



## **SUMMARY OF FINAL RULE ON COMPETITIVE ACQUISITION PROGRAM**

The Centers for Medicare & Medicaid Services (“CMS”) has issued an interim final rule to implement a competitive acquisition program (“CAP”) for Part B drugs beginning January 1, 2006. The rule was published in the Federal Register on July 6, 2005. Additional comments on the rule may be submitted to CMS until September 6, 2005.

Under the CAP, physicians may elect annually to receive drugs that will be administered to Medicare patients from a vendor under contract to CMS. The vendor will be responsible for billing Medicare and the patient for the drugs. Those physicians who choose not to enroll in the CAP program will continue to purchase drugs directly and will be paid under the average sales price (“ASP”) system.

CMS published a proposed rule to implement the CAP in February of 2005. In response to the proposed rule, ASCO submitted comments to CMS addressing its concerns with the proposed regulations. CMS responded to some of these comments in the preamble to the final rule or in the final rule themselves. The following is an overview of the final rule, focusing on issues of particular importance to oncologists, together with a discussion of the responses to ASCO’s comments.

### **OVERVIEW OF THE CAP**

#### **Drugs to be Included in the CAP**

The CAP will go into effect nationwide on January 1, 2006, for a large group of commonly prescribed drugs, not limited to oncology drugs or drugs used by a specific specialty. Vendors will be required to furnish drugs covered by 181 Healthcare Common Procedure Coding System (“HCPCS”) codes. Each vendor must agree to furnish at least one CAP drug for each HCPCS code. Most drugs used in cancer treatment are included in the CAP drugs.

During its initial implementation, CMS chose not to include in the CAP drugs with very low volumes of billing and certain drugs that, according to CMS, pose special implementation issues. Drugs not in the CAP include:

- Drugs that do not have permanent J-codes
- Oral anticancer and oral antiemetic drugs covered by Medicare Part B
- Drugs administered through infusion pumps and covered under the durable medical equipment benefit
- Opiates and other controlled substances
- Orphan drugs that are approved exclusively for the treatment of orphan indications. Among the orphan drugs that will not be included in the CAP are oprelvekin (Neumega®), aldesleukin (Proleukin®), arsenic trioxide (Trisenox®), and denileukin diftitox (Ontak®).
- Intravenous immune globulin
- Leuprolide (Lupron®) because of issues related to the least costly alternative policy adopted by many carriers

- Vaccines

Going forward, CMS may consider including at least some of these drugs in the CAP as it refines and develops drug categories for future stages of implementation.

### **Process for Ordering and Supplying Drugs**

The rules establish a procedure for the CAP vendor to supply drugs on essentially the same terms as CMS had proposed.

- The physician would order drugs from the vendor. Information that would be included in the first order for each patient new to the vendor would be:
  - Date
  - Beneficiary name, address, phone number
  - Physician identifying information (including shipping address)
  - Drug name
  - Strength
  - Quantity ordered
  - Dose
  - Frequency/instructions
  - Anticipated date of administration (to allow flexibility, the physician can specify a range of dates over a 7-day period)
  - Beneficiary Medicare information/number
  - Supplementary insurance information (if applicable)
  - Medicaid information (if applicable)
  - Patient information: date of birth, allergies, height/weight, ICD-9
  - Gender
- Portions of this information would not have to be submitted to the extent prohibited by state law. Abbreviated information may be sent on all subsequent orders for a patient for whom the CAP vendor has previously received complete information and for whom there have been no changes to the original information.
- Vendors are required to ship drugs at least five days a week. Routine delivery of drugs must be made within two business days and emergency delivery must be made within one business day.<sup>1</sup> For example, if the physician places an order by 5:00 pm on Monday, the physician must receive the drugs by 5:00 pm Wednesday under the standard schedule. These timeframes may be further reduced where product stability or integrity requires it.
- The physician may order an entire course of therapy at the same time. The vendor, however, could divide the order into “appropriately spaced shipments” based on the physician’s description of the anticipated dates of drug administration. If shipment of

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<sup>1</sup> Vendors are provided additional time to deliver drugs to American Samoa, Guam, or the Northern Mariana Islands.



the order is divided, the subsequent parts of the order must arrive at least two business days before the expected date of administration as stated by the physician in the order.

- Vendors must ship drugs unopened and in the manufacturer's packaging. If the manufacturer's packaging contains multiple individual units (e.g., vial trays), the vendor may split the package into quantities appropriate for shipping.
- Physicians may return a drug to the vendor if the physician has reason to question the drug's integrity.
- Practices may not transport drugs from one location to another once they have been delivered.

### **Submission and Processing of Claims**

The process for claims handling adopted by CMS is also essentially the same as CMS proposed.

- The vendor would send the drugs to the physician with an identifying prescription number. If the vendor split an order into multiple shipments, the vendor would create a different prescription number for each shipment.
- On or after the anticipated date of drug administration, the vendor would submit a claim for the drugs to a specially designated carrier, also by using the prescription number.
- CAP drugs would not have to be stored separately from other drugs. Physicians would be required, however, to maintain a separate electronic or paper inventory for each CAP drug obtained.
- When the physician administers a drug, he or she would submit a claim to his or her 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. Physicians obtaining drugs through the CAP would be required to agree to submit claims within 14 days of the date of service, unless there were extenuating circumstances.
- 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. If Medicare is the secondary payer, the vendor would first bill the primary insurer and then Medicare.
- In the case of claims that are denied for medical necessity or other reasons, both the physician and the vendor have appeal rights. If the vendor dispenses drugs and cannot

obtain Medicare payment because the physician's claims are denied, the vendor has the right to complain to its carrier. If problems persist, the carrier may recommend to CMS that the physician's performance be reviewed or that the physician be suspended from the CAP. The carrier will gather information and submit it to CMS along with a recommendation, and CMS will then decide on a course of action. If CMS decides to suspend a physician from the CAP, the physician may request a reconsideration of CMS's decision.

### **Using Drug from Inventory in Emergency Situations**

In emergency situations, a physician could use a drug from his or her own inventory and seek replacement drug from the vendor. This would be allowed only if (1) the drugs were required immediately, (2) the physician could not have anticipated the need for the drugs, (3) the vendor could not have delivered the drugs in a timely manner, and (4) the drugs were administered in an emergency situation. An emergency situation is defined as an unforeseen occurrence or situation determined by the physician, in his or her clinical judgment, to require prompt action or attention.

### **Versions of Multiple Source Drugs Not Available from the Vendor**

Where medical necessity requires that a beneficiary receive a specific formulation of a drug, and that formulation is not provided by the physician's vendor, the physician may purchase the drug directly and bill Medicare under the ASP system. In these circumstances, the physician will place a special modifier on the claim form, which will allow the physician to receive reimbursement both for the drug and the administration.

### **Unused Drug**

When a drug is not administered, or when a physician administers a smaller amount of the drug than originally anticipated, the physician must notify the vendor. The physician and the vendor will then work together to determine how best to handle the unused drug. 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 order that the vendor need not ship the drug.

If there is some drug remaining in a vial, CMS states that the CAP vendor has the responsibility to accept return of the unused portion for disposal and to pay for the shipping involved. This process of returning partial vials to the vendor for disposal could not be used for empty or nearly empty vials.

The vendor retains title to the drugs until they are administered to a patient. Vendors are therefore responsible for shipping costs associated with the return of drugs.

### **Vendor Discretion**

The CAP vendors must generally provide the drugs ordered by physicians. Issues related to vendor discretion include the following:

- Vendors cannot establish a formulary but, instead, must supply all drugs subject to the CAP. In the case of multiple source drugs covered by the same J-code, a vendor is required to supply only one version of the drug.
- Vendors must furnish the drugs ordered by the physician even if they believe that Medicare will not cover the drugs. Vendors may call the physician to discuss the order (if, for example, the vendor believes the order is inconsistent with a local coverage determination) and may issue an advance beneficiary notice to the beneficiary requesting the beneficiary to pay for the drug if Medicare denies coverage. If the physician does not change the order or the beneficiary does not agree to pay for the drug, the vendor must nevertheless supply the drug.
- To help patients with coinsurance issues, vendors are required to offer assistance such as referral to independent charities, a payment plan, or waiver of coinsurance based on the individual patient's financial assistance. The vendor, however, is permitted to cease shipping drugs for a beneficiary where the beneficiary has failed to pay any balance owed to the vendor within 45 days from the postmark date of the vendor's bill to the beneficiary. If the beneficiary requests assistance from the vendor (such as locating an independent charity or waiving coinsurance), the vendor must wait 15 days from the beneficiary's request for assistance before terminating drug shipments.

### **Selection of Vendors**

CMS will be selecting vendors that can serve a national competitive acquisition area. A vendor must have been in the business of furnishing Part B injectable drugs for at least three years. No regulatory requirements beyond those applicable to other wholesalers and pharmacies are imposed. Prospective vendors have to submit information to CMS about their financial capability. Vendors need to have compliance plans and codes of conduct.

Vendors are required to have a grievance process to deal with physician complaints. A physician could also complain to the vendor's carrier if still dissatisfied. Beneficiaries who have complaints about coinsurance billing have the same options.

### **Vendor Bidding Process**

Prospective vendors will submit bids that specify a price for each drug by J-code. To evaluate the bids, CMS will weight the price bid for each drug by the previous year's volume of Medicare claims for that drug, resulting in a "composite bid" that will be used for comparison purposes. Winning bidders will be selected based on the composite bid from those bidders that meet the threshold quality and financial standards. CMS will accept the five lowest qualified

bidders but will not accept any vendor whose composite bid exceeds 106 percent of ASP. The bids for some drugs may be higher than 106 percent of ASP, but the weighted average for all drugs cannot be.

The statute requires that the Medicare payment amount for a given drug be the same for all vendors, even if their bids differed. The Medicare payment amount will therefore be based on the median price bid by the winning bidders, and this median bid will be updated by an inflation factor to set the actual Medicare payment amount. Composite bids for 2006 cannot exceed 106 percent of the ASP for the second quarter of 2005. The actual payment amount for 2006, however, will be determined by increasing the median bid for each drug by the projected increase in the producer price index for pharmaceuticals between the second quarter of 2005 and the midpoint of 2006. As a result, the 2006 payment amount to a vendor for a drug may be higher or lower than 106 percent of the drug's ASP in 2006.

For drugs that have been introduced during and after 2004, and for which there are established prices under the ASP system, CMS is creating a separate drug category for bidding purposes. Vendors will be required to include bids for these drugs, but the bids will not be included in the "composite bid" because there is inadequate utilization data with which to weight the bid for these drugs. Instead, the bids for these drugs must individually be at or below 106 percent of ASP.

### **Adjustments in Payments to Vendors**

Under the statute, contracts with vendors are for three years. Each vendor must annually report to CMS its acquisition cost for each drug, and based on those costs CMS will adjust the payment rates for years 2 and 3 of the contract. To determine the amount of the payment adjustment, CMS will adjust the bid amount that the vendor originally submitted by the percentage change in its acquisition cost. When the bids have been adjusted in this manner, new Medicare payment amounts will be calculated based on the medians of the adjusted bids.

For those drugs introduced too late to be included in the bidding process, including those drugs introduced during the second or third year of a vendor's contract, the vendor will have the option to add such new drugs to the vendor's CAP list as they are introduced. CMS will establish a payment rate to the vendor at 106 percent of the new drug's ASP. The vendor, however, can choose, for the entire three-year period of its contract, not to supply drugs that it did not bid on. If the vendor chooses not to furnish new drugs, the physician participating in the CAP will be able to order the drug directly and receive payment under the ASP system.

Ordinarily, Medicare will adjust payments to the vendors only annually. Medicare will adjust payment amounts quarterly, however, to reflect introduction of a new drug, expiration of a drug patent, substitution of a drug for a drug withdrawn from the market, or a material shortage that results in a significant price increase. Such adjustments will include calculating appropriate payments for new drugs.

### **Annual Election Process**



Physicians will elect annually whether to obtain their drugs under the CAP or instead continue to purchase them and seek reimbursement. Physicians electing the CAP will be required to agree to:

- Share information with the vendor to facilitate the collection of the deductible and coinsurance.
- Promptly file claims.
- Pursue claims that are denied for lack of medical necessity.
- Notify the vendor when a drug is not administered.
- Maintain an inventory record for each CAP drug.
- Comply with the rules on emergency drug replacement and on seeking ASP-based reimbursement for medically required formulations different from those offered by the vendor.

Physicians who fail to comply with the rules could be excluded from the CAP.

The annual CAP election period will run from October 1 to November 15 each year. Physicians will decide during that period whether they want to enroll in the CAP and, if so, they will select their vendor. Group practices must enroll or not enroll as an entire group. By October 1, 2005, CMS will make available on its Internet site a directory of the CAP vendors and the NDC numbers of the drugs each vendor will be providing. The CAP election form can be downloaded, completed, and returned to the physician's local carrier.

Under certain circumstances, physicians will have the option to choose a different vendor or "opt out" of the CAP outside of the annual election process. Such circumstances would include: (i) where the vendor ceases to participate in the CAP; (ii) where an individual physician leaves a group practice that was participating in the CAP; or (iii) where the vendor refuses to ship drugs to the physician on behalf of a particular beneficiary.

### **Beneficiary Education**

Physicians who enroll in the CAP will be required to provide a CMS fact sheet to each Medicare beneficiary during the beneficiary's first visit to the office after the physician has enrolled in the CAP. Physicians can add information specific to the patient.

### **RESPONSES TO ASCO'S COMMENTS**

*Comment: The CAP should be made available nationwide in 2006 for all drugs.*

Although CMS chose not to include all drugs in the CAP during its implementation stage, the CAP will go into effect nationwide on January 1, 2006, for a large group of commonly prescribed drugs, not limited to oncology drugs or drugs used by a specific specialty.

*Comment: CMS should make explicit that vendors would be required to fill all orders. Vendors should also be prohibited from requiring patients to sign an advance beneficiary notice.*

The preamble to the final rule clarified that vendors must fill all orders received from physicians participating in the CAP, except that vendors may cease to fill orders for beneficiaries who have failed to pay any balance owed to the vendor within 45 days from the postmark date of the vendor's bill to the beneficiary. Vendors may also call the physician to discuss the order (if, e.g., the vendor believes the order is inconsistent with a local coverage determination) and/or may ask beneficiaries to sign an advance beneficiary notice prior to filling an order.

*Comment: Physicians, in ordering drugs, should not be required to provide "additional patient information," including date of birth, allergies, height, weight, and diagnosis code.*

CMS rejected this recommendation, stating that the vendor needed that information to appeal denied claims. However, to ease the burden of submitting orders, the physician must only submit such information on the first order for each patient and where the information has changed since the last order.

*Comment: For practices with more than one office, CMS should require 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.*

The preamble clarifies that a practice may specify multiple offices, and CMS has amended the proposed order form to include a space for shipping address. CMS also specified that practices may not transport drugs from one location to another once they have been ordered.

*Comment: CMS proposed that physicians be required to submit all claims for drug administration services within fourteen days of the date of service. ASCO suggested that this time limit be extended to thirty days after the date of service.*

The fourteen day requirement was retained, but the local carrier may grant exceptions in rare cases due to extenuating circumstances.

*Comment: The proposed rule contemplated that the physician specify an expected date of administration for each drug ordered. If the drug supplied by the vendor was not used on that date the physician would be required to notify the vendor and "reach an agreement on how to handle the unused drug, consistent with applicable State and Federal Law." ASCO noted three issues with this proposal: (i) it is difficult for physicians to predict the exact date on which drugs will be administered; (ii) it would be more practical for vendors, rather than physicians, to be responsible for tracking the dates of usage; and (iii) the process for disposing of unused drugs should be clarified.*

CMS agreed that it would be difficult for a physician to establish in advance the exact date of drug administration. Consequently, when specifying the expected date of administration, physicians will be allowed to provide vendors with a range of dates over a 7-day period.

ASCO's other comments were not addressed.

*Comment: CMS should provide physicians with a separate payment for administrative costs associated with obtaining drugs through the CAP.*

CMS addressed this comment, but chose not to adopt ASCO's proposal. CMS takes the position that physicians can evaluate any increased administrative burden against the benefits of the CAP when deciding whether to elect participation in the CAP.

*Comment: Vendors should be required to disclose any requirements for participating physicians to use particular hardware or software prior to the election period.*

This comment was not addressed.

*Comment: CMS should clarify physicians' responsibilities in the case of denied claims. Physicians' duty should be only to seek review by the carrier, and any 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 interim final rule extended appeal rights directly to the vendors. Physicians must reasonably cooperate with any vendor appeal.

*Comment: The process for resolution of beneficiary disputes should be made clear to beneficiaries.*

CMS stated that it shared the concern that beneficiaries receive proper information regarding dispute resolution. CMS is currently creating educational materials that would inform beneficiaries of their rights. All vendors will also be required to provide participating physicians with information on how beneficiaries can use the grievance process.

*Comment: The proposed rule does not set out a clear mechanism for resolution of disputes related to quality of service or beneficiary billing.*

This comment was not addressed.

*Comment: Vendors should be prohibited from opening drug containers prior to sending them to physicians.*

The interim final rule specifies that vendors must ship drugs unopened and in the manufacturer's packaging. Where the manufacturer's packaging contains multiple individual units (e.g., vial trays) the vendor may split the package into quantities appropriate for shipping.

*Comment: Physicians should be able to return damaged or suspicious drugs.*

Physicians may return a drug to the vendor where the physician has reason to question the drug's integrity. The vendor should then follow-up with the physician regarding why the physician questioned the drug's integrity.

*Comment: Vendors should be required to carry substantial liability insurance.*

This comment was not addressed.

*Comment: Vendors should be required to indemnify physicians for any losses caused by the vendor.*

According to CMS, this request is beyond the scope of the rules.

*Comment: CMS should audit compliance with and enforce the standards of the CAP.*

This comment was not specifically addressed.

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

CMS stated that vendors would need to comply with HIPAA privacy requirements with respect to patient-specific data but did not address the issue of physician-specific data.

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

This comment was not addressed.

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

The interim final rule clarified how the CAP would deal with new drugs. The vendor will have the option to add new drugs to the CAP list as they are introduced. If the vendor chooses not to furnish such drugs, the physician participating in the CAP will be able to order the drug directly and receive payment under the ASP system

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

The interim final rule sets forth certain circumstances where a physician will have the option to switch vendors or "opt out" of the CAP outside of the annual selection process. One such circumstance is where the CAP vendor is terminated from the program mid-year.

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



Those options would be available if CMS terminates the vendor. Beyond that situation, this comment was not addressed.

*Comment: CMS should not require physicians to furnish a CMS-created fact sheet describing the CAP to each patient. Rather, such issues should be handled on a patient-by-patient basis.*

CMS chose not to adopt this suggestion. Instead, each CAP-participating physician will be required to provide a fact sheet to each beneficiary on the beneficiary's first visit following the physician's election of the CAP.