CMS-1325-IFC-2 **Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals**

Submitter : Mr. James Greenwood **Date & Time:** 01/20/2006

Organization : Biotechnology Industry Organization

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attached

Provisions

Provisions

see attached

CMS-1325-IFC-23-Attach-1.PDF

CMS-1325-IFC-23-Attach-1.PDF

January 20, 2006

BY ELECTRONIC DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1325-IFC3 (Medicare Program; Exclusion of Vendor Purchases Made Under the Competitive Acquisition Program (CAP) for Outpatient Drugs and Biologicals Under Part B for the Purpose of Calculating the Average Sales Price (ASP)

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) interim final rule with comment period regarding exclusion of vendor purchases made under the Competitive Acquisition Program (CAP) for outpatient drugs and biologicals under Part B for the purpose of calculation the

average sales price (ASP) (the "Interim Final Rule").[1] BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

Representing an industry that is devoted to discovering new treatments and ensuring patient access to them, BIO is concerned greatly about the impact of Medicare's reimbursement on access to drugs and biologicals. If Medicare's payment rates do not compensate providers appropriately for their acquisition costs, Medicare beneficiaries may be denied access to essential drugs and biologicals. Over time, if physicians and hospitals are not able to provide these innovative therapies to their patients, manufacturers could be discouraged from developing new therapies.

Because Medicare's reimbursement for most separately paid drugs and biologicals is based on ASP, it is important that CMS collect from manufacturers the information the agency needs to calculate accurate rates. BIO consistently has urged CMS to provide clear guidance that will help manufacturers submit accurate data. We have been pleased by CMS' efforts to work with manufacturers to resolve questions about ASP reporting obligations.

In the Interim Final Rule, CMS responds to suggestions to exclude prices offered to CAP vendors from ASP calculations. For the initial three-year contract period under the CAP, units of CAP drugs that are administered to beneficiaries by participating CAP physicians will be excluded from ASP calculations.[2] CMS states that this exclusion is necessary for implementing the CAP, and the agency intends to examine the effect of this exclusion at the end of the initial three-year period of the program.[3]

To ensure that this change to ASP calculations and reporting is implemented smoothly, BIO offers the following comments. First, CMS should revise the definition of "unit" to exclude from ASP calculations all units of

---

1 70 Fed. Reg. 70478 (November 21, 2005).
2 Id. We refer to the units of drugs sold to CAP vendors for use under the CAP as "CAP units."
3 Id. at 70479.

CAP drugs sold at a discount to CAP vendors for use in the CAP. Second, CMS should establish a method for manufacturers to estimate CAP units when data are not available. Third, even if CMS does not revise the definition of "unit," it should permit manufacturers to rely on their own data to identify CAP units. Fourth, if CMS does not revise the definition of "unit," it must ensure that manufacturers have ample time to review the data and complete their ASP calculations. Fifth, because CAP units will be excluded from ASP calculations during the length of the initial CAP contract period, we ask CMS to clarify whether the initial contract period will be shortened to two and a half years instead of three years due to the delayed start of the CAP. Finally, we reiterate our prior comments urging CMS to expedite the addition of newly approved drugs to the CAP and include single indication orphans in the CAP. We discuss these comments in more detail below.

I. CMS Should Revise the Definition of "Unit" to Include All Units of CAP Drugs Sold to CAP Vendors for Use Under the CAP

In the Interim Final Rule, CMS revises the definition of "unit" at 42 C.F.R. § 414.802 to exclude "units of CAP drugs (as defined in § 414.902) administered to a beneficiary by a participating CAP physician (as defined in § 414.902)." We are concerned that this definition could be read to require a manufacturer to trace and demonstrate administration of each unit to a beneficiary. This information would be extremely difficult for manufacturers to collect and verify. Furthermore, although CMS will require CAP vendors to provide manufacturers with "information necessary to determine which sales to the approved CAP vendor are sales of CAP drugs that are excluded from the ASP calculation,"[4] manufacturers would be required to certify reports based on these data and could be subject to substantial penalties for misrepresentation of ASP data.[5]

We believe that manufacturers should not be held responsible for data they did not collect and cannot verify. Defining "unit" as "unit of CAP drugs sold at a discount to CAP vendors for use under the CAP" would allow manufacturers to use their own data to calculate their ASPs. It also would simplify manufacturers' calculations by requiring them to exclude only the units sold to CAP vendors at discounts that could affect their ASPs. We urge

---

4 Id. at 70480.

5 Social Security Act § 1847A(d)(4)(A); 42 C.F.R. § 414.804(a)(5).

CMS to revise the definition of "unit" to ensure that manufacturers are required to certify only their own data, not data reported by other entities, and help to protect manufacturers from unfair penalties.

Additionally, CMS' definition may require prices for some CAP drugs to be included in ASP calculations, contrary to the agency's conclusion that "the best outcome for both the ASP methodology and the CAP programs would be one in which prices under CAP did not affect payment amounts under the ASP methodology,"[6] In particular, under the CAP, a drug could be shipped to a physician but not be administered to a beneficiary due to a change in the patient's condition. If the physician is unable to schedule another patient to receive the drug during its shelf life, the drug would not be administered under the CAP. Under CMS' revised definition, these units would be included in a manufacturer's ASP calculations, even though they were sold to the CAP vendor for use in the CAP. In order to ensure that the discounts CAP vendors receive for these units do not affect the ASP methodology, we recommend that CMS revise the definition of "unit" to exclude "units of CAP drugs (as defined in § 414.902) sold at a discount to CAP vendors for use under the CAP."

II. CMS Should Provide Guidance Regarding Estimation of CAP Units When Data Are Not Available

Manufacturers should be able to identify CAP units through either invoices for direct sales to vendors or chargebacks and rebates on indirect sales. In some cases, these data may be available only on a lagged basis, however. When CAP unit data are not available within the time frame necessary to include them in the ASP calculation, BIO requests that CMS provide guidance regarding a methodology for estimating those units. As we explained above, CAP units that are subject to rebates and chargebacks could be identified through those transactions. To the extent a manufacturer treats rebate and chargeback transactions as lagged data under 42 C.F.R. §414.804(a)(3), however, there currently is no sanctioned method for using such lagged data to identify units to be excluded from ASP calculations. We recommend that CMS provide guidance on how to identify excluded CAP units that are identifiable only on a lagged basis, either by directing manufacturers to apply the same methodology they currently use to estimate such units as to sales excluded from

---

[6] 70 Fed. Reg. at 70480.

the ASP calculation under section 414.804(a)(4) or by specifying a methodology.

Should CMS choose to specify an estimation methodology, we suggest that this methodology be analogous to that used for estimating lagged price concessions, as described at 42 C.F.R. § 414.804(a)(3). Under such a methodology, a manufacturer would calculate a percentage of total sales and units attributable to the CAP for an NDC by dividing the total number of CAP units of that NDC for the most recent 12-month period by the total number of units sold of that NDC for the same period. The manufacturer would multiply the resulting percentage by the total sales and units of the NDC for the reporting quarter to determine the estimated number of CAP sales and units. Should CMS choose to specify this or any other estimation methodology, BIO recognizes that CMS also may choose to direct the application of such a methodology not just to CAP units but to all sales that are ineligible for the ASP calculation and that are identifiable only through lagged data.

To implement this approach, we recommend that CMS renumber the current paragraphs (a)(5), and (6), as (a)(6) and (7) and insert the following new paragraph (a)(5):

> *(5) To the extent that data on units associated with sales referenced in paragraph (a)(4) of this section and excluded units, as described in section 414.802, are available on a lagged basis, the manufacturer must estimate this amount in accordance with the methodology described in paragraphs (a)(5)(i) through (a)(5)(iii) of this section.*
>
> *(i) For each such National Drug Code, the manufacturer calculates a percentage equal to the sum of the excluded units for the most recent 12-month period available divided by the total number of units of that National Drug Code sold in the same 12-month period.*
>
> *(ii) The manufacturer then multiplies the percentage described in paragraph (a)(5)(i) of this section by the total sales and units of the National Drug Code sold in the quarter. (The manufacturer must*

carry a sufficient number of decimal places in the calculation of the price concessions percentage in order to round accurately the total sales and units.) The result of this multiplication then is subtracted from the total sales (numerator) and units (denominator) for the quarter being submitted.

(iii) Example. The total number of excluded units identifiable through lagged data over the most recent 12-month period for National Drug Code 12345-6789-01 equals 20,000. The total number of units sold for the same period equals 60,000. The percentage of sales for this period attributable to excluded units identified through lagged data equals 20,000/60,000 = .33333. The total units sold during the reporting quarter equals 15,000 and the total sales dollar volume for the reporting quarter is $20,000. The manufacturer's estimated sales and units attributable to excluded sales identified through lagged data: for sales, $20,000 X .33333, or $6,666, and for units, 15,000 X .33333, or 4,999.95.

Should CMS choose to specify an estimation methodology, BIO also requests that CMS provide guidance regarding the application of that methodology during the CAP start-up period, when 12 months of data are not yet available. BIO recommends that CMS permit the use of three, six, and nine-month estimation periods as data for those respective periods become available.

III. Even If CMS Does Not Revise the Definition of "Unit," It Should Allow Manufacturers to Rely on Their Own Data to Identify CAP Units

Even if CMS decides not to revise the definition of "unit," BIO recommends that CMS allow manufacturers to use their own data, when available, either in lieu of or to supplement vendor reports. In some instances, these data may be more reliable than vendor reports, or easier to integrate into

the manufacturer's ASP calculation, and thus would allow manufacturers to calculate more accurate ASP figures. Manufacturers spend many internal resources, including the certification process to ensure accurate and complete ASP submissions. Therefore, we believe that in certain circumstances our data are the most accurate data. Lastly, manufacturer data also may be available sooner than vendor reports, giving manufacturers more time to prepare their quarterly ASP submissions.

IV. If CMS Does Not Revise the Definition of "Unit," It Must Ensure that Manufacturers Have Sufficient Time to Prepare Their ASP Submissions

The Interim Final Rule explains that CMS will require approved CAP vendors to provide manufacturers with "information necessary to determine which sales to the approved CAP vendor are sales of CAP drugs that are excluded from the ASP calculation."[7] Because the Medicare statute imposes significant penalties for the submission of incorrect data and provides no method for correcting errors, manufacturers use careful, time-consuming processes to perform and verify their ASP calculations. Manufacturers must isolate, quantify, and filter all sales transactions for the quarter, perform the ASP calculations, and allow appropriate personnel to review the data before they certify the results. If manufacturers are required to incorporate vendor data into their calculations, they will need even more time to prepare their submissions. Given the already tight timeline for ASP reporting, BIO asks CMS to ensure that manufacturers have sufficient time to review their data and perform their calculations.

V. CMS Should Clarify the Length of the Initial CAP Contract Period

CMS states that CAP units will be excluded from ASP calculations "for the initial 3-year contract period under the CAP."[8] Because the start of the CAP has been delayed until July 1, 2006, it appears that the initial contract period will be two and a half years instead of three years. We ask CMS to clarify the length of the initial contract period so we can understand how long CAP units will be excluded from ASP calculations.

---

7 Id.

8 Id. at 70479.

VI. CMS Should Require Vendors to Make Newly-Approved Drugs Available Under the CAP

As we explained in our comments on the final physician fee schedule rule for 2006, BIO is concerned that CMS' process for vendors to request permission to add new therapies to their lists will not ensure timely access to innovative drugs and biologicals.[9] Under CMS' system, access to a new drug will be delayed by several months after it is approved for marketing, until the manufacturer reports an ASP, the CAP vendor requests permission to add the drug to its list, and CMS reviews and approves the request. Additionally, because the process will not be implemented this year, any new therapy first marketed in 2006 or any existing drug for which an ASP had not been determined at the time the bidding began may not be available under the CAP until at least 2007. We urge CMS to reconsider this decision and require vendors to make available to CAP-participating physicians new drugs upon Food and Drug Administration approval. CMS should reimburse vendors at 106 percent of ASP or wholesale acquisition cost (WAC) plus 6 percent until ASP data are gathered and reported.

VII. CMS Should Include Single Indication Orphan Drugs in the CAP Category

BIO remains disappointed that CMS decided not to include single indication orphan drugs in the CAP's single drug category.[10] Although CMS acknowledged comments explaining that including single indication orphan drugs in the CAP would minimize the burden on physicians who administer them and would improve beneficiary access to these therapies, CMS disagreed with requests to require CAP vendors to provide these drugs and biologicals. Instead, CMS created a process to allow vendors to request approval from CMS to supply single indication orphan drugs. We are concerned that this process will do little to improve beneficiary access to these therapies. By making inclusion of single indication orphans optional, CMS returns the burden to the physician to urge the vendor to provide these drugs and gives beneficiaries and physicians no assurance that they will be provided. We strongly recommend

---

[9] Letter from James C. Greenwood, President & CEO, BIO, to Mark McClellan, Administrator, CMS, regarding the physician fee schedule final rule for 2006, at 9, available at http://www.bio.org/healthcare/medicare/20051223.pdf.

[10] 70 Fed. Reg. 70115, 70241 (November 21, 2005).

that CMS reconsider this decision and require CAP vendors to provide these drugs. In this context we consider 'orphan drug' to mean any chemical entity designated as an orphan by FDA, regardless of manufacturing source of supply. We recommend, however, that alpha 1-proteinase inhibitor (J0256) continue to be excluded from the CAP to best protect beneficiary access to this therapy.

VIII. Conclusion

In conclusion, BIO appreciates this opportunity to comment on this Interim Final Rule. We hope our suggestions will help CMS continue to provide clear guidance that will help manufacturers submit the data needed to calculate appropriate Medicare payment rates for drugs and biologicals. Please contact Jayson Slotnik at 202-962-9200 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

James C. Greenwood
President and CEO
Biotechnology Industry Organization

CMS-1325-IFC-3 **Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals**

Submitter : Ms. Maya Bermingham **Date & Time:** 01/20/2006

Organization : PhRMA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment - PhRMA Comments regarding File Code CMS-1325-IFC3.

CMS-1325-IFC-33-Attach-1.PDF

PhRMA

January 20, 2006

Dr. Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-IFC3
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Interim Final Rule on Excluding Competitive Acquisition Program Vendor Purchases from Average Sales Price Calculations; File Code CMS-1325-IFC3

Dear Dr. McClellan:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the above-referenced interim final rule issued by the Centers for Medicare and Medicaid Services (CMS), which concerns the exclusion of Competitive Acquisition Program (CAP) vendor purchases from Average Sales Price (ASP) calculations.[1] PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

In the interim final rule, CMS explained that "both the CAP and ASP payment methodologies are best served by excluding units supplied under the CAP from ASP," because such an exclusion "give[s] manufacturers an incentive to provide discounts to approved CAP vendors that will . . . result in lower prices under the CAP."[2] For reasons detailed below, PhRMA believes that CMS could better achieve this goal by simplifying the CAP exclusion in the interim final rule, thereby reducing the burdens on CAP vendors and avoiding increased complexity in ASP calculations.

* * *

[1] Medicare Program; Exclusion of Vendor Purchases Made Under the Competitive Acquisition Program (CAP) for Outpatient Drugs and Biologicals Under Part B for the Purpose of Calculating the Average Sales Price (ASP), Interim final rule with comment period, 70 Fed. Reg. 70478 (Nov. 21, 2005).

[2] Id. at 70480.

The interim final rule would exclude from manufacturers' ASP calculations "units of CAP drugs . . . administered to a beneficiary by a participating CAP physician."[3] To implement this exclusion, CMS will "requir[e] CAP vendors to provide manufacturers with information necessary to determine which sales to the approved CAP vendor are sales of CAP drugs that are excluded from the ASP calculation"[4] (which presumably would involve information on which of the units sold to the vendor ultimately were administered to a beneficiary by a participating CAP physician). Instead of knowing whether a unit sold to a CAP vendor was excluded from ASP at the time of the sale, a manufacturer would need to wait for the report from the CAP vendor on which units had (and had not) been administered to beneficiaries by participating physicians. Moreover, the CAP vendor itself might not know the ultimate disposition of some of the units purchased from the manufacturer during a particular quarter at the time the manufacturer was finalizing its ASP calculations for that quarter, creating further uncertainty about the included/excluded status of units sold during the quarter.

Because this approach would needlessly create new reporting burdens for CAP vendors and significantly increase the complexity of ASP calculations (thereby increasing the risk of error), PhRMA strongly encourages CMS to revise and simplify the new CAP exclusion. Specifically, CMS should exclude from ASP calculations any units that a manufacturer sold directly to a CAP vendor for distribution under CAP (regardless of whether a particular unit ultimately was administered to a beneficiary by a participating physician). While simpler and more efficient than the current rule, this approach would be just as effective in advancing CMS' goal of "giv[ing] manufacturers an incentive to provide discounts to approved CAP vendors that will . . . result in lower prices under the CAP."[5] Further, this approach would "[better serve] both the CAP and ASP payment methodologies,"[6] by avoiding complications that would increase the risk of error in ASP calculations. Finally, a simpler CAP exclusion would be equally consistent with the statutory provisions CMS cited as authority for the existing exclusion.[7] Consequently, we hope that CMS will quickly reform the CAP exclusion to adopt the simpler approach suggested here.

If CMS did not simplify the existing CAP exclusion, it would need to assure manufacturers explicitly that they could rely on the information reported by CAP vendors in calculating ASP (since manufacturers would have no independent knowledge of whether units sold to a CAP vendor were subsequently administered to beneficiaries by participating physicians), and to specify a deadline for vendor reports that gave manufacturers sufficient time

---

3 42 CFR § 414.802. This exclusion will apply during the first three years of the CAP. Id.

4 70 Fed. Reg. at 70480.

5 Id. In fact, this simpler approach could be more effective in encouraging discounts to CAP vendors, because it would eliminate the risk that some of the units sold to a vendor for CAP distribution might still have to be included in ASP because they were not subsequently administered to beneficiaries by participating physicians.

6 Id. (emphasis added).

7 As authority for the exclusion, CMS cited the provisions in Social Security Act (SSA) §§ 1847A and 1847B suggesting that Congress intended the CAP and ASP programs to be completely independent of each other, and SSA § 1847A(b)(2), authorizing CMS to establish "methods for counting units" for ASP purposes. 70 Fed. Reg. at 70479.

to incorporate the reported information into their ASP calculations. Further, CMS would need to provide guidance on all of the various questions and uncertainties raised by the language of the existing exclusion. We have provided below a list describing a few of the scenarios that could occur under CAP and some of the questions they would raise with respect to the current exclusion. While this list is by no means exhaustive, it helps to illustrate the scope of the implementation problems associated with the current exclusion, and the significant benefits of adopting a simpler approach.

1. During a certain quarter, a manufacturer sells 100 units of a drug to a CAP vendor for distribution under CAP. Shortly before the ASP submission for that quarter is due, the CAP vendor is still uncertain about the ultimate disposition of five of the units (e.g., the vendor is still holding some units in inventory awaiting orders from participating physicians, some units have been delivered to participating physicians but the vendor cannot determine whether they were administered to beneficiaries, or the vendor learns from the physician that some units have not yet been administered because beneficiaries rescheduled their appointments). Should these five units be included in the manufacturer's ASP calculations? Since the manufacturer sold the units during the reporting quarter, it needs to classify them as "included" or "excluded" in order to finalize its ASP calculations for that quarter. Any solution to this problem must recognize that manufacturers cannot report an "interim" ASP to CMS that would be restated once the CAP vendor provided updated information on the disposition of the units purchased during the reporting quarter, since ASPs are used on a "real time" basis to set providers' quarterly payment rates and ASP-based payment rates cannot be revised retroactively.

CMS also would need to specify the type of information CAP vendors must report to manufacturers. In the scenario here, for example, assume that CMS decides that units with an unknown final disposition (at the time when ASP submission are almost due) should be treated as non-administered units included in ASP. Would the vendor only report summary conclusions to the manufacturer (five of the 100 units the vendor purchased that quarter should be included in ASP), or would vendors' reports need to provide details on the specific circumstances accounting for non-excluded units? Assuming that details would be required, exactly what information would be reported in this example (and the other scenarios described below)? Since a "unit" is defined for ASP purposes as "the product represented by the 11-digit National Drug Code,"[8] can one assume that vendors must report information at the 11-digit NDC level?

2. A CAP vendor purchases a single-use vial from a manufacturer for distribution under CAP; receives a drug order from a participating physician; and ships the vial to the physician for administration to a Medicare beneficiary. The beneficiary's treatment plan changes and the drug is no longer required. The physician contacts the CAP vendor to reach agreement on how to handle the unopened vial, and the vendor sells the drug to the physician for use with a non-Medicare patient. Is the vial included in the manufacturer's ASP calculations?

3. A CAP vendor purchases a multi-use vial (four doses/vial) from a manufacturer for distribution under CAP; receives an order from a participating physician; and ships the vial to the physician for administration to four Medicare beneficiaries. Due to scheduling changes, only two of the beneficiaries are present to receive therapy. The physician contacts the vendor to

[8] 42 CFR § 414.802.

reach agreement on how to handle the two remaining doses in the multi-use vial, and the vendor sells the two doses to the physician for use with non-Medicare patients. Should the full vial be fully or partly excluded from the manufacturer's ASP calculations?

4. A CAP vendor purchases drugs from a manufacturer for distribution under CAP, but the volume of demand from participating physicians is lower than anticipated. The vendor converts the CAP inventory to commercial inventory and sells the drug through the retail class of trade. Should the drugs be included in the manufacturer's ASP calculations? Does the answer depend on whether the vendor diverts the drugs to retail distribution after the reporting quarter closes? How should the manufacturer account for the diversion in its Average Manufacturer Price (AMP) calculations if it learns of the diversion after ASP and AMP have already been reported to CMS? How should the manufacturer account for lagged price concessions?

5. A CAP vendor purchases a single-use vial from a manufacturer for distribution under CAP; receives an order from a participating physician; and ships the vial to the physician for administration to a Medicare beneficiary. The physician administers a portion of the vial to the beneficiary, but the beneficiary does not need the full vial and the remainder of the vial is not used. Under the revised CAP provisions in the physician fee schedule rule, unused drug is considered "administered" (for purposes of determining whether the vendor can bill Medicare for the unused drug) only in cases involving an opened single-use vial where the vendor and the physician have both made good faith efforts to minimize waste.[9] Does this concept of "administration" also apply for purposes of determining whether a unit of a drug is excluded from ASP?[10] If so, must the vendor determine whether the physician made good faith efforts to reduce waste before reporting to the manufacturer whether the vial is excluded from ASP (and what if the vendor cannot obtain this information before the manufacturer needs to finalize its ASP submission)? If this definition of "administration" does not apply for purposes of ASP exclusion, what is the definition that applies in this context?

6. A CAP vendor purchases a single-use vial from a manufacturer for distribution under CAP; receives an order from a participating physician; and ships the vial to the physician for administration to a Medicare beneficiary. The beneficiary's treatment plan changes and the drug is no longer required. The physician contacts the vendor to reach agreement on how to handle the unopened single-use vial. The vendor and physician both are unable to use the vial and it is destroyed. Is the vial included in the manufacturer's ASP calculations?

7. A CAP vendor purchases a unit from a manufacturer for distribution under CAP; receives an order for an emergency resupply of a participating physician's private inventory pursuant to

---

[9] 70 Fed. Reg. 70116, 70248 (Nov. 21, 2005). Specifically, the physician must have "made good faith efforts to minimize the unused portion of the CAP drug in how he or she scheduled patients and . . . ordered, accepted, stored and used the drug," and the vendor must have "made good faith efforts to minimize the unused portion of the drug in how it supplied the drug." Id.

[10] CMS seemed to suggest otherwise in the physician fee schedule rule, stating that unused drug meeting these criteria would be "consider[ed] administered for the limited purpose of [SSA] section 1847B(a)(3)(A)(iii)(II) [conditioning payments to CAP vendors on administration of the drug]." Id.

42 CFR § 414.906(e); and ships the unit to the physician (who then uses the unit to resupply his or her private inventory). Is the unit included in the manufacturer's ASP calculations?

8. A CAP vendor purchases drugs from a wholesaler, and the drugs are subsequently distributed to participating physicians and administered to Medicare beneficiaries. Must a CAP vendor report to the manufacturer that drugs acquired from a wholesaler were administered under CAP, and must the manufacturer then exclude those drugs from its ASP calculations? If so, would the manufacturer attribute the drugs to the reporting quarter in which it received the vendor's report, since the manufacturer could not determine the date when it sold the units in question to a wholesaler? If not, how should the manufacturer handle the now-excluded units without "re-opening" previously-reported ASPs from past quarters?

As noted earlier, PhRMA believes that it is not necessary for CMS to address these complexities — or any of the other complications associated with the CAP exclusion in the interim final rule. Instead, CMS should eliminate these problems by making a small modification to the existing exclusion (i.e., by excluding from ASP any units a manufacturer sold directly to a CAP vendor for purposes of distribution under CAP). Simplifying the CAP exclusion in this manner would improve CAP's efficiency, reduce reporting burdens on CAP vendors, avoid adding needless complications to manufacturers' ASP calculations, and advance CMS' goal of encouraging manufacturers to give discounts to CAP vendors that reduce CAP prices. Given the significant benefits of this approach, we encourage CMS to adopt it promptly before CAP begins operating.

* * *

PhRMA hopes that these comments will be useful to CMS in refining the interim final rule and planning for successful CAP implementation. We look forward to further dialogue with CMS on these issues and trust the Agency will not hesitate to contact us with any questions, comments, or requests for additional information.

Sincerely,

Richard Smith /mjb

Richard I. Smith
Senior Vice President for
Policy, Research, and Strategic Planning

Diane E. Bieri (mjb)

Diane E. Bieri
Acting General Counsel, Vice President
and Compliance Officer