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April 21, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Comments on the Proposal for Competitive Acquisition of Outpatient Drugs and Biologicals Under Medicare Part B

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the proposed rules governing the Competitive Acquisition Program (CAP) for drugs administered in physician offices, which were published in the Federal Register on March 4, 2005. ASCO is the national organization representing physicians who specialize in the treatment of cancer. Drugs used in cancer chemotherapy represent a substantial portion of the drugs covered by Medicare Part B, and ASCO's members therefore are very interested in the design and implementation of the CAP.

ASCO has a number of concerns with the proposed regulations. As requested in the Federal Register notice, our comments are organized by the subjects specified in the notice.

DRUGS TO BE INCLUDED IN THE CAP

The statute allows CMS to phase in the CAP, and CMS has asked for comments on various possibilities. In terms of the drugs covered by the CAP, one approach would be to start with the relatively large number of drugs typically used by oncologists, a second approach would be to start with a smaller number of drugs used by other specialties, and a third approach would be to include all drugs in the CAP. In terms of geography, the CAP could initially begin nationwide or, alternatively, only in certain regions.

- **Implementation of the CAP**

As outlined in these comments, ASCO believes that there are a number of issues that require clarification to ensure that the CAP will operate appropriately. We are uncertain whether the CAP will be widely accepted by oncologists because of these uncertainties and the additional administrative burdens that the program will impose. Nevertheless, ASCO urges that the CAP be made available nationwide in 2006 for all drugs.

The current reimbursement system, which sets payment at 106% of a historical average sales price, results in some drugs being unavailable to some physicians at a price that is less than the Medicare payment amount. Physicians should have the opportunity to avoid these out-of-pocket losses, as well as other drug-associated losses such as bad debt, by electing to participate in the CAP. During the legislative consideration of the

1900 Duke Street, Suite 200 Alexandria, VA 22314 Telephone: (703) 299-0150 Fax: (703) 299-1044 E-mail: asco@asco.org

Medicare Modernization Act, the CAP was portrayed as an option that would be available to physicians who would otherwise incur losses. This protection should be offered to physicians who want it without delay beyond 2006.

CLAIMS PROCESSING OVERVIEW

As described in the proposal, in response to orders from physicians with respect to specific patients, the vendor would send the drugs to the physician with an identifying prescription number. When the physician administers a drug, he would submit a claim to his local carrier showing the drug administration codes, the J-codes for the drugs administered, and the prescription number supplied by the vendor for the drugs administered.

The local carrier would adjudicate the claim as usual and would determine whether it was a Medicare-covered service, applying local coverage determinations as applicable. If the service was covered, the local carrier would notify the carrier that handles vendor drug claims of the prescription number involved, at which time the drug carrier would pay the vendor and the vendor would be permitted to bill the patient, or the patient's secondary insurer, for the coinsurance.

- **Requirement for vendor to fill all orders**

It is implicit in the proposed regulations that a vendor must fill all physician orders, but this should be made explicit. Vendors may be tempted to refuse filling a particular order for various reasons – e.g., the patient involved has not paid coinsurance owed to the vendor for a previous order, the Medicare carrier has denied coverage of a similar previous order, the vendor thinks that the carrier might deny coverage, etc. The regulations should state unequivocally that the vendor may not refuse to fill a properly completed physician's order for any reason whatever. Similarly, the regulations should provide that the vendor cannot require the patient to sign an advance beneficiary notice, in which the patient agrees to pay for the drug in the event of a coverage denial.

- **Information to be submitted with the order**

The proposal would require the physician, in ordering a drug, to specify the "frequency/instructions," the anticipated date of drug administration, information about the patient's secondary insurance, and "additional patient info: date of birth, allergies, Ht/Wt/ICD-9, etc." Information on secondary insurance is appropriate because the vendor will need that information in billing for the coinsurance, but much of the other information would not appear to be relevant to the vendor's duties, and there should not be a requirement for its submission.

Specifically, information on "frequency/instructions," date of birth, allergies, height, weight, and diagnosis code seems to contemplate that the vendor will perform a pharmacist-type review of the order and label the drugs with instructions for use. We do not see any basis in the law for such action. We believe that the statute intends that the vendor act like a drug wholesaler does now, simply filling orders.

- **Delivery of drugs to office**

CMS is proposing that all drugs will be delivered to the physician's office and not the patient. ASCO agrees with this proposal. To ensure proper handling, drugs should be delivered only to physicians.

- **Practices with multiple locations**

Many practices have more than one office location. CMS should require the vendors to deliver each order to the office specified by the practice and not permit vendors to require that practices designate a single address for shipments.

- **Time for submission of claims**

CMS is proposing that the physician would be required to submit all claims for drug administration services with fourteen days of the date of service. While we understand the need for prompt submission of claims, since the vendor is not paid for the drug until the drug has been administered, that schedule is too rapid for many practices. ASCO recommends instead that drug administration claims be required to be submitted within 30 days after the date of service.

- **Disposition of unused drug**

The proposal contemplates that the physician, in ordering drugs for a particular patient, will specify an expected date of administration. If the drug supplied by a vendor is not administered on that date, the physician would notify the vendor and "reach an agreement on how to handle the unused drug, consistent with applicable State and Federal Law." If the vendor and the physician agree that the drug could be used at a later time for another Medicare patient, the physician would generate a new order for that other patient but note on the form that the vendor need not ship the drug. We have several issues with this aspect of the proposal.

First, the proposal appears to contemplate that the physician can predict the exact date on which drugs will be administered to the patient. A patient's schedule for cancer chemotherapy is subject to change based on the patient's condition, and it should not be assumed, as the proposal does, that a failure to administer a particular drug on the date predicted in advance means that the drug will go unused.

Second, it would be much more practical for the vendor to track the use of drug than the physician. The proposal contemplates that physicians would develop a new system of inventory records for each drug. An additional requirement that each drug must be tracked against the expected administration date provided to the vendor would be another system that would need to be developed and would be quite burdensome. We suggest that the vendor track the expected administration dates against claims submission, and if there is a substantial discrepancy (e.g., no claim submission within a reasonable time after the expected administration date), the vendor would query the physician about the status of the drug.

Third, the process for disposing of unused drug should be clarified. The proposal implies that the disposition of unused drug is at the discretion of the vendor and that, if the vendor cannot develop a solution that is consistent with the state and federal law, the vendor incurs the financial loss. While we understand that CMS cannot resolve all of the state law questions that may be involved, it would be useful if CMS clarified the principles involved. In particular:

  - Is the vendor allowed to do anything with the unused drug that is permissible under state law or are there any restrictions under the CAP or other federal law that would apply?

  - To what extent is the physician required to cooperate with the vendor with respect to unused drug? For example, if the vendor concludes that it can legally take the unused drug back from the physician, is the physician required to send

the drug back? If so, the physician should be permitted to charge the vendor a fee for the service of returning the drug; is such a charge allowed?

- Is the physician required to mitigate the vendor's loss by offering to administer the drug to a different Medicare patient?

- If it is permissible under state law, can the physician negotiate with the vendor to purchase the drug from the vendor at an agreed-upon price?

- **Payment for administrative costs**

CMS is proposing not to make any payment to physicians for the administrative costs associated with obtaining drugs through the CAP on the ground that the inventory and clerical costs do not exceed those that are incurred by physicians who buy drugs and seek reimbursement. ASCO disagrees with this conclusion and requests that a separate payment be established. As we will now outline, at each step in the process of procuring, using, and billing for drugs under the CAP, the administrative work is greater than under the reimbursement system.

The costs of ordering drugs under the CAP would be significantly greater than under the reimbursement system. Under the reimbursement system, physicians generally maintain an inventory for each type of drug and order additional units when the inventory falls below a certain level. Oncologists often use an automated storage and inventory control system that tracks the remaining amount of each drug. By contrast to this relatively simple method of ordering in bulk, the CAP requires orders to be submitted to the vendor for each patient, and those orders would need to provide significant patient-specific information instead of simply the number of units requested.

An additional significant new cost would be the creation of an inventory record for each drug, as the proposal would require. The identity of each drug received from the CAP vendor would need to be entered into a record together with the identifying number furnished by the CAP, and a further entry into the inventory record would be required when the drug was administered. Physicians currently do not maintain any similar inventory records, and the additional work involved would appear to be substantial.

The storage costs would be at least as large under the CAP as under the reimbursement method, and storage may be more difficult to manage. Although the proposal states that the CAP drug inventory would not need to be segregated from other inventory, there may need to be some form of segregation so that the office staff can ascertain the amount of inventory available for non-Medicare patients. For example, if a physician has ten vials of a particular drug on hand, it will not be clear from visual observation whether all of the vials have been received from the vendor for Medicare patients or whether part of the inventory is available for non-Medicare patients.

At the billing stage, there would be more work under the CAP than under the reimbursement method. The content of the claims would be identical in most respects under both systems, but the CAP claim would need to include a prescription number for each of the drug codes billed. Retrieving the prescription number for each drug and including it in the claim would be significant additional work beyond what is now required.

CMS has proposed that if the drug is not used on what was reported to the vendor as the expected date of administration, the physician would be required to notify the vendor. ASCO has recommended in these

comments that physicians should be relieved of that duty, but as proposed, this would be a new reporting obligation that is not comparable to any work in the reimbursement system.

In sum, ASCO does not see the basis for CMS's conclusion that no extra administrative costs are incurred by physicians participating in the CAP. To the contrary, there would appear to be significant additional work involved. We recommend that a reasonable payment be established that would fully cover the extra costs involved. The payment amount could be paid with respect to each drug administered. That is, the claim submitted to Medicare for an encounter involving drug administration would include a code for the drug handling service with the units reported for the code equal to the number of drugs administered during the encounter.

- **Vendor-imposed technology costs**

If a vendor imposes any requirements that physicians use particular hardware or software in submitting orders or otherwise participating in the CAP, CMS should require the vendor to clearly disclose those requirements prior to the election period. If physicians are responsible for the costs of such technology, that obligation should also be stated clearly in the information about the vendor.

DISPUTE RESOLUTION

Under the proposal, only the physician would have appeal rights in the case of claims that are denied for medical necessity or other reasons. If the vendor dispenses drugs and cannot obtain Medicare payment because the physician's claims are denied, CMS is proposing that the vendor should have the right to complain to its carrier if the losses with respect to an individual physician exceed an "acceptable threshold." If that occurs, the carrier will counsel the physician to submit clean claims and to pursue administrative appeal rights on denied claims. If problems persist, the carrier could recommend to CMS that the physician be suspended from the CAP, and CMS would decide whether to do so.

CAP vendors would also be required to have procedures to handle complaints about service from physicians and about billing issues from patients.

- **CMS should clarify physicians' responsibilities in the case of denied claims**

ASCO agrees with CMS that, under the statute, only the physician has appeal rights with respect to denied claims. We request that CMS clarify the extent of the physician's responsibility to appeal denied claims. We believe that the physician's duty should be only to seek review by the carrier (or redetermination by the carrier under the new appeals regulations). Further appeals should be at the discretion of the physician, who should be permitted to weigh the chance of success against the expense and burden of the appeal.

- **The process for resolution of beneficiary disputes should be made clear to beneficiaries**

The proposal indicates that beneficiary billing disputes would be handled by the beneficiary first using the vendor's grievance process and, if the beneficiary is dissatisfied with the result, requesting intervention by the vendor's carrier. The carrier would investigate the facts and then facilitate correction to the claim record and beneficiary file.

This process should be made very clear to beneficiaries. We suggest that CMS develop standard language that vendors would be required to include in every bill to beneficiaries explaining the grievance

process and the method for subsequently appealing any issues to the designated carrier. The information should make clear that the beneficiary's physician is not involved in the billing and has no authority to resolve any disputes.

- **CMS and carrier involvement in unresolved disputes**

The proposed rule does not set out a clear mechanism for resolution of disputes related to quality of service or beneficiary billing. The preamble states only that the Medicare carrier will attempt to resolve such disputes if the vendor and the physician or beneficiary cannot. We believe that the process should be more definitive. At a minimum, the carrier should be given a clear mandate to resolve disputes, the process for doing so should be clear and should offer the parties an opportunity to participate in a meaningful way, the carrier should have the legal authority to impose a solution, and there should be oversight of the carrier's actions by CMS.

CONTRACTING PROCESS – QUALITY AND PRODUCT INTEGRITY ASPECTS

The proposed regulations include a number of provisions intended to ensure that the vendors provide drugs that meet quality and product integrity standards.

- **Vendors should be prohibited from opening drug containers**

The statute authorizes CMS to impose product integrity safeguards. An issue that the regulations should deal with expressly is the authority of vendors to open drug containers. ASCO is concerned, for example, that if a vendor believes that a particular patient's order does not require a full container of drug, the vendor, acting as a pharmacy, may open a container and dispense only the portion that the vendor believes is necessary by transferring a portion of the drug to another container for shipment to the ordering physician.

Any compromise of package integrity in this manner would be unacceptable. The regulations should clearly require vendors to ship products to physicians in containers that are unopened and otherwise in the same condition as received from the drugs' manufacturers.

- **Return of damaged or suspicious drugs**

The rules should permit physicians to return to the vendor without penalty any drug that arrives in damaged condition or whose integrity the physician reasonably believes may have been compromised. The vendor should not be permitted to require the physician to seek a remedy from the company that delivered the product.

- **Vendors should be required to carry substantial liability insurance**

The proposed financial standards should include a requirement that vendors carry substantial liability insurance. In the event that vendor errors cause harm to patients, their liability for damages could be substantial, and the metrics in the proposed regulations for financial adequacy to conduct a drug distribution business may not be adequate to ensure their ability to pay damages. Thus, liability insurance in sufficient amount to cover potentially serious adverse events should be required.

- **Vendors should be required to indemnify physicians for any losses they cause**

If actions by the vendors in handling the drugs result in injury to patients, it is possible that claims will be made against the physicians who administered the drugs. The regulations should require vendors to indemnify physicians for any losses, damages, and costs (including attorneys fees) incurred by the physician as a result of the vendor's negligence, errors, or omissions.

- **CMS should audit compliance with and enforce the standards**

The only review and enforcement mechanism in the proposed regulations with respect to the quality and other standards appears to be the vendor's certifications that it is in compliance. We believe that CMS should take a more affirmative role in determining vendor compliance by, for example, inspecting vendor facilities, monitoring complaints, auditing vendor compliance with time schedules in the regulations, and so forth.

BIDDING ENTITY QUALIFICATIONS

The proposal notes that vendors would be considered covered entities under HIPAA, including the HIPAA Privacy Rule. ASCO would like to raise two HIPAA issues.

- **CMS should clarify whether vendors have the right to sell physician-specific data**

The CAP vendors will have detailed patient- and physician-specific data about the drug therapies used. Although HIPAA would require vendors to remove patient identifiers before selling or distributing the data, it would appear that the distribution of data with physician identifiers would not violate HIPAA. ASCO requests that CMS clarify whether vendors are permitted to sell or otherwise transfer physician-specific data, or any other data acquired as a CAP vendor, for purposes other than carrying out the CAP contract. If the vendors do have the right to transfer data to third parties for non-CAP purposes, ASCO recommends that CMS require the vendors to disclose their policies on any non-CAP data transfers that they might make so that physicians may take those policies into account in selecting a vendor or deciding whether to participate in the CAP.

- **CMS should clarify the extent to which vendors may market to patients**

The HIPAA Privacy Rule allows covered entities limited rights to contact patients for marketing purposes. CMS should clarify whether the CAP vendors have the right to communicate information to patients other than information related to coinsurance obligations. For example, in the absence of restrictions under the CAP, HIPAA might permit the vendors to provide patients with general health information and information about drugs other than those prescribed by their physician. CMS should clarify the types of information that vendors may provide to patients without their consent.

CAP BIDDING PROCESS – EVALUATION AND SELECTION

- **New drugs should be available from the CAP immediately or, alternatively, through the reimbursement process**

The proposal indicates that adjustments to the vendors' payment schedule will generally be made only annually. There would be more frequent adjustments in certain cases, including introduction of a new drug, but such adjustments would not be more often than quarterly. This proposal implies that a CAP vendor would not be obligated to furnish newly approved drugs to physicians for a period of some months.

It is essential that all newly approved Medicare-covered drugs be immediately available to Medicare beneficiaries. This availability is especially important in the case of new cancer drugs, which may extend beneficiaries' lives. One approach would be for CMS to coordinate with the Food and Drug Administration to learn about the approval of new drugs covered by Part B and to immediately revise the vendor payment schedule to include new drugs. Alternatively, CMS should clarify in the regulations that physicians who have agreed to obtain their drugs from a CAP vendor are nevertheless free to buy and seek reimbursement for new drugs until they are available from the vendor.

PHYSICIAN ELECTION PROCESS

Physicians would elect annually whether to participate in the CAP, and CMS is proposing that physicians who elect to participate would be required to remain in the program for at least one calendar year. The election would ordinarily take place in the period October 1 through November 15 of each year, but a CAP participating physician could select a replacement vendor mid-year if the selected vendor leaves the program.

- **Physicians should have the option to elect reimbursement if the selected CAP vendor leaves the program mid-year**

CMS seeks comment on the options that should be available to a physician if the physician's selected CAP vendor leaves the program in the middle of the year. ASCO recommends that the physician have the choice of leaving the CAP program or selecting a different CAP vendor. A physician should not be compelled to select a different CAP vendor, since the vendor originally selected by the physician may have been the only vendor acceptable to that physician.

- **Physicians should have the option to elect reimbursement or change vendors based on problems with the vendor**

The proposal allows vendors to exit the CAP midyear and, under certain circumstances, allows a physician to be expelled from the program. The proposal, however, does not include a parallel provision allowing physicians to change vendors or leave the program midyear if the physician's vendor is unsatisfactory. ASCO recommends that the regulations permit such action if the vendor has a record of unsatisfactory service, unresolved disputes, or similar negative acts. For example, the regulations could permit a physician to apply to CMS for permission to leave the program midyear because of dissatisfaction with the vendor, and CMS would grant the application unless the basis for the request was unreasonable.

BENEFICIARY EDUCATION

CMS is proposing to prepare a fact sheet on the CAP program that would be made available to beneficiaries and to physicians who could provide it to beneficiaries. CMS asks for comment on the burden involved in requiring physicians to furnish it to their patients.

- **CMS should not require physicians to furnish the fact sheet to patients**

ASCO appreciates CMS's efforts to develop patient education materials related to the CAP program. We agree that patients who receive a coinsurance bill for drugs from the CAP vendor may be confused. These issues are best handled, however, on a patient-by-patient basis rather than requiring physicians to

distribute a CMS fact sheet to every patient. Physicians have an incentive to clear up any confusion on the part of their patients and will take the steps they believe are necessary, which may vary from patient to patient.

CMS MONITORING OF PROGRAM

Finally, ASCO recommends that CMS establish a process for monitoring the effects of the CAP on patient access to drugs and on physician practices, particularly with respect to extra costs imposed on practices. Such a program would permit CMS to identify potential problems and rectify them.

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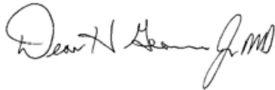
Thank you for the opportunity to comment on the proposed regulations.

Sincerely,



Dean H. Gesme, MD
Chair, Clinical Practice Committee