## LEGAL CORNER

## **Medicare's Competitive Acquisition Program**

Legal Implications

by Karen S. Lovitch, Esq., and Stephen R. Bentfield, Esq.

n August 2005, CMS suspended the Competitive Acquisition Program (CAP) vendor bidding process to allow more time to review public comments and to implement changes to the bidding process. One month later, in September 2005, the agency published a clarification regarding the initial election period and certain technical errors in the Interim Rule.<sup>1</sup> At press time, CMS had not yet announced a publication date for the Final Rule; however, it now expects that the initial physician CAP election period will occur in Spring 2006 and that the CAP program will begin in July 2006. In effect, physicians will have two enrollment periods in 2006: the initial enrollment period in Spring 2006 (for CAP participation in 2006) and the annual election period starting October 1, 2006 (for CAP participation in 2007). This one-time situation may give physicians who are undecided about CAP participation a chance to observe how the program works in 2006 before signing up during the election period for 2007.

Because CMS still plans on restricting a physician's ability to select a Vendor outside of the CAP selection process or to opt out of the CAP for the remainder of the annual election period, physicians must know the limited options available for resolving enrollment-related matters and grievances with CAP vendors. Specifically, a physician may take such actions only if:

- The selected approved Vendor ceases participation in the CAP.
- The physician leaves a group practice that is participating in the CAP.
- The participating CAP physician relocates to another competitive acquisition area.
- Other "exigent circumstances," as defined by CMS. (Note: To date, CMS has found only the initial CAP implementation to constitute an "exigent circumstance," thereby

allowing for a physician election period at a time other than the regular, annual election period.)

In addition, if the Vendor refuses to ship to the participating physician based on a beneficiary's failure to pay his or her outstanding cost-sharing amounts, the physician can withdraw from the CAP for the remainder of the year upon immediate notice to CMS and the approved Vendor. (Note: the Interim Rule requires the Vendor to undertake certain actions before it may refuse to make further shipments to a participating physician on behalf of a beneficiary.)

A physician who does not choose to participate during the CAP election period must wait until the following year to sign up, unless the physician did not enroll because he or she is new to the Medicare program. In this instance, physicians may elect to participate in the CAP within 90 days of the activation of their billing number.

The Interim Rule does not provide any other means for physicians to change their election choice. Notably, the rule *does not* permit a change in election if a physician finds that participating in the CAP is a financial burden or if a physician develops serious concerns about the Vendor's customer service. Instead, CMS stated that it has built in safeguards to address operational issues; participating physicians may use these safeguards if they are unsatisfied with their Vendor's performance. In addition to communicating program issues to their local carrier, participating physicians may also use the dispute resolution process to address such issues.

CMS regulations require each Vendor to establish a grievance process. And the agency expects that quality and service issues will be resolved through these grievance processes, which could potentially result in the termination of the Vendor's contract for serious quality or service issues.

If the issue is not resolved to the physician's satisfaction, an additional level of review will be available through an alternative dispute resolution process administered by a carrier designated by CMS. Through this process, CMS's designated carrier will gather information as appropriate from the local carrier, the physician, the beneficiary, and the Vendor and make recommendations to CMS on whether the Vendor has met service and quality obligations. CMS's designated carrier ultimately will issue a written decision, including numbered findings of fact. CMS would then review the recommendation and gather additional information if necessary before deciding whether to terminate the Vendor. In addition, Vendors will use this process to review suspensions or terminations from the CAP.

Although CMS has expanded its grievance and dispute resolution process, it remains to be seen whether this will be an effective method for resolving physician complaints regarding service and quality related to the CAP program. For example, because there are no applicable statutory or regulatory deadlines for rendering decisions, this process could be lengthy and therefore offer little recourse. Bottom line: the CAP is an optional program requiring a minimum one-year commitment so physicians must carefully consider their choices before deciding to participate. I

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## **References**

<sup>1</sup>See Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B: Interpretation and Correction. 70 Fed. Reg. 52,930 (Sept. 6, 2005).