CMS Issues Proposed Rule for the Competitive Acquisition Program

The Centers for Medicare & Medicaid Services ("CMS") has issued a proposed rule to implement a competitive acquisition program ("CAP") for certain drugs covered under Medicare Part B.¹ Beginning January 1, 2006, physicians will have a choice between: (1) obtaining these drugs from entities selected to participate in the CAP; or (2) acquiring and billing for the drugs under the average sales price ("ASP") drug payment methodology. According to CMS, the CAP could result in savings for the Medicare program and could reduce the financial burden on physicians who administer Part B drugs.

Drugs Subject to the CAP

- **Competitively Biddable Drugs and Biologicals** - The CAP relates only to drugs covered under Medicare Part B. The CAP statutory definition of “competitively biddable drugs and biologicals” includes most drugs paid under Part B, such as drugs furnished “incident to” a physician’s service, and not otherwise paid on a cost-based or a prospective payment basis.² Drugs specifically excluded from the CAP by statute include Part B covered vaccines, drugs infused through a covered item of durable medical equipment ("DME"), and blood and blood products (not including clotting factor and intravenous immune globulin).³ CMS has proposed to define competitively biddable CAP drugs as only those furnished incident to a physician's service, despite the potentially broader statutory definition.⁴ The agency’s primary rationale for this approach is that the MMA establishes the physician as the key decision-maker on whether the drugs will be acquired through the CAP process.

- **Drug Categories** - CMS identified, and is seeking comment on, two options for establishing covered drug categories: (1) covering all drugs furnished incident to a physician’s services; or (2) phasing in CAP drugs by physician specialty.⁵ If CMS were to phase in the CAP by physician specialty, it could either begin with drugs furnished by oncologists, which represent the largest portion of expenditures for physician-administered drugs under Medicare, or begin with specialties that use fewer Part B covered drugs.⁶ Even if CMS decides to phase in the CAP by physician specialty, all physicians (including non-specialists) who administer the drugs selected would be eligible to elect to obtain these drugs through the CAP.

---

¹ 70 Fed. Reg. 10745 (Mar. 4, 2005). The proposed rule was issued pursuant to section 303(d) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA").

² MMA § 303(d); Social Security Act ("SSA") § 1847B.

³ Id.

⁴ Proposed 42 C.F.R. § 414.902.

⁵ 70 Fed. Reg. at 10750.

⁶ Id.
The categories established for selection by physicians will be the same categories open for bids by potential vendors. For example, if a category embracing all drugs typically administered by oncologists is established, vendors would bid on all of the Healthcare Common Procedure Coding System (“HCPCS”) codes contained in the category, and a physician who elects to participate in the CAP would be electing to acquire that category from the vendor. Vendors would not be able to submit bids on only some of the HCPCS codes in the category, and physicians would not be able to elect to acquire only some of the HCPCS codes in the category from the vendor.\footnote{id at 10751.}

In the case of multiple source drugs, a vendor would not be required to provide every National Drug Code (“NDC”) associated with a HCPCS code,\footnote{proposed 42 c.f.r. § 414.908(d).} but the vendor would be required to inform CMS and the potential physician participants of the specific NDCs it would provide. Although CMS has the authority under the MMA to exclude competitively biddable drugs and biologicals from the CAP if it finds that inclusion would not result in significant savings or would have an adverse impact on access to those drugs, CMS is not exercising that authority at this time.\footnote{ss a § 1847b(a)(1)(B); proposed 42 c.f.r. § 414.906(b); 70 fed. reg. at 10751.}

**Competitive Acquisition Areas**

A competitive acquisition area for purposes of the CAP is defined as “an appropriate geographic region established by the Secretary.”\footnote{ss a § 1847b(a)(2)(C); proposed 42 c.f.r. § 414.902.} CMS may limit, but not below two, the number of qualified entities that are awarded contracts for any competitively biddable drug category and competitive acquisition area.\footnote{ss a § 1847b(b)(3).} CMS will consider the following factors in defining competitive acquisition areas: how promptly physicians need drugs provided to their practices; current geographic service areas of vendors; density of distribution centers; distances drugs and biologicals are typically shipped; costs associated with shipping and handling; the relationship between vendors and their suppliers; and state licensing laws that may preclude vendors from operating in a particular state.\footnote{70 fed. reg. at 10752.}

CMS believes that it has broad authority to phase in the CAP in geographical areas and has identified three options for defining competitive acquisition areas: a national acquisition area; regional acquisition areas; and statewide acquisition areas.\footnote{Id.}

**Prescribing Under the CAP**

In describing the operation of the CAP, CMS emphasizes that the program is not intended to change a physician’s flexibility to choose whether to write a prescription for a single treatment or a course of treatments. Physicians will not be required to submit a prescription or order to the vendor for individual treatments of a drug.

---

7 Id. at 10751.
8 Proposed 42 C.F.R. § 414.908(d).
9 SSA § 1847B(a)(1)(B); proposed 42 C.F.R. § 414.906(b); 70 Fed. Reg. at 10751.
10 SSA § 1847B(a)(2)(C); proposed 42 C.F.R. § 414.902.
11 SSA § 1847B(b)(3).
12 70 Fed. Reg. at 10752.
13 Id.
CMS is proposing to allow a physician to obtain a drug under the ASP methodology in “furnish as written” cases when “medical necessity” requires that a specific formulation of a drug be furnished to the patient. When a vendor has not been contracted to furnish a specific formulation of a drug or a product defined by the product’s NDC number, and the specified product is “medically necessary,” the physician could purchase the product for the beneficiary from a source other than the CAP vendor and bill Medicare using the ASP methodology.  

CMS is proposing that, for drugs that are not included in the CAP and for drug categories that the physician does not elect to obtain from the CAP, the physician would continue to bill and be paid under the ASP methodology. CMS seeks comments on whether physicians should be required to obtain all categories of drugs that a particular CAP vendor provides from the vendor, or whether physicians should be allowed to choose the categories of drugs that they will obtain from the vendor.  

**Contracting Process**

- **Quality and Financial Requirements** - CMS would evaluate bids from potential vendors to determine if they meet quality, service, financial performance, solvency, and dispute resolution standards. Vendors would be required to have adequate administrative arrangements, experience, capabilities, licensure, and business integrity. Each CAP vendor would be required to develop and maintain a written compliance plan to prevent fraud, waste, and abuse and to adhere to a code of conduct developed to avoid conflicts of interest and the appearance of impropriety. CAP vendors would be considered Medicare Part B suppliers for payment purposes.

- **Bid Pricing** - Bidders would be permitted to submit the same bid price for all acquisition areas in which they wish to compete, or to submit separate bid prices for each area. The submitted bid price would be required to include all costs related to the delivery of the drug to the selecting physician, the costs of dispensing the drug, and management fees. Costs related to the administration of the drug or wastage, spillage, or spoilage could not be included in the submitted bid.

CMS is proposing to establish a “composite bid” constructed from the bid prices for the individual drugs in the CAP category. The composite bid would be constructed by weighing each HCPCS bid by the HCPCS code’s share of volume, measured in HCPCS units of drugs, in a particular drug category during the prior year. Within each category, the drug weights would sum to one. Based on data availability, the volume data used for bids in the first CAP bidding cycle would be from 2004, since bidding is anticipated to occur in the middle of 2005. As illustrated by the composite bid example provided by CMS, it would be possible for

---

14 Proposed 42 C.F.R. § 414.906(c)(2)(ii).
15 70 Fed. Reg. at 10755.
16 Proposed 42 C.F.R. §§ 414.908(b), 414.914.
17 Id. at § 414.910(c).
18 70 Fed. Reg. at 10762-64.
19 Id. at 10762.
a bidder to be the low bidder on more individual drugs than other bidders but still have the highest composite bid.

- **Selection** - CMS is proposing a two-step bidder selection process. First, all bidders would be required to meet the quality and financial requirements. Second, CMS would evaluate the composite bids from the bidders that meet those requirements. CMS proposes to select up to the five lowest bidders for each drug category in each area. CMS would not select any bid for a category that is higher than 106% of the weighted ASP for the drugs in that category. (This would not prevent the CAP vendor from proposing prices on single drugs that are greater than 106% of that drug’s ASP.)

- **Single Drug Price** - CMS is proposing to establish a single price for each drug in a competitive acquisition area based on the median bid of the winning bidders. The qualified vendors would be informed of the established CAP price before signing the contract with CMS.

CMS is proposing to set the price for a new drug that is properly assigned to a category established under the CAP and for which the issuance of a new HCPCS code is required at the price established for that drug under the ASP payment methodology for new drugs.

Contracts for the acquisition of competitively biddable drugs under the CAP must be for a period of three years. To set the price for each drug in a category for the second and third years of the contract, vendors would be required annually to provide CMS with the “reasonable, net acquisition costs” for each category. CMS considers “reasonable, net acquisition costs” to be those costs actually incurred by the vendor that are necessary and proper for acquiring the drugs that the vendor is obligated to provide under a CAP contract. Actual acquisition costs would be net of all discounts and rebates provided by the vendor’s own suppliers. CMS would require full disclosure of the vendor’s acquisition costs for drugs in the CAP contract, which would include the vendor’s purchases of these drugs from all manufacturers and the total number of units purchased from each manufacturer. The vendor would be required to submit full documentation of all discounts that result in a reduction of actual cost to the vendor.

CMS is considering establishing a threshold percentage change in net acquisition cost that would be used to determine whether there should be an adjustment (either upward or downward) to the single prices for the drugs in that category. If the change in a vendor’s costs were to meet the threshold, CMS would use a two-step process to recalculate the single drug

---

20 Proposed 42 C.F.R. § 414.908(b).
21 70 Fed. Reg. at 10763.
22 Id. at 10764. If there were four winning bidders for a drug category in an area, CMS would use the average of the two bid prices in the middle to set the single price. Similarly, if there were two winning bidders, CMS would use the average to set the single price.
23 Id.
24 Proposed 42 C.F.R. § 414.906(c).
prices for that category. First, CMS would adjust the bid price that the vendor originally submitted by the percentage change indicated in the information that the vendor disclosed. Second, CMS would recalculate the single price for the drug as the median of the adjusted bid prices.\textsuperscript{26}

CMS would make more frequent adjustments, but not more than quarterly, when a new drug is introduced, when a drug patent expires, and when there is a material shortage that results in a significant price increase for a drug.\textsuperscript{27} CMS is considering restricting the circumstances under which it would make adjustments to account for shortages to those in which there is a declared public health emergency.\textsuperscript{28}

**Implications for Pharmaceutical Manufacturers**

Comments on the proposed CAP regulation must be submitted to CMS by April 26, 2005. In determining whether or not to comment, pharmaceutical manufacturers may want to consider the following potential implications of the CAP proposal.

- **Program Scope and Physician Participation** - Two main factors will determine the significance of the CAP during its first few years of implementation: (1) CMS's final decision on the scope of drugs to be included in the CAP; and (2) the number of affected physicians who make the annual election to obtain drugs through the CAP instead of acquiring and billing for the drugs under the ASP payment system. Thus, the CAP could be, in effect, a small-scale pilot program or a major driver of Part B drug reimbursement affecting 80% or more of drugs covered under Part B. A dramatic shift in the locus of Part B drug purchasing/billing from the physicians' office to a select few “specialty pharmacy” CAP vendors could have major implications on manufacturers’ discounting and marketing practices.

- **Geography of CAP Areas** - If CMS establishes a national competitive service area and maintains its proposed policy of selecting no more than the lowest five bidders to be CAP vendors, the winning bidders would have substantial potential negotiating leverage. A national competitive region or designation of a few large regions would also create a marked difference between the competitive marketplace for Part B drugs and the 34-region marketplace for Part D plans.

- **Price Negotiations with CAP Vendors** - The ability of CAP vendors to negotiate deep discounts with manufacturers would also be influenced by other CAP design features and by the existing ASP system. While CAP vendors would not be required to provide all of the NDCs for a particular drug, they would not have the same flexibility that Part D plans have to establish formularies. Since any price concessions granted to CAP vendors would be reflected in the calculation of ASP, manufacturers may be unwilling to provide significantly deeper discounts than those offered to other purchasers. On the other hand, the single CAP price paid to a CAP vendor would be fixed for at least one year, which would likely drive potential

\textsuperscript{26} Id. at 10765.

\textsuperscript{27} Proposed 42 C.F.R. § 414.906(c).

\textsuperscript{28} 70 Fed. Reg. at 10765.
CAP vendors to seek some kind of financial protection against drug price increases that may occur during the year.

- **Acquisition Cost Reporting** - While the stated objective of the acquisition cost reporting process outlined in the proposed rule is to provide data to support subsequent-year increases in the single CAP price payable by Medicare, it could lay the groundwork for future uses of actual acquisition cost payment methodologies for drugs provided in other parts of Medicare, such as the Part D drug benefit.

- **Implications for Future Part B and Part D Payment Policies** - Several other features of the CAP -- the size of competitive regions, limitation of prices to the weighed average of a price benchmark, and limiting the number of vendors to a handful of “lowest bidders” -- may be of interest to policy-makers interested in changing Part D. Also, the success or failure of the CAP in containing drug prices could be an important factor as Congress considers whether to move Medicare coverage of physician-administered drugs from Part B to Part D of the program.

---

This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions concerning the material discussed in this client alert, please call the following members of our Health Care Reimbursement practice group:

<table>
<thead>
<tr>
<th>Name</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anna Kraus</td>
<td>202.662.5320</td>
<td><a href="mailto:akraus@cov.com">akraus@cov.com</a></td>
</tr>
<tr>
<td>Alan Spielman*</td>
<td>202.662.5852</td>
<td><a href="mailto:aspielman@cov.com">aspielman@cov.com</a></td>
</tr>
<tr>
<td>Ruth Miller</td>
<td>202.662.5363</td>
<td><a href="mailto:rmiller@cov.com">rmiller@cov.com</a></td>
</tr>
<tr>
<td>Ellen Flannery</td>
<td>202.662.5484</td>
<td><a href="mailto:eflannery@cov.com">eflannery@cov.com</a></td>
</tr>
<tr>
<td>Richard Kingham</td>
<td>44.(0)20.7067.2018</td>
<td><a href="mailto:rkingham@cov.com">rkingham@cov.com</a></td>
</tr>
<tr>
<td>Michael Labson</td>
<td>202.662.5220</td>
<td><a href="mailto:mlabson@cov.com">mlabson@cov.com</a></td>
</tr>
<tr>
<td>Ethan Posner</td>
<td>202.662.5317</td>
<td><a href="mailto:eposner@cov.com">eposner@cov.com</a></td>
</tr>
<tr>
<td>Peter Safir</td>
<td>202.662.5162</td>
<td><a href="mailto:psafir@cov.com">psafir@cov.com</a></td>
</tr>
</tbody>
</table>

* Senior Advisor for Health Care Reimbursement Policy (non-lawyer)

Covington & Burling is one of the world’s preeminent law firms known for handling sensitive and important client matters. This alert is intended to bring breaking developments to our clients and other interested colleagues in areas of interest to them. Please send an email to unsubscribe@cov.com if you do not wish to receive future alerts.

© 2005 Covington & Burling. All rights reserved.