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
CMS-10145, OMB 0938-0954

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).

Additional legislation affecting the CAP was included in 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) which amended Section 1847b(a)(3) of the Social Security Act and requires that CAP implement a post payment review process. This process assures 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, and were further described in our final rule with comment published in the Federal Register on November 27, 2007 (72 FR 66260).

In 2009, CMS finalized additional refinements to the program and updates to regulation text at 42 CFR 414.906. These items were published in the November 25, 2009 Federal Register (74 FR 61905) and included changing the frequency of payment updates to vendors drug prices from an annual process to a quarterly process.

The CAP is currently on hold and CMS has not set a time for future rounds of vendor bidding. We are seeking an extension of this package in order to facilitate the reintroduction of this program at a future date.

This request covers the operational requirements stipulated in the Code of Federal Regulations (CFR) for the CAP related to the submission of information by CAP vendors and physicians to facilitate program operations. Other approved CAP PRA packages include:

- Information collection requirements for the CAP Vendor Application and Bid Form (CMS 10133, OMB# 0938-0955) that is used by potential vendors (i.e. bidders) to provide information related to the characteristics of their company and to submit their bid prices for CAP drugs; and,
- Information collection requirement for the CAP Physician Election Agreement Form (CMS-10167, OMB#0938-0987) which is used annually by physicians to elect to participate in the CAP or to make changes to the previous year's selections.

Our responses below focus on CAP operational aspects and do not include detailed information about the Vendor Application and Bid Form or the Physician Election Agreement.

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 CMS 10133 and CMS 10167 are utilized in the program and are described in separate PRA packages. Additional 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, and these items are addressed in this package.

In 2009, CMS finalized additional refinements to the program and updates to regulation text at 42 CFR 414.906. These items were published in the November 25, 2009 Federal Register (74 FR 61905) and included changing the frequency of payment updates to vendors drug prices from an annual process to a quarterly process.

The CAP is currently on hold and CMS has not set a time for future rounds of vendor bidding. We are seeking an extension of this package in order to facilitate the reintroduction of this program at a future date.

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. As updated in the 2009 rulemaking process in 42 CFR 414.906, the CAP vendor must submit reasonable net acquisition cost data (RNAC) on a quarterly 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. 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. 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

Vendors' RNAC reports are submitted electronically using encrypted copies of spreadsheets; no signatures are required. A specific collection instrument is not used for this activity.

4. Duplication of Similar Information

The information requested does not duplicate other information.

5. Small Businesses

The RNAC reports do not affect small business. Other activities under the CAP may affect small businesses such as physicians who elect to participate in the program. Physicians 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 typically required for providers who participate in Medicare.

6. Less Frequent Collection

The provisions in this collection are used to support processes required under 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). The updated RNAC reporting requirement was supported by public comments received in response to rulemaking, and is perceived by the vendor community as a desirable requirement and could influence vendor participation.

7. Special Circumstances

Not applicable

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice that is associated with this extension published on March 25, 2011 (76 FR 16790). No comments were received.

We have received no additional comments regarding previous notices or the Paperwork Reduction Act notice associated with the quarterly RNAC reporting that was published in the CY2010 Physician Fee Schedule Rule. Our request for the re-approval of this package does not make any changes to this collection since the CY2010 Physician Fee Schedule Rule, so a subsequent notice was not published. Comments from interested parties and teleconference "listening sessions" held in early 2009 led us to propose the updated RNAC reporting policy, and the change was supported by comments from the vendor community responding to the proposed rule.

Other previously published notices include the following: a 30-day notice regarding this information collection was originally 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. A 60-day Federal Register notice was published on April 25, 2008. 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 incorporate their feedback as appropriate 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) and the supporting statement for CMS 10167 (OMB# 0938-0987).

9. Payments/Gifts to Respondents

There were no payments/gifts to respondents.

10. Confidentiality

RNAC reports are treated as proprietary data to the extent that the Law permits. 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 submit reasonable net acquisition costs (RNAC) for drugs that they supply through the CAP each quarter (changed from annual to quarterly reporting in 2009) 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 experienced 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 3,000 physicians will participate in the program. This is based on experience gained with the program since July 1, 2006. For 2010, we believe that this estimate remains accurate.

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 42 CFR 414.910. 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 42 CFR 414.916 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

This ICR does not have any program changes or adjustments.

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.