

CMS 10145: Medicare Part B Drug and Biological
Competitive Acquisition Program
and Supporting Regulations in 42 CFR
Sections 414.906, 414.908, 414.910, 414.914, 414.916, and
414.917

A. Background

Competitive Acquisition Program (CAP)

Section 303(d) of the MMA provides an alternative payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. In particular, Section 303(d) of the MMA amends Title XVIII of the Social Security Act (the Act) by adding a new section 1847B, which establishes a competitive acquisition program for the acquisition of and payment for Part B covered drugs and biologicals furnished on or after January 1, 2006.

Beginning July 1, 2006, physicians were given a choice between acquiring and billing for Part B covered drugs under the Average Sales Price (ASP) drug payment methodology or electing to receive these drugs from vendors/suppliers selected for CAP, through a competitive bidding process. The provisions for this payment system are described in the proposed rule (42 CFR Part 414 Subpart K) published March 4, 2005 (70 FR 10746), an interim final rule published July 6, 2005 (70 FR 39022), a final rule with comment published November 21, 2005 (70 FR 70236), a proposed rule published on July 7, 2007 (72 FR 38153), and a final rule with comment published on November 27, 2007 (72 FR 66260).

Since its inception, additional legislation has augmented the CAP. Section 108 of the Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006 (MIEA-TRHCA) amended Section 1847b(a)(3) of the Social Security Act and requires that CAP implement a post payment review process. This procedure is done 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. These programmatic changes went into effect on April 1, 2007 via instructions to the CAP designated claims processor. The specific details about these changes can be found in our final rule with comment published in the Federal Register on November 27, 2007 (72 FR 66260).

Competitive bidding is seen as a means of using the dynamics of the marketplace to provide incentives for suppliers to provide reasonably priced products and services of high quality in an efficient manner.

The CAP's objectives include the following:

- to provide an alternative method to the Average Sales Price mechanism for physicians to

- obtain Part B drugs to administer to Medicare beneficiaries, and
- to reduce drug acquisition and billing burdens for Physicians.

Medicare Part B currently covers a limited number of prescription drugs. For the purposes of this document, the term “drugs” will hereafter refer to both drugs and biologicals. Currently, covered Medicare drugs generally include drugs furnished incident to a physician's service, durable medical equipment (DME) drugs, statutorily covered drugs, and other drugs.

The CAP covers injectable drugs furnished incident to a physician's service. Under the “incident-to” provision described in section 1861(s)(2) of the Social Security Act (the Act), the physician must incur a cost for the drug, and must bill for it. The Act limits coverage to drugs that are not usually self-administered.

A competition is held every three years in order to award contracts to entities that will supply drugs and biologicals for the program. A three year contract is awarded to at least two vendors per geographic area who have and maintain: 1) sufficient means to acquire and deliver competitively biddable drugs within the specified contract area; 2) arrangements in effect for shipping at least 5 days each week for the competitively biddable drugs under the contract and means to ship drugs in emergency situations; 3) quality, service, financial performance, and solvency standards; and 4) A grievance and appeals process for dispute resolution. A vendor’s contract may be terminated during the contract period if their Federal or State License for the distribution of drugs is revoked. In addition, the statute provides for quarterly price adjustments if necessary. Winning vendors must also qualify for enrollment in Medicare.

This request covers information collection requirements related to the CAP Vendor Application and Bid Form, the CAP Physician Election Agreement, and CAP operational procedures. The CAP Vendor Application and Bid Form is used by potential vendors to provide information related to the characteristics of their company and to submit their bid prices for CAP drugs. The Physician Election Agreement is used annually by physicians to elect to participate in the CAP or to make changes to the previous year’s selections. Finally, the operational requirements stipulated in the Code of Federal Regulations (CFR) for the CAP relate to the submission of information by CAP vendors and physicians to facilitate program operations. A copy of the related statutes and sections of the CFR are attached.

B. Justification

1. Need and Legal Basis

The Competitive Acquisition Program (CAP) is required by Section 303(d) of the MMA amends Title XVIII of the Social Security Act (the Act) by adding a new section 1847B, which establishes a competitive acquisition program for the payment for Part B covered drugs and biologicals furnished on or after January 1, 2006. Physicians are given a choice between buying and billing these drugs under the average sales price (ASP) system, or obtaining these drugs from vendors selected in a competitive bidding process. The initial

provisions for this payment system are described in the proposed rule published March 4, 2005 (70 FR 10746), the interim final rule published July 6, 2005 (70 FR 39022), and the final rule with comment published November 21, 2005 (70 FR 70236). The collection tools in this application are currently utilized in the program.

The CAP Vendor Application and Bid Form is used by potential vendors to provide information related to the characteristics of their company and to submit their bid prices for CAP drugs. The Physician Election Agreement is used annually by physicians to elect to participate in the CAP or to make changes to the previous year's selections. Finally, the information requirements for the CAP stipulated in the Code of Federal Regulations (CFR) relate to the submission of information by any CAP vendors and physicians to facilitate program operations. A copy of the related statues and sections of the Code of Federal Regulations (CFR) are attached.

2. **Information Users**

The information collected by these documents is used by CMS and its Medicare contractor to meet programmatic requirements established by the MMA 2003. Data collected per 42 CFR 414.906 is used by CMS and the approved contractor for payment purposes and updates to the CAP drug list as mandated in section 303(d)(3) of the MMA 2003. The information collected pertaining to 42 CFR 414.908 is used by CMS to facilitate the physician election process as stipulated in section 303(d)(1)(A)(ii) of the MMA 2003 and for standard programmatic procedures. 42 CFR 414.910 pertains to information collected in the CAP Vendor Application and Bid Form. The vendor bidding process is required per section 303(d)(1)(b)(1) of the MMA 2003. As specified in 42 CFR 414.914, the CAP vendor must submit reasonable net acquisition data (RNAC) on an annual basis. CMS uses this data to update prices for drugs available through the CAP as statutorily mandated in section 303(d)(1)(c)(7) of the MMA 2003. Section 42 CFR 414.916 pertains to data that CMS and its contractor uses to promulgate the program's appeals process for vendors, known as the "dispute resolution process." This process is referenced in section 303(d)(1)(b)(2)(A)(1)(ii) (II) of the MMA and is referenced in the Physician Election Agreement. Section 42 CFR 414.917 relates to information collected for the dispute resolution process for physicians.

3. **Improved Information Technology**

The Physician Election Agreement is available online and may be filled out electronically, but must be signed and submitted in hardcopy form to local carriers. Similarly, the Vendor Bidding Form is also available online, but must be signed and submitted in hardcopy to CMS.

4. **Duplication of Similar Information**

The information requested does not duplicate other information.

5. **Small Businesses**

The Physician Election Agreement will be used by physicians' offices to elect to participate in CAP, and therefore will affect small businesses. Physician burden is minimized since this form must only be completed and submitted annually. Physicians must also submit information to support standard program operational procedures such as medical record review. However, this is a part of standard operating procedure for physicians participating in Medicare since such requirements are endemic to Medicare participation in general.

6. **Less Frequent Collection**

The provisions in this collection are used to support processes specifically enumerated in the Medicare Modernization Act of 2003 and the Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006. Less frequent collection of these would violate statutes (see question 2 responses for specific citations in the MMA and the MIEA-TRHCA).

7. **Special Circumstances**

Not applicable

8. **Federal Register Notice/Outside Consultation**

A 60-day Federal Register notice was published on April 25, 2008.

CMS will publish information regarding this information collection on its web site in order to notify the interested public regarding our plans and in order to accept comments from the public regarding the information collection. A 30-day notice regarding this information collection was published in the Federal Register on March 4, 2005, a subsequent notice was published in the Federal Register on July 6, 2005, and a 60-day notice was published in the Federal Register on November 27, 2007. Paperwork Reduction Act notices about TRHCA-related changes to the CAP were posted in the Federal Register with our proposed rule on July 7, 2007 and our final rule with comments on November 27, 2007. We have received no comments about them.

In the course of our program oversight responsibilities, we consult with our contractors to discuss issues related to data collection. We receive their input and do our best to be mindful of their feedback when conducting our operations. Additionally, we are also open to any feedback from participating CAP physicians. Providers are asked to contact the CAP vendor or designated carrier to discuss any issues that may arise during their participation in the CAP. Additionally, we have held teleconferences that have given physicians the opportunity to ask questions about the CAP. A detailed description of outside consultation for other work associated with the CAP forms may be found in the supporting statement for CMS-10133 (OMB 0938-0955).

9. **Payments/Gifts to Respondents**

There were no payments/gifts to respondents.

10. **Confidentiality**

The CAP Vendor Application and Bid Form is used to submit bid prices and collect vendor information. FAR provisions relating to the confidentiality of information, as provided in section 1847B (a)(1)(C) of the Social Security Act, apply to the CAP. Also, potential drug vendors are instructed to mark confidential any part of their application they wish to keep confidential. Moreover, CAP vendors are covered entities for the purposes of the Health Insurance Portability and Accountability Act (HIPAA), and communication from CAP physicians are also subject to applicable HIPAA privacy and security requirements. Additionally, CMS and its contractors will abide by HIPAA and any other applicable privacy and security rules in the course of their oversight on the CAP.

11. **Sensitive Questions**

Other than the proprietary information noted above in answer #10, there are no sensitive questions included in the data collection requirements for the vendor bidding forms, the Physician Election Agreement, or the programmatic information submission requirements.

12. **Burden Estimate (Total Hours & Wages)**

Competitive acquisition as the basis for payment (§414.906)

A CAP vendor must annually submit their reasonable net acquisition costs (RNAC) for drugs that they supply through the CAP so that payment amounts for CAP drugs can be updated as per section 303(d) of the MMA 2003. The burden associated with this requirement is the time and effort necessary for a CAP vendor to provide this information. There can only be a maximum of five vendors in the CAP program, which exempts this requirement from the Paperwork Reduction Act (PRA). Therefore, we are not estimating burden hours for this task.

A CAP vendor may submit requests to add or substitute drugs onto the CAP drug list as needed. The burden associated with this is the time and effort necessary for a CAP vendor to provide this information. There can only be a maximum of five vendors in the CAP program, which exempts this requirement from the Paperwork Reduction Act (PRA). Therefore, we are not estimating burden hours for this task.

Competitive acquisition program (§414.908)

A physician shall be provided an application process for the selection of an approved contractor on an annual basis. The application form will facilitate physician enrollment and designation of their approved CAP vendor. The burden associated with this requirement is currently discussed and accounted for in a separate PRA package (CMS-10167; OMB-0938-0987).

Physicians participating in the CAP must, as stipulated in §414.908(a)(3), provide

information to a CMS contractor, the CAP vendor, in order to facilitate programmatic operations. Specifically, a CAP physician must submit information to help with the collection of applicable deductible and coinsurance as described in §414.906(a)(3), notify the CAP vendor when a drug is not administered, file a Medicare claim, and place orders for a CAP drug. The burden associated with these requirements is the time and effort necessary for CAP physicians to provide this information.

The CAP became operational on July 1, 2006, and our burden estimates are based on experience gained with the program and the CAP claims volume during the first full fiscal year of operation from October 1, 2006 - September 30, 2007:

Number of CAP claims = 721, 069

Time for information collection for all CAP claims = 5 minutes

Time for notifying a CAP vendor when drug is not administered (for 1/4 of all CAP claims) = 10 minutes

For the tasks of ordering CAP drugs, notifying a CAP vendor when a drug is not administered, and submitting information to help with the collection of applicable deductible and coinsurance, we estimate the burden to be a weighted average of 6 minutes per claim, an annual total of 31,188 hours.

We also estimate that 3000 physicians will participate in the program. This is based on experience gained with the program since July 1, 2006.

The submission of a Medicare claim is a customary Medicare business practice, so we will not estimate a burden.

Bidding process (§414.910)

Vendors may bid to furnish competitively biddable drugs in all areas of the United States, or a specific region that meets the requirements of this section. The burden associated with these requirements is currently discussed and accounted for in a separate PRA package (CMS-10133; OMB 0938-0955).

Vendor Contract (§414.914)

The terms of the contract between the agency and the approved vendor/contractor will be for a term of three years. During the contract period, the contractor must disclose to CMS or its agent upon request information related to the verification of drug administration claims. The approved vendor's/contractor's reasonable, net acquisition costs must also be disclosed on an annual basis.

The burden associated with these tasks is the time and effort necessary for a CAP vendor to provide such information. As stated previously, there can only be a maximum of five vendors in the CAP program, which exempts these requirements from the Paperwork Reduction Act (PRA). Therefore, we are not estimating burden hours for this task.

Dispute Resolution for vendors and beneficiaries (§414.916)

Cases of an approved vendor's dissatisfaction with denied drug claims are resolved through a

voluntary alternative dispute resolution process. Since the requirements set forth in this section are pursuant to administrative action, audit, or investigation, the requirements of this section are exempt from the PRA as stipulated under 5 CFR 1320.4(a)(2).

Dispute resolution and process for suspension or termination of approved CAP contract and termination of physician participation under exigent circumstances (§414.917)

If a participating CAP physician finds a CAP vendor's service, or the quality of a CAP drug supplied by the CAP vendor, to be unsatisfactory, then the physician may address the issue through an alternative dispute resolution process administered by CMS and its agent, the CAP designated carrier. Additionally, if a physician requests to terminate their participation in the program under exigent circumstances provisions described in 414.908(a)(2)(v), they must submit information to CMS and the CAP designated carrier.

Both the dispute resolution and the exigent circumstance contract termination processes require the submission of information from physicians. We believe such information is exempt from the PRA under 5 CFR 1320 3(h)(6), which indicates that facts or opinions collected from a single person or entity are not subject to the PRA.

13. **Capital Costs**

There are no capital costs required for this data collection.

14. **Cost to the Federal Government**

There are no additional costs to the Federal government. Information is collected and processed in the normal course of federal duties.

15. **Changes to Burden**

Section 108 of the Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006 (MIEA-TRHCA) amended Section 1847b(a)(3) of the Social Security Act and requires that CAP implement a post payment review process. This procedure is done 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. Operationally, this translates to the requirement that CAP vendors submit drug administration verification information to CMS or its agent as requested. Since there can only be a maximum of five vendors in the CAP program as stipulated in §414.908(b)(i)(A), this requirement is exempt from the Paperwork Reduction Act (PRA), and we are not estimating burden hours for this task.

Physicians participating in the CAP must, as stipulated in §414.908(a)(3), provide information to the CAP vendor in order to facilitate programmatic operations. Specifically, a CAP physician must submit information to help with the collection of applicable deductible and coinsurance as described in §414.906(a)(3), notify the CAP vendor when a drug is not administered, file a Medicare claim, and place orders for a CAP drug. The burden associated

with these requirements is the time and effort necessary for CAP physicians to provide this information. In the previous PRA package, we stated that the burden associated with these requirements was accounted for in PRA package CMS-10167 (OMB 0938-0987). While the requirements pertaining to drug ordering will still be accounted for in CMS-10167 (OMB 0938-0987), the remaining requirements are now being addressed through this PRA package.

A CAP vendor must annually submit their reasonable net acquisition costs (RNAC) for drugs that they supply through the CAP so that payment amounts for CAP drugs can be updated as per section 303(d) of the MMA 2003. The burden associated with this requirement is the time and effort necessary for a CAP vendor to provide this information. In the previous PRA package, we stated that this requirement would require each of the ten contractors 8 hours of work on an annual basis to submit the necessary information. However, there can only be a maximum of five vendors in the CAP program as stipulated in section 414.908(b)(i)(A). Therefore, this requirement is exempted from the Paperwork Reduction Act (PRA), and we are no longer estimating burden hours for this task.

16. **Publication and Tabulation Dates**

There are no publication or tabulation dates.

17. **Expiration Date**

There is no mandated expiration date.

18. **Certification Statement**

There are no exceptions to the certification statement.

C. **Collections of Information Employing Statistical Methods**

Question is not applicable. No sampling techniques are proposed or are appropriate.