recommendations as the Comptroller General determines appropriate.

''(C) TOPICS.—The topics specified in this subparagraph, for the study under subparagraph (A) concerning the competitive acquisition program, are the following:

''(i) Beneficiary access to items and services under the program, including the impact on such access of awarding contracts to bidders that—

''(I) did not have a physical presence in an area where they received a contract; or

''(II) had no previous experience providing the product category they were contracted to provide.

''(ii) Beneficiary satisfaction with the program and cost savings to beneficiaries under the program.

''(iii) Costs to suppliers of participating in the program and recommendations about ways to reduce those costs without compromising quality standards or savings to the Medicare program.

''(iv) Impact of the program on small business suppliers.

''(v) Analysis of the impact on utilization of different items and services paid within the same Healthcare Common Procedure Coding System (HCPCS) code.

''(vi) Costs to the Centers for Medicare & Medicaid Services, including payments made to contractors, for administering the program compared with administration of a fee schedule, in comparison with the relative savings of the program.

''(vii) Impact on access, Medicare spending, and beneficiary spending of any difference in treatment for diabetic testing supplies depending on how such supplies are furnished.

''(viii) Such other topics as the Comptroller General determines to be appropriate.''

REPORT ON ACTIVITIES OF SUPPLIERS

Pub. L. 108–173, title III, §302(e), Dec. 8, 2003, 117 Stat. 2233, as amended by Pub. L. 110–275, title I, §154(c)(2)(C), July 15, 2008, 122 Stat. 2566, provided that: ''The Inspector General of the Department of Health and Human Services shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act [42 U.S.C. 1395w–3], as amended by subsection (a) [probably should be (b)(1)], are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability. Not later than July 1, 2011, the Inspector General shall submit to Congress a report on such study.''

STUDY BY GAO

Pub. L. 105–33, title IV, §4319(c), Aug. 5, 1997, 111 Stat. 394, provided that: ''The Comptroller of the United States shall study the effectiveness of the establishment of competitive acquisition areas under section 1847(a) of the Social Security Act [42 U.S.C. 1395w–3(a)], as added by this section.''

§ 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) of section 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

(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

The amount specified in this paragraph for a biosimilar biological product described in paragraph (1)(C) is the sum of—

(A) 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

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

(c) Manufacturer's average sales price

(1) In general

For purposes of this section, subject to paragraphs (2) and (3), the manufacturer's ''average sales price'' means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit—

(A) the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by

(B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.

(2) Certain sales exempted from computation

In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

(A) Sales exempt from best price

Sales exempt from the inclusion in the determination of ''best price'' under section 1396r–8(c)(1)(C)(i) of this title.

(B) Sales at nominal charge

Such other sales as the Secretary identifies as sales to an entity that are merely

nominal in amount (as applied for purposes of section 1396r–8(c)(1)(C)(ii)(III) of this title, except as the Secretary may otherwise provide).

(3) Sale price net of discounts

In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1396r–8 of this title). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.

(4) Payment methodology in cases where average sales price during first quarter of sales is unavailable

In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section—

(A) in the case of a drug or biological furnished prior to January 1, 2019, based on—

(i) the wholesale acquisition cost; or

(ii) the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals; and

(B) in the case of a drug or biological furnished on or after January 1, 2019—

(i) at an amount not to exceed 103 percent of the wholesale acquisition cost; or

(ii) based on the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.

(5) Frequency of determinations

(A) In general on a quarterly basis

The manufacturer's average sales price, for a drug or biological of a manufacturer, shall be calculated by such manufacturer under this subsection on a quarterly basis. In making such calculation insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks. For years after 2004, the Secretary may establish a uniform methodology under this subparagraph to estimate and apply such costs.

(B) Updates in payment amounts

The payment amounts under subsection (b) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price calculated for the most recent calendar quarter for which data is available.

(C) Use of contractors; implementation

The Secretary may contract with appropriate entities to calculate the payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program instruction or otherwise, any of the provisions of this section.

(6) Definitions and other rules

In this section:

(A) Manufacturer

The term ''manufacturer'' means, with respect to a drug or biological, the manufacturer (as defined in section 1396r–8(k)(5) of this title), except that, for purposes of subsection (f)(2), the Secretary may, if the Secretary determines appropriate, exclude repackagers of a drug or biological from such term.

(B) Wholesale acquisition cost

The term ''wholesale acquisition cost'' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

(C) Multiple source drug

(i) In general

The term ''multiple source drug'' means, for a calendar quarter, a drug for which there are 2 or more drug products which—

(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''),

(II) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the United States during the quarter.

(ii) Exception

With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.

(D) Single source drug or biological

The term ''single source drug or biological'' means—

(i) a biological; or

(ii) a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(E) Exception from pharmaceutical equivalence and bioequivalence requirement

Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

(F) Determination of pharmaceutical equivalence and bioequivalence

For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

(G) Inclusion of vaccines

In applying provisions of section 1396r–8 of this title under this section, ''other than a vaccine'' is deemed deleted from section 1396r–8(k)(2)(B) of this title.

(H) Biosimilar biological product

The term ''biosimilar biological product'' means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 262 of this title.

(I) Reference biological product

The term ''reference biological product'' means the biological product licensed under such section 262 of this title that is referred to in the application described in subparagraph (H) of the biosimilar biological product.

(d) Monitoring of market prices

(1) In general

The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.

(2) Comparison of prices

Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with—

(A) the widely available market price for such drugs and biologicals (if any); and

(B) the average manufacturer price (as determined under section 1396r–8(k)(1) of this title) for such drugs and biologicals.

(3) Limitation on average sales price

(A) In general

The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).

(B) Applicable threshold percentage defined

In this paragraph, the term ''applicable threshold percentage'' means—

(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and

(ii) in 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.

(C) Authority to adjust average sales price

If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—

(i) the widely available market price for the drug or biological (if any); or

(ii) 103 percent of the average manufacturer price (as determined under section 1396r–8(k)(1) of this title) for the drug or biological.

(4) Civil money penalty

(A) Misrepresentation

If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of the manufacturer's average sales price for a drug or biological, the Secretary may apply a civil money penalty in an amount of up to $10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied.

(B) Failure to provide timely information

If the Secretary determines that a manufacturer described in subsection (f)(2) has failed to report on information described in section 1396r–8(b)(3)(A)(iii) of this title with respect to a drug or biological in accordance with such subsection, the Secretary shall apply a civil money penalty in an amount of $10,000 for each day the manufacturer has failed to report such information and such amount shall be paid to the Treasury.

(C) False information

Any manufacturer required to submit information under subsection (f)(2) that know-

ingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law.

(D) Increasing oversight and enforcement

For calendar quarters beginning on or after January 1, 2022, section 1396r–8(b)(3)(C)(iv) of this title shall be applied as if—

(i) each reference to ''under this subparagraph and subsection (c)(4)(B)(ii)(III)'' were a reference to ''under this subparagraph, subsection (c)(4)(B)(ii)(III), and subparagraphs (A), (B), and (C) of section 1395w–3a(d)(4) of this title''; and

(ii) the reference to ''activities related to the oversight and enforcement of this section and agreements under this section'' were a reference to ''activities related to the oversight and enforcement of this section and under subsection (f)(2) of section 1395w–3a of this title and subparagraphs (A), (B), and (C) of this subsection 1395w–3a(d)(4) of this title and, if applicable, agreements under this section''.

(E) Procedures

The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (A), (B), or (C) in the same manner as they apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(5) Widely available market price

(A) In general

In this subsection, the term ''widely available market price'' means the price that a prudent physician or supplier would pay for the drug or biological. In determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.

(B) Considerations

In determining the price under subparagraph (A), the Inspector General shall consider information from one or more of the following sources:

(i) Manufacturers.
(ii) Wholesalers.
(iii) Distributors.
(iv) Physician supply houses.
(v) Specialty pharmacies.
(vi) Group purchasing arrangements.
(vii) Surveys of physicians.
(viii) Surveys of suppliers.
(ix) Information on such market prices from insurers.
(x) Information on such market prices from private health plans.

(e) Authority to use alternative payment in response to public health emergency

In the case of a public health emergency under section 247d of this title in which there is a documented inability to access drugs and biologicals, and a concomitant increase in the price,[1] of a drug or biological which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug or biological price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug or biological has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

(f) Quarterly report on average sales price

(1) In general

For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisition cost) for the drug or biological under this section, see section 1396r–8(b)(3) of this title.

(2) Manufacturers without a rebate agreement under subchapter xix

(A) In general

If the manufacturer of a drug or biological described in subparagraph (C), (E), or (G) of section 1395u(*o*)(1) of this title or in section 1395rr(b)(14)(B) of this title that is payable under this part has not entered into and does not have in effect a rebate agreement described in subsection (b) of section 1396r–8 of this title, for calendar quarters beginning on January 1, 2022, such manufacturer shall report to the Secretary the information described in subsection (b)(3)(A)(iii) of such section 1396r–8 of this title with respect to such drug or biological in a time and manner specified by the Secretary. For purposes of applying this paragraph, a drug or biological described in the previous sentence includes items, services, supplies, and products that are payable under this part as a drug or biological.

(B) Audit

Information reported under subparagraph (A) is subject to audit by the Inspector General of the Department of Health and Human Services.

(C) Verification

The Secretary may survey wholesalers and manufacturers that directly distribute drugs or biologicals described in subparagraph (A), when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of such a drug or biological refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section

[1] So in original. The comma probably should not appear.

1320a–7a of this title (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(D) Confidentiality

Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph (other than the wholesale acquisition cost for purposes of carrying out this section) is confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs or biologicals by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section (including the determination and implementation of the payment amount), or to carry out section 1320a–7b of this title;

(ii) to permit the Comptroller General of the United States to review the information provided;

(iii) to permit the Director of the Congressional Budget Office to review the information provided;

(iv) to permit the Medicare Payment Advisory Commission to review the information provided; and

(v) to permit the Medicaid and CHIP Payment and Access Commission to review the information provided.

(g) Payment adjustment for certain drugs for which there is a self-administered NDC

(1) OIG studies

The Inspector General of the Department of Health and Human Services shall conduct periodic studies to identify National Drug Codes for drug or biological products that are self-administered for which payment may not be made under this part because such products are not covered pursuant to section 1395x(s)(2) of this title and which the Inspector General determines (based on the same or similar methodologies to the methodologies used in the final recommendation followup report of the Inspector General described in paragraph (3) or in the November 2017 final report of the Inspector General entitled ''Excluding Noncovered Versions When Setting Payment for Two Part B Drugs Would Have Resulted in Lower Drug Costs for Medicare and its Beneficiaries'') should be excluded from the determination of the payment amount under this section.

(2) Payment adjustment

If the Inspector General identifies a National Drug Code for a drug or biological product under paragraph (1), the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this paragraph) and the Secretary shall, to the extent the Secretary deems appropriate, apply as the amount of payment under this section for the applicable billing and payment code the lesser of—

(A) the amount of payment that would be determined under this section for such billing and payment code if such National Drug Code for such product so identified under paragraph (1) were excluded from such determination; or

(B) the amount of payment otherwise determined under this section for such billing and payment code without application of this subsection.

(3) Application to certain identified products

In the case of a National Drug Code for a drug or biological product that is self-administered for which payment is not made under this part because such product is not covered pursuant to section 1395x(s)(2) of this title that was identified by the Inspector General of the Department of Health and Human Services in the final recommendation followup report of the Inspector General published July 2020, entitled Loophole in Drug Payment Rule Continues To Cost Medicare and Beneficiaries Hundreds of Millions of Dollars, beginning July 1, 2021, the amount of payment under this section for the applicable billing and payment code shall be the lesser of—

(A) the amount of payment that would be determined under this section for such billing and payment code if such National Drug Code for such drug or biological products so identified were excluded from such determination; or

(B) the amount of payment otherwise determined under this section for such billing and payment code without application of this subsection.

(h) Refund for certain discarded single-dose container or single-use package drugs

(1) Secretarial provision of information

(A) In general

For each calendar quarter beginning on or after January 1, 2023, the Secretary shall, with respect to a refundable single-dose container or single-use package drug (as defined in paragraph (8)), report to each manufacturer (as defined in subsection (c)(6)(A)) of such refundable single-dose container or single-use package drug the following for the calendar quarter:

(i) Subject to subparagraph (C), information on the total number of units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined using a mechanism such as the JW modifier used as of November 15, 2021 (or any such successor modifier that includes such data as determined appropriate by the Secretary).

(ii) The refund amount that the manufacturer is liable for pursuant to paragraph (3).

(B) Determination of discarded amounts

For purposes of subparagraph (A)(i), with respect to a refundable single-dose container or single-use package drug furnished during a quarter, the amount of such drug that was discarded shall be determined based on the amount of such drug that was unused and

discarded for each drug on the date of service.

(C) Exclusion of units of packaged drugs

The total number of units of the billing and payment code of a refundable single-dose container or single-use package drug of a manufacturer furnished during a calendar quarter for purposes of subparagraph (A)(i), and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (3)(A)(ii), shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

(2) Manufacturer requirement

For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, provide to the Secretary a refund that is equal to the amount specified in paragraph (3) for such drug for such quarter.

(3) Refund amount

(A) In general

The amount of the refund specified in this paragraph is, with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which—

(i) the product of—

(I) the total number of units of the billing and payment code for such drug that were discarded during such quarter (as determined under paragraph (1)); and

(II)(aa) in the case of a refundable single-dose container or single-use package drug that is a single source drug or biological, the amount of payment determined for such drug or biological under subsection (b)(1)(B) for such quarter; or

(bb) in the case of a refundable single-dose container or single-use package drug that is a biosimilar biological product, the amount of payment determined for such product under subsection (b)(1)(C) for such quarter; exceeds

(ii) an amount equal to the applicable percentage (as defined in subparagraph (B)) of the estimated total allowed charges for such drug under this part during the quarter.

(B) Applicable percentage defined

(i) In general

For purposes of subparagraph (A)(ii), the term ''applicable percentage'' means—

(I) subject to subclause (II), 10 percent; and

(II) if applicable, in the case of a refundable single-dose container or single-use package drug described in clause (ii), a percentage specified by the Secretary pursuant to such clause.

(ii) Treatment of drugs that have unique circumstances

In the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in paragraph (8)(B)(ii), the Secretary, through notice and comment rulemaking, may increase the applicable percentage otherwise applicable under clause (i)(I) as determined appropriate by the Secretary.

(4) Frequency

Amounts required to be refunded pursuant to paragraph (2) shall be paid in regular intervals (as determined appropriate by the Secretary).

(5) Refund deposits

Amounts paid as refunds pursuant to paragraph (2) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title.

(6) Enforcement

(A) Audits

(i) Manufacturer audits

Each manufacturer of a refundable single-dose container or single-use package drug that is required to provide a refund under this subsection shall be subject to periodic audit with respect to such drug and such refunds by the Secretary.

(ii) Provider audits

The Secretary shall conduct periodic audits of claims submitted under this part with respect to refundable single-dose container or single-use package drugs in accordance with the authority under section 1395*l*(e) of this title to ensure compliance with the requirements applicable under this subsection.

(B) Civil money penalty

(i) In general

The Secretary shall impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who has failed to comply with the requirement under paragraph (2) for such drug for a calendar quarter in an amount equal to the sum of—

(I) the amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and

(II) 25 percent of such amount.

(ii) Application

The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(7) Implementation

The Secretary shall implement this subsection through notice and comment rulemaking.

(8) Definition of refundable single-dose container or single-use package drug

(A) In general

Except as provided in subparagraph (B), in this subsection, the term ''refundable single-

dose container or single-use package drug'' means a single source drug or biological (as defined in subsection (c)(6)(D)) or a biosimilar biological product (as defined in subsection (c)(6)(H)) for which payment is made under this part and that is furnished from a single-dose container or single-use package.

(B) Exclusions

The term ''refundable single-dose container or single-use package drug'' does not include—

(i) a drug or biological that is either a radiopharmaceutical or an imaging agent;

(ii) a drug or biological approved by the Food and Drug Administration for which dosage and administration instructions included in the labeling require filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process; or

(iii) a drug or biological approved by the Food and Drug Administration on or after November 15, 2021, and with respect to which payment has been made under this part for fewer than 18 months.

(9) Report to Congress

Not later than 3 years after November 15, 2021, the Office of the Inspector General, after consultation with the Centers for Medicare & Medicaid Services and the Food and Drug Administration, shall submit to the Committee on Finance of the Senate and the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives, a report on any impact this section is reported to have on the licensure, market entry, market retention, or marketing of biosimilar biological products. Such report shall be updated periodically at the direction of the Committee on Finance of the Senate and the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives.

(i) Judicial review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of—

(1) determinations of payment amounts under this section, including the assignment of National Drug Codes to billing and payment codes;

(2) the identification of units (and package size) under subsection (b)(2);

(3) the method to allocate rebates, chargebacks, and other price concessions to a quarter if specified by the Secretary;

(4) the manufacturer's average sales price when it is used for the determination of a payment amount under this section; and

(5) the disclosure of the average manufacturer price by reason of an adjustment under subsection (d)(3)(C) or (e).

(Aug. 14, 1935, ch. 531, title XVIII, § 1847A, as added Pub. L. 108–173, title III, § 303(c)(1), Dec. 8, 2003, 117 Stat. 2239; amended Pub. L. 110–173, title I, § 112, Dec. 29, 2007, 121 Stat. 2500; Pub. L. 111–148, title III, § 3139(a), Mar. 23, 2010, 124 Stat. 439; Pub. L. 116–39, § 6, Aug. 6, 2019, 133 Stat. 1062; Pub. L. 116–260, div. CC, title IV, §§ 401(a), (b), 405, Dec. 27, 2020, 134 Stat. 2995, 2996, 3002; Pub. L. 117–58, div. I, § 90004, Nov. 15, 2021, 135 Stat. 1343.)

Editorial Notes

AMENDMENTS

2021—Subsecs. (h), (i). Pub. L. 117–58 added subsec. (h) and redesignated former subsec. (h) as (i).

2020—Subsec. (b)(2)(A). Pub. L. 116–260, § 401(a)(1)(A), inserted ''or subsection (f)(2), as applicable'' before period at end.

Subsec. (b)(3). Pub. L. 116–260, § 401(a)(1)(B), inserted ''or subsection (f)(2), as applicable,'' before ''determined by'' in introductory provisions.

Subsec. (b)(6)(A). Pub. L. 116–260, § 401(a)(1)(C), inserted ''or subsection (f)(2), as applicable,'' before ''determined by'' in introductory provisions.

Subsec. (c)(6)(A). Pub. L. 116–260, § 401(b)(2), substituted '', except that, for purposes of subsection (f)(2), the Secretary may, if the Secretary determines appropriate, exclude repackagers of a drug or biological from such term.'' for period at end.

Subsec. (d)(4)(A). Pub. L. 116–260, § 401(b)(1)(A), substituted ''Misrepresentation'' for ''In general'' in heading.

Subsec. (d)(4)(B). Pub. L. 116–260, § 401(b)(1)(D), added subpar. (B). Former subpar. (B) redesignated (E).

Pub. L. 116–260, § 401(b)(1)(B), substituted ''subparagraph (A), (B), or (C)'' for ''subparagraph (B)''.

Subsec. (d)(4)(C), (D). Pub. L. 116–260, § 401(b)(1)(D), added subpars. (C) and (D).

Subsec. (d)(4)(E). Pub. L. 116–260, § 401(b)(1)(C), redesignated subpar. (B) as (E).

Subsec. (f). Pub. L. 116–260, § 401(a)(2), designated existing provisions as par. (1), inserted heading, and added par. (2).

Subsecs. (g), (h). Pub. L. 116–260, § 405, added subsec. (g) and redesignated former subsec. (g) as (h).

2019—Subsec. (c)(4). Pub. L. 116–39 substituted ''payable under this section—'' for ''payable under this section for the drug or biological based on—'' in introductory provisions, added subpars. (A) and (B), and struck out former subpars. (A) and (B) which read as follows:

''(A) the wholesale acquisition cost; or

''(B) the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.''

2010—Subsec. (b)(1)(C). Pub. L. 111–148, § 3139(a)(1)(A), added subpar. (C).

Subsec. (b)(8). Pub. L. 111–148, § 3139(a)(1)(B), added par. (8).

Subsec. (c)(6)(H), (I). Pub. L. 111–148, § 3139(a)(2), added subpars. (H) and (I).

2007—Subsec. (b)(1). Pub. L. 110–173, § 112(b)(1), inserted ''paragraph (7) and'' after ''Subject to'' in introductory provisions.

Subsec. (b)(1)(A). Pub. L. 110–173, § 112(a)(1), inserted ''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'' after ''paragraph (3)''.

Subsec. (b)(4)(A), (B). Pub. L. 110–173, § 112(a)(2), inserted ''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,'' after ''paragraph (3)''.

Subsec. (b)(6). Pub. L. 110–173, § 112(a)(3), added par. (6).

Subsec. (b)(7). Pub. L. 110–173, § 112(b)(2), added par. (7).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, § 3139(b), Mar. 23, 2010, 124 Stat. 440, provided that: ''The amendments made by

subsection (a) [amending this section] shall apply to payments for biosimilar biological products beginning with the first day of the second calendar quarter after enactment of legislation providing for a biosimilar pathway (as determined by the Secretary [probably means the Secretary of Health and Human Services]).''

REPORT ON SALES TO PHARMACY BENEFIT MANAGERS

Pub. L. 108–173, title III, §303(c)(2), Dec. 8, 2003, 117 Stat. 2245, provided that:

''(A) STUDY.—The Secretary [of Health and Human Services] shall conduct a study on sales of drugs and biologicals to large volume purchasers, such as pharmacy benefit managers and health maintenance organizations, for purposes of determining whether the price at which such drugs and biologicals are sold to such purchasers does not represent the price such drugs and biologicals are made available for purchase to prudent physicians.

''(B) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the study conducted under paragraph (1), and shall include recommendations on whether such sales to large volume purchasers should be excluded from the computation of a manufacturer's average sales price under section 1847A of the Social Security Act [42 U.S.C. 1395w–3a], as added by paragraph (1).''

INSPECTOR GENERAL REPORT ON ADEQUACY OF REIMBURSEMENT RATE UNDER AVERAGE SALES PRICE METHODOLOGY

Pub. L. 108–173, title III, §303(c)(3), Dec. 8, 2003, 117 Stat. 2245, provided that:

''(A) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study on the ability of physician practices in the specialties of hematology, hematology/oncology, and medical oncology of different sizes, especially particularly large practices, to obtain drugs and biologicals for the treatment of cancer patients at 106 percent of the average sales price for the drugs and biologicals. In conducting the study, the Inspector General shall conduct an audit of a representative sample of such practices to determine the adequacy of reimbursement under section 1847A of the Social Security Act [42 U.S.C. 1395w–3a], as added by paragraph (1).

''(B) REPORT.—Not later October 1, 2005, the Inspector General shall submit to Congress a report on the study conducted under subparagraph (A), and shall include recommendations on the adequacy of reimbursement for such drugs and biologicals under such section 1847A [42 U.S.C. 1395w–3a].''

APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES

Amendment by section 303 of Pub. L. 108–173, insofar as applicable to payments for drugs or biologicals and drug administration services furnished by physicians, is applicable only to physicians in the specialties of hematology, hematology/oncology, and medical oncology under this subchapter, see section 303(j) of Pub. L. 108–173, set out as a note under section 1395u of this title.

Notwithstanding section 303(j) of Pub. L. 108–173 (see note above), amendment by section 303 of Pub. L. 108–173 also applicable to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology, see section 304 of Pub. L. 108–173, set out as a note under section 1395u of this title.

§ 1395w–3b. Competitive acquisition of outpatient drugs and biologicals

(a) Implementation of competitive acquisition

(1) Implementation of program

(A) In general

The Secretary shall establish and implement a competitive acquisition program under which—

(i) competitive acquisition areas are established for contract award purposes for acquisition of and payment for categories of competitively biddable drugs and biologicals (as defined in paragraph (2)) under this part;

(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program, rather than under section 1395w–3a of this title; and

(iii) each physician who elects to obtain drugs and biologicals under the program makes an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part.

This section shall not apply in the case of a physician who elects section 1395w–3a of this title to apply.

(B) Implementation

For purposes of implementing the program, the Secretary shall establish categories of competitively biddable drugs and biologicals. The Secretary shall phase in the program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate.

(C) Waiver of certain provisions

In order to promote competition, in carrying out the program the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Exclusion authority

The Secretary may exclude competitively biddable drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the application of competitive bidding to such drugs or biologicals—

(i) is not likely to result in significant savings; or

(ii) is likely to have an adverse impact on access to such drugs or biologicals.

(2) Competitively biddable drugs and biologicals and program defined

For purposes of this section—

(A) Competitively biddable drugs and biologicals defined

The term ''competitively biddable drugs and biologicals'' means a drug or biological described in section 1395u(*o*)(1)(C) of this title and furnished on or after January 1, 2006.