Summary of the Proposed Competitive Acquisition Program (CAP) Rule

The Centers for Medicare and Medicaid Services (CMS) has issued proposed rules to implement a competitive acquisition program ("CAP") for Part B drugs beginning January 1, 2006. The proposal will be published in the Federal Register on March 4, 2005, and comments must be submitted by April 26, 2005.

Under the CAP, physicians may elect annually to receive all of the drugs in a specified category that will be administered to Medicare patients from a contract vendor selected by CMS. The contractor will be responsible for billing Medicare and the patient for the drugs.

Drug Subject to the CAP in 2006

CMS is proposing to limit the CAP to drugs administered in physician offices, not drugs administered through durable medical equipment or the few oral drugs covered under Part B. CMS has proposed several options for phasing in the CAP. Under one option, the drugs initially subject to the CAP would be drugs typically used by oncologists. Other drugs would be added over the next few years. A second option would be to start with specialties that are not heavy users of Part B drugs. A third option would be to eliminate the phase-in and cover all incident-to drugs. CMS does not express a preference for any of the options.

The proposal includes an example of how CMS would select the drugs that the vendors would have to supply. Using the 2003 Medicare claims data, CMS identified all of the drugs used by medical oncologists for which there were at least 100 claims and for which the allowed charges were greater than $10,000. Vendors would be required to supply a drug for each of the HCPCS J-codes so identified, but in the case of multiple-source drugs, they would only be required to supply one manufacturer's version. Vendors would be required to inform physicians during the election period as to which manufacturer's products they would be dispensing in the case of multiple-source drugs.

Process for Ordering Drugs and Submitting Claims

Drug ordering and claims processing would proceed as follows:

The physician would order drugs from the vendor. Information that would be included in the order besides the obvious would be "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."

- The physician could order an entire course of therapy at the same time. The vendor, however, could divide the order into "appropriately spaced shipments."

- The vendor would send the drugs to the physician with an identifying prescription number. 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. If the vendor split an order into multiple shipments, the vendor would create a different prescription number for each shipment.

- 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 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. 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.

- CMS is asking for comments on whether Medicare should make a partial payment to the vendor if the physician delays in submitting claims to its local carrier. Specifically, one possibility would be for Medicare to make a partial payment to the vendor if the physician has not submitted a claim within 28 days of the anticipated date of administration of the drugs involved. If it did make a partial payment, CMS contemplates recouping the payment if the physician does not file a claim within 90 days. A partial payment would not permit the vendor to bill the patient for coinsurance, which is permitted only after a claim for administration of the drug has been submitted.

In emergency situations, a physician could use a drug from his 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.

Although a physician who agrees to obtain drugs from a vendor must ordinarily obtain all drugs for Medicare patients from the vendor, CMS is proposing an exception to allow physicians to purchase a drug and seek reimbursement under the ASP-based methodology if medical necessity requires a specific formulation to be administered to a patient and the vendor does not furnish that formulation. A special modifier would be required on the claim, which would be subject to post-payment review to determine whether the specific formulation was medically necessary. The physician would also use the ASP-based reimbursement method for drugs that are not included in the CAP.

CMS is not proposing to make any payment to physicians for administrative work. CMS believes that the clerical and inventory expenses related to use of the CAP are no greater than for ASP-based reimbursement and that the payment for such work is bundled into the payment for the drug administration codes.

If drug supplied by a vendor is not administered "on the expected date of administration," 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.

In the case of claims that are denied for medical necessity or other reasons, only the physician will have appeal rights. 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" (as to the amount of which CMS seeks comment). 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.

Selection of Vendors

The statute permits CMS to establish regional competitive acquisition areas so that vendors do not have to offer national service. The proposal identifies several options that CMS is considering: a national competitive acquisition area, regional areas (CMS suggests the possibility of four areas), and single-state areas. CMS does not indicate a preference for one of the options. CMS says that, in response to a request for information it issued last December, it has received 15 responses from companies interested in being vendors, most on a national basis.

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 proposed. Prospective vendors would have to submit information to CMS about their financial capability. Vendors would have to have compliance plans and codes of conduct.

Vendors would be 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 would have the same options.

Vendors would be required to ship drugs at least five days a week. Routine shipments would be required to occur within one to two business days. Emergency orders received by 3 p.m. would need to be delivered the next day.

Vendor Bidding Process

Vendors would submit bids that specify a price for each drug by J-code. To evaluate the bids, CMS would weight the price bid for each drug by the previous year's volume of claims for that drug, resulting in a "composite bid" that will be used for comparison purposes. CMS has not yet determined how to weight new drugs in this process. Winning bidders will be selected based on the composite bid from those bidders that meet the threshold quality and financial standards.

CMS would accept the five lowest qualified bidders but would not accept any vendor whose composite bid exceeded 106 percent of ASP. The statute requires that the Medicare payment amount for a given drug be the same for all vendors in a competitive acquisition area, even if their bids differed. CMS is proposing to set the Medicare payment amount at the median price bid by the winning bidders.

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. CMS proposes that it may establish a threshold amount, such as a 5 percent increase or decrease in price paid by the vendor, below which it would ignore the change. For price

increases above or below that threshold amount, CMS would adjust the bid amount that the vendor originally submitted by the percentage change in its acquisition cost. When the bids had been adjusted in this manner, new Medicare payment amounts would be calculated based on the medians of the adjusted bids.

Medicare would adjust the payments quarterly, rather than annually, to reflect introduction of a new drug, expiration of a drug patent, or a material shortage that results in a significant price increase.

Annual Election Process

Physicians would elect annually whether to obtain all of their drugs under the CAP or instead continue to purchase them and seek reimbursement. Physicians electing the CAP would 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 would run from October 1 to November 15 each year. Physicians would decide during that period whether they wanted to enroll in the CAP and, if so, they would select their vendor. Group practices must enroll or not enroll as an entire group.