparagraph (B), the
manu 14 facturer shall either accept such offer or 15
propose a counteroffer to such offer. 16 “(ii)

COUNTEROFFER REQUIRE 17 MENTS.—If a manufacturer
proposes a 18 counteroffer, such counteroffer— 19 “(I)
shall be in writing; and 20 “(II) shall be justified based on
21 the factors described in subsection (e). 22 “(D)

RESPONSE TO COUNTEROFFER.— 23 After receiving a
counteroffer under subpara 24 graph (C), the Secretary
shall respond in writ 25 ing to such counteroffer.

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1 “(E) DEADLINE.—All negotiations between 2 the
Secretary and the manufacturer of the se 3 lected drug
shall end prior to the first day of 4 November following
the selected drug publica 5 tion date, with respect to the
initial price appli 6 cability year.

7 “(F) LIMITATIONS ON OFFER AMOUNT.— 8 In negotiating
the maximum fair price of a se 9 lected drug, with
respect to an initial price ap
10 plicability year for the selected drug, and, as 11
applicable, in renegotiating the maximum fair 12 price for
such drug, with respect to a subse 13 quent year during
the price applicability period 14 for such drug, the
Secretary shall not offer (or 15 agree to a counteroffer for)
a maximum fair 16 price for the selected drug that—

17 “(i) exceeds the ceiling determined 18 under

subsection (c) for the selected drug 19 and year; or
20 “(ii) as applicable, is less than the 21 floor determined
under subsection (d) for 22 the selected drug and year.

23 “(G) TREATMENT OF DETERMINATION.— 24 The
determination of a maximum fair price

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1 under this section is not subject to administra 2 tive or
judicial review.

3 “(c) CEILING FOR MAXIMUM FAIR PRICE.— 4 “(1)
GENERAL CEILING.—

5 “(A) IN GENERAL.—The maximum fair 6 price negotiated
under this section for a se 7 lected drug, with respect to
the first year of the 8 price applicability period with
respect to such 9 drug, shall not exceed the lower of the
amount

10 under subparagraph (B) or the amount under 11
subparagraph (C).

12 “(B) SUBPARAGRAPH (B) AMOUNT.—An 13 amount equal
to the following:

14 “(i) COVERED PART D DRUG.—In the 15 case of a covered
part D drug (as defined 16 in section 1860D–2(e)), the
sum of the 17 plan specific enrollment weighted amounts
18 for each prescription drug plan or MA–PD 19 plan (as
determined under paragraph (2)). 20 “(ii) PART B DRUG OR
BIOLOGICAL.— 21 In the case of a drug or biological
product 22 covered under part B of title XVIII, the 23

payment amount under section 24 1847A(b)(4) for the drug or biological 25 product for the year prior to the year of

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1 the selected drug publication date with re 2 spect to the initial price applicability year 3 for the drug or biological product. 4 “(C) SUBPARAGRAPH (C) AMOUNT.—An 5 amount equal to the applicable percent de 6 scribed in paragraph (3), with respect to such 7 drug, of the following:

8 “(i) INITIAL PRICE APPLICABILITY 9 YEAR 2026.—In the case of a selected drug 10 with respect to which such initial price ap 11 plicability year is 2026, the average non 12 Federal average manufacturer price for 13 such drug for 2021 (or, in the case that 14 there is not an average non-Federal aver 15 age manufacturer price available for such 16 drug for 2021, for the first full year fol 17 lowing the market entry for such drug), in 18 creased by the percentage increase in the 19 consumer price index for all urban con 20 sumers (all items; United States city aver 21 age) from September 2021 (or December 22 of such first full year following the market 23 entry), as applicable, to September of the 24 year prior to the year of the selected drug

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1 publication date with respect to such initial 2 price

applicability year.

3 “(ii) INITIAL PRICE APPLICABILITY 4 YEAR 2027 AND
SUBSEQUENT YEARS.—In 5 the case of a selected drug
with respect to 6 which such initial price applicability year
is 7 2027 or a subsequent year, the lower of— 8 “(I) the
average non-Federal av 9 erage manufacturer price for
such

10 drug for 2021 (or, in the case that 11 there is not an
average non-Federal 12 average manufacturer price
available 13 for such drug for 2021, for the first 14 full year
following the market entry 15 for such drug), increased by
the per 16 centage increase in the consumer price 17
index for all urban consumers (all 18 items; United States
city average) 19 from September 2021 (or December 20 of
such first full year following the 21 market entry), as
applicable, to Sep 22 tember of the year prior to the year
of 23 the selected drug publication date 24 with respect to
such initial price appli 25 cability year; or

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1 “(II) the average non-Federal av 2 erage manufacturer
price for such 3 drug for the year prior to the selected 4
drug publication date with respect to 5 such initial price
applicability year.

6 “(2) PLAN SPECIFIC ENROLLMENT WEIGHTED 7
AMOUNT.—For purposes of paragraph (1)(B)(i), the 8 plan
specific enrollment weighted amount for a pre 9 scription

drug plan or an MA–PD plan with respect

10 to a covered Part D drug is an amount equal to the 11
product of—

12 “(A) the negotiated price of the drug 13 under such
plan under part D of title XVIII, 14 net of all price
concessions received by such 15 plan or pharmacy
benefit managers on behalf of 16 such plan, for the most
recent year for which 17 data is available; and

18 “(B) a fraction—

19 “(i) the numerator of which is the 20 total number of
individuals enrolled in 21 such plan in such year; and

22 “(ii) the denominator of which is the 23 total number of
individuals enrolled in a 24 prescription drug plan or an
MA–PD plan 25 in such year.

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1 “(3) APPLICABLE PERCENT DESCRIBED.—For 2 purposes
of this subsection, the applicable percent 3 described in
this paragraph is the following: 4 “(A) SHORT-MONOPOLY
DRUGS AND VAC 5 CINES.—With respect to a selected drug
(other 6 than an extended-monopoly drug and a long 7
monopoly drug), 75 percent.

8 “(B) EXTENDED-MONOPOLY DRUGS.— 9 With respect to
an extended-monopoly drug, 65 10 percent.

11 “(C) LONG-MONOPOLY DRUGS.—With re 12 spect to a
long-monopoly drug, 40 percent. 13 “(4)

EXTENDED-MONOPOLY DRUG DEFINED.— 14 “(A) IN

GENERAL.—In this part, subject 15 to subparagraph (B), the term ‘extended-monopoly drug’ means, with respect to an initial price applicability year, a selected drug for which at least 12 years, but fewer than 16 19 years, have elapsed since the date of approval 20 of such drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act or since the 22 date of licensure of such drug under section 23 351(a) of the Public Health Service Act, as applicable.

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1 “(B) EXCLUSIONS.—The term ‘extended 2 monopoly drug’ shall not include any of the following:

4 “(i) A vaccine that is licensed under 5 section 351 of the Public Health Service 6 Act and marketed pursuant to such section 7.

8 “(ii) A selected drug for which a manufacturer had an agreement under this 10 part with the Secretary with respect to an

11 initial price applicability year that is before 12 2030.

13 “(C) CLARIFICATION.—Nothing in subparagraph (B)(ii) shall limit the transition of a 15 selected drug described in paragraph (3)(A) to 16 a long-monopoly drug if the selected drug meets 17 the definition of a long-monopoly drug.

18 “(5) LONG-MONOPOLY DRUG DEFINED.— 19 “(A) IN GENERAL.—In this part, subject 20 to subparagraph (B), the

term ‘long-monopoly 21 drug’ means, with respect to an initial price ap 22 plicability year, a selected drug for which at 23 least 16 years have elapsed since the date of 24 approval of such drug under section 505(c) of 25 the Federal Food, Drug, and Cosmetic Act or

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1 since the date of licensure of such drug under 2 section 351(a) of the Public Health Service Act, 3 as applicable.

4 “(B) EXCLUSION.—The term ‘long-monop 5 oly drug’ shall not include a vaccine that is li 6 censed under section 351 of the Public Health 7 Service Act and marketed pursuant to such sec 8 tion.

9 “(6) AVERAGE NON-FEDERAL AVERAGE MANU 10 FACTURER PRICE.—In this part, the term ‘average 11 non-Federal average manufacturer price’ means the 12 average of the non-Federal average manufacturer 13 price (as defined in section 8126(h)(5) of title 38, 14 United States Code) for the 4 calendar quarters of 15 the year involved.

16 “(d) TEMPORARY FLOOR FOR SMALL BIOTECH 17 DRUGS.—In the case of a selected drug that is a quali 18 fying single source drug described in section 1192(d)(2) 19 and with respect to which the first initial price applica 20 bility year of the price applicability period with respect to 21 such drug is 2029 or 2030, the maximum fair price nego 22 tiated under this section for such drug for such

initial 23 price applicability year may not be less than 66 percent 24 of the average non-Federal average manufacturer price for 25 such drug (as defined in subsection (c)(6)) for 2021 (or,

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1 in the case that there is not an average non-Federal average 2 manufacturer price available for such drug for 2021, 3 for the first full year following the market entry for such 4 drug), increased by the percentage increase in the consumer 5 price index for all urban consumers (all items; 6 United States city average) from September 2021 (or De 7 cember of such first full year following the market entry), 8 as applicable, to September of the year prior to the se 9 lected drug publication date with respect to the initial 10 price applicability year.

11 “(e) FACTORS.—For purposes of negotiating the 12 maximum fair price of a selected drug under this part with 13 the manufacturer of the drug, the Secretary shall consider 14 the following factors (and, with respect to extended-mo 15 nopoly drugs and long-monopoly drugs, shall not, except 16 in making a determination of a material change under 17 subsection (f)(2)(D), consider factors other than those de 18 scribed in subparagraphs (B) and (C) of paragraph (1)): 19 “(1) MANUFACTURER-SPECIFIC INFORMA 20 TION.—The following information, with respect to 21 such selected drug,

including as submitted by the 22 manufacturer:

23 “(A) Research and development costs of 24 the
manufacturer for the drug and the extent to

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1 which the manufacturer has recouped research 2 and
development costs.

3 “(B) Market data for the drug. 4 “(C) Unit costs of
production and distribu 5 tion of the drug.

6 “(D) Prior Federal financial support for 7 novel
therapeutic discovery and development 8 with respect to
the drug.

9 “(E) Data on patents and on existing and 10 pending
exclusivity for the drug.

11 “(F) National sales data for the drug. 12 “(G)
Information on clinical trials for the 13 drug.

14 “(2) INFORMATION ON ALTERNATIVE TREAT 15 MENTS.—The
following information, with respect to 16 such selected
drug and therapeutic alternatives to 17 such drug:

18 “(A) The extent to which such drug rep 19 resents a
therapeutic advance as compared to 20 existing
therapeutic alternatives and, to the ex 21 tent such
information is available, the costs of 22 such existing
therapeutic alternatives.

23 “(B) Approval by the Food and Drug Ad 24 ministration
of such drug and therapeutic alter 25 natives of such drug.

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1 “(C) Comparative effectiveness of such 2 drug and
therapeutic alternatives to such drug, 3 taking into
consideration the effects of such 4 drug and therapeutic
alternatives of such drug 5 on specific populations, such
as individuals with 6 disabilities, the elderly, the
terminally ill, chil 7 dren, and other patient populations.

8 “(D) The extent to which such drug and 9 therapeutic
alternatives to such drug address 10 unmet medical
needs for a condition for which 11 treatment or diagnosis
is not addressed ade 12 quately by available therapy.

13 In considering information described in subpara 14
graph (C), the Secretary shall not use evidence or 15
findings from comparative clinical effectiveness re 16
search in a manner that treats extending the life of 17 an
elderly, disabled, or terminally ill individual as of 18 lower
value than extending the life of an individual 19 who is
younger, nondisabled, or not terminally ill.

20 “(f) RENEGOTIATION PROCESS.—

21 “(1) IN GENERAL.—In the case of a renegoti 22
ation-eligible drug (as defined in paragraph (2)) that 23 is
selected under paragraph (3), the Secretary shall 24
provide for a process of renegotiation (for years (be 25
ginning with 2028) during the price applicability pe-