Submitter : Mrs. Dawn Holcombe **Date:** 09/06/2005

Organization : Oncology Network of Connecticut, LLC

Category : Health Care Professional or Association

Issue Areas/Comments

Background

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Thank you for the opportunity to comment on the Interim Final Rule on the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals. We deeply appreciate CMS making the decision to postpone implementation of the CAP program until considering commentary on this Interim Final Rule. We also hope that CMS will listen to the hundreds of comments submitted for both the Proposed and Interim Rules and turn back to Congress with the information that both ASP and CAP, as now defined in the law, are unworkable programs for oncology given the realities of cancer treatment, and if continued and expanded as planned, will lead to untenable tradeoffs of product integrity and access to care, as well as a NEW widespread definition of ASP ? A Suspect Product.

We made many comments on the proposed rule regarding the elements of the rule that basically make CAP an unworkable concept as now conceived ? so many elements are contradictory to the delivery of timely, quality, and effective cancer care. These comments are attached to this document, so they will not be repeated in this letter. Upon reading the Interim Final Rule, there were few changes made from the Proposed Rule to mitigate the concerns about these elements. In fact, new additional information on the volume of contaminated drugs has come to light that calls the advisability of the program into question further and even raises the concern that CAP (and an uncorrected ASP) will afford an opportunity for an unparalleled threat to the safety of the nation?s cancer drug supply.

Please consider the scope of our comments today to encompass every point made in the attached document, as well as the points made in this letter. The ASP comments are an essential part of the CAP comments, since CAP vendors are now measured against ASP.

GENERAL

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Flawed components of existing CAP and ASP programs
- Continued use of term ?ASP? (in the manner in which it is currently defined for physicians)
- Use of ASP as a base - ?Average Selling Price? implemented in a more wholesale fashion for oncology care drugs will lead to those drugs becoming more and more ?A Suspect Product?.
- Expansion of ASP to other entities such as hospitals and CAP vendors before above mentioned flaws are corrected
- CAP program reliance on an individual prescription to request drug to be delivered at some later time for treatment
- CAP program expectation that drugs shipped after receipt of a prescription will reach a patient in a timely fashion for efficient oncology care
- CAP program expectation that variation from planned treatment will be minor and able to be anticipated in an other than emergency situation
- CAP program expectation that single CAP vendors should jerry-rig a network of distributors and wholesalers to meet terms of nationwide coverage
- CAP program expectation that the additional administrative burden on physicians demanded of participants will be offset by expected savings in inventory also shows a lack of understanding of the basic business principles of managing inventory and of the clinical issues in patient care.
- The CAP program assumes erroneously that it will reduce physician inventory needs
- The CAP program adds cost and infrastructure in a duplicative nature to an already efficient system.
- The CAP program allows for a non-medical entity, the CAP vendor, to choose to suspend provision of CAP drugs after specific steps, if co-payments are not current.

In summary, comments received from oncology physicians have repeatedly shown there to be inherent flaws in the statutory design of the CAP program that are incompatible with the delivery of cancer care.
- There is no fix that will make the CAP program, as defined in the MMA, viable for oncology care at this point. CMS should focus on its implementation in other specialties, such as mental health, that seem to be clamoring for it, as evidenced by the comments received under the Proposed CAP Rule, so that it may still comply with the MMA time frames.

See Attachment for a full discussion of my comments on this Interim Final Rule

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

The following elements make it impossible to execute in 2006 either a CAP program or the expansion of the ASP based program in an oncology setting, as the two are now defined, without a) putting the oncology patients of America at severe risk for counterfeit, diverted, adulterated, and mishandled drugs, b) jeopardizing patient health and treatment by causing significant delays in treatment, and c) jeopardizing the cancer care delivery system by causing extraordinary unreimbursed administrative burdens and setting payments at a rate far below cost for physicians, hospitals, and drug distribution systems.

Unfortunately, the flaws in the program are embedded in the MMA language, so there is little CMS can do to make any reasonable corrections in time for an implementation soon. This whole situation brings a new meaning to the CMS marketing campaign ?Ask Me About Medicare 2006?.

Section 1847B(a)(1)(B) of the Act specifically requires the
Secretary to establish categories of drugs that will be included in the
CAP, and requires the Secretary to phase-in the program with respect to
these categories, as the Secretary determines to be appropriate.
Section 1847B(a)(1)(D) of the Act further authorizes the Secretary to

exclude competitively biddable drugs and biologicals from the competitive bidding system if the application of competitive bidding to those drugs and biologicals--

(1) Is not likely to result in significant savings; or

(2) Is likely to have an adverse impact on access to those drugs and biologicals.

As will be shown below, both ASP and CAP, as now defined, present a clear and present danger to both the access and, more importantly, QUALITY of those drugs and biologicals used to treat cancer patients. We respectfully request that the Secretary consider these issues and remove those drugs and biologicals used to treat (both for treatment and supportive care) cancer patients from the CAP program entirely. There were about 500 comments received on the Proposed Rule. Almost one-half of them praised the CAP program and asked that it be applied to mental health drugs. At least 10% were unreadable. However, the other half (over 190 specifically) clearly articulated major (still unresolved in the Interim Final Rule) concerns for both administrative burden and quality/access/risk issues for both patients and practices due to the major elements of the CAP program. Yet, CMS did not respond to these well-articulated and voluminous concerns other than to say that a) they still felt that any administrative burden would be offset by savings, or b) it was a voluntary program and practices could choose not to participate. One would hope that the Secretary would be responsive to this clear outpouring of concern for the frequently stated pending adverse impact of the CAP program and retool it to apply to medical specialties other than oncology. The program was clearly conceived and designed without input or awareness of the medical and operational realities of delivering cancer care, and that was reflected in the quantity and concern expressed in the comments received on the program. The program itself may be very viable, and indeed, valuable, in other specialty settings, but it is not appropriate for cancer care.

CMS-1325-IFC-158-Attach-1.DOC

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September 2, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-IFC, P.O. Box 8013
Baltimore, MD 21244-9013

Re: Comments on the Interim Final Rule on the Competitive Acquisition Program for Part B Drugs and Biologicals

Thank you for the opportunity to comment on the Interim Final Rule on the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals. We deeply appreciate CMS making the decision to postpone implementation of the CAP program until considering commentary on this Interim Final Rule. We also hope that CMS will listen to the hundreds of comments submitted for both the Proposed and Interim Rules and turn back to Congress with the information that both ASP and CAP, as now defined in the law, are unworkable programs for oncology given the realities of cancer treatment, and if continued and expanded as planned, will lead to untenable tradeoffs of product integrity and access to care, as well as a NEW widespread definition of ASP – **A Suspect Product**.

We made many comments on the proposed rule regarding the elements of the rule that basically make CAP an unworkable concept as now conceived – so many elements are contradictory to the delivery of timely, quality, and effective cancer care. These comments are attached to this document, so they will not be repeated in this letter. Upon reading the Interim Final Rule, there were few changes made from the Proposed Rule to mitigate the concerns about these elements. In fact, new additional information on the volume of contaminated drugs has come to light that calls the advisability of the program into question further and even raises the concern that CAP (and an uncorrected ASP) will afford an opportunity for an unparalleled threat to the safety of the nation's cancer drug supply.

Please consider the scope of our comments today to encompass every point made in the attached document, as well as the points made in this letter. The ASP comments are an essential part of the CAP comments, since CAP vendors are now measured against ASP.

The following elements make it impossible to execute in 2006 either a CAP program or the expansion of the ASP based program in an oncology setting, as the two are now defined, without a) putting the oncology patients of America at severe risk for counterfeit, diverted, adulterated, and mishandled drugs, b) jeopardizing patient health and treatment by causing significant delays in treatment, and c) jeopardizing the cancer care delivery system by causing extraordinary unreimbursed administrative burdens and setting payments at a rate far below cost for physicians, hospitals, and drug distribution systems.

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Flawed components of existing CAP and ASP programs ***(Corrections needed to make program viable for cancer care – noted in italics)*****:**

- **Continued use of term "ASP" (in the manner in which it is currently defined for physicians)**
  - Inclusion of distributor prompt payment discounts and administrative fees/discounts *(Remove these from ASP calculations)*
  - No real time adjustment for market price adjustments *(Minimum Monthly, ideally weekly adjustment of price increases/changes)*
  - Inclusion of drug re-packager product in market counts *(solely manufacturer vial counts at point of origination – note and eliminate sales data from re-packagers)*
  - Lack of recognition of actual handling and drug acquisition costs (at least 12% in physician office settings, 26% - 28% in hospital settings, similar in specialty pharmacy

settings) over and above actual purchase price *(adjust +6% to reflect actual handling and drug acquisition costs in varying sites of service)*

- Lack of recognition of manufacturer policies on class of trade pricing and the affect of those policies on the open market. Drugs sold exclusively to groups and priced differently for those groups mean other groups can never have access to those prices. An ASP that lumps those different prices together will result in a payment that matches no prices paid by varying groups for drugs. An artificial reimbursement price that bears no reality to actual market price and costs serves no-one well, least of all cancer patients who then have reduced access to treatment when providers cannot afford to buy the drugs they need. *(Recognize either manufacturer Wholesale Acquisition Cost (WAC) and tie reimbursement levels to that single standard price OR negotiate/recognize Medicare pricing with manufacturers so that all classes of trade serving Medicare patients can purchase at that rate) Either scenario allows for one price that can be extended to actual purchasers rather than an artificial price at which no one can purchase product.)*

- **Use of ASP as a base** *(remove concept of ASP from federal policy, replace with Wholesale Acquisition Cost (WAC) – a constant and single priced number)* During the discussions of the last year, physicians, hospitals and even CAP vendors have continually notified CMS that ASP (and even ASP + 6%) does not cover the costs of purchase and acquisition of oncology product. Recently the reason why that practice actually endangers the nation's cancer drug supply became highlighted in a non-fiction, documentary book. The book "Dangerous Doses" by Katherine Eban chronicles investigations (by The Florida Bureau of Statewide Pharmaceutical Services (BSPS), the Florida Department of Law Enforcement (FDLE) the FBI, the FDA Office of Criminal Investigations, and others) - all well documented - launched over the last 4 years to identify and prosecute criminal activity in the secondary drug wholesaler markets, which led to adulteration, contamination and counterfeiting of drugs, especially high price cancer drugs ripe for undetected substitution. The ASP-based program itself sets up a market dynamic whereby buyers serving Medicare - be they doctors, pharmacies, or CAP vendors - are scrambling to find those elusive low prices that allow them to survive under this artificial ASP. The major dynamic driving the proliferation of the illegal market activity originating in Florida, as spotlighted by the author, was that there was always a market (legitimate or not) for buying product at prices lower than manufacturer prices – and easily ignoring the fact that the only way that was usually possible was if it wasn't really quality manufacturer product. Drugs began and ended through legitimate channels, but through diversion and criminal activity, infiltrated the system in a manner unbeknownst to manufacturers, major distributors, or providers. This happened in a wholesale manner…through the doors of just one illicit pharmacy passed enough counterfeit medicine to treat over 28,000 cancer patients for an entire month. Physicians and patients would not know they received that counterfeit drug, only that for some reason, the treatment didn't seem to be working as they hoped.

  This suggests that continuation of reliance on ASP and expansion of the ASP concept (before it is fixed to reflect market reality) to hospital and CAP vendors will drive the cancer drug system toward even greater incentives for bad product to enter the system (as more and more seek to beat the mandated reimbursement max of ASP) and the underground and illicit vendors will find their bargain prices on questionable product to be in demand by someone in the stream. One could argue that **"Average Selling Price"** implemented in a more wholesale fashion for oncology care drugs **will lead to those drugs becoming** more and more **"A Suspect Product".**

- **Expansion of ASP to other entities such as hospitals and CAP vendors before above mentioned flaws are corrected**, further exacerbating the problems caused by the flaws

(Recognize flaws in current ASP program as evidenced by widespread application to physician practices in 2005, and correct before widening application to other providers)

- **CAP program reliance on an individual prescription to request drug to be delivered at some later time for treatment**
    - Oncologic care is individual and varies greatly (20 – 35% of the) at the time of expected treatment. Only a single centralized inventory system allows for up to the minute required adjustments in treatments without waste of unused drug or delays caused by unavailable drug. Cancer treatment **cannot** be delivered by prescription for later fulfillment. ***(This concept is completely incompatible with the basic tenets of oncology care – and thus renders the CAP program itself untenable if it relies on filling prescription orders for cancer treatments. CAP programs may well still be a viable option for diagnoses unrelated to oncology care, or if they apply to non-prescription based orders of drugs for dispensation at the physician's practice to patients as needed.)***
- **CAP program expectation that drugs shipped after receipt of a prescription will reach a patient in a timely fashion for efficient oncology care.**
    - Cancer patients cannot afford to wait 1 to 2 business days or more for shipment of treatment. Changes in care based upon patient health status must be dealt with immediately. Patients and treating physicians cannot be put at risk for the consequences of such delayed treatment. ***(This concept is completely incompatible with the basic tenets of oncology care – and thus renders the CAP program itself untenable if it relies on delivering drug at some time following assessment of current patient health status. CAP programs may well still be a viable option for diagnoses unrelated to oncology care.)***
- **CAP program expectation that variation from planned treatment will be minor and able to be anticipated in an other than emergency situation.**
    - As mentioned above, this is a common occurrence in cancer treatment and to suggest that physicians would be charged with non-compliance for such changes based upon patient health status shows a complete lack of understanding about the realities of cancer treatment. We would welcome the chance to guide interested parties through the process and help them to understand this issue. ***(If CAP were to be applied to any physician specialty, care would need to be taken to understand whether, as in oncology, patient health status and treatment variation occurs with regular frequency – and whether that frequency would make such a CAP program unviable for that specialty. There is no correction that would make this program viable for oncology patients due to the frequency of such changes and the effect delays in treatment would have on patient health)).***
- **CAP program expectation that single CAP vendors should jerry-rig a network of distributors and wholesalers to meet terms of nationwide coverage.** *(Any CAP program should consider the existing distribution mechanisms and only accept vendors at any point in the process who can demonstrate 3 – 5 years successful and violation-free records for handling of specific drugs covered by the program to all geographic areas covered by the program. There is too much risk in allowing one vendor to cobble together a group of vendors with unknown track records or worse, no history of ever handling the product. Handling other injectable drugs is not an equitable substitute for proven safe handling of oncology drugs and biologicals.)* Cancer drugs are extremely fragile and require delicate handling. There are a limited number of distributors that have been supplying such drugs for decades for a reason – it is a costly proposition to get set up to handle such drugs safely and efficiently. To create a program whose primary function is to bring new distribution systems to handle such life-altering drugs, in such a

quick fashion, to invite companies to take on the responsibilities of handling on a wide scale in a rapid manner, is to invite disaster. It makes the program look as though it is willing to take any and all takers based upon lowest bids, without setting up sufficient safeguards to protect those whose lives depend upon those drugs.

The above-mentioned book "Dangerous Doses" by Katherine Eban, an investigative reporter, does an excellent job of factually reporting the well documented uncovering of a vast web of fly-by-night wholesalers and profiteers channeling counterfeit, adulterated and mishandled drugs into the trusted mainstream drug system. CAP seeks to create a new distribution system for cancer drugs (the Competitive Acquisition Program (CAP) vendor) that is actually encouraging jerry-rigged national feeder networks of suppliers and distributors - and rely on existing state licensing to validate the legitimacy of the vendors. This book highlights the proliferation of criminal activity before, during and after regulatory review and enhancement in just one state, Florida. Currently Florida has, on paper at least, the most stringent regulations of all 50 states but the execution and actual oversight of those regulations are still so under funded that major loopholes still exist. Imagine the tractor trailer sized loopholes that must exist in other states – shown by the speed at which questionable vendors fled Florida to set up unchecked drug wholesale businesses in other states. Cancer patients cannot afford a federal program that sets the stage for increased proliferation of criminal activity in cancer drugs, but that will be an unintended consequence of creation of a whole new distribution system for cancer drugs.

- **CAP program expectation that the additional administrative burden on physicians demanded of participants will be offset by expected savings in inventory also shows a lack of understanding of the basic business principles of managing inventory and of the clinical issues in patient care.** *(Pay the industry accepted fair rate for costs of acquisition and handling above and beyond the actual purchase price of drug for each class of trade, recognize that a separate inventory and those additional costs will still also be required due to realities of program demands, even if drugs not purchased directly by physician).* No small business entity such as a physician practice can afford to manage an inventory of small, expensive products on paper or electronically. Reality dictates that a separate physical inventory will be required to protect the practice's own investment in drugs, and to protect the practice from fraud charges associated with handling of drugs obtained from CAP vendors. Every drug that is handled outside of the physician's old order process will require separate staff resources for ordering, unpacking and inventory management. Physicians who provide care for cancer patient in their offices have repeatedly noted that the ASP + 6% rate does not cover their full cost of purchase and acquisition for cancer drugs – that such costs are about 12% over their purchase costs. Potential CAP vendors have also noted to CMS and manufacturers that the ASP+6% based rate does not cover their costs. A recent study by the Medicare Payment Advisory Commission (MedPAC) found that costs of acquisition and handling of cancer drugs in the hospital setting exceeded purchase price by up to 28%.
- **The CAP program assumes erroneously that it will reduce physician inventory needs.** Due to the realities of cancer care, the program is essentially actually mandating that physicians will still required to maintain a full oncology inventory, just to back up the inadequacies of the CAP program. The CAP program sets forth an expectation that changes in treatment plans will occur rarely. In reality, treatment changes will be frequent and unforeseeable. However, not only will physicians have to have sufficient inventory to continue to provide care for patients, but use of that inventory on a frequent basis will put the physician at risk for non-CAP-compliance charges. *(If the CAP program were to continue, it would need to recognize that CAP drug shipments would frequently not arrive in a timely fashion and that physician inventories would be needed, and should not be penalized for utilization.*

- **The CAP program adds cost and infrastructure in a duplicative nature to an already efficient system.** *(CAP should seek to work with existing distribution networks and not require additional information responsibilities from already busy physician practices.)* Few of the potential bidders already are part of the oncology drug distribution system. For them to enter, and make their necessary profits, and obtain information that is not now a part of the required information stream, is to add expense and consumption of resources not now required. Far from making the delivery of cancer care more efficient, it hinders and restricts delivery of cancer treatments. This will lower the quality and access of cancer care to Medicare beneficiaries, not enhance it.
- **The CAP program allows for a non-medical entity, the CAP vendor, to choose to suspend provision of CAP drugs after specific steps, if co-payments are not current.** ***(This element must be completely removed for the CAP program to be even considered by physicians. No non-treating entity should ever have the right to effectively interfere with ongoing, active treatment of a cancer patient.)*** Small business entities, physician practices, have dealt with the bad debt and co-payment issues for cancer patients for decades. It is part of the cost of doing business, and physicians take their commitment very seriously to treat first and deal with the financial ramifications in some manner later. There is no reason why CAP vendors should not be expected to recognize the same cost of doing business if they wish to enter the cancer care market.

Further specific comments on actual items in the Interim Final Rule, by section:

1. General Overview of the CAP

CMS States: We recognize that the timeframe for implementation is ambitious but we believe that it is important to provide the physicians' community with an alternative to the current buy and bill system as soon as possible.

Interestingly, when you read the comments actually submitted, comments from oncology physician practices almost universally focused on the flaws of both the ASP and CAP programs, citing that both programs have fatal base assumptions and policies that make them untenable. As many also noted, the real problem is not the supposed "burden" of the current buy and bill system, it is the imbalance and continued inaccuracies of the payment system for professional services. Oncology physician practices want to be paid a fair rate that covers their costs of professional services, and then also a fair rate that covers their costs to purchase AND ACQUIRE the drugs needed for quality cancer treatment. The above line appears to be a "marketing" line created to "sell" the CAP program to those who do not fully understand the elements that make it a clinically and operationally unworkable solution for oncology, although there do seem to be other specialties willing and ready to embrace the concept.

B. Operational Aspects of the CAP

1. Statutory Requirements Concerning Claims Processing

CMS states: Response: As we stated in the proposed rule, the statute uses the term prescription but does not define it. Further, the process envisioned in the statute contains elements more commonly consistent with orders as well as elements usually associated with prescriptions.
We do not believe that the Congress intended us to abide by a rigid definition of a prescription. We note that CAP vendors must comply with State licensing requirements in all cases, and that our definition of

prescription as used in the statute is not meant in any way to override those requirements. For purposes of this interim final rule, we will define the CAP drug ordering process as a prescription order and will add a definition of the term to the regulations text at Sec. 414.902.

This arbitrary definition of a "prescription order" is clearly an attempt to make the flawed CAP program fit the real world, and to set up a situation where additional vendors could be inserted into the already efficient cancer drug delivery system. A prescription and all the regulatory obligations that it entails are clearly defined in medical, legal and regulatory policy. Only doctors may write prescriptions and only pharmacists may fill them. Distributors accept orders and then deliver drugs to centralized inventory, and drugs are removed from that inventory according to a prescription. There are no blurred lines in those definitions.

For a non-medical entity to arbitrarily create a definition that mixes and matches the two very clear and distinctly separate definitions of "prescription" and "order" is a violation of the basic medical reasons for creation of those distinct definitions. CAP should be retooled to deal with either prescriptions (but NOT for oncology) or orders, but not a made up "prescription order" definition.

In summary, comments received from oncology physicians have repeatedly shown there to be inherent flaws in the statutory design of the CAP program that are incompatible with the delivery of cancer care.

- Cancer treatment is not suited to handling via prescription with time delays awaiting drug. It is individual, and subject to daily variations in patient health status that affect the planned treatment. Drugs must be available at the time of observation of the change in health status, not subject to order and later receipt.
- The more channels through which a drug passes, the great the chance that counterfeit, adulterated, mishandled, or impure drug will enter the distribution system, thereby endangering patients and their treatment. Oncology drugs have very low tolerances to keep them clinically effective and must be treated in a different manner than more stable drugs with less of a life-threatening clinical outcome.
- Cancer patients should not be subject to non-medical entities deciding to stop their treatments by refusing to ship drugs, under any circumstances.
- Artificial pricing (ASP) that bears no resemblance to market based reality forces up demand somewhere along the drug distribution system for "cheap" product, and it usually would be invisible to the treating physician or patient. Only the results (or lack thereof) would be noticeable. In the case of cancer patients, if that "cheap" product is counterfeit, adulterated, mishandled, or impure, the consequences are likely to be life-threatening. ASP should not have to mean A Suspect Product to Medicare cancer patients.
- Unbeknownst to the majority of cancer providers, counterfeit, adulterated, mishandled, or impure cancer drugs have already penetrated America's drug supply. We need to learn from the recent unveiling of this situation and not create new infrastructures that will enable such "bad" medicine to proliferate even further. A house with only a few doors and windows (the current cancer drug delivery and handling system) can be secured far more easily than a house with many doors and windows (the CAP program imposed on the cancer drug delivery and handling system.).
- There is no fix that will make the CAP program, as defined in the MMA, viable for oncology care at this point. CMS should focus on its implementation in other specialties, such as mental health, that seem to be clamoring for it, as evidenced by the comments received under the Proposed CAP Rule, so that it may still comply with the MMA time frames.

Sincerely,

Dawn Holcombe, Executive Director, Oncology Network of CT, LLC

CMS-1325-P-428

Submitter : Mrs. Dawn Holcombe **Date:** 04/26/2005
Organization : Oncology Network of CT LLC
Category : Individual
Issue Areas/Comments

GENERAL

GENERAL

Please see the attachment to this form regarding my serious concerns about the viability of the CAP program as proposed and its insuitability for oncology care.

CMS-1325-P-428-Attach-1.DOC

Delivered in an email attachment through the online comment process

April 26, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS –1325-P
P.O. Box 8010, Baltimore, MD 21244-8010.

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

Dear CMS:

The Oncology Network of Connecticut, LLC (ONC) 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.

On March 4, 2005, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule implementing the Competitive Acquisition Program (CAP) for Medicare Part B drugs. The CAP program was established by Medicare Prescription Drug, Improvement and Modernization Act of 2003 (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.

Upon review of the proposed rule by members of community oncology practices, the group that is supposed to be served by the CAP program as a viable alternative to the ASP + 6% program, we have identified a number of serious concerns regarding CMS' approach and the program's proposed structure and operations that render the program unworkable for oncologists.

I. Categories of Drugs to be included under the CAP.")

CMS proposes three phase-in options:

Option 1 – Under Option 1, CMS would initially implement the 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. .

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.

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.

Comment: These options are less a request for comment than a request for preferred choices. One would expect that once CMS determines a final option, adequate opportunity for public comment will be given before enforcing one of the options on physicians. Regarding our preferred choice: Oncology is a complex specialty and starting a program that disrupts the normal flow of business and clinical operations as dramatically as this proposed rule does without first investigating the impact could be disastrous to access for cancer care for Medicare patients. Please do not institute a CAP program as outlined in this proposal for oncology services unless all the issues and concerns raised by practicing community oncologists are given fair review. In the proposed rule itself, CMS states that the Secretary has authority to exclude drugs and biologicals from the CAP on the grounds that including those drugs would have an adverse impact on access to those drugs and biologicals. As you will see from comments throughout the rest of this letter, for the Secretary NOT to exclude oncology drugs on that basis would be directly in opposition to the reason for creating such authority.

Because, as will be explained further in these comments, the CAP program itself provides no recognition of the very real operating costs and burdens placed upon physician practices by implementation of this program, the resulting adverse impact that the program itself will place on physician practices should, once studied, serve to exclude oncology drugs from the CAP program under the above mentioned Section of the act. CMS should take the time to quantify that adverse impact before implementing the CAP program.

1. Statutory Requirements Concerning Claims Processing

Under this section of the proposed rule, CMS sets forth criteria for resupplying inventories of drugs administered by physicians.

Comment: The rules under which CAP drugs may be used to resupply inventories of physicians do not address 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. If patient needs changed and an alternative regimen is indicated, that may not be an "emergency", but it is highly unreasonable to expect a patient to arrive, be tested, require the physician to submit another order, and tell the patient to return in another day or two when the new mixture of drug arrives (hoping that patient status has not changed again in the interim.)

How would the CAP program address restocking of drug if the physician uses a drug from his private inventory in a category covered by the CAP vendor, but the CAP vendor doesn't carry that particular drug? The physician has the right to expect accurate replacement, without substitution.

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, 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, 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 compensatc 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).

This section of the proposed rule also sets forth a mechanism for physicians to order drugs and for vendors to ship drugs to physicians and then receive payment from the carrier.

Comment: CMS states "It is not our intention to restrict the 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." By definition, the CAP process creates a dramatic and operationally significant change in ordering procedure. Physicians order from non-CAP vendors to stock a single, centralized, inventory. There is no need for staff or systems to track beyond basic drug quantity levels. CAP imposes a requirement for staff and systems to track inventory on a per patient, and even per prescription basis. Additionally, CAP creates a mandatory vendor imposition on the physician which will probably not be the physician's vendor of choice, thus creating double effort to place and track orders and shipments and product. CAP formularies will narrow a physician's choices for product within a category and create extra work for the office if the products provided by a CAP vendor are deemed to be unsuitable from the physicians' quality and operational perspective, since alternative product will need to be ordered.

Physician practices do not now provide to external parties, outside of the carrier claims, additional information such as that expected under the CAP program to be provided to CAP vendors. This is a completely incremental burden on staff and system resources, totally uncompensated under this proposal. The expectation that a physician would send a CAP vendor one prescription for an entire course of treatment but that a CAP vendor

would create a separate prescription number for each shipment component of that course of treatment, and that the physician practice would be required to track each prescription number for submission on the claim form creates an operational nightmare for practices. When the reality is that 1/3 of the time planned courses of treatment change, this creates great potential for confusion and error on the part of all involved.

The proposal states that "the drug and prescription number would be shipped to the physician and would be maintained until the date of drug administration." There is no recognition of the significant drug handling and inventory costs of that expectation. MedPac staff recently studied the costs of such drug handling and inventory in the hospital outpatient setting and identified that 26% to 28% of drug costs were incurred in such handling. (See MedPac meeting testimony – in the transcripts from the meeting held March 10, 2005). Oncology practices have long maintained that such costs in their offices run about 12% of total drug purchase expenditures. With recompense for these costs under the CAP program, physicians will find little incentive to consider using the program. These costs are not now recognized in any other CMS payment to oncologists.

The required prescription numbers are not part of the National Data Set created under HIPAA in recent years, and would be a burden to oncology practices to address in their current practice management systems, as well as a significant cost item.

CMS is seeking public comment on whether physicians must obtain all categories of drugs from a particular CAP vendor, or whether physcians should be allowed to choose the categories they wish to obtain. Absolutely, physicians must be given a choice of categories. As mentioned previously, 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.

The data that the physician is required to transmit is far greater than that used in writing a prescription. The CAP program is inserting a full layer of complexity and data transfer that now does not exist and will create increased administrative cost at all levels for very little additional value. Physicians do not have the staff or the resources in current practice structure to comply with these rules, however, if staff must be added to comply, there is no planned compensation to cover the costs of compliance.

Comment: If physicians choose to place "furnish as written" modifiers on their drug orders, they are still subject to post payment reviews and carrier determination that a specific NDC number was not medically necessary will result in a claim denial. That process takes the medical decisionmaking completely out of the physician hands, yet it is the physician who holds the responsibility and liability for the quality and effectiveness of drugs used for patient care, and who has access to the full information about the patient's condition and health status.

The CMS proposal states that "the physician would notify the vendor and reach an agreement on how to handle the unused drug consistent with applicable State and Federal law." should a drug ordered not be administered. This CAP proposal ignores the fact that most pharmacy regulations indicate that drug, once ordered in a patient's name, may not be returned or reused or reshelved. The entire process of converting oncology inventories from a single centralized non-patient specific inventory to individualized patient inventory will bring millions of dollars of incremental waste into the medical system, on a per practice basis – waste that does not now exist under the current general inventory system.

2. Vendor Quality Control

The proposed rule provides that quality and service issues that relate to the vendor's performance are treated through the vendors own, internal grievance process.

Vendors are being paid to delivery highly volatile and at times, toxic drugs to physicians who need them to treat critically ill patients. It is essential that vendors are held to the highest standard for quality and performance. Doctors, who will be dependent on the vendors to obtain these drugs, need to know that when complaints are raised about poor quality and performance, carriers and CMS will take them seriously. Vendors who fail to perform should be subject to investigation and sanction, up to and including exclusion from the program. It is unrealistic to believe that doctors 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. The program should also make vendors responsible for liability related to any omissions or errors in handling these drugs within their quality parameters, and for failing to ensure that purchased drug cannot be pedigreed back to the manufacturer.

3. Dispute Resolution

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. 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.

4. Contracting Process – Quality and Product Integrity Aspects

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. In effect, this gives a vendor permission to establish a formulary by choosing which drugs it will make available through the CAP.

Comment: 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 program. 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 if they 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, the absence of safeguards is troubling, especially given the absence of clear standards allowing physicians to disenroll from CAP based upon vendor performance. (See comments below regarding CAP Program Operations.)

Oncology care is complex to administer, and while active ingredients may be similar, inactive ingredients of drugs within a category may act in quite different fashions when combined with the rest of the drugs in a complex multi-treatment regimen. CMS states that "we are proposing that vendors will not be required to provide every National Drug Code associated with a HCPCS code." Physicians must be provided with full disclosure prior to selecting a CAP vendor of each brand of drug that vendor will carry, and given the option to not receive certain categories of drugs from a CAP vendor. Without that opt out protection, the operating and quality of care costs of allowing vendors to restrict their inventory to what becomes the cheapest drug for them to provide will be significant because physicians will be facing inventories full of the drugs they have always avoided (the version of a drug that takes extra time to reconstitute – or one that fails to mix properly, leaving particulate matter and needed benefit at the bottom of the bag instead of in the patient). Formularies created for the purpose of saving the vendor acquisition costs may become so limited that physicians will be forced to practice using "dispense as written" specificity for drugs and work outside of the CAP program through the ASP program, incurring cost and additional effort on all sides.

Some categories of drugs may include drugs that have differing FDA approvals or indications. A prime example are the Procrit and Aranesp drugs. These are commonly considered interchangeable, but in fact do have differing indications. There are also two interferon drugs on the market, but each have different indications and approvals. A vendor may bid for one drug in the category and create a formulary based upon market share manufacturer pricing, and thus not make the other drug available in that category. However, if physicians who elect the CAP program are required to acquire drugs in a certain category only from the CAP vendor, they are left unable to acquire the other drug even if it were the only one in that category with a given indication. Indications change frequently, and the bidding process for CAP vendors doesn't seem to leave room for changing category contents as indications change. The variable nature of oncology care and rapidly changing approvals and indications for different drugs and combinations of drugs make formulary management of oncology cumbersome and ineffective.

5. 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. 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, physicians 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. Under the circumstances, physicians must be permitted to obtain drugs through the ASP system.

6.. 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 vendors should be required to meet this standard 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.

7. Bidding Entity Qualifications

Vendors are expected to show a history of delivering Part B injectable drugs for at least 3 years. Oncology drugs are complex, with strict parameters for handling and storage. CAP vendors should be expected to show a history of at least 3 years of delivering each category of drugs for which they submit a bid. 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 neophytes the responsibility of handling oncology and supportive care drugs.

8. 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." However, 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 market of available drugs to their financial gain, and to the detriment of access to care for Medicare beneficiaries and their physicians.

9. CAP Bidding Process – Evaluation and Selection

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

spillage and spoilage are part of the cost of doing business with fragile and delicate stability products. It is unreasonable to exclude these costs of drug handling from both the vendors that ship drugs and the physicians who process and administer the drugs.

The composite bidding process ignores the quality issues of specific drugs in any given category. Drugs are automatically eliminated from bidding consideration if not obtainable at significant enough savings to the Medicare program, yet the cheapest and possibly least usable versions in a category may be the only drugs being made available through the CAP vendors.

10. Beneficiary Education

There is a real, but unrecognized additional cost pending for Medicare beneficiaries if the responsibility for copayment collection moves from the physician practice to the CAP vendor. CAP co-payment collection policies may lead to denials and reduced access to care for some Medicare cancer patients. CMS is not proposing to require physicians to provide beneficiaries with education on the program, there will be a significant administrative burden for physician practices caused by the program. Patients rely on their physicians to guide them through the treatment process, and any disruption of care will send patients immediately back to the physician office with a variety of physicial, financial, medical and psychosocial issues.

11. Physician application process

CMS is estimating that physicians will need 15 minutes each to fulfill the application requirements. The decision process will actually be far more complicated. 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.

12. 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. This rule dramatically underestimates the impact on physician practices, even practices participating in the CAP program, due to underestimation of costs of unreimbursed drug handling and inventory costs, as well as management of new prescription and ordering requirements and additional demands for information sharing with CAP vendors. It would be advisable for CMS to evaluate the impact of participation in a CAP program on physician practices before they actually participate. It also would be advisable to remember that if drug related billings are removed from practice business, the revenue generation thresholds for

practices will drop several fold – thus making them qualify even more as small businesses subject to adverse impact of untested programs.

The CMS proposal suggests that "because the drug remains the property of the vendor until the time of administration, the physician can also reduce the cost associated with storage and individual drug supplier negotiations." This is an unrealistic perspective. The burden to the physician and the related costs actually increase under the CAP program due to the need for separate inventory management and running of concurrent inventories – both for staff and facility resources.

Sincerely,

Dawn Holcombe
Executive Director
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Submitter : Mr. Jason Scull **Date:** 09/06/2005

Organization : Infectious Diseases Society of America

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1325-IFC-159-Attach-1.DOC

IDSA
Infectious Diseases Society of America

September 6, 2005

Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Comments on Interim Final Rule [Docket No. CMS-1325-IFC]: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B

Dear Dr. McClellan:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Competitive Acquisition Program (CAP) interim final rule published on July 6, 2005.

Before addressing the interim final rule, we must first raise again our significant concern that IDSA's physician members continue to experience serious problems in acquiring most antibiotics and other products at or below the Average Sales Price (ASP). These problems were underscored in IDSA's March 7, 2005 letter to CMS and in a meeting with CMS officials on May 10, 2005, during which we also discussed our members' concerns with the CAP proposed rule. CMS officials indicated, during the meeting, that they were aware that the ASP program does not sufficiently reimburse for antibiotics. We also would like to call to your attention our concern about CMS's proposal to implement an ASP + 8% drug payment methodology in the inpatient setting. A payment methodology that pays hospitals more than individual physicians would be grossly unfair, and the proposal indicates that CMS is not serious about maintaining patient access to services in the physician office setting. If CMS has the flexibility to provide ASP + 8% to hospitals, it should use this flexibility to provide the same rate to physicians who currently are subsidizing treatments for Medicare beneficiaries.

While IDSA appreciates the time CMS staff have spent developing the CAP, we are disappointed that most of our comments to the proposed rule were not incorporated into the interim final rule. The CAP remains administratively burdensome, offers little clarity on the definition of "emergency situations", and provides no means for physicians to acquire drugs immediately (short of using existing non-CAP inventories). We fear that many infectious diseases (ID) physicians, who cannot acquire antibiotics below the ASP, will choose to discontinue infusion services to Medicare beneficiaries rather than deal with the

additional administrative hassles, costs, and uncertainties of participating in the CAP. However, IDSA remains committed to assisting CMS in creating a CAP final rule that will ensure Medicare beneficiaries continue to have access to life-saving anti-infective drugs and biologicals in the physician office setting. With this in mind, IDSA will comment on the following issues raised by the interim final rule:

- Patient-specific ordering and inventory systems as well as duplicative information requirements translate into additional staff time and physicians' costs.

- The definition of emergency situations remains unclear, and there is no system for same day drug acquisition.

- The notion that CMS will monitor utilization of the emergency "resupply provision" to detect patterns of abuse is troubling to infectious diseases physicians, who will utilize this provision on a regular basis due to the nature of the conditions they treat.

- Vaccines commonly used in emergency situations, such as the tetanus and diphtheria vaccines, should not be excluded from the initial drug category.

- Physicians should have maximum flexibility to administer CAP drugs at locations other than the office setting (such as in patients' homes).

BACKGROUND

IDSA represents more than 8,000 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases. The Society's members focus on the epidemiology, diagnosis, investigation, treatment, and prevention of infectious diseases in the United States and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, surgical infections, those with cancer or transplants who have life-threatening infections caused by unusual microorganisms, HIV/AIDS, and new and emerging infections, such as severe acute respiratory syndrome (SARS) and influenza. Many ID physicians infuse or inject drugs and biologicals in their offices, and therefore, will be significantly affected by the CAP program.

ADMINISTRATIVE BURDEN

While CMS continues to insist that the administrative burden of the CAP will be minimal, ID physicians on the frontlines of outpatient drug administration remain unconvinced and seriously concerned. ID physicians are certain that additional staff time will be necessary to place patient-specific drug orders, file patient-specific claims, keep track of dose-specific prescription order numbers, and maintain patient-specific inventories (either physical or electronic) of CAP drugs.

The patient-specific and dose-specific nature of the CAP will increase the administrative burden and costs for physicians who choose to participate in this new acquisition program.

The ordering system envisioned by the CAP is significantly more complex than the bulk orders physicians currently make through the ASP program. Instead of writing one large order for 20 doses of a drug, physicians participating in the CAP will be required to order each dose individually and keep track of the prescription order number of each dose for purposes of claims matching by the Medicare carriers.

In addition, physicians participating in the CAP will be required to include an estimated date of service on the drug order and an actual date of service on the claim. Such duplicative information will require extra staff time and cost physicians, most of whom operate small practices that cannot absorb additional unreimbursed expenses. Furthermore, it remains unclear why physicians are required to provide an estimated and actual date of service to the vendor. Physicians should only be required to provide and vendors should only need the actual date of service (on the claims) in order to ensure payment by Medicare carriers.

Perhaps most worrisome are the separate physical or electronic inventories that physicians participating in the CAP will need to maintain. CMS's contention that the separate inventory requirement will *not* entail significantly more staff time and money is unrealistic.

While IDSA understands that CMS is constrained by statutory requirements, and that certain tracking policies are necessary to ensure vendor participation, physicians who choose to participate in the CAP should not be forced to absorb additional administrative costs, which will be substantial. A number of our members who provide office-based infusion services have indicated to IDSA that they will not be participating in the CAP. They project that their costs will rise under the CAP and they cannot afford to absorb additional costs to care for Medicare patients. To remedy this problem, IDSA urges CMS to establish a new payment for administrative costs associated with the CAP.

EMERGENCY SITUATIONS

IDSA and other medical specialties, in comments to the proposed rule, sought clarification as to what circumstances constitute an emergency situation under the CAP. In the interim final rule, CMS has interpreted emergency situation to mean *"a situation that in the physician's clinical judgment requires immediate treatment of the patient."* This statement provides little clarity and potentially is problematic, depending on how it is monitored and enforced.

The interim final rule includes a provision that requires a one-business-day delivery for drugs needed in emergency situations. However, for ID physicians, who often need drugs immediately to prevent complications and/or avoid costly hospital stays, a one-business-day delivery provision is not prompt enough. Often, physicians do not and will not have the needed drugs within their office-based inventories. Therefore, CMS must require same day drug deliveries or allow immediate drug acquisition when the diagnosing physician can show a clear and present danger to the patient. Such a provision could be modeled after the "furnish as written" provision, which allows physicians to obtain a drug under the ASP methodology in certain situations. Without such a provision, Medicare will be forced to pay for unnecessary

hospital stays for patients suffering from acute infectious diseases that could have been treated more cost-effectively in physicians' offices.

Due to the nature of their patients' acute conditions, ID physicians likely will utilize the emergency resupply provision provided in the rule on a regular basis and more often than other specialties. CMS stated in the interim final rule that *the resupply provision should be used sparingly (and only in emergency situations) and that utilization of this option would be monitored to detect patterns of abuse.* IDSA and its clinician members view this statement seriously and believe that it likely foreshadows future problems for them as they care for patients with acute symptoms. Such fears and uncertainty may cause ID physicians to decide not to participate in the CAP. As such, we seek assurances that CMS (and Medicare carriers) will provide broad latitude to ID physicians when monitoring utilization of the resupply provision.

EXCLUDED DRUGS

IDSA disagrees with CMS's decision to exclude certain vaccines, such as the tetanus and diphtheria vaccines, from inclusion in the CAP because they are used in emergency situations. We are unconvinced that these vaccines are more commonly used in emergency situations than many antibiotics included in the initial category of 169 drugs. Drugs frequently used in emergency situations should not be excluded from the CAP. If CMS were to exclude such drugs, ID physicians effectively would be excluded from participating in the CAP.

DELIVERY OF THE CAP DRUGS

While IDSA empathizes with vendors' product integrity and liability concerns regarding the transportation and administration of drugs at locations other than the office setting, we believe the risk is minimal. In the interim final rule CMS asked for comments about how physicians could deliver and administer drugs to patients in their homes under the CAP. IDSA and its members strongly encourage maximum flexibility to allow physicians to do this. We propose to allow physicians to pull drugs from their non-CAP inventories to administer to patients in their homes. The physicians could then utilize the resupply provision to replace these non-CAP drugs. The current resupply provision has four criteria (geared to the replacement of drugs administered in emergency situations). In order for physicians to deliver and oversee the administration of drugs in patients' homes, CMS would need to add a separate criterion that permits CAP drugs to be used to resupply drugs that have been admininistered to a patient in his or her home.

CONCLUSION

IDSA appreciates the opportunity to comment on the CAP interim final rule. We strongly believe that infectious diseases physicians need a viable alternative to the flawed ASP methodology for acquiring drugs and biologicals. While the recent decision to delay implementation of the CAP until July 2006 is troubling, it provides CMS with more time to review comments and hopefully to draft a final rule that encourages widespread physician and

vendor participation in the CAP, to the ultimate benefit of Medicare beneficiaries. IDSA and its members firmly believe the changes outlined above will help CMS accomplish this goal.

If you have any questions concerning this matter, please contact Robert J. Guidos, JD, IDSA's Director of Public Policy and Government Relations, at (703)-299-0200.

Sincerely,

Walter E. Stamm, MD
President

Submitter :

Date: 09/06/2005

Organization : **American Pharmacists Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1325-IFC-160-Attach-1.DOC

American Pharmacists Association

Improving medication use. Advancing patient care.

APhA

September 6, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1325-IFC
PO Box 8013
Baltimore, MD 21244-8013

Re: CMS-1325-IFC

Dear Sir/Madam:

Thank you for the opportunity to comment on the interim final rule implementing a competitive acquisition program (CAP) for certain Medicare Part D drugs and biologicals not paid on a cost or prospective payment system basis. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 53,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

The interim final rule provides for an alternative to the current payment methodology for the limited number of drugs and biologics available under Medicare Part B. Currently, Part B drugs and biologicals not paid on a cost or prospective payment basis are reimbursed at 106% of the Average Sales Price (ASP). Under the interim final rule, which implements changes mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the Act), physicians would have the option to continue purchasing and seeking reimbursement for Part B drugs as they do now, or obtaining these drugs from a vendor selected through a competitive bidding process.

APhA recognizes the Centers for Medicare and Medicaid Services' (CMS) desire to provide an alternative payment system for Part B drugs. The creation of the competitive acquisition program is part of Congress' and CMS' continuing efforts to implement an "appropriate" reimbursement system for Part B drugs. Since passage of the Act in 2003, the reimbursement system has been revised twice: first moving from 95% to 85% of the Average Wholesale Price (AWP) in 2004, and then moving from AWP to 106% of the Average Sales Price (ASP) in 2005. With the introduction of the CAP in 2006, CMS hopes that the ASP and CAP payment methodologies will more accurately reflect actual product costs. The CAP system is expected to benefit the Medicare program, because as the Agency states in its regulation, the program will only accept bids that fall below the payment level of 106% of the ASP which should result in lower reimbursement costs for the Medicare program. Although APhA

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supports efforts to revise the system to more accurately reflect product costs and the costs to provide the product, we have several concerns with the competitive acquisition program. Because the interim final regulation generally mirrors the Agency's initial March 2005 proposal to implement the CAP, many of the concerns that follow are the same as those previously communicated to the Agency in response to the proposed rule. We urge the Agency to consider and address these concerns in future regulations.

Competitive Acquisition Areas

The MMA directs the Secretary of the Department of Health and Human Services to establish competitive acquisition areas in which vendors may bid to supply Part B drugs. In the Agency's March 2005 proposed regulation, CMS requested comments on how the areas should be determined. The Agency specifically requested comments on whether the Agency should establish state-wide areas, a number of regional areas, or one national area. In the interim final regulation, CMS establishes a nationwide competitive acquisition area. APhA is disappointed with the Agency's decision to create a single nationwide area. A national level will make it difficult, if not impossible, for smaller pharmacies and other suppliers to participate as CAP vendors. Because fewer vendors will be able to compete on a national level, physicians will have fewer CAP vendors to select from and competition among the vendors will decrease. A nationwide area will also present licensing problems. To participate in a national area, vendors will be required to obtain a pharmacy and/or drug distributor license in all 50 states, the District of Columbia, Puerto Rico, and the U.S. territories.

According to the preamble of the regulation, the Agency is considering establishing regional or state-based acquisition areas in the future. The single nationwide area will likely be temporary – in use only for the "initial stage of the program." While APhA is encouraged by CMS' intention to establish smaller acquisition areas in the future; the Agency does not provide any information on the length of the initial implementation phase or when smaller geographic areas will be defined. We ask the Agency to provide a timeline for the initial stage of the program and clarify when the Agency will redefine the competitive acquisition areas. As CMS works to redefine the areas, we suggest that the Agency consider state-wide competitive acquisition areas. Pharmacies and other drug distributors are licensed on a state level; therefore, state-wide acquisition areas seem most appropriate. State-wide acquisition areas would also allow a greater number of pharmacies to participate in the CAP and encourage competition. And a state-based system would not prevent bidders who wish to provide CAP drugs in multiple regions or nationwide from submitting multiple bids to do so.

Proposed Claims Processing and Operational Overview

The regulation contains an overview of the claims processing system for drugs obtained through the competitive acquisition program. According to the regulation, after selecting a CAP vendor, physicians will order Part B drugs needed for specific patients from the vendor. When the vendor receives the order from a physician, the vendor will assign the order a prescription order number and ship the drug to the physician. The CAP vendor will then submit a claim for the cost of the drug product to the designated Medicare carrier, which will reimburse the vendor after verifying that the physician has administered the drug to the patient. The carrier will verify administration of the product by matching the prescription order number on the vendor's claim for the drug product to the prescription order number on the claim submitted by the physician for the cost of administering the drug. The vendor will then bill the patient for any applicable deductible or co-payment for the drug.

According to CMS, this process will reduce the financial and administrative burden on physicians since they will "no longer have to buy the drugs, collect the copayments, or bill Medicare for the drugs."[1] While APhA supports efforts to decrease administrative burdens for providers, we are concerned that the regulation claims to simplify the drug acquisition and reimbursement process, when it simply shifts the administrative and financial burden from one provider (the physician) to another (the pharmacist or other vendor). Pharmacies that participate in the CAP will be responsible for taking prescription orders from physicians, assigning prescription order numbers, contacting the designated Medicare carrier to verify that the beneficiary has current Part B coverage, shipping the drug to the physician, estimating when the drug has been administered and it is "safe" to submit the drug claim, and determining when it is appropriate to bill the beneficiary for the deductible or copayment and the applicable amount.

The CAP claims processing system is far more complex than the current reimbursement system for Part B drugs. For example, the pharmacy cannot submit a claim for the drug product until the drug has been administered by the physician. How will the pharmacist know that the drug has been administered? While CMS will request that physicians administer the drug within two weeks of receipt of the drug, the physician is not required to do so. The pharmacist will not be able to determine if the drug has been administered unless they contact the physician, or submit the claim two weeks after the drug product was delivered and hope that it has been administered so the claim will be filled.

The claims process could also result in lengthy delays between the time the pharmacy supplies the physician with the product and the time the pharmacy is reimbursed. Consider what would happen if a physician decides not to administer a product after it has been delivered. The pharmacy could not bill Medicare for the product since it was not administered. According to the regulation, the physician would be expected to contact the vendor and "discuss what to do" which may include allowing the product to remain in the physician's drug inventory or returning the drug to the vendor.[2] If the physician keeps the drug product as part of the practice's CAP drug supply – which would be the only option in states that prohibit product returns or if the drug had been opened – the pharmacy would only receive reimbursement upon the eventual administration of the product to another Medicare beneficiary.

The CAP claims process could also create situations in which the pharmacy would receive only partial, or in some cases no reimbursement, for the product supplied. For example, after a Medicare carrier approves the pharmacy's drug product claim, the pharmacy would bill the beneficiary for the applicable deductible or coinsurance amount. But what happens if the beneficiary fails to pay the pharmacy? The beneficiary has little incentive to pay – the beneficiary has already received the product – or the beneficiary may decide they are unable to afford the coinsurance. The pharmacy's only option would be to waive the cost-sharing amount, keep pursuing payment from the beneficiary, or refuse to supply further products for that beneficiary until the bill has been paid.

Pharmacies would also risk not receiving full payment when the physician only administers a portion of the drug product originally ordered. CAP vendors are required to furnish drugs to physicians in unopened containers or vials. In situations where the drug is dosed by body weight or some other variable, the amount of medication shipped to the physician may not match the amount actually administered to the patient, resulting in excess drug product. Under the regulation, if the physician is

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[1] Centers for Medicare and Medicaid Services. Press Release. "CMS Offers New Option for Physicians who Administer Drugs in Their Offices." June 27, 2005.
[2] 70 FR at 39,048.

unable to use the remainder of the product for subsequent dosing or for another beneficiary, the vendor is required to accept a return of the excess product from the physician for disposal. The vendor is only allowed to bill the Medicare carrier for the portion administered to the beneficiary. As a result, the pharmacy will only receive reimbursement for a portion of the product actually supplied. The pharmacy will be forced to absorb the costs of the excess product that must be destroyed. In this situation, the cost for the vendor to obtain and supply the product may exceed the partial reimbursement the vendor receives from the Medicare program; especially when you consider that the vendor is required to pay the shipping cost for the physician to return the excess product.

As described above, partial reimbursement or delayed product reimbursement would create an untenable situation for many pharmacies. However, one of the most disturbing provisions of the CAP is the requirement that vendors supply a drug to the physician even if the vendor believes the drug order is not consistent with a local coverage determination and the reimbursement claim will be denied. Although the regulation suggests that the pharmacy or other vendor attempt to obtain an Advanced Beneficiary Notice (ABN) from the patient before supplying the drug, the vendor is still *required* to supply the drug even if the beneficiary refuses to sign the ABN. If the pharmacy supplies the drug to the physician – as required – and the claim is denied by the Medicare carrier, the pharmacy's only option would be to appeal the drug claim denial – with no guarantee of success. This is unacceptable. Pharmacies operate on a small profit margin, they cannot supply product with no real assurances when, and in some cases, if ever, they will be reimbursed.

APhA urges CMS to revise the claims system for CAP products. Pharmacies or other vendors should be able to bill the Medicare carrier for the drug product at the time of delivery to the physician. When the pharmacy delivers the product to the physician, the pharmacy has fulfilled its responsibilities; it has dispensed a prescription order by the physician for a specific patient. Like any other retail transaction, payment should be due upon receipt of the product, not the first time the product is actually used. If the pharmacy is not allowed to bill for the full cost of the drug product at the time of delivery, the Agency should, at a minimum, allow the pharmacy to seek partial payment from the Medicare carrier when the product is shipped. The Medicare carrier could reimburse the pharmacy for the remaining amount upon receipt of the physician's claim for administration services.

Determining the Single Price for a Category of Drugs

Under the CAP, CMS will set a single price for each Part B drug supplied through the competitive acquisition program. The single price will apply to the entire competitive acquisition area and will be based on the median cost submitted in vendor bids accepted by CMS. Vendors must accept the single price as the reimbursement rate in order to participate in the program.

According to the regulation, the single price will not only serve as the reimbursement rate for vendors; the Agency also intends to include the single drug price in the quarterly Average Sales Price (ASP) calculation. APhA strongly opposes the inclusion of the single drug prices determined under the CAP in the computation of ASP. The ASP is supposed to be based on manufacturer-reported sales to purchasers in the U.S. The reported prices include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates other than those provided under the Medicaid drug rebate program. However, the ASP calculation does not contain sales subject to the Medicaid best price calculation or nominal sales. These exclusions were created in order to help prevent unusually discounted or unusually high sales prices from artificially lowering or raising the "average" sales price.

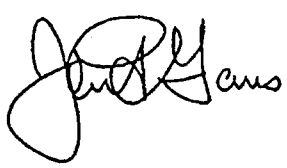
Like sales subject to the Medicaid best price calculation, single drug prices determined by CMS under the CAP should be exempt from the ASP calculation. Single drug prices for the CAP are not based on manufacturer-reported sales, but are set by CMS based on the bids submitted by the potential vendors. These rates that may be unusually low because of the competitive acquisition program's design. Because few pharmacies or other vendors will be able to meet the requirements for CMS approval as a CAP vendor, the number of approved vendors will be small. With only a few vendors supplying CAP drugs to the entire country, each vendor will supply a large number of physicians who elect to participate in the CAP. Because vendors will be purchasing large quantities of drug products from manufacturers, vendors may be able to negotiate significantly lower prices with manufacturers – prices that are not available to pharmacies or other suppliers. If the Agency includes the CAP single drug prices in the ASP calculation, the ASP will not accurately represent the "average" price available to pharmacies and other purchasers. Most pharmacies and other vendors will not have access to this lower price. Inclusion of the CAP prices will inappropriately lower the ASP to a level that may not adequately cover pharmacies' or other suppliers' costs to acquire and deliver drug products.

APhA urges the Agency to exclude CAP single drug prices from calculation of the ASP. Inclusion of the CAP prices in the ASP may lower reimbursement rates to a level that is not sufficient to cover pharmacies' and other vendors' costs to acquire part B products. If pharmacies and other vendors are unable to provide Part B drugs at the new reimbursement rate, many pharmacies may choose to discontinue providing these drug products to physicians and their patients.

In conclusion, APhA urges the Agency to reexamine the design of the CAP. Some of the program requirements will prevent pharmacies and other suppliers from participating as a CAP vendor. Most pharmacies do not have the resources necessary to supply drugs in a national competitive area, and the claims processing system will force vendors to carry a significant financial risk that most pharmacies cannot afford. If the program is implemented as described in the interim final regulation and the requirements prevent pharmacies from participating in the program, the effects will extend far beyond the pharmacies. A lack of participation by pharmacies will reduce competition among vendors and decrease the number of vendors that physicians can select from, and may negatively affect beneficiaries' access to Part B medications.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan K. Bishop, Associate Director, Regulatory Affairs at 202-429-7538 or SBishop@APhAnet.org with any questions.

Sincerely,



John A. Gans, PharmD
Executive Vice President

cc: Susan C. Winckler, RPh, Esq, Vice President, Policy & Communications and Staff Counsel
Susan K. Bishop, MA, Associate Director, Regulatory Affairs

Submitter : **Mr. Samuel Shepard** **Date: 09/06/2005**

Organization : **American Association of Clinical Urologists**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-161-Attach-1.PDF

September 6, 2005

Dr. Mark McClellen, M.D., Ph.D
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

Dear Dr. McClellen:

Thank you for this opportunity to comment on the interim final rule "CMS-1325-IFC", the Competitive Acquisition Program (CAP) for Medicare Part B drugs. The American Association of Clinical Urologists (AACU) understands the motivation behind the proposed changes to the Medicare program, but we are concerned that administrative barriers still present in the interim final rule will prevent urologists from participating.

We feel the establishment of a physician advisory panel would still facilitate effective implementation of the CAP program. The panel should be composed of specialty physician representatives who administer Medicare Part B drugs. This structure is commonly used in other Medicare programs. A physician advisory panel would assist CMS in resolving practical problems encountered when implementing a new program (i.e. delivery, inventory issues, incorporating prescription numbers) and thereby ensure physician participation and optimum patient access.

Covered Drugs and Biologicals
Our members provide a variety of drug therapies for prostate and bladder cancer. They are frustrated that other regulations such as the Least Costly Alternative Policy might hamper the availability of drugs in the CAP program due to the financial impact that policy will have on CAP vendors. AACU continues to be concerned that the application of LCA to the CAP will greatly interfere with the success of this program.

Claims Processing Overview
CAP administrative requirements state that "a separate electronic or paper inventory for each CAP drug obtained" must be maintained. This implies additional administrative costs and record keeping. In our previous comments we iterated that this burden drains office and administrative resources without any obvious benefit. We believe that this interim final rule has not addressed this issue. Staff and clerical time spent on CAP inventory upkeep is time spent away from providing patient care.

In addition, CAP vendors may insert themselves into the doctor-patient relationship attempting to collect payment for Part B drugs. We anticipate that our member urologists would be inundated with many questions and concerns from their patients after being contacted by a new third party entity when they are not fulfilling their cost-sharing obligations. Doctors will be on the front line, having to explain the implementation of this new program.

CAP Bidding Process—Evaluation and Selection

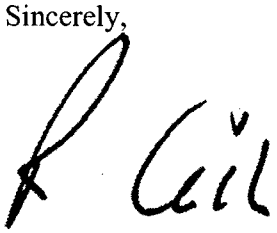
Because there are serious concerns within the pool of potential vendors who might bid to distribute CAP drugs, thus causing a change in the CAP implementation timeline, we believe CMS must address the question of who pays for drug waste in a more logical and clear manner. Until that issue is sufficiently solved within the CAP program, CMS should not expect widespread participation by potential vendors.

In addition, AACU urges CMS to use their administrative power to change the policy that governs the vendors' purchase prices for various drugs when calculating ASP. Because the CAP program is national in scope, it will provide leverage to the large vendors to demand deep discounts for the Medicare Part B drugs they purchase. Physicians, who participate in the CAP, will in effect, underwrite their purchasing power. It will seem punitive when the non-participating physician finds the ASP for the second, third or fourth quarter in the years following their decision to not participate, falling below the price that is available to him. No individual could hope to buy at the same price provided the large volume buyers.

The establishment of the CAP should not be used to create unfair competition between the individual physician and large vendors with respect to the price they purchase medications at. The intent of moving reimbursement to a ASP+6% basis was to establish fairness in the system, not to punish small groups of physicians who lack the market share necessary to demand large, volume discounts. If the vendors' purchase prices for Medicare Part B medications are eliminated from the calculations for ASP, then fairness will be maintained, physicians will be able to make business decisions during the CAP election period without artificial distortions of the drug purchasing environment and our patients will be well served.

Thank you for the opportunity to comment on the Competitive Acquisition Program Interim Final Rule as proposed by CMS. Again, we are eager to work with CMS to implement CAP to ensure continued high quality health care delivery to our patients.

Sincerely,



Peter C. Albertsen, M.D.
President, AACU

Submitter : **Dr. Anil Raiker** **Date: 09/06/2005**

Organization : **Pinellas Cancer Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS e-mail reply: We choose not to participate in the CAP Program due to increase in manual power and hours for no additional reimbursement. It will require more storage space to store the patients medication and keep track of the meds for no additional reimbursement. Billing needs to be done within a certain time limit specified by CMS which may not be possible especially for a one physician practice like ours if the billling person goes on vacation or is sick. We have a lot of questions about how CAP is going to work. For example; who is liable if the pharmacy does not send the chemo therapy meds on time, etc. Many times depending upon lab tests we need to cancel chemo due to the patient being to sick to get treatment. This will lead to a lot of waste on very expensive chemo drugs. We will have to hire more personnel both in the billing department and Record Keeping due to the increase in overhead.

Sincerley,

Anil N. Raiker, MD

Submitter : Mr. Jim Hayes **Date:** 09/06/2005

Organization : Allergan Inc.

Category : Drug Industry

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Please see attached document.

CMS-1325-IFC-163-Attach-1.PDF

ALLERGAN

2525 Dupont Drive, P.O. Box 19534, Irvine, CA 92623-9534 • (714) 246-4500

September 6, 2005

VIA ELECTRONIC SUBMISSION

Mark McClellan, M.D., Ph.D. Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Interim Rule
CMS-1325-IFC
"Provisions of the Interim Final Rule"

Dear Dr. McClellan:

On behalf of Allergan Inc. ("Allergan"), we are pleased to submit comments in response to the above-captioned Interim Final Rule ("IFR") on the Competitive Acquisition Program for outpatient drugs and biologicals under Part B (the "CAP"). Allergan develops and manufactures BOTOX® (Botulinum Toxin Type A) Purified Neurotoxin Complex. BOTOX® is a biological used to treat patients with blepharospasm (a disorder involving involuntary closure of the eyelids), strabismus (a disorder of muscles that move the eyes), cervical dystonia (abnormal movements of the neck muscles) and severe primary axillary hyperhidrosis (disorder of sweat glands).[1] BOTOX® is administered by physicians in their offices as well as in hospital outpatient departments. BOTOX® is covered as a biological provided incident-to a physician's service under Medicare Part B.

We were pleased with many parts of the IFR and appreciated CMS's responsiveness to comments submitted by interested stakeholders in response to the Notice of Proposed Rulemaking. At the same time, we agree with the Centers for Medicare and Medicaid Services's ("CMS's") decision, announced August 3, 2005, to delay implementation of the CAP program so that CMS may finalize the program informed by comments from interested stakeholders on outstanding issues identified from review of the IFR.

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[1] The current package labeling includes the following indications for BOTOX®:
BOTOX® is indicated for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.
BOTOX® is indicated for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.
BOTOX® is indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.
The efficacy of BOTOX® treatment in deviations over 50 prism diopters, in restrictive strabismus, in Duane's syndrome with lateral rectus weakness, and in secondary strabismus caused by prior surgical over-recession of the antagonist has not been established. BOTOX® is ineffective in chronic paralytic strabismus except when used in conjunction with surgical repair to reduce antagonist contracture.
In addition, BOTOX® Cosmetic, which has distinct labeling, packaging and NDC-coding, has been approved by the FDA for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients ≤65 years of age. BOTOX® Cosmetic is never covered by Medicare.

In summary, our comments are as follows:

- We are pleased with the decision to include botulinum toxin type A (HCPCS code J0585) under the CAP program. This will provide neurologists, ophthalmologists, physical medicine and rehabilitation and other physician specialists who administer botulinum toxin type A flexibility when offering chemodenervation treatment to their patients.

- We agree with CMS's determination that CAP vendors will not have the authority to develop formularies, but rather, will defer to physicians' judgment in shipping products as ordered.

- We also agree with CMS's decision that the judgment of the treating physician will be the standard for determining whether an emergency condition exists to allow for treatment from the physician's own supplies to be replenished later by the CAP vendor. We would recommend that CMS advise CAP vendors that the physician's order appropriately governs whether or not the CAP vendor is obligated to ship in these emergency situations. The CAP vendor must not be permitted to substitute its own judgment as to whether a valid emergency existed or whether the drug would be covered under these circumstances.

- We are pleased by CMS's recent clarification, by way of response to a Question and Answer posting on the CMS website, that CAP vendors will be permitted to bill for drugs that are ordered, shipped but only partially used consistent with the current CMS policy for discarded drugs. We would urge CMS to confirm this policy in a revised final rule.

- We would encourage CMS to take sufficient time before implementing the CAP program to address several operational issues that physicians, manufacturers and vendors have raised about the new program, including: (1) assuring that the chemodenervation series of codes, which are used to report the administration of botulinum toxin type A, are recognized in the claims processing system as reflecting the administration of this biological—standard injection codes do not apply to treatment with botulinum toxin type A; (2) providing clear instructions for tracking receipt, storage, and administration of CAP drugs and discard or return of unused CAP drugs and how such tracking should distinguish CAP drugs from other supplies of the same drugs; (3) how to handle situations where the amount ordered may be less than the amount actually required to be administered; and (4) how to handle situations where the patient is scheduled for treatment at one office location at the time the drug is ordered, but actually receives the drug at another office location.

These points are explained more fully below.

1. CMS correctly determined that botulinum toxin type A should be included in the CAP program

We were pleased to see botulinum toxin type A (HCPCS code J0585)[2] listed among the drugs and biologicals that CMS has identified are appropriate for inclusion in the CAP program. Among beneficiaries in the Medicare program, botulinum toxin type A is used for a number of discrete disorders of movement (focal dystonias, spasticity from stroke or brain injury) or disorders characterized by

[2] The descriptor for code J0585 is: "botulinum toxin type A, per unit."

excessive cholinergic activity (severe primary axillary hyperhidrosis). Most of these patients are treated by highly specialized physicians, including neurologists, ophthalmologists and physiatrists. Physicians in these specialties rarely administer injectable drugs and biologicals billed to third party payers as part of their office practices (i.e., in comparison to other specialties, such as oncology or rheumatology, where such practice is common). For these physicians, purchasing and billing for drugs and biologicals often involves substantial administrative burden, which may not be adequately covered by reimbursement rates for drugs that are intended to cover acquisition cost alone.

When the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") was passed authorizing the CAP program, surveys revealed that many physicians who administer botulinum toxin type A were interested in switching to the program to avoid the burden of purchasing and billing for this biological. We are pleased, therefore, that these physicians will have the option to enroll in the CAP program to obtain botulinum toxin type A for their patients.

2. CMS correctly interpreted the MMA as requiring vendors to offer at least one product per HCPCS code and to preclude the development of formularies.

We were pleased that CMS confirmed in the IFR that CAP vendors must provide at least one National Drug Code (NDC) for each HCPCS included in a CAP category. This is consistent with the statutory mandate to provide "at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area."[3]

Physicians who elect to participate in the CAP program because they wish to avoid the administrative hassles of purchasing and billing for injectable drugs and biologicals should not be forced to accept a restrictive formulary limiting access to drugs and biologicals that otherwise are available under the Part B program. Patients should not be deprived of the therapies that their physicians consider to be the most appropriate for their care simply because their physicians have elected to enroll in the CAP program.

We believe CMS should go one step further and require vendors to offer at least one NDC for each single source drug and biological, even when a specific single source product is billed using the same HCPCS code as another single source product. There are historical reasons why a number of biologicals that were first introduced 10 to 20 years ago (or earlier) were assigned non-proprietary names that do not describe unique single source products. It is likely that many of these products, if they were to come to market today, would be assigned unique non-proprietary names for each single source product. These products would likely have unique HCPCS codes as well. Where FDA has not determined that two products are therapeutically equivalent, CAP vendors should be required to offer at least one NDC per single source product per HCPCS code. This will ensure that all patients will have access to the specific products which their physicians determine to be appropriate for them.

3. Physician judgment should determine when an emergency condition warrants immediate treatment from the physician's own supply with replenishment supplied by the CAP vendor.

We were very pleased that CMS concluded that the physician's own judgment is the appropriate standard to apply for determining whether or not an emergency condition exists warranting immediate treatment from the physician's supply with subsequent replenishment of stock by the CAP vendor. This will allow physicians to treat their patients when medically appropriate without unnecessary delays to obtain drugs

[3] Soc. Sec. Act § 1847B(b)(1).

from the CAP vendor. Given the strict timelines for delivery under the CAP program (i.e., one business day for emergency orders), we believe that physicians will only rarely need to exercise this option with respect to botulinum toxin type A.

To assure that this policy is carried out appropriately, we would encourage CMS to instruct CAP vendors that they must ship drugs ordered to replace emergency use of the physician's own supplies in the same manner that the CAP vendor is required to ship any order from the physician. The CAP vendor must not be permitted to withhold shipment because the vendor does not agree that an emergency existed or because the vendor believes the drug will not be covered in the particular case.

4. The discard policy that applies to Part B drugs generally should apply to drugs provided under the CAP program

In the IFR, CMS stated that discarded drugs would not be eligible for payment under the CAP. CMS recognized that this would be different from policy the applies for drugs and biologicals otherwise available under Part B outside of the CAP program. CMS did not identify the specific statutory provision on which the Agency was relying that led CMS to determine that discarded drugs would be ineligible for reimbursement under the CAP.

We were very troubled by the policy on discarded drugs announced in the IFR. Botulinum toxin type A is supplied in single use vials containing 100 units per vial. Some patients may be treated with a single vial per treatment session; while others may require several vials per treatment session. There is no single dosage of botulinum toxin type A that applies to all patients or even to patients with specific indications for use of botulinum toxin type A. For example, the package labeling indicates that the median dose in clinical trials for treating patients with cervical dystonia was 236 units. Seventy-five percent of patients required 300 units or less, but 25-percent of patients required dosages in excess of 300 units. Patients treated for blepharospasm may require dosages less than 100 units. In addition, the amount that may be required for treatment may vary from treatment session to treatment session in a particular patient. Therefore, it is difficult for physicians to order botulinum toxin type A in such a way that there will never be unused drug.

With respect to Part B drugs paid under the ASP methodology, CMS has addressed this issue in the discard policy presented in the Medicare Claims Processing Manual. Botulinum toxin type A is the specific example used to describe the discard policy in the Manual.[4] Under this sensible policy, physicians are encouraged to group patients for treatment, when feasible, to avoid discarded drug supplies. However, when discard is unavoidable, Medicare will reimburse remaining amounts in a vial. The same policy should apply under the CAP program.

We were pleased to see the recently published Question and Answer in which CMS apparently has determined that the policy announced in the IFR would be changed: *"[U]nder the Average Sales Price system, a physician is able to bill the program for unused drugs if the physician acted in good faith with respect to the ordering and use of the drugs. We expect that vendors will be able to bill the program for unused drugs under the CAP program in a similar fashion if physicians and vendors act in good faith with respect to the ordering and use of the drugs."*[5]

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[4] Medicare Claims Processing Manual (Pub 100-4) Chapter 17 Drugs and Biologicals, Section 40 Discarded Drugs and Biologicals.

[5] "Response to CAP Vendor Questions"
<http://www.cms.hhs.gov/providers/drugs/compbid/capquestions08102005[1].pdf>

We would strongly encourage CMS to clarify in a revised final rule that the current discard policy under Part B applies to the CAP program as well.

We would note that the MMA provisions authorizing the CAP program do not appear to conflict with the application of the current drug discard policy to the CAP. The MMA provides: the "bid price submitted in a contract offer for a competitively biddable drug or biological shall—. . . not include any costs related to the administration of the drug or biological, or wastage, spillage or spoilage."[6] This limitation is not incompatible with the current Part B drug discard policy. As is the case with drugs paid under the ASP-based methodology, where the payment rate is determined at the HCPCS unit level without regard for wastage or spoilage, the CAP vendors bid price at the HCPCS unit level would not consider wastage or spoilage. The discard policy would be applied to determine the number of HCPCS units that appropriately may be reimbursed. If the amount actually ordered and shipped (at the NDC level) exceeds the amount actually used, then the vendor would be permitted to bill Medicare the appropriate number of HCPCS units reflecting the amount of the product ordered and shipped consistent with the discard policy.

In addition, although we agree that the CAP vendor—rather than the physician—should bear the cost of shipping unused supplies back to the CAP vendor, we would urge CMS not to require, as a matter of CMS policy, that physicians return unused portion of a drug or biological from an opened, single use vial. Requiring physicians to return unused portions of drugs or biologicals from opened single use vials is inconsistent with current practice, would incur unnecessary cost to the vendor, and could incur potential risk to those required to handle the unused supplies (e.g., where drugs have been drawn up in syringes and would need to be shipped in these syringes or reinserted into the opened vials). Return of supplies should be required by the CAP program only when such return is required under a state's pharmacy laws.

5. CMS should address important operational issues before the CAP program is implemented

We were very pleased with CMS's decision to delay implementation of the CAP program for at least six months. Although we understand that the tight timeline to implementation was imposed by Congress, CMS appropriately recognized that such a complex program should not be implemented in a hurried fashion. We have received inquiries from a number of providers about operations of the CAP program. Below are some specific issues that have been brought to our attention.

a. CMS's claims processing system handling the CAP program must include the chemodenervation series of codes among the codes accepted to show administration of botulinum toxin type A. Standard injection codes are not used to report treatment with botulinum toxin type A.

In the IFR, CMS indicates that the claims processing systems will identify that a claim has been submitted to evidence the physician's administration of the drug, and this "signal" will allow processing of the CAP vendor's claim for the drug. For most Part B drugs and biologicals included under the CAP, the CPT/HCPCS code used to report the administration of the drug will be one of the injection codes (e.g., codes for intravenous injection or for intramuscular injection). With botulinum toxin type A, however, administration of the drug comprises a specific type of procedure called chemodenervation. These are generally reported under one of the following codes:

[6] Soc. Sec. Act § 1847B(c)(6)(B).

Code	Descriptor
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (eg, for blepharospasm, hemifacial spasm)
64613	Chemodenervation of muscle(s); cervical spinal muscle(s) (eg, for spasmodic torticollis)
64614	Chemodenervation of muscle(s); extremity(s) and/or trunk muscle(s) (eg, for dystonia, cerebral palsy, multiple sclerosis)
67345	Chemodenervation of extraocular muscle

Note, this list is not intended to be exhaustive. First, new codes to report chemodenervation of eccrine glands in the treatment of patients with severe focal hyperhidrosis are expected to be published in CPT 2006. Second, certain chemodenervation procedures are reported under other codes, for example 43201 "Esophagoscopy, rigid or flexible; with directed submucosal injection(s), any substance" has been used to report chemodenervation of lower esophageal sphincter muscles by injection of botulinum toxin through endoscopic visualization in the treatment of patients with achalasia.

b. Physicians need instructions for tracking receipt, storage, and administration of CAP drugs and discard or return of unused CAP drugs and how such tracking should distinguish CAP drugs from other supplies of the same drugs.

We appreciate CMS's comments advising physicians that they will not be required to keep drugs and biologicals obtained from CAP vendors in physically separate inventories from other supplies of the same drugs and biologicals. However, physicians need instructions as to what kinds of documentation they will be required to maintain to track receipt, storage and administration of CAP drugs as well as tracking discard or return of any unused supplies. Although we understand that CMS may not want to mandate standardized forms for such purposes, guidelines and examples would be very helpful to allay physician concerns that paperwork to track CAP supplies will be onerous.

c. Physicians need instructions how to handle situations where the amount ordered may be less than the amount actually required to be administered.

In the comments above, we discuss situations where the amount administered may be less than the amount ordered and remaining supplies may be discarded. The opposite situation may occur as well—i.e., physicians may order less than they ultimately may administer. A couple of examples will illustrate the situations that may occur.

Example 1—The physician orders 250 units of botulinum toxin type A to treat a patient. The CAP vendor ships 3 vials of botulinum toxin type A (300 units). When examining the patient at the treatment session, the physician determines that 300 units would be more appropriate and administers the full 300 units s/he received from the CAP vendor. In this example, the amount actually administered matches the amount shipped by the CAP vendor, but it is greater than the amount ordered by the physician. How should this be handled?

Example 2—The physician orders 200 units of botulinum toxin type A to treat a patient. The CAP vendor ships 2 vials of botulinum toxin type A (200 units). When examining the patient at the

treatment session, the physician determines that 300 units would be more appropriate and administers the 200 units s/he received from the CAP vendor plus 100 units s/he has from his/her own supplies. In this example, the amount administered is the full amount shipped by the CAP vendor plus additional "emergency" supplies. How should this be handled?

d. Physicians need instructions how to handle situations where the patient is scheduled for treatment at one office location at the time the drug is ordered, but actually receives the drug at another office location.

In the IFR, CMS indicated that where a physician practices at multiple locations, the drug must be administered at the same physical location where the drug has been shipped by the CAP vendor. In other words, the physician would not be permitted to transport the drug to another practice location. We understand that CMS may by concerned that transporting the drugs or biologicals is inconsistent with certain state pharmacy requirements. Alternatively, CMS may be concerned about the integrity of the drug or biological if transported from one practice location to another.

Although we understand concerns about product integrity and nuances of state pharmacy laws, we see no reason why transporting CAP drugs and biologicals between practice locations should be per se prohibited by the CAP program. Physicians are knowledgeable about special handling requirements of specific drugs and biologicals and may be able to transport the drugs in a manner that poses no risk to product integrity. Physicians are acutely aware of the end result of improper handling of drugs and biologicals—lack of effectiveness or adverse events—and they would not transport drugs in a manner that would risk these adverse outcomes. Moreover, physicians can check with individual state pharmacy authorities to determine whether transportation of drugs and biologicals under these circumstances would raise any issues under state laws. Assuming there are no state pharmacy law concerns, it would seem federal Medicare law should not interfere with this practice.

Physicians generally will order drugs and biologicals to be shipped to the practice location where the patient will be treated. However, circumstances may occur where patients will "show up" at other practice locations for treatment. It would be unfortunate if patients are told that they cannot have their treatment until an appointment is re-scheduled at the practice location where the drug has been shipped.

* * * *

We appreciate having the opportunity to comment on the IFR and do hope CMS will consider these recommendations in preparing a revised final rule prior to implementation of the CAP program. If you have any questions about our comments, please contact Jim Hayes, Director, Reimbursement Strategy and Healthcare Policy, Neuroscience Division at 714-246-6401 or by e-mail at hayes_jim@allergan.com. Thank you.

Sincerely yours,

/s/ Jim Hayes
Director, Reimbursement Strategy and Healthcare Policy
Neuroscience Division
Allergan Inc.

Submitter : Mr. Brian Abraham **Date:** 09/06/2005

Organization : MedImmune

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1325-IFC-164-Attach-1.DOC

MedImmune

September 6, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-IFC
PO Box 8013
Baltimore, Maryland 21244-8013

Dear Administrator McClellan:

MedImmune, Inc., is pleased to offer our comments on the interim final rule for the Competitive Acquisition Program (CAP). MedImmune is a fully integrated biotechnology company that manufactures and markets drugs administered in the physician office setting to Medicare beneficiaries. Specifically, physicians provide our drugs Ethyol® (amifostine) as part of anti-cancer therapies and CytoGam® (cytomegalovirus intravenous immunoglobulin, human) for transplant patients.

As a company that strongly desires to preserve beneficiary access to breakthrough therapies, including new technologies, we welcome alternative programs for physicians who are looking for better ways to obtain and supply drugs to their patients. We are committed to helping the Centers for Medicare and Medicaid Services (CMS) achieve that reform while ensuring that patients who need therapies are not limited by their own or their physicians' financial judgments ahead of sound medical decision making.

We applaud CMS's second iteration of this regulation because of so many clarifications and improvements presented. We were very pleased to see that CMS continued to focus on the objective of ensuring that patients receive Part B drugs in a timely and efficient manner, while at the same time yielding savings to the government.

We also are very pleased that CMS has clarified and amplified that physicians are the primary decision makers about the drugs their patients should receive. However, we agree with other commenters that CAP vendors should offer physicians the choice of a particular National Drug Code (NDC) number when more than one (single-source) item is available, within the HCPCS code that the vendor must offer participating physicians.

Finally, we commend CMS for continuing to provide mechanisms and assurances that the agency will, and suppliers and providers should, reach out to Medicare beneficiaries to educate them about the program when it will impact them.

Competitive Acquisition Areas

As we stated in our initial comments to the proposed rule, we believe that launching the CAP in one, nationwide geographic area may be too ambitious to start this program.

Unfortunately, in the IFC, CMS disagrees with us, and has stated that the program will begin with this single area. [1] We reiterate our concerns that such a large geographic area will lead to the following difficulties:

- patients not receiving drug in a timely manner,
- physicians not being able to track orders for their patients,
- vendors not being able to trace shipments to physicians, and
- billing difficulties for beneficiaries.

We urge CMS to reconsider a smaller geographic rollout in order to work out logistical, clinical, and financial impediments that may occur.

Physicians' Clinical Judgment Preserved

We agree with CMS that Medicare carriers' Local Coverage Determinations (LCDs) should trigger claim denials and that vendors cannot refuse to ship drug simply because they anticipate that the claim may not be paid by the designated carrier.[2] Also, we thank CMS for emphasizing that physicians' clinical judgment is primary, and again, the vendor cannot refuse to ship because it disagrees with the medical decision of the physician – or more likely, with the level of risk that the vendor will undertake in shipping the drug.[3] We also think that vendors' ability to ask beneficiaries to sign an Advanced Beneficiary Notice (ABN)[4] will help offset this level of risk to the vendors.

We also strongly support CMS's reiteration of the "furnish as written" provision of the rule.[5] We believe that if a physician needs to order a drug that is the most appropriate formulation for his or her patient, the administrative process should not dampen that medical decision. Along those lines, we are concerned that physicians may not be able to make a pure clinical judgment when there are two or more biologicals or single-source drugs (with different NDC numbers) within the same HCPCS code.

We thank CMS for protecting beneficiary access to biologicals and single-source drugs by explicitly stating CAP vendors must provide at least one National Drug Code (NDC) for each HCPCS in the category.[6] This requirement reflects the statute's clear instructions for vendors to provide "at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area."[7] However, to better address Medicare beneficiaries' drug and biological needs and provide greater choice under the CAP, we believe that CAP vendors should provide substantially more than one NDC per HCPCS. When a vendor

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[1] 70 Fed Reg 39035-6.
[2] Ibid., 39038.
[3] Ibid., 39039.
[4] Ibid.
[5] Ibid., 39043.
[6] Ibid. at 39034.
[7] Social Security Act (SSA) § 1847B(b)(1).

offers more than one NDC per HCPCS, physicians should be permitted to specify which NDC they are ordering.

Indeed, to ensure that Medicare beneficiaries have the same access under the CAP that is available for beneficiaries treated by physicians purchasing and billing for therapies, we ask CMS to go one step further and require vendors to bid on at least one NDC for each single source drug and biological, even when the single source therapies are billed using the same HCPCS code. Single source drugs and biologicals are not rated as therapeutic equivalents in the Orange Book and have not otherwise been found to be pharmaceutically equivalent or bioequivalent by the Food and Drug Administration (FDA).[8] They are unique products that should be carried by each CAP vendor in order to ensure patient access to them. For example, multiple brands of certain biologicals currently are included within a single HCPCS code even though the brands are not therapeutically equivalent. Each brand may have a unique effect on the patient; efficacy, allergic reactions, and response times can vary from patient to patient. It is essential that each patient receive the specific brand that is best suited for his or her condition so that patient treatment options are not dependent upon a physician's CAP election.

We also recommend that vendors be allowed to incorporate new NDCs as soon as they are available on the market or additional NDCs during the year for drugs already included in a CAP HCPCS. The IFC allows vendors to furnish more than one NDC for a HCPCS code, and, in limited circumstances, vendors may substitute a different NDC for the NDC currently offered.[9] The IFC does not clearly state whether vendors can incorporate new or additional NDCs, not merely to substitute for NDCs offered, but also to expand choice under the CAP. We firmly believe that CAP vendors should be allowed to add NDCs throughout the year to improve beneficiary and physician choice of treatment options. We suggest that payment for these additional NDCs continue to be based upon the established price for the HCPCS code.

Minimizing Risk to CAP Vendors

For CAP vendors to participate in the program and offer the drugs MedImmune and other companies manufacture, they cannot carry the enormous amount of risk the proposed rule[10] and even this IFC describe and imply. Therefore, we agree with CMS's decision to delay the program until July 1, 2006, by which time you should have received sufficient feedback from the stakeholder community, including potential vendors, that will help decrease the risk to them. In the meantime, we are pleased that CMS has clarified the regulation in several ways that help potential vendors make positive decisions on participating.

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[8] Under the definition applied in SSA § 1847A(c)(6)(D), a single source drug or biological is: (I) a biological or (II) a drug which is not a multiple source drug and which is distributed under a new drug application approved by the FDA.
[9] 42 C.F.R. § 414.906(f).
[10] 70 Fed Reg 10746-73.

We agree that vendors should be allowed to split shipments on an as-needed basis.[11] That way, if a physician decides to discontinue using that drug for any reason, the vendor is not stuck with an entire course of therapy in a practically interminable accounts receivable situation. We also ask CMS to continue to emphasize, as you do in the IFC[12], that CMS's wastage policy should be consistent with Part B rules, and vendors should be paid for the entire amount of drug they ship. By making this regulation consistent with the wastage policy that physicians purchasing under the ASP system must adhere to, CMS will keep the systems in parity, and not sway physicians to choose one over the other based on differing regulations at the physician office level. After all, it would have to be the physician that reports how much drug down to the unit level was introduced into the patient.

Most important, we applaud CMS's clarification on CAP vendors' ability to file an appeal of a denied claim.[13] We are very pleased that CMS recognized the vendors' status as financial stakeholders when a claim is denied. We believe that by allowing vendors to participate in the appeal process, they will be less likely to second-guess the clinical judgment of a physician, more likely to ship drug expeditiously, and less inclined to bill beneficiaries inappropriately.

Beneficiary Protections

We believe that every patient who needs our drugs or other manufacturers' products should have access to them. We are therefore very pleased to see the many provisions of the IFC that protect beneficiaries by facilitating their access to CAP drugs. If a patient is in need of a drug that has not been ordered under the CAP, CMS has stated that the physician can pull the drug from his or her own stock, and retroactively replace the drug used on that patient.[14] This part of the rule will help physicians treat patients in the manner they need to be treated, not on a schedule out of accord with medical propriety.

We also support CMS's efforts to minimize the logistical, financial, and administrative burdens on beneficiaries by (1) implementing the claims crossover system expeditiously for secondary (and primary) payers to Medicare, and (2) allowing vendors to publish sources of assistance that beneficiaries can contact if they cannot afford their coinsurance for CAP drugs.[15]

Conclusion

MedImmune sees several significant improvements in the program, and we believe it will work well ultimately. But, there seems to be a long way to go to ensuring that no particular stakeholder in the system has too great a stake, including indirect stakeholders such as manufacturers. As always, we offer any type of assistance you may need in

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[11] 70 Fed Reg 39041.
[12] Ibid., 39062.
[13] Ibid., 39055.
[14] Ibid., 39046-7.
[15] Ibid., 39052-3.

making the CAP successful. If you have questions about this or other matters at CMS, please contact Brian Abraham, Associate Director of Reimbursement, at abrahamb@medimmune.com, or (301) 398-4626.

Very best regards,
/s/
Caroline York
Vice President, Reimbursement and Government Affairs

Submitter : Ellen Stovall **Date:** 09/06/2005

Organization : Cancer Leadership Council

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Comments of the Cancer Leadership Council (CLC) are attached.

Submitter : Alan Kirschenbaum **Date:** 09/06/2005

Organization : Hyman, Phelps & McNamara, P.C.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

This comment is submitted on behalf of Watson Pharma, Inc. In a discussion of least costly alternative policies in the preamble to the Interim Final Rule, CMS indicates that injectable leuprolide is not included in the initial stage of implementing the CAP because every carrier has applied a least costly alternative policy to this product. Watson respectfully submits that the factual predicate for CMS's exclusion of injectable leuprolide is inaccurate. As explained at pages 8-9 in the attached "White Paper," there are five jurisdictions, representing almost 10 percent of Medicare Part B beneficiaries in the U.S., where there is no least costly alternative policy for this therapeutic class. Therefore, the price established for leuprolide under the CAP bidding process would determine the payment amount for a substantial proportion of Medicare beneficiaries. Watson requests that CMS reverse its decision and include leuprolide injection in the CAP implementation. See Attachment.

CMS-1325-IFC-166-Attach-1.DOC

July 20, 2005

OVERVIEW OF MEDICARE REIMBURSEMENT FOR LUTEINIZING HORMONE RELEASING HORMONE (LHRH) AGONISTS

Introduction

On July 6, 2005, the Centers for Medicare and Medicaid Services (CMS) published an interim final rule relating to the Competitive Acquisition Program (CAP).[1] Section 303 (d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the implementation of a CAP for certain Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis.

The CAP has implications for the ways physicians select and schedule treatments and how they acquire and bill for drugs administered to Medicare patients. The primary focus of this paper concerns Medicare reimbursement for LHRH agonists, the implementation of the CAP by CMS, and the impact of CAP on timely beneficiary access to LHRH therapy.

Background

Prostate cancer is the most common cancer in America. After lung cancer, prostate cancer is the leading cause of cancer-related deaths among men in the U.S. In 2005, over 232,000 men will be diagnosed with prostate cancer, and over 30,000 men will die from it. One new case occurs every 2.5 minutes and a man dies from prostate cancer every 17 minutes. Every year, 70,000 men require additional treatment due to a recurrence of prostate cancer.[2]

A nonsmoking man is more likely to get prostate cancer than lung, bronchus, colon, rectal, bladder, lymphoma, melanoma, oral and kidney cancers combined. It is estimated that there are over two million American men currently living with prostate cancer. One in six American men will develop prostate cancer in the course of his lifetime. A man is 33 percent more likely to develop prostate cancer than an American woman is to get breast cancer.[2]

Because prostate cancer is a relatively slow-growing cancer, the 5-year survival rate for prostate cancer diagnosed at all stages is 98 percent. The relative 10-year survival rate is 84 percent and the 15-year survival rate is 56 percent.[2]

Optimal treatment of prostate cancer requires assessment of risk. Prostate cancers are best characterized by their clinical (TNM) stage determined by digital rectal exam (DRE), Gleason grade in the biopsy specimen, and serum prostate-specific antigen (PSA) level.[3]

Risk and Health Outcomes

The chance of having prostate cancer increases rapidly after age 50. More than 70 percent of all prostate cancers are diagnosed in men over the age of 65. Explanation as to why risk of prostate cancer increases with age is still unclear. The only well-established risk factors for prostate cancer

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[1] 70 Fed. Reg. 39022 (July 6, 2005).

[2] http://www.prostatecancerfoundation.org/site/c.itIWK2OSG/b.46631/k.8E90/Prostate_Cancer_Information.htm

[3] http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf

are age, ethnicity, and family history of the disease. African-American men are 65% more likely to be diagnosed with prostate cancer than Caucasians and are more than twice as likely to die from it. The increase in the number of new cases is probably due to the widespread use of PSA screening in previously unscreened males and a concomitant increase in the detection of early-stage prostate cancers.[2]

As the population ages, the number of new cases is expected to grow substantially. Prostate cancer incidence increases with age faster than any other cancer, but age-adjusted death rates from prostate cancer have begun to decline. This suggests that unless prostate cancer is becoming biologically less aggressive, increased public awareness with earlier detection and treatment of prostate cancer has begun to affect this prevalent cancer.[3]

Treatment Options

There are currently 14 treatment options that have been approved by the United States Food and Drug Administration (FDA) for prostate cancer. The options include: antiandrogens, corticosteroids, GnRH/LHRH analogs, female hormones, GnRH antagonists, and various chemotherapeutic agents.[4] Other drug compendia, such as the United States Pharmacopoeia - Drug Information (USP-DI), list additional treatment options including androgen synthesis inhibitors and various chemotherapeutic agents.[5]

For localized prostate cancer, surgery (radical prostatectomy), radiation therapy (external beam radiotherapy), and brachytherapy are the main treatment options.[6] Physicians may also consider watchful waiting whereby the patient's condition is monitored, without immediate active treatment.[7] Primary treatment with radical prostatectomy or radiation therapy in patients with localized disease is associated with 10-year survival rates of more than 75 percent.[5] However, despite advances in diagnostic techniques that allow earlier detection, approximately 14 percent of patients present with locally advanced or metastatic disease, and 40 percent of patients have recurrent disease after definitive primary therapy.[5]

Androgens or male hormones, such as testosterone, fuel the growth of prostate cancer cells. Hormonal (or hormone-suppression) therapy (e.g., luteinizing hormone releasing hormone (LHRH) analogs) is designed to turn off the production of the androgens. If prostate cancer is diagnosed at an advanced stage (when it has metastasized beyond the prostate) or if the cancer returns after localized therapy such as surgery or radiation, additional treatment with hormonal therapy is typically initiated.[2]

For patients with advanced or recurrent disease, or whose cancer progresses rapidly with blastic bone and/or other metastases and a rising PSA, the primary goal is to slow tumor growth by reducing stimulation of the prostate by testosterone. Androgen ablation is considered the most

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[4] http://www.accessdata.fda.gov/scripts/cder/drugsatfda/

[5] http://www.thomsonhc.com/hcs/librarian/PFPUI/

[6] *Report to the Nation on Prostate Cancer 2004.* Santa Monica, Ca: Prostate Cancer Foundation; 2004. Available at: http://medscape.com/prostatecancer.

[7] American Cancer Society. *Cancer Facts & Figures 2005.* Available at: http://cancer.org/downloads/STT/CAFF2005fPWSecured.pdf

common form of systemic therapy and may be achieved surgically by removing the testes (bilateral orchiectomy) or hormonally by suppressing testosterone production (pharmacologic castration).[2] Some patients, particularly older men, are not suitable candidates for surgery, and others may find it unacceptable. For these patients, hormonal treatment is an effective alternative.

Hormone treatment may control prostate cancer for long periods by shrinking the volume of the tumor, thereby alleviating pain and other symptoms.[6] Hormonal options include estrogens, antiandrogens, agonists of luteinizing hormone-releasing hormone (LHRH or GnRH), LHRH antagonists, 5-α-reductase inhibitors, and androgen synthesis inhibitors. Estrogen administration results in reduction of testosterone concentrations to castrate levels within 1 to 2 weeks but is associated with serious cardiovascular side effects, including edema and congestive heart failure.[8] For patients in whom surgery and estrogen administration are either not indicated or unacceptable, LHRH agonists are a viable treatment option. Pooled data suggest that LHRH agonists are associated with 2-year overall survival rates equivalent to that achieved with orchiectomy.[9]

LHRH Analogs

LHRH agonists are peptide analogs of naturally occurring LHRH that interfere with the synthesis of testosterone. Continuous stimulation of the pituitary by LHRH agonists desensitizes the pituitary gland, which suppresses the release of luteinizing hormone (LH), resulting in a decrease of testosterone levels comparable to that following surgical castration.[5] LHRH agonists are frequently used to help relieve the symptoms associated with advanced disease when the cancer has spread beyond the prostate. In such cases, these agonists may provide an alternative for the patient who either cannot, or elects not to, have an orchiectomy or receive estrogen therapy. In a pooled analysis of 2-year survival data, LHRH agonist therapy and bilateral orchiectomy were found to be equivalent in terms of survival.[8] Therefore, these agents are typically chosen by urologists and oncologists for patients with hormone-sensitive advanced prostate cancer.[5]

When LHRH agonists are first administered, the drug binds to LHRH receptors in the pituitary, stimulating the production of LH and Follicle-stimulating hormone FSH and resulting in a transient increase in testosterone production.[5] LH and FSH released from the anterior pituitary transiently increase testosterone concentrations in men. Initial administration of LHRH analogs stimulates release of gonadotropins, LH and FSH, from the anterior pituitary gland. However, continuous administration of LHRH analogs in the treatment of prostate cancer suppresses secretion of gonadotropin releasing hormone (GnRH), with a resultant fall in LH, FSH, and testosterone concentrations and a pharmacologic castration.

Leuprolide, histrelin, goserelin, and triptorelin are synthetic GnRH or LHRH analogs, indicated for the palliative treatment of advanced prostate cancer.[10,11,12,13,14,15] Goserelin is also indicated for use

[8] Scher HI, Isaacs JT, Zelefsky MJ, Scardino PT. Prostate Cancer. In: Aveloff MD, Armitage JO, Lichter AS, Niederhuber JE, eds. *Clinical Oncology.* 2nd ed. New York, NY: Churchill Livingstone; 2000.
[9] Seidenfeld J, Samson DJ, Hasselblad V, et al. Single-agent androgen suppression in men with advanced prostate cancer: a systematic review and meta-analysis. *Ann Intern Med.* 2000;132;566-577.
[10] Prescribing Information. Viadur. Bayer Pharmaceuticals Corporation.
[11] Prescribing Information. Lupron Depot. TAP Pharmaceuticals, Inc.
[12] Prescribing Information. Eligard. Sanofi Synthelabo.
[13] Prescribing Information. Vantas. Valera Pharmaceuticals, Inc.

in combination with radiotherapy (RT) and flutamide for the treatment of locally confined Stage T2b-T4 (Stage B2-C) prostate cancer.[15] Available products include:

- Viadur® (leuprolide acetate implant)[9],
- Lupron Depot® (leuprolide acetate for depot suspension)[10]
- Eligard® (leuprolide acetate for injectable suspension)[11]
- Vantas® (histrelin implant)[12]
- Trelstar® (triptorelin pamoate for injectable suspension)[13]
- Zoladex® (goserelin acetate implant)[14]

LHRH agonists are peptides and are therefore not orally bioavailable. These agents can be injected or implanted as long-acting formulations; therefore, administration may be required 1 to 4 times per year, although monthly formulations are also available. LHRH analogs are administered in the physician office (95 percent) or hospital outpatient setting (5 percent).[16]

Length of treatment of prostate cancer using LHRH analogs can be indefinite, depending on response. However, treatment is typically continued to maintain suppression of testosterone. As set forth in Table 1, many products are available in different concentrations and doses, with variable dosing schedules ranging from monthly to annual administration.

Table 1. LHRH Agonist Formulations and Dosing Frequency

Product	Dose	Frequency of Administration
Viadur	65 mg	12 months
Lupron Depot 7.5 mg	7.5 mg	1 month
Lupron Depot - 3 month	22.5 mg	3 months
Lupron Depot - 4 month	30 mg	4 months
Eligard 7.5 mg	7.5 mg	1 month
Eligard 22.5 mg	22.5 mg	3 months
Eligard 30 mg	30 mg	4 months
Eligard 45 mg	45 mg	6 months
Vantas	50 mg	12 months
Trelstar Depot	3.75 mg	1 month
Trelstar LA	11.25 mg	3 months
Zoladex 3.6	3.6 mg	1 month
Zoladex 10.8	10.8 mg	3 months

[14] Prescribing Information. Trelstar. Watson Pharma.
[15] Prescribing Information. Zoladex. AstraZeneca Pharmaceuticals, LP.
[16] NAMCS and NHAMCS data, 2002. Lash Group analysis.

Medicare Reimbursement for LHRH Agonist in the Physician Office Setting

Medicare Part B supplemental medical insurance benefit covers drugs used with durable medical equipment or infusion devices and certain drugs used in association with organ transplantation, dialysis, chemotherapy, and pain management. Included in these categories are drugs used in the treatment of advanced prostate cancer, such as leuprolide acetate (Lupron), goserelin acetate (Zoladex), and triptorelin pamoate (Trelstar).

The Centers for Medicare & Medicaid Services (CMS) contracts with companies, known as carriers, to process and reimburse most Part B claims, including claims for physician-administered drugs. Approximately twenty carriers currently serve 54 specific jurisdictions in the United States. Physicians submit claims for drugs and procedures to the carrier in their area, and are subsequently reimbursed by Medicare.

Medicare's reimbursement methodology for covered prescription drugs is defined by section 1842(o) of the Social Security Act (the Act), as amended by P.L. 108-173, §303(c)(1), the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The Act states that beginning January 1, 2005, reimbursement for most Part-B covered drugs is to be set at 106 percent of the average sales price (ASP), based on ASP data submitted quarterly by manufacturers. ASP is calculated based on total sales revenues and units sold, excluding certain sales to government entities and nominal sales.

CMS will calculate the volume-weighted ASP during each quarter for all drugs included in each HCPCS billing code. CMS will then use that figure to set the Part B physician office reimbursement rate two quarters later, and will continue to update the reimbursement rate every quarter, based on the most recent data submitted by manufacturers. Thus, for example, 3rd quarter 2005 ASP data will be used to set 1st quarter 2006 allowable reimbursement amounts.

Table 2 sets forth the 3rd quarter 2005 Medicare reimbursement for LHRH agonist drugs.

Table 2. Medicare Reimbursement for LHRH Agonists in the Physician Office Setting

Product	Generic Name	HCPCS Billing Code	Billing Units	Q3 2005 Reimbursement[17]
Trelstar	triptorelin pamoate	J3315	3.75 mg	$370.74
Eligard	leuprolide acetate	J9217	7.5 mg	$229.85
Lupron				
Zoladex	goserelin acetate	J9202	3.6 mg	$185.20
Vantas	histrelin implant	J3490/J9999	50 mg	$3,027.40
Viadur	leuprolide acetate implant	J9219	65 mg	$2,314.14

[17] July 2005 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing File, Effective July 1, 2005. CMS.

Local Coverage Determinations

Medicare carriers issue local coverage determinations (LCDs) in order to further specify the circumstances under which a service is covered by the program. According to CMS's Medicare Program Integrity Manual:

> Contractors publish LCDs to provide guidance to the public and medical community within their jurisdictions. Contractors develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments and comments from the provider community.[18]

The contractors are required to ensure that all LCDs are consistent with all statutes, rulings, regulations, and national coverage, payment, and coding policies. Within these parameters, local carriers may create policies that state coverage and reimbursement limitations within their jurisdictions.

Least Costly Alternative

Section 1862(a)(1)(A) of the Act sets forth certain procedures and costs that may be excluded from coverage and payment by Medicare. The policy states that if two services are clinically comparable, then Medicare may not cover the additional expense of the more costly service, because this additional expense is not attributable to an item or service that is medically reasonable and necessary. Thus, Medicare will only pay the amount corresponding to the least costly alternative (LCA).

The Program Integrity Manual provides further guidance to carriers that wish to apply LCA status: "Least costly alternative is a national policy provision that shall be applied by contractors when determining payment for all durable medical equipment (DME). Contractors have the discretion to apply this principal to payment for non-DME services as well."[19]

Many carriers have implemented a least costly alternative policy for LHRH and GnRH agonists. As noted in many carrier LCDs, a single dose of the drug goserelin acetate (i.e., 3.6 mg implant) has been found by many experts to be clinically comparable to a single dose of leuprolide acetate (7.5 mg depot suspension).[8,20] Thus, in jurisdictions where a carrier applies the least costly alternative policy, physicians that administer leuprolide are generally reimbursed the goserelin amount. As of the 3rd quarter of 2005, the Medicare Part B reimbursement amount for a single, monthly dose of goserelin acetate is $185.20, compared to the reimbursement amount for a single dose of leuprolide acetate ($229.85).

In some instances, however, the full reimbursement amount may still be paid if the physician can document why the more costly treatment option is medically necessary. Furthermore, some carriers allow reimbursement to be made at the higher amount if the beneficiary was already being

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[18] Medicare Program Integrity Manual. Chapter 13, Section 1.3

[19] Medicare Program Integrity Manual. Chapter 13, Section 4.

[20] Relative Effectiveness and Cost-Effectiveness of Methods of Androgen Suppression in the Treatment of Advanced Prostatic Cancer. Summary, Evidence Report/Technology Assessment: Number 4, January 1999. Agency for Health Care Policy and Research, Rockville, MD. http://www.ahrq.gov/clinic/epcsums/prossumm.htm

treated with the more expensive drug at the time the least costly alternative policy was enacted. Many states have such "grandfather" clauses for patients.[21]

Physicians may also request that patients sign an advanced beneficiary notice (ABN). An ABN is a written notice that a physician or supplier gives to a Medicare beneficiary. The purpose of the ABN is to inform a beneficiary before he or she receives specified items or services that otherwise might be paid for by Medicare that Medicare probably will not pay for them for that particular beneficiary on that particular occasion. The ABN allows the beneficiary to make an informed consumer decision whether or not to receive the items or services for which he or she may have to pay out of pocket or through other insurance.

In a review conducted by the Lash Group of the current status of LCA policies in 54 US jurisdictions, 49 jurisdictions have an active LCA policy that includes leuprolide and goserelin. Only 35 jurisdictions include leuprolide implant in the LCA, and only 1 jurisdiction includes triptorelin. [22] There are five jurisdictions – Illinois, Michigan, Minnesota, Montana, and Wisconsin – that do not have an active LCA policy, and thus reimbursement is at the full ASP-based amount established for each LHRH agonist.

The independent nature of the Medicare Part B carriers creates a unique reimbursement environment in each jurisdiction. While physicians typically practice in only one jurisdiction, and thus need only track the coverage and reimbursement of LHRH products in a particular area, any provider that tried to function nationally would be need to track the unique reimbursement environment in each of the 54 jurisdictions in the United States.

Implementation of a Competitive Acquisition Program for Medicare Physicians

Beginning in 2006, CMS will offer an alternative mechanism for physicians to acquire covered drugs – the Competitive Acquisition Program (CAP). Physicians will have a choice between buying drugs and receiving reimbursement under the ASP system or obtaining these drugs from CMS-approved vendors and receiving reimbursement only for the relevant administration procedures. These vendors will supply the drugs, bill Medicare, and collect the coinsurance from patients. The objective of this program is to deliver savings to CMS while giving physicians an alternative to the current buy-and-bill drug acquisition system. The details of the CAP are set forth in section 1847B of the Social Security Act, as added by section 303(d) of the MMA.

On July 6, 2005, CMS published in the Federal Register an interim final rule relating to the CAP. [23] The interim final rule enables CMS to proceed with the steps necessary to implement this program in 2006. Among the details set forth are the procedures and rules for physicians and vendors and the drugs that will be included in the CAP beginning in 2006.

[21] Memorandum from Thomas A. Scully, Administrator, CMS, to Dara Corrigan, Acting Principle Deputy Inspector General, OIG, regarding "OIG Draft Report: Medicare Reimbursement for Lupron (OEI-03-03-00250)".
[22] Three additional jurisdictions have issued draft LCDs that would add triptorelin to their LCAs, but these LCDs have not yet been finalized.
[23] 70 Fed. Reg. 39022 (July 6, 2005).

In the interim final rule, CMS clarified that "physicians would not be able to elect to acquire only some of the HCPCS codes in that category from the approved vendor."[24] Physicians who elect to participate in CAP must acquire all eligible CAP drugs through the CAP vendor and may not selectively buy and bill for Part B drugs included in the CAP. CMS has stated that the intent of the CAP is to relieve physicians from the burdens of bearing financial risk for drugs prior to administration and collecting coinsurance payments from patients.

Vendors are likewise required to supply at least one product, identified by national drug code (NDC), within each HCPCS billing code. Thus, where there are multiple vial sizes or concentrations of a product that all fit within the same HCPCS billing code (e.g., Trelstar Depot and Trelstar LA), CAP vendors are not required to supply all formulations, but must supply at least one in each billing code. Under contract with CMS, vendors must provide the drug to the physician.

The interim final rule clarifies that existing local Part B coverage policies will apply to drugs acquired and billed through the CAP as they do to drugs acquired and billed by physicians who do not enroll in CAP. Specifically, physicians who submit claims under CAP must comply with, and are subject to the rules of, applicable LCDs, including least costly alternative policies.[25] Thus, should a physician in a state with an LCA policy order leuprolide acetate from the CAP vendor, the vendor may be subject to receiving reimbursement at a reduced rate, based on reimbursement rate of the least costly alternative product (i.e., goserelin).

If the vendor believes a drug order is not consistent with an LCD, the vendor may contact the physician to determine why the physician believes it will be covered. Additionally, if the physician declines to change the order, the CAP vendor may ask the beneficiary to sign an ABN. However, regardless of the vendor's success in collecting a signed ABN from the patient, the vendor must fulfill the physician's order.[26]

Finally, CMS has identified 181 drugs that are frequently administered incident to a physician's service, and therefore will be included in the CAP for 2006. Included in the list drugs are the LHRH agonists triptorelin pamoate (J3315), goserelin acetate implant (J9202), and leuprolide acetate implant (J9219). Specifically excluded from the CAP are histrelin implant (J3490/J9999) and leuprolide acetate depot (J9217).

Table 3. LHRH Agonists Included in CAP for 2006

triptorelin pamoate (Trelstar)	goserelin acetate (Zoladex)	leuprolide acetate implant (Viadur)

To justify exclusion of some drugs in the LHRH class, CMS provided separate explanations. In the case of histrelin, CMS clarified that all new drugs that lack an assigned HCPCS billing code will be excluded from the CAP due to the lack of identifiable claims data to measure billing volume and

[24] Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B (CMS-1325-IFC). p70 Fed. Reg. at 39033.
[25] 70 Fed. Reg. at 39039.
[26] Id.

individual billing codes to identify the drugs. Thus, under this provision many new drugs have been excluded from CAP.

The justification for excluding leuprolide acetate is specific to the circumstances of the product. In response to a comment regarding the application of LCA policies to vendor reimbursement, CMS notes that "every carrier has applied an LCA policy to injectable forms of leuprolide (not, however, to leuprolide implant)." CMS has decided to exercise its authority under 1847B(a)(1)(B) to exclude leuprolide (J9217) "because leuprolide is subject to LCA policies in all carrier jurisdictions, its inclusion in the current CAP drug category would have the effect of requiring vendors to supply the drugs at the cost of goserelin in each instance in which a participating CAP physician orders it."[27] Thus, excluded from CAP, physicians who enroll in CAP still buy and bill for leuprolide while using the CAP vendor to supply goserelin or triptorelin.

Conclusion

Implementation of CAP according to the details set forth in the interim final rule will add complexity to the process of using LHRH agonists due to the differential treatment of the products in this class of drugs. Physicians will need to monitor coverage and the acceptable method of acquisition and billing for each LHRH product. CAP vendors will also need to monitor the reimbursement and coverage policies for each of the included LHRH drugs for each jurisdiction.

CMS excluded leuprolide based on the assumed universal operational burden on CAP vendors to supply leuprolide at a loss. However, the exclusion of leuprolide, and thus the selective inclusion of otherwise eligible LHRH agonists in the CAP, is based on inaccurate assumptions.

CMS assumes that all jurisdictions have an active LCA policy for leuprolide, and uses the universal application of reduced reimbursement under these LCA policies as reason for exclusion of the drug from the CAP. In other words, CMS believes that the established CAP price would have no effect because reimbursement for leuprolide would in all cases be at a lower LCA amount. However, contrary to CMS's assumption, there are five jurisdictions, representing almost 10 percent of Medicare Part B beneficiaries in the US, where there is not an active LCA policy.[28] Therefore, the price established for leuprolide under the CAP bidding process would determine the payment amount for a substantial portion of the U.S. Excluding one drug among three direct competitors allows physicians to selectively use the CAP program yet still buy and bill when advantageous to the physician. This is contrary to CMS' intent that physicians not be able to acquire only some of the drugs in a category from the approved vendor.[29] In addition, because the reimbursement under the CAP is likely to be lower than the otherwise applicable ASP-based reimbursement,[30] excluding from the CAP one drug among three competitors costs Medicare more money, and also gives an unfair commercial advantage to the excluded drug in non-LCA stakes.

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[27] 70 Fed. Reg. at 39029.
[28] Medicare enrollment data. July 2003. Lash Group Analysis.
[29] 70 Fed. Reg. at 39033.
[30] 70 Fed. Reg. at 39073.

Submitter :

Date: 09/06/2005

Organization :

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B

Comments on interim final rule:

1 Billing guidance should be provided to both CAP vendors and providers regarding MA PFFS enrollees.
2 MA PFFS plans should be provided access to physician CAP election information, both initial enrollment and ongoing status due to opt out provision.
3 MA PFFS plans should be provided a CAP vendor drug pricing file prior to implementation and on an ongoing basis to ensure paying Medicare allowable equivalent.
4 MA PFFS plans should be assured access to each CAP vendors drug list and drug substitutions on an ongoing basis.

Submitter : Mary Hayter
Organization : Smith & Nephew
Category : Drug Industry
Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1325-IFC-168-Attach-1.DOC

Wound Management
Smith & Nephew, Inc.
1615 L Street, NW – Suite 650
Washington, D.C. 20036

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We are smith&nephew

Tuesday, September 06, 2005

The Honorable Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments to Interim Final Rule/CMS-1325-IFC
Sections I.A.1 and II.A.2

Dear Dr. McClellan:

Smith & Nephew is a global medical device company and the world leader in advanced wound management.

Thank you for the opportunity to comment on the Interim Final Rule regarding the Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B. Our comments are focused on how the agency references DERMAGRAFT™, particularly as it is named in Section I.A.1 of the Rule, and the possible implications for how the agency has described metabolically active dermal tissue products in Section II.A.2 of the Interim Rule.

DERMAGRAFT is a Human Fibroblast-Derived Dermal Substitute composed of fibroblasts [metabolically active living cells], and a bioabsorbable scaffold. This FDA-approved product is used by physicians to treat and heal diabetic foot ulcers. In March 2001, CMS determined that DERMAGRAFT was a biological for reimbursement purposes and removed the product from the device transitional pass-through list for use in the Hospital Outpatient Prospective Payment System effective April 1, 2001. As of January 1, 2002 [with delayed implementation to April 1, 2002], CMS granted DERMAGRAFT biological pass-through status and assigned it transitional pass-through code C 9201. DERMAGRAFT has since rotated off the transitional pass through list and now has its own APC 9201.

DERMAGRAFT is available through physician prescription only and is provided incident to a physician's service, i.e., a debridement of the ulcer, which is performed either in a hospital outpatient department or a physician's office. DERMAGRAFT cannot be self-administered by the patient. As such, CMS properly identifies DERMAGRAFT as one example of a Part B covered drug furnished incident to a physician's service in the Background portion of the Rule [Section I.A.1].[1]

[1] **As noted in the Rule, consistent with CMS policy, the agency properly acknowledges, "[f]or the purposes of this interim final rule with comment period, the term 'drugs' will hereafter refer to both drugs and biologicals." 70 Fed. Reg. 39022, 39023 [July 6, 2005].**

When defining those drugs it is not including in the Competitive Acquisition Program [CAP], however, CMS contradicts its otherwise consistent treatment of DERMAGRAFT™ as a biological for reimbursement purposes since 2001. CMS states parenthetically, "Tissues [dermal, metabolically active, etc.] are not considered drug products, and do not appropriately belong under the category of physician administered drugs that we have devised in response to the comments." 70 Fed. Reg. 39022, 39031 [July 6, 2005]. While we agree with CMS's overall conclusion that metabolically active tissue products, like DERMAGRAFT, should not be subject to the CAP at this time, we strongly disagree with CMS's apparent rationale to reach this conclusion.

As reflected in the Proposed Rule for the CAP, Section 1847B[a][1][D] of the Social Security Act "authorizes the Secretary to exclude competitively biddable drugs and biologicals from the competitive bidding system if the application of competitive bidding to such drugs and biologicals...[1] Is not likely to result in significant savings; or [2] Is likely to have an adverse impact on access to such drugs and biologicals." 70 Fed. Reg. 10746, 10749.

In our view, the rationale for excluding tissue products from the CAP rests in this statutory provision. Consistent with its previous positions, CMS classified DERMAGRAFT as a single source specified covered outpatient drug for reimbursement purposes. *See* 69 Fed. Reg. 65682, 65776 and 65784 [November 15, 2004]. Further, in Calendar Year 2004, Medicare spent approximately $ 3.4 million or about two-tenths of one percent of its spending on DERMAGRAFT. See Government Accountability Office Report titled, *Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting* [June 30, 2005].

These facts support the conclusion that DERMAGRAFT is not available from several sources and is of such low volume within the Medicare system, that subjecting it to the CAP at this time is not likely to result in significant cost savings to Medicare.

In conclusion, we request that CMS withdraw the above-quoted parenthetical statement from the Interim Rule. By doing so, CMS will be removing an inconsistency within the Rule itself as well as a statement that contradicts its long-standing treatment of DERMAGRAFT as a biological for reimbursement purposes. As noted above, we believe there are several reasonable rationales available to CMS to exclude DERMAGRAFT from the CAP. The assertion that metabolically active tissue products are not drugs, however, is not one of them.

Thank you again for the opportunity to provide these comments. I am available to speak with CMS representatives further about this issue as needed, and would welcome the opportunity to do so.

Best regards,

Mary E. Hayter

Mary E. Hayter
Vice President, Government Affairs

Submitter : Ellen Stovall **Date:** 09/06/2005

Organization : Cancer Leadership Council

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Comments of the Cancer Leadership Council (CLC) are attached.

CMS-1325-IFC-169-Attach-1.DOC

September 6, 2005

Via Electronically

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS: 1325-IFC
Post Office Box 8013
Baltimore, MD 21244-9013

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B [CMS-1325-IFC]

To Whom It May Concern:

The Cancer Leadership Council (CLC), including cancer patients, physicians, and researchers, submits these comments in response to the interim final rule with comment period establishing the Competitive Acquisition Program (CAP) for Medicare Part B drugs and biologicals, published in the Federal Register on July 6, 2005. We understand that the process for evaluating and selecting bidders for CAP has been temporarily suspended, but we offer these recommendations for revision of the program before its implementation is resumed.

The CLC is concerned about several provisions of CAP which may adversely affect cancer patients' access to life-saving cancer therapies. These include:

Patient Coinsurance

The interim rule would permit CAP vendors to stop providing drugs to patients who have not paid their coinsurance within 45 days. The rule requires vendors to consider alternatives for collection of coinsurance, including establishing a payment plan or referring the patient to a charitable organization. However, the vendor has the right, if these options do not result in payment of coinsurance, to terminate a patient's access to drugs.

In the current system where the oncologist orders and purchases cancer drugs, it has been our experience that oncologists absorb the cost of any coinsurance that cannot be paid by patients. We do not anticipate or expect that patients will have the same experience with CAP vendors, and the result will be disruptions in care if patients cannot pay their coinsurance. This will be an unacceptable situation, which patients may be able to avoid only if their oncologists decline to enroll in CAP. We urge CMS to amend the program to eliminate the ability of CAP vendors to terminate the provision of drugs to patients who cannot pay their coinsurance.

Patient Support Initiatives

The regulations require vendors to have procedures to resolve complaints and inquiries about drug shipments, but there are no clear standards for systems or procedures that vendors must maintain. Although the establishment of a call center or other patient support center may not result in the easy resolution of conflicts related to payment of patient coinsurance, it may ensure that patients have ready answers to questions about billing, payment schedules, and other matters.

Prohibition on Movement of Drugs Between Offices

The regulations would prohibit physicians from moving drugs ordered through CAP from one office to another, even if the offices are part of the same practice. We understand that these provisions were included at the urging of prospective CAP vendors as a protection against spoilage or breakage, but we recommend that they be eliminated.

Cancer patients benefit from the ability to receive chemotherapy in their physician's office, and those in remote areas have enjoyed the advantages of receiving treatment in satellite offices, a practice that has minimized the distance they must travel to receive care. The prohibition against movement of drugs between offices will either limit the access to care in satellite offices or will force those physicians who maintain satellite offices to forego enrollment in CAP.

We urge a revision of this standard to reflect the needs of cancer patients treated by physicians with satellite offices, including those in rural areas. Oncologists, nurses, and other staffers in oncologists' offices have significant experience in transporting and handling cancer drugs, which suggests that CAP vendors' concerns about breakage and spoilage are unfounded.

*****

We appreciate the opportunity to offer these comments that reflect the special needs of cancer patients under CAP. We urge revisions in the interim final rule to prevent disruptions of care under CAP.

Sincerely,

Cancer Leadership Council

American Cancer Society
American Psychosocial Oncology Society
American Society of Clinical Oncology
Cancer Care, Inc.
Cancer Research and Prevention Foundation
Coalition of Cancer Cooperative Groups
International Myeloma Foundation
Kidney Cancer Association
Lance Armstrong Foundation
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Prostate Cancer Coalition
North American Brain Tumor Coalition
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Sarcoma Foundation of America
The Susan G. Komen Breast Cancer Foundation
Us TOO International Prostate Cancer Education and Support Network
Y-ME National Breast Cancer Organization

Contact: Ellen Stovall
National Coalition for Cancer Survivorship
1010 Wayne Avenue – 7th Floor
Silver Spring, Maryland 20910
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estovall@canceradvocacy.org

Submitter : **Ms. Sarah Pitluck** **Date: 09/06/2005**

Organization : **Genentech, Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1325-IFC-170-Attach-1.DOC

Genentech
IN BUSINESS FOR LIFE

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September 6, 2005

Sent electronically

Mark McClellan, MD, PhD
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments to Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B; Interim Final Rule (CMS-1325-IFC)

Dear Dr. McClellan:

Genentech, Inc. is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS') request for comments on the Interim Final Rule (IFR), entitled "Competitive Acquisition of Outpatient Drugs and Biologicals under Part B," published in the *Federal Register* on July 6, 2005. Genentech is a leading biotechnology company, headquartered in South San Francisco, California, with products available for serious and life-threatening medical conditions including cancer, asthma, and stroke. Many of our products are administered incident to a physician's service and are covered under Part B of the Medicare program. As such, we are interested in ensuring that the Competitive Acquisition Program (CAP) is implemented appropriately and that patients have continued access to needed therapies.

As indicated in our comments submitted in response to the CAP Proposed Rule published in the *Federal Register* on March 4, 2005, Congress' primary policy objective in establishing CAP was to offer physicians a choice—while maintaining patient access to life-saving therapies—in acquiring drugs and biologicals ("drugs") under Part B of the Medicare program. Congress also intended for CAP to be implemented without increasing physicians' administrative burden associated with purchasing and administering Part B drugs. We support these policy objectives, and urge CMS to ensure that CAP facilitates Congress' overarching goal that Medicare beneficiaries have access to appropriate health care products and services as determined necessary by their physician.

Genentech commends CMS for recognizing the need to issue an IFR with comment, and to delay initiation of CAP in order to clarify important details, which remain unresolved. We support a number of policies addressed in the IFR designed to protect a physician's choice as well as Medicare beneficiaries' access to the best available therapies and future innovations.

Prior to final implementation, we encourage CMS to reiterate these policies, outlined below, in the Final Rule.

Although the CAP IFR effectively addresses a number of concerns raised in the Proposed Rule, some important policy issues remain unclear. As such, we respectfully request that CMS refrain from implementing any part of the program until these issues are resolved fully. Specifically, Genentech encourages CMS to:

1) Require vendors to include new products in CAP immediately upon approval by the Food and Drug Administration (FDA);

2) Apply the existing Part B policy for discarded drugs (i.e., "wastage") to CAP so that vendors can file claims for unused portions of drug;

3) Allow different physician specialties within a group practice to determine whether to participate in CAP; and

4) Allow physicians to select various CAP vendors for different CAP categories, as applicable.

Policies Genentech Supports in CAP IFR

The IFR clarifies and improves upon several important issues raised in the CAP Proposed Rule, which we urge CMS to finalize prior to the program's implementation. Specifically, we request clarification in the Final Rule of the following policies:

- Requirement that CAP vendors offer at least one drug for each Healthcare Common Procedure Coding System (HCPCS) code within a CAP category;

- Prohibition against the ability of CAP vendors to impose any formulary restrictions on single source products within a CAP category, or future categories;

- Requirement that vendors provide beneficiaries with information on sources of cost-sharing assistance when requested;

- Requirement that CAP vendors provide participating physicians available National Drug Codes (NDCs) for each HCPCS code required under CAP well in advance of the deadline for physicians to elect to participate;

- Ability for physicians to obtain drugs not offered by their CAP vendor using the average sales price (ASP) methodology, and to require products be "furnished as written" when certain conditions are met;

- Assurance that CAP vendors are prohibited from refusing to deliver prescribed products for covered indications, including uses beyond those indicated in the FDA-approved label;

- Requirement that vendors must adhere to rigorous quality, service, and financial standards in order to participate in CAP;

- Continuation of education programs and services to disseminate information and provide providers, patients, vendors, and Medicare contractors assistance regarding CAP;

- Confirmation that CMS cannot interfere in relationships between manufacturers and distributors, and cannot require manufacturers to enter into relationships or negotiate with CAP vendors;

- Assurance that all vendor cost data will be protected as proprietary, and will remain confidential and unidentifiable by manufacturer or wholesaler; and

- Inclusion of Producer Price Index updates for prescription preparations to more accurately reflect prices for drugs initially included under CAP to the mid-point of calendar year 2006 when the program is scheduled to begin.

Policy Changes Needed to Ensure Successful CAP Implementation

Genentech urges CMS to adopt the following policy recommendations in the CAP Final Rule to ensure Medicare beneficiaries' access to prescribed products after FDA approval, as well as a providers' ability to obtain Part B products for their patients is consistent regardless of the methodology selected.

1) Immediate Inclusion of New Drugs in CAP Following FDA Approval

As currently written in the IFR, new and innovative products expected to enter the market following the implementation of CAP are disadvantaged compared to products already on the market. This provision directly impedes one of the major goals of CAP, which is to provide physicians with a choice in methods for obtaining drugs and biologics in Part B of the Medicare program. To ensure access to new products by physicians and beneficiaries, we urge CMS to revise this policy in the Final Rule to instead specify that CAP vendors be required to offer, immediately upon market availability, new products that otherwise would be included under CAP, to participating physicians. In addition, we recommend that CMS specify that CAP vendors be allowed to incorporate throughout the year new products identified by a newly-assigned NDC for HCPCS codes already included in the program.

As written, the IFR excludes from CAP products that are not yet assigned a permanent Healthcare HCPCS code, specifically a J code used to describe most physician-administered drugs and biologics. Once a permanent HCPCS code is assigned, the IFR states that CAP vendors have the option to offer the product and if so, establishes reimbursement based on ASP plus 6%, consistent with Medicare payment for Part B products administered under the ASP methodology.

If implemented as written, Medicare beneficiaries could be denied access to the most current, best available therapies. As you are aware, it typically takes at least 12 months to obtain a permanent J code for a new product. Given this time lag, the availability of new products under CAP cannot be assured, if at all, until after such products have been adopted widely in other settings of care. Moreover, since CAP vendor contracts will be established for a 3-year period, the inclusion of new drugs in the program may be delayed even longer until vendor contracts can be re-negotiated. For physicians opting to participate in CAP, the language in the IFR places new products at a significant disadvantage compared to products on the market when CAP begins, effectively denying patients whose physicians have chosen CAP access to the most innovative therapies available.

Although the IFR allows CAP-participating physicians to purchase non-CAP products through the traditional "buy-and-bill" method, such a requirement is inconsistent with the overall intent of CAP, which is to provide physicians with the *choice* of obtaining products via one method or the other. Physicians interested in participating in CAP have indicated the willingness to do so largely because of the administrative advantages the program likely will offer. These physicians should not be forced to prescribe new products and acquire them only through the "buy and bill" methodology they specifically elected to avoid. Specialties that have minimal experience using the "buy and bill" methodology will be particularly adverse to acquiring drugs under both systems once electing to participate in CAP.

By not requiring CAP vendors to offer new and innovative products as soon as they become available, participating physicians face a significant disincentive to prescribe these products, creating access barriers for select Medicare beneficiaries. Additionally, this provision in the IFR creates perverse incentives for competing products offered in the same therapeutic class, which may perpetuate concerns regarding beneficiary access. If the issue of requiring new products to be included under CAP immediately upon FDA approval is not resolved prior to publication of the Final Rule, CAP will be the only venue within Medicare Part B for which new products are not made available as soon as marketing approval is received.

Through discussions with CMS staff, we are aware of the Agency's concerns in mandating that CAP vendors offer new products immediately upon FDA approval; however, we provide the following solutions to help CMS overcome those concerns and ensure the program's success.

Coding and Billing for New Products under CAP

We urge CMS to modify the IFR to instruct CAP vendors to offer new products immediately upon approval by the FDA, and to bill Medicare for new products using existing miscellaneous HCPCS J codes,[1] as is done currently under Part B of the Medicare program. Such miscellaneous or unclassified HCPCS J codes can be used to bill single-source products, and can be (and frequently are) annotated with specific NDCs to identify the exact product administered. Under the existing "buy and bill" system, providers must identify the product used by indicating the NDC or product name on the claim form in order to receive payment. Providers, therefore, are accustom to submitting some additional information for new products and many have indicated that providing such information is not cumbersome. Moreover, only a small number of new products requiring individual HCPCS codes are introduced into the market each year,[2] indicating that providers and CMS will not be unduly burdened by a requirement to provide the NDC for new products administered under CAP.

This modification will ensure that new products will be made immediately available to all providers serving Medicare beneficiaries', further ensuring that beneficiaries have timely access to the best available therapies.

[1] J3490, *unclassified drugs*; J3590, *unclassified biologics*; and J9999, *not otherwise classified, antineoplastic drug.*
[2] Data on file at the Biotechnology Organization illustrates that annually since 2001, less than 10 new recombinant/monoclonal antibody products covered under Medicare Part B were approved by the FDA, and required the manufacturer to apply for an individual HCPCS code.

Payment for New Products under CAP

To ensure CAP vendors are held harmless by a requirement to make immediately available newly-approved products, Genentech recommends that vendors be reimbursed at ASP + 6% for such products, which is consistent with how such products are reimbursed under traditional Part B. As written, the IFR specifies reimbursement at ASP + 6% for new products voluntarily offered by CAP vendors. If vendors are required to supply all new single-source drugs, described by a single HCPCS code within a CAP category, and are assured reimbursement at 106% of ASP [or 106% of wholesale acquisition cost (WAC) until a full quarter of ASP data is available], they should not be subject to negative financial implications.

2) Application of Existing Part B Policy for Discarded Drugs to CAP

Genentech recommends that CMS clarify in the CAP Final Rule that CAP vendors may file claims for unused portions of a drug administered under CAP as physicians currently do under the traditional "buy and bill" method. Specifically, we recommend that the Agency provide additional detail in the Final Rule that supports its response to CAP vendor questions that "...vendors will be able to bill the program for unused drugs under the CAP program in a similar fashion if physicians and vendors act in good faith with respect to the ordering and use of the drugs."[3] Moreover, CMS has indicated in past correspondence to contractors and physicians that "...if a physician must discard the remainder of a vial after administering to a Medicare patient, Medicare covers the amount of drug discarded in addition to the amount administered; up to a whole multiple of vials. However, documentation must reflect in the patient's medical record the exact dosage of the drug given and a statement that the unused portion of the drug was discarded."[4] We encourage CMS to keep existing policies on discarded drugs consistent within the Part B program under CAP or the ASP-payment methodology.

3) Ability for Different Specialties within a Group Practice to Determine CAP Participation Separately

Genentech is concerned that the IFR policy that requires all physicians billing under a group billing number be subject to participation in CAP and the required use of only one CAP vendor per category would prohibit individual physicians within a group practice to prescribe the most appropriate therapy for their patients' needs. Physicians of different specialties within a group practice should be able to decide separately whether to participate in CAP. If CMS does not allow individual physicians within a group to make their own decisions regarding CAP, physicians may elect to provide care at other sites which are less convenient for patients and may decrease patient access to needed therapies.

4) Ability for Physicians to Select Different Vendors for Different CAP Categories

Genentech encourages CMS to give physicians the ability to choose the category(ies) of drugs they wish to obtain from any given CAP vendor after the initial phase-in period. Although the IFR first recommends implementation of CAP for a single category of drugs, the Agency may decide to add other categories in the future. If and when additional categories are created, a physician who wishes to acquire a category of CAP drugs from a

[3] Document entitled "CMS Response to Vendor Questions" posted on the CMS Website on August 10, 2005. Accessed at http://www.cms.hhs.gov/providers/drugs/compbid/capquestions081005.pdf.
[4] As referenced in "Medicare Provider News" from Wisconsin Physicians Services, September 2001. Accessed at http://www.wpsic.com/medicare/provider/pdfs/0901mn.pdf.

particular vendor should not be forced to purchase a different category from the same vendor. A single CAP vendor may offer products appropriate for some, but not all, of a physician's patients.

Conclusion

Genentech appreciates the opportunity to comment on the CAP IRF, and urges the Agency to fulfill Congressional intent for the program by ensuring that patients have access to the medical therapies chosen in consultation with their physician, including new therapies approved after the implementation of the program. We appreciate CMS' commitment to successful implementation of CAP and to addressing the remaining issues mentioned above. We look forward to working with the Agency and all interested stakeholders to ensure CAP is implemented effectively and efficiently in 2006.

Please contact me or Heidi Wagner at (202) 296-7272 if you have any questions about our comments or need additional information.

Sincerely,

Walter Moore
Vice President, Government Affairs

cc: Herb Kuhn, Director, Center for Medicare Management

Submitter : **Ms. Carolyn Aldige** **Date: 09/06/2005**

Organization : **Cancer Research and Prevention Foundation**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

September 6, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS: 1325-IFC
Post Office Box 8013
Baltimore, MD 21244-9013
Re: Comments on the Interim Final Rule on the Competitive Acquisition Program for Part B Drugs and Biologicals

The Cancer Research and Prevention Foundation (CRPF) is a national, non-profit organization with the mission of cancer prevention through research and education. CRPF submits these comments in response to the interim final rule with comment period establishing the Competitive Acquisition Program (CAP) for Medicare Part B drugs and biologicals, published in the Federal Register on July 6, 2005.

We understand that the process for evaluating and selecting bidders for CAP has been temporarily suspended, but we offer these recommendations for revision of the program before its implementation is resumed.

CRPF is concerned about several provisions of the CAP which may adversely affect cancer patients? access to life-saving cancer therapies and the ability of providers to effectively deliver this care.

Our first area of concerns surrounds patient coinsurance. The interim rule permits CAP vendors to stop providing drugs to patients who have not paid their coinsurance within 45 days. The rule requires vendors to consider alternatives for collection of coinsurance, including establishing a payment plan or referring the patient to a charitable organization. However, the vendor has the right, if these options do not result in payment of coinsurance, to terminate a patient?s access to drugs.

In the current system of care, where the oncologist orders and purchases cancer drugs, it has been our experience that oncologists absorb the cost of any coinsurance that cannot be paid by patients. It is reasonable to assume that patients will not have the same experience with CAP vendors, and the result will be disruptions in care if patients cannot pay their coinsurance. This is unacceptable. Our Foundation urges CMS to amend the program to eliminate the ability of CAP vendors to terminate the provision of drugs to patients who cannot pay their coinsurance.

Our second concern is the absence of clear standards for systems or procedures that vendors must maintain for patient support initiatives. The regulations require vendors to have procedures to resolve complaints and inquiries about drug shipments, but no direct channel for patient questions. The establishment of a call center or other patient support center may ensure that patients have ready answers to questions about billing, payment schedules, and other matters and request that a mechanism of patient support be included.

Finally, we are concerned with provisions prohibiting movement of drugs between offices, even if the offices are part of the same practice. Cancer patients benefit from the ability to receive chemotherapy in their physician?s office, and those in remote areas have enjoyed the advantages of receiving treatment in satellite offices, a practice that has minimized the distance they must travel to receive care. The prohibition against movement of drugs between offices will either limit the access to care in satellites offices or will force those physicians who maintain satellite offices to forego enrollment in CAP.

The Foundation urges a revision of this standard to reflect the needs of cancer patients treated by physicians with satellite offices, including those in rural areas. Oncologists, nurses, and other staffers in oncologists? offices have significant experience in transporting and handling cancer drugs, which suggests that CAP vendors? concerns about breakage and spoilage are unfounded.

CRPF appreciates the opportunity to offer these comments that reflect the special needs of cancer patients and potential disruptions to cancer care under CAP.

Sincerely,

Carolyn R. Aldige
President and Founder

Submitter : **Ms. Maya Bermingham** **Date: 09/06/2005**

Organization : **PhRMA**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

PhRMA Comments on CMS-1325-IFC are attached.

CMS-1325-IFC-172-Attach-1.PDF

PhRMA

September 6, 2005

VIA EMAIL
www.cms.hhs.gov/regulations/ecomments

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: **CMS-1325-IFC; Comments Regarding the Competitive Acquisition Program Interim Final Rule With Comment Period**

Dear Dr. McClellan:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the Competitive Acquisition Program (CAP) interim final rule issued by the Centers for Medicare and Medicaid Services (CMS).[1] PhRMA is a voluntary, nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

The interim final rule clarifies and improves upon the proposed rule in several respects. Given the importance of establishing a sound, carefully-considered foundation for CAP from the outset, we also welcome the decision to consider comments on the interim final rule and issue a revised final rule before proceeding with the CAP bidding process. To ensure that CAP is successful in facilitating appropriate care for Medicare beneficiaries, the final rule should make additional changes in accordance with the following principles:

- CAP should be implemented in a manner that respects physicians' medical judgments and improves their ability to offer patients the most medically appropriate drug therapies, thereby enhancing patient access;

[1] "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Interim Final Rule with Comment Period," 70 Fed. Reg. 39022 (July 6, 2005).

- To encourage physician participation, CAP should be designed to minimize burdens on physicians, assure their confidence in the integrity of the products delivered by CAP vendors, and avoid restrictions on physician choices (including the choice of purchasing and billing for any Part B drug patients need that are not available through CAP); and

- To maximize participation both by physicians and prospective vendors, CAP should be carried out in accordance with clearly-defined, transparent rules (including roll-out timelines) informed by input from all of the program's stakeholders.

Our detailed comments on specific provisions in the interim final rule are set out below.

* * *

A. Categories of Drugs to be Included Under CAP; Competitive Acquisition Areas

1. Temporarily Limiting CAP to Physician-Administered Drugs

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) requires CMS to establish categories of competitively biddable drugs and biologicals that will be included in CAP. The MMA defines "competitively biddable drugs and biologicals" as drugs or biologicals described in section 1842(o)(1)(C) of the Social Security Act (SSA) and furnished on or after January 1, 2006.[2] As the proposed rule noted, the statutory definition includes "drugs administered incident to a physician's service (for example, drugs commonly furnished by oncologists), drugs administered through DME (for example, inhalation drugs), with the exception of DME infusion drugs, and some drugs usually dispensed by pharmacies (for example, oral immunosuppressive drugs)."[3]

The proposed rule would have permanently limited the scope of CAP to physician-administered Part B drugs.[4] In our comments on the proposed rule, we suggested that limiting the program to physician-administered drugs during the phase-in period would be a prudent measure that would facilitate a smooth implementation process. We also encouraged CMS to consider extending CAP to the full range of "competitively biddable drugs," as defined in the MMA, once the phase-in experience provides a foundation for evaluating the feasibility of such an expansion. The interim final rule appropriately limits CAP to physician-administered drugs during CAP's "phase-in" period. CMS should

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[2] SSA § 1847B(a)(2)(A).

[3] 70 Fed. Reg. at 10749.

[4] For instance, the proposed rule stated, "[W]e do not believe it is possible to include drugs other than those administered as incident to a physician's service as part of this program." 70 Fed. Reg. 10749.

"continue to consider whether the statute allows expansion of the program to Part B drugs that are administered through DME or dispensed by pharmacies."[5]

2. Phase-In Issues: Drug Categories and Competitive Acquisition Areas

The proposed rule described several options for limiting CAP's scope during the initial phase-in period, both by drug category and geographic area. In the interim final rule, CMS decided to create a single drug category (which would encompass most physician-administered drugs) and a single nation-wide competitive acquisition area during CAP's initial years. CMS would use its phase-in authority to exclude some physician-administered drugs from CAP during this initial period, but CAP would include "approximately 85 percent of physicians' Part B drugs by billed charges."[6] After the phase-in, CMS expects that multiple drug categories (probably defined around physician specialties) will be developed, and that competitive acquisition areas will be defined based on "regions, States, or some other smaller geographic area."[7]

As explained in our comments on the proposed rule, PhRMA believes that an initial roll-out that encompasses all physician-administered Part B drugs in a limited number of sub-national competitive acquisition areas would achieve the appropriate balance between the various goals CMS has articulated for the phase-in period. This approach would permit a focused, smaller-scale implementation effort, while also allowing CMS to identify the issues and concerns relevant to all of the physician specialties that administer Part B drugs. A geographical phase-in that includes all physician-administered drugs will enable CMS to identify issues representative of a full-scale CAP in a smaller, more controlled environment, keeping the program manageable as CMS irons out identified issues and prepares for nation-wide implementation.

We continue to believe that establishing multiple competitive acquisition areas, as opposed to a single nation-wide region, would provide the best opportunity for successful CAP implementation. Multiple CAP areas would maximize competition among vendors by allowing smaller companies to enter the market. At the same time, this approach should also attract participation by larger national or regional vendors interested in reaching a larger marketplace, because such vendors could submit bids for all or a subset of the sub-national areas included in the phase-in effort. We encourage CMS to embrace this approach in the CAP final rule.

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[5] 70 Fed. Reg. at 39027.

[6] 70 Fed. Reg. at 39030.

[7] 70 Fed. Reg. at 39036.

B. Claims Processing and Operational Overview

1. Physician Choice in Prescribing Appropriate Therapies

The MMA requires that physicians make an annual election about whether to participate in CAP.[8] The interim final rule, like the proposed rule, clarifies that participating physicians may still obtain Part B drugs outside CAP and receive reimbursement at 106% of Average Sales Price (ASP) under limited circumstances. Giving physicians some flexibility to obtain drugs outside CAP will encourage physician participation in CAP. If CAP works as intended, participating physicians will have every incentive to use CAP drugs when therapeutically appropriate for the individual patient; there is no reason a physician who preferred to avoid the traditional "buy and bill" system would resort to that system unless the drugs available through the CAP vendor were not appropriate for a particular patient.

The interim final rule states that participating physicians may obtain Part B drugs outside CAP in two types of situations. The first type involves "furnish as written" situations, where a participating physician's CAP vendor offers a drug (or drugs) within a certain HCPCS code, but the physician decides that a patient needs another drug falling within that HCPCS code that is not available through the CAP vendor. The "furnish as written" option is an important safeguard to ensure that patients of participating physicians can receive the most medically appropriate therapies. However, we are concerned by language in the interim final rule suggesting that this option could only be used in limited circumstances and would impose extra burdens on physicians. For example, the rule states that:

> The "furnish as written" option is intended to be used only occasionally in limited circumstances where a patient's medical condition requires a particular formulation of a drug at the NDC level — it is not intended to be used in routine situations as a means to circumvent the normal CAP ordering process. An example of a situation when the "furnish as written" option would be appropriate is where a participating CAP physician is treating a patient with a documented allergy to certain excipients or preservatives who requires a specific formulation of a product that the approved CAP vendor does not furnish as part of its CAP contract. In this case, documentation of the allergy is a justification to use another product. However, the documentation must be maintained in the patient's medical record. Use of the "furnish as written" modifier will permit the physician to bill under the ASP system in this limited

[8] SSA § 1847B(a)(1)(A)(ii).

circumstance even though the physician has elected to participate in the CAP.[9]

Physicians are in the best position to identify the drugs that are medically necessary for their individual patients and should therefore be able to obtain non-CAP drugs for their patients through the least burdensome process possible. Thus, CMS should allow physicians to bill for drugs not available through their CAP vendors using the normal procedures for submitting Part B claims and should assure physicians that their judgments about medical necessity will not be scrutinized or "second-guessed" in these situations, nor will they be expected to satisfy special documentation requirements when using the "furnish as written" option. This is important to ensure that physicians understand that CAP participation will not impinge in any way on their ability to treat patients in accordance with their best medical judgments and feel no pressure to forego more appropriate treatments in favor of CAP drugs.

In the CAP proposed rule, CMS stated that participating physicians could also receive reimbursement at 106% of ASP for "drug categories that the physician does not select," and requested comments "on whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or should be allowed to choose the categories [of] drugs he wishes to obtain from the vendor."[10] The interim final rule states that although CAP will initially be implemented with a single category of drugs (which would make such choices impossible), CMS "plan[s] to add additional categories of drugs," and when this occurs, "physicians will be allowed to select the categories of drugs that they will obtain from the CAP" and "it will be possible to select a different vendor for each category if the physician decides that it best meets his or her needs."[11]

PhRMA agrees that physicians should be able to elect to obtain different categories of CAP drugs from different CAP vendors after the phase-in period. In addition to encouraging physician participation in CAP, providing physicians with these choices will help to ensure that patients continue to have access to the drug therapies they need and spur competition among CAP vendors to attract physician participation. To realize these benefits more quickly, we encourage CMS to develop multiple categories of competitively biddable drugs at CAP's inception, instead of waiting until after the phase-in period.

The interim final rule also states that CMS will "encourage physicians to elect vendors in a manner that will minimize the number of vendors used by one practice," by

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[9] 70 Fed. Reg. at 39043. Likewise, the interim final rule states that: "A patient known not to respond appropriately to a certain formulation of a product may require a specific formulation of a product that is still within the same HCPCS, but not furnished under the approved CAP vendor's CAP contract because the approved CAP vendor submitted a bid to provide a different NDC within the HCPCS code. Documentation of treatment failure or adverse effects from specific formulations may provide justification to use another product . . . ." Id.

[10] 70 Fed. Reg. at 10755.

[11] 70 Fed. Reg. at 39049.

limiting physicians to "one vendor per category" and requiring that "[p]hysicians billing under a group billing number . . . reach agreement among themselves on whether to participate in CAP and which vendor to select for each category."[12] However, it is not clear how CMS will ensure that all members of a practice group have reached such an agreement, or whether ASP-based reimbursement would be permitted in a case where a physician who was unaware of his or her group's participation in CAP purchased a drug offered by the group's vendor and billed Medicare under the ASP system. We request that CMS clarify these issues.

2. Resupplying in Emergency Situations

The MMA requires CMS to establish rules that allow physicians to resupply their inventories with drugs supplied by CAP vendors when: (1) the drugs were required immediately; (2) the physicians could not have "reasonably anticipated" the immediate need for the drugs; (3) the CAP vendor could not deliver the drugs in a timely manner; and (4) the drugs were administered in an "emergency situation."[13] The interim final rule properly recognized the need for a flexible definition of "emergency situation" that could encompass the broad array of circumstances where an immediate, unanticipated need for a particular drug may arise, defining an "emergency situation" as "an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention . . . ."[14] This flexible definition will encourage physician participation and appropriate patient care.

3. Assuring Patient Access to Unique Therapies that Share a HCPCS Code

The MMA requires CMS to conduct a competition in the case of multiple source drugs "for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area."[15] In our comments on the proposed rule, we asked that CMS emphasize that Congress did not authorize CAP vendors to construct restrictive lists that would discourage physicians from participating in CAP. In the interim final rule, CMS agreed that "the statute does not contemplate a formulary," and consequently, vendors may not "establish formularies by offering drugs from only some of the [HCPCS] codes included in a category."[16] This decision is critical both in encouraging physicians to participate in CAP and in preserving choices for patients of participating physicians.

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[12] 70 Fed. Reg. at 39049.

[13] SSA § 1847B(b)(5).

[14] 70 Fed. Reg. at 39093 (42 CFR § 414.902).

[15] SSA § 1847B(b)(1). "Billing and payment codes" refers to HCPCS codes. See H. Rep. No. 108-391, at 594 (2003).

[16] 70 Fed. Reg. at 39034.

Our comments on the proposed rule also urged CMS to clarify that CAP vendors must provide at least one formulation (i.e., at least one NDC) for all single-source drugs that fall within the same HCPCS code.[17] CMS did not adopt this suggestion (or a similar suggestion that vendors should offer at least one drug for "each distinctive treatment or therapy represented within a HCPCS code"), stating that these proposals "would be difficult to distinguish from establishing the type of formulary that many commenters opposed."[18]

Although we appreciate CMS's recognition that formularies should not be created under CAP, our proposal to require vendors to offer at least one NDC for each single-source drug within a HCPCS code would not create formularies; instead, it would require that vendors broaden their offerings to ensure that all CAP-covered drugs without generic equivalents were available to participating physicians. We continue to urge CMS to adopt it. Requiring that vendors only offer a single NDC per HCPCS code could severely restrict the choices patients and physicians need, and reduce CAP's utility, in those circumstances where different single-source drugs that are not generic equivalents are grouped together in the same HCPCS code. We also recommend that CMS allow vendors to offer additional NDCs beyond those they have contracted to offer, should the vendors so choose. CMS could reimburse vendors for these NDCs at the established CAP prices for their respective HCPCS codes. These measures would establish important safeguards that would help to ensure patients receive the most appropriate medication and would expand the choices available to physicians under CAP, thus reducing the need to purchase drugs outside the program pursuant to the "furnish as written" procedures.

4. Coverage Issues

Under CAP, vendors are responsible for delivering drugs to physicians in a timely manner.[19] In the proposed rule, CMS noted that physicians and their carriers will be responsible for checking to determine whether competitively biddable drugs are used consistently with any Local Coverage Determinations.[20] We urged CMS to clarify in the final rule that CAP vendors may not withhold a drug or biological they contracted to supply based upon their own "coverage determination." The rule clarifies this point by providing that:

> If the vendor believes a drug order is not consistent with an LCD [Local Coverage Determination], the vendor may call the physician to . . . determine why the physician believes [the order] will be covered under the local carrier's LCD. If the physician declines to change the order, but the vendor

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[17] By "single-source" drugs, we mean: (1) a biological; or (2) a drug that is not a multiple source drug and that is distributed under a new drug application approved by the FDA. See SSA § 1847A(c)(6)(D).

[18] 70 Fed. Reg. at 39034.

[19] SSA § 1847B(b)(2)(A)(i)(II).

[20] 70 Fed. Reg. at 10756.

> still believes the local carrier will not cover the drug, the vendor may ask the beneficiary to sign an Advance Beneficiary Notice (ABN) . . . . However, in the event the vendor is not successful in collecting an ABN from the beneficiary, and the physician refuses to change the order, the vendor will still be required to provide the drug to the physician . . . .[21]

We agree with the clarification that a vendor cannot refuse to supply CAP drugs to physicians based on the vendor's analysis of coverage issues. As the interim final rule notes, the requirement that vendors deliver the drug ordered by the physician is essential "to ensure that the physician's judgment about the appropriate treatment for the beneficiary is primary in the decision-making process."[22]

In our comments to the proposed rule, we also asked that CMS emphasize that CAP will not modify Medicare's existing rules on coverage of off-label uses[23] or modify Medicare's existing processes for determining whether a particular claim is covered. CMS states in the interim final rule that "[i]t is not our intention to change our policy on the carrier's authority to make decisions about whether a particular medication will be covered."[24] Similarly, CMS rejected a suggestion that vendors be allowed to determine the medical necessity of off-label uses, observing that "[d]eterminations of medical necessity are made by the Medicare carriers and are not made by suppliers, such as the approved CAP vendor."[25] This is an important principle that should be reaffirmed in the final rule.

5. Application of "Least Costly Alternative" Policies Under CAP

Another issue concerning coverage policies that CMS addressed in the interim final rule is the application of "least costly alternative" (LCA) policies under CAP. LCA policies are local carrier policies that limit the payment for a particular drug to the payment rate for a lower-cost drug that the carrier considers equivalent. Although LCA policies only reduce the payment rate for the higher-cost drug, CMS considers them coverage policies, under the theory that the excess costs of the higher-cost drug are not

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[21] 70 Fed. Reg. at 39039 (emphasis added).

[22] Id.

[23] See Medicare Benefit Policy Manual § 50.4.2 (carriers may cover off-label uses of a drug "if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice"); § 50.4.5 (medically accepted indications for anti-cancer drugs include off-label uses supported by specified compendia or peer-reviewed journal articles, or "determined by the carrier to be medically accepted generally as safe and effective").

[24] 70 Fed. Reg. at 39038.

[25] Id.

"reasonable and necessary," i.e., the LCA policy results in the "partial denial" of claims for the higher-cost drug on medical necessity grounds.

Asked to clarify whether LCA policies applied to CAP payments, CMS stated in the interim final rule that "[SSA] Section 1862(a)(1)(A) provides that, notwithstanding any other provision in the Medicare statute (that is, including Section 1847B), no payment may be made under Part A or Part B for any expenses . . . that are not reasonable and necessary"; consequently, "[i]f a carrier applies an LCA policy to a particular drug, the approved vendor's claim for that drug, when ordered by a participating CAP physician in that carrier's jurisdiction, would be subject to LCA."[26] Thus, the drug claim "will be paid subject to the LCA policy, rather than the CAP-established price."[27]

PhRMA believes that LCA policies cannot properly be used to displace the prices established through the CAP bidding process, for two reasons. First, as a general matter, there is nothing in the Medicare statute or its legislative history suggesting that coverage decisions can be based on the consideration of cost, and CMS has twice withdrawn proposals to adopt regulations introducing cost into the coverage decision-making process. Thus, LCA is not properly considered a coverage policy; LCA policies are payment policies that should not be shoehorned into coverage decisions. Second, given LCA's status as a payment policy, LCA is especially inappropriate in the CAP context because it conflicts with the express statutory requirements on payments to CAP vendors. The MMA specifically requires that CAP payments "shall be based on bids submitted and accepted"[28] and that a uniform "single payment amount" for a drug shall apply throughout a competitive acquisition area,[29] which would not be the case if the single payment amount established through competitive bidding was displaced in portions of a competitive acquisition area where the local carrier had adopted an LCA policy. Consequently, we urge CMS to revisit this issue in the CAP final rule and adhere to the CAP payment policies Congress established in the MMA.

6. Supplying Patient Information to CAP Vendors

The proposed rule listed various items of information that physicians would be required to include in their orders to CAP vendors, most of which seem necessary for filling the order or for the vendor's billing purposes. However, the information also would include "Additional Patient Info: date of birth, allergies, Ht/Wt/ICD-9, etc."[30] In response to questions about why CAP vendors needed this patient information, the interim final rule states that:

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[26] 70 Fed. Reg. at 39039.

[27] Id.

[28] SSA § 1847B(d)(1).

[29] Id.

[30] 70 Fed. Reg. at 10756.

> Based on our decisions regarding the approved CAP vendor's ability to break up shipments in appropriate circumstances, our conclusion that approved CAP vendors may directly appeal the denial of their drug claims, and the fact, with limited exceptions, that approved CAP vendors must ship CAP drugs upon receipt of a prescription order, we believe it is important for approved CAP vendors to have the information specified above. For example, ICD-9 information may help an approved CAP vendor assess whether it should seek to obtain an ABN from the beneficiary. Dosing information will help an approved CAP vendor determine whether it can appropriately split a prescription order into separate shipments. Patient date of birth is required by the Medicare claims processing system and is a required field on the claim form.[31]

It remains unclear why a vendor would require information on a patient's height and weight for any of these purposes; for example, this information is not needed to determine if an order can be split into multiple shipments, because physicians will already provide information on the "dose" required and the "frequency" and "anticipated date" of administration on the CAP drug order form.[32] Therefore, we encourage CMS to delete the requirement that physicians supply this category of patient information to CAP vendors.

C. Contracting Process — Quality and Product Integrity Aspects

1. Quality and Product Integrity Standards

Like the proposed rule, the interim final rule incorporates carefully-crafted standards designed to ensure that only reputable and experienced vendors that can guarantee product integrity are chosen to participate in CAP. We believe requiring strict compliance with quality and product integrity standards is essential both for patient safety and for establishing a successful CAP. PhRMA looks forward to working with CMS to ensure that these important standards are met.

2. Discarded Drug

In response to a comment to the proposed rule, CMS provides guidance on how to manage drug waste and returns in the preamble to the interim final rule. There, CMS states, "We expect that approved CAP vendors will furnish drugs in a manner that will minimize unused drug," and, "We further expect approved CAP vendors to offer and ship units of a drug that match the beneficiary's dosing requirement and HCPCS billing

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[31] 70 Fed. Reg. at 39040-41.

[32] 70 Fed. Reg. at 39041.

amount as closely as practical [so that] a degree of waste will be prevented."[33] CMS recognized, however, that "in situations where a drug is dosed by body weight or body surface area, the amount of drug in vials may not match the patient's actual dose, and the vendor will be forced to ship excess drug."[34] If the excess drug may not be dispensed to another beneficiary under a state's pharmacy law and the physician is required to return the excess drug to the CAP vendor, the vendor is expected to accept the excess drug for disposal.[35] However, CMS then explains that:

> The vendor bills Medicare only for the amount of drug administered to the beneficiary and the beneficiary's coinsurance amount will be calculated from the quantity of drug that is administered. Since the CAP statute authorizes us to pay the approved CAP vendor only upon administration of the drug, any discarded drug (or drug that is considered waste) will not be eligible for payment.[36]

PhRMA supports CMS's effort to minimize drug waste; however, we respectfully disagree with CMS's decision not pay the CAP vendor for the excess drug in situations in which shipping drug in excess of the patient's prescribed dose cannot be avoided and the excess drug cannot be dispensed to another beneficiary. There is no evidence that this statutory language was intended to change Medicare general policy on discarded drugs, i.e., CMS encourages physicians to schedule patients in such a way that they may use drug efficiently, but "if a physician must discard the remainder of a vial or other package after administering it to a Medicare patient, the program covers the amount of drug discarded along with the amount administered."[37] Where the shipment of excess drug is unavoidable, CMS should not financially penalize the CAP vendor by denying payment for the excess drug; the statute itself does not require this, and such a policy could discourage robust participation by potential CAP vendors, which is important to CAP's success. PhRMA therefore urges CMS to reconsider its current position and, in the CAP final rule, agree to pay CAP vendors for excess drug in the very limited circumstance described above.

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[33] 70 Fed. Reg. at 39062.

[34] Id.

[35] 70 Fed. Reg. at 39063.

[36] Id.

[37] Medicare Claims Processing Manual, ch. 17, § 40.

D. CAP Bidding Process — Evaluation and Selection

1. Imposing a Composite Bid Ceiling

CMS proposed that bidders eligible for selection as CAP vendors would only include those whose "composite bids" did not exceed a specified ceiling.[38] The interim final rule adopts this proposal, stating that CMS will require that "the weighted average of the bids for all the drugs in the category . . . be less than or equal to 106 percent of the weighted average of the ASPs for all the drugs in a category."[39]

As PhRMA noted in our comments on the proposed rule, this ceiling is not required or authorized by the MMA, and it conflicts with CAP's underlying market-based philosophy. While Congress hoped that CAP would generate cost savings (though, as CMS correctly notes, this is not the program's only goal[40]), Congress selected the market mechanism as the vehicle to reduce costs under CAP. Consequently, we would encourage CMS to embrace that same philosophy and rely on market forces to contain costs, structuring CAP to promote broad participation by potential vendors and robust competition.

By avoiding price ceilings, CMS would also encourage vendor participation; assure that bidders lacked any incentive to de-emphasize quality, product integrity and customer service efforts; avoid the complexities associated with constructing an ASP-based composite ceiling; and allow CAP to serve a "safety valve" function in instances where the 106% of ASP payment rate might reduce access to a particular drug. We are concerned that the 106% of ASP payment rate may not prove adequate to ensure patient access for all Part B drugs, which are critical therapies used to treat cancer and other serious diseases that must remain available to Medicare beneficiaries; imposing price ceilings that prevent CAP from serving as a safety valve would needlessly increase the risk of compromised access to care, particularly as the cancer demonstration project credited with alleviating access problems under the ASP-based system might end in 2006.

The interim final rule would set the initial CAP payment for specific drugs within a CAP category based on the median bid for the drug among the winning bidders, updated for inflation. The provision for an inflation update represents a significant improvement from the CAP proposed rule, and this improvement will help to promote vendor participation in CAP. Even with this improvement, however, the median bid approach would be an appropriate method for setting CAP payments for specific drugs only if the selection of winning bidders were not constrained by artificial price ceilings.

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[38] 70 Fed. Reg. at 10763.

[39] 70 Fed. Reg. at 39070.

[40] 70 Fed. Reg. at 10748.

2. Post-Award Price Adjustments

The MMA provides for: (1) periodic disclosures to CMS (not more often than quarterly) of vendors' "reasonable, net acquisition costs" for CAP drugs; and (2) appropriate price adjustments over the three-year contract term to reflect significant increases or decreases in vendors' disclosed acquisition costs.[41] Under the proposed rule, vendors would have submitted annual disclosures of their reasonable, net acquisition costs, and prices would generally have been updated annually based on those disclosures.[42] The interim final rule adopts this proposal, but also states that "when the administrative mechanisms of the CAP are operational and vendors have more experience under the program, we will consider whether more frequent reporting would be appropriate."[43]

While we appreciate the willingness to consider the idea of more frequent cost reporting, we would encourage quarterly cost disclosures and pricing updates even during the phase-in period. This approach would produce greater savings in instances where vendors' overall costs for CAP drugs were declining, while providing greater protection for vendors (and thus encouraging continued participation in CAP) in instances where vendors were experiencing cost increases.

3. Integrating New Drugs Into CAP

Under the MMA, CMS must establish rules regarding "the use under [CAP] of the alternative payment amount provided under [SSA] section 1847A" in setting CAP payments for new "drugs and biologicals . . . for which a payment and billing code has not been established."[44] SSA § 1847A(c)(4) provides for a temporary alternative payment based on: (1) wholesale acquisition cost (WAC); or (2) pre-MMA payment methodologies. CMS has implemented this provision (in the ASP-based system) by adopting a temporary payment rate equal to 106% of WAC for new drugs first sold on or after December 1, 2004.[45] Neither the proposed nor the interim final rule specifies which payment option under SSA § 1847A(c)(4) will be implemented for new CAP drugs.[46] We continue to recommend that CMS explicitly incorporate the 106% of WAC methodology it recently adopted for the ASP-based system into the CAP final rule.

The proposed and interim final rules describe similar tests for determining which new drugs would be eligible for the § 1847A(c)(4) payment rate. Under the CAP

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[41] SSA § 1847B(c)(7).

[42] 70 Fed. Reg. at 10764-65; 70 Fed. Reg. at 39075-76.

[43] 70 Fed. Reg. at 39076.

[44] SSA § 1847B(d)(2).

[45] CMS Transmittal No. 480, § I.B(5) (Feb. 25, 2005).

[46] For instance, the interim final rule states that new drugs will be reimbursed at the § 1847A "alternative payment amount." 70 Fed. Reg. 39094 (42 CFR § 414.906(c)(2)).

proposed rule, CMS would have applied this rate to a competitively biddable drug "[f]or which a payment and billing code has not been established."[47] In the interim final rule, CMS would similarly apply the rate if "the drug is properly assigned to a category established under the CAP . . . and [it] is a drug for which a HCPCS code must be established."[48] This standard is similar to the statutory language that grants § 1847A(c)(4) payment to drugs "for which a payment and billing code has not been established."[49] Together, these statutory and regulatory provisions suggest that new drugs without HCPCS codes can be included in CAP and paid at the § 1847A(c)(4) alternative payment rate.

However, certain statements in the preamble to the interim final rule create uncertainty about this issue. For instance, the rule states that CMS "will provide for payment [at the § 1847A(c)(4) rate] to CAP vendors for these new drugs . . . after the drug receives a code" and that "[n]ew drugs may be included in the CAP once they are assigned a permanent HCPCS code."[50] Given the potential inconsistency of these statements in the preamble with others in the interim final rule — and with the MMA — PhRMA urges CMS to state explicitly in the final rule that new drugs without HCPCS codes can be included in CAP and paid at 106% of WAC.

In our comments on the proposed rule, we encouraged CMS to develop a mechanism for ensuring that new drugs falling within a CAP category are promptly available from CAP vendors contracted to supply that category of drugs. We suggested that CMS, for example: (1) task its "designated carrier" for CAP claims to notify CAP vendors as soon as a new drug is introduced that falls within the category or categories they supply; and (2) include provisions in its CAP contracts obligating the vendor to begin filling orders for such new drugs, at a 106% of WAC payment rate, upon receipt of such a notification. However, the interim final rule states that it would be inappropriate, "especially during the initial stages of implementing the CAP, to impose a requirement on vendors to include all new drugs introduced too late to be taken into consideration during the bidding period," because "[s]uch a requirement may impose unpredictable, and sometimes difficult or impossible, burdens on vendors."[51] PhRMA appreciates CMS's willingness to revisit this issue after the "initial stages of implementing the CAP," and we share the goal of minimizing burdens on CAP vendors. However, vendors should not have difficulty supplying new drugs within their contracted category if they were guaranteed a 106% of WAC payment rate for these drugs, and expanding access to new drugs under CAP could significantly enhance physician convenience and participation.

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[47] 70 Fed. Reg. at 10770 (proposed 42 CFR § 414.906(c)(2)(i)).

[48] 70 Fed. Reg. at 39094 (42 CFR § 414.906(c)(2)(i)).

[49] SSA § 1847B(d)(2).

[50] 70 Fed. Reg. at 39075, 39092. Similarly, the interim final rule states that drugs billed under "not otherwise classified" HCPCS codes (which include new drugs that have not yet been assigned their own HCPCS code) will be excluded from CAP. Id. at 39030.

[51] 70 Fed. Reg. at 39075.

Consequently, we encourage CMS to re-evaluate this issue and adopt a well-defined mechanism for promptly incorporating new drugs into CAP in the final rule.

In PhRMA's comments on the proposed rule, we also requested that CMS recognize physicians' right to bill for new drugs, should those drugs not be immediately available from their CAP vendors. We are pleased that the interim final rule provides that "[i]f a new drug . . . is not offered by the participating CAP physician's CAP vendor, [the] participating CAP physician can purchase it and bill for it under the ASP payment system."[52] This flexibility will encourage physicians to participate in CAP.

4. Confidentiality of Pricing Information

As noted earlier, CAP vendors must periodically disclose their "reasonable, net acquisition costs" for drugs to CMS. The proposed rule would have required annual disclosures that would "reflect the vendor's purchases of these [CAP] drugs from all manufacturers, and the total number of units purchased from each manufacturer,"[53] but did not include provisions concerning the confidentiality of this information.

The preamble to the interim final rule recognizes that the MMA includes protections for confidential pricing information provided to CMS by CAP vendors.[54] Likewise, the CAP final rule should expressly incorporate these protections into the actual regulations. Moreover, the regulations should specifically recognize the protections afforded by the Trade Secrets Act (18 U.S.C. § 1905), which also protects confidential pricing data vendors submit to CMS during the bidding process or in their periodic disclosures of net acquisition costs. Unless vendors and manufacturers have clear assurances that their proprietary pricing information will be appropriately protected, their ability to negotiate discount arrangements that benefit Medicare could be impaired.

E. Ensuring Public Input and Transparency

PhRMA appreciates CMS's efforts to work with CAP stakeholders in developing the program, and we believe the decision to accelerate issuance of the final rule and postpone implementation of CAP in the interim is a prudent measure that will reduce phase-in difficulties and enhance the program's effectiveness. We hope that there will be ongoing opportunities for stakeholder input regarding the program. Such an approach will ensure the transparency needed to maximize physician and vendor participation and facilitate Medicare beneficiaries' access to appropriate medications.

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[52] 70 Fed. Reg. at 39092.

[53] 70 Fed. Reg. at 10765.

[54] See SSA § 1874B(a)(1)(C), (c)(5) (stating, respectively, that "the Secretary may waive . . . provisions of the Federal Acquisition Regulation . . . other than provisions relating to confidentiality of information," and that the confidentiality provisions of SSA § 1927(b)(3)(D) "shall apply to periods during which a bid is submitted with respect to a competitively biddable drug or biological").

F. Other Issues

PhRMA respectfully requests that CMS confirm as part of the CAP final rule that manufacturers that contract with CAP vendors to supply their products directly to physicians on the vendor's behalf are not "subcontractors" of the CAP vendors with respect to the CAP contracts between the vendors and CMS. In addition, CMS should state explicitly that CAP does not interfere with contractual obligations between manufacturers and distributors of their products.

* * *

PhRMA hopes that these comments will be useful in crafting the CAP final rule and in implementing the program. We look forward to further dialogue on these issues and trust that CMS will not hesitate to contact us with any questions, comments, or requests for additional information.

Sincerely,

Diane E. Bieri
Acting General Counsel, Compliance Officer, and Vice President

Richard I. Smith
Senior Vice President for Policy, Research, and Strategic Planning

Submitter : **Ms. Katherine Yang** **Date: 09/06/2005**

Organization : **Pfizer Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

Pfizer Inc. submits the attached general comments.

CMS-1325-IFC-173-Attach-1.DOC

CMS-1325-IFC-173-Attach-2.DOC

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Katherine L. Yang
Senior Corporate Counsel, US Pharmaceuticals

September 6, 2005

Submitted Electronically

Mark McClellan, M.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
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Washington, D.C. 20201

Re: CMS-1325-IFC (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B)

Dear Dr. McClellan:

Pfizer Inc. appreciates this opportunity to comment on the interim final rule (with comment period) to implement a competitive acquisition program ("CAP") for certain Medicare Part B drugs not paid on a cost or prospective payment system basis ("Interim Final CAP Rule")[1]. Pfizer is a research-based, global pharmaceutical company dedicated to the discovery and development of innovative medicines and treatments that improve the quality of life of people around the world. Pfizer markets a variety of Medicare Part B covered drugs including chemotherapeutic and ophthalmic agents as well as other physician administered therapies.

[1] Published at vol. 70 Federal Register, p. 39022 et seq. (July 6, 2005).

As stated in our comments to the proposed CAP rule, we believe that a well designed competitive acquisition program holds great promise for physicians, patients and the Medicare program. At the same time, we recognize the significant operational and programmatic challenges that CAP presents. Accordingly, we commend CMS for proceeding with an interim final rule to allow for further public input and for instituting a more reasonable timeline for implementing the CAP.

As CMS finalizes the CAP regulations, we believe it is critical that the resolution of the operational issues not compromise the overall objective of *improving*, while modernizing, the Medicare program. To that end, our comments focus specifically on two critical principles that should guide the CAP reform:

- **Medicare beneficiary access to Part B therapies must not be sacrificed to implement CAP**.

- **To ensure optimal participation, CAP should represent a net benefit for physicians**—honor the physician's judgment regarding the most appropriate therapy, minimize additional administrative burdens, offer a reliable alternative means for obtaining Part B drugs.

Certain clarifications made in the Interim Final CAP Rule further these principles and we commend CMS for its efforts to date toward ensuring a successful competitive acquisition program. Those clarifications, as noted below, should be preserved in the final rule. Additional recommendations that we believe should be incorporated in the final rule are set forth below. Pfizer specific comments are meant to complement, and should be read in conjunction with, the comments to the Proposed CAP Rule submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA"), which we broadly endorse.

A. Patient Access to Part B Therapies Must be Protected

Medicare patients will have no direct say in whether their Part B drugs will be acquired through a CAP vendor. That decision will rest solely with the physician and will apply to all of their Medicare patients.

1. No Formularies. Under the circumstances, and given that the impact of a successful CAP model is likely to be neutral for individual beneficiaries, we stated in our comments to the Proposed CAP Rule that it would be highly inequitable to build a CAP model that is premised on allowing vendors to capture additional savings or revenue by restricting beneficiary access to drugs, for example, by permitting the use of formularies or the implementation of other non-clinical incentives to prescribe one agent over another.

In the Interim Final CAP Rule, CMS agreed—

- By rejecting the recommendation made by other commenters that formularies be permitted—definitively stating that "the statute does not contemplate a formulary."[2]
- By reiterating the statutory requirement that potential cap vendors must offer at least one drug in each HCPCS code included in a category of biddable drugs.[3]

In light of the unambiguous statutory provision against formularies, this point should be reiterated in the final regulations.

2. No Financial or Clinical Pre-Screenings by Vendors. To protect patient privacy and to prevent vendors from conducting financial or clinical pre-screenings of patients, which could adversely impact a specific beneficiary's access to the prescribed therapy, in our prior comments we urged CMS to permit vendors to obtain only such patient information as is necessary to (i) verify Part B enrollment; and (ii) permit the vendor to submit a clean claim for the drug to the designated carrier and to any other insurer for the beneficiary.

In the Interim Final CAP Rule, CMS clarified that—

- The vendor cannot refuse to supply CAP drugs to physicians based on the vendor's own coverage analysis.[4]
- The CAP rule does not change CMS' policy regarding the carrier's authority to make coverage decisions regarding Part B drugs.[5]
- With regard to coverage of off-label uses, "[d]eterminations of medical necessity are made by Medicare carriers and are not made by suppliers, such as the approved CAP vendor."[6]

Nevertheless, the Interim Final CAP Rule still requires ordering physicians to supply the vendor with other patient information including ICD-9, and patient height and weight. CMS states that such information is necessary so that vendors will be in a position to seek an Advance Beneficiary Notice ("ABN") in case coverage for the drug is denied and to directly appeal the denial of a drug claim.[7]

We believe the better course, which protects the patient's privacy and prevents the vendor from engaging in clinical or financial pre-screening, is to permit the vendor to obtain additional information, such as the ICD-9, if the carrier denies coverage for the

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[2] 70 Fed. Reg, at 39034.
[3] Id.
[4] Id. at 39039
[5] Id. at 39038.
[6] Id.
[7] 70 Fed. Reg. at 39040-41.

drug for clinical reasons, but not at the time the drug is ordered by the physician. This will permit the vendor to fully exercise its right to appeal the coverage denial. With regard to the ABN, the vendor can notify its participating physicians to seek the ABN under certain circumstances, where coverage may be in question, without requiring specific information on individual patients.

B. CAP Must Represent a Better Alternative for More Physicians

To ensure wide participation by physicians, the CAP must be a better alternative for more physicians. The Interim Final CAP Rule avoids creating disincentives to participate by supporting the authority of the physician's clinical judgment in providing the "furnish as written" exception and by its definition of "emergency situation", which supports a workable "resupply" mechanism for drugs that are needed for a patient immediately. Those provisions should be reiterated and strengthened in the final rule.

We also endorse CMS' decision not to limit the CAP initially to a specific specialty such as oncology. By including a more comprehensive list of competitively biddable drugs, more physicians can participate in the CAP—not only oncologists, but also specialists, such as ophthalmologists, who may not use many Part B drugs, but have similar incentives to seek an alternative to the current "buy and bill" model for physician administered drugs. We believe that even more physicians would find CAP an appealing alternative if the regulations encouraged vendors to offer new drugs without the risk of delayed payment and to supply low-volume drugs, which need not be included in the vendor's formal bid.

1. Vendors Should be Encouraged to Offer New Drugs

The Interim Final CAP Rule permits vendors to offer new drugs, but it remains unclear when, and at what payment rate, the vendors will be reimbursed. To make the CAP a more comprehensive option for physicians, CMS should clarify in the final rule that vendors may provide new drugs to their participating physicians, so long as the drug is one for which a HCPCS code must be established, and they will be reimbursed the same amount as under the ASP system, i.e., 106% of WAC until an ASP-based payment amount is established. Clarifying the amount and timing of payment for new drugs may provide sufficient incentive for vendors to offer them to their participating physicians. The Medicare programs itself will not incur extra costs as the payment amount is no more than would be paid under the default ASP system.

2. Vendors Should be Permitted to Supply Low-Volume Drugs.

Under the Interim Final CAP Rule, vendors will not bid on or offer certain low volume drugs for which CMS feels it does not have adequate data to establish a relative weight for the bidding process. We agree with CMS that such drugs should not be included in the vendor bids, but would strongly urge CMS to permit approved vendors to offer such physician administered drugs and bill the program for the same ASP-based amount the physician would have been entitled to bill. Again, the Medicare program

would not incur extra costs as the payment amount would be the same as under the ASP-based system.

The objective of both the recommendation regarding new drugs and low-volume drugs is to make CAP more appealing as a comprehensive alternative to the buy-and-bill system. Accordingly, CMS should make it clear in the final rule that a physician electing CAP still has the option of acquiring such drugs outside CAP.

* * * *

Again, we thank you for this opportunity to submit our recommendations on how to ensure the successful implementation of the CAP program. We look forward to working with CMS and other CAP stakeholders in the coming months to build an efficient alternative system that can enhance the delivery of appropriate care for beneficiaries and provide physicians with added flexibility with respect to their Part B services.

Respectfully submitted,

/s/

Katherine L. Yang
Senior Corporate Counsel, US Pharmaceuticals
Pfizer Inc.

Submitter : **Ms. Susan Fox** **Date: 09/06/2005**

Organization : **CaremarkRx**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Background

Background

see attachment

GENERAL

GENERAL

See attachment

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

see attachment

CMS-1325-IFC-174-Attach-1.DOC

CMS-1325-IFC-174-Attach-2.DOC

CMS-1325-IFC-174-Attach-3.DOC

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September 6, 2005

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
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Re: Comments on Interim Final Rule for the Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B, **CMS-1325-IFC** (published at 70 *Federal Register* 39022, July 6, 2005)

Dear Administrator McClellan:

Caremark appreciates the opportunity to provide comments on the Interim Final Rule (Rule) to implement the Competitive Acquisition Program (CAP) pursuant to Section 303(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA or, the Act).

Caremark Rx, Inc. (Caremark) is a leading pharmacy benefit management (PBM) company, providing through its affiliates comprehensive drug benefit services to over 2,000 health plan sponsors and their plan participants throughout the U.S. Caremark's clients include employers, health plans, managed care organizations, insurance companies, unions, government agencies, the Federal Employees Health Benefits Program (FEHBP), CalPERS, and other funded benefit plans. Caremark operates a national retail pharmacy network with over 60,000 participating pharmacies, seven mail-service pharmacies, the industry's only FDA-regulated repackaging plant, and 21JCAHO-accredited specialty pharmacies for the delivery of advanced medications to individuals with chronic or genetic diseases and disorders. Caremark processes over 550 million prescriptions annually.

Caremark is one of the nation's largest providers of specialty pharmacy products, offering clinically appropriate services to the community for more than 26 years. Based on our extensive experience in specialty pharmacy, we are pleased to provide our comments regarding the Rule. We thank CMS for taking the time to analyze and respond to many of the issues that we raised in our initial comment letter to the Proposed Rule. As you will see below, in some cases we have raised the same issues that were discussed in our initial comment letter. We have done so where the CMS may not have responded to the issue or where the CMS response may not have alleviated all of our concerns and, in those cases, we provide additional insight into why we believe that these issues should be reconsidered.

We have organized our comments in two parts. The first part discusses our key concerns, which we believe must be addressed in order for the CAP to be economically viable. Unless these issues are addressed, we believe that many potential CAP vendors will not be able to participate in the program. The second part discusses our remaining comments in the order the issues are discussed in the preamble to the Rule.

I. Key Issues

1. Unused Product

CMS states that unused CAP drugs will come in three forms: (i) unopened vial/packages; (ii) an opened vial, and (iii) drug in a syringe, IV bag or other device or container used for drug administration. While CMS states that CAP vendors must make efforts to ship drugs in units that match the beneficiary's dosing requirements and the HCPCS billing amount as closely as practical, CMS recognizes that it is virtually impossible for CAP vendors to ship the exact amount of the drug administered. This is because the amount of the drug administered will depend on the condition, body surface area, and weight of the patient, and the amount ordered and delivered will be dependent on the packaging in which a particular product is available. Thus, no matter how careful the CAP vendor or how closely matched the order to the patient's needs, unused drugs are a necessary and inevitable part of drug delivery Since CAP vendors will be competing to provide drugs at the lowest price possible, they will not be able to build in any margin for unused drugs. As a result, many potential CAP vendors will not find it economically viable to participate.

CMS states that it does not have the authority to address this problem because Section 1847B(c)(6) prohibits payment for the "administration... wastage, spillage or spoilage" of the drug. " However, the same section also authorizes payment for "all costs related to the delivery of the drug or biological to the selecting physician," as well as "costs of dispensing (including shipping) of such drug or biological and management fees." We do not believe that unused drugs constitute "wastage, spillage or spoilage." On the contrary, partial amounts remaining in opened vials, or in containers used for drug administration, are a necessary and unavoidable cost of delivering and dispensing the drug, since without incurring this usage it would not be possible to administer the drug to the beneficiary. This is in contrast to drug product that is spilled or spoiled en route to the physician, or wasted by opening extra vials and using none of the contents.

Despite CMS' response in the interim final rule, we believe that CMS has the statutory authority to allow CAP vendors to be reimbursed for unused product in a manner similar to the methodology used when reimbursing physicians today. Medicare currently covers the amount of the drug that is reasonable and necessary for the patient's condition. If a physician must discard the remainder of unused product, the Medicare program will cover an amount of the discarded drug along with the amount administered. This type of policy would prove consistent with how physicians are reimbursed today and would not discriminate based on whether

that physician participates in the CAP program or not. If CMS does not consider changing this policy, potential CAP vendors may not consider bidding and it could impede the success of CAP implementation.

In the case of drug product remaining in partially used vials or packages, these should be included as an integral part of the cost of the product paid to the CAP vendor, since the drug could not be administered without opening the vial or package. In the case of drugs spilled or spoiled or lost en route, the CAP vendor should bear these costs, since the product is still owned by it until delivered to the physician's office. Finally, in the case of totally unused vials or packages, the physician should take ownership of these (whether he/she has opened them or not). This is not only consistent with the statute, but a fair allocation of the costs and risks involved, and the best way to appropriately align incentives to reduce the amount of unused product. CAP vendors have control over the method of shipment, and so should bear the risk of damage or loss during this process, while physicians have control over the amount ordered, and so can limit their orders to the closest package needed. In addition, for totally unused vials or packages, the physician can always keep these in inventory for later use, since they have full control over the product's storage. Returning unused product to the CAP vendor is generally not a viable option, not only because of legal limitations on this practice, but also because, as a safety issue, once the product is out of the control of the CAP vendor, it cannot be certain of its the proper handling and storage.

Recommendation: CAP vendors should be paid for the full amount of the drug ordered and delivered to the physician. CMS should use the same payment methodology in CAP that is used when reimbursing Medicare physicians for appropriate amounts of unused product today. Unused amounts in partially used vials or packages should be paid as part of the CAP. Totally unopened or unused vials or packages should be purchased by physicians for their own inventory.

2. Calculation of ASP

Manufacturers have many different classes of trade in selling their products and determining drug prices. Generally, they limit their very lowest prices to physicians, and charge higher prices to wholesalers and retailers. Oftentimes, the prices charged to physicians and other favored classes of trade are substantially below those charged to others purchasers. Thus, if these prices are included in the calculation of ASP, for many, (if not most) CAP vendors, ASP will be below their acquisition costs, making it economically infeasible for them to participate in the CAP. Since physicians and these other favored classes of trade cannot participate in the CAP, there is no reason to include the prices they would pay manufacturers in determining the CAP vendors' charges. This is also consistent with CMS' stated reason for limiting CAP prices to ASP plus 106 percent, namely, that it is "reasonable to expect that potential vendors will be able to realize sufficient efficiency in obtaining and delivering Part B drugs... to produce a composite bid at

or below this threshold." This holds true only as long as drug prices that are unavailable to CAP vendors, no matter how efficient they are, are excluded.

Similarly, for any physician that is reimbursed outside the CAP (i.e. under the ASP methodology), we believe that their reimbursement should be based on the manufacturer's ASP for the class of trade for which the physician is eligible. This will result in a much more accurate matching of federal reimbursement to the actual costs incurred by the physician, which is the primary objective of the ASP methodology. In addition, by eliminating opportunities to profit at the expense of the federal government under the ASP methodology, it will eliminate an economic incentive for physicians not to choose the CAP. This will strengthen the CAP by putting it on a more equal footing with the ASP methodology, so that physicians choose one option or the other for reasons other than financial gain. The administrative benefits of the CAP will not be outweighed by financial considerations, and this will result in more physicians choosing the CAP. The increased volumes will, in turn, make the CAP more attractive to potential CAP vendors, increasing competition and strengthening the program as a whole.

Recommendation: In calculating the average sales price (ASP) for purposes of limiting CAP bidding and prices to 106 percent of the weighted ASP, only those manufacturer classes of trade for which CAP vendors are eligible should be included. Similarly, in calculating ASP for purposes of reimbursing physicians under the ASP methodology, only the class of trade for which the physician is eligible should be included.

II. Other Issues

1. Phase-In of the CAP

CMS recognizes that the schedule for implementing the CAP is ambitious, and acknowledged the suggestion of many commenters that CMS proceed with a limited trial period or phased-in approach. As evidenced by the suspension of the CAP bidding process, the many unresolved concerns about the viability of the CAP, coupled with the radical change that the CAP represents from the current reimbursement system, is more reason than ever for CMS to proceed cautiously with a more limited program. Starting with drugs commonly prescribed by one of the specialties other than oncology (for example, neurology, ophthalmology, or rheumatology) will provide CMS with the opportunity to test all aspects of the program, for CAP vendors and physicians to determine whether participation is viable for them, and for all parties to identify and address any operational or other issues before implementing the CAP on a full-scale basis. While this does potentially delay the anticipated benefits of the CAP, these benefits assume a properly working program, which is what the more limited phase-in will assure. A more limited phase-in will also encourage more entities to consider bidding as a CAP vendor, since their risks with an untested program will be limited. We believe, given our experience with specialty pharmacy distribution, that it would be

administratively difficult for a vendor to enter this market without an implementation phase-in. While we understand that limiting the program to oncology drugs does represent a phase-in, we are concerned that starting with the largest group of Part B drugs will not mitigate the risks associated with proceeding with the CAP before the many difficult financial and operational issues are satisfactorily resolved.

Recommendation: The CAP should be phased-in more gradually, starting with specialties that use fewer Part B drugs, rather than with oncology, which is by far the largest category of Part B drugs.

2. **"Furnished as written" situations**

While CMS acknowledges the concern that the "furnished as written" option may be "overused and subject to gaming," it nevertheless implements this option as described in the proposed rule without directly addressing this concern. CMS simply states that this option is intended to be used "only occasionally in limited circumstances" where the patient's medical condition requires it, and that documentation of the medical condition will be kept in the patient's record. While this may be the case, there is still no reason not to allow the CAP vendor the first opportunity to fill the order through the CAP system or otherwise at the ASP price. If the CAP vendor declines, the physician should then be able to obtain the drug under the ASP system. By requiring physicians to give the CAP vendor this right to fill the order, CMS will reduce the likelihood of physicians attempting to use the "furnished as written" option to obtain drugs outside the CAP when it is financially advantageous for them to do so. It will strengthen the CAP by limiting the orders filled outside the CAP to only those that cannot be filled within the CAP, and will also make CMS less dependent on the post payment review by the carrier of use of "furnished as written" option, which is insufficient, on its own, to limit or detect abuses.

Recommendation: For "furnished as written" situations, the CAP vendor should be given the first opportunity to fill the order.

3. **Timely Filing of Claims by Physicians**

CMS acknowledges that "the vendor's payment depends on the physician's administration of the drug that the vendor has already purchased and provided" and that "it is reasonable for the vendor to expect to be paid timely." In addition, CMS points out that, based on physician's current filing practices, the requirement for physicians to file claims within 14 days of administering the drug "will not be problematic for most physicians." Nevertheless, the only recourse provided to vendors when physicians do not file the claim on a timely basis is, after "repeated non-compliance" by the physician, to "ask the designated carrier to assist in working with the physician to resolve the situation."

A request for assistance has no legal weight and is not meaningful recourse. Failure to provide meaningful recourse for vendors or disincentives for non-compliance by physicians will simply weaken the CAP, since if physicians fail to file their claims in a timely manner – for whatever reason – the CAP fails to function. An effective incentive for physicians to file, and appropriate recourse for CAP vendors if they do not, is to deem the physician to have purchased the drug from the vendor at the CAP price. CAP vendors cannot and should not be expected to operate differently from every other provider or distributor of a product, by allowing the recipient to take possession of the product without any financial responsibility to pay for it or – the equivalent in the CAP – to file the drug administration claim for it. Since the physician ordered the product and already holds the product, it is makes sense that that the physician should either administer the drug as ordered and file the claim, or otherwise takes ownership of it and uses it as he or she wishes.

To enable vendors to bill physicians after the 14 day filing period has expired, we suggest that a process be established by CMS that will notify CAP vendors when claims have not been filed by physicians within the specified time period, so that the CAP vendor may take appropriate steps to bill the physician accordingly.

Recommendation: Physicians should be deemed to have purchased the drugs at the CAP price if the drug administration claim is not filed within 14 days of the anticipated date of service.

4. Obtaining Advanced Beneficiary Notices

We appreciate CMS' recognition that the CAP vendor has the right to obtain an Advanced Beneficiary Notice (ABN) when it disagrees with the physician about coverage. However, CMS states that "in the event the vendor is not successful in collecting an ABN from the beneficiary, and the physician refuses to change the order, the vendor will still be required to provide the drug to the physician under its contract with us." We don't believe this is appropriate, since it is the CAP vendor, not the physician, who bears the cost of the drugs. The right to condition service on the furnishing of an ABN is a basic protection that is afforded all Medicare providers, and CAP vendors should be situated no differently simply because they do not interact directly with the beneficiary until after the drug is already administered, and so are not in a position to deny treatment or ensure that their interests are protected.

It is not adequate protection for CAP vendors, if payment is denied, to "ask the designated carrier for assistance under the dispute resolution process," since there is no legal obligation on any party to pay the CAP vendor in that situation.

Because CAP vendors will not have any control over what drug the physician orders, or for what medical conditions and circumstances, they will be relying on physicians to make these determinations appropriately. In addition, the CAP vendor will have no direct contact with the beneficiary, and so no opportunity

before the drug is administered to obtain an ABN when necessary. Therefore, in those cases where a physician decides it is appropriate to obtain an ABN for his/her own services in administering the drug in question, the physician should be required to have a copy on file for the CAP vendor. In addition, in those situations where the CAP vendor and physician disagree about a drug's coverage, the physician should be required to obtain an ABN for the CAP vendor if requested by the CAP vendor to do so.

If the physician refuses or fails to obtain the ABN from the beneficiary, the CAP vendor should be allowed to deny service. Alternately, if the drug has already been delivered before the CAP vendor learns that the physician did not obtain the ABN, the physician should be deemed to have purchased the drug from the CAP vendor if the claim is subsequently denied by CMS.

Recommendation: To protect the vendor from coverage denials, physicians should be required to obtain a signed advance beneficiary notice (ABN) from the beneficiary where (i) the physician obtains an ABN for his/her own services in administering the drug in question, and (ii) the CAP vendor requests an ABN based on the CAP vendor's determination that Medicare coverage is uncertain.

5. Beneficiary Cost Sharing

We appreciate CMS clarifying that the CAP vendor will not be required to continue providing CAP drugs for beneficiaries who do not pay their deductible or coinsurance. This is a critical protection, without which the program would not be economically feasible for many, if not most, CAP vendors. We do, however, have a couple of concerns with the conditions imposed on CAP vendors in this situation.

First, CMS requires that, in addition to informing beneficiaries at the time of billing of the types of cost-sharing assistance that may generally be available, the CAP vendor must provide a more specific referral to a bona fide and independent charitable organization if the beneficiary requests this within 45 days after the CAP vendor sends the bill, and then wait a further 15 days after sending this information to receive payment, and only then, if payment is not received, may the CAP vendor refuse to make additional shipments for that beneficiary. This requires the CAP vendor to wait at least 60 days before it may take action, and during which additional products (some of which could be very costly) may be sent out for that beneficiary. In addition, since the CAP vendor may only bill the beneficiary after the drug is administered and the drug claim filed by the physician and the claim matched and verified and paid by the designated carrier, the initial bill to the beneficiary may easily only be sent a month or more after the drug is delivered to the physician, so that CAP vendors will have to wait until approximately 3 months after providing the drug to receive payment or be able to take action to limit their losses. In some instances this could exceed the duration of the patient's entire

course of treatment, which could represents a substantial outlay of very expensive drugs by the CAP vendor.

A much more efficient process, and one that will allow for quicker resolution, is to have the physician provide information on cost-sharing assistance, including referrals to a bona fide charity if the beneficiary requests this, at the time the drug is administered. If the beneficiary is interested in or needs financial assistance for the drug cost sharing, he/she more than likely needs it for the physician's services as well, and so the physician is likely already going to be providing this information to the beneficiary. In addition, this interaction occurs much sooner than the date the CAP vendor bills for the services, and can be completed there and then in the doctor's office. While the physician may not know the exact cost of the drug, this specificity is not necessary for purposes of the beneficiary deciding if he/she needs financial help and, in any event, the physician should certainly be able to provide an approximate cost range for this purpose.

Second, we believe that CMS does have the authority to recognize and take into account bad debts suffered by CAP vendors, either in the bidding or payment process. The fact that this is addressed for other specific provider types by statute and regulation lends support, rather than the opposite, for CMS taking it into account here. Unlike those other providers, where specific statutory and regulatory provisions may have been required, the CAP is unique in that the MMA provides broad authority for CMS to implement the CAP, and determine what is appropriately taken into account as part of the drug costs for purposes of bidding and payment. It is standard accounting and business practice to treat bad debt as a part of the cost of delivering a product or service, and the same principle should apply here. Thus, as long as the CAP vendor has put forth "reasonable" collection efforts as specified in 42 CFR 413.80, the CAP vendor should be allowed to count bad debt as an allowable cost to be reimbursed by CMS.

Recommendation: CAP vendors must be given the same rights regarding collection of cost sharing obligations from beneficiaries, and the same rights in the event beneficiaries do not meet these obligations, as other Medicare Part B providers have currently, namely, to have bad debts be recognized as a cost of doing business and reimbursed by CMS through the CAP.

6. CAP Vendor – Physician Relationship

Since CAP vendors will be entirely dependent on physicians' actions in filing their drug administration claims and otherwise meeting their CAP obligations, CAP vendors must be allowed the right to decline to work with a physician who (i) has previously failed to pay for drugs on a timely basis, or (ii) materially breaches his/her contractual obligations to the CAP vendor or his/her CAP participation agreement with CMS, (iii) acts in a manner that obstructs the purpose or intent of the CAP or otherwise hinders it effectiveness, or (iv) otherwise acts in bad faith. While CMS repeatedly acknowledges how CAP vendors will have to rely on

physicians for various purposes, including filing their claims on a timely basis, cooperating with the CAP vendor appealing a denial, assisting in obtaining beneficiary information and, where necessary, ABN, CMS nevertheless continues to maintain that as long as a physician is not currently suspended, he or she may select any CAP vendor he/she wishes, including a CAP vendor that might have generated a suspension request. Given the critical reliance of CAP vendors on physicians' compliance – in many cases without any legal recourse available to the CAP vendor in the event of the physician's noncompliance – CAP vendors should have the right not to work with a physician if it has a reasonable basis for concern as specified in items (i)-(iv) above. This is necessary because the CAP vendor will be totally dependent on the actions of the physician in fulfilling his/her CAP obligations to receive reimbursement from CMS. It is also especially important for the CAP vendor to have some recourse when it will potentially be selling drug products to the physician, and thus, potentially be owed significant amounts by a physician in certain situations contemplated in these comments.

Recommendation: Drug CAP vendors should be allowed to decline the selection by a particular physician or terminate an existing relationship with a physician for good cause.

7. **Non-administered Drugs**

Once a CAP vendor has delivered a drug product to the physician, the CAP vendor has no control over storage or safekeeping of that product. Therefore, for product integrity and safety reasons, a CAP vendor cannot accept back into inventory a drug where possession of that drug has left the control of the CAP vendor. Such drugs would simply have to be discarded, resulting in significant loss and wastage. Since the ordering of the drug is the physician's decision, and once delivered, the drug is in the control and safekeeping of the physician, the physician should take responsibility for the drug. The physician may either administer the drug as anticipated and submit the claim within 14 days of the anticipated date or service, or if the physician chooses not to administer the drug within this timeframe for any reason, he/she will be deemed to have purchased the drug into his/her inventory at the CAP price.

Recommendation: If a physician decides for any reason not to administer an ordered drug, the physician should be deemed to have purchased the drug for his/her own inventory and should not be permitted to return it.

8. **Restricting Physicians to One Vendor**

We understand that initially there will be only one drug category under the CAP. However, CMS state that in the future there will be more than one category, and that physicians will be able to choose a CAP vendor for each category. Consistent with our position that drug categories should be defined broadly, we believe that each physician should select a single CAP vendor, and obtain all his or her CAP

drugs through that vendor. This will make most sense if the drug categories are broadly defined (e.g. including all drugs typically prescribed by a particular specialty), since it will be administratively simpler for physicians and CAP vendors to deal with one CAP vendor relationship per physician, and will obviate the need for the physician to seek another CAP vendor in order to obtain other drugs not offered by the first CAP vendor. By requiring CAP vendors to offer a full menu of drugs and physicians to choose a single CAP vendor, CMS will lessen the opportunities for CAP vendors and physicians to pick and choose between more and less financially advantageous drugs. This will improve the integrity and efficiency that the CAP potentially offers. Physicians will not need to select and interact with more than one CAP vendor, and each CAP vendor will similarly establish a relationship with, and support the needs of its physicians. It will also give CAP vendors greater leverage in negotiating with manufacturers for better prices. To the extent that a particular drug is not offered by a CAP vendor because of an exclusive manufacturer arrangement, this drug would be obtainable by the physician outside the CAP through the ASP methodology. It would be unfair to include such a drug under the CAP when most CAP vendors would not have the means to offer it. Moreover, it would provide an incentive for the manufacturer to reconsider the exclusive distribution relationship if it would like the drug to be available through the CAP. It is anticipated that this would be a narrow exception for a very limited number of products, particularly as CAP vendors become an increasingly important purchasing group for manufacturers.

Recommendation: When a physician selects a CAP vendor, that selection should apply to all drug categories provided by that CAP vendor.

9. Clinical Aspects of the CAP

While many, if not most, states will already require a pharmacy license, it should be an explicit qualification for a bidding entity under the CAP. CAP vendors should comply with OBRA' 90 requirements for pharmacies, including drug safety screening, and patient counseling by a pharmacist. This is important in that the role of the CAP vendor extends well beyond that of a traditional wholesaler or distributor, and more closely resembles that of a specialty pharmacy provider. Appropriate clinical expertise and clinical safety edits by CAP vendors will contribute significantly to the success and effectiveness of the CAP, by improving patient care and clinical outcomes and should be required.

Additional specific clinical services that should be minimal CAP offerings include: (i) providing access to a qualified pharmacist on a 24/7/365 basis to respond to patient and physician inquiries or emergencies, and (ii) the ability to track and recall specific drug products by NDC code and by lot number, to ensure timely and effective identification of patients who have received a particular lot of a drug that has been subject to a drug recall.

In implementing the CAP, CMS has a unique opportunity not merely to change the distribution channel for Part B drugs to reduce costs, but to improve drug safety and reduce medical errors in the Part B program. This is especially relevant as CMS prepares to implement the Part D program, which is likely to result in many more individuals taking outpatient prescription drugs, and so bring the issue of drug safety and adverse drug interactions to the forefront. As drug therapy has become a core element of health care services for the elderly, the issues of polypharmacy and appropriate drug utilization can no longer be overlooked. Thus, under Part D, concurrent and retrospective drug utilization review (DUR) will be required to reduce medication errors and adverse drug reactions. Beneficiaries on drug therapy paid for under Part B deserve no less, particularly as the Part D claims data will be available for DUR purposes.

Recommendation: At a minimum, CAP vendors should be required to be licensed pharmacies in good standing in each state in which they seek to operate, and the CAP should require CAP vendors to perform, and appropriately reimburse then for performing, basic clinical safety programs like DUR.

10. Electronic Prescribing

While only Part D plan sponsors are required to support and comply with the foundation e-prescribing standards by January 1, 2006 (and with the final e-prescribing standards when effective, but no later than January 1, 2009), beginning January 1, 2009, any provider using e-prescribing under the Part D program must do so according to the final e-prescribing standards. Given the benefits of e-prescribing including increased patient safety and improved efficiencies, we encourage CMS to consider regulations that would require CAP vendors to comply with the foundation and final e-prescribing standards as issued under the Medicare Part D program. This may encourage physicians who are considering adoption of e-prescribing under Part D to do so, since this would enable them to leverage e-prescribing in the context of Part B. The use of e-prescribing and compliance with e-prescribing standards under the CAP also help to increase the efficiency of the program, and will help promote broader adoption and expansion of e-prescribing generally. Finally, because most CAP vendors will be required to comply with certain technical requirements and thus will likely have a fairly rigorous technical infrastructure in place, it is unlikely that compliance with these e-prescribing standards will impose an undue hardship on them.

Recommendation: CAP vendors should be capable of accepting and submitting e-prescribing transactions in accordance with final e-prescribing standards.

11. Requirements for Group Practices

As CMS recognizes, the CAP is entirely dependent for its proper operation on physicians acting responsibly and complying with their CAP obligations. However, even if physicians technically meet their CAP obligations, there are potentially several ways in which the CAP could be used to create financial advantage. This is particularly the case because the CAP is structured on an individual physician basis, and is entirely voluntary. Since many physicians do not practice on an individual basis, but as part of a single or multi-specialty group practice, this raises the possibility that a group practice may channel different purchases through different physicians, thereby allowing the group to choose on a per drug basis whether to use the CAP process or the ASP methodology. To avoid this type of gaming, group practices (including any entities controlled by a group practice) should be required to choose as a group to participate in the CAP. As such, physicians that are part of the group practice should not be permitted to elect out of the CAP and bill separately for drugs covered under the CAP. While we understand that it may be difficult to know whether a particular physician is a part of a group practice that has elected to participate in the CAP, at the very least it should not be permissible for physicians at the same location as a group practice that has elected to participate in the CAP to bill for CAP-covered drugs otherwise than through the CAP.

Recommendation: Protections need to be established to prevent physicians groups from gaming the system by combining or channeling their drug acquisitions through the CAP or the ASP system as they choose.

Conclusion

Caremark is committed to working with CMS to ensure the success of the CAP and to its continued provision of high quality clinical patient care and physician support services. In order to maximize the opportunity for the success of the CAP, Caremark believes that CMS should:

- Ensure that CAP vendors are properly compensated by specifying that they be fully paid for the drugs they deliver as ordered.
- Ensure that CAP prices are fairly determined by including in ASP for this purpose only those manufacturer classes of trade for which CAP vendors are eligible.
- Implement the program prudently, in consideration of the operational challenges that program participants will face.
- Seek to establish a balanced business relationship between the CAP vendor and physicians that recognizes the interdependence of the parties and the unique economic reliance of the CAP vendor on the physician's actions.

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- Ensure the clinical integrity of the drug delivery system by requiring that CAP vendors be appropriately qualified as pharmacies providing critical clinical patient care, DUR and physician support services.

Finally, Caremark believes that it is important to recognize that, in order to be successful, the CAP must evolve. Clinical and financial management of complex products administered by physicians presents a unique challenge. The experience and insights gained during initial implementation will be very valuable, and should be considered together with experience in related health care areas, such as the management of pharmacy drug benefits, to see how the program could be enhanced to further align participant incentives to improve clinical and financial outcomes.

Caremark appreciates this opportunity to provide comments on the Interim Rule for the Competitive Acquisition of Part B Drugs and Biologics in the Medicare program. We look forward to working collaboratively with CMS in the future on this and other programs. If you have any questions, or would like discuss our comments please do not hesitate to contact Wendy Parker, Vice President Federal Relations for Caremark, at 202-772-3500.

Sincerely,

Susan E. Fox

Susan E. Fox
Vice President Public Policy

Submitter : **Dr. Amanullah Khan** **Date: 09/06/2005**

Organization : **Cancer Center Associates**

Category : **Federal Government**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-175-Attach-1.TXT

Cancer Center Associates

Amanullah Khan, M.D., Ph.D., Sultan A. Chowdhary, M.D., Mohammad Qasim, M.D., Akbar Rizvi, M.D.

5959 Harry Hines Blvd. Suite 620 Dallas, Tx 75235 214-905-1300	4510 Medical Center Dr. Suite 303 McKinney, Tx 75069 972-548-9690	2698 N Galloway Suite 103 Mesquite, Tx 75150 972-686-6646	2501 Scripture Suite 300 Denton, Tx 76201 940-380-8155	900 No Grand Ave Suite 100 Gainesville,Tx 75240 940-735-1414	605 N Maple Muenster, Tx 76252

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Mediciad Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Comments on the Interim File Rule Implementing the Competitive Acquisition Progtam (CAP) – CMS-1325-IFC

Dear Dr. McClellan:

Cancer Center Associates represents a small group of ongology physicians located in the Dallas, Texas area – real doctors treating real patients afflicted with the life threatening disease of cancer. The mainstay of cancer treatment is drug therapy. For practicing community oncologists, the acquisition of drugs needed to treat patients is critical to successful cancer treatment. We must not only have confidence that we are able to acquire the drugs that we trust, know , and need, but that they will be delivered at the right time and in the correct amount for our patients – including patients who struggle financially and may be unable to keep up with co-payments.

From the community oncologist's prespective, CAP represents a fundamental change in the drug acquisition process. Under CAP, in effect, while physicians will still be responsible for ordering drugs and treating patients, they will not be the primary customer. Rather, vendors chosen by and under contract to CMS will fill the physician's order, and vendors will be held accountable to quality standards and delivery time frames established and enforced by CMS.

Unlike the current system that is time-tested and patient safe, the CAP system is new and has never been attempted in community oncology, even on a pilot basis. Given that we are dealing with cancer treatment, oncologists must approach CAP with caution and will want assurances that adequate safeguards are in place should something go wrong. While we are mindful that CMS did make some changes in the Iterim Final Rule to address physicians concerns raised in response to the proposed rulemaking, major concerns remain. Overall, we believe that absent fundamental changes and piloting, most community practices will conclude that CAP is simply too risky for patients, too burdensome for physicians, and too costly to implement. There are several areas of concern; **increased administrative burden, access to medically necessary drugs, drug deliveries, order splitting, emergencies, impact on rural areas, physician "lock-in", vendors right to stop shipment for non-payment of co-pays, dispute resolution, extra costs introduced.**

The Cancer Center Associates

In the past year, community ongology practices have had to expend precious time and resources to absorb what were fundamental changes to Medicare reimbursement for cancer care. We are now being asked to consider a conceptual, entirely new, and untested system of delivering drug treatment. Particurlarly given the critical nature of cancer treatment, we are extremely concerned that this system is being introduced nationwide without any analyses and testing.

CAP runs the risk of creating undue treatment delays, patient inconvenience, and a system that significantly reduces the quality of cancer care in this country. Given there has been no testing and analyses, is it worth taking the risk with a very vulnerable group of Americans – seniors with cancer – by launching a national program? From an economic perspective, CAP introduces new costs to the Medicare Part B system including most notably the profit of the CAP vendor. CMS admits that CAP bids may well be over the ASP + 6% (the Medicare reimbursement rate) in 2006.

Thank you for the opportunity to comment on CAP and elcome the opportunity to work with CMS to reform Medicare reimbursement such that it retains the hallmarks of community oncology – quality, accessible, and affordable cancer care.

Sincerely,

Dr. Amanullah Khan
Dr. Sultan Chowhdary

Submitter : Dr. Sultan Chowdhary **Date:** 09/06/2005

Organization : Cancer Center Associates

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-176-Attach-1.TXT

CMS-1325-IFC-176-Attach-2.TXT

Cancer Center Associates

Amanullah Khan, M.D., Ph.D., Sultan A. Chowdhary, M.D., Mohammad Qasim, M.D., Akbar Rizvi, M.D.

5959 Harry Hines Blvd. Suite 620 Dallas, Tx 75235 214-905-1300	4510 Medical Center Dr. Suite 303 McKinney, Tx 75069 972-548-9690	2698 N Galloway Suite 103 Mesquite, Tx 75150 972-686-6646	2501 Scripture Suite 300 Denton, Tx 76201 940-380-8155	900 No Grand Ave Suite 100 Gainesville,Tx 75240 940-735-1414	605 N Maple Muenster, Tx 76252 940-735-1414

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Mediciad Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Comments on the Interim File Rule Implementing the Competitive Acquisition Progtam (CAP) – CMS-1325-IFC

Dear Dr. McClellan:

Cancer Center Associates represents a small group of ongology physicians located in the Dallas, Texas area – real doctors treating real patients afflicted with the life threatening disease of cancer. The mainstay of cancer treatment is drug therapy. For practicing community oncologists, the acquisition of drugs needed to treat patients is critical to successful cancer treatment. We must not only have confidence that we are able to acquire the drugs that we trust, know , and need, but that they will be delivered at the right time and in the correct amount for our patients – including patients who struggle financially and may be unable to keep up with co-payments.

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Unlike the current system that is time-tested and patient safe, the CAP system is new and has never been attempted in community oncology, even on a pilot basis. Given that we are dealing with cancer treatment, oncologists must approach CAP with caution and will want assurances that adequate safeguards are in place should something go wrong. While we are mindful that CMS did make some changes in the Iterim Final Rule to address physicians concerns raised in response to the proposed rulemaking, major concerns remain. Overall, we believe that absent fundamental changes and piloting, most community practices will conclude that CAP is simply too risky for patients, too burdensome for physicians, and too costly to implement. There are several areas of concern; **increased administrative burden, access to medically necessary drugs, drug deliveries, order splitting, emergencies, impact on rural areas, physician "lock-in", vendors right to stop shipment for non-payment of co-pays, dispute resolution, extra costs introduced.**

In the past year, community ongology practices have had to expend precious time and resources to absorb what were fundamental changes to Medicare reimbursement for cancer care. We are now being asked to consider a conceptual, entirely new, and untested system of delivering drug treatment. Particurlarly given the critical nature of cancer treatment, we are extremely concerned that this system is being introduced nationwide without any analyses and testing.

CAP runs the risk of creating undue treatment delays, patient inconvenience, and a system that significantly reduces the quality of cancer care in this country. Given there has been no testing and analyses, is it worth taking the risk with a very vulnerable group of Americans – seniors with cancer – by launching a national program? From an economic perspective, CAP introduces new costs to the Medicare Part B system including most notably the profit of the CAP vendor. CMS admits that CAP bids may well be over the ASP + 6% (the Medicare reimbursement rate) in 2006.

The Cancer Center Associates

Thank you for the opportunity to comment on CAP and elcome the opportunity to work with CMS to reform Medicare reimbursement such that it retains the hallmarks of community oncology – quality, accessible, and affordable cancer care.

Sincerely,

Dr. Amanullah Khan
Dr. Sultan Chowhdary

Submitter : Dr. Steven Tucker

Date: 09/06/2005

Organization : Medical Oncology Assoc. of So. Calif. (MOASC)

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1325-IFC-177-Attach-1.DOC

MEDICAL ONCOLOGY ASSOCIATION OF SOUTHERN CALIFORNIA, INC.

September 6, 2005

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

Re: Competitive Acquisition Program (CAP) File code CMS-1325-IFC

Dear Dr. McClellan:

We welcome the opportunity to comment on the rules for the Competitive Acquisition Program (CAP), published as an Interim Final Rule with comment in the July 6, 2005, Federal Register.

The Medical Oncology Association of Southern California (MOASC) is an advocate for, protects, and advances the interests of cancer patients and their treating physicians in providing effective and state of the art cancer care.

Upon review and discussions with major oncology organizations, MOASC supports the position as expressed by ASCO, COA and ACCC.

It is our belief that the CAP program will:

- **Increase administrative burden;**
  Some examples of this increase of administrative burden for a medical practice may be when the medical practice will need to: 1) to keep separate its inventory from the CAP program inventory, 2) need to identify and track which drugs are covered under the CAP program and which drugs will fall out of the CAP program coverage; 3) increase paperwork bureaucracy required for treatment changes to the vendor which will create time delay in receipt of drug by the medical practice and delivery to the patient.

- **Deny or hinder access to medically necessary drugs;**
  For example when a patient is unable to pay the co-pay of the drug to the distributor and therefore the distributor will not deliver the drug to the medical practice, the patient will not be able receive the recommended treatment. If patient experiences an increase in morbidity or early mortality due to the inconsistent administration of the therapy, who are the responsible parties to assign liability? Further, the physician is hindered from providing medicine from an alternative source as such would be Medicare fraud as presented by CAP program rules. CAP program allows for solvency of distributor and is not expected that the distributors will provide "free drug." Currently malpractice insurers would not provide coverage under this clinical scenario.

It is our belief that the CAP program will: (cont.)

- **Increase burden on cancer patients;** cancer patient and physicians will be at the mercy of the distributor's drug delivery system on routine basis and adequate description of emergency medicine scenarios remains unresolved.

- **Adversely impact rural and small clinics;** all clinics regardless of size and location will be required to create a bureaucratic infrastructure will clinical and financial oversight. The compensation of such expense is anticipated to be for smaller and rural clinics a greater cost than the creation of the system. Rural and small volume oncology clinics will be the hardest hit. The CAP program will indirectly force patients into large urban centers.

- **Restrict physician autonomy;** given the high degree of flux and fluidity of the oncology reimbursement system, practices that make erroneous assumptions about the CAP system and the business model are required to be "lock-in" annually.

The CAP program rules are not comprehensive enough to define what will happen in the above scenarios. Many more clinical and financial examples have been provided by national oncology leadership such as ASCO, COA, and ACCC.

The Medical Oncology Association of Southern California, Inc. (MOASC) suggests holding implementation of the program until a comprehensive advisory panel has reviewed all possible concerns with the relevant stake holders. Such a panel could aid and advise CMS in the successful implementation of the CAP program in the future. MOASC would be willing to participate in such a panel. As constructed, CAP runs the risk of creating undue treatment delays, patient inconvenience, and a system that significantly reduces the quality of cancer care in the United States.

We believe that the fallacies identified in this letter are widely known and enough concern that the CAP vendor bidding process was suspended by CMS in August 2005.

Again, thank you for the opportunity to provide our comments on this important proposal. We continue to look forward to working together to provide the best care to, not only Medicare beneficiaries in California but to patients with cancer in the United States.

Sincerely,

Steven J. Tucker
Steven J. Tucker, M.D.
President

Mariana S-B Lamb
Mariana S-B Lamb, M.S
Executive Director

Cary A. Presant
Cary A. Presant, M.D.
Chairman of the Board

Submitter : Dr. Benton Wheeler **Date:** 09/07/2005

Organization : West Clinic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I cannot sum it up better than the Community Oncology Alliance comments, a copy of which is attached. Not only is the CAP program untested and dangerous to cancer patients, unethical in its ability to deny potentially life saving treatments to cancer payments, but there is no way it will save money for Medicare. I can find no reason to implement it as is. It will not do what it was designed to do. Sincerely, Benton M. Wheeler

CMS-1325-IFC-178-Attach-1.PDF

Community Oncology Alliance

Dedicated to high quality, affordable, and accessible cancer care

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1790 Kirby Parkway, #101
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communityoncology.org

August 23, 2005

Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

On behalf of the Community Oncology Alliance (COA), I am writing to offer our support for your decision to suspend the proposed Competitive Acquisition Program (CAP) vendor bidding process as of August 3, 2005, to allow for a full review of comments to the CAP Interim Final Rule published in the Federal Register on July 6, 2005.

Per our most recent comments of July 27, 2005, and prior comments submitted to CMS on April 26, 2005, the proposed CAP represents a fundamental change in the drug acquisition process. In the absence of any piloting of the CAP, this conceptual, new cancer drug delivery system is simply too risky and onerous for patients, too burdensome for physicians, and too costly to implement.

COA's concerns regarding CMS' proposed design are briefly summarized as follows:

- **Vendors' right to stop cancer treatment for non-payment of co-pays** — The Interim Final Rule gives vendors the responsibility for collecting patient co-payments and allows them to unilaterally discontinue delivery of cancer drugs to oncology clinics for specific patients if a co-payment is unpaid or uncollected. Allowing a CAP vendor, which is not a medical professional and has no relationship to the patient, to effectively stop a patient's course of treatment for a life-threatening disease, is unethical and unconscionable.

- **Additional medical visits for patients** — The CAP will cause cancer patients to incur additional medical visits because initial drugs and therapy changes will have to be ordered from the CAP vendor. For a patient group under tremendous health and mental pressures, this is an onerous requirement.

- **Administrative burden for cancer clinics** — The CAP places new administrative burdens on community cancer clinics through an onerous claims process, new tracking requirements, and the need to maintain and manage two sets of inventories for CAP drugs and non-CAP drugs. These new burdens are not compensated by Medicare and will increase financial pressures on community cancer clinics, which are already facing declining reimbursement for services.

- **Access to medically necessary drugs** — In effect, CAP vendors, not oncologists, will control what drugs are available and when and how they will be delivered, depriving oncologists of the ability to provide and modify treatments as medically necessary.

- **Drug deliveries, order splitting, and emergencies** — Every day, cancer patients present with health status changes that can lead to unplanned and unanticipated changes in treatment. Yet, under the CAP, the rules governing when a physician can use CAP-acquired drugs to re-supply his or her inventory after an unplanned use or an emergency are overly restrictive. Restricting a physician's ability to use the CAP acquired drugs to resupply their own inventories will result in delayed treatments and increased healthcare costs.

- **Impact on rural clinics** — The Interim Final Rule prohibits physicians from transporting medications. This means that rural oncology clinics will have to add additional staff and additional storage capacity to accept, inspect, and inventory the CAP deliveries whenever the vendor's shipment arrives, greatly increasing the cost of providing treatment in rural areas.

- **Physician "lock-in"** — The Interim Final Rule makes clear that once a physician elects CAP, he or she will be locked into their agreement for one year. Physicians do not have the right to opt out of the program even if they are dissatisfied with the performance of the CAP vendor, find the operational/financial burdens of compliance with the program to be overwhelming to their practice, or, worse yet, find that the quality of cancer care they provide is adversely impacted by the actions of the CAP vendor. Given the impact on patient care, physicians must be able to terminate a CAP election agreement for cause at any time.

For the outlined reasons above, COA certainly supports the suspension of the CAP vendor bidding process. We strongly urge CMS to makes changes in the design of the CAP to address our concerns outlined above and in our prior comments. Most importantly, given the experimental nature of this untested program, we strongly recommend that prior to resuming the bidding process and rollout of the CAP on a nationwide basis, that CMS undertake a CAP pilot program.

Testing the CAP is essential to demonstrating the ability of the system to deliver cancer drugs to community oncology practices in a timely, safe, and cost-effective manner so that the quality of patient care is maintained. We are very concerned that with this suspension the emphasis will be on making the CAP a financially attractive business for CAP vendors and not a program designed to ensure the health and wellbeing of cancer patients.

The current physician-controlled, quality-assured cancer drug delivery system is time tested. Time and again we have seen quality problems arise when payers attempt to cut costs. Additionally, the tampering of the nation's drug supply, including cancer drugs, is a real problem and the likelihood of drug adulteration increases as the drug delivery system is complicated and as physicians are further removed from the quality control process, as is the case with the CAP as currently designed. We call your attention to issues brought to light in the book, *Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply.*[1]

We would welcome the opportunity to further discuss our complete comments on the CAP Interim Final Rule and would make ourselves available to meet with you at your convenience.

COA thanks you for your continued commitment to reform Medicare reimbursement and your support of community oncology.

Sincerely,

Leonard Kalman, M.D.

Dr. Leonard Kalman
President

[1] Katherine Eban, Harcourt, Inc., 2005

Submitter : Mrs. Ann Berkey **Date:** 09/07/2005

Organization : McKesson Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-179-Attach-1.DOC

McKesson Corporation
One Post Street
San Francisco, CA 94104

Ann Richardson Berkey
Vice President
Public Affairs

McKESSON

September 6, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1325-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Via Electronic Submission

Re: Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B [CMS-1325-IFC] 70 Fed.Reg. 39022

Dear Dr. McClellan:

On behalf of McKesson Corporation (hereinafter "McKesson"), we are pleased to provide our comments in response to the CMS interim final rule to implement a Competitive Acquisition Program (CAP) for certain Medicare Part B medications under Title III of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (hereinafter "MMA").

For over 170 years, McKesson has led the industry in the delivery of medicines and health care products to drug stores. Today, a Fortune 15 corporation, we deliver vital medicines, medical supplies, and health information technology solutions that touch the lives of more than 100 million patients each day in health care settings that include over 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities, 700 home care agencies, and 25,000 retail pharmacies. McKesson also supplies pharmaceuticals to the entire Veterans Affairs system, as well as to a significant number of Department of Defense and other government facilities. In addition, we repackage over 1.5 billion doses of drugs annually and provide analytical testing services in support of these operations.

As the largest pharmaceutical supply management and health information technology company in the world, we also have more than a decade of experience providing specialty pharmaceutical services for providers and patients with chronic conditions, including more than 60 million members of managed care plans. These high-cost, often injectable bio-pharmaceutical drugs require special handling and storage, as well as complex shipping and distribution processes to ensure product integrity. The services associated with such complex distribution processes expand access to necessary

medication treatments, increase cost-effectiveness, and improve the convenience and quality of patient care by enabling the administration of these drugs in a lower cost, outpatient setting.

McKesson has established a strong record of support and involvement in important federal and state health initiatives. We have been a pioneer in the introduction of drug savings cards to help lower the costs of pharmaceuticals through our administration of the successful Together Rx ™ card and our subsequent introduction of the CMS-endorsed Rx Savings Access™ card. The Together Rx™ card has delivered over $600 million in savings since June 2002 to more than 1.5 million low-income seniors. McKesson's Rx Savings Access™ card is providing Medicare beneficiaries with an average savings of 15-25% on the most commonly prescribed medicines and is accepted by over 95% of pharmacies nationwide. To date, more than 235,000 Medicare-eligible seniors are enrolled in this card and have realized over $52 million in savings on their prescription drugs.

McKesson has also taken a proactive approach to providing disease management programs for commercial, Medicaid and Medicare populations where we leverage our experience with patient services, pharmacy management and healthcare quality improvement activities. In nine states where we provide disease management services to Medicaid patients, we estimate those states are saving approximately two dollars for every dollar spent with McKesson, while improving both the health status of the patient population and physician satisfaction with the program. Late last year, we were awarded one of the Chronic Care Improvement Program (CCIP) demonstration projects by CMS for Medicare beneficiaries.

McKesson was one of four companies that responded to an RFI from CMS and expressed interest in participating as a CAP vendor on a nationwide basis. We continue to support the efforts of CMS to create and implement a successful program. We are pleased that many of our CAP recommendations, submitted to CMS on April 26, have been addressed; however, we still have significant concerns regarding the following provisions:

- **Acquisition Costs:** We believe that CAP purchases should be excluded from ASP calculations. The viability of this program hinges on the ability of a CAP vendor to negotiate drug acquisition costs at lower levels than ASP. According to our analysis of recent net acquisition costs and published ASPs, *many* Part B drugs *cannot be acquired* directly from the manufacturer for less than ASP+6%.

  The exclusion of CAP from ASP was supported by comments from House Ways and Means Chairman Bill Thomas. As one of the main authors of the Medicare Modernization Act, Chairman Bill Thomas wrote that "While some may strictly read Section 1847(A)(c) and Section 1847B of the Social Security Act as not specifically exempting CAP negotiated prices from the computation or

determination of ASP, such a reading would fail to take into account the distinct relationship between the two systems. It was the intent of Congress that these two programs should not interact, and that the prices developed under CAP should not be incorporated into ASP calculations. The ASP and CAP methodologies were always intended to be independent of each other." (*letter from Chairman Thomas to CMS, 4/26/05*).

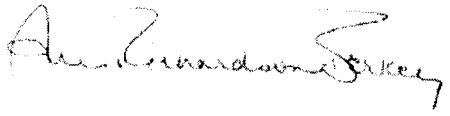
The CAP did not exist when ASP exclusions were defined. We believe this gives CMS discretion to include or exclude CAP prices from ASP as they find consistent with the legislative intent of MMA. In order to ensure a successful CAP, and to fulfill the legislative intent of MMA, we believe it is consistent that CMS exclude CAP from ASP.

- **Price Reporting:** CMS requested additional information about prompt pay discounts in Section II C 3 (b) [CAP Bidding Process; Determining the Single Price for a Category of Drugs (page 39076)]. We recommend that prompt pay discounts be excluded from ASP reporting. Prompt pay or cash discounts, which are terms that are used interchangeably in our business, are provided by manufacturers to distributors as a function of the time-value of money. These discounts are standard financing incentives used to encourage customers to process and pay their invoices faster. In order to earn the discount, the wholesaler must pay the vendor within a specified time period, which is generally 30 days. The speed of the payment determines whether the wholesaler earns or forfeits the discount. These discounts are completely unrelated to the cost or pricing of the drug and should not be included in the calculation of the average sales price. Since prompt pay or cash discounts must be earned and are dependent on the ability of the wholesaler to pay the invoice within a specified time period, we do not believe it is relevant or appropriate to include in the ASP calculation.

- **Price Determination:** We recommend that CMS recalculate the bid price if a winning bidder chooses not to sign a contract with CMS. Under Section II C 3 a [Evaluating Bid Prices by the Composite Bid Price (page 39069)], we support the process by which only the winning bids are used to set the single price. However, we recommend CMS clarify that if a winning bidder should decide to withdraw from the program after the single price determination, the single price should subsequently be recalculated, excluding the bid submitted by the withdrawing bidder. We are concerned that the CAP is vulnerable to bidders who may choose to submit very low bids and subsequently back out of the program.

We commend CMS for their thoughtful responses to the preliminary comments and thank you for the opportunity to share our insights. Please do not hesitate to contact me at (415) 983-8494 or ann.berkey@mckesson.com should you have questions or need further information.

Sincerely,



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