AMENDMENT NO.llll Calendar No.lll 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 lllllllll 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 lllllll

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Inflation Reduction Act of 2022".

TITLE I—COMMITTEE ON FINANCE

Subtitle A—Deficit Reduction

SEC. 10001. AMENDMENT OF 1986 CODE.

Except as otherwise expressly provided, whenever in this subtitle an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provi-

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

PART 1—CORPORATE TAX REFORM

SEC. 10101. CORPORATE ALTERNATIVE MINIMUM TAX.

(a) IMPOSITION OF TAX.—

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

"(2) CORPORATIONS.—

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

"(i) 15 percent of the adjusted financial statement income for the taxable year (as determined under section 56A), over

"(ii) the corporate AMT foreign tax credit for the taxable year.

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

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

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

“(1) APPLICABLE CORPORATION DEFINED.—

“(A) IN GENERAL.—The term ‘applicable corporation’ means, with respect to any taxable year, any corporation (other than an S corporation, a regulated investment company, or a real estate investment trust) which meets the average annual adjusted financial statement income test of subparagraph (B) for one or more taxable years which—

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

“(ii) end after December 31, 2021.

“(B) AVERAGE ANNUAL ADJUSTED FINANCIAL STATEMENT INCOME TEST.—For purposes of this subsection—

“(i) a corporation meets the average annual adjusted financial statement income test for a taxable year if the average annual adjusted financial statement income of such corporation for the 3-taxable-year period ending with such taxable year exceeds $1,000,000,000, and

“(ii) in the case of a corporation described in paragraph (2), such corporation meets the average annual adjusted financial statement income test for a taxable year if—

“(I) the corporation meets the requirements of clause (i) for such taxable year (determined after the application of paragraph (2)), and

“(II) the average annual adjusted financial statement income of such corporation (determined without regard to the application of paragraph (2)) for the 3-taxable-year-period ending with such taxable year is $100,000,000 or more.

“(C) EXCEPTION.—Notwithstanding subparagraph (A), the term ‘applicable corporation’ shall not include any corporation which otherwise meets the requirements of subparagraph (A) if—

“(i) such corporation—

“(I) has a change in ownership, or

“(II) has a specified number (to be determined by the Secretary and which shall, as appropriate, take into account the facts and circumstances of the taxpayer) of consecutive taxable years, including the most recent taxable year, in which the corporation does not meet the average annual adjusted financial statement income test of subparagraph (B), and

“(ii) the Secretary determines that it would not be appropriate to continue to treat such corporation as an applicable corporation.

The preceding sentence shall not apply to any corporation if, after the Secretary makes the determination described in clause (ii), such corporation meets the average annual adjusted financial statement income test of subparagraph (B) for any taxable year beginning after the first taxable year for which such determination applies.

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

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

“(E) OTHER SPECIAL RULES.— “(i) CORPORATIONS IN EXISTENCE FOR LESS THAN 3 YEARS.—If the corporation was in existence for less than 3-taxable years, subparagraph (B) shall be applied on the basis of the period during which such corporation was in existence.

“(ii) SHORT TAXABLE YEARS.—Adjusted financial statement income for any 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.

"(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

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

"(C) COMMON PARENT.—For purposes of subparagraph (A), the term 'common parent' has the meaning given such term under section 163(n)(5).

"(3) REGULATIONS OR OTHER GUIDANCE.— The Secretary shall provide regulations or other guidance for the purposes of carrying out this sub section, including regulations or other guidance— "(A) providing a simplified method for de termining whether a corporation meets the re quirements of paragraph (1), and "'(B) addressing the application of this subsection to a corporation that experiences a change in ownership.".

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

(4) CONFORMING AMENDMENTS.—

(A) Section 55(a) is amended by striking "In the case of a taxpayer other than a cor poration, there" and inserting "There". (B)(i) Section 55(b)(1) is amended— (I) by striking so much as precedes 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

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".

(D) Section 12 is amended by adding at the end the following new paragraph: "(5) For alternative minimum tax, see section 55.".

(E) Section 882(a)(1) is amended by inserting ", 55," after "section 11". (F) Section 6425(c)(1)(A) is amended to read as follows:

"(A) the sum of—

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

"(ii) the tax imposed by section 55, plus

"(iii) the tax imposed by section 59A, over".

(G) Section 6655(e)(2) is amended by inserting ", adjusted financial statement income (as defined in section 56A)," before "and modified taxable income" each place it appears in subparagraphs (A)(i) and (B)(i).

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

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

"SEC. 56A. ADJUSTED FINANCIAL STATEMENT INCOME. "(a) IN

General.—For purposes of this part, the term ‘adjusted financial statement income’ means, with respect to any corporation for any taxable year, the net income or loss of the taxpayer set forth on the taxpayer’s applicable financial statement for such taxable year, adjusted as provided in this section.

“(b) Applicable Financial Statement.—For purposes of this section, the term ‘applicable financial statement’ means, with respect to any taxable year, an applicable financial statement (as defined in section 451(b)(3) or as specified by the Secretary in regulations or other guidance) which covers such taxable year.

“(c) General Adjustments.—

“(1) Statements covering different taxable years.—Appropriate adjustments shall be made in adjusted financial statement income in any case in which an applicable financial statement covers a period other than the taxable year.

“(2) Special rules for related entities.—

“(A) Consolidated financial statements.—If the financial results of a taxpayer are reported on the applicable financial statement for a group of entities, rules similar to the rules of section 451(b)(5) shall apply.

“(B) Consolidated returns.—Except as provided in regulations prescribed by the Secretary, if the taxpayer is part of an affiliated group of corporations filing a consolidated return for any taxable year, adjusted financial statement income for such group for such tax-

able year shall take into account items on the group's applicable financial statement which are properly allocable to members of such group.

"(C) TREATMENT OF DIVIDENDS AND OTHER AMOUNTS.—In the case of any corporation which is not included on a consolidated return with the taxpayer, adjusted financial statement income of the taxpayer with respect to such other corporation shall be determined by

only taking into account the dividends received from such other corporation (reduced to the extent provided by the Secretary in regulations or other guidance) and other amounts which are includible in gross income or deductible as a loss under this chapter (other than amounts required to be included under sections 951 and 951A or such other amounts as provided by the Secretary) with respect to such other corporation.

"(D) TREATMENT OF PARTNERSHIPS.—

"(i) IN GENERAL.—Except as provided by the Secretary, if the taxpayer is a partner in a partnership, adjusted financial statement income of the taxpayer shall be adjusted to only take into account the taxpayer's distributive share of adjusted financial statement income of such partnership.

"(ii) ADJUSTED FINANCIAL STATEMENT INCOME OF PARTNERSHIPS.—For the purposes of this part, the adjusted financial statement income of a partnership shall be the partnership's net income or loss set forth on such partnership's applicable financial statement (adjusted under rules similar to the rules of this section).

"(3) ADJUSTMENTS TO TAKE INTO ACCOUNT CERTAIN ITEMS OF FOREIGN INCOME.—

"(A) IN GENERAL.—If, for any taxable year, a taxpayer is a United States shareholder of one or more controlled foreign corporations, the adjusted financial statement income of such taxpayer shall be adjusted to take into account such taxpayer's pro rata share (determined under rules similar to the rules under section 951(a)(2)) of items taken into account in computing the net income or loss set forth on the applicable financial statement (as adjusted under rules similar to those that apply in determining adjusted financial statement income) of

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

"(B) NEGATIVE ADJUSTMENTS.—In any case in which the adjustment determined under subparagraph (A) would result in a negative adjustment for such taxable year—

"(i) no adjustment shall be made under this paragraph for such taxable year, and

"(ii) the amount of the adjustment determined under this paragraph for the succeeding taxable year (determined without regard to this paragraph) shall be reduced by an amount equal to the negative adjustment for such taxable year.

"(4) EFFECTIVELY CONNECTED INCOME.—In the case of a foreign corporation, to determine adjusted financial statement income, the principles of section 882 shall apply.

"(5) ADJUSTMENTS FOR CERTAIN TAXES.—Adjusted financial statement income shall be appropriately adjusted to disregard any Federal income taxes, or income, war profits, or excess profits taxes (within the meaning of section 901) with respect to

a foreign country or possession of the United States, which are taken into account on the taxpayer's applicable financial statement. To the extent provided by the Secretary, the preceding sentence shall not apply to income, war profits, or excess profits taxes (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-

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 retain allocations) to the extent such amounts were not otherwise taken into account in determining adjusted financial statement income.

"(8) RULES FOR ALASKA NATIVE CORPORATIONS.—Adjusted financial statement income shall be appropriately adjusted to allow—

"(A) cost recovery and depletion attributable to property the basis of which is determined under section 21(c) of the Alaska Native Claims Settlement Act (43 U.S.C. 1620(c)), and

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

"(9) AMOUNTS ATTRIBUTABLE TO ELECTIONS FOR DIRECT PAYMENT OF CERTAIN CREDITS.—Adjusted financial statement income shall be appropriately adjusted to disregard any amount treated as a payment against the tax imposed by subtitle A pursuant to an election under section 6417, to the

extent such amount was not otherwise taken into account under paragraph (5).

"(10) CONSISTENT TREATMENT OF MORTGAGE SERVICING INCOME OF TAXPAYER OTHER THAN A REGULATED INVESTMENT COMPANY.—

"(A) IN GENERAL.—Adjusted financial statement income shall be adjusted so as not to include any item of income in connection with a mortgage servicing contract any earlier than when such income is included in gross income under any other provision of this chapter.

"(B) RULES FOR AMOUNTS NOT REP RESENTING REASONABLE COMPENSATION.— The Secretary shall provide regulations to pre vent the avoidance of taxes imposed by this chapter with respect to amounts not rep resenting reasonable compensation (as deter mined by the Secretary) with respect to a mort gage servicing contract.

"(11) ADJUSTMENT WITH RESPECT TO DE FINED BENEFIT PENSIONS.—

"(A) IN GENERAL.—Except as otherwise provided in rules prescribed by the Secretary in regulations or other guidance, adjusted finan cial statement income shall be—

"(i) adjusted to disregard any amount of income, cost, or expense that would oth erwise be included on the applicable finan cial statement in connection with any cov ered benefit plan,

"(ii) increased by any amount of in come in connection with any such covered benefit plan that is included in the gross income of the corporation under any other provision of this chapter, and

"(iii) reduced by

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

"(B) COVERED BENEFIT PLAN.—For purposes of this paragraph, the term 'covered benefit plan' means—

"(i) a defined benefit plan (other than a multiemployer plan described in section 414(f)) if the trust which is part of such plan is an employees' trust described in section 401(a) which is exempt from tax under section 501(a),

"(ii) any qualified foreign plan (as defined in section 404A(e)), or

"(iii) any other defined benefit plan which provides post-employment benefits other than pension benefits.

"(12) TAX-EXEMPT ENTITIES.—In the case of an organization subject to tax under section 511, adjusted financial statement income shall be appropriately adjusted to only take into account any adjusted financial statement income—

"(A) of an unrelated trade or business (as defined in section 513) of such organization, or "(B) derived from debt-financed property (as defined in section 514) to the extent that income from such property is treated as unrelated business taxable income.

"(13) SECRETARIAL AUTHORITY TO ADJUST ITEMS.—The

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

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

“(B) to carry out the principles of part II of subchapter C of this chapter (relating to corporate liquidations), part III of subchapter C of

this chapter (relating to corporate organizations and reorganizations), and part II of subchapter K of this chapter (relating to partnership contributions and distributions).

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

“(1) IN GENERAL.—Adjusted financial statement income (determined after application of subsection (c) and without regard to this subsection) shall be reduced by an amount equal to the lesser of—

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

“(B) 80 percent of adjusted financial statement income computed without regard to the deduction allowable under this subsection. “(2) FINANCIAL STATEMENT NET OPERATING LOSS CARRYOVER.—A financial statement net operating loss for any taxable year shall be a financial statement net operating loss carryover to each taxable year following the taxable year of the loss. The portion of such loss which shall be carried to subsequent taxable years shall be the amount of such loss

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

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

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

(2) CLERICAL AMENDMENT.—The table of sections for part VI of subchapter A of chapter 1 is amended by inserting after the item relating to section 56 the following new item:

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

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

“(l) CORPORATE AMT FOREIGN TAX CREDIT.—

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

“(A) the lesser of—

“(i) the aggregate of the applicable corporation’s pro rata share (as determined under section 56A(c)(3)) of the amount of income, war profits, and excess profits taxes (within the meaning of section 901) imposed by any foreign country or possession of the United States which are—

“(I) taken into account on the applicable financial statement of each controlled foreign corporation with re spect to which the applicable corporation is a United States shareholder, and

“(II) paid or accrued (for Federal income tax purposes) by each such controlled foreign corporation, or

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

“(B) in the case of an applicable corporation that is a domestic corporation, the amount of income, war profits, and excess profits taxes (within the meaning of section 901) imposed by any foreign country or possession of the United States to the extent such taxes are—

“(i) taken into account on the applicable corporation’s applicable financial statement, and

“(ii) paid or accrued (for Federal income tax purposes) by the applicable corporation.

“(2) CARRYOVER OF EXCESS TAX PAID.—For any taxable year for which an applicable corporation chooses to have the benefits of subpart A of part III of subchapter N, the excess of the amount described in paragraph (1)(A)(i) over the amount described in paragraph (1)(A)(ii) shall increase the amount described in paragraph (1)(A)(i) in any of the first 5 succeeding taxable years to the extent not taken into account in a prior taxable year.

"(3) REGULATIONS OR OTHER GUIDANCE.— The Secretary shall provide for such regulations or other guidance as is necessary to carry out the purposes of this subsection.".

(d) TREATMENT OF GENERAL BUSINESS CREDIT.— Section 38(c)(6)(E) is amended to read as follows: "(E) CORPORATIONS.—In the case of a corporation—

"(i) the first sentence of paragraph (1) shall be applied by substituting '25 percent of the taxpayer's net income tax as exceeds $25,000' for 'the greater of' and all that follows,

"(ii) paragraph (2)(A) shall be applied without regard to clause (ii)(I) thereof, and

"(iii) paragraph (4)(A) shall be applied without regard to clause (ii)(I) thereof.".

(e) CREDIT FOR PRIOR YEAR MINIMUM TAX LIABILITY.—

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

"(e) APPLICATION TO APPLICABLE CORPORATIONS.—In the case of a corporation—

"(1) subsection (b)(1) shall be applied by substituting 'the net minimum tax for all prior taxable years beginning after 2022' for 'the adjusted net minimum tax imposed for all prior taxable years beginning after 1986', and

"(2) the amount determined under subsection (c)(1) shall be increased by the amount of tax imposed under section 59A for the taxable year.".

(2) CONFORMING AMENDMENTS.—Section 53(d) is amended—

(A) in paragraph (2), by striking ", except that in the case" and all that follows through "treated as zero", and

(B) by striking paragraph (3).

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

PART 2—CLOSING THE CARRIED INTEREST LOOPHOLE

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

(a) IN GENERAL.—Section 1061 is amended by striking subsections (a) and (b) and inserting the following new subsections:

"(a) IN GENERAL.—If one or more applicable partnership interests are held by a taxpayer at any time during the taxable year, the taxpayer's net applicable partnership gain for such taxable year shall be treated as short-term capital gain.

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

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

“(A) the taxpayer’s net long-term capital gain determined by only taking into account gains and losses with respect to one or more applicable partnership interests described in subsection (a), and

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

“(2) HOLDING PERIOD EXCEPTION.— “(A) IN GENERAL.—Net applicable partnership gain shall be determined without regard

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

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

“(ii) The date on which the partnership in which such applicable partnership interest is held acquired substantially all of the assets held by such partnership.

“(iii) If the partnership described in clause (i) owns, directly or indirectly, interests in one or more other partnerships, the dates determined by applying rules similar to the rules in clauses (i) and (ii) in the case of each such other partnership.

“(B) SHORTER HOLDING PERIOD IN CERTAIN CIRCUMSTANCES.—Subparagraph (A) shall be applied by substituting ‘3 years’ for ‘5 years’ in the case of—

“(i) a taxpayer (other than a trust or estate) with an adjusted gross income (determined without regard to sections 911, 931 and 933) of less than $400,000, and

“(ii) any income with respect to any applicable partnership interest that is attributable to a real property trade or business within the meaning of section 469(c)(7)(C).

“(iii) The Secretary is directed to provide guidance regarding determination of the amount described in subsection (a) as applied in paragraph (1) hereof, and any necessary and appropriate reporting by any partnership to carry out the purposes of this section. —

“(3) SECTION 83 TO NOT APPLY.—This section shall be applied without regard to section 83 and any election in effect under section 83(b). "(4) SPECIAL RULE.—To the extent provided by the Secretary, subsection (a) shall not apply to income or gain attributable to any asset not held for portfolio investment on behalf of third party investors.".

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

(1) in paragraph (1), by striking "to such other entity" and inserting "with respect to a trade or business that is not an applicable trade or business", (2) in paragraph (3), by striking "an interest in a partnership to the extent of the partnership's proportionate interest in any of the foregoing" and inserting "except as otherwise provided by the Secretary, an interest in a partnership if such partnership has a direct or indirect interest in any of the foregoing", and

(3) in paragraph (4)—

(A) by striking "The term" and inserting "Except as otherwise provided by the Secretary, the term", and

(B) in subparagraph (A), by striking "corporation" and inserting "C corporation". (c) RECOGNITION OF GAIN ON TRANSFERS OF APPLICABLE PARTNERSHIP INTERESTS TO UNRELATED PARTIES.—Section 1061(d) is amended to read as follows: "(d) TRANSFER OF APPLICABLE

PARTNERSHIP INTEREST.—If a taxpayer transfers any applicable partnership interest, gain shall be recognized notwithstanding any other provision of this subtitle.”.

(d) REGULATIONS.—Section 1061(e) is amended by striking the period at the end and inserting the following: “, including regulations or other guidance to—

“(1) to prevent the avoidance of the purposes of this section, including through the distribution of property by a partnership and through carry waivers, and

“(2) to provide for the application of this section to financial instruments, contracts or interests in entities other than partnerships to the extent necessary or appropriate to carry out the purposes of this section.”.

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

PART 3—FUNDING THE INTERNAL REVENUE SERVICE AND IMPROVING TAXPAYER COMPLIANCE

SEC. 10301. ENHANCEMENT OF INTERNAL REVENUE SERVICE RESOURCES.

(a) APPROPRIATIONS.—

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

September 30, 2022:

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

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

(II) ENFORCEMENT.—For necessary expenses for tax enforcement activities of the Internal Revenue Service to determine and collect owed taxes, to provide legal and litigation support, to conduct criminal investigations (including investigative technology), to provide digital asset monitoring and compliance activities, to

enforce criminal statutes related to violations of internal revenue laws and other financial crimes, to purchase and hire passenger motor vehicles (31 U.S.C. 1343(b)), and to provide other services as authorized by 5 U.S.C. 3109, at such rates as may be determined by the Commissioner, $45,637,400,000, to remain available until September 30, 2031: *Provided,* That these amounts shall be in addition to amounts otherwise available for such purposes.

(III) OPERATIONS SUPPORT.—For necessary expenses of the Internal Revenue Service to support taxpayer services and enforcement programs, including rent payments; facilities services; printing; postage; physical security; headquarters and other IRS-wide administration activities; research and statistics of income; telecommunications; information technology development, enhancement, operations, maintenance, and security;

the hire of passenger motor vehicles (31 U.S.C. 1343(b)); the operations of the Internal Revenue Service Oversight Board; and other services as authorized by 5 U.S.C. 3109, at such rates as may be determined by the Commissioner, $25,326,400,000, to remain available until September 30, 2031: *Provided,* That these amounts shall be in addition to amounts otherwise available for such purposes.

(IV) BUSINESS SYSTEMS MODERNIZATION.—For necessary expenses of the Internal

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

(ii) TASK FORCE TO DESIGN AN IRS RUN FREE "DIRECT EFILE" TAX RETURN SYSTEM.—For necessary expenses of the Internal Revenue Service to deliver to Congress, within nine months following the date of the enactment of this Act, a report on (I) the cost (including options for differential coverage based on taxpayer adjusted gross income and return complexity) of developing and running a free direct efile tax return system, including costs to build and administer each release, with a focus on multi-lingual and mobile-friendly features and safeguards for taxpayer data; (II) taxpayer opinions, expectations, and level of trust, based on surveys, for such a free direct efile system; and (III) the opinions of an independent third-party on the overall feasibility, approach, schedule, cost, organizational design, and Internal Rev enue Service capacity to direct efile tax return system, $15,000,000, to remain available until September 30, 2023: *Provided,* That these amounts shall

be in addition to amounts otherwise available for such purposes.

(B) TREASURY INSPECTOR GENERAL FOR TAX ADMINISTRATION.—For necessary expenses of the Treasury Inspector General for Tax Administration in carrying out the Inspector General Act of 1978, as amended, including purchase and hire of passenger motor vehicles (31 U.S.C. 1343(b)); and services authorized by 5 U.S.C. 3109, at such rates as may be determined by the Inspector General for Tax Administration, $403,000,000, to remain available until September 30, 2031: *Provided,* That these amounts shall be in addition to amounts otherwise available for such purposes.

(C) OFFICE OF TAX POLICY.—For necessary expenses of the Office of Tax Policy of the Department of the Treasury to carry out functions related to promulgating regulations under the Internal Revenue Code of 1986, $104,533,803, to remain available until September 30, 2031: *Provided,* That these amounts shall be in addition to amounts otherwise available for such purposes.

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

(E) TREASURY DEPARTMENTAL OFFICES.—For necessary expenses of the Departmental Offices of the Department of the Treasury to provide for oversight and implementation support for actions by the Internal Revenue Service to implement this Act and the amendments made by this Act, $50,000,000, to remain available until September 30, 2031: *Provided*, That these amounts shall be in addition to amounts otherwise available for such purposes.

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

(1)(A)(i) will be spent over the ten-year period ending with fiscal year 2031.

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

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

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

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

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

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

(ii) REQUIRED DATE.—For purposes of clause (i), the required date is the date 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 TAXPAYERS.—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

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

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

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

(A) the rate of basic pay may be established by the Secretary of the Treasury (or the Secretary's delegate) at a rate that does not exceed the salary set in accordance with section 104 of title 3, United States Code; and

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

ances, differentials, bonuses, awards, and similar cash payments, may not exceed the maximum amount of total annual compensation payable at the salary set in accordance with section 104 of title 3, United States Code.

Subtitle B—Prescription Drug Pricing Reform

PART 1—LOWERING PRICES THROUGH DRUG PRICE NEGOTIATION

SEC. 11001. PROVIDING FOR LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS.

(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;

"(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 (beginning with 2026).

“(2) PRICE APPLICABILITY PERIOD.—The term ‘price applicability period’ means, with respect to a qualifying single source drug, the period beginning with the first initial price applicability year with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug.

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

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

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

“(A) beginning on the sooner of— “(i) the date on which the manufacturer of the drug and the Secretary enter

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

“(ii) February 28 following the selected drug publication date with respect to such selected drug; and

"(B) ending on November 1 of the year that begins 2 years prior to the initial price applicability year.

"(c) OTHER DEFINITIONS.—For purposes of this part:

"(1) MAXIMUM FAIR PRICE ELIGIBLE INDIVIDUAL.—The term 'maximum fair price eligible individual' means, with respect to a selected drug—

"(A) in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual

who is enrolled under a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title if coverage is provided under such plan for such selected drug; and

"(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under part B of title XVIII, including an individual who is enrolled under an MA plan under part C of such title, if such selected drug is covered under such part.

"(2) MAXIMUM FAIR PRICE.—The term 'maximum fair price' means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c)) with respect to such period, the price negotiated pursuant to section 1194, and updated pursuant to section 1195(b), as applicable, for such drug and year.

"(3) REFERENCE PRODUCT.—The term 'reference product' has the meaning given such term in section 351(i) of the Public Health Service Act.

"(4) UNIT.—The term 'unit' means, with respect to a drug or biological product, the lowest

identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished. The determination of a unit, with respect to a drug or biological product, pursuant to this paragraph shall not be subject to administrative or judicial review.

"(5) TOTAL EXPENDITURES.—The term 'total expenditures' includes, in the case of expenditures with respect to part D of title XVIII, the total gross covered prescription drug costs (as defined in section 1860D–15(b)(3)). The term 'total expenditures' excludes, in the case of expenditures with respect to part B of such title, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

"(d) TIMING FOR INITIAL PRICE APPLICABILITY YEAR 2026.—Notwithstanding the provisions of this part, in the case of initial price applicability year 2026, the fol lowing rules shall apply for purposes of implementing the program:

"(1) Subsection (b)(3) shall be applied by substituting 'September 1, 2023' for ', with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year'.

"(2) Subsection (b)(4) shall be applied—

"(A) in subparagraph (A)(ii), by substituting 'October 1, 2023' for 'February 28 following the selected drug publication date with respect to such selected drug'; and

"(B) in subparagraph (B), by substituting 'August 1, 2024' for 'November 1 of the year that begins 2 years prior to the initial price applicability year'.

"(3) Section 1192 shall be applied— "(A) in subsection (b)(1)(A), by substituting 'during the period beginning on June 1, 2022, and ending on May 31, 2023' for 'during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year';

"(B) in subsection (d)(1)(A), by substituting 'during the period beginning on June 1, 2022, and ending on May 31, 2023' for 'during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the

year of such drug publication date), with respect to such year'; and

"(C) in subsection (e)(3)(B), by substituting 'during the period beginning on June 1, 2022, and ending on May 31, 2023' for 'during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year'.

"(4) Section 1193(a) shall be applied by substituting 'October 1, 2023' for 'February 28 following the selected drug publication date with respect to such selected drug '.

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

"(B) in subparagraph (B), by substituting 'February 1, 2024' for 'the June 1 following the selected drug publication date'; and "(C) in subparagraph (E), by substituting 'August 1, 2024' for 'the first day of following the selected drug publication date, with respect to the initial price applicability year'.

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

"(B) in paragraph (2), by substituting 'March 1, 2025' for 'March 1 of the year prior to such initial price applicability year'.

"SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS AS SELECTED DRUGS.

"(a) IN GENERAL.—Not later than the selected drug publication date with respect to an initial price applicability year, in accordance with subsection (b), the Secretary shall select and publish a list of—

"(1) with respect to the initial price applicability year 2026, 10 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 10) such negotiation-eligible drugs with respect to such year);

"(2) with respect to the initial price applicability year 2027, 15 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), 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-

ess 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, with respect to an initial price applicability year, do the following:

“(A) Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of title XVIII, as determined by the Secretary, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

“(B) Select from such ranked drugs with respect to such year the negotiation-eligible drugs with the highest such rankings.

“(2) HIGH SPEND PART D DRUGS FOR 2026 AND 2027.—With respect to the initial price applicability year 2026 and with respect to the initial price appli-

cability year 2027, the Secretary shall apply paragraph (1) as if the reference to ‘negotiation-eligible drugs described in subsection (d)(1)’ were a reference to ‘negotiation-eligible drugs described in subsection (d)(1)(A)’ and as if the reference to ‘total expenditures for such drugs under parts B and D of title XVIII' were a reference to 'total expenditures for such drugs under part D of title XVIII'.

"(c) SELECTED DRUG.—

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

"(A) is approved or licensed (as applicable)—

"(i) under section 505(j) of the Federal Food, Drug, and Cosmetic Act using such drug as the listed drug; or

"(ii) under section 351(k) of the Public Health Service Act using such drug as the reference product; and

"(B) is marketed pursuant to such approval or licensure.

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

"(A) that is included on the list published under subsection (a) with respect to an initial price applicability year; and

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

shall not be subject to the negotiation process under section 1194 with respect to such negotiation period and shall continue to be considered a selected drug under this part with respect to the number of negotiation-eligible drugs published on the list under subsection (a) with respect to such initial price applicability year.

“(d) NEGOTIATION-ELIGIBLE DRUG.— “(1) IN GENERAL.—For purposes of this part, subject to paragraph (2), the term ‘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, as defined in subsection (e), that is described in either of the following subparagraphs (or, with respect to the initial price applicability year 2026 or 2027, that is described in subparagraph (A)):

“(A) PART D HIGH SPEND DRUGS.—The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part D of title XVIII, as determined by the Secretary in accordance with paragraph (3), during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year.

"(B) PART B HIGH SPEND DRUGS.—The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part B of title XVIII, as determined by the Secretary in ac-

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

"(2) EXCEPTION FOR SMALL BIOTECH DRUGS.—

"(A) IN GENERAL.—Subject to subparagraph (C), the term 'negotiation-eligible drug' shall not include, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets either of the following:

"(i) PART D DRUGS.—The total expenditures for the qualifying single source 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 1 percent of the total expenditures under such part D, as so determined, for all covered part D drugs (as defined 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

manufacturer of the drug has an agreement in effect under section 1860D–14A during such year.

“(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—

“(I) are equal to or less than 1 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs covered under such part B during such year; and

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

“(B) CLARIFICATIONS RELATING TO MANUFACTURERS.—

"(i) AGGREGATION RULE.—All persons treated as a single employer under subsection (a) or (b) of section 52 of the

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

"(ii) LIMITATION.—A drug shall not be considered to be a qualifying single source drug described in clause (i) or (ii) of subparagraph (A) if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii), effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

"(C) DRUGS NOT INCLUDED AS SMALL BIOTECH DRUGS.—The following shall not be considered a qualifying single source drug described in subparagraph (A):

"(i) A vaccine that is licensed under section 351 of the Public Health Service Act and is marketed pursuant to such section.

"(ii) A new formulation, such as an extended release formulation, of a qualifying single source drug.

“(3) CLARIFICATIONS AND DETERMINATIONS.— “(A) PREVIOUSLY SELECTED DRUGS AND SMALL BIOTECH DRUGS EXCLUDED.—In applying subparagraphs (A) and (B) of paragraph (1), the Secretary shall not consider or count— “(i) drugs that are already selected drugs; and

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

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

“(e) QUALIFYING SINGLE SOURCE DRUG.—

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

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

"(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval; and

"(iii) that is not the listed drug for any drug that is approved and marketed under section 505(j) of such Act. "(B) BIOLOGICAL PRODUCTS.—A biological product—

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

and is marketed under section 351 of such Act;

"(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 11 years will have elapsed since the date of such licensure; and

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

"(2) TREATMENT OF AUTHORIZED GENERIC DRUGS.—

"(A) IN GENERAL.—In the case of a qualifying single source drug described in subparagraph (A) or (B) of paragraph (1) that is the listed drug (as such term is used in section 505(j) of the Federal Food, Drug, and Cosmetic Act) or a product described in clause (ii) of subparagraph (B), with respect to an authorized generic drug, in applying the provisions of this part, such authorized generic drug and such listed drug or such product shall be treated as the same qualifying single source drug.

“(B) AUTHORIZED GENERIC DRUG DEFINED.—For purposes of this paragraph, the term ‘authorized generic drug’ means—

“(i) in the case of a drug, an authorized generic drug (as such term is defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act); and

“(ii) in the case of a biological product, a product that—

“(I) has been licensed under section 351(a) of such Act; and

“(II) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark than the reference product.

“(3) EXCLUSIONS.—In this part, the term ‘qualifying single source drug' does not include any of the following:

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

“(B) LOW SPEND MEDICARE DRUGS.—A drug or biological product with respect to which the total expenditures under parts B and D of title XVIII, as determined by the Secretary, during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year, is less than—

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

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

average) for the 12-month period ending with

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

“(f) NO ADMINISTRATIVE OR JUDICIAL REVIEW.— The determination of negotiation-eligible drugs under subsection (d), the determination of qualifying single source drugs under subsection (e), and the selection of drugs under this section are not subject to administrative or judicial review.

“SEC. 1193. MANUFACTURER AGREEMENTS.

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

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

manufacturer in order for the manufacturer to provide access to such price—

“(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, 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)—

“(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 subparagraph (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

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 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, as described in paragraph (1)(B) or (2)(B), as applicable;

“(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 of renegotiation pursuant to section 1194(f)) with respect to such drug—

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

“(B) information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part; and

“(5) the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program.

“(b) Agreement in Effect Until Drug Is No Longer a Selected Drug.—An agreement entered into under this section shall be effective, with respect to a selected drug, until such drug is no longer considered a se lected drug under section 1192(c).

“(c) CONFIDENTIALITY OF INFORMATION.—Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.

“(d) NONDUPLICATION WITH 340B CEILING PRICE.—Under an agreement entered into under this section, the manufacturer of a selected drug shall not be required to provide access to the maximum fair price under subsection (a)(3), with respect to such selected drug and maximum fair price eligible individuals who are eligible to

be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug, except that the manufacturer shall provide for the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if the maximum fair price is below the ceiling price for such selected drug.

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

"(1) shall during the negotiation period with respect to 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) renegotiate, in accordance with the process specified pursuant to subsection (f), such maximum fair price for such drug for the purpose described in section 1193(a)(2) if such drug is a renegotiation-eligible drug under such subsection.

"(b) NEGOTIATION PROCESS REQUIREMENTS.— "(1) METHODOLOGY AND PROCESS.—The Secretary shall develop and use a consistent methodology and process, in accordance with paragraph (2), for negotiations under subsection (a) that aims to achieve the lowest maximum fair price for each selected drug.

"(2) SPECIFIC ELEMENTS OF NEGOTIATION PROCESS.—As part of the negotiation process under this section, with respect to a selected drug and the negotiation period with respect to the initial price applicability year with respect to such drug, the following shall apply:

"(A) SUBMISSION OF INFORMATION.—Not later than March 1 of the year of the selected drug publication date, with respect to the selected drug, the manufacturer of the drug shall submit to the Secretary, in accordance with section 1193(a)(4), the information described in such section.

"(B) INITIAL OFFER BY SECRETARY.—Not later than the June 1 following the selected drug publication date, the Secretary shall provide the manufacturer of a selected drug with a written initial offer that contains the Secretary's proposal for the maximum fair price of the drug and a list of the factors described in section 1194(e) that were used in developing such offer.

"(C) RESPONSE TO INITIAL OFFER.— "(i) IN GENERAL.—Not later than 30 days after the date of receipt of an initial offer under subparagraph (B), the manufacturer shall either accept such offer or propose a counteroffer to such offer.

“(ii) COUNTEROFFER REQUIREMENTS.—If a manufacturer proposes a counteroffer, such counteroffer—

“(I) shall be in writing; and

“(II) shall be justified based on the factors described in subsection (e).

“(D) RESPONSE TO COUNTEROFFER.—After receiving a counteroffer under subparagraph (C), the Secretary shall respond in writing to such counteroffer.

“(E) DEADLINE.—All negotiations between the Secretary and the manufacturer of the selected drug shall end prior to the first day of November following the selected drug publication date, with respect to the initial price applicability year.

“(F) LIMITATIONS ON OFFER AMOUNT.—In negotiating the maximum fair price of a selected drug, with respect to an initial price applicability year for the selected drug, and, as applicable, in renegotiating the maximum fair price for such drug, with respect to a subsequent year during the price applicability period for such drug, the Secretary shall not offer (or agree to a counteroffer for) a maximum fair price for the selected drug that—

“(i) exceeds the ceiling determined under subsection (c) for the selected drug and year; or

"(ii) as applicable, is less than the floor determined under subsection (d) for the selected drug and year.

"(G) TREATMENT OF DETERMINATION.— The determination of a maximum fair price

under this section is not subject to administrative or judicial review.

"(c) CEILING FOR MAXIMUM FAIR PRICE.— "(1) GENERAL CEILING.—

"(A) IN GENERAL.—The maximum fair price negotiated under this section for a selected drug, with respect to the first year of the price applicability period with respect to such drug, shall not exceed the lower of the amount under subparagraph (B) or the amount under subparagraph (C).

"(B) SUBPARAGRAPH (B) AMOUNT.—An amount equal to the following:

"(i) COVERED PART D DRUG.—In the case of a covered part D drug (as defined in section 1860D–2(e)), the sum of the plan specific enrollment weighted amounts for each prescription drug plan or MA–PD plan (as determined under paragraph (2)). "(ii) PART B DRUG OR BIOLOGICAL.— In the case of a drug or biological product covered under part B of title XVIII, the payment amount under section 1847A(b)(4) for the drug or biological product for the year prior to the year of

the selected drug publication date with respect to the initial price applicability year for the drug or biological product. "(C) SUBPARAGRAPH (C) AMOUNT.—An amount equal to the applicable percent described in paragraph (3), with respect to such drug, of the following:

"(i) INITIAL PRICE APPLICABILITY YEAR 2026.—In the case of a selected drug with respect to which such initial price applicability year is 2026, the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug

publication date with respect to such initial price applicability year.

"(ii) INITIAL PRICE APPLICABILITY YEAR 2027 AND SUBSEQUENT YEARS.—In the case of a selected drug with respect to which such initial price applicability year is 2027 or a subsequent year, the lower of— "(I) the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year; or

"(II) the average non-Federal average manufacturer price for such drug for the year prior to the selected drug publication date with respect to such initial price applicability year.

"(2) PLAN SPECIFIC ENROLLMENT WEIGHTED AMOUNT.—For purposes of paragraph (1)(B)(i), the plan specific enrollment weighted amount for a prescription drug plan or an MA–PD plan with respect to a covered Part D drug is an amount equal to the product of—

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

“(B) a fraction—

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

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

“(3) APPLICABLE PERCENT DESCRIBED.—For purposes of this subsection, the applicable percent described in this paragraph is the following:

“(A) SHORT-MONOPOLY DRUGS AND VACCINES.—With respect to a selected drug (other than an extended-monopoly drug and a long monopoly drug), 75 percent.

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

“(C) LONG-MONOPOLY DRUGS.—With respect to a long-monopoly drug, 40 percent.

“(4) EXTENDED-MONOPOLY DRUG DEFINED.—

“(A) IN

GENERAL.—In this part, subject 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 years, have elapsed since the date of approval of such drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act or since the date of licensure of such drug under section 351(a) of the Public Health Service Act, as applicable.

"(B) EXCLUSIONS.—The term 'extended monopoly drug' shall not include any of the following:

"(i) A vaccine that is licensed under section 351 of the Public Health Service Act and marketed pursuant to such section.

"(ii) A selected drug for which a manufacturer had an agreement under this part with the Secretary with respect to an initial price applicability year that is before 2030.

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

"(5) LONG-MONOPOLY DRUG DEFINED.— "(A) IN GENERAL.—In this part, subject to subparagraph (B), the term ‘long-monopoly drug’ means, with respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval of such drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act or

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

“(B) EXCLUSION.—The term ‘long-monopoly drug’ shall not include a vaccine that is licensed under section 351 of the Public Health Service Act and marketed pursuant to such section.

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

“(d) TEMPORARY FLOOR FOR SMALL BIOTECH DRUGS.—In the case of a selected drug that is a qualifying single source drug described in section 1192(d)(2) and with respect to which the first initial price applicability year of the price applicability period with respect to such drug is 2029 or 2030, the maximum fair price negotiated under this section for such drug for such initial price applicability year may not be less than 66 percent of the average non-Federal average manufacturer price for such drug (as defined in subsection (c)(6)) for 2021 (or,

in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year.

“(e) FACTORS.—For purposes of negotiating the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary shall consider the following factors (and, with respect to extended-monopoly drugs and long-monopoly drugs, shall not, except in making a determination of a material change under subsection (f)(2)(D), consider factors other than those described in subparagraphs (B) and (C) of paragraph (1)):

“(1) MANUFACTURER-SPECIFIC INFORMATION.—The following information, with respect to such selected drug, including as submitted by the manufacturer:

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

which the manufacturer has recouped research and development costs.

“(B) Market data for the drug.

“(C) Unit costs of production and distribution of the drug.

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

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

“(F) National sales data for the drug.

“(G) Information on clinical trials for the drug.

“(2) INFORMATION ON ALTERNATIVE TREATMENTS.—The following information, with respect to such selected drug and therapeutic alternatives to such drug:

“(A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and, to the extent such information is available, the costs of such existing therapeutic alternatives.

“(B) Approval by the Food and Drug Administration of such drug and therapeutic alternatives of such drug.

"(C) Comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives of such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.

"(D) The extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

In considering information described in subparagraph (C), the Secretary shall not use evidence or findings from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

"(f) Renegotiation Process.—

"(1) In general.—In the case of a renegotiation-eligible drug (as defined in paragraph (2)) that is selected under paragraph (3), the Secretary shall provide for a process of renegotiation (for years (beginning with 2028) during the price applicability pe-