

**DESCRIPTION OF SUBTITLE J— DRUG PRICING
BUDGET RECONCILIATION LEGISLATIVE RECOMMENDATIONS**

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Prepared by the Staff
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INTRODUCTION

The House Committee on Ways and Means has scheduled a committee markup of Subtitle J — Drug Pricing: Budget Reconciliation Legislative Recommendations. This document,¹ prepared by the staff of the Joint Committee on Taxation, provides a description of the bill.

¹ This document may be cited as follows: Joint Committee on Taxation, *Description of Subtitle J — Drug Pricing: Budget Reconciliation Legislative Recommendations* (JCX-40-21), September 11, 2021. This document can also be found on the Joint Committee on Taxation website at www.jct.gov. All section references herein are to the Internal Revenue Code of 1986, as amended (herein “Code”), unless otherwise stated.

SUBTITLE J — DRUG PRICING

A. Selected Drug Manufacturer Excise Tax Imposed During Noncompliance Periods

Present Law

Annual Fee on Branded Prescription Pharmaceutical Manufacturers and Importers

An annual fee is imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs for sale to any specified government program or pursuant to coverage under any such program.²

The aggregate annual fee imposed on all covered entities is \$2.8 billion for calendar year 2021.³ The aggregate fee is apportioned among the covered entities each year based on their relative market share of branded prescription drug sales taken into account during the previous calendar year.

A covered entity's annual fee equals an amount that bears the same ratio to the aggregate annual fee of \$2.8 billion as the entity's branded prescription drug sales taken into account during the preceding calendar year bear to the aggregate branded prescription drug sales of all covered entities taken into account during the preceding calendar year. Sales taken into account during any calendar year with respect to a covered entity are: (1) zero percent of sales not more than \$5 million; (2) 10 percent of sales over \$5 million but not more than \$125 million; (3) 40 percent of sales over \$125 million but not more than \$225 million; (4) 75 percent of sales over \$225 million but not more than \$400 million; and (5) 100 percent of sales over \$400 million.

A covered entity is any manufacturer or importer with gross receipts from branded prescription drug sales. All persons treated as a single employer under section 52(a) or (b) or under section 414(m) or (o) are treated as a single covered entity. Thus, for example, corporations that are members of the same controlled group of corporations under section 52(a) are treated as a single covered entity. In applying the single employer rules under sections 52(a) and (b), foreign corporations are not excluded. If more than one person is liable for payment of the fee, all such persons are jointly and severally liable for payment of such fee.

Branded prescription drug sales are sales of branded prescription drugs made to any specified government program, or pursuant to coverage under any such program. The term branded prescription drugs includes any drug which is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act and for which an application was submitted under section 505(b) of such Act. Branded prescription drugs also include any biological product the license for which was submitted under section 351(a) of the Public Health Service Act ("PHSA"). Branded

² Sec. 9008 of the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152.; *see also* Treas. Reg. sec. 51.1 - 51.11.

³ The aggregate annual fee amount for each year is set by statute; for calendar year 2019 and thereafter the amount is \$2.8 billion.

prescription drug sales do not include sales of any drug or biological product with respect to which an orphan drug tax credit was allowed for any taxable year under section 45C. The exclusion for orphan drug sales does not apply to any drug or biological product after such drug or biological product is approved by the Food and Drug Administration for marketing for any indication other than the rare disease or condition with respect to which the section 45C credit was allowed.

Specified government programs include: (1) the Medicare Part D program⁴; (2) the Medicare Part B program⁵; (3) the Medicaid program⁶; (4) any program under which branded prescription drugs are procured by the Department of Veterans Affairs; (5) any program under which branded prescription drugs are procured by the Department of Defense; or (6) the TRICARE retail pharmacy program.⁷

The fees are treated in the same manner as those excise taxes identified in subtitle F of the Code, "Procedure and Administration," for which the only avenue for judicial review is a civil action for refund. Thus, the fees may be assessed and collected using the procedures in subtitle F without regard to the restrictions on assessment in section 6213.

The fee is required to be paid no later than an annual payment date determined by the Secretary of the Treasury, but in no event later than September 30th of each calendar year.

Finally, the fee is considered to be a nondeductible tax for purposes of section 275 and therefore is not deductible against income taxes.

Manufacturers Excise Taxes

Chapter 32 of the Code imposes excise taxes on sales by manufacturers of certain articles. The use of an article subject to tax by a manufacturer, producer, or importer of such article is treated as a sale for the purpose of imposing certain excise taxes.⁸ Articles subject to the manufacturers excise tax include certain gas guzzler automobiles, tires, fuels, coal, vaccines, sporting goods, and firearms. In general, uniform rules related to imposition, payment, reporting, and claiming of credits or refunds apply to each of the excise taxes in Chapter 32.⁹

In general, manufacturers excise taxes are imposed on the sale of the applicable taxable article by the manufacturer, producer, or importer. A manufacturer is a person who produces a taxable article from new, raw, or used material (including scrap, salvage, or junk) by processing,

⁴ Part D of title XVIII of the Social Security Act.

⁵ Part B of title XVIII of the Social Security Act.

⁶ Title XIX of the Social Security Act.

⁷ 10 U.S.C. sec. 1074g.

⁸ Sec. 4218.

⁹ Secs. 4216-4227, 6416.

manipulating, or changing the form of an article, or by combining or assembling two or more articles.¹⁰ An importer of a taxable article is any person who brings such an article into the United States from a source outside the United States, or who withdraws such an article from a customs bonded warehouse for sale or use in the United States.

The price for which an article is sold and on which the excise tax is imposed is determined under certain rules.¹¹ These rules provide for: (1) the inclusion of containers, packaging, and certain transportation charges in the price, (2) the determination of a constructive sale price if an article is sold at retail, sold on consignment, or sold for less than the fair market price, and (3) the determination of the tax due in the case of partial payments or installment sales. The rules also provide that in determining the price of an article on which an excise tax is imposed, the amount of excise tax imposed by Chapter 32 is excluded whether or not stated as a separate charge. If the manufacturer computes the tax on a sale price that is determined without regard to the excise tax and the proper excise tax is charged as a separate item, the amount of tax so charged does not become a part of the taxable sale price, and no tax is due on the tax so charged.¹² If the manufacturer does not state a separate charge as tax, it will be presumed that the price charged to the purchaser includes the proper excise tax, and the proper percentage of such price will be allocated to the tax.¹³

Certain sales are exempt from the excise taxes imposed on manufacturers, including sales for use by the purchaser for further manufacture or for resale to a second purchaser for use in further manufacture, and for export or for resale to a second purchaser for export.¹⁴ If an article is sold free of tax for resale to a second purchaser for further manufacture or for export, the exemption will not apply unless, within the six-month period beginning on the date of sale by the manufacturer, the manufacturer receives proof that the article has been exported or resold for use in further manufacture.¹⁵ In general, the exemptions will not apply unless the manufacturer, the first purchaser, and the second purchaser (if any) are registered with the Secretary.¹⁶

A credit or refund is generally allowed for overpayments of manufacturers excise taxes.¹⁷ Overpayments may occur when tax-paid articles are sold for export and for certain specified uses and resales, when there are price adjustments, and where tax paid articles are subject to further manufacture. Generally, no credit or refund of any overpayment of tax is allowed or made unless the person who paid the tax establishes one of four prerequisites: (1) the tax was not

¹⁰ Treas. Reg. sec. 48.0-2(a)(4)(i).

¹¹ Sec. 4216.

¹² Treas. Reg. sec. 48.4216(a)-2(a)(1).

¹³ *Ibid.* See Treas. Reg. sec. 48.4216(a)-2(a)(2) for a formula to compute the taxable sale price.

¹⁴ See sec. 4221(a) for the complete list of exemptions. Some of these exemptions do not apply for purposes of certain manufacturers excise taxes.

¹⁵ Sec. 4221(b).

¹⁶ Sec. 4222.

¹⁷ Sec. 6416.

included in the price of the article or otherwise collected from the person who purchased the article; (2) the tax was repaid to the ultimate purchaser of the article; (3) for overpayments due to specified uses and resales, the tax has been repaid to the ultimate vendor or the person has obtained the written consent of such ultimate vendor; or (4) the person has filed with the Secretary the written consent of the ultimate purchaser of the article to the allowance of the credit or making of the refund.¹⁸

Taxable vaccines are among the articles currently subject to excise tax.¹⁹ However, prescription drugs currently are not subject to excise tax.

Description of Proposal

The proposal creates a new drug price negotiation program administered by the Secretary of Health and Human Services (“HHS”). Manufacturers, producers, and importers subject to the program who do not comply with certain requirements are subject to a new excise tax on drug sales during periods of noncompliance. The drug price negotiation program and selected drug excise tax are discussed in more detail below.

Drug Price Negotiation Program

Under the drug price negotiation program, beginning in 2023, HHS will choose selected drugs from a list of negotiation eligible drugs. HHS will publish the list by April 15 of a plan year (which for this purpose, means a plan year for self-funded plans and a policy year for insured coverage), effective with respect to an initial plan applicability year two years later.

By June 15 of the year in which a selected drug is published, manufacturers of the selected drug must enter into an agreement with HHS to negotiate a maximum fair price (“MFP”) for the drug. The negotiation between HHS and the manufacturer takes place during a voluntary negotiation period beginning on the earlier of (1) the date on which HHS and the manufacturer enter into an agreement, or (2) June 15 of the year in which the selected drug is chosen. The voluntary negotiation period ends on March 31 of the following year. Upon the conclusion of the voluntary negotiation period, HHS and the manufacturer must agree to a MFP with respect to the selected drug for the initial plan applicability year. The manufacturer must charge the MFP to fair price eligible individuals and hospitals, physicians, and other providers of services and suppliers to such individuals. Fair price eligible individuals include individuals: (1) enrolled under the Medicare Part D program²⁰ or a Medicare Advantage Prescription Drug plan under the Medicare Part C program²¹; (2) enrolled under a group health plan or health insurance coverage offered in the group or individual market,²² if an agreement is in place with respect to

¹⁸ Sec. 6416(a).

¹⁹ Sec. 4131.

²⁰ Part D of title XVIII of the Social Security Act.

²¹ Part C of title XVIII of the Social Security Act.

²² See sec. 2791 of the PHSA, 42 U.S.C. sec. 300gg-91.

such plan or coverage;²³ or (3) entitled to benefits under the Medicare Part A program²⁴ or enrolled under the Medicare Part B program.²⁵

For years after the initial plan applicability year, the MFP is indexed to inflation by reference to the consumer price index. The MFP of a selected drug generally cannot exceed 120 percent of the average international market price (“AIM price”), an average price determined by reference to the price of the drug in Australia, Canada, France, Germany, Japan, and the United Kingdom for the year. For drugs without an AIM price, the MFP cannot exceed 85 percent of the average manufacturer price for the year.²⁶ The manufacturer is subject to the MFP limitations with respect to a drug until the end of the last year during which the drug is a selected drug.

The proposal also establishes rules for the renegotiation of MFPs, for information sharing between manufacturers and HHS, and for repayments to Treasury in a case where a selected drug for which an AIM price is not initially available becomes available in a subsequent year.

Selected Drug Excise Tax

The proposal creates a new manufacturers excise tax under Chapter 32. The tax is imposed on all sales by a manufacturer, producer, or importer of a selected drug on a day during a noncompliance period. A day is during a noncompliance period if it occurs:

1. After the June 15 date on which the manufacturer must enter into negotiations with HHS if the manufacturer has not entered into negotiations by such date;
2. After the March 31 end of the voluntary negotiation period if the manufacturer has not agreed to an MFP by such date;
3. After the last date of a renegotiation period, if the HHS Secretary has specified a renegotiation period and the manufacturer has not agreed to a renegotiated MFP;
4. Beginning on the date on which HHS has certified that information required to be submitted by the manufacturer has not been submitted and is overdue; or

²³ Individuals enrolled in such plans or coverage are fair price eligible individuals only if an agreement is in place with respect to such plan or coverage. The proposal modifies the group health plan requirements to account for this treatment. These modifications are codified at Part A of title XXVII of the PHSA, Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, and subchapter B of chapter 100 of the Code.

²⁴ Part A of title XVIII of the Social Security Act.

²⁵ Part B of title XVIII of the Social Security Act.

²⁶ See 42 U.S.C 1396-48(k)(1)(A).

5. Beginning on the date which HHS has certified that a repayment is due to Treasury, relating to a case where a drug for which an AIM price is not initially available has become available in a subsequent year, is overdue.

The amount of the tax is such that the applicable percentage is equal to the ratio of such tax divided by the sum of such tax and the price for which the selected drug is sold. Or, in other words:

$$\text{applicable percentage} = \frac{\text{tax}}{\text{tax} + \text{price}}$$

Thus, the base on which the tax is imposed is tax inclusive. The applicable percentage is initially 65 percent. It is increased by 10 percentage points after each 90 days in a noncompliance period. The applicable percentage is capped at 95 percent. For purposes of determining the increase in the applicable percentage, days in the noncompliance period are cumulative whether or not the days are consecutive.

The Secretary of the Treasury has authority under an anti-abuse rule to treat sales as occurring during a day in a noncompliance period if the manufacturer times such sales specifically for purposes of avoiding the excise tax. Finally, under section 275, manufacturers are prohibited from deducting the excise tax payments against their income taxes.

The following example illustrates the application of the excise tax: Manufacturer A produces drug A, which HHS selects and publishes as a selected drug on April 15 of a plan year, effective with respect to an initial plan applicability year two years later. Manufacturer A fails to enter into negotiations with HHS with respect to drug A by June 15 of the year in which the drug is chosen. Its sales on June 16 are sales during a noncompliance period, and are subject to the excise tax.

Assume that, prior to imposition of the excise tax, Manufacturer A charged \$100 for drug A. If, after imposition of the excise tax, Manufacturer A charges \$100 and does not separately state a tax, the price is deemed to be \$35, and Manufacturer A owes \$65 in tax.²⁷ Alternatively, Manufacturer A could separately state a price of \$100 and a tax of \$186, in which case it would owe \$186 in tax.²⁸

Assume Manufacturer A enters into negotiations with HHS on June 21. For purposes of determining the applicable percentage, Manufacturer A has had five days in a noncompliance period. If, on the following March 31, Manufacturer A has not agreed to an MFP, for purposes of determining the applicable percentage, April 1 would be the sixth day in a noncompliance period.

²⁷ In other words, $\$65/(\$65+\$35)$ equals 65 percent. Because Manufacturer A did not state a separate charge as tax, it is presumed that the price charged includes the excise tax. Treas. Reg. sec. 48.4216(a)-2(a)(1).

²⁸ In other words, $\$186/(\$186+\$100)$ equals 65 percent.

Effective Date

The excise tax is effective for sales after the date of enactment of the proposal.