Crosswalk Document for CMS 10167; OMB0938-0987: Competitive Acquisition Program (CAP) for Medicare Part B Drugs: CAP 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 Additionally, they facilitate the ease at which a respondent can complete this application since an outdated form may cause confusion for a respondent.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 technical 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 official" was slightly edited to remove outdated information. This is a technical 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). The submission of an NPI for a provider on Medicare claims is mandatory effective May 23, 2008. 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 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 technical 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.