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September 1, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-IFC
P.O. Box 8013
Baltimore, MD 21244-9013

**Re: Comments on the Interim Final Rule on the
Competitive Acquisition Program for Part B Drugs
and Biologicals**

These comments are submitted by the American Society of Clinical Oncology (“ASCO”) in response to the interim final rule establishing the Competitive Acquisition Program (“CAP”) for Medicare Part B drugs and biologicals, which was published in the Federal Register on July 6, 2005. ASCO is the national organization representing physicians who specialize in the treatment of cancer. Our members administer chemotherapy and other drugs covered by Part B and are very interested in the CAP.

ASCO appreciates the changes that CMS made in response to comments by ASCO and others on the proposed rule. The changes provided important clarifications and improvements. We have a few comments on the interim rule.

Patient Coinsurance

ASCO is very concerned about provisions in the interim rule that permit vendors to terminate the provision of drugs for patients who have not paid their coinsurance within 45 days. Although the rule does require vendors to consider alternatives, such as establishing a payment plan or referral of the patient to a charitable organization, ultimately the vendor has the right to terminate a patient’s access to drugs.

We believe that this harsh rule will be a major impediment to oncologists’ participating in the CAP. Cancer patients will look to their oncologists, not the drug vendor, if their drug supply, and therefore also their treatment for a life-threatening condition, are terminated. Oncologists will have no effective response for them and will likely avoid this situation by not enrolling in the CAP.

CMS should address this issue in some other manner. Oncologists currently are required to absorb the cost of any unpaid coinsurance, and vendors could reasonably be placed in the same position. The interim rule’s decision that cancer patients who cannot pay their coinsurance should simply go without treatment is not a tenable and humane resolution of this issue.

2006 Annual Meeting
June 2–June 6, 2006
Atlanta, Georgia

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Phone: (703) 631-6200
Fax: (703) 818-6425
Website: www.asco.org

Payment for Administrative Costs

In our comments on the proposed rule, we pointed out that physicians participating in the CAP will incur significant administrative costs beyond those that would be incurred under the buy and bill system. CMS responded that physicians should weigh those costs against the benefits of the CAP when considering whether to participate but declined to provide any additional payment.

The lack of payment for the additional administrative costs involved will, we believe, significantly discourage CAP enrollment. Since implementation of the program has been delayed, ASCO recommends that CMS commission a study to quantify the extra administrative costs involved. Based on the results of such a study, CMS may conclude that an additional payment is appropriate to facilitate CAP enrollment.

Prohibition on Moving Drugs Between Offices

The regulations prohibit physicians from transporting CAP drugs from one practice location to another (42 C.F.R. § 414.908(a)(3)(x)). This prohibition was added in response to comments from prospective vendors that were concerned about possible spoilage or breakage that could occur in such a move and about the possibility of liability if deteriorated drug were administered to patients. (70 Fed. Reg. at 39047) CMS noted that drugs are sometimes administered to patients in their homes and asked for comment on how the vendor concerns about product integrity could be accommodated with home administration.

ASCO believes that the prohibition on transporting drugs between practice locations should be rescinded. Oncologists, especially those serving rural areas, often use satellite offices on an intermittent basis, such as one day a week. The oncologist traveling to a satellite office may carry the drugs for the patients scheduled for chemotherapy that day. It may not be possible for drugs to be shipped directly to the satellite office because it is unoccupied at times or because the regular occupants are not oncologists familiar with handling drugs. The prohibition on transporting drugs may make it impossible for oncologists administering chemotherapy in satellite locations to enroll in the CAP.

We do not believe that transporting drugs from one practice location to another presents a special risk that warrants its prohibition. Oncologists and their staffs are very knowledgeable about maintaining drug integrity. They must routinely handle and store large quantities of drugs properly. In the case of oncology, transporting drugs to satellite offices is much more important than carrying drugs to patient homes for administration there, which CMS has acknowledged should be accommodated. Transporting drugs from one office to another can be safely managed and should not be barred.

Specifying the Estimated Date of Drug Administration

When ordering a drug from the CAP, the physician is required to specify the estimated date of administration. In the preamble to the interim rule, CMS states that it will allow the date to be stated as a range of up to seven days. (70 Fed. Reg. at 39040) The 7-day time period was selected because drugs are often administered on a weekly basis, and the 7-day period was intended “to provide the physician with flexibility to shift the specific date of administration of needed drugs within a specified period without overlapping the next treatment period.”



One purpose of the estimated date of administration apparently relates to the requirement for the physician to notify the vendor when a drug is not administered. (42 C.F.R. § 414.908(a)(3)(vi)) Although the regulation itself does not specify when the duty to notify the vendor arises, the preamble suggests that the notification must take place if the drug is not administered on the previously specified expected date of administration. (70 Fed. Reg. at 39048)

ASCO supports CMS's decision to allow flexibility in estimating the expected date of administration. Plans for administering drugs to cancer patients are often modified based on the patient's condition.

For purposes of notifying the vendor that a drug has not been administered, we believe that more flexibility should be allowed. For example, if a patient's condition does not permit the administration of chemotherapy on a scheduled day, it would not be uncommon to reschedule the chemotherapy session for the same day a week later. This 8-day delay would apparently require the physician to notify the vendor that the drug had not been used on schedule.

We question whether the CAP vendors and physician-enrollees would be well served by a requirement for communicating information about relatively short delays in drug administration. It certainly would be a burden on the physician, and if the drug is still scheduled to be used for the patient, the information would seem to be of no value to the vendor.

We believe that rule should be modified to require the physician to notify the vendor only when there will be a significant delay in administering the drug to the patient or when the drug is not expected to be administered to the patient at all.

Patient Support Activity

Patients may have questions for CAP vendors relating to billing, payment schedules, and other matters. The regulations do not include any clear requirement for the vendors to have a responsive patient support function that will answer patient questions. Rather, the regulations appear to require only that vendors have procedures to resolve "complaints" and "inquiries about drug shipments." (42 C.F.R. § 414.914(f)(3)) ASCO is concerned that if the vendors do not have an easily accessible and responsive mechanism for answering all patient inquiries, patients will turn to their oncologists for answers, and oncologists will not be in a position to assist them.

Therefore, ASCO recommends that the regulations include specific requirements for vendors to maintain a mechanism, such as a call center, adequately staffed and available for extended hours to respond to patient issues.

Vendor Sale of Physician-Identified Data

In our comments on the proposal, ASCO asked whether the vendors would be permitted to sell data on drug use that included physician identifiers. If so, we suggested that vendors should be required to disclose their policies so that physicians could take them into account in deciding whether to participate in the CAP and in selecting a particular vendor.



In responding to the comments, CMS stated that vendors would need to comply with HIPAA privacy requirements with respect to patient-specific data, but the issue of physician-specific data was not addressed. We believe that data on drug use by specific named physicians would not be subject to restrictions under HIPAA if it did not contain patient identifiers. ASCO therefore renews its request that CMS state its policy on whether vendors can sell physician-specific data and, if so, that vendors should be required to disclose those policies.

Thank you for the opportunity to submit these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "John V. Cox". The signature is fluid and cursive, with a large initial "J" and "C".

John V. Cox, DO
Chair, Clinical Practice Committee