FAQ Results

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Question #8663: Are service fees included in the Average Sale Price (ASP) calculation?

Answers: Bona fide service fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug, are not included in the calculation of ASP. We interpret "bona fide service fees" means expenses that generally would have been paid for by the manufacturer at the same rate had these services been performed by other or similarly situated entities. Manufacturers must use the definition of bona fide service fees specified in 42 CFR 414.802 in calculating the ASP for reporting periods beginning January 1, 2007 and thereafter. In the 2006 final ASP reporting rule (see Federal Register, V.71, No.213, P.69666 - 69670, December 1, 2006), we discuss our interpretation of the definition of bona fide service fees and how manufacturers may apply the definition in calculating ASPs.

Question #3315: Can manufacturers exclude from ASP data submission all drug prices charged to disproportionate share hospitals?

Answers: All sales to disproportionate share hospitals that participate in the 340B program should be excluded from the ASP calculation.

Question #8662: What guidance has CMS provided on how fees paid to Group Purchasing Organizations (GPOs) or Pharmacy Benefit Managers (PBMs) are treated in the calculation of Average Sale Price (ASP)?

Answers: In our discussion of “Fees Not Considered Price Concessions” in the 2006 final ASP reporting rule (see Federal Register, V.71, No.213, P.69666-69670, December 1, 2006), we stated that to the extent fees paid to GPOs or PBMs meet the definition of bona fide service fees in 42 CFR 414.802 they are excluded from the calculation of the ASP. This discussion also addressed how the definition of bona fide service fees is to be applied. We did not define they types of entities to which a bona fide service fee may be paid. At this time, we have not provided further

specific guidance with respect to treatment of fees paid by manufacturers to GPOs or PBMs. In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculation of ASP, consistent with the general requirements and the intent of the Social Security Act, Federal regulations, and its customary business practices. These assumptions should be submitted along with the ASP data.

Question #8664: Are administrative fees included in the Average Sale Price (ASP) calculation?

Answers: Administrative fees should be included in the calculation of ASP, unless they meet the definition of bona fide service fees. Administrative fees that satisfy the definition of bona fide service fees are not included in the calculation of ASP. (See FAQ #8663)

Question #7765: I have concerns regarding the average sales price (ASP) payment limit for a certain Medicare Part B drug and would like to talk to CMS about this, who should I contact?

Answers: Send an e-mail to Sec303aspdata@cms.hhs.gov indicating your specific concerns.

Question #8952: Does a vendor applicant still have to submit an 855B form if they are already a Medicare supplier?

Answers: 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.

Question #3309: Are repackagers required to submit ASP data?

Answers: Yes.

Question #8963: How are unused drugs associated with an NDC that contains several vials to be managed?

Answers: 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.

Question #3311: Do sales in the U.S. include sales in the commonwealth territories, trust territories, and protectorates?

Answers: US sales do not include sales in the commonwealth territories, trust territories, and protectorates.

Question #3326: Can manufacturers submit ASP information to CMS via e-mail?

Answers: We are exploring options for secure electronic transmission of the ASP information to CMS. At the present time, the data should not be e-mailed.

Question #8965: 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?

Answers: 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.

Question #8968: 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?

Answers: 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.

Question #8951: 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?

Answers: 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.

Question #3317: Should the manufacturer's ASP calculation be rounded to a specific decimal place?

Answers: Yes. Carry to the 3rd decimal place and round the calculation to 2 decimal places.

Question #7759: For each Average Sales Price (ASP) data submission, who should sign the certification forms?

Answers: Each quarterly Average Sales Price (ASP) data submission must be certified by one of the following: 1) manufacturer's Chief Executive Officer (CEO), 2) manufacturer's Chief Financial Officer (CFO), or 3) an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO Manufacturers are reminded that the name and the title of the CEO, CFO or Authorizing Official must be clearly legible on the form.

Question #8967: Can physicians participate in both the CAP and ASP systems?

Answers: 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.

Question #7762: Does CMS grant extensions to the average sales price (ASP) deadline?

Answers: No. The law specifies that the average sales price (ASP) data are due to CMS 30 days after the quarter ends. If a deadline falls on a non-Federal work day, the ASP data are due to CMS the next business day. For example, if a deadline falls on a Saturday, the ASP data are due to CMS the following Monday.

Question #3320: Should the ASP calculations include sales of hemophilic drugs to home health care providers?

Answers: Sales of hemophilic drugs to home health care providers should be included in the calculation of ASP.

Question #8964: Will agreements between physicians and CAP vendors for the collection of beneficiary coinsurance be exempt from certain Medicare laws concerning inducements?

Answers: 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.

Question #3325: Will CMS accept paper submission of ASP data?

Answers: The ASP data should be submitted electronically.