CMS 10167: Medicare Part B Drug and Biological Competitive Acquisition Program Physician Election Agreement

A. Background

Competitive Acquisition Program (CAP)

Section 303(d) of the Medicare Modernization Act (MMA) of 2003 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 2003 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 a proposed rule 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.

Physicians elect into the CAP during an annual physician election period in the fall. To be eligible to participate in the CAP, physicians must: 1) administer Medicare Part B drugs "incident to a physician's service" in an office setting, and 2) be enrolled as a Medicare Part B provider with authority to prescribe or order Medicare Part B Drugs. For physician groups, all members must elect to participate in CAP if they have reassigned benefits and are billing under the group National Provider Identification (NPI).

This request pertains to the CAP Physician Election Agreement, which is used by physicians to elect to participate in the CAP or to make changes to their previous year's selections. In 2005, the Physician Election Agreement was originally included in Paperwork Reduction Act (PRA) package CMS-10133 (OMB 0938-0955), which also includes the CAP Vendor Application and Bid Form. It was subsequently separated from these materials due to a change in the CAP's implementation date From January 1, 2006 to July 1, 2006. This required that the vendor application materials be submitted for emergency clearance from the Office of Management and Budget (OMB) in November 2005 in a separate PRA package (CMS10133; OMB 0938-0955).

A copy of 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). Subsequent regulatory language about the CAP was published in a proposed rule from July 7, 2007 (72 FR 38153), and a final rule with comment from November 27, 2007 (72 FR 66260).

The collection tool in this application, the Physician Election Agreement, is currently utilized in the program. It is used annually by physicians to elect to participate in the CAP or to make changes to their previous year's selections. The CAP election process is statutorily mandated as established by sections 303(d)(1)(a)(1)(A)(ii) and 303(d)(1)(a)(1)(A)(iii) of the MMA 2003. 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, its Medicare contractor, and the Approved CAP Vendor to meet programmatic requirements pertaining to physician election as established by sections 303(d)(1)(a)(1)(A)(ii) and 303(d)(1)(a)(1)(A)(iii) of the MMA 2003. The programmatic regulations pertaining to CAP physician election can be found at 42 CFR 414.908. The information is also used to coordinate general programmatic efforts.

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. This collection may accept electronic signatures if such an option were available and compatible in the future.

4. **Duplication of Similar Information**

The information requested does not duplicate any other effort and the information cannot be obtained from any other source.

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.

6. **Less Frequent Collection**

The instrument in this collection is used to support processes specifically enumerated in the Medicare Modernization Act of 2003. Less frequent collection of this information would violate statutes (see question 2 responses for specific citations in the MMA).

7. **Special Circumstances**

Not applicable

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

A 60-day Federal Register notice was published on April 1, 2008.

Much effort has been made to consult with persons outside the agency on the CAP both before and after the program's implementation. Prior to the beginning of the CAP, CMS contracted with an outside source that collected background information for the CAP. An important element of this contract was consultation with groups representing beneficiaries, physicians, drug suppliers, and drug manufacturers to obtain input on the implementation of this provision.

Additionally, CMS directly solicited public feedback through a number of mechanisms. On April 1, 2004, CMS hosted an open door forum at CMS headquarters to discuss all aspects of the drug competitive bidding system and to gather input from the public, including providers and others who may be affected by the program. Individuals were invited to speak or distribute written comments at the meeting.

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 potential bidding entities for the CAP were invited and encouraged to submit responses regarding a list of Medicare Part B drugs and geographical locations of competitive acquisition areas. CMS announced this RFI both before and after publication via a CMS listserv notice to physicians on December 16, 2004, a listserv notice for potential vendors via the PHARMACYODF-L listserv on December 17, 2004, and through an announcement on the Pharmacy Open Door Forum on January 13, 2005.

CMS is continuing its efforts to solicit information from individuals and groups outside the agency. Currently, a contractor has been tasked with evaluating the CAP, and has consulted with entities external to the agency such as physicians and beneficiaries. CMS also continues to periodically hold open door forums and sponsor teleconferences that allow for direct public feedback.

Additionally, in the course of our program oversight responsibilities, we consult with our contractors to discuss issues related to data collection and physician election. We receive their input and do our best to be mindful of their feedback when conducting our operations. Moreover, a continuous process is in place which allows participating CAP physicians to submit feedback about the CAP. Providers are asked to contact the CAP vendor or designated carrier to discuss any issues that may arise during their participation in the CAP.

A 60 day Federal Register notice regarding this collection was published on December 2, 2005 (70 FR 72303). A 180 day Federal Register notice was published on July 22, 2005 (70 FR 42327). No public comments were received about either of these.

9. **Payments/Gifts to Respondents**

There were no payments/gifts to respondents.

10. **Confidentiality**

The CAP Physician Election Agreement is used annually by physicians to elect to participate in the CAP or to make changes to their previous year's selections. Communication from CAP physicians is subject to applicable Health Insurance Portability and Accountability Act (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**

There are no sensitive questions included in the Physician Election Agreement.

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

As stipulated in §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.

In the previous PRA package for this collection instrument, we estimated that 10,000 physicians would complete the application and that each application would take 2 hours to complete, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. This resulted in a total burden estimate of 20,000 hours. We also assumed that administrative personnel would be responsible for completing the election form and that that salaries of such individuals would be $20 per hour, resulting in an average annual public cost estimate of $400,000 per year.

The CAP became operational on July 1, 2006, and our current estimates are based on experience gained with the program since then:

# of physicians who will complete the form annually = **3800**
# of hours required to complete the form = 2
Total number of hours annually = (# of physicians) x (# of hours) = **7600 hours**
Salaries of administrative personnel: $20
Average annual public cost estimate = (personnel salary) x (# of annual hours) = **$152,000**

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**

The burden associated with this instrument collection is the time and effort necessary to complete the Physician Election Agreement. The estimated annual number of hours needed to complete this application is 7600 hours for 3800 physicians, as compared to our previous estimates of 20,000 hours for 10,000 physicians. This program adjustment change was based on experience garnered through CAP operations.

Other changes have been made to the collection instrument, but we do not believe that they have affected the associated burden. The following description is arranged by each section of the Physician Election Agreement:

Section I: Meaning of Election

- Some editorial changes were made to update the form for the timeframe in which it will be used. Specifically, we plan to utilize this form for physicians who elect to participate in the CAP for 2009. Programmatic requirements pertaining to physician election were established by sections 303(d)(1)(A)(ii) and 303(d)(1)(A)(iii) of the Medicare Modernization Act (MMA) of 2003. These technical changes present no additional burden to respondents since an election agreement must be completed during any election period. Additionally, they facilitate the ease at which a respondent can complete this application since an outdated form may cause confusion for a respondent.
- Some editorial changes were made in this section in which text was bolded and underlined. These technical revisions were made for clarification purposes to ease application completion and do not represent any change in respondent burden.
- A change was made regarding the timeframe in which physicians must obtain all CAP drugs and biological from an approved CAP vendor. In general, physicians are required to do so for one year, which represents the duration in which their CAP physician election agreement is effective. However, the CAP has previously held additional election periods due to "exigent circumstances" (72 FR 73841; 72 FR 8176) stemming from changes in program operations. For physicians who choose to

participate in the CAP during these periods, the duration in which physicians must receive CAP drugs and biologicals from an approved CAP vendor is less than 1 year as specified by CMS. The substantive change made to the CAP physician election agreement accounts for this. It does not represent an additional burden to physicians since the election agreement form must be completed during any physician election period. Additionally, this change facilitates the completion of this application since the lack of such language may cause confusion about a respondent's participation timeframe in the program.

Section II: Term and Termination of Agreement

- The form has been updated to reflect the timeframe in which it will be used. Specifically, we plan to utilize this form for physicians who elect to participate in the CAP for 2009. Editorial revisions were also made to clarify the language in this section. Specifically, citation 42 CFR 414.914(h) was updated to 42 CFR 414.914(i) to reflect an editorial modification from the last rulemaking period. Additionally, a grammatical revision was made as well. These technical changes present no additional burden to respondents, and the clarification will help a respondent more easily complete the collection instrument.
- The citation 42 CFR 414.908(a)(2) was added to supplement existing language for this regulation. Additionally, the phrase "…or opt out of the CAP for the remainder of the annual election period" was included to reflect existing language at this citation. These technical changes were made to clarify existing text in this section and present no additional burden to respondents.

Section III: Prescription order, Claim Submission, and Collection of Payments

- All references to local carriers were updated to also mention Medicare Administrative Contractors (MACs). As stipulated by section 911 of the MMA 2003, the contracting authority for Medicare Part A and Part B fee for service programs must transition to a MAC authority, so the language in this section of the election agreement was updated to reflect this ongoing process. This revision facilitates the completion of this application since the lack of such language may cause confusion about what sort of entity processes a respondent's Medicare claims. This technical change does not represent an additional burden for collection instrument respondents.
- We have updated the language in this section to reflect regulatory changes made during the 2007 rulemaking period.
  - Physicians now have 30 days to submit their CAP drug administration claims instead of 14 days as stated in the November 27, 2007 edition of the Federal Register (72 FR 66274). This is a substantive change, and the burden associated with claims submission is addressed in a separate PRA package (CMS 10145; OMB 0938-0945).
  - In order to correct an oversight from the previous submission of this PRA packet, we included language specifying that physicians must use the CAP modifier and the CAP prescription order number when submitting claims for drug administration. These practices have been in place since the CAP was implemented on July 1, 2006. As stated in the Federal Register, the CAP

prescription order number was originally used to verify CAP drug administration via a claims matching process (70 FR 39043). It is still currently used to facilitate CAP claims processing and for the post-pay review process implemented by TRHCA 2006 (72 FR 66269). The CAP modifier is used by local carriers in their claims processing to identify that a given claim is being submitted for the CAP as indicated in CMS transmittal #699 (change request 4064) as released on October 7, 2005. These are technical changes since such procedures are already practiced in the CAP, and the burden associated with claims submission is addressed in a separate PRA package (CMS 10145; OMB 0938-0945).

Section IV: Agreement to File Claims and Pursue Appeals

- On April 1, 2007, CMS implemented changes to the CAP as required by the Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006 (MIEA-TRHCA). As discussed in the Federal Register on November 27, 2007, the MIEA-TRHCA changed the CAP claims processing methodology and implemented a post-payment review process (72 FR 66260). Physicians may be asked to submit medical records or other documentation to support the post payment review process and to facilitate claims payment, and we have added language to indicate as such. We have also removed language pertaining to the old claims processing procedure that is now obsolete due to the MIEA-TRHCA. While these represent substantive changes, the burden associated with the submission of claims processing-related information is addressed in a separate PRA package (CMS 10145; OMB 0938-0945).
- All references to local carriers were updated to also mention Medicare Administrative Contractors (MACs). As stipulated by section 911 of the MMA 2003, the contracting authority for Medicare Part A and Part B fee for service programs must transition to a MAC authority, so the language in this section of the election agreement was updated to reflect this ongoing process. This revision facilitates the completion of this application since the lack of such language may cause confusion about what sort of entity processes a respondent's Medicare claims. This technical change does not represent an additional burden for collection instrument respondents.
- Several editorial changes were made in this section. First, the title was augmented to better reflect the information contained within the section. Second, language pertaining to citation 42 CFR 405.801 was corrected for clarification purposes. These changes were technical in nature and do not represent any change in burden for collection instrument respondents.

Section VI: Drug Ordering, Replacement, and "Furnish As Written" Drugs

- Several editorial changes were made for clarification purposes. Specifically, one phrase regarding the CAP J2 modifier was reworded and several numbered points were reformatted. These technical changes do not represent any change in burden for collection instrument respondents.
- The specific "furnish as written" modifier, J3, was added into the collection instrument language for clarification purposes. This modifier has been in use since the CAP was implemented on July 1, 2006 and allows physicians to specify particular formulations of medications due to medical necessity (70 FR 39043). This substantive change

presents no additional burden to respondents since the inclusion of the J3 modifier for "furnish as written" CAP claims is currently a requirement of program participation.

- All references to local carriers were updated to also mention Medicare Administrative Contractors (MACs). As stipulated by section 911 of the MMA 2003, the contracting authority for Medicare Part A and Part B fee for service programs must transition to a MAC authority, so the language in this section of the election agreement was updated to reflect this ongoing process. This revision facilitates the completion of this application since the lack of such language may cause confusion about what sort of entity processes a respondent's Medicare claims. This technical change does not represent an additional burden for collection instrument respondents.

Section VIII: Other Conditions of the CAP

- Several editorial changes were made. First, the phrase "ASP+6" was replaced with "ASP (buy and bill)." While both these phrases represent the same policy, the latter is the less colloquial version of this phrase. Second, the header "business name" was capitalized for grammatical purposes. Third, the word "representative" was replaced with "official" for clarification purposes. These technical changes do not represent any additional burden for collection instrument respondents.
- A reference to the post payment review process was added. This substantive change was made to reflect changes to the CAP brought about by the MIEA-TRHCA 2006 (for additional information on this legislation, see Section IV, bullet 1 of this document). The burden associated with the submission of claims-related information is addressed in a separate PRA package (CMS 10145; OMB 0938-0945).
- The definition for "authorized representative" was replaced with "authorized official." The latter definition is used in general Medicare enrollment as found in the CMS 855B form. We are utilizing this definition in order to better align the election procedures for the CAP with Medicare at large. This is a substantive revision that does not change the burden for respondents.

Information Collection

- We are now requiring that respondents submit an email address in order to receive email updates about the CAP. As discussed in the July 6, 2005 edition of the Federal Register, the Medicare contractor for the CAP, known as the CAP designated carrier, is tasked with undertaking outreach and education initiatives in order to ensure that those who provide services to beneficiaries receive the information they need to understand the CAP so that it is administered appropriately and billed correctly (70 FR 39084). An email address for each practice represented in the CAP would facilitate this goal. This substantive change presents no additional burden to a respondent and the information can be easily collected within the two hours estimated for completion of this information collection.
- Several editorial changes were made to the section that respondents must complete. First, some text was bolded and underlined for clarification purposes. Second, box 1 and box 17 were revised to read "Organization or Physician's Legal Business Name as reported to the IRS" for clarification purposes since both individual and groups of physicians may elect into the CAP. Third, the requirement for physicians to provide a

mailing address was eliminated since such information is no longer needed. Fourth, the text in boxes 19 and 20 were slightly reworded for clarification purposes. All these technical revisions represent no change in policy and do not change the burden for respondents.

- All references to local carriers were updated to also mention Medicare Administrative Contractors (MACs). As stipulated by section 911 of the MMA 2003, the contracting authority for Medicare Part A and Part B fee for service programs must transition to a MAC authority, so the language in this section of the election agreement was updated to reflect this ongoing process. This revision facilitates the completion of this application since the lack of such language may cause confusion about what sort of entity processes a respondent's Medicare claims. This technical change does not represent an additional burden for collection instrument respondents.
- A section requesting contact information from the respondent has now been created in the event of any follow up inquiries about the election form. While a telephone number was already required in the previous version of this form, we are now requesting the name for a specific person at this contact number. A local carrier/MAC and the CAP designated carrier process the information on this collection instrument, and this revision will help facilitate this procedure if additional information is needed. In general, this will also assist the program's election process, which is statutorily mandated by sections 303(d)(1)(A)(ii) and 303(d)(1)(A)(iii) of the Medicare Modernization Act (MMA) of 2003. This technical revision poses no change in respondent burden since such information is easily collectible within the 2 hour timeframe estimated for completion of this form. Additionally, this may also result in less disruption at a given applicant's office since it will prevent a local carrier or the CAP designated carrier from contacting an office multiples times in order to pinpoint the appropriate contact person.
- A telephone number for each physician referenced in a given application is now being requested. While one telephone number per application was already requested in previous versions of this form, we are now requesting it on a per physician basis since all providers may not be easily contacted at a single number. This technical revision poses no change in respondent burden since such information is easily collectible within the 2 hour timeframe estimated for completion of this form. Additionally, this may also result in less disruption at a given applicant's office since it will prevent a local carrier or the CAP designated carrier from contacting an office multiples times in order to pinpoint the appropriate contact information for a given physician.
- The 1996 Health Insurance Portability and Accountability Act (HIPAA) required that each physician, supplier, and other health care provider conducting HIPAA standard electronic transactions, be issued a unique national provider identifier (NPI). For Medicare purposes this means that submission of an NPI for a provider is mandatory effective May 23, 2008, and Medicare will not pay for referred/ordered services or items unless the name and NPI number of a provider is on a Medicare claim. Previously, Medicare allowed for the use of a Unique Provider Identification Number (UPIN) or NPI. Since the NPI will soon become a mandatory requirement, all sections in this application that requested the Unique Provider Identification Number (UPIN) for each physician listed in the application have been revised. Instead, these sections

now request a given physician's Provider Transaction Access Number (PTAN) since the use of an NPI requires a PTAN. NPI and PTAN information are required for the processing of CAP claims. This substantive revision poses no change in respondent burden since such information is required for Medicare participation and should be easily available to respondents. Additionally, the use of the NPI in claims processing represents a customary Medicare business practice.

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.