I

118TH CONGRESS
2D SESSION

H. R. 9425

To amend the Federal Food, Drug, and Cosmetic Act to authorize tobacco user fee assessments for all regulated tobacco products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 30, 2024

Ms. MCCLELLAN introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize tobacco user fee assessments for all regulated tobacco products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Tobacco User Fee Modernization Act of 2024''.

SEC. 2. TOBACCO PRODUCT USER FEES.

(a) INCREASE IN TOTAL AMOUNT.—Section 919(b)(1) of the Federal Food, Drug, and Cosmetic Act

(21 U.S.C. 387s(b)(1)) is amended by striking subparagraph (K) and inserting the following:

''(K) For each of fiscal years 2019 through 2024, $712,000,000.

''(L) For fiscal year 2025, $826,200,000.

''(M) For fiscal year 2026 and each subsequent fiscal year, the amount that was applicable for the previous fiscal year, increased by the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending June 30 preceding the fiscal year.''.

(b) APPLICATION OF USER FEES TO ALL TOBACCO PRODUCTS.—Subparagraph (A) of section 919(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)(2)) is amended to read as follows:

''(A) IN GENERAL.—

''(i) FISCAL YEARS 2025 THROUGH 2027.—For fiscal years 2025 through 2027, user fees shall be assessed and collected under subsection (a) only with respect to the classes of tobacco products listed in subparagraph (B)(i), and the total such user fees with respect to each such

class shall be an amount that is equal to the applicable percentage of each such class for the fiscal year, as determined in accordance with subparagraph (B)(ii), multiplied by the amount specified in paragraph (1) for the fiscal year.

''(ii) SUBSEQUENT FISCAL YEARS.—Except as specified in subparagraph (C), for fiscal year 2028 and each subsequent fiscal year, user fees shall be assessed and collected under subsection (a) with respect to each class of tobacco products listed in subparagraph (B)(i) and other tobacco products as follows:

''(I) For the classes of tobacco products listed in subparagraph (B)(i):

''(aa) For each fiscal year, the total user fees assessed and collected for all the classes of tobacco products listed in subparagraph (B)(i) together shall be an amount that is equal to the product obtained by multiplying—

"(AA) the total of the sum of the gross domestic sales for the classes of tobacco products listed in subparagraph (B)(i) during the previous full calendar year, divided by the sum of the gross domestic sales for the classes of tobacco products listed in subparagraph (B)(i) and other tobacco products during such calendar year; by

"(BB) the amount specified in paragraph (1) for such fiscal year.

"(bb) For each fiscal year, the total user fees assessed and collected for each individual class of tobacco products listed in subparagraph (B)(i) shall be an amount that is equal to the product obtained by multiplying—

"(AA) the applicable percentage for each class as

determined under subparagraph (B)(ii); by

"(BB) the amount determined under subitem (aa).

"(II) For other tobacco products, for each fiscal year, the total user fees assessed and collected for all such other tobacco products shall be an amount that is equal to the product obtained by multiplying—

"(aa) the total of the gross domestic sales for other tobacco products during the previous full calendar year, divided by the sum of the gross domestic sales for the classes of tobacco products listed in subparagraph (B)(i) and other tobacco products during such calendar year; by

"(bb) the amount specified in paragraph (1) for such fiscal year.".

(c) OTHER TOBACCO PRODUCTS.—

(1) AMENDMENT.—Section 919(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)(2)) is amended by adding at the end the following:

''(C) EFFECT OF FAILURE TO FINALIZE REGULATIONS ON TIME.—The Secretary shall finalize updates to the regulations under part 1150 of title 21, Code of Federal Regulations, to provide for the assessment and collection of user fees for other tobacco products beginning not later than fiscal year 2028. The Secretary shall continue to assess and collect fees under subsection (a) with respect to each class of tobacco products listed in subparagraph (B)(i) until the first fiscal year commencing after the effective date of the final regulation to implement provisions for assessment and collection of user fees for other tobacco products.

''(D) INFORMATION TO BE SUBMITTED.—

''(i) IN GENERAL.—In addition to any other reporting requirements under this Act and any implementing regulation, each manufacturer or importer of any tobacco product shall submit to the Secretary the

information required under this subparagraph—

"(I) not later than—

"(aa) March 1, 2027, for calendar year 2026; and

"(bb) April 20, 2027, for the period of January 1, 2027, through March 30, 2027; and

"(II) quarterly thereafter, or in accordance with such other reporting requirements as the Secretary may establish by regulation.

"(ii) REQUIREMENTS.—The information required to be submitted under this subparagraph shall consist of—

"(I) the identification information of the manufacturer or importer, to include—

"(aa) the Employer Identification Number (EIN);

"(bb) company name;

"(cc) the phone number (including area code);

"(dd) the email address; and

"(ee) the mailing address where communications and assessments from the Food and Drug Administration can be received;

"(II) the class or classes of tobacco products, to include the classes listed in subparagraph (B)(i) and other tobacco products, for which the manufacturer or importer has domestic sales; and

"(III) the gross domestic sales data, where the manufacturer or importer has domestic sales, for each class of tobacco products listed in subparagraph (B)(i) and other tobacco products.".

(2) PROHIBITED ACT.—Section 301(q)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)(1)(B)) is amended by inserting "919(b)(2)(D)," before "or 920".

(d) ALLOCATION OF ASSESSMENTS.—Paragraph (4) of section 919(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)) is amended to read as follows:

''(4) ALLOCATION OF ASSESSMENTS.—The percentage share of each manufacturer or importer of a particular class of tobacco products listed in paragraph (2)(B)(i) and other tobacco products of the total user fees to be paid by all manufacturers or importers of that class of tobacco products listed in paragraph (2)(B)(i) and other tobacco products shall be—

''(A) for tobacco product classes listed in paragraph (2)(B)(i), the percentage determined for purposes of allocations under subsections (e) through (h) of section 625 of Public Law 108–357 (7 U.S.C. 518d); and

''(B) for other tobacco products, the percentage determined by dividing—

''(i) the total gross domestic sales of other tobacco products for a manufacturer or importer for the prior fiscal quarter; by

''(ii) the total gross domestic sales of other tobacco products for all manufacturers and importers for that same quarter.''.

(e) REALLOCATIONS.—Clause (iv) of section 919(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)(2)(B)) is amended to read as follows:

''(iv) REALLOCATIONS.—In the case of a class or partial class of tobacco products that is not listed in section 901(b) or deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter, the amount of user fees that would otherwise be assessed to such class or partial class of tobacco products shall be reallocated to the classes or partial classes of tobacco products that are subject to this chapter in the same manner and based on the same relative percentages otherwise determined under clause (ii), adjusted as necessary to reflect partial classes if any.''.

(f) LIABILITY.—Paragraph (5) of section 919(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)) is amended to read as follows:

''(5) ASSESSMENT LIABILITY.—The quarterly assessment amount owed by a manufacturer or importer of tobacco products listed in paragraph (2)(B)(i) or other tobacco products shall be—

''(A) based on removals (as defined in section 5702(j) of the Internal Revenue Code of 1986) or gross domestic sales, as relevant, during the prior fiscal period; and

''(B) remitted to the Food and Drug Administration regardless of whether the manufacturer or importer meets the definition of manufacturer or importer in the fiscal quarter in which—

''(i) the assessment is calculated; or

''(ii) the manufacturer or importer receives notification of the amount of assessment owed to the Food and Drug Administration.''.

(g) CONFORMING AMENDMENTS.—Paragraph (7) of section 919(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)) is amended to read as follows:

''(7) MEMORANDUM OF UNDERSTANDING.—The Secretary may request any appropriate Federal agency to enter into a memorandum of understanding that provides for the regular and timely transfer from the head of such agency to the Secretary of information regarding any tobacco product manufacturer or importer required to pay user fees. The Secretary shall maintain all disclosure restrictions established by the head of such agency regarding the information provided under the memorandum of understanding.''.

(h) DEFINITIONS.—Section 919(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)) is amended by adding at the end the following:

''(8) DEFINITIONS.—For purposes of this subsection:

''(A) The term 'gross domestic sales' means the total amount in dollars, not to include taxes, duties, and fees, of the sale by manufacturers and importers of finished tobacco products in the United States.

''(B) The term 'other tobacco product' means a tobacco product that is made or derived from tobacco, or contains nicotine from any source, that does not fit within a product class listed in paragraph (2)(B)(i).''.

(i) INSPECTION AUTHORITY.—The fifth sentence of section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended by striking ''sales data other than shipment data, pricing data'' and inserting ''sales data (other than shipment data and, for tobacco products, sales data relating to tobacco product user fees under section 919), pricing data (other than pricing data relating to tobacco product user fees under section 919)''.

(j) APPLICABILITY.—

(1) IN GENERAL.—The amendments made by this section shall apply—

(A) in the case of such amendments made by subsections (a), (e), and (i), beginning on the date of enactment of this Act; and

(B) in the case of other amendments made by this section, beginning on October 1, 2027.

(2) SPECIAL RULE.—If the date of enactment of this Act occurs after fiscal year 2024, then the Secretary of Health and Human Services shall assess and collect the increase in total amount by taking the amount specified in subparagraph (L) or (M) of section 919(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387c(b)(1)), as appropriate, and assessing such amount equally across each fiscal quarter for the relevant fiscal year.

○