

tween the amount paid and the correct amount due is less than \$1.”

REPORT BY HEALTH INSURANCE BENEFITS ADVISORY COUNCIL ON METHODS OF REIMBURSEMENT OF PHYSICIANS FOR THEIR SERVICES

Pub. L. 92-603, title II, §224(b), Oct. 30, 1972, 86 Stat. 1395, directed Health Insurance Benefits Advisory Council to conduct a study of methods of reimbursement for physicians' services under Medicare with respect to fees, extent of assignments accepted by physicians, and share of physician-fee costs which Medicare program does not pay and submit such study to Congress by Jan. 1, 1973.

**Executive Documents**

EXECUTIVE ORDER NO. 13947

Ex. Ord. No. 13947, July 24, 2020, 85 F.R. 59171, which related to a payment model pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price, was revoked by Ex. Ord. No. 13948, § 5, Sept. 13, 2020, 85 F.R. 59650, set out below.

EX. ORD. NO. 13948. LOWERING DRUG PRICES BY PUTTING AMERICA FIRST

Ex. Ord. No. 13948, Sept. 13, 2020, 85 F.R. 59649, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Purpose.* Americans pay more per capita for prescription drugs than residents of any other developed country in the world. It is unacceptable that Americans pay more for the exact same drugs, often made in the exact same places. Other countries' governments regulate drug prices by negotiating with drug manufacturers to secure bargain prices, leaving Americans to make up the difference—effectively subsidizing innovation and) [sic] lower-cost drugs for the rest of the world. The Council of Economic Advisers has found that Americans finance much of the biopharmaceutical innovation that the world depends on, allowing foreign governments, many of which are the sole healthcare payers in their respective countries, to enjoy bargain prices for such innovations. Americans should not bear extra burdens to compensate for the shortfalls that result from the nationalized public healthcare systems of wealthy countries abroad.

In addition to being unfair, high drug prices in the United States also have serious economic and health consequences for patients in need of treatment. High prices cause Americans to divert too much of their scarce resources to pharmaceutical treatments and away from other productive uses. High prices are also a reason many patients skip doses of their medications, take less than the recommended doses, or abandon treatment altogether. The consequences of these behaviors can be severe. For example, patients may develop acute conditions that result in poor clinical outcomes or that require drastic and expensive medical interventions.

In most markets, the largest buyers pay the lowest prices, but this has not been true for prescription drugs. The Federal Government is the largest payer for prescription drugs in the world, but it pays more than many smaller buyers, including other developed nations. When the Federal Government purchases a drug covered by Medicare—the cost of which is shared by American seniors who take the drug and American taxpayers—it should insist on, at a minimum, the lowest price at which the manufacturer sells that drug to any other developed nation.

SEC. 2. *Policy.* (a) It is the policy of the United States that the Medicare program should not pay more for costly Part B or Part D prescription drugs or biological products than the most-favored-nation price.

(b) The “most-favored-nation price” shall mean the lowest price, after adjusting for volume and differences in national gross domestic product, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organisation for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product.

SEC. 3. *Payment Model on the Most-Favored-Nation Price in Medicare Part B.* To the extent consistent with law, the Secretary of Health and Human Services shall immediately take appropriate steps to implement his rulemaking plan to test a payment model pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price. The model would test whether, for patients who require pharmaceutical treatment, paying no more than the most-favored-nation price would mitigate poor clinical outcomes and increased expenditures associated with high drug costs.

SEC. 4. *Payment Model on the Most-Favored-Nation Price in Medicare Part D.* To the extent consistent with law, the Secretary shall take appropriate steps to develop and implement a rulemaking plan, selecting for testing, consistent with section 1315a(b)(2)(A) of title 42, United States Code, a payment model pursuant to which Medicare would pay, for Part D prescription drugs or biological products where insufficient competition exists and seniors are faced with prices above those in OECD member countries that have a comparable per-capita gross domestic product to the United States, after adjusting for volume and differences in national gross domestic product, no more than the most-favored-nation price, to the extent feasible. The model should test whether, for patients who require pharmaceutical treatment, paying no more than the most-favored-nation price would mitigate poor clinical outcomes and increased expenditures associated with high drug costs.

SEC. 5. *Revocation of Executive Order.* The Executive Order of July 24, 2020 (Lowering Drug Prices by Putting America First) [Ex. Ord. No. 13947, formerly set out above], is revoked.

SEC. 6. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

**§ 1395v. Agreements with States**

**(a) Duty of Secretary; enrollment of eligible individuals**

The Secretary shall, at the request of a State made before January 1, 1970, or during 1981 or after 1988, enter into an agreement with such State pursuant to which all eligible individuals in either of the coverage groups described in subsection (b) (as specified in the agreement) will be enrolled under the program established by this part.

**(b) Coverage of groups to which applicable**

An agreement entered into with any State pursuant to subsection (a) may be applicable to either of the following coverage groups:

(1) individuals receiving money payments under the plan of such State approved under subchapter I or subchapter XVI; or

(2) individuals receiving money payments under all of the plans of such State approved under subchapters I, X, XIV, and XVI, and part A of subchapter IV.

Except as provided in subsection (g), there shall be excluded from any coverage group any individual who is entitled to monthly insurance benefits under subchapter II or who is entitled to receive an annuity under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.]. Effective January 1, 1974, and subject to section 1396a(f) of this title, the Secretary shall, at the request of any State not eligible to participate in the State plan program established under subchapter XVI, continue in effect the agreement entered into under this section with such State subject to such modifications as the Secretary may by regulations provide to take account of the termination of any plans of such State approved under subchapters I, X, XIV, and XVI and the establishment of the supplemental security income program under subchapter XVI.

**(c) Eligible individuals**

For purposes of this section, an individual shall be treated as an eligible individual only if he is an eligible individual (within the meaning of section 1395o of this title) on the date an agreement covering him is entered into under subsection (a) or he becomes an eligible individual (within the meaning of such section) at any time after such date; and he shall be treated as receiving money payments described in subsection (b) if he receives such payments for the month in which the agreement is entered into or any month thereafter.

**(d) Monthly premiums; coverage periods**

In the case of any individual enrolled pursuant to this section—

(1) the monthly premium to be paid by the State shall be determined under section 1395r of this title (without any increase under subsection (b) thereof);

(2) his coverage period shall begin on which-ever of the following is the latest:

(A) July 1, 1966;

(B) the first day of the third month following the month in which the State agreement is entered into;

(C) the first day of the first month in which he is both an eligible individual and a member of a coverage group specified in the agreement under this section; or

(D) such date as may be specified in the agreement; and

(3) his coverage period attributable to the agreement with the State under this section shall end on the last day of whichever of the following first occurs:

(A) the month in which he is determined by the State agency to have become ineligible both for money payments of a kind specified in the agreement and (if there is in effect a modification entered into under subsection (h)) for medical assistance, or

(B) the month preceding the first month for which he becomes entitled to monthly benefits under subchapter II or to an annuity or pension under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.].

**(e) Subsection (d)(3) terminations deemed resulting in section 1395p enrollment**

Any individual whose coverage period attributable to the State agreement is terminated pursuant to subsection (d)(3) shall be deemed for purposes of this part (including the continuation of his coverage period under this part) to have enrolled under section 1395p of this title in the initial general enrollment period provided by section 1395p(c) of this title. The coverage period under this part of any such individual who (in the last month of his coverage period attributable to the State agreement or in any of the following six months) files notice that he no longer wishes to participate in the insurance program established by this part, shall terminate at the close of the month in which the notice is filed.

**(f) “Carrier” as including State agency; provisions facilitating deductions, coinsurance, etc., and leading to economy and efficiency of operation**

With respect to eligible individuals receiving money payments under the plan of a State approved under subchapter I, X, XIV, or XVI, or part A of subchapter IV, or eligible to receive medical assistance under the plan of such State approved under subchapter XIX, if the agreement entered into under this section so provides, the term “carrier” as defined in section 1395u(f)<sup>1</sup> of this title also includes the State agency, specified in such agreement, which administers or supervises the administration of the plan of such State approved under subchapter I, XVI, or XIX. The agreement shall also contain such provisions as will facilitate the financial transactions of the State and the carrier with respect to deductions, coinsurance, and otherwise, and as will lead to economy and efficiency of operation, with respect to individuals receiving money payments under plans of the State approved under subchapters I, X, XIV, and XVI, and part A of subchapter IV, and individuals eligible to receive medical assistance under the plan of the State approved under subchapter XIX.

**(g) Subsection (b) exclusions from coverage groups**

(1) The Secretary shall, at the request of a State made before January 1, 1970, or during 1981 or after 1988, enter into a modification of an agreement entered into with such State pursuant to subsection (a) under which the second sentence of subsection (a) shall not apply with respect to such agreement.

(2) In the case of any individual who would (but for this subsection) be excluded from the applicable coverage group described in subsection (b) by the second sentence of such subsection—

(A) subsections (c) and (d)(2) shall be applied as if such subsections referred to the modification under this subsection (in lieu of the agreement under subsection (a)), and

(B) subsection (d)(3)(B) shall not apply so long as there is in effect a modification entered into by the State under this subsection.

<sup>1</sup> See References in Text note below.

**(h) Modifications respecting subsection (b) coverage groups**

(1) The Secretary shall, at the request of a State made before January 1, 1970, or during 1981 or after 1988, enter into a modification of an agreement entered into with such State pursuant to subsection (a) under which the coverage group described in subsection (b) and specified in such agreement is broadened to include (A) individuals who are eligible to receive medical assistance under the plan of such State approved under subchapter XIX, or (B) qualified medicare beneficiaries (as defined in section 1396d(p)(1) of this title).

(2) For purposes of this section, an individual shall be treated as eligible to receive medical assistance under the plan of the State approved under subchapter XIX if, for the month in which the modification is entered into under this subsection or for any month thereafter, he has been determined to be eligible to receive medical assistance under such plan. In the case of any individual who would (but for this subsection) be excluded from the agreement, subsections (c) and (d)(2) shall be applied as if they referred to the modification under this subsection (in lieu of the agreement under subsection (a)), and subsection (d)(2)(C) shall be applied (except in the case of qualified medicare beneficiaries, as defined in section 1396d(p)(1) of this title) by substituting "second month following the first month" for "first month".

(3) In this subsection, the term "qualified medicare beneficiary" also includes an individual described in section 1396a(a)(10)(E)(iii) of this title.

**(i) Enrollment of qualified medicare beneficiaries**

For provisions relating to enrollment of qualified medicare beneficiaries under part A, see section 1395i-2(g) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1843, as added Pub. L. 89-97, title I, § 102(a), July 30, 1965, 79 Stat. 312; amended Pub. L. 89-384, § 4(a), (b), Apr. 8, 1966, 80 Stat. 105; Pub. L. 90-248, title II, §§ 222(a), (b), (e), 241(e), Jan. 2, 1968, 81 Stat. 900, 901, 917; Pub. L. 93-233, § 18(l), Dec. 31, 1973, 87 Stat. 970; Pub. L. 93-445, title III, § 308, Oct. 16, 1974, 88 Stat. 1358; Pub. L. 96-499, title IX, §§ 945(e), 947(a), (c), Dec. 5, 1980, 94 Stat. 2642, 2643; Pub. L. 98-21, title VI, § 606(a)(3)(E), Apr. 20, 1983, 97 Stat. 171; Pub. L. 98-369, div. B, title III, § 2354(b)(15), July 18, 1984, 98 Stat. 1101; Pub. L. 100-360, title III, § 301(e)(1), July 1, 1988, 102 Stat. 749; Pub. L. 100-485, title VI, § 608(d)(14)(H), Oct. 13, 1988, 102 Stat. 2416; Pub. L. 101-239, title VI, § 6013(b), Dec. 19, 1989, 103 Stat. 2164; Pub. L. 101-508, title IV, § 4501(d), Nov. 5, 1990, 104 Stat. 1388-165.)

**Editorial Notes**

**REFERENCES IN TEXT**

The Railroad Retirement Act of 1974, referred to in subsec. (d)(3)(B), is act Aug. 29, 1935, ch. 812, as amended generally by Pub. L. 93-445, title I, § 101, Oct. 16, 1974, 88 Stat. 1305, which is classified generally to subchapter IV (§ 231 et seq.) of chapter 9 of Title 45, Railroads. For further details and complete classification of this Act to the Code, see Codification note set out preceding

section 231 of Title 45, section 231t of Title 45, and Tables.

Section 1395u(f) of this title, referred to in subsec. (f), was repealed by Pub. L. 108-173, title IX, § 911(c)(5), Dec. 8, 2003, 117 Stat. 2384.

**AMENDMENTS**

1990—Subsec. (h)(3). Pub. L. 101-508 added par. (3).

1989—Subsec. (i). Pub. L. 101-239 added subsec. (i).

1988—Subsecs. (a), (g)(1). Pub. L. 100-360, § 301(e)(1)(A), formerly § 301(e)(1), as redesignated by Pub. L. 100-485, § 608(d)(14)(H)(i), inserted "or after 1988" after "during 1981".

Subsec. (h)(1). Pub. L. 100-360, § 301(e)(1)(A), formerly § 301(e)(1), as redesignated by Pub. L. 100-485, § 608(d)(14)(H)(i), inserted "or after 1988" after "during 1981".

Pub. L. 100-360, § 301(e)(1)(B), as added by Pub. L. 100-485, § 608(d)(14)(H)(ii), inserted cl. (A) designation after "include" and added cl. (B).

Subsec. (h)(2). Pub. L. 100-360, § 301(e)(1)(C), as added by Pub. L. 100-485, § 608(d)(14)(H)(ii), inserted "(except in the case of qualified medicare beneficiaries, as defined in section 1396d(p)(1) of this title)" after "shall be applied".

1984—Subsec. (d)(3)(B). Pub. L. 98-369 substituted "1974" for "1937".

1983—Subsec. (d)(1). Pub. L. 98-21 substituted "without any increase under subsection (b) thereof" for "without any increase under subsection (c) thereof".

1980—Subsec. (a). Pub. L. 96-499, § 945(e), inserted "or during 1981," after "January 1, 1970,".

Subsec. (e). Pub. L. 96-499, § 947(a), inserted provision that the coverage period under this part of any individual who filed notice that he no longer wished to participate in the insurance program established by this part was to terminate at the close of the month in which the notice was filed.

Subsec. (g)(1). Pub. L. 96-499, § 945(e), inserted "or during 1981," after "January 1, 1970,".

Subsec. (g)(2)(C). Pub. L. 96-499, § 947(c)(3), struck out cl. (C) which authorized individuals facing exclusion from the applicable coverage group to terminate their enrollment under this part by the filing of a notice indicating he no longer wished to participate in the insurance program established by this part.

Subsec. (h)(1). Pub. L. 96-499, § 945(e), inserted "or during 1981," after "January 1, 1970,".

1974—Subsec. (b). Pub. L. 93-445 substituted "under the Railroad Retirement Act of 1974" for "or pension under the Railroad Retirement Act of 1937".

1973—Subsec. (b). Pub. L. 93-233 provided for continuation of State agreements for coverage of certain individuals in connection with establishment of supplemental security income program.

1968—Pub. L. 90-248, § 222(b)(4), inserted "(or are eligible for medical assistance)" in section catchline.

Subsec. (a). Pub. L. 90-248, § 222(e)(1), substituted "1970" for "1968".

Subsec. (b)(2). Pub. L. 90-248, § 241(e)(1), struck out "IV," after "I," and inserted "and part A of subchapter IV" after "XVI".

Subsec. (c). Pub. L. 90-248, § 222(e)(2), struck out "and before January 1, 1968" after "such date" and "before January 1968" after "thereafter" just before the period.

Subsec. (d)(2)(D). Pub. L. 90-248, § 222(e)(3), struck out "(not later than January 1, 1968)" after "such date".

Subsec. (d)(3)(A). Pub. L. 90-248, § 222(b)(1), substituted "ineligible both for money payments of a kind specified in the agreement and (if there is in effect a modification entered into under subsection (h)) for medical assistance" for "ineligible for money payments of a kind specified in the agreement".

Subsec. (f). Pub. L. 90-248, § 222(b)(2), inserted "or eligible to receive medical assistance under the plan of such State approved under subchapter XIX" and "and individuals eligible to receive medical assistance under the plan of the State approved under subchapter XIX" after "or part A of subchapter IV" and "and part A of subchapter IV", respectively.

Pub. L. 90-248, §241(e)(2), struck out “IV,” before “X,” in two places, and inserted “or part A of subchapter IV,” after “XVI,” first place it appears in first sentence and “, and part A of subchapter IV” after “XVI” in second sentence.

Subsec. (g)(1). Pub. L. 90-248, §222(b)(3), substituted “1970” for “1968”.

Subsec. (h). Pub. L. 90-248, §222(a), added subsec. (h). 1966—Subsec. (b). Pub. L. 89-384, §4(a), inserted reference to subsec. (g) in exclusionary provision.

Subsec. (g). Pub. L. 89-384, §4(b), added subsec. (g).

#### Statutory Notes and Related Subsidiaries

##### EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-508 applicable to calendar quarters beginning on or after Jan. 1, 1991, without regard to whether or not regulations to implement such amendment are promulgated by such date, see section 4501(f) of Pub. L. 101-508, set out as a note under section 1396a of this title.

##### EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101-239 effective Jan. 1, 1990, see section 6013(c) of Pub. L. 101-239, set out as a note under section 1395i-2 of this title.

##### EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100-360, see section 608(g)(1) of Pub. L. 100-485, set out as a note under section 704 of this title.

Pub. L. 100-360, title III, §301(e)(3), July 1, 1988, 102 Stat. 750, provided that: “The amendment made by paragraph (1) [amending this section] shall take effect on January 1, 1989, and the amendments made by paragraph (2) [amending section 1396a of this title] shall take effect on July 1, 1989.”

##### EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98-369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98-369, set out as a note under section 1320a-1 of this title.

##### EFFECTIVE DATE OF 1983 AMENDMENT; TRANSITIONAL RULE

Amendment by Pub. L. 98-21 applicable to premiums for months beginning with January 1984, but for months after June 1983 and before January 1984, the monthly premium for June 1983 shall apply to individuals enrolled under parts A and B of this subchapter, see section 606(c) of Pub. L. 98-21, set out as a note under section 1395r of this title.

##### EFFECTIVE DATE OF 1980 AMENDMENT

Pub. L. 96-499, title IX, §947(d), Dec. 5, 1980, 94 Stat. 2643, provided that: “The amendments made by this section [amending this section and section 1395q of this title] apply to notices filed after the third calendar month beginning after the date of the enactment of this Act [Dec. 5, 1980].”

##### EFFECTIVE DATE OF 1974 AMENDMENT

Amendment by Pub. L. 93-445 effective Jan. 1, 1975, see section 603 of Pub. L. 93-445, set out as a note under section 402 of this title.

##### EFFECTIVE DATE OF 1973 AMENDMENT

Amendment by Pub. L. 93-233 effective Jan. 1, 1974, see Pub. L. 93-233, §18(z-3)(1), Dec. 31, 1973, 87 Stat. 974.

##### TERMINATION PERIOD FOR CERTAIN INDIVIDUALS COVERED PURSUANT TO STATE AGREEMENTS

Pub. L. 96-499, title IX, §947(e), Dec. 5, 1980, 94 Stat. 2643, provided that: “The coverage period under part B

of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] of an individual whose coverage period attributable to a State agreement under section 1843 of such Act [42 U.S.C. 1395v] is terminated and who has filed notice before the end of the third calendar month beginning after the date of the enactment of this Act [Dec. 5, 1980] that he no longer wishes to participate in the insurance program established by part B of title XVIII shall terminate on the earlier of (1) the day specified in section 1838 [42 U.S.C. 1395q] without the amendments made by this section, or (2) (unless the individual files notice before the day specified in this clause that he wishes his coverage period to terminate as provided in clause (1)) the day on which his coverage period would terminate if the individual filed notice in the fourth calendar month beginning after the date of the enactment of this Act.”

##### DISTRICT OF COLUMBIA; AGREEMENT OF COMMISSIONER WITH SECRETARY FOR SUPPLEMENTARY MEDICAL INSURANCE

Pub. L. 90-227, §2, Dec. 27, 1967, 81 Stat. 745, provided that: “The Commissioner [now Mayor of District of Columbia] may enter into an agreement (and any modifications of such agreement) with the Secretary under section 1843 of the Social Security Act [42 U.S.C. 1395v] pursuant to which (1) eligible individuals (as defined in section 1836 of the Social Security Act) [42 U.S.C. 1395o] who are eligible to receive medical assistance under the District of Columbia's plan for medical assistance approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] will be enrolled in the supplementary medical insurance program established under part B of title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], and (2) provisions will be made for payment of the monthly premiums of such individuals for such program.”

#### § 1395w. Appropriations to cover Government contributions and contingency reserve

##### (a) In general

There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Federal Supplementary Medical Insurance Trust Fund—

(1)(A) a Government contribution equal to the aggregate premiums payable for a month for enrollees age 65 and over under this part and deposited in the Trust Fund, multiplied by the ratio of—

(i) twice the dollar amount of the actuarially adequate rate per enrollee age 65 and over as determined under section 1395r(a)(1) of this title for such month minus the dollar amount of the premium per enrollee for such month, as determined under section 1395r(a)(3) of this title, to

(ii) the dollar amount of the premium per enrollee for such month, plus

(B) a Government contribution equal to the aggregate premiums payable for a month for enrollees under age 65 under this part and deposited in the Trust Fund, multiplied by the ratio of—

(i) twice the dollar amount of the actuarially adequate rate per enrollee under age 65 as determined under section 1395r(a)(4) of this title for such month minus the dollar amount of the premium per enrollee for such month, as determined under section 1395r(a)(3) of this title, to

(ii) the dollar amount of the premium per enrollee for such month; minus