Section 303(d) of the 2003 Medicare Modernization Act mandated creation of a drug Competitive Acquisition Program (CAP) for Part B drugs and biologicals administered “incident to” a physician’s service. CMS’s rationale for the CAP is shown in Inset 1. The intended January 1, 2006, launch date was delayed in order to allow CMS to reconsider key program provisions.1

**Anticipated Timeline and Events for CAP**

- Several prospective CAP vendors submitted applications to CMS by the December 22, 2005, deadline.
- Announcement of CAP vendor awards was expected by early March 2006.
- A minimum of 2, and up to 5, awarded vendors must sign CMS contracts in order for CAP implementation to proceed.2
- CAP is voluntary for physicians. The first step in CAP implementation will be 2006 physician election of CAP versus “buy-and-bill,” scheduled to commence in early April 2006.4
- Launch of CAP is projected for the first week of July 2006.4
- In October, physician CAP versus buy-and-bill election will commence for the 2007 calendar year.3
- Six months after CAP launch (approximately December 31, 2006) will mark approved CAP vendors’ first opportunity to terminate CMS contracts (the author’s extrapolation from original terms of vendor contract).8

**What Impact Will CAP Have on Stakeholders?**

**CAP-electing physicians.** In its proposed rule, CMS cites benefits that will accrue to CAP-electing physicians. However, CMS has not acknowledged the additional administrative burden of CAP for these physicians, which, in this author’s view, constitutes offsetting harms, including obligations to separately track drugs and biologicals shipped to the physician office but discontinued before patient administration; cooperate with the CAP vendor in disposition of partially used vials of drug; submit drug claims within 14 days of administration; and participate in grievance procedures initiated by the CAP vendor.8

**Patients served by CAP-electing physicians.** Patients are potentially impacted both clinically and administratively. Patients may be impacted clinically by potential treatment delay because nonemergent drugs and biologicals must be ordered from the CAP vendor for each patient, not taken from physician office drug inventory. Patients may be impacted administratively in that their cost-share obligation will be to the CAP vendor, not to the treating physician. If patients are unable to meet their cost-share obligations, then, according to regulation, CAP vendors must inform them of the availability of 1, 2, or all 3 of the following forms of assistance: (1) referral to a bona fide and independent charitable organization, (2) implementation of a reasonable payment plan, and/or (3) a full or partial waiver of the cost-sharing amount. If patients’ cost-share obligation remains unpaid after a specified time period after referral, and if the CAP vendor does not make available other assistance alternatives, then the CAP vendor may withhold further shipments of drugs and biologicals for that patient.9

**CAP vendors.** CAP has been designated average-selling-price (ASP) exempt (see Inset 2 for the definition and calculation of ASP) for the first 3 years of the program.10 Regulations provide CAP vendors with the ability to specify (select) manufacturers within multisource Healthcare Common Procedure Coding System (HCPCS) categories. However, regulations provide no basis for vendor leverage in product selection within single-source HCPCS categories. Furthermore, regulations

---

**Inset 1**

“Beginning January 1, 2006, physicians will have a choice between (1) obtaining these drugs from entities selected to participate in the CAP in a competitive bidding process, or (2) acquiring and billing for competitively biddable Part B covered drugs under the ASP drug payment methodology. The provisions for acquiring and billing for drugs through this new system, as well as additional information about this new drug payment system, are described in this proposed rule. The competitive acquisition program may provide opportunities for Federal savings to the extent that aggregate bid prices are less than 106 percent of ASP.

“However, the CAP has other purposes than the potential to achieve savings. The competitive acquisition program provides opportunities for physicians who do not wish to be in the business of drug acquisition. Engaging in drug acquisition may require physicians to bear financial burdens such as employing working capital and bearing financial risk in the event of nonpayment for drugs. The CAP is designated to reduce this financial burden for physicians. In addition, physicians who furnish drugs often cite the burden of collecting coinsurance on drugs and that drug coinsurance can represent large amounts for a beneficiary and physician. The Competitive Acquisition Program eliminates the need for physicians to collect coinsurance on CAP drugs from Medicare beneficiaries.”3

---

**Inset 2**

“Section 303(c) of the Medicare Modernization Act (MMA) revised the drug payment methodology by creating a new pricing system based on a drug’s ASP [average selling price]. Effective January 2005, Medicare pays for the vast majority of Part B-covered drugs and biologicals using a drug payment methodology based on the ASP. In accordance with section 1847A of the Social Security Act (the Act), manufacturers submit the ASP data for their products to us on a quarterly basis. These data include the manufacturer’s total sales (in dollars) and number of units of a drug to all purchasers in the United States in a calendar quarter (excluding certain sales exempted by statute), with limited exceptions. The sales price is net of discounts such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927 of the Act). The Medicare payment rate is based on 106 percent of the ASP, less applicable deductible and coinsurance, and is updated quarterly.”10
This conclusion is driven by the following considerations. First, compared with the same products paid for under buy-and-bill through CAP—and may even experience a net cost increase—believe that CMS is unlikely to achieve additional savings reimbursement for Part B drugs and biologicals, this author considers excess funding through implementation of ASP + 6% vendor financial experience. Having removed what it discussed previously, will not be the main drivers of CAP available with respect to multisource products, which, as implies—and program success is indeed dependent upon—will drive CAP vendor financial results—not less-expensive multisource products. This is due to a sharply limited upside gross defined by 6% of product’s ASP balanced against significant per-prescription supply costs, projected unbilled waste, projected CMS claims denials, and projected patient bad debt on cost-share responsibilities.

Manufacturers of CAP drugs and biologicals. CAP vendors’ limited supply role, coupled with lack of influence over choice or use of single-source products, provides vendors no contracting leverage with manufacturers of these products. In addition, this writer anticipates that few physicians will elect CAP in 2006, minimizing manufacturers’ CAP market share exposure. Together, these factors limit brand manufacturers’ interest in CAP. The situation is quite different with respect to multisource products: CAP physicians must submit “prescriptions” to CAP vendors at an HCPCS code level,11 without specifying manufacturer, vial size, or packaging. In response, CAP vendors will supply only those National Drug Code (NDC) numbers with respect to which they are contracted with CMS. In other words, it is likely that CAP vendors will use their significant negotiating leverage with manufacturers of multisource products to generate preferred supplier arrangements tied to favorable pricing relative to ASP.

CMS. In addition to competition between CAP vendors for CMS contracts, the term “competitive acquisition” also implies—and program success is indeed dependent upon—CAP vendors’ negotiating leverage in the acquisition of drugs and biologicals. Unfortunately, negotiating leverage is only available with respect to multisource products, which, as discussed previously, will not be the main drivers of CAP vendor financial experience. Having removed what it considers excess funding through implementation of ASP + 6% reimbursement for Part B drugs and biologicals, this author believes that CMS is unlikely to achieve additional savings through CAP—and may even experience a net cost increase compared with the same products paid for under buy-and-bill. This conclusion is driven by the following considerations. First, anticipating difficulty in negotiating favorable product acquisition cost with brand manufacturers, prospective CAP vendors are not likely to have bid significantly below the ASP + 6% upper limit permitted by CMS. Second, CMS is likely to incur new incremental cost to fund CAPs administrative structure and services.

Elan Rubinstein, PharmD, MPH
Principal
EB Rubinstein Associates
371 Southridge Dr.
Oak Park, CA 91377
(818) 991-6995
ebra@pacbell.net

DISCLOSURE
The author discloses that he has provided advice to a company in preparation of its CAP vendor application to CMS, performed its HCPCS-level CAP financial analysis, and assisted in development of its CAP business strategy. He has also consulted with several biotechnical manufacturers regarding the pros and cons of contracting with CAP vendors.

REFERENCES
5. Medicare Program. Revisions to payment policies under the physician fee schedule for calendar year 2006 and certain provisions related to the competitive acquisition program of outpatient drugs and biologicals under Part B. CMS 1502-FC, CMS 1325-F. Federal Register. Vol. 70. No. 223:70257 (November 21, 2005).
9. CMS 1325-IFC. Federal Register. Vol. 70. No. 128:39096, section 414.914 (g) (1, 2, 3) (July 6, 2005).