
42 U.S. Code § 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.

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