# FAQ Results

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**Question #7761:** Who should I contact to verify receipt of the Average Sales Price (ASP) file CD-ROM or the floppy that I sent?

**Answers:** Contact Glenn McGuirk in the Division of Ambulatory Services at 410-786-5723, or send him an email at glenn.mcguirk@cms.hhhs.gov

**Question #8962:** Will CMS allow the CAP vendor to file a claim for an unused portion of drug?

**Answers:** 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.

**Question #3322:** Should manufacturers separately report information on those sales made at a nominal price each quarter?

**Answers:** Information on sales made at a nominal price is an integral part of the manufacturer's ASP calculation. While manufacturers may choose to separately report information on those sales, we are not currently requiring this information to be separately reported from the ASP. As we gain more experience with the ASP system, we may require this information to be separately reported in the future.

**Question #8961:** 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?

**Answers:** [illegible]

**Answers:** 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.

**Question #8960:** Does the policy on the unused portion of a CAP drug apply to multidose vials?

**Answers:** 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.

**Question #8958:** Will CMS implement a minimum order size (by dollar amount)?

**Answers:** The Competitive Acquisition Program for Medicare Part B Drugs (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.

**Question #8969:** 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?

**Answers:** 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.

**Question #8971:** 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?

**Answers:** 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.

**Question** Will physicians be allowed to use the CAP to develop an inventory of drugs?

**#8959:**

**Answers:** 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.

**Question #8953:** Will a CAP vendor be required to maintain a physical presence (i.e. a location) in all States or Territories covered by the CAP?

**Answers:** 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.

**Question #9894:** When are the Medicare Part B payment allowances updated for seasonal influenza vaccines?

**Answers:** Medicare Part B payment allowances for the seasonal influenza vaccines are updated on September 1 annually.

**Question #8956:** 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?

**Answers:** 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.

**Question #8957:** Does the ordering physician have ownership of the CAP drug once it has been delivered to the physician's office?

**Answers:** 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.

**Question #8954:** Will bids that incompletely meet the application criteria be automatically rejected?

**Answers:** 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.

**Question #8970:** 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?

**Answers:** 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.

**Question #8955:** Can a vendor add an orphan drug at any time or must it include the orphan in the bid?

**Answers:** 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.