

(3) The establishment of procedures to carry out the provisions of this part, as applicable, with respect to—

(A) maximum fair price eligible individuals who are enrolled in a prescription drug plan under part D of subchapter XVIII or an MA-PD plan under part C of such subchapter; and

(B) maximum fair price eligible individuals who are enrolled under part B of such subchapter, including who are enrolled in an MA plan under part C of such subchapter.

(4) The establishment of a negotiation process and renegotiation process in accordance with section 1320f-3 of this title.

(5) The establishment of a process for manufacturers to submit information described in section 1320f-3(b)(2)(A) of this title.

(6) The sharing with the Secretary of the Treasury of such information as is necessary to determine the tax imposed by section 5000D of the Internal Revenue Code of 1986, including the application of such tax to a manufacturer, producer, or importer or the determination of any date described in section 5000D(c)(1) of such Code. For purposes of the preceding sentence, such information shall include—

(A) the date on which the Secretary receives notification of any termination of an agreement under the Medicare coverage gap discount program under section 1395w-114a of this title and the date on which any subsequent agreement under such program is entered into;

(B) the date on which the Secretary receives notification of any termination of an agreement under the manufacturer discount program under section 1395w-114c of this title and the date on which any subsequent agreement under such program is entered into; and

(C) the date on which the Secretary receives notification of any termination of a rebate agreement described in section 1396r-8(b) of this title and the date on which any subsequent rebate agreement described in such section is entered into.

(7) The establishment of procedures for purposes of applying subsections (d)(2)(B) and (f)(1)(C) of section 1320f-1 of this title.

(b) Compliance monitoring

The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under section 1320f-2 of this title and establish a mechanism through which violations of such terms shall be reported.

(Aug. 14, 1935, ch. 531, title XI, §1196, as added and amended Pub. L. 117-169, title I, §§11001(a), 11002(a)(3), Aug. 16, 2022, 136 Stat. 1849, 1861.)

Editorial Notes

REFERENCES IN TEXT

Section 5000D of the Internal Revenue Code of 1986, referred to in subsec. (a)(6), is classified to section 5000D of Title 26, Internal Revenue Code.

AMENDMENTS

2022—Subsec. (a)(7). Pub. L. 117-169, §11002(a)(3), substituted “subsections (d)(2)(B) and (f)(1)(C) of section

1320f-1 of this title” for “section 1320f-1(d)(2)(B) of this title”.

§ 1320f-6. Civil monetary penalties

(a) Violations relating to offering of maximum fair price

Any manufacturer of a selected drug that has entered into an agreement under section 1320f-2 of this title, with respect to a year during the price applicability period with respect to such drug, that does not provide access to a price that is equal to or less than the maximum fair price for such drug for such year—

(1) to a maximum fair price eligible individual who with respect to such drug is described in subparagraph (A) of section 1320f(c)(2) of this title and who is dispensed such drug during such year (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs); or

(2) to a hospital, physician, or other provider of services or supplier with respect to maximum fair price eligible individuals who with respect to such drug is described in subparagraph (B) of such section and is furnished or administered such drug by such hospital, physician, or provider or supplier during such year;

shall be subject to a civil monetary penalty equal to ten times the amount equal to the product of the number of units of such drug so furnished, dispensed, or administered during such year and the difference between the price for such drug made available for such year by such manufacturer with respect to such individual or hospital, physician, provider of services, or supplier and the maximum fair price for such drug for such year.

(b) Violations relating to providing rebates

Any manufacturer that fails to comply with the rebate requirements under section 1320f-1(f)(4) of this title shall be subject to a civil monetary penalty equal to 10 times the amount of the rebate the manufacturer failed to pay under such section.

(c) Violations of certain terms of agreement

Any manufacturer of a selected drug that has entered into an agreement under section 1320f-2 of this title, with respect to a year during the price applicability period with respect to such drug, that is in violation of a requirement imposed pursuant to section 1320f-2(a)(5) of this title, including the requirement to submit information pursuant to section 1320f-2(a)(4) of this title, shall be subject to a civil monetary penalty equal to \$1,000,000 for each day of such violation.

(d) False information

Any manufacturer that knowingly provides false information pursuant to section 1320f-5(a)(7) of this title shall be subject to a civil monetary penalty equal to \$100,000,000 for each item of such false information.

(e) Application

The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply

to a civil monetary penalty under this section in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(Aug. 14, 1935, ch. 531, title XI, §1197, as added and amended Pub. L. 117-169, title I, §§11001(a), 11002(a)(4), Aug. 16, 2022, 136 Stat. 1850, 1861.)

Editorial Notes

AMENDMENTS

2022—Subsecs. (b) to (e). Pub. L. 117-169, §11002(a)(4), added subsec. (b) and redesignated former subsecs. (b) to (d) as (c) to (e), respectively.

§ 1320f-7. Limitation on administrative and judicial review

There shall be no administrative or judicial review of any of the following:

(1) The determination of a unit, with respect to a drug or biological product, pursuant to section 1320f(c)(6) of this title.

(2) The selection of drugs under section 1320f-1(b) of this title, the determination of negotiation-eligible drugs under section 1320f-1(d) of this title, and¹ the determination of qualifying single source drugs under section 1320f-1(e) of this title the² application of section 1320f-1(f) of this title.³

(3) The determination of a maximum fair price under subsection (b) or (f) of section 1320f-3 of this title.

(4) The determination of renegotiation-eligible drugs under section 1320f-3(f)(2) of this title and the selection of renegotiation-eligible drugs under section 1320f-3(f)(3) of this title.

(Aug. 14, 1935, ch. 531, title XI, §1198, as added and amended Pub. L. 117-169, title I, §§11001(a), 11002(a)(5), Aug. 16, 2022, 136 Stat. 1851, 1861.)

Editorial Notes

AMENDMENTS

2022—Par. (2). Pub. L. 117-169, §11002(a)(5), which directed the amendment of subsec. (b)(2) of this section by inserting “the application of section 1320f-1(f) of this title,” after “section 1320f-1(e) of this title”, was executed by making the insertion in par. (2) to reflect the probable intent of Congress.

SUBCHAPTER XII—ADVANCES TO STATE UNEMPLOYMENT FUNDS

§ 1321. Eligibility requirements for transfer of funds; reimbursement by State; application; certification; limitation

(a)(1) Advances shall be made to the States from the Federal unemployment account in the Unemployment Trust Fund as provided in this section, and shall be repayable, with interest to the extent provided in section 1322(b) of this title, in the manner provided in sections 1101(d)(1), 1103(b)(2), and 1322 of this title. An advance to a State for the payment of compensation in any 3-month period may be made if—

(A) the Governor of the State applies therefor no earlier than the first day of the month

preceding the first month of such 3-month period, and

(B) he furnishes to the Secretary of Labor his estimate of the amount of an advance which will be required by the State for the payment of compensation in each month of such 3-month period.

(2) In the case of any application for an advance under this section to any State for any 3-month period, the Secretary of Labor shall—

(A) determine the amount (if any) which he finds will be required by such State for the payment of compensation in each month of such 3-month period, and

(B) certify to the Secretary of the Treasury the amount (not greater than the amount estimated by the Governor of the State) determined under subparagraph (A).

The aggregate of the amounts certified by the Secretary of Labor with respect to any 3-month period shall not exceed the amount which the Secretary of the Treasury reports to the Secretary of Labor is available in the Federal unemployment account for advances with respect to each month of such 3-month period.

(3) For purposes of this subsection—

(A) an application for an advance shall be made on such forms, and shall contain such information and data (fiscal and otherwise) concerning the operation and administration of the State unemployment compensation law, as the Secretary of Labor deems necessary or relevant to the performance of his duties under this subchapter,

(B) the amount required by any State for the payment of compensation in any month shall be determined with due allowance for contingencies and taking into account all other amounts that will be available in the State's unemployment fund for the payment of compensation in such month, and

(C) the term “compensation” means cash benefits payable to individuals with respect to their unemployment, exclusive of expenses of administration.

(b) The Secretary of the Treasury shall, prior to audit or settlement by the Government Accountability Office, transfer in monthly installments from the Federal unemployment account to the account of the State in the Unemployment Trust Fund the amount certified under subsection (a) by the Secretary of Labor (but not exceeding that portion of the balance in the Federal unemployment account at the time of the transfer which is not restricted as to use pursuant to section 1103(b)(1) of this title). The amount of any monthly installment so transferred shall not exceed the amount estimated by the State to be required for the payment of compensation for the month with respect to which such installment is made.

(Aug. 14, 1935, ch. 531, title XII, §1201, as added Oct. 3, 1944, ch. 480, title IV, §402, 58 Stat. 790; amended Aug. 6, 1947, ch. 510, §5(b), 61 Stat. 794; 1949 Reorg. Plan No. 2, §1, eff. Aug. 19, 1949, 14 F.R. 5225, 63 Stat. 1065; Aug. 28, 1950, ch. 809, title IV, §404(a), 64 Stat. 560; Aug. 5, 1954, ch. 657, §3, 68 Stat. 671; Pub. L. 86-778, title V, §522(a), Sept. 13, 1960, 74 Stat. 978; Pub. L. 94-566, title II,

¹ So in original. The word “and” probably should not appear.

² So in original. Probably should be preceded by “, and”.

³ So in original.