

Community Oncology Alliance

Dedicated to high quality, affordable, and accessible cancer care

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HAND-DELIVERED

April 26, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS – 1325-P, Comments on the Notice of Proposed Rulemaking for the
Competitive Acquisition of Outpatient Drugs and Biologicals under Part B

Dear Dr. McClellan:

The Community Oncology Alliance (COA) welcomes the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rules implementing provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) requiring establishment of a competitive acquisition program (CAP) for certain Medicare Part B drugs.

As you are well aware, COA represents the interests of community cancer clinics, where over 80% of Americans battling cancer are treated. COA was formed specifically to support and advocate for Medicare payment reform that is balanced, appropriate, and reflective of the realities of delivering modern-day cancer care.

Previously, we provided CMS with extensive comments regarding the impact of changes in the Medicare physician fee schedule and reimbursement methodology for Part B drugs on cancer treatment. We understand that CAP was a part of the same payment reform package and that CAP was intended to help, not hurt, community cancer clinics by reducing the financial burden of drug acquisition. We also understand that CMS did not create CAP, but is mandated by the MMA to implement it.

Regrettably, we have concluded that CMS' proposed design for CAP exacerbates CAP's statutory flaws.¹ The resulting program, conceptually and operationally, can best be described as, "bad medicine and bad economics." In terms of "bad medicine," CAP:

- Gives vendors, not oncologists, control over what drugs are available, when and how they will be delivered and deprives oncologists of the flexibility to modify treatments as medically necessary.

¹ The statute prohibits a CAP vendor from delivering drugs or biologicals to a selecting physician except upon receipt of a prescription, and the vendor's payment is conditioned upon the administration of the drug. 42 U.S.C. Section 1395w-3b. As a result, electing physicians will be required to maintain paper or electronic individual inventories of drugs and biologicals. Beyond the administrative burden, individual inventories create the potential for millions of dollars of "waste" from unused and unusable medications.

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April 26, 2005

- Once oncologists elect a CAP vendor, they will be locked-in to their contracts for a year, irrespective of vendors' performance.
- Gives vendors the responsibility for collecting patient co-payments and allows them to discontinue delivery of cancer drugs to oncology clinics for specific patients if co-payments are unpaid or uncollected. Putting CAP vendors between patients and their oncologists and nursing team creates unacceptable medical and legal risks to both patients and treating physicians.
- Forces patients to return for extra visits because ordering and resupply rules are too rigid. To a person fighting cancer, every second spent out of a cancer clinic living a normal, productive life is an extremely important part of the healing process.

Given Congress' timetable for CAP implementation, CMS has not had adequate time to consult with practicing community oncologists about the design of CAP. The concept outlined in the MMA may make sense in competitively bidding routine prescription drugs, but CAP simply ignores the reality of delivering complicated, chemotherapy regimens, most involving multiple, toxic drugs.

In terms of "bad economics," CAP is oblivious to the financial realities of cancer treatment in 2005. Some of the major "economic" problems are:

- Cancer care in 2005 involves increasing use of new brand drugs versus generics. There is no incentive or reason for brand manufacturers to competitively bid their drugs outside of formulary that in turn restricts access to care.
- CAP will place new administrative burdens on community cancer clinics. In addition to onerous claims process and tracking requirements, clinics will have to manage individual patient drug inventories under CAP. These new burdens are not compensated by Medicare and will increase financial pressures on CAP participating clinics.
- If community cancer clinics are unable to obtain medically necessary drugs to treat their patients or if they are unable to absorb the additional financial burden imposed by CAP, cancer patients will be sent to hospitals where treatment will be more costly.

We are extremely concerned that CMS is proposing to implement CAP first in cancer care without any cost or risk analyses. After all, we are dealing with the treatment of cancer, where life and death hangs in the balance. The current cancer care delivery system has evolved over the past 15-20 years when cancer treatment shifted from hospital-based to the outpatient, community setting. Easily accessible cancer care, combined with earlier disease diagnosis and more targeted therapy, have actually decreased the cancer mortality rate in recent years. CAP changes a time-tested, efficient delivery system with an untested concept. It is akin to allowing new cancer drugs to be introduced to clinical use without rigorous FDA clinical trials, analyses, and approval.

We are providing our comments to you in a separate document, which is attached to this letter. Section I is a summary of our major concerns. Section II includes an extensive, section-by-section analysis. Where appropriate, we have offered specific recommendations.

Mark B. McClellan, MD, PhD
April 26, 2005

In closing, we urge CMS to postpone the implementation of CAP until such time as a workable framework can be developed and extensive analysis is conducted. Such actions can only be achieved if CMS takes the time to listen to community oncologists and other physicians who treat patients under Medicare Part B. As a fellow physician, you will understand our commitment to our patients to provide effective, medically necessary treatment and our concern that CAP increases burden without improving care.

Thank you again for your consideration. We welcome the opportunity to answer your questions or provide you with additional information regarding our concerns. We will make ourselves available to meet with you as soon as possible to discuss the CAP program and other critical issues facing community cancer clinics.

Sincerely,

Leonard Kalman, MD, President
Frederick M. Schnell, MD, Vice President
Linda Bosserman, MD, Secretary
Community Oncology Alliance

cc: Mr. Ira Burney (CMS/OL)
Mr. Marc Hartstein (CMS/CMM/HAPG)
Mr. Herbert Kuhn (CMS/CMM)
Mr. Bob Loyal (CMS/OFM/PIG/DPE)
Mr. Jim Menas (CMS/CMM/HAPG/DPS)
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Mr. Stephen Phillips (CMS/CMM/HAPG/DPS)
Ms. Liz Richter (CMS/CMM/HAPG)
Mr. Don Thompson (CMS/CMM/HAPG/DAS)

Comments on the Proposed Rules Implementing the Competitive Acquisition Program (CAP) published in the Federal Register on March 5, 2005

Prepared by the Community Oncology Alliance

April 26, 2005

Part I - Introduction and Summary

On March 4, 2005, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule implementing CAP for Medicare Part B drugs. The CAP program was established by the MMA and is intended to provide physicians with an alternative way of obtaining Medicare Part B drugs. Under CAP, beginning January 1, 2006, physicians who choose to participate in CAP will obtain Medicare Part B drugs from vendors who have been selected through a competitive bidding process. Under CAP, vendors, not physicians, are responsible for billing Medicare carriers and collecting beneficiary co-payments.

According to CMS, while CAP *may* provide opportunities for Federal savings to the extent that aggregate bid prices are less than 106 percent of the average sales price (ASP), an important goal of CAP is to eliminate the financial burden on physicians by providing an alternative means for physicians to obtain Part B drugs. In other words, CAP is supposed to provide an alternative for physicians who do not want to be in the business of acquiring and billing both Medicare and patients for cancer drugs.

The Community Oncology Alliance (COA), however, analyzed the proposed rule and identified a number of serious concerns regarding CMS' approach that render the program unworkable for oncologists. COA's detailed analysis and recommendations are set forth in Part II of this document. COA's major concerns are summarized as follows:

--- CMS must have CAP operational by October 1, 2005, the beginning of the annual election period. Yet, the proposed rule reflects that CMS is still very much in the information gathering stage of program development and has not yet even fully conceptualized critical operational features or implementation tasks such as developing a pricing methodology and designing and running a bidding process. The rush to meet deadline, however, seriously compromises CAP's chance for a successful launch and further, compromises the public's opportunity to comment on proposed rules as required by the Administrative Procedure Act (APA).

--- CMS' proposed claims processing system fails to relieve physicians of the cost and burden of purchasing drugs. In fact, it is more burdensome since physicians must not only file detailed claims, they also must track each drug by prescription, maintain at least a paper or electronic inventory of drugs for each patient individually, notify the vendor when a drug is not administered, provide the vendor with information to assist in the collection of deductibles and co-insurance and pursue appeals when a claim is denied – all without compensation.

---- Physicians will be locked into a contract with a CAP vendor for a year with little or no recourse if the vendor fails to perform and provide the level of service required to meet the needs of a busy oncology clinic. Oncologists rely on the timely delivery of quality drugs and biologicals to treat patients who are receiving complicated drug protocols which must be administered within a slotted timeframe to ensure efficacy of the treatment. If a vendor fails to perform, physicians must be able to immediately terminate their CAP elections with the option of either purchasing the drugs themselves or electing a new CAP vendor.

---- The proposed rule overly restricts a physician's choice of and access to medically necessary drugs. Among other issues, for multi-source drugs, the proposed rule would allow CAP vendors the option to choose which drug(s) within the class will be provided. CMS also is considering requiring physicians to obtain all categories of drugs from a particular CAP vendor (rather than allowing the physician to choose the categories of drugs he or she wishes to obtain from the vendor). Finally, the proposed rule severely limits when and under what circumstances a physician can use CAP drugs to resupply inventory and fails to provide timely access to drugs in an emergency.

---- CAP vendors, who are neither legally nor ethically responsible for the course of a patient's treatment, will be responsible for collecting Medicare copayment from secondary insurers or from patients. Should CAP vendors be unable to collect co-payments, nothing in the statute or proposed rule prohibits vendors from stopping delivery of the drugs to the community cancer clinic.

Part II - Section by Section Analysis and Recommendations

1. Overview of CAP

Implementation Tasks and Timetable

The MMA provides that CAP is to be effective on January 1, 2006. Prior to issuance of the proposed rule, CMS engaged in several activities to help the agency design and implement CAP. Specifically, CMS hired a contractor to obtain basic information, develop alternative proposals, and consult with stakeholder groups. CMS also conducted one Special Open Door Listening Session on April 1, 2004, established an electronic mailbox, and issued a Request for Information, which yielded 15 responses. Nevertheless, as noted below, the proposed rule suggests that CMS is still very much in the information gathering stage and is still deliberating various options regarding basic program operations. As a result, the proposed rule lacks specificity regarding a number of key program requirements.

Beyond the need to identify key program requirements, CMS has identified a laundry list of activities that must be completed prior to CAP's effective date, including designating or developing quality, service, and financial performance standards for vendors; creating a pricing methodology; designing and running a bidding process from solicitation through contract award; providing physicians with an opportunity to elect to participate and select a vendor; educating beneficiaries about the program; and conducting other activities specified in the statute and

described in the proposed rule. In reality, however, the CAP bidding process and the selection of vendors must be completed by fall, 2005, which is the beginning of the first annual election period.

Comment: With only eight (8) months before CAP's effective date, and less than five (5) months before the beginning of the first annual election period, COA is concerned that CMS does not have adequate time to deliberate and reach closure on key program requirements *and* complete all of the tasks necessary to initiate CAP. Furthermore, CMS' interest in broadly soliciting input on very basic issues at this stage in the CAP implementation process suggests that CMS lacks sufficient information and understanding of the drug acquisition process and its impact on community cancer care and the delivery of cancer treatment to formulate viable proposals for the CAP program.

Recommendation: While we are cognizant that Congress decreed that CAP should be effective on January 1, 2006, we strongly urge CMS to take the time it needs to fully understand how CAP can best be structured to attain Congress' objectives and benefit physicians without compromising access to drug therapies and treatment. Further, to ensure an effective launch with adequate vendor and physician participation, CMS must delay the effective date of CAP to such a time

2. Categories of Drugs to be included under the CAP

a. Categories of Drugs to be included in CAP

The MMA provides some flexibility in the development of CAP by giving the Secretary of the Department of Health and Human Services (HHS) the authority to select appropriate categories of drugs and appropriate geographic areas for the program. CMS proposes three phase-in options:

Option 1 – Under Option 1, CMS would initially implement CAP for a limited set of drugs that are typically administered by oncologists. Drugs typically administered by other specialties would be included over the next few years. CMS believes that one advantage of this approach is that it allows CMS to focus implementation efforts on one specialty with a more homogeneous set of concerns and issues. Also, by limiting the targeted drugs to those typically administered by oncologists, the physician education process would be streamlined and potentially more effective. Finally, oncologists use a high proportion of the physician-administered drugs that could be included under CAP, therefore making the program more attractive to potential vendors. A potential downside is that a focus on oncology drugs may be too narrow and would deprive other physicians of the opportunity to participate.

Option 2 – Under Option 2, CMS would choose a limited set of drugs that are typically administered by one or more physician specialties that use Part B drugs less intensively. Such an approach would allow operational issues to be addressed more gradually, but may restrict the potential benefits of the program. Further, a restricted approach may not elicit sufficient response from potential vendors.

Option 3 – Under Option 3, CAP would be implemented for all Part B drugs that are furnished incident to a physician’s service regardless of specialty.

CMS states that it is not proposing any particular option at this time but is actively considering all of these options and is encouraging recommendations on other approaches for further analysis. CMS further states that it may adopt one of the options described above, or an option brought to its attention through the comment process, in the final rule. Importantly, the categories that are established for physicians to select will be the same categories that would be open for bids of potential vendors. Thus, for example, if a category embracing all drugs typically administered by oncologists is established, vendors would bid on all HCPCS codes contained in the category and a physician who elects to participate in CAP would be electing to acquire that category from the vendor.

Comment: CMS’ approach violates the Administrative Procedures Act (APA) requiring that agencies must publish a notice of proposed rulemaking in the Federal Register that provides interested persons with an opportunity to participate in the rule making through submission of written comments. 5 U.S.C. § 553. It is well established that a notice of proposed rulemaking must provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully.² Here, CMS has made no specific proposal regarding the phase-in of CAP. Instead, CMS has offered three options and is seeking additional ideas from interested entities. While CMS’ interest in soliciting new ideas is appreciated, contrary to CMS’ own statement, it cannot adopt a proposal without giving the public the opportunity to comment on it.

Recommendation: Once CMS has decided what “phase-in” approach it will take, a second notice must be published in the Federal Register to allow for public comment before the proposal can be adopted as a final rule.

b. Allowing Vendors to Limit Availability of Drugs within Categories (i.e., formularies)

While vendors will be required to bid on all HCPCS codes within a category, (e.g. drugs used by oncologists), CMS is proposing that vendors not be required to provide every National Drug Code associated with a HCPCS code.³ In effect, this gives a vendor permission to establish a formulary by choosing which drugs it will make available through CAP.

Comment: Cancer treatment is complex and poses many risks to patients. Although oncology drugs may be in the same class and category, they are not fungible. Active ingredients, for example, may be similar, but inactive ingredients may act quite differently when combined with other drugs in a complex, multi-treatment regimen. Certain drugs may be less effective or more costly to administer (e.g., the drug takes extra time to reconstitute, or fails to mix properly — leaving particulate matter and needed treatment, at the bottom of the bag instead of in the patient). Furthermore, different drugs within the same class or category can have different FDA

² Florida Power & Light Company v. U.S., 846 F.2d 765, 269 U.S. App. D.C. 377 (CADC 1988), cert denied 109 S.Ct 1952, 490 U.S. 1045, 104 L. Ed. 2d 422.

³ Although this proposal is discussed in the preamble to the proposed rule, it is not included in the actual text of the proposed rule.

approvals and different indications for use. A prime example is Procrit and Aranesp. For certain types of treatments, some may consider these drugs to be interchangeable; however, the drugs are different because each drug has a different indication for use. Similarly, interferon drugs, while in the same category, also have different indications and FDA approvals.

When a health insurer or prescription drug plan limits access to drugs through a formulary, certain safeguards generally are required to ensure that patients are assured access to medically necessary drugs and that formularies are not overly restrictive or driven solely by pricing. For example, under Medicare Part D, formularies must be developed by Pharmacy and Therapeutics (P&T) committees. Formularies must also be non-discriminatory and must provide for exceptions and appeals. Finally, prescription drug plan sponsors are prohibited from making certain formulary changes and if formulary changes are made, plans must provide notice or a one-time supply to assist the beneficiary through transitions.

Unlike Medicare Part D, however, CMS has not proposed any minimum standards or safeguards to govern which drugs must be covered by CAP vendors within a designated category of drugs. If vendors are allowed to restrict access or are allowed to change the drugs offered without notice to the participating physicians, physicians are unlikely to elect to participate in CAP. For those that do elect to participate, if formularies become too limited, they will be forced to resort to “dispense as written” specificity for drugs and work outside of CAP through the ASP program, incurring cost and additional effort on all sides. (See additional comments below regarding CAP Operations.) Finally, we note that while CMS states in the preamble to the proposed rule that, upon request, vendors will be required to provide potential physician participants with specific information about the NDCs within each HCPCS code that it provides and that this information must also be disclosed to CMS as part of the bidding application, the proposed rule contains no such provisions.

Recommendation: The final rule must make clear that formularies are not permitted. Further, the final rule should provide that during the annual election period and upon request thereafter, a CAP vendor must fully disclose each drug that the vendor will make available pursuant to its CAP contract. In addition, vendors must be prohibited from making any changes in the list of drugs available through CAP within 90 days of the annual election period or, after the expiration of 90 days following the election period, without 90 days advance written notice to all participating physicians. Finally, physicians should have the right to opt out of CAP should a vendor fail to make proper disclosures or fail to make drugs available that the physician determines are medically necessary for the treatment of his/her patients.

c. Exclusion of drugs

Section 1847B(a)(1)(D) of the Act gives the Secretary authority to exclude competitively biddable drugs and biologicals from CAP on grounds that including those drugs and biologicals would not result in significant savings or would have an adverse impact on access to those drugs and biologicals. While the preamble to the proposed rule states that CMS has made no findings regarding these two issues at this time, and the rule merely tracks the statutory language without elaboration, neither the preamble nor the rule identify how CMS intends to monitor either savings or adverse impact on access.

Comment: CAP is a new and untested acquisition program for Part B drugs — a significant percentage of which are drugs to treat cancer. Timely, clinically effective treatment is critical to cancer care and in its absence, death is likely. CMS does not know what impact CAP will have on access to oncology drugs or oncology practices. Further, CMS does not know whether CAP will actually produce cost savings.

Recommendation: Given the high stakes involved, we believe it is imperative that CMS commit to and identify a methodology for monitoring how CAP affects the impact on oncology practices, including access to treatment and whether there is any impact on cost.

3. Competitive Acquisition Areas

The law authorizes the Secretary to establish appropriate geographic regions or “competitive acquisition areas” within which to conduct CAP competitions. Competitive acquisition areas constitute the geographic boundaries within which entities will compete for contracts to provide competitively biddable drugs. The size of the geographic area will be a crucial factor in determining the number of entities that bid for and ultimately are awarded contracts.

CMS has proposed several basic options for defining the competitive acquisition area. These include: (1) establishing a national competitive acquisition area, (2) establishing regional competitive acquisition areas; and (3) establishing statewide competitive acquisition areas. According to CMS, a large, national acquisition area is attractive to vendors because it is less administratively burdensome and offers the greatest opportunity to gain market share. At the same time, however, a large acquisition area would likely discourage smaller regional drug distributors from participating in CAP, thereby reducing competition. Sub-national regions offer an opportunity to implement CAP in stages, bringing one region into the program at a time. This approach might permit CMS to work out problems in the early stages that would be important to gaining physician and vendor participation. A state approach is attractive because it uses clearly defined geopolitical borders that coincide with current vendor licensing requirements. A state-based approach could also support a geographic phase in of the program.

Comment: CMS is considering all of the above options and is also soliciting additional ideas. While all of the proposed options have merit, the biggest problem with CMS’ approach is that CMS may violate the APA should it adopt a proposal that has not been published and subjected to a period of public comment.

Recommendation: Once CMS has decided how to define a “competitive acquisition area,” a second notice must be published in the Federal Register before the proposal can be adopted as a final rule.

4. Statutory Requirements Concerning Claims Processing

- a. Physician responsibilities and burden

Under the proposed rule, 42 C.F.R. §414.908, physicians will be given the opportunity to select an approved CAP vendor on an annual basis. Physicians must complete and sign a CAP election agreement. In addition, the physician will be required to submit a written order or prescription to the approved vendor. CMS is proposing that each drug order be accompanied by the following information:

- * Date of order
- * Beneficiary name
- * Physician identifying information
- * Drug name
- * Strength
- * Quantity ordered
- * Doses
- * Frequency/instructions
- * Anticipated date of administration
- * Beneficiary Medicare information/Health insurance (HIC) number
- * Supplementary Insurance info
- * Medicaid info
- * Shipping address
- * Additional patient info: date of birth, allergies, Ht/Wt/ICD-9 etc.

CAP participating physicians must also provide information to the approved vendor to facilitate collection of applicable deductibles and coinsurance, notify the vendor when a drug is not administered, agree to file a “clean” Medicare claim within 14 days of the date of drug administration that includes the name and HCPCS code of the drug administered, the prescription number for each drug administered, and the date of service, and agree to submit an appeal accompanied by all required documentation necessary to support payment if the participating CAP physician’s drug administration claim is denied. Physicians will also have to maintain a separate electronic or paper inventory for each CAP drug obtained.

No provision is made to compensate the physician for any of the above activities. Yet, if a vendor is not paid on claims, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician and if the problem persists, the vendor may ask the carrier to investigate the physician’s performance and recommend the suspension of the physician’s CAP election agreement. While the proposed rule does provide for reconsideration and appeal of a physician’s exclusion, if the carrier’s decision is ultimately upheld, “CMS publishes a final reconsideration determination against the participating CAP physician in the Federal Register.” Proposed 42 C.F.R. § 414.916(b).

Comment: The CAP process creates a dramatic and operationally significant change in how physicians acquire Medicare Part B drugs. When ordering from a non-CAP vendor, physicians stock a single, centralized, inventory. CAP requires each practice to order drugs and track inventory on a prescription basis for each patient, track the date of administration, bill claims within 14 calendar days of administration and share information with vendors to assist them in collecting co-payments.

For a program that was designed to get physicians out of the drug acquisition business, CAP does little to lessen the administrative burden on physicians. In fact, we believe that it increases the burden. At the same time, it strips physicians of any claim to payment. Moreover, the reward for signing on as an unpaid agent of the vendor potentially is investigation and a public pronouncement of exclusion from the program.

Recommendation: CMS must restructure CAPS' proposed claims process and tracking requirements to significantly reduce the administrative burden on physicians.

b. Written order or prescription

The statute (MMA) provides that the contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. The statute further provides that this section does not require a physician to submit a prescription for each individual treatment, or change a physician's flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or course of treatment.

For purposes of CAP, CMS has chosen to interpret the term "prescription" to include a written "order" submitted to the vendor. CMS states its intention not to restrict a physician's flexibility when ordering drugs from a CAP vendor or to require that a physician participating in CAP would order drugs differently from a CAP vendor than he or she would a non-CAP vendor.

Comment: As proposed, a CAP "vendor" will supply pharmaceuticals to a physician's office for a particular beneficiary (patient). The "vendor" then submits a claim with a prescription number for the pharmaceutical agent to a designated carrier. That claim must be matched to a claim filed by the physician that shows the date of administration by the physician. This is not a typical supplier arrangement but rather describes the "filling" or dispensing of a "prescription" for a specific patient.

There are three problems with this approach. First, federal and state law make clear that only a licensed pharmacist may dispense a prescription. Second, requiring CAP participating physicians to maintain individual, patient-specific inventories will further increase costs substantially to physicians. Based on the fact that approximately one-third of treatment regimens are switched during the treatment cycle, there will be a significant waste problem that will increase waste disposal costs to physicians and increase drug reimbursement costs to Medicare. Third, physician billing systems are not set up to handle prescription numbers on billing claims, thus major and costly system retooling will be required.

Recommendation: It is clear that the statute (MMA) very specifically uses the word "prescription," which cannot be loosely interpreted by CMS to mean an "order."

c. Order splitting

CMS proposes allowing the physician to place an order for a beneficiary's entire course of treatment at one time but allow the vendor to split the order into appropriately spaced shipments.

According to CMS, the vendor would create a separate prescription number for each shipment and the physician would track each prescription separately and place the appropriate prescription number(s) on each drug administration claim.

Comment: It is unclear how CMS could authorize a vendor to split a shipment of pharmaceuticals needed to treat a patient without the express consent of the physician who order the drugs or under what licensing authority a vendor would be allowed to create prescription numbers. How does the vendor know how to “appropriately” space shipments? Further, allowing the vendor to split shipments creates additional administrative burden for the physician and clinical staff administering the treatment.

Recommendation: Vendors should be prohibited from splitting shipments unless approved by the physician who orders the drugs.

d. Inventory resupply

CMS has proposed that drugs acquired under the CAP may be used to resupply inventories but only if the physician can demonstrate all of the following to the Secretary: (1) the drugs are 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.

Comment: The standard for allowing physicians to resupply inventories with CAP drugs is too onerous and does not take into consideration certain common reasons why a CAP drug may not have been used. About one-third of the time, a scheduled treatment for an oncology patient does not happen as planned. This may be due to scheduling issues or, more commonly, the patient’s needs changes and an alternative regimen is indicated. In most cases, such changes cannot be categorized as “emergencies.” Yet, it is highly unreasonable and very costly to require a patient, who has already been examined and tested, to return in another day or two, in order to obtain a new mixture of drugs, rather than obtain treatment from the physician’s inventory. The resupply rules will be especially difficult for rural oncology clinics where patients in debilitated health must travel long distances to obtain treatment. Delaying treatment and requiring patients to return on another day or wait long hours in order to receive new shipments of drugs acquired through the CAP vendor, is an enormous inconvenience to the patient and a cost to the practice. More importantly however, delaying treatment can adversely affect patients’ health and ultimately drive up health care costs.

Recommendation: Physicians should be permitted to resupply their inventories if any one of the four conditions is applicable.

e. Unused drugs

CMS proposes that, if for some reason, the CAP-acquired drug cannot be administered to the beneficiary 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 state and federal law.

Comment: CMS' proposal ignores the fact that most pharmacy regulations indicate that a drug, once dispensed in a patient's name, may not be returned, reused, or reshelfed. The conversion of oncology drug inventories from a single, centralized, non-patient specific inventory to a patient-specific, individualized inventory creates the potential for millions of dollars of "waste" from unused and unusable medications.

Recommendation: We understand that the requirement that a vendor only provide drugs to a participating CAP physician prohibition based upon a prescription is statutory. Nevertheless, we urge CMS to work with Congress to address impediments to a viable CAP program.

f. Uncompensated costs

One of the goals of CAP is to reduce the financial burden of drug acquisition on physician practices. However, as long as chemotherapy and other therapies to treat cancer are incident to a physician's services, physician practices will still incur costs associated with drug handling and inventory. The preamble to the proposed rules, for example, states, "the drug and prescription number would be shipped to the physician and would be maintained until the date of drug administration." However, no provision is made to compensate the physician for these costs.

Comment: At a recent MedPAC meeting, MedPAC staff identified the costs of drug handling and inventory in the hospital outpatient setting at 26% to 28% of drug costs. Oncology practices have long maintained that drug handling and inventory costs run about 12% of total drug purchase expenditures. While the CAP program does not eliminate these costs for oncology practices, physicians are not compensated for these costs under any other fee schedule.

Recommendation: CMS must recognize and compensate oncologists for the costs of drug handling and inventory.

g. Furnish as written

CMS proposes that when a CAP participating physician has determined that it is medically necessary to use another brand of product within the HCPCS or a product with an NDC that is not being furnished by the vendor, that the physician be allowed to bill for the drug under ASP. The physician would place a "furnish as written" modifier on his or her claim form and bill the Medicare carrier for the drug and the administration fee.

Comment: We support CMS proposal to permit physicians 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 and the vendor has not been contracted to furnish a specific formulation of a drug or product defined by the product's NDC number. However, we are concerned that physicians are still subject to post payment reviews and carrier determinations that a specific NDC number was not medically necessary. This process takes the medical decision-making completely out of the physician's hands, yet it is the physician who holds the responsibility and the liability for the quality and effectiveness of drugs used for patient care, and has access to the full information.

Recommendation: CMS must make clear that “furnish as written” orders are reviewed under the same standards and process used under Medicare Part B for non-CAP drug acquisitions.

h. Physician choice of drug categories

CMS is seeking comments on whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or whether the physician should be allowed to choose the categories of drugs he wishes to obtain from the vendor.

Comment: CAP vendors may create formularies that are inconsistent with the physician’s preferred medical practice, or may ignore certain variations in drug approvals or indications within categories. Oncology care is so complex that without the flexibility to deselect certain categories, quality and patient access risks increase dramatically. Furthermore, promoting choice will increase competition among vendors and should have a positive impact on quality and price.

Recommendation: COA strongly recommends that physicians be given a choice of which categories of drugs to obtain from a particular CAP vendor. There is no basis for implementing formularies.

i. Collecting beneficiary co-payments

The statute requires that the vendor bill Medicare and the beneficiary, and that the beneficiary may not be billed until after the drug has been administered to the beneficiary by the physician, who has filed a claim for the drug administration. CMS is proposing that the vendor be allowed to bill the beneficiary and/or his or her third party insurance after drug administration has been verified by matching the physician claim with the vendor claim using the prescription number, and final payment is made by the Medicare program.

Comment: Despite the impact on cash flow, community oncologists generally are reluctant to refuse to treat a patient who cannot afford to pay a co-payment. Vendors, however, are not ethically or legally responsible for the course of a patient’s treatment. If a vendor is unable to collect co-payments from a patient, nothing prohibits the vendor from stopping delivery of drugs to the physician’s office. Allowing vendors to stop delivering drugs to an outpatient setting is likely to endanger patients or force them into more costly in-patient settings for treatment. Further, physicians could be exposed to liability if the physician is unable to complete a course of treatment because a vendor is refusing delivery.

Recommendation: The final rule must make clear that vendors cannot refuse to deliver drugs because they are unable to collect co-payments. Alternatively, if CMS does allow vendors to stop delivering drugs, this must be made very clear to physicians during the CAP election period that the vendor may suspend treatment to any patient not paying their co-insurance. Additionally, physicians must be permitted to immediately opt out of CAP and obtain drugs through the ASP system in any single case where a vendor has decided to not ship drug(s) for a

patient not paying the Medicare co-payment or if the patient's secondary insurance carrier has denied the claims.

5. Contracting Process-Quality and Product Integrity

Vendor Quality Control

Sections 1847B(b)(2)-(3) of the MMA makes clear that vendors must meet financial and quality of care requirements aimed at assuring the stability and safety of CAP. The statute also provides that vendors have sufficient capacity to acquire and deliver drugs within a geographic area, to deliver drugs in emergency situations, and to ship drugs at least 5 days a week. The MMA also requires that the criteria for awarding vendor contracts include the vendor's ability to ensure product integrity. CMS correctly notes in the preamble that physicians would be reluctant to participate in CAP if they have little confidence that CAP vendors would be reliable and provide quality CAP products. The preamble further states that CMS seeks to "define a set of overall financial and quality standards that would ensure that reputable, and experienced vendors are chosen to participate in CAP and states we propose that CMS be allowed to suspend or terminate a vendor's contract if the vendor falls out of compliance with any of these quality requirements."

Unfortunately, the proposed rule does not identify those standards. Rather, the proposed rule states only that CMS will select approved vendors based upon certain criteria including but not limited to the "ability to ensure product integrity," "financial performance and solvency," and "record of integrity and the implementation of internal integrity measures." Proposed rule at 42 C.F.R. § 414.908(b).

On the other hand, proposed rule 42 C.F.R. §414.916(d) provides that issues regarding quality and service that relate to the vendor's performance raised by the participating CAP physician are treated through the vendors own internal grievance process. If the approved vendor does not resolve a quality issue to the participating CAP physician's satisfaction, the participating CAP physician may escalate the matter to the designated carrier. Unlike the unpaid physician who is subject to investigation and exclusion, CMS merely provides that the "designated carrier attempts to develop solutions that satisfy program requirements and the needs of both the participating CAP physician and the approved vendor." Proposed 42 C.F.R. §414.916(d).

Comment: Vendors are being paid to deliver highly volatile and, at times, toxic drugs to physicians who need them to treat critically ill patients. It is essential that vendors be held to the highest standard for quality and performance. Physicians, who will be dependent on the vendors to obtain these drugs, need to know that when complaints are raised about poor quality and performance that vendors and CMS will take them seriously. It is unrealistic to believe that physicians will participate in CAP if there is no effective process for addressing quality concerns and if they believe they have no recourse if a vendor is not performing as expected. It is unsettling and contrary to good business practice that physicians are locked into their choice of the CAP vendor(s) for a year regardless of performance and quality.

Recommendation: CMS must strengthen the rules pertaining to quality and performance standards of vendors and clarify the procedures that will be used to investigate allegations

involving the poor performance of vendors. Vendors who fail to perform should be subject to investigation and sanction, up to and including exclusion from the program.

We also recommend that CMS develop standard “hold harmless” language for the CAP election agreement that ensures that participating physicians are held harmless for the negligence and non-performance of CAP vendors.

Finally, CMS must make clear that physicians may disenroll from CAP at any time, especially in cases of quality non-performance.

6. Bidding Entity Qualifications

a. Vendor experience and capabilities

Under the proposed rule, 42 C.F.R. § 414.908(b)(1)(iv), vendors are expected to show a history of delivering Part B injectable drugs for at least 3 years.

Comment: Oncology drugs are complex medications/chemicals, with strict parameters for handling and storage. Experience with other drugs does not guarantee successful experience with oncology drugs, and the risks and liability for Medicare patients and physicians is too great to allow inexperienced vendors the responsibility of handling oncology and cancer-related supportive care drugs.

Recommendation: A CAP vendor should be required to demonstrate a history of at least 3 years of delivering each category of drugs for which they submit a bid.

b. Timeframes for routine and emergency shipment

CMS is seeking comments on how to define timely delivery for routine and emergency drug shipments. CMS is proposing that routine shipments of drugs furnished under CAP would occur within one or two business days. However, the duration of the delivery time period must not exceed the drugs stability in appropriate shipping containers and packaging. CMS also proposes that emergency drug orders be furnished on the next day for orders received by the vendor before 3 p.m. (vendor’s local time). CMS is seeking comments on the feasibility of providing same-day deliveries received for emergency situations.

Comment: Same day deliveries are feasible and necessary.

Recommendations: Vendors should be required to have the capacity to make same day deliveries when drugs are needed on an emergency basis. At the time the drug is ordered, the physician should receive a commitment from the CAP vendor for a day and time of delivery, and vendors must be held accountable for compliance to that commitment.

CMS must make clear that physicians may disenroll from CAP at any time, especially in cases of delivery non-performance.

c. Conflicts of Interest

The CMS proposal sets forth a code of conduct for CAP vendors, and identifies a conflict of interest as being “where a drug vendor, its representative, or contractor provides a product or service for a Medicare provider or beneficiary and the drug vendor, representative or contractor has a relationship with another person, entity product or service that impairs or appears to impair the drug vendor’s or contractor’s objectivity to provide the Medicare covered product or service.”

Comment: The creation of formularies for the purpose of steering market share toward one drug in a category over another in response to contracting discounts and rebates would appear to meet this definition of conflict of interest. If physicians are required to acquire drugs within categories as defined and by the CAP vendor, and the CAP vendor offers only a limited selection of the possible drugs, the CAP vendor has restricted the availability of drugs for its financial gain, and to the detriment of access to care for Medicare beneficiaries and their physicians.

Recommendation: Formularies should not be allowed.

7. **CAP Bidding Process – Evaluation and Selection**

a. Composite Bid Process

CMS proposes employing a composite bid process. The composite bid would be implemented in two steps. First, bidders would have to demonstrate that they meet certain quality and financial thresholds. Second, each bidder would submit its bid constructed by weighing each HCPCS bid by the HCPCS code’s share of volume of drugs in a particular drug category during the prior year. The calculated composite bid would be equal to the average price per HCPCS unit for drugs in that category. CMS would then select up to five bidders, based upon price, for a drug category in each competitive acquisition area. However, CMS would not select any bid for a category that is higher than 106 percent of the weighted ASP for the drugs in that category.

Comment: As proposed, the bid process automatically eliminates drugs that are not obtainable at significant savings to the Medicare program. The result is that only the cheapest and possibly least usable versions of a drug in a category will be made available through CAP vendors.

Recommendation: CMS must revise the bid process to avoid a race to the bottom, where price considerations trump quality and efficacy concerns. Giving physicians choice and the ability to “walk with their feet” should help make vendors more sensitive and responsive to quality concerns.

b. Drug administration, waste, spillage, and spoilage

The bidding process also specifically excludes recognition of any costs related to the administration of the drug or wastage, spillage, or spoilage in submitted bids.

Comment: Wastage, spillage, and spoilage are part of the cost of treating cancer patients with drug products that are highly toxic and unstable.

Recommendation: While we recognize that the exclusion of drug administration costs, wastage, spillage, and spoilage are statutory, CMS must adjust payments to physicians for services to more accurately reflect their costs.

8. Physician Election Process

Pursuant to proposed 42 C.F.R. § 414.908, physicians will be asked to make an election and select a qualified CAP vendor on an annual basis by October 1. Once selected, the physician will only be able to go to another vendor if the approved vendor ceases to participate in CAP, or other exigent circumstances defined by the Secretary such as when the CAP physician relocates to another competitive acquisition area or leaves a group practice that is participating in CAP.

Comment: While the statute does provide for an annual election, nothing in the statute requires or supports the use of a “lock-in” period for physicians. CMS must be mindful that vendors would be inclined to charge higher rates to their captive customers if a lock-in period is required, while physicians are unlikely to sign up for the program if they cannot leave it at will. This is a new, untested program. If physicians develop serious concerns about the vendor, or the program, or unanticipated costs of supporting the program, as small businesses with a low capacity for financial risk, they need the flexibility to depart.

Recommendation: CMS must make clear that physicians may disenroll from CAP at any time.

9. Beneficiary Education

Beneficiaries are likely to be confused by the CAP program. CAP co-payment collection policies also may lead to denials and reduced access to care for some Medicare cancer patients. To educate beneficiaries, CMS is proposing to develop a beneficiary-focused fact sheet, and to update existing materials, to reflect these changes. The fact sheet would be available for physicians who elect to participate in the CAP to provide to beneficiaries at the time of service. CMS seeks comment on the administrative burden associated with this activity. CMS is not proposing any additional options for specific outreach to beneficiaries.

Comment: Patients rely on their physicians to guide them through the treatment process, and any confusion regarding billing or disruption of care will send patients immediately back to the physician office with a variety of physical, financial, medical, and psychosocial issues.

Recommendation: CMS should conduct outreach and beneficiary education to patients receiving treatment under Medicare Part B.

10. Collection of Information Requirements

CMS is estimating that physicians will need 15 minutes each to fulfill the application requirements.

Comment: At COA, we believe the decision process will actually be far more complicated and take much longer than 15 minutes. As stated elsewhere in the CMS proposed rule, practices will need to evaluate the costs of purchasing and acquiring drugs under the ASP option, and compare the costs of acquiring drugs under the CAP program, plus evaluate discrepancies between the drugs now selected for patient care and whatever specific drugs are carried under the CAP vendor formulary – and assess any relevant issues for patient care and operational burdens. The CMS proposed rule assumes that physicians must maintain a separate electronic or paper inventory for CAP drugs, but reality dictates that a physically separate inventory will also be needed, with all the attendant costs.

Recommendation: CMS should revise its estimate to reflect the additional time it will take physicians to evaluate CAP. CMS must fully analyze the application requirements and administrative costs by conducting a test with real community oncology practices and reporting back on the results.

11. Regulatory Impact Analysis

For purposes of the RFA, physicians and non-physician practitioners are considered small businesses if they generate revenues of \$8.5 million or less. According to CMS, there are in excess of 20,000 physicians and other practitioners that receive Medicare payment for drugs. These physicians are concentrated in the specialties of oncology, urology, and rheumatology. Of the physicians in these specialties, approximately 40 percent are in oncology and 45 percent are in urology. CMS was unable to draw any specific conclusion regarding the impact of this proposed rule on physicians because it depends on what drugs they provide to Medicare beneficiaries, whether the drugs will be included in the CAP program, and whether the physician chooses to obtain drugs through CAP.

Comment: While we agree that certain impacts are dependent on how individual physician's react to the program, their own practices, and on information that is not yet known, we believe that overall, CAP will reduce reimbursement to oncologists, increase administrative and pharmacy costs, and ultimately affect access to treatment as more clinics are forced to close and send their patients to more costly hospital settings. Physicians who feel compelled to participate in CAP will find they will need to absorb more uncompensated costs including unreimbursed drug handling and inventory costs and the increased administrative burden of the new ordering and claims processing system. In sum, the burden to the physician and the related costs actually increase under CAP due to the need for separate inventory management and running of concurrent inventories — both for staff and facility resources.

Recommendation: CMS should do a complete impact analysis that both examines and quantifies the true cost of CAP to a community oncology practice and also quantifies the overall impact of CAP on the delivery of cancer care in this country.