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42 U.S. Code § 1395w-3a

Use of average sales price payment methodology

(a) Application

(1) In general

Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1395u(*o*)(1)(C) of this title and that are furnished on or after January 1, 2005.

(2) Election

This section shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) ofsection 1395w–3b of this title for that section to apply instead of this section for the payment for drugs and biologicals.

(b) Payment amount

(1) In general

Subject to paragraph (7) and subsections (d)(3)(C) and (e), the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 106 percent of the amount determined under paragraph (3) for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008;

(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D)), 106 percent of the amount determined under paragraph (4) or in the case of such a drug or biological product that is a selected drug (as referred to in section 1320f–1(c) of this title), with respect to a price applicability period (as defined in section 1320f(b)(2) of this title), 106 percent of the maximum fair price (as defined in section 1320f(c)(3) of this title) applicable for such drug and a year during such period; or

(C) in the case of a biosimilar biological product (as defined in subsection (c)(6)(H)), the amount determined under paragraph (8).

(2) Specification of unit

(A) Specification by manufacturer

The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 1396r–8(b)(3)(A)(iii) of this title or subsection (f)(2), as applicable.

(B) Unit defined

In this section, the term "unit" means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may

establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.

(3) Multiple source drug

For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1396r–8(b)(3)(A)(iii) of this title or subsection (f)(2), as applicable, determined by—

(A) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(i) the manufacturer's average sales price (as defined in subsection (c)); and

(ii) the total number of units specified under paragraph (2) sold; and

(B) dividing the sum determined under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all National Drug Codes assigned to such drug products.

(4) Single source drug or biological

The amount specified in this paragraph for a single source drug or biological is the lesser of the following:

(A) Average sales price

The average sales price as determined using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(B) Wholesale acquisition cost (WAC)

The wholesale acquisition cost (as defined in subsection (c)(6)(B)) using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(5) Basis for payment amount

The payment amount shall be determined under this subsection based on information reported under subsection (f) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(6) Use of volume-weighted average sales prices in calculation of average sales price

(A) In general

For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1396r–8(b)(3)(A)(iii) of this title or subsection (f)(2), as applicable, determined by—

(i) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the manufacturer's average sales price (as defined in subsection (c)), determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code; and

(II) the total number of units specified under paragraph (2) sold; and

(ii) dividing the sum determined under clause (i) by the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the total number of units specified under paragraph (2) sold; and

(II) the total number of billing units for the National Drug Code for the billing and payment code.

(B) Billing unit defined

For purposes of this subsection, the term "billing unit" means the identifiable quantity associated with a billing and payment code, as established by the Secretary.

(7) Special rule

Beginning with April 1, 2008, the payment amount for—

(A) each single source drug or biological described in section 1395u(*o*)(1)(G) of this title that is treated as a multiple source drug because of the application of subsection (c)(6)(C)(ii) is the lower of—

(i) the payment amount that would be determined for such drug or biological applying such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied; and

(B) a multiple source drug described in section 1395u(*o*)(1)(G) of this title (excluding a drug or biological that is treated as a multiple source drug because of the application of such subsection) is the lower of—

(i) the payment amount that would be determined for such drug or biological taking into account the application of such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied.

(8) Biosimilar biological product

(A) In general

Subject to subparagraph (B), the amount specified in this paragraph for a biosimilar biological product described in paragraph (1)(C) is the sum of—

(i) the average sales price as determined using the methodology described under paragraph (6) applied to a biosimilar biological product for all National Drug Codes assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph; and

(ii) 6 percent of the amount determined under paragraph (4) for the reference biological product (as defined in subsection (c)(6)(I)).

(B) Temporary payment increase

(i) In general

In the case of a qualifying biosimilar biological product that is furnished during the applicable 5-year period for such product, the amount specified in this paragraph for such product with respect to such period is the sum determined under subparagraph (A), except that clause (ii) of such subparagraph shall be applied by substituting "8 percent" for "6 percent".

(ii) Applicable 5-year period

For purposes of clause (i), the applicable 5-year period for a qualifying biosimilar biological product is—

(I) in the case of such a product for which payment was made under this paragraph as of September 30, 2022, the 5-year period beginning on October 1, 2022; and

(II) in the case of such a product for which payment is first made under this paragraph during a calendar quarter during the period beginning October 1, 2022, and ending December 31, 2027, the 5-year period beginning on the first day of such calendar quarter during which such payment is first made.

(iii) Qualifying biosimilar biological product defined

For purposes of this subparagraph, the term "qualifying biosimilar biological product" means a

biosimilar biological product described in paragraph (1)(C) with respect to which—

(I) in the case of a product described in clause (ii)(I), the average sales price under paragraph (8)(A)(i) for a calendar quarter during the 5-year period described in such clause is not more than the average sales price under paragraph (4)(A) for such quarter for the reference biological product; and

(II) in the case of a product described in clause (ii)(II), the average sales price under paragraph (8)(A)(i) for a calendar quarter during the 5-year period described in such clause is not more than the average sales price under paragraph (4)(A) for such quarter for the reference biological product.