

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Pub. L. 111-347, title III, §301(a)(3), Jan. 2, 2011, 124 Stat. 3666, provided that: “The amendments made by this subsection [enacting this section] shall apply to payments received pursuant to contracts entered into on and after the date of the enactment of this Act [Jan. 2, 2011].”

PROHIBITION ON REIMBURSEMENT OF FEES

Pub. L. 111-347, title III, §301(b), Jan. 2, 2011, 124 Stat. 3666, provided that:

“(1) IN GENERAL.—The head of each executive agency shall take any and all measures necessary to ensure that no funds are disbursed to any foreign contractor in order to reimburse the tax imposed under section 5000C of the Internal Revenue Code of 1986.

“(2) ANNUAL REVIEW.—The Administrator for Federal Procurement Policy shall annually review the contracting activities of each executive agency to monitor compliance with the requirements of paragraph (1).

“(3) EXECUTIVE AGENCY.—For purposes of this subsection, the term ‘executive agency’ has the meaning given the term in section 4 of the Office of Federal Procurement Policy Act ([former] 41 U.S.C. 403) [see 41 U.S.C. 133].”

APPLICATION

Pub. L. 111-347, title III, §301(c), Jan. 2, 2011, 124 Stat. 3666, provided that: “This section [enacting this section and provisions set out as notes under this section] and the amendments made by this section shall be applied in a manner consistent with United States obligations under international agreements.”

CHAPTER 50A—DESIGNATED DRUGS

Sec.

5000D. Designated drugs during noncompliance periods.

§ 5000D. Designated drugs during noncompliance periods**(a) In general**

There is hereby imposed on the sale by the manufacturer, producer, or importer of any designated drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of—

(1) such tax, divided by

(2) the sum of such tax and the price for which so sold.

(b) Noncompliance periods

A day is described in this subsection with respect to a designated drug if it is a day during one of the following periods:

(1) The period beginning on the March 1st (or, in the case of initial price applicability year 2026, the October 2nd) immediately following the date on which such drug is included on the list published under section 1192(a) of the Social Security Act and ending on the earlier of—

(A) the first date on which the manufacturer of such designated drug has in place an agreement described in section 1193(a) of such Act with respect to such drug, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(2) The period beginning on the November 2nd immediately following the March 1st de-

scribed in paragraph (1) (or, in the case of initial price applicability year 2026, the August 2nd immediately following the October 2nd described in such paragraph) and ending on the earlier of—

(A) the first date on which the manufacturer of such designated drug and the Secretary of Health and Human Services have agreed to a maximum fair price under an agreement described in section 1193(a) of the Social Security Act, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(3) In the case of any designated drug which is a selected drug (as defined in section 1192(c) of the Social Security Act) that the Secretary of Health and Human Services has selected for renegotiation under section 1194(f) of such Act, the period beginning on the November 2nd of the year that begins 2 years prior to the first initial price applicability year of the price applicability period for which the maximum fair price established pursuant to such renegotiation applies and ending on the earlier of—

(A) the first date on which the manufacturer of such designated drug has agreed to a renegotiated maximum fair price under such agreement, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(4) With respect to information that is required to be submitted to the Secretary of Health and Human Services under an agreement described in section 1193(a) of the Social Security Act, the period beginning on the date on which such Secretary certifies that such information is overdue and ending on the date that such information is so submitted.

(c) Suspension of tax**(1) In general**

A day shall not be taken into account as a day during a period described in subsection (b) if such day is also a day during the period—

(A) beginning on the first date on which—

(i) the notice of terminations of all applicable agreements of the manufacturer have been received by the Secretary of Health and Human Services, and

(ii) none of the drugs of the manufacturer of the designated drug are covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act, and

(B) ending on the last day of February following the earlier of—

(i) the first day after the date described in subparagraph (A) on which the manufacturer enters into any subsequent applicable agreement, or

(ii) the first date any drug of the manufacturer of the designated drug is covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act.

(2) Applicable agreement

For purposes of this subsection, the term “applicable agreement” means the following:

- (A) An agreement under—
 - (i) the Medicare coverage gap discount program under section 1860D-14A of the Social Security Act, or
 - (ii) the manufacturer discount program under section 1860D-14C of such Act.
- (B) A rebate agreement described in section 1927(b) of such Act.

(d) Applicable percentage

For purposes of this section, the term “applicable percentage” means—

- (1) in the case of sales of a designated drug during the first 90 days described in subsection (b) with respect to such drug, 65 percent,
- (2) in the case of sales of such drug during the 91st day through the 180th day described in subsection (b) with respect to such drug, 75 percent,
- (3) in the case of sales of such drug during the 181st day through the 270th day described in subsection (b) with respect to such drug, 85 percent, and
- (4) in the case of sales of such drug during any subsequent day, 95 percent.

(e) Definitions

For purposes of this section—

(1) Designated drug

The term “designated drug” means any negotiation-eligible drug (as defined in section 1192(d) of the Social Security Act) included on the list published under section 1192(a) of such Act which is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing.

(2) United States

The term “United States” has the meaning given such term by section 4612(a)(4).

(3) Other terms

The terms “initial price applicability year”, “price applicability period”, and “maximum fair price” have the meaning given such terms in section 1191 of the Social Security Act.

(f) Special rules

(1) Coordination with rules for possessions of the United States

Rules similar to the rules of paragraphs (2) and (4) of section 4132(c) shall apply for purposes of this section.

(2) Anti-abuse rule

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

(g) Exports

Rules similar to the rules of section 4662(e) (other than section 4662(e)(2)(A)(ii)(II)) shall apply for purposes of this chapter.

(h) Regulations

The Secretary shall prescribe such regulations and other guidance as may be necessary to carry out this section.

(Added Pub. L. 117-169, title I, §11003(a), Aug. 16, 2022, 136 Stat. 1862.)

Editorial Notes

REFERENCES IN TEXT

The Social Security Act, referred to in text, is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Sections 1191 to 1194 of the Act are classified to sections 1320f to 1320f-3, respectively, of Title 42, The Public Health and Welfare. Sections 1860D-14A and 1860D-14C of the Act are classified to sections 1395w-114a and 1395w-114c, respectively, of Title 42. Section 1927 of the Act is classified to section 1396r-8 of Title 42.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Pub. L. 117-169, title I, §11003(d), Aug. 16, 2022, 136 Stat. 1864, provided that: “The amendments made by this section [enacting this chapter and amending section 275 of this title] shall apply to sales after the date of the enactment of this Act [Aug. 16, 2022].”

Subtitle E—Alcohol, Tobacco, and Certain Other Excise Taxes

Chapter	Sec. ¹
51. Distilled spirits, wines, and beer	5001
52. Tobacco products and cigarette papers and tubes	5701
53. Machine guns and certain other firearms ²	5801
54. Greenmail	5881
55. Structured settlement factoring transactions	5891

Editorial Notes

AMENDMENTS

2002—Pub. L. 107-134, title I, §115(b), Jan. 23, 2002, 115 Stat. 2438, added item relating to chapter 55.

1997—Pub. L. 105-33, title IX, §9302(g)(3)(D), Aug. 5, 1997, 111 Stat. 673, added item relating to chapter 52 and struck out former item relating to chapter 52 “Cigars, cigarettes, smokeless tobacco, pipe tobacco, and cigarette papers and tubes”.

1988—Pub. L. 100-647, title V, §5061(c)(4), Nov. 10, 1988, 102 Stat. 3680, substituted “Cigars, cigarettes, smokeless tobacco, pipe tobacco, and cigarette papers and tubes” for “Tobacco, cigars, cigarettes, smokeless tobacco, and cigarette papers and tubes” in item relating to chapter 52.

Pub. L. 100-647, title I, §1018(u)(16), Nov. 10, 1988, 102 Stat. 3590, inserted “smokeless tobacco,” after “cigarettes,” in item relating to chapter 52.

1987—Pub. L. 100-203, title X, §10228(c), Dec. 22, 1987, 101 Stat. 1330-418, added item relating to chapter 54.

CHAPTER 51—DISTILLED SPIRITS, WINES, AND BEER

Subchapter	Sec. ¹
A. Gallonage and occupational taxes	5001
B. Qualification requirements for distilled spirits plants	5171
C. Operation of distilled spirits plants	5201
D. Industrial use of distilled spirits	5271
E. General provisions relating to distilled spirits	5291
F. Bonded and taxpaid wine premises	5351
G. Breweries	5401
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J. Penalties, seizures, and forfeitures relating to liquors	5601

¹Section numbers editorially supplied.

²Chapter heading amended by Pub. L. 90-618 without corresponding amendment of analysis.

¹Section numbers editorially supplied.