

Medicare Part B Drug and Biological
Competitive Acquisition Program Vendor Application and Bid
Form
CMS-10133, OMB 0938-0955

A. Background

Competitive Acquisition Program (CAP)

Section 303 (d) of the Medicare Modernization Act (MMA) requires the implementation of a competitive acquisition program for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis. The CAP is an alternative to the Average Sales Price (ASP or “buy and bill”) method of acquiring many Part B drugs and biologicals administered incident to a physician’s services. Under the ASP methodology, a physician directly purchases such drugs, submits Medicare claims for the drug and its administration, and collects the related coinsurance from beneficiaries. Under the CAP, a physician places a beneficiary specific drug order with an approved CAP vendor, which then ships the drug to the physician, submits a claim for the drug to Medicare, and collects cost sharing amounts from the beneficiary. The physician administers the drug and submits the corresponding claim for drug administration. For the physician, this program decreases the amount of financial resources that are devoted to drug inventory, and eliminates the risk of bad debt from uncollected coinsurance. The provisions for this new payment system are described in the proposed rule (42 CFR Part 414 Subpart K) published March 4, 2005 (70 FR 10746), the interim final rule published July 6, 2005 (70 FR 39022), and a final rule published on November 21, 2005 (70 FR 70116). Subsequent proposed and final rules about the CAP were published on July 12, 2007 (72 FR 38153), November 27, 2007 (72 FR 66260), July 7, 2008 (73 FR 38522), and November 19, 2008 (73 FR 69753).

The CAP was implemented on July 1, 2006 with one approved CAP vendor supplying drugs for the program under a three year contract. In 2008, a competition for the 2009-2011 vendor contracts was held. However, CMS could not finalize a contract with any of the successful bidders. Therefore, the CAP was put on hold on January 1, 2009 as the 2006-2008 vendor contract expired.

This pause is being used as an opportunity to solicit and consider feedback about the program and to develop potential options for re-implementing the program. However, CMS does not have the statutory authority to halt the program or to keep it on hold indefinitely. The re-implementation schedule has yet to be finalized.

This extension request covers the CAP Vendor Application and Bid Form, which has been used by bidders to provide a response to CMS’ solicitation for approved CAP vendor bids and to submit their bid prices for CAP drugs. This form was originally included in package CMS 10133 in March 2005. CAP Physician election materials were then separated from the

vendor application material (see PRA package CMS 10167, OMB 0938-0987) because of a delay in the CAP's implementation. The first version of the CAP Vendor Application and Bid Form received emergency PRA clearance so that it could be used during the first round of CAP bidding in the fall of 2005. CAP bidding for 2006-2008 vendor contracts began after the publication of a final rule (CMS-1502-FC and CMS-1325-F) on November 21, 2005, and the bidding period concluded on December 22, 2005. In 2008, this PRA package was 'approved without changes' and was used during the competition for 2009-2011 vendor contracts.

The current approval for this PRA package expires on August 31, 2009. Though the program is currently on hold and a timeline for the resumption of the CAP has not been established, the CAP Vendor Application and Bid Form will be required to conduct the next round of vendor bidding. Having a vehicle to collect responses from bidders is necessary should the new administration choose to re-implement the CAP quickly. Bidding for CAP vendor contracts precedes the contract's implementation date by 9-12 months, and must precede the election period in which physicians can join the program.

Therefore, we are seeking a three year PRA extension for the current CAP Vendor Application and Bid Form. Due to the evolving nature of this program, we do not have a timetable established for future bidding, nor do we have a list of drugs that will be included in the process. Additionally, should the new administration require that the program be re-implemented with changes that would require revisions to the bid form, we will edit this information collection document to reflect any statutory or regulatory changes that may be made to the program, and will re-submit this PRA package for approval.

B. Justification

1. Need and Legal Basis

The Competitive Acquisition Program (CAP) is required by Section 303(d) of the MMA, which amends Title XVIII of the Act by adding section 1847B, which establishes a competitive acquisition program for the payment of Part B covered drugs and biologicals furnished on or after January 1, 2006. Physicians have 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 a final rule published on November 21, 2005 (70 FR 70116). Subsequent proposed and final rules about the CAP were published on July 12, 2007 (72 FR 38153), November 27, 2007 (72 FR 66260), July 7, 2008 (73 FR 38522), and November 19, 2008 (73 FR 69753). The first round of bidding concluded on December 22, 2006. The second round of bidding concluded on February 15, 2008.

A 3-year contract is awarded to vendors who have and maintain the following statutory requirements: 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. The CAP Vendor Application and Bid Form is a collection tool which is used by potential vendors to describe how the bidding entity meets these requirements, and to submit their bid prices for CAP drugs in future CAP bidding. Due to the evolving nature of this program, we do not have a timetable established for future bidding, nor do we have a list of drugs that will be included in the process. Though the CAP is currently on hold and CMS does not currently have a timeline for the resumption of the CAP, the CAP Vendor Application and Bid Form will be required when the CAP is re-implemented.

2. **Information Users**

The information collected on the CAP Vendor Application and Bid Form will be used by CMS during the bidding evaluation process to evaluate the vendors bid prices, their credentials, experience, and to assess their ability to provide quality service to physicians and beneficiaries.

3. **Improved Information Technology**

The forms will be available through the CAP website. The CAP Vendor Application and Bid Form is a response to a solicitation for a contract and must be downloaded from the website, printed and submitted by mail.

4. **Duplication of Efforts**

The information requested does not duplicate other information.

5. **Small Businesses**

Not applicable. These information collection requirements do not impact small businesses.

6. **Less Frequent Collection**

The CAP Vendor Application and Bid Form will be used during the CAP bidding process. The bidding process will occur every 3 years, or more frequently as additional drugs and geographic areas are phased into the CAP. We do not expect bidding to occur more frequently than on an annual basis. Less frequent collection will impair the agency's ability to properly evaluate vendors and their bid prices.

7. **Special Circumstances**

Not applicable.

8. Federal Register Notice/Outside Consultation

A 60-day Federal Register notice was published on March 20, 2009. No comments were received.

The 60-day FR notice for the resubmission of this information collection request was published on April 21, 2006, and no comments were received from the public. In 2008, our request for the re-approval of this package did not entail any substantive or material changes to this collection, so a notice period was not required.

Formal Outside Consultation

CMS contracted with an outside source that collected background information on CAP. An important element of this contract was consultation with groups representing beneficiaries, physicians and suppliers, drug suppliers, and drug manufacturers to obtain input on the implementation of this provision.

Public Meetings and Comments

On April 1, 2004, CMS held an open door forum (ODF) at CMS headquarters to discuss all aspects of the drug competitive bidding system. Areas for comment included:

1. Which drugs (or categories of drugs) are best suited to competitive bidding and which drugs (or categories of drugs) should be excluded?
2. How should appropriate geographic regions be established?
3. What standards should be used to evaluate a drug vendor's quality, service, and solvency?
4. What standards should be used to evaluate the integrity of a drug vendor's distribution system?
5. What standards should be used to evaluate a drug vendor's capacity to supply drugs in a timely manner?
6. What should be included in a drug vendor code of conduct?
7. How and when should price adjustments occur if a contractor's reasonable net acquisition cost changes?
8. How can Medicare verify that a drug delivered to a physician under the competitive bidding program has been administered to the beneficiary?
9. What is the most appropriate process for restocking physician inventories for drugs used to treat beneficiaries in emergency situations?
10. How will drug vendors obtain patient billing information from physician's offices?

Individuals were invited to speak or distribute written comments at the meeting on the topics mentioned above. The purpose of this meeting was to gather input from the public, including the providers and others who may be affected by the program.

On January 10, 2008, CMS held a special ODF teleconference for potential bidders on vendor bidding for 2009-2011 contracts. Individuals were invited to ask questions about the

program and the bidding process.

Outreach Efforts through the CMS Website

On December 17, 2004, CMS invited industry to submit responses to a Request for Information (RFI) published on the CMS website. The RFI was intended to assess potential vendors' interest in bidding on contracts to supply drugs and biologicals, which drugs potential vendors may be interested in supplying, and which geographic areas of the United States potential vendors may want to serve. Representatives of entities that may consider bidding for contracts to supply drugs and biologicals under the CAP were invited and encouraged to submit responses regarding a list of Medicare Part B drugs and geographical locations of competitive acquisition areas.

On December 16, 2004, CMS announced, through the CMS Listserv for physicians, PHYSICIANS-L, that it has issued a Request for Information (RFI) on the Competitive Acquisition Program for Medicare Part B drugs and Biologicals. On December 17, 2004, CMS issued a similar announcement through the CMS Listserv for pharmacies, PHARMACYODF-L. The RFI was also announced and described at the January 13, 2005 Pharmacy Open Door Forum.

CMS has also posted general information about the CAP on the following website: <http://www.cms.hhs.gov/CompetitiveAcquisforBios/>. This website has been and will continue to be updated as information about the CAP is released to the public.

During CAP vendor bidding for 2009-2011 contracts, CMS also released announcements through the CMS Listserv for physicians, PHYSICIANS-L, and the CMS Listserv for pharmacies, PHARMACYODF-L.

CAP Proposed Rules, Interim Final Rule with Comment Period, and Final Rules

In 2005, a proposed rule was published on March 4th (70 FR 10746) , and the comment period ended on April 26, 2005. After a review of public comments, which included numerous comments from physicians and physician groups, CMS published an interim final rule on July 6, 2005 (70 FR 39022). The comment period for the interim final rule ended on September 6, 2005. A final rule was published on November 21, 2005 (70 FR 70116).

Subsequent proposed and final rules about the CAP were published on July 12, 2007 (72 FR 38153), November 27, 2007 (72 FR 66260), July 7, 2008 (73 FR 38522), and November 19, 2008 (73 FR 69753).

9. **Payments/Gifts to Respondents**

There will be no payments/gifts to respondents.

10. **Confidentiality**

As a matter of policy to protect the proprietary information of the bidders, CMS will not disclose individually identifiable information contained in the bids, to the extent permitted by law. However, CMS can show information on the bids on an anonymous basis in a debriefing session. Although a decision about using a bid evaluation contractor has not been made, CMS could share information on the bids to an evaluation contractor, which would in turn be required to maintain the confidential nature of the information. Any published evaluation about the bidders will be anonymous or in aggregate form.

11. **Sensitive Questions**

Other than the proprietary information noted above in answer #10, there are no sensitive questions included in the bidding forms.

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

Previously, our burden estimates indicated that 12 respondents would submit bids at most annually. The annual burden amount was 480 hours (40 hours for each bidder) at a total annual public cost of approximately \$9600 per year.

The CAP is currently on hold and we do not have a timetable for the next round of vendor bidding. The burden estimate below has been updated to reflect the program's postponement as per consultation with CMS's Office of Strategic Operations and Regulatory Affairs (OSORA). OSORA has indicated that we could not maintain our previous burden estimate because of the program's postponement. Moreover, they indicated that we could not change our burden estimate to 'zero' due to operational issues.

Therefore, the reporting requirements for the CAP Vendor Application and Bid Form are as follows:

10 bid respondents @ .10 hours per respondent = 1 hour annual hour burden

If we further assume that administrative personnel would be responsible for completing the election form and their salaries are \$20 per hour, the average annual public cost is estimated to be \$20.00 per year.

These estimates assume that 10 potential vendors will submit bids annually. The bidding process will occur every 3 years, or more frequently as additional drugs and geographic areas are phased into the CAP. We do not expect bidding to occur more frequently than on an annual basis.

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. Applications will be processed in the normal course of federal duties.

15. **Changes to Burden**

The burden estimate was updated to reflect the program's postponement as per consultation with CMS's Office of Strategic Operations and Regulatory Affairs (OSORA). OSORA has indicated that our burden estimate cannot be 'zero' due to operational issues. They also indicated that we could not maintain our previous burden estimate because of the program's postponement.

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 not applicable. No statistical sampling techniques are proposed or are appropriate.