

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.

(B) Program

The term “program” means the competitive acquisition program under this section.

(C) Competitive acquisition area; area

The terms “competitive acquisition area” and “area” mean an appropriate geographic region established by the Secretary under the program.

(D) Contractor

The term “contractor” means an entity that has entered into a contract with the Secretary under this section.

(3) Application of program payment methodology**(A) In general**

With respect to competitively biddable drugs and biologicals which are supplied under the program in an area and which are prescribed by a physician who has elected this section to apply—

(i) the claim for such drugs and biologicals shall be submitted by the contractor that supplied the drugs and biologicals;

(ii) collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsibility of such contractor and shall not be collected unless the drug or biological is administered to the individual involved; and

(iii) the payment under this section (and related amounts of any applicable deductible and coinsurance) for such drugs and biologicals shall be made only to such contractor upon receipt of a claim for a drug or biological supplied by the contractor for administration to a beneficiary.

(B) Process for adjustments

The Secretary shall provide a process for adjustments to payments in the case in which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

(C) Information for purposes of cost-sharing

The Secretary shall provide a process by which physicians submit information to contractors for purposes of the collection of any applicable deductible or coinsurance amounts under subparagraph (A)(ii).

(D) Post-payment review process

The Secretary shall establish (by program instruction or otherwise) a post-payment review process (which may include the use of statistical sampling) to assure that payment is made for a drug or biological under this section only if the drug or biological has been administered to a beneficiary. The Secretary shall recoup, offset, or collect any overpayments determined by the Secretary under such process.

(4) Contract required

Payment may not be made under this part for competitively biddable drugs and biologicals prescribed by a physician who has

elected this section to apply within a category and a competitive acquisition area with respect to which the program applies unless—

(A) the drugs or biologicals are supplied by a contractor with a contract under this section for such category of drugs and biologicals and area; and

(B) the physician has elected such contractor under paragraph (5) for such category and area.

(5) Contractor selection process**(A) Annual selection****(i) In general**

The Secretary shall provide a process for the selection of a contractor, on an annual basis and in such exigent circumstances as the Secretary may provide and with respect to each category of competitively biddable drugs and biologicals for an area by selecting physicians.

(ii) Timing of selection

The selection of a contractor under clause (i) shall be made at the time of the election described in section 1395w-3a(a) of this title for this section to apply and shall be coordinated with agreements entered into under section 1395u(h) of this title.

(B) Information on contractors

The Secretary shall make available to physicians on an ongoing basis, through a directory posted on the Internet website of the Centers for Medicare & Medicaid Services or otherwise and upon request, a list of the contractors under this section in the different competitive acquisition areas.

(C) Selecting physician defined

For purposes of this section, the term “selecting physician” means, with respect to a contractor and category and competitive acquisition area, a physician who has elected this section to apply and has selected to apply under this section such contractor for such category and area.

(b) Program requirements**(1) Contract for competitively biddable drugs and biologicals**

The Secretary shall conduct a competition among entities for the acquisition of competitively biddable drugs and biologicals. Notwithstanding any other provision of this subchapter, in the case of a multiple source drug, the Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area.

(2) Conditions for awarding contract**(A) In general**

The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) with respect to the acquisition of competitively biddable drugs and biologicals within a category unless the

Secretary finds that the entity meets all of the following with respect to the contract period involved:

(i) Capacity to supply competitively biddable drug or biological within category

(I) In general

The entity has sufficient arrangements to acquire and to deliver competitively biddable drugs and biologicals within such category in the area specified in the contract.

(II) Shipment methodology

The entity has arrangements in effect for the shipment at least 5 days each week of competitively biddable drugs and biologicals under the contract and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.

(ii) Quality, service, financial performance and solvency standards

The entity meets quality, service, financial performance, and solvency standards specified by the Secretary, including—

(I) the establishment of procedures for the prompt response and resolution of complaints of physicians and individuals and of inquiries regarding the shipment of competitively biddable drugs and biologicals; and

(II) a grievance and appeals process for the resolution of disputes.

(B) Additional considerations

The Secretary may refuse to award a contract under this section, and may terminate such a contract, with an entity based upon—

(i) the suspension or revocation, by the Federal Government or a State government, of the entity's license for the distribution of drugs or biologicals (including controlled substances); or

(ii) the exclusion of the entity under section 1320a-7 of this title from participation under this subchapter.

(C) Application of Medicare Provider Ombudsman

For provision providing for a program-wide Medicare Provider Ombudsman to review complaints, see section 1395ee(b) of this title, as added by section 923 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.¹

(3) Awarding multiple contracts for a category and area

The Secretary may limit (but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the following:

(A) The bid prices for competitively biddable drugs and biologicals within the category and area.

(B) Bid price for distribution of such drugs and biologicals.

(C) Ability to ensure product integrity.

(D) Customer service.

(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

(F) Such other factors as the Secretary may specify.

(4) Terms of contracts

(A) In general

A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

(B) Period of contracts

A contract under this section shall be for a term of 3 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

(C) Integrity of drug and biological distribution system

A contractor (as defined in subsection (a)(2)(D)) shall—

(i) acquire all drug and biological products it distributes directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and

(ii) comply with any product integrity safeguards as may be determined to be appropriate by the Secretary.

Nothing in this subparagraph shall be construed to relieve or exempt any contractor from the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] that relate to the wholesale distribution of prescription drugs or biologicals.

(D) Compliance with code of conduct and fraud and abuse rules

Under the contract—

(i) the contractor shall comply with a code of conduct, specified or recognized by the Secretary, that includes standards relating to conflicts of interest; and

(ii) the contractor shall comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the Inspector General of the Department of Health and Human Services.

(E) Direct delivery of drugs and biologicals to physicians

Under the contract the contractor shall only supply competitively biddable drugs and biologicals directly to the selecting physicians and not directly to individuals, except under circumstances and settings where an individual currently receives a drug or biological in the individual's home or other non-physician office setting as the Secretary may provide. The contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. This section does not—

¹ See References in Text note below.

- (i) require a physician to submit a prescription for each individual treatment; or
- (ii) change a physician's flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or a course of treatment.

(5) Permitting access to drugs and biologicals

The Secretary shall establish rules under this section under which drugs and biologicals which are acquired through a contractor under this section may be used to resupply inventories of such drugs and biologicals which are administered consistent with safe drug practices and with adequate safeguards against fraud and abuse. The previous sentence shall apply if the physicians can demonstrate to the Secretary all of the following:

- (A) The drugs or biologicals are required immediately.
- (B) The physician could not have reasonably anticipated the immediate requirement for the drugs or biologicals.
- (C) The contractor could not deliver to the physician the drugs or biologicals in a timely manner.
- (D) The drugs or biologicals were administered in an emergency situation.

(6) Construction

Nothing in this section shall be construed as waiving applicable State requirements relating to licensing of pharmacies.

(c) Bidding process

(1) In general

In awarding a contract for a category of drugs and biologicals in an area under the program, the Secretary shall consider with respect to each entity seeking to be awarded a contract the bid price and the other factors referred to in subsection (b)(3).

(2) Bid defined

In this section, the term "bid" means an offer to furnish a competitively biddable drug or biological for a particular price and time period.

(3) Bidding on a national or regional basis

Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.

(4) Uniformity of bids within area

The amount of the bid submitted under a contract offer for any competitively biddable drug or biological for an area shall be the same for that drug or biological for all portions of that area.

(5) Confidentiality of bids

The provisions of subparagraph (D) of section 1396r-8(b)(3) of this title shall apply to periods during which a bid is submitted with respect to a competitively biddable drug or biological under this section in the same manner as it applies to information disclosed under such section, except that any reference—

- (A) in that subparagraph to a "manufacturer or wholesaler" is deemed a reference to a "bidder" under this section;

(B) in that section to "prices charged for drugs" is deemed a reference to a "bid" submitted under this section; and

(C) in clause (i) of that section to "this section", is deemed a reference to "part B of subchapter XVIII".

(6) Inclusion of costs

The bid price submitted in a contract offer for a competitively biddable drug or biological shall—

- (A) include all costs related to the delivery of the drug or biological to the selecting physician (or other point of delivery); and
- (B) include the costs of dispensing (including shipping) of such drug or biological and management fees, but shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.

(7) Price adjustments during contract period; disclosure of costs

Each contract awarded shall provide for—

- (A) disclosure to the Secretary the contractor's reasonable, net acquisition costs for periods specified by the Secretary, not more often than quarterly, of the contract; and
- (B) appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a contractor's reasonable, net acquisition costs, as so disclosed.

(d) Computation of payment amounts

(1) In general

Payment under this section for competitively biddable drugs or biologicals shall be based on bids submitted and accepted under this section for such drugs or biologicals in an area. Based on such bids the Secretary shall determine a single payment amount for each competitively biddable drug or biological in the area.

(2) Special rules

The Secretary shall establish rules regarding the use under this section of the alternative payment amount provided under section 1395w-3a of this title to the use of a price for specific competitively biddable drugs and biologicals in the following cases:

(A) New drugs and biologicals

A competitively biddable drug or biological for which a payment and billing code has not been established.

(B) Other cases

Such other exceptional cases as the Secretary may specify in regulations.

(e) Cost-sharing

(1) Application of coinsurance

Payment under this section for competitively biddable drugs and biologicals shall be in an amount equal to 80 percent of the payment basis described in subsection (d)(1).

(2) Deductible

Before applying paragraph (1), the individual shall be required to meet the deductible described in section 1395l(b) of this title.

(3) Collection

Such coinsurance and deductible shall be collected by the contractor that supplies the drug or biological involved. Subject to subsection (a)(3)(B), such coinsurance and deductible may be collected in a manner similar to the manner in which the coinsurance and deductible are collected for durable medical equipment under this part.

(f) Special payment rules**(1) Use in exclusion cases**

If the Secretary excludes a drug or biological (or class of drugs or biologicals) under subsection (a)(1)(D), the Secretary may provide for payment to be made under this part for such drugs and biologicals (or class) using the payment methodology under section 1395w-3a of this title.

(2) Application of requirement for assignment

For provision requiring assignment of claims for competitively biddable drugs and biologicals, see section 1395u(o)(3) of this title.

(3) Protection for beneficiary in case of medical necessity denial

For protection of individuals against liability in the case of medical necessity determinations, see section 1395u(b)(3)(B)(ii)(III) of this title.

(g) Judicial review

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

- (1) the establishment of payment amounts under subsection (d)(1);
- (2) the awarding of contracts under this section;
- (3) the establishment of competitive acquisition areas under subsection (a)(2)(C);
- (4) the phased-in implementation under subsection (a)(1)(B);
- (5) the selection of categories of competitively biddable drugs and biologicals for competitive acquisition under such subsection or the selection of a drug in the case of multiple source drugs; or
- (6) the bidding structure and number of contractors selected under this section.

(Aug. 14, 1935, ch. 531, title XVIII, §1847B, as added Pub. L. 108-173, title III, §303(d)(1), Dec. 8, 2003, 117 Stat. 2245; amended Pub. L. 109-432, div. B, title I, §108(a), Dec. 20, 2006, 120 Stat. 2983.)

Editorial Notes**REFERENCES IN TEXT**

Section 1395ee(b) of this title, referred to in subsec. (b)(2)(C), was added by section 942(a)(5) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, not section 923 of that Act, and relates to the Council for Technology and Innovation, not to the Medicare Provider Ombudsman.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. subsec. (b)(4)(C), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

AMENDMENTS

2006—Subsec. (a)(3)(A)(iii). Pub. L. 109-432, §108(a)(1), substituted “and biologicals shall be made only to such

contractor upon receipt of a claim for a drug or biological supplied by the contractor for administration to a beneficiary.” for “and biologicals—

“(I) shall be made only to such contractor; and

“(II) shall be conditioned upon the administration of such drugs and biologicals.”

Subsec. (a)(3)(D). Pub. L. 109-432, §108(a)(2), added subpar. (D).

Statutory Notes and Related Subsidiaries**EFFECTIVE DATE OF 2006 AMENDMENT**

Pub. L. 109-432, div. B, title I, §108(c), Dec. 20, 2006, 120 Stat. 2983, provided that: “The amendments made by subsection (a) [amending this section] shall apply to payment for drugs and biologicals supplied under section 1847B of the Social Security Act (42 U.S.C. 1395w-3b)—

“(1) on or after April 1, 2007; and

“(2) on or after July 1, 2006, and before April 1, 2007, for claims that are unpaid as of April 1, 2007.”

CONSTRUCTION OF 2006 AMENDMENT

Pub. L. 109-432, div. B, title I, §108(b), Dec. 20, 2006, 120 Stat. 2983, provided that: “Nothing in this section [amending this section and enacting provisions set out as a note above] shall be construed as—

“(1) requiring the conduct of any additional competition under subsection (b)(1) of section 1847B of the Social Security Act (42 U.S.C. 1395w-3b); or

“(2) requiring any additional process for elections by physicians under subsection (a)(1)(A)(ii) of such section or additional selection by a selecting physician of a contractor under subsection (a)(5) of such section.”

REPORT

Pub. L. 108-173, title III, §303(d)(2), Dec. 8, 2003, 117 Stat. 2252, provided that: “Not later than July 1, 2008, the Secretary [of Health and Human Services] shall submit to Congress a report on the program conducted under section 1847B of the Social Security Act [42 U.S.C. 1395w-3b], as added by paragraph (1). Such report shall include information on savings, reductions in cost-sharing, access to competitively biddable drugs and biologicals, the range of choices of contractors available to physicians, the satisfaction of physicians and of individuals enrolled under this part [probably means part B of title XVIII of the Social Security Act, 42 U.S.C. 1395j et seq.], and information comparing prices for drugs and biologicals under such section and section 1847A of such Act [42 U.S.C. 1395w-3a], as added by subsection (c).”

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-4. Payment for physicians' services**(a) Payment based on fee schedule****(1) In general**

Effective for all physicians' services (as defined in subsection (j)(3)) furnished under this