

**SEC. 9008. IMPOSITION OF ANNUAL FEE ON BRANDED PRESCRIPTION PHARMACEUTICAL MANUFACTURERS AND IMPORTERS.**

**(a) IMPOSITION OF FEE.—**

(1) IN GENERAL.—Each covered entity engaged in the business of manufacturing or importing branded prescription drugs shall pay to the Secretary of the Treasury not later than the annual payment date of each calendar year beginning after 2010 a fee in an amount determined under subsection (b). **[As revised by section 1404(a)(1) of HCERA]**

(2) ANNUAL PAYMENT DATE.—For purposes of this section, the term “annual payment date” means with respect to any calendar year the date determined by the Secretary, but in no event later than September 30 of such calendar year.

**(b) DETERMINATION OF FEE AMOUNT.—**

(1) IN GENERAL.—With respect to each covered entity, the fee under this section for any calendar year shall be equal to an amount that bears the same ratio to the applicable amount as—**[As revised by section 1404(a)(2)(A) of HCERA]**

(A) the covered entity’s branded prescription drug sales taken into account during the preceding calendar year, bear to

(B) the aggregate branded prescription drug sales of all covered entities taken into account during such preceding calendar year.

(2) SALES TAKEN INTO ACCOUNT.—For purposes of paragraph (1), the branded prescription drug sales taken into account during any calendar year with respect to any covered entity shall be determined in accordance with the following table:

With respect to a covered entity’s aggregate branded prescription drug sales during the calendar year that are:	The percentage of such sales taken into account is:
Not more than \$5,000,000 .....	0 percent
More than \$5,000,000 but not more than \$125,000,000.	10 percent
More than \$125,000,000 but not more than \$225,000,000.	40 percent
More than \$225,000,000 but not more than \$400,000,000.	75 percent
More than \$400,000,000 .....	100 percent.

(3) SECRETARIAL DETERMINATION.—The Secretary of the Treasury shall calculate the amount of each covered entity’s fee for any calendar year under paragraph (1). In calculating

such amount, the Secretary of the Treasury shall determine such covered entity's branded prescription drug sales on the basis of reports submitted under subsection (g) and through the use of any other source of information available to the Secretary of the Treasury.

(4) **APPLICABLE AMOUNT.**—*[As added by section 1404(a)(2)(B) of HCERA]* For purposes of paragraph (1), the applicable amount shall be determined in accordance with the following table:

Calendar year	Applicable amount
2011 .....	\$2,500,000,000
2012 .....	\$2,800,000,000
2013 .....	\$2,800,000,000
2014 .....	\$3,000,000,000
2015 .....	\$3,000,000,000
2016 .....	\$3,000,000,000
2017 .....	\$4,000,000,000
2018 .....	\$4,100,000,000
2019 and thereafter .....	\$2,800,000,000.

(c) **TRANSFER OF FEES TO MEDICARE PART B TRUST FUND.**—There is hereby appropriated to the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Social Security Act an amount equal to the fees received by the Secretary of the Treasury under subsection (a).

(d) **COVERED ENTITY.**—

(1) **IN GENERAL.**—For purposes of this section, the term “covered entity” means any manufacturer or importer with gross receipts from branded prescription drug sales.

(2) **CONTROLLED GROUPS.**—

(A) **IN GENERAL.**—For purposes of this subsection, all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 or subsection (m) or (o) of section 414 of such Code shall be treated as a single covered entity.

(B) **INCLUSION OF FOREIGN CORPORATIONS.**—For purposes of subparagraph (A), in applying subsections (a) and (b) of section 52 of such Code to this section, section 1563 of such Code shall be applied without regard to subsection (b)(2)(C) thereof.

(3) **JOINT AND SEVERAL LIABILITY.**—If more than one person is liable for payment of the fee under subsection (a) with respect to a single covered entity by reason of the application of paragraph (2), all such persons shall be jointly and severally liable for payment of such fee. *[As added by section 1404(a)(3) of HCERA]*

(e) **BRANDED PRESCRIPTION DRUG SALES.**—For purposes of this section—

(1) **IN GENERAL.**—The term “branded prescription drug sales” means sales of branded prescription drugs to any specified government program or pursuant to coverage under any such program.

(2) **BRANDED PRESCRIPTION DRUGS.**—

- (A) IN GENERAL.—The term “branded prescription drug” means—
- (i) any prescription drug the application for which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)), or
  - (ii) any biological product the license for which was submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).
- (B) PRESCRIPTION DRUG.—For purposes of subparagraph (A)(i), the term “prescription drug” means any drug which is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).
- (3) EXCLUSION OF ORPHAN DRUG SALES.—The term “branded prescription drug sales” shall not include sales of any drug or biological product with respect to which a credit was allowed for any taxable year under section 45C of the Internal Revenue Code of 1986. The preceding sentence shall not apply with respect to any such drug or biological product after the date on which such drug or biological product is approved by the Food and Drug Administration for marketing for any indication other than the treatment of the rare disease or condition with respect to which such credit was allowed.
- (4) SPECIFIED GOVERNMENT PROGRAM.—The term “specified government program” means—
- (A) the Medicare Part D program under part D of title XVIII of the Social Security Act,
  - (B) the Medicare Part B program under part B of title XVIII of the Social Security Act,
  - (C) the Medicaid program under title XIX of the Social Security Act,
  - (D) any program under which branded prescription drugs are procured by the Department of Veterans Affairs,
  - (E) any program under which branded prescription drugs are procured by the Department of Defense, or
  - (F) the TRICARE retail pharmacy program under section 1074g of title 10, United States Code.
- (f) TAX TREATMENT OF FEES.—The fees imposed by this section—
- (1) for purposes of subtitle F of the Internal Revenue Code of 1986, shall be treated as excise taxes with respect to which only civil actions for refund under procedures of such subtitle shall apply, and
  - (2) for purposes of section 275 of such Code, shall be considered to be a tax described in section 275(a)(6).
- (g) REPORTING REQUIREMENT.—Not later than the date determined by the Secretary of the Treasury following the end of any calendar year, the Secretary of Health and Human Services, the Secretary of Veterans Affairs, and the Secretary of Defense shall report to the Secretary of the Treasury, in such manner as the Secretary of the Treasury prescribes, the total branded prescription drug sales for each covered entity with respect to each specified government program under such Secretary’s jurisdiction using the following methodology:

(1) **MEDICARE PART D PROGRAM.**—The Secretary of Health and Human Services shall report, for each covered entity and for each branded prescription drug of the covered entity covered by the Medicare Part D program, the product of—

(A) the per-unit ingredient cost, as reported to the Secretary of Health and Human Services by prescription drug plans and Medicare Advantage prescription drug plans, minus any per-unit rebate, discount, or other price concession provided by the covered entity, as reported to the Secretary of Health and Human Services by the prescription drug plans and Medicare Advantage prescription drug plans, and

(B) the number of units of the branded prescription drug paid for under the Medicare Part D program.

(2) **MEDICARE PART B PROGRAM.**—The Secretary of Health and Human Services shall report, for each covered entity and for each branded prescription drug of the covered entity covered by the Medicare Part B program under section 1862(a) of the Social Security Act, the product of—

(A) the per-unit average sales price (as defined in section 1847A(c) of the Social Security Act) or the per-unit Part B payment rate for a separately paid branded prescription drug without a reported average sales price, and

(B) the number of units of the branded prescription drug paid for under the Medicare Part B program.

The Centers for Medicare and Medicaid Services shall establish a process for determining the units and the allocated price for purposes of this section for those branded prescription drugs that are not separately payable or for which National Drug Codes are not reported.

(3) **MEDICAID PROGRAM.**—The Secretary of Health and Human Services shall report, for each covered entity and for each branded prescription drug of the covered entity covered under the Medicaid program, the product of—

(A) the per-unit ingredient cost paid to pharmacies by States for the branded prescription drug dispensed to Medicaid beneficiaries, minus any per-unit rebate paid by the covered entity under section 1927 of the Social Security Act and any State supplemental rebate, and

(B) the number of units of the branded prescription drug paid for under the Medicaid program.

(4) **DEPARTMENT OF VETERANS AFFAIRS PROGRAMS.**—The Secretary of Veterans Affairs shall report, for each covered entity and for each branded prescription drug of the covered entity the total amount paid for each such branded prescription drug procured by the Department of Veterans Affairs for its beneficiaries.

(5) **DEPARTMENT OF DEFENSE PROGRAMS AND TRICARE.**—The Secretary of Defense shall report, for each covered entity and for each branded prescription drug of the covered entity, the sum of—

(A) the total amount paid for each such branded prescription drug procured by the Department of Defense for its beneficiaries, and

(B) for each such branded prescription drug dispensed under the TRICARE retail pharmacy program, the product of—

- (i) the per-unit ingredient cost, minus any per-unit rebate paid by the covered entity, and
- (ii) the number of units of the branded prescription drug dispensed under such program.

(h) SECRETARY.—For purposes of this section, the term “Secretary” includes the Secretary’s delegate.

(i) GUIDANCE.—The Secretary of the Treasury shall publish guidance necessary to carry out the purposes of this section.

(j) EFFECTIVE DATE.—*[Replaced by section 1404(a)(4) of HCERA]* This section shall apply to calendar years beginning after December 31, 2010.

(k) CONFORMING AMENDMENT.—Section 1841(a) of the Social Security Act is amended by inserting “or section 9008(c) of the Patient Protection and Affordable Care Act of 2009” after “this part”.