

CAP Bidding Reminders

Q: Where can the latest version of the Competitive Acquisition Program for Medicare Part B Drugs (CAP) Approved CAP Vendor Application and Bid Form be found?

A: The latest version of the approved vendor application form, the list of CAP drugs with weights, the list of CAP drugs, and additional instructions on applying to be an approved CAP vendor are available at the CAP website:

http://www.cms.hhs.gov/CompetitiveAcquisforBios/03_infovendors.asp. We remind applicants that bids should not be submitted using previous versions of the application or the bid forms.

Q: Does a vendor applicant still have to submit an 855B form if they are already a Medicare supplier?

A: CAP vendors are a new Medicare supplier type. Therefore, CAP vendor applicants are required to submit a completed 855B form indicating that they are applying to be a CAP vendor. On Page 7 of the 855B, you will be asked to identify the type of supplier being applied for. Check the box for “Competitive Acquisition Program (CAP) Part B Drug Vendor”. Please note that a valid National Provider Identifier (NPI) is required for enrollment as a Medicare supplier.

Vendor Requirements

Q: Will a CAP vendor be required to maintain a physical presence (i.e. a location) in all States or Territories covered by the CAP?

A: A physical location in all States or Territories is not required unless mandated by State or Territorial Laws. A relationship with a subcontractor as described in 70 FR 70245 may be an acceptable method to establish a physical presence in a location that requires it.

General Vendor Application Information

Q: Will bids that incompletely meet the application criteria be automatically rejected?

A: We invite all interested parties to submit applications. We do not plan to make exceptions or allowances for potential vendors that do not meet financial or quality criteria. However, we also appreciate that some standards may be subject to interpretation, particularly to bidding entities that are composed of several organizations. We recommend that any bidders fully and completely explain how application standards have been met in the appropriate narrative sections of the application.

Orphan Drugs

Q. Can a vendor add an orphan drug at any time or must it include the orphan in the bid?

A. Under Section 414.906(f) (2) (iii) vendors are allowed to petition CMS to add certain single indication orphan drugs to their CAP drug lists. The process for making this request is outlined in Section 414.906(f)(3). Such requests do not need to be included with the vendor's initial bid.

Q. How will payment be made for single indication orphan drugs that the approved CAP vendor requests to voluntarily add to their CAP drug list if they do not have a weight?

A. In the November 21 Final Rule with comment (70 FR 70242) we stated that payment for these drugs would be made at ASP + 6 percent. The ASP + 6 percent price that the approved CAP vendor will receive for the drug will be the price in effect for the quarter that the addition to the vendor's list takes effect. For example if the approved CAP vendor receives permission from CMS to add a single indication orphan drug to his or her CAP drug list beginning January 1, 2006, the price for the drug will be the ASP price on the January 1, 2006 ASP + 6 pricing file. Future updates to the ASP + 6 prices for the drug will be based on the process described in the July 6, 2005 interim Final Rule with comment (70 FR 39075). Updates to the payment amount will be based on the mechanism for annual updates of single price amounts based on the approved CAP vendor's reasonable net acquisition costs.

CAP Drugs and Drug ordering

Q. Does the ordering physician have ownership of the CAP drug once it has been delivered to the physician's office?

A. The CAP vendor maintains ownership of the drug until it is administered to the Medicare beneficiary. The drug may not be administered to anyone other than the beneficiary without, at a minimum, the permission of the vendor. As previously stated in the IFC, physicians are required to keep track of each CAP drug obtained for each beneficiary. However, this is not a requirement for physicians to physically maintain separate inventories. The physician merely has to track the drugs separately, either on paper or electronically.

Q: Will CMS implement a minimum order size (by dollar amount)?

A: The CAP is not designed to require minimum order quantities. However, we anticipate that most physicians who elect to participate in the CAP will place CAP orders for several beneficiaries and/or several courses of treatment at one time in order to lessen the burden of ordering and receiving CAP drugs. Furthermore, the variety of drugs available through the CAP makes it more likely that a participating CAP physician can order most of a beneficiary's drug therapy through the CAP, rather than just a few select items. Therefore, we believe that the design of the program makes a minimum order size unnecessary. The ordering and shipping process is intended to be flexible. Specifically, we note that a CAP vendor may combine shipments for more than one beneficiary at a time and may also split large shipments, provided that delivery complies with timeframes described in Sections 414.902 and 414.914 (f) of the CAP regulations.

Q: Will physicians be allowed to use the CAP to develop an inventory of drugs?

A: No, physician offices will not be allowed to build an inventory of CAP drugs. As discussed on page 39047 of the July 6, 2005 Interim Final Rule with Comment, the CAP utilizes a beneficiary specific ordering process and an emergency replacement procedure, and it does not contemplate the development of a stock of inventory in the physician's office. We believe that because of potential program integrity and drug diversion concerns, the emergency replacement provision is the more appropriate way of providing needed drugs to beneficiaries when the beneficiary's clinical condition does not allow time to obtain the drug from the approved CAP vendor. In the CAP final rule (70 FR 70248), we stated that in the event a participating CAP physician administers a smaller amount of the CAP drug than was originally intended, or does not administer the drug in the time frame specified on the prescription order, that the physician must contact the approved CAP vendor to discuss what to do. We stated that if it was permissible under State law, the drug was unopened, and the participating CAP physician and the approved CAP vendor agreed, the physician could retain the drug for administration to another beneficiary. However, a new prescription order and a new beneficiary specific prescription order number would need to be created before the drug could be administered. In addition, in the IFC (70 IFC 39041), we specified that participating CAP physicians may place an order for a beneficiary's entire course of treatment at one time, and with the physician's agreement, the vendor may ship the course of treatment at one time, or may choose to split shipments into smaller parts as long as the shipments arrived at least two business days prior to the administration date specified in the prescription order, consistent with routine delivery guidelines.

Unused Drugs

Q: Does the policy on the unused portion of a CAP drug apply to multidose vials?

A: No, as stated on page 70248 of the November 21, 2005 CAP final rule, the CMS policy regarding payment for unused drugs applies only to single dose vials.

Q: Does the policy on the unused portion of a CAP drug described in the final rule apply to all single dose vials regardless of size?

A: The criteria for payment of the unused portion of a CAP drug is explained on page 70248 of the November 21, 2005 CAP final rule. The policy is not dependent on the size of the vial being ordered. This policy also applies to single use ampules. We consider the unused portion of a drug remaining in an opened single-use vial to be administered for the limited purpose of section 1847B(a)(3)(A)(iii)(II) of the Act, but only if the participating CAP physician has made good faith efforts to minimize the unused portion of the CAP drug in how he or she scheduled patients and how he or she ordered, accepted, stored, and used the drug, and only if the approved CAP vendor has made good faith efforts to minimize the unused portion of the drug in how it supplied the drug.

Q: Will CMS allow the CAP vendor to file a claim for an unused portion of drug?

A: We expect that approved CAP vendors will furnish drugs and interact with physicians in a manner that will minimize unused drug. Specifically, physicians and approved CAP vendors will both make a good faith effort to order, label, ship, and store drugs in a manner that will allow the legal reuse of an unopened and intact container of a drug. Generally speaking, under the Average Sales Price system, a physician is able to bill the program for unused drugs if the physician acted in good faith with respect to the ordering and use of the drugs. We expect that vendors will be able to bill the program for unused drugs under the CAP program in a similar fashion if physicians and vendors act in good faith with respect to the ordering and use of the drugs.

Q: How are unused drugs associated with an NDC that contains several vials to be managed?

A: In the July 6 2005 Interim Final Rule with comment (70 IFC 39061), we stated that “packages containing multiple individual units of drug (like vial trays) may be split into quantities that are appropriate for a beneficiary’s dose.” The remaining vials would be retained by the vendor. Consistent with Medicare billing rules, only the quantity actually administered to the Medicare beneficiary may be billed to Medicare by the vendor. The vendor claim would specify the HCPCS code for the drug and the number of units of the drug that were administered to the beneficiary.

Beneficiary Issues

Q: Will agreements between physicians and CAP vendors for the collection of beneficiary coinsurance be exempt from certain Medicare laws concerning inducements?

A: No. We have made no provision for exemption from any current laws. As stated in the Final Rule, arrangements between participating CAP physicians and approved CAP vendors must not violate the physician self-referral (“Stark”) prohibition, the Federal antikickback statute, or any other Federal or State law or regulation governing billing or claims submission. We also stated in the Final Rule (70 FR 70251-2) that we would not dictate or specify the breadth or the specific obligations contained in these arrangements, other than to note that they must comply with applicable law and that the approved CAP vendor may not coerce participating CAP physicians into entering any such arrangement.

Q: Will it be necessary for a CAP vendor to obtain an Assignment of Benefits (AOB) form from beneficiaries prior to billing Medicare for drugs and biologicals shipped to CAP physician offices pursuant to a valid CAP physician order?

A: Mandatory assignment applies to Part B drugs and biologicals, see Section 1842(o)(3) of the Social Security Act; therefore, a physician or supplier does not have to obtain a signed assignment of benefits form from the beneficiary in connection with Part B drug claims. In addition, while normally the supplier would need to obtain the beneficiary’s signature to file a claim, the approved CAP vendor may sign the claim form

on behalf of the beneficiary pursuant to 42 CFR 424.36(c), because the CAP drug claim will involve no personal contact between the approved CAP vendor and the beneficiary.

Q. How will the Coordination of Benefits be administered between the local Medicare carrier, the CAP vendor's designated carrier, and the various Medigap insurers?

A. CAP will be the most successful when the physician, the beneficiary, the CAP vendor and the Medicare contractors work closely together on billing and other administrative concerns. We support this process through Medicare's existing Coordination of Benefits processes. In the Interim Final Rule (page 39052 of the Federal Register), we describe how this process provides for the automatic crossover of many Medicare beneficiaries' claims to their supplemental insurance provider after Medicare has paid its portion of the claim. For beneficiaries with supplemental insurance, their coinsurance obligation is usually met through this automatic coordination of benefit process, so that the beneficiary is not required to pay the coinsurance at the time of service. In addition, the CAP vendor would not have the burden of billing the supplemental insurance since this would happen automatically.

The recently consolidated claims crossover process introduces standardization and efficiencies for the automatic crossover of claims to all participating supplemental insurers, including Medigap plans, employer retiree supplemental plans, TRICARE, and State Medicaid Agencies, for their use in calculating their financial liability after Medicare. Under this consolidated crossover process, supplemental insurers execute a national Coordination of Benefits Agreement with a single CMS contractor, the national Coordination of Benefits Contractor (COBC), for purposes of receiving Medicare crossover claims. We expect that most supplemental insurers will participate in the national consolidated crossover process because of the consistencies and efficiencies that result from a standard national process. Participation by supplemental insurers will, in turn, result in standardization and efficiencies for suppliers, including CAP vendors, who seek reimbursement from these insurers.

Operational Issues:

Q: Can physicians participate in both the CAP and ASP systems?

A: A physician can not participate in both the CAP and ASP systems for the same drugs in the same practice. However, all participating CAP physicians may continue to bill under the ASP methodology for drugs not included in the CAP, or in cases where a beneficiary requires a particular formulation of a drug that the approved CAP vendor does not supply, using the "furnish as written" process. In addition, as discussed on page 70257 of the November 21, 2005 final rule, if a group practice has elected to participate in the CAP, and a physician is a member of the group, he or she has reassigned his or her benefits to the group, and is billing using the group's PIN, then the physician can not "buy and bill" separately from the group outside of the CAP. However, if a physician is a member of a group practice but does not reassign his benefits to the group and bills using

his or her individual PIN, rather than the group's PIN, the physician can make a determination about whether to participate in the CAP separate from that of the group.

Claims Processing

Q: If the CAP physician submits a drug claim to the local carrier later than the 30 day claim filing period after drug administration, will that claim be rejected or delayed by the carrier? In this situation, what will be the impact on payment of the drug vendor's claim? If the CAP vendor submitted its drug claim to the designated carrier in a timely manner relative to the date of intended drug administration, but the CAP physician submitted a drug claim to the local carrier that was not 'clean' (wrong prescription number, or other error), how much additional time will CMS allow the CAP physician to resubmit a 'clean' claim?

A: Medicare regulations at 42 CFR 424.44 define the timely filing period for all Medicare fee-for-service claims. In general, claims must be filed on, or before, December 31 of the calendar year following the year in which the services were furnished. For example, a Medicare supplier or provider who treats a Medicare beneficiary in March 2005 would need to submit its claim to the Medicare program by December 31, 2006. However, if a supplier does not submit the claim within one year of the date of service, the Medicare payment is reduced by 10%. For physicians who elect to participate in the CAP, we have instituted a requirement that they file their Medicare claims within 30 days of drug administration. If a participating CAP physician routinely fails to abide by this requirement and the vendor is unable to resolve the situation on its own, the vendor may ask for the assistance of the designated carrier's dispute resolution staff. The designated carrier would investigate the complaint and could decide to recommend that CMS terminate the physician's participation in the CAP.

The initial Medicare payment to the approved CAP vendor is not dependent upon the participating CAP physician's filing of the drug administration, and the physician's claim being approved for payment by the CMS claims processing system. Originally, payment for the CAP vendor was contingent on a physician filing their claims. However, the Tax Relief and Healthcare Act (TRHCA) of 2006 changed the payment structure of CAP so that a CAP vendor's drug claim can be paid independent of a physician's administration claim.

After payment, a CAP vendor's drug claim is also subject to a post pay review process. TRHCA required the implementation of this process 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. Drug verification and medical necessity are also determined on a post pay basis. The procedures used to verify valid claims and ensure proper payment for drugs supplied under the CAP are based on established post-payment review processes used in other parts of the Medicare program.

If a claim is returned to the participating CAP physician because it is not processable (not clean), then the timing requirements for submitting a claim revert to the Medicare regulations at 42 CFR 424.44 (cited above) that define the timely filing period for all Medicare fee-for-service claims. If a supplier does not submit a claim within one year of the date of service, payment by the Medicare program is reduced by ten percent.

Financial Responses to the CAP Vendor Application

Q: Company X, which is seeking an approved CAP contract, is owned by a parent company Y. Which company's financial reports should be submitted in response to financial data requests on page 5 and the response to the previous year's financial statement required in Attachment 8?

A: Financial information, including audited financial statements, submitted in response to this solicitation must come from the organization whose full legal name is identified on page 4 of the Vendor Application and Bid Form. It is acceptable to supplement this information with information from a parent company or a subsidiary. However, any supplementary information must be submitted separately (not combined with the applicant's data) and must indicate the full legal name of the company that it represents.

Q: If there is no financial data available to answer a specific question from page 5 of the Vendor Application and bid form, is it acceptable to leave the space blank when replying?

A: Omitting information increases the risk of having a bid rejected due to it being incomplete. As stated on page 2 of the Vendor Application and Bid Form, applicants "must submit all information required by this form and its attachments." Replies such as "no information available" or a value of "zero" are acceptable; if necessary, attach an explanation for the answer.

Q: On the Balance Sheet/Profit and Loss Statement on page 5, is it acceptable to combine cash and inventory for the reply to Part A Block 3b Accounts Receivable

A: All assets must be reported separately. Cash and inventory should be broken out separately. If additional space is required, please use the space in Part C Block 2 Other Pertinent Data, or attach an additional page.