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BELLEVUE HEMATOLOGY / ONCOLOGY
BERNARD GROSSMAN, M.D., FACP
DAVID SCHAEBLER, M.D.
SCOTT K. KINDSFATHER, M.D.

APR 26 2005

MEDICAL ONCOLOGY
HEMATOLOGY

408 BELLEVUE AVENUE
TRENTON, NJ. 08618
(609) 396-5800

April 22, 2005

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

To whom it may concern:

I am writing to comment on CMS-1325P – The Competitive Acquisition Program of Outpatient Drugs and Biologicals. There are several issues which warrant addressing before the implementation date of 1/1/2006.

1. The integrity of the drugs – How can the medical practice be assured of the integrity of the drug when received in the office and take on the liability of administering these drugs to the patient? We would have no way of determining if the drug has been compromised in transit or stored correctly in their facility. Our office has had a long relationship with our wholesalers and we may be forced to switch to another vendor with whom we are not familiar and have no knowledge of their competency.
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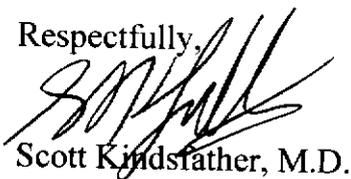
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These are just a few of the problems which can be anticipated if CAP is implemented as proposed. Clearly, this has not been thought out enough and implementation should be delayed until these issues can be addressed. If this program proceeds as originally proposed, this would preclude physicians from treating their patients with the usual high quality of care they deserve.

Respectfully,



Scott Kindsfater, M.D.

LGD

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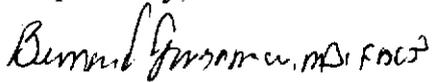
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Respectfully,



Bernard Grossman, M.D., FACP

LGD

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Respectfully,



Linda DeAngelis
Practice Administrator

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Respectfully,



David Schaebler, M.D.

LGD



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APR 26 2005

McFarland Clinic PC

April 18, 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

To Whom it may Concern:

We are a group of four Medical Oncologists practicing as part of a large multi-specialty clinic in central Iowa. We would like to comment on the proposed Medicare Program for the competitive acquisition of outpatient drugs and biologicals.

Comments on General Overview of CAP. File Code CMS-1325-P

As a general comment, we feel that this program will greatly add to the complexities of giving care to the Medicare population. We feel that it will add another layer of bureaucracy and in the end will ultimately increase the cost of medical care. It will further complicate the billing process and greatly confuse our patients. Lastly, and perhaps most importantly, we feel that this program will limit and restrict appropriate care for many of our patients.

Comments on Statutory Requirements Concerning Claims Processing

Many of our patients do not have co-insurance and are simply unable to afford the 20% of drug costs not covered by Medicare. Patients without co-insurance are frequently those patients who are least able to cover these costs on their own. In the past, we have been able to discuss these issues with our patients face to face and frequently made the decision to proceed with treatment knowing full well that we would not be able to collect the 20% co-payment. We did this because our principle mission has been to provide quality care to the public that we serve. Under the new CAP Program the vendors will now be responsible for collecting any applicable deductibles and co-payments. It is doubtful that vendors will be willing to make the same considerations with our patients that we have done in the past. The ultimate result will be that many deserving patients will go without appropriate care. This is a point that we cannot over emphasize. We feel that this program as implemented will restrict medical care.

As an example, we recently saw a patient in our practice with ovarian cancer. This woman required a complex chemotherapy program including Carboplatin and Paclitaxel to be cured of her disease. Unfortunately this woman does not have co-insurance and simply cannot afford to pay the 20% co-pay on the cost of these medications. Despite this, we felt obligated to proceed with life saving therapy. By doing so we understood that we would be assuming some of the financial burden of her care. Without doubt however, this is a practice that "big business vendors" will not tolerate. As the current system is designed, we feel that this woman will be denied life saving therapy.

The current third party payment system already generates a medical bill that is difficult to decipher for even our most sophisticated patients. They receive bills for physician services, drug administration and drug costs from the physicians office. Factor into this deductibles and co-payments and the system becomes extremely confusing and frightening to the public. Under the CAP Program, yet another third party is added. The inevitable result will be to further complicate an already nightmarish program.

The practice of oncology is rapidly changing. New drugs for the treatment of cancer are rapidly becoming available and just as importantly, published studies expand the usefulness of drugs beyond their initial indication. The FDA may approve the use of a drug for one type of cancer but shortly thereafter, additional studies indicate that this drug is also useful in other forms of cancer. Currently, if we feel that a patient should receive a chemotherapy agent that is not approved for that indication there are mechanisms whereby that patient can still obtain this potentially life saving therapy. Initially, we can contact our local carrier and supply supportive literature to justify the drugs use in that setting. If however, our carrier still denies coverage, the majority of pharmaceutical companies will agree to replace drug that is used in that patient. This allows us to give what we feel is the best treatment and yet not shoulder the full burden of the cost if this medication. We do not see how this system or a similar system will work under the proposed CAP Program. What lines of communication between provider, vendor, pharmaceutical industry and local carrier are being established to facilitate, in a timely fashion, the use of drugs for indications not yet approved by the FDA?

Comments on Administrative Burden on Physicians

While the proposed CAP Program relieves physicians of collecting co-insurance for CAP drugs, the physician must comply with other administrative requirements. Physicians must maintain a separate electronic or paper inventory for each CAP drug obtained. Physicians would be required to submit claims to the local Medicare carrier when drugs are administered. When drugs are not administered, we will need to notify the vendor and rather than allowing us to use drugs at a later time it is our understanding that the proposed rules state that the vendor and physician must somehow reach an agreement on how to handle the unused drug. This is a daily event in our practice. Despite all this physicians are not entitled to any reimbursement for the administrative costs accrued as a result of participating in CAP! We submit that there are very real administrative costs to drug procurement and storage. It is astounding that the proposed system fails to make this recognition and yet still asks physicians to participate.

Under the current system, we have one inventory of drugs in our office. We draw from this inventory for all of our patients whether they have Medicare or other private insurance. The proposed CAP system will require that we have separate inventory for Medicare patients. The nightmare that this creates for us cannot be over emphasized.

It is obvious to us in reviewing the proposed CAP Program that the formulators of this program made little effort to understand or to take into account the complexities of oncologic care from the physicians perspective. We would urge that prior to the hasty implementation of such a program appropriate studies be done which fully explore and delineate its consequences.

Sincerely,



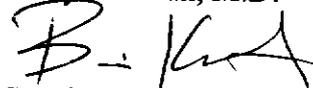
Michael Guffy, M.D.



Joseph Merchant, M.D



Larry Otteman, M.D.



Bassim Kobrossy, M.D.

MG:law



APR 26 2005

APR 26

Washington DC Regional Office

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April 26, 2005

By Hand Delivery

Mark McClellan, M.D., Ph.D., 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: Comments on CMS-1325-P (Medicare Program;
Competitive Acquisition of Outpatient Drugs and
Biologicals Under Part B) – Impact, Section 303**

Dear Administrator McClellan:

TAP Pharmaceuticals Products Inc. (“TAP” or the “company”) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services’ (“CMS”) proposed rule regarding the Competitive Acquisition Program (“CAP”), published in the Federal Register on March 4, 2005 (the “Proposed Rule”). TAP is one of the nation’s leading pharmaceutical companies and is committed to delivering high quality pharmaceutical products for patients. The company provides innovative and effective products in diversified treatment areas, including oncology, gastroenterology, and gynecology.

As a member of the Pharmaceutical Research and Manufacturers of America (“PhRMA”), TAP supports the comments on the Proposed Rule submitted by this association on behalf of the pharmaceutical industry. The company writes separately, however, to highlight several issues that are of particular concern to us.

“Overview of the CAP”

The statute provides some flexibility in the implementation of the CAP by requiring an appropriate “phase-in” of the program. We are concerned that due to the



aggressive implementation timeline for this program, and the major changes involved for both providers and beneficiaries that CMS take extra care to select a more limited phase-in option. A limited phase-in will minimize disruption of patient care, allowing providers and their patients to become more familiar with the CAP program before initiating a larger rollout of the program.

“Categories of Drugs to be Included Under the CAP”

Preserving patient access and quality of care will be essential to a successful launch of the CAP program. TAP is concerned, however, that some components of the Proposed Rule are not consistent with this objective. The Proposed Rule’s § 414.908(d) states that vendors will not be required to provide every National Drug Code (“NDC”) associated with a Health Care Common Procedural Coding System (“HCPCS”) code. Section 1847B(b)(1) of the Act states that “in the case of a multiple source drug, the Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive area.”

We are concerned that this could limit physician access to certain drug dosage forms, which could in turn necessitate an alteration of a patient’s current treatment plan. A number of HCPCS codes have many products with multiple NDCs associated with one HCPCS code. Requiring only one NDC for each HCPCS code means a patient could not only be limited to one product within a category of Food and Drug Administration (“FDA”) approved treatment options, but they may also be limited to certain dosage forms. For example, HCPCS code J9217 includes leuprolide acetate suspension products to treat prostate cancer, namely Eligard® and Lupron Depot®, at multiple dosage formulations including 1, 3, 4, and 6-month doses. If a vendor is required to provide only one NDC associated with this code, it is possible that a vendor could limit availability to not only one of the products, but also to only one of its depot formulations. This means that a prostate cancer patient could be forced to change both his current treatment as well as the frequency with which he receives his therapy.

Furthermore, if only two vendors are contracted for a region, and both vendors choose to limit providers to the same option within a HCPCS code, then choosing to participate in the CAP in that region may be untenable for providers and patients.

“Claims Processing Overview”

The Proposed Rule states that after physicians order a CAP drug they would check that they are planning to use the drug consistent with any local coverage determination policies (“LCDs”), just as they would do now if obtaining the drug under the current payment methodology. TAP is deeply concerned by the application of LCDs, such as Least Costly Alternative (“LCA”) to the CAP, and the potential for limiting patients’ access to the full range of FDA approved prostate cancer therapies.



TAP continues to believe that the application of LCA under the new ASP+6% payment system is inappropriate, as the LCA policy was designed to be a fix for the AWP-based reimbursement system. The implementation of the ASP+6% reimbursement formula was designed to meet this same goal, and its mutual existence with the LCA policy threatens prostate cancer patients' access to medical therapies.

Consideration of applying the LCA policy to the CAP program will be even more problematic. If the CAP is subject to LCA, it will be difficult for vendors to provide anything but the least costly agent to the patient. Vendors choosing to collect the higher co-pay for a product whose allowable is above the least costly agent will have no method in place to get the patient to sign the Advanced Beneficiary Notice permitting the vendor to bill the patient for the more expensive product.

It is also important to note that Medicare carriers do not uniformly apply this policy. For example, the product that each carrier determines to be the least costly agent varies by carrier, and a number of carriers include a grandfather clause in their policies, while others do not. Additionally, while some carriers have not implemented the policy at all, others have suspended or are considering suspending their current policies until they determine the impact of the new ASP+6% methodology. For those carriers who adhere to the LCA policy, the least costly agent can also vary based on quarterly ASPs. The expectation that vendors will be able to manage the accounting of all of the individual carriers' application of this policy in addition to their quarterly allowables, and do what is necessary to recoup their own costs means that patients may suffer the unintended consequence of limited access to therapy.

“CAP Bidding Process – Evaluation and Selection”

Throughout this section, the Proposed Rule uses the terms “HCPCS,” “HCPCS drugs,” and “Drugs” interchangeably. We would like additional clarification on the use of these terms and how the individual NDCs are handled.

This section also refers to the determination of a mechanism for setting the single price for each category of drugs in the second and third years of this 3-year contract. The basis of the original bid is to “include all costs related to the delivery of the drug to the selecting physician and the costs of dispensing (including shipping) of the drug and management fees.” Upon consideration of bid adjustments for years two and three of the contract, these costs should also be reported and included with the reported “reasonable, net acquisition costs” as the basis of the year-to-year adjustment.

“Beneficiary Education”

As mentioned in this section, the CAP does have potential for significant confusion among beneficiaries, and CMS must take extra care to ensure there is ample



information readily available to patients impacted by this program. Of even greater concern, however, is the handling of those patients who would normally need assistance covering the expense of their co-pays. Physicians typically play a direct role in identifying patient assistance programs for these vulnerable individuals, and it is unclear how this assistance would be offered under the CAP.

“Regulatory Impact Analysis”

TAP is deeply concerned that this program will have a greater impact on beneficiaries than assumed by CMS. As mentioned in our comments to the section entitled, “Beneficiary Education”, indigent patients could be significantly impacted if they do not receive proper assistance in identifying those programs that can help them cover their co-pays. If these beneficiaries are then unable to make their co-pays, or are delayed in making payments, we are concerned that vendors might not release therapies ordered for them, or possibly bring collection agency action against them. Patients may be frightened by these developments, leading them to believe that they cannot continue to receive their medication.

If the CAP program is subject to the varied LCA policies of the local Medicare carriers, then access to the most appropriate therapy for a patient is also at risk. TAP strongly recommends that CMS consider preventing the application of this policy to the CAP.

Conclusion

In summary, TAP continues to be concerned that the application of LCA to the CAP and the requirement to provide only one NDC per HCPCS code will have serious ramifications for patients with advanced prostate cancer and urges CMS to make patient access a primary focus as it establishes the final rule for this program. Furthermore, additional clarification is needed on how the most vulnerable patients will be navigated through this new system without risk of losing access to their medication.

TAP appreciates the opportunity to comment on this significant issue and looks forward to working with CMS to ensure that beneficiaries have continued access to much needed pharmaceutical products. We sincerely hope that the agency will give thoughtful consideration to our comments and will incorporate our suggestions in the final rule. Please contact Laura Cline at 410-280-9726 if you have any questions regarding our comments or need any additional information.

Respectfully Submitted,

A handwritten signature in cursive script that reads "Laura Cline". The signature is written in black ink and is positioned above the typed name.

Laura Cline
National Manager
Government Affairs

APR 26 2005

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BILL THOMAS, CALIFORNIA,
CHAIRMAN

Congress of the United States

U.S. House of Representatives

COMMITTEE ON WAYS AND MEANS APR 26

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CHRIS CHOCOLA, INDIANA

ALLISON H. GILES,
CHIEF OF STAFF

April 26, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Hubert Humphrey Building, Room 314-G
200 Independence Ave., SW
Washington, D.C. 20201

Dear Dr. McClellan:

I am writing in response to your proposed rule on the Competitive Acquisition Program (CAP) for Medicare Part B drugs (CMS-1325-P). The CAP was included in the Medicare Modernization Act (MMA, P.L. 108-173) to provide a method for physicians to remove themselves from the business of acquiring Part B covered drugs and enable them to focus exclusively on the administration of those drugs.

As you are aware, under the pre-MMA payment system, physicians received a significant share of their Medicare compensation by profiting from the "spread" between the acquisition cost of covered drugs and the higher amount reimbursed by Medicare. Under the MMA, the drug reimbursement system has been reformed to help ensure that Medicare payments more closely track actual acquisition costs. At the same time, administrative payments for physician services were increased by 117 percent over pre-MMA levels, to ensure that payments more closely reflect the cost of providing those services. Under the system in place in 2005, however, physicians are still responsible for acquiring the drugs they administer, and will still receive direct payments for those drugs.

The CAP provides an opportunity for physicians to leave the logistics of acquiring drugs and collecting reimbursements to a third party. In this way, physicians will only be responsible for their own costs of providing services, not for the cost of the drugs themselves. Physicians will be able to choose a CAP vendor to provide all of their drugs. That vendor will be responsible for supplying the drugs to the physician office, collecting beneficiary copayments, and receiving reimbursement from Medicare.

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.

The "election" language in section 1847A(a)(2) – under which physicians can choose either to purchase drugs under the ASP system or to select a vendor under CAP – would be undermined if the exercise of that election had the result of changing the very prices upon which the election were made. The election to use (or not use) CAP under section 1847B was clearly not intended to affect ASP payment rates under section 1847A. Without this clear distinction, the choice of those physicians who elected to use ASP instead of CAP would be undermined.

In your proposed rule, you pose a number of questions about the potential scope of CAP. I would like to comment on two of those questions:

Drugs Covered: The statute authorizing CAP (section 1847B of the Social Security Act, as added by the MMA) states that “the Secretary shall phase in the program with respect to those categories [of competitively biddable drugs and biologicals] beginning in 2006 in such manner as the Secretary determines to be appropriate.”

Congress recognized the importance of providing the Secretary with sufficient flexibility to implement this new program. However, the ultimate intent was for the CAP program to encompass all Part B drugs furnished incident to a physician’s service, not just drugs from a particular specialty. In order for vendors to participate in this program, they need to be able to work with a large category of drugs in order to be viable. Similarly, for the program to be attractive to physicians, they will want to obtain all drugs in their practice through their single chosen CAP vendor. Thus even with any phase-in, the program should start with a sufficiently large category of drugs to provide a sufficiently-sized market for vendors and should ramp up quickly to include all physician-administered Part B drugs.

Competitive Acquisition Areas: The CAP statute also allows the Secretary to establish “appropriate geographic regions” for the program. While the Secretary may establish regions to facilitate the administration of the program, it was the intent of Congress for CAP to be a national program. National coverage will provide the opportunity for all physicians across the country to participate in the program. Furthermore, broad geographic coverage will provide an adequate-sized market for CAP vendors.

The MMA conference committee did not want to impose a single, untested drug acquisition program on doctors. That is why two different and separate structures are incorporated into the legislation, in order to provide physicians a choice of programs. In writing the legislation, Congress provided the Secretary with sufficient flexibility to ensure that both programs could be implemented independently and successfully. It would truly be ironic if the Secretary’s flexibility provided for in the legislation was used to defeat the creation of these two new programs by limiting the scope of one structure or inappropriately linking the two structures together in a way that was never intended.

The CAP for Part B drugs will enable physicians to focus on patient care rather than on drug acquisition, while providing a structure that will ensure beneficiaries have access to the drugs they need. I look forward to working with you as we move forward to implement this important program.

Best regards,

A handwritten signature in black ink that reads "Bill Thomas". The signature is written in a cursive style with a long horizontal stroke at the end.

Bill Thomas
Chairman

WMT/kw



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Number of pages being transmitted including the cover page: 3

From:	Shannon L. Hopkins	Date:	March 24, 2005
Fax No.	212-273-4446	Telephone No.	646-733-5768
Matter No.:	040170-1		
Subject:	<i>Marsden v. Select Medical Corp. No. 04-4020</i> Freedom of Information Act Request		

Message/Document(s) faxed:

Please see attached.

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March 24, 2005

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Baltimore, Maryland 21244-1850

COSRO 1128

Re: *Marsden v. Select Medical Corp.* No.04-4020
Freedom of Information Act Request

Dear Sir or Madam:

Pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and regulations promulgated by the Centers for Medicare & Medicaid Services ("CMS"), under the Code of Federal Regulations, 42 C.F.R. Chapter IV, we hereby request that you provide us with copies of the documents described below, which are in the possession, custody or control of the CMS during the period January 1, 2002 through December 31, 2004, with respect to Select Medical Corp. ("Select Medical" or "Select" or the "Company"):

1. All documents regarding any studies, analysis, reviews, investigations, examinations or other inquiries by the CMS of Select Medical;¹
2. All documents and correspondence concerning both actual and proposed Medicare regulations relating to regulation of hospitals operating within hospitals, referrals by host hospitals to hospitals-within-hospitals and Medicare payments under the long-term care hospital prospective payment system; and



¹ By "documents" we mean, all records, letters, memoranda, notes, correspondence, reports, submissions, findings, agreements, orders, whether in paper, electronic (including email) or any other form.

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Centers for Medicare and Medicaid Services

March 24, 2005

Page 2

3. All documents concerning any meetings or other communications between CMS and Select Medical and its officers, directors and employees.

Should you find that the information provided above regarding the requested records and documents is inadequate, please notify us and indicate what additional information you will need to identify and locate any of the requested records and/or documents.

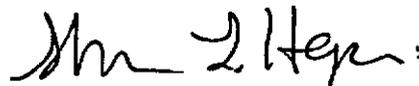
If there are any records and/or documents in the possession, custody or control of the CMS that are responsive to this Request which you will not produce, please advise us in writing and provide a description of those records and/or documents as well as a statement explaining the reasons for their non-production. In addition, please disclose and produce any segregable portions of records and documents requested herein that are not exempt from production in accordance with this Request.

You are hereby authorized to incur costs of up to \$1,000.00 in connection with identifying, locating, and duplicating the requested records and documents. If it appears that the costs of responding to this Request will exceed \$1,000.00, please notify us.

Finally, we represent a class of plaintiffs in a class action lawsuit against Select Medical. In connection with this litigation, we have an immediate need to receive the requested documents and information no later than Wednesday, April 13, 2005. We would greatly appreciate your cooperation in expediting our request.

Should you have any questions or should you require any further information regarding this Request, please do not hesitate to call me at 646-733-5768.

Sincerely,



Shannon L. Hopkins

SLH

**CENTERS FOR MEDICARE & MEDICAID SERVICES
FREEDOM OF INFORMATION ACT REQUEST**

Case #: C05FOI1128(RHR)

Date Received 03/25/2005 Due Date 4/29/2005 Response Date _____ Processing Days _____

Requester: Shannon L. Hopkins

Subject: Copies regarding Select Medical Corp. during the period of 1/1/02 thru 12/31/04.

Referred To: RO III OSORA CMM

Category of Requester: Commercial _____ Educational/Scientific or News Media _____ Other _____

IS THERE PROGRAM CONCERN ABOUT DISCLOSING THESE RECORDS? _____ Yes _____ No

Ongoing Deliberations Invasion of Privacy Circumvention of Agency Rules
 Decision-making Process Pending Litigation Proprietary Information
 Open Investigation Other (Specify) _____

ACTIONS: Direct Reply No Records Found Referral to Next Review Level
 Not FOIA Records Not Reasonably Described Request withdrawn
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ACTUAL COSTS OF RESPONDING TO REQUEST

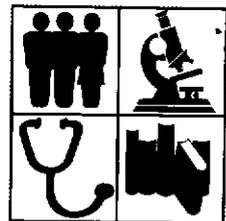
ACTUAL PROCESSING COSTS:	Hours	Hourly Wage	Total	Invoiced Fees
Reading/Interpreting/Logging				XXXXXXXXXXXXXXXXXXXX.....
Clarifying/Negotiating/Consultation				XXXXXXXXXXXXXXXXXXXX.....
Searching for Records				\$
Review/Edit/Delete (DFOI Only)				\$
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IDS A

Infectious Diseases Society of America

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April 26, 2005

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

Re: Comments on Proposed Rule [Docket No. CMS-1325-P]: 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) Proposed Rule (proposed rule) published on March 4, 2005.

Before addressing the CAP, we must first note that IDSA's physician members are experiencing serious problems in acquiring many antibiotics and other products at or below the Average Sales Price (ASP). IDSA submitted physician cost data to CMS in a letter dated March 7, 2005, which clearly illustrates the on-going problem. We have not yet heard back from CMS about how the agency intends to fix this problem. However, the problems with the flawed ASP program underscore the importance of ensuring the implementation of a viable CAP for infectious diseases (ID) physicians providing in-office drug therapy.

IDSA appreciates the time CMS staff has devoted to the Medicare Prescription Drug, Improvement, and Modernization Act's implementation, including the restructuring of drug infusion and injection codes, the implementation of the ASP methodology, and most recently, the issuance of the CAP proposed rule for public comment. IDSA, through its comments, is eager to assist CMS in creating a CAP final rule that will better ensure Medicare beneficiaries continue to have access to life-saving drugs and biologicals in the physician office-based setting. With this in mind, IDSA will comment on the following issues raised by the proposed rule:

Claims Processing Overview

- The definition of "emergency" situations, including what circumstances constitute an emergency, needs to be more clearly outlined in the final rule. The unique role that ID specialists play in quickly responding to and managing acute, life-threatening infectious agents in their local communities necessitates that the CAP final rule accurately define what constitutes an "emergency."

- A system needs to be put in place to obtain drugs with minimal delay. Infectious diseases specialists may not be able to maintain pre-existing inventories of every drug they might possibly need on hand at all times.
- IDSA favors a multi-specialty phase-in of the CAP using one or two widely used drug categories.

Categories of Drugs to be Included Under the CAP

- Physicians should be able to opt in and out of the CAP on a category specific basis.
- Categories should be limited in size to include functionally similar drugs (or particular families of drugs) to allow flexibility in obtaining drugs and biologicals through the CAP.

Competitive Acquisition Areas

- IDSA favors competitive acquisition areas that factor in both population density and geographic boundaries.

Collection of Information Requirements

- IDSA believes that the clerical and administrative resources needed to order, maintain, and file claims for per-patient drug doses will be overly burdensome to physicians. Alternatives must be considered.

BACKGROUND

IDSA represents nearly 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, and treatment of infectious diseases as well as strive to prevent them in the U.S. and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, those with cancer or transplants who have life-threatening infections caused by unusual microorganisms, food poisoning, HIV/AIDS, and new and emerging infections, such as severe acute respiratory syndrome (SARS).

CLAIMS PROCESSING OVERVIEW

Infectious diseases specialists must quickly react to and treat a variety of conditions in their office-based practices that require life saving antibiotics and antivirals to be readily available. Such situations may range from an *Escherichia coli* H7:0157 outbreak in a small town to an individual case of methicillin-resistant *Staphylococcus aureus* (MRSA) that has been referred to an infectious diseases specialist late on a Friday afternoon by a local physician. Infectious diseases specialists frequently encounter "emergency" situations where lifesaving drugs are needed immediately and on any given day of the week including Saturday and Sunday. As such, IDSA and its members seek clarification as to what constitutes an "emergency" use of drugs under the CAP. IDSA believes strongly that the definition of "emergency" situations in the physician office-based setting should include drugs that are needed on an immediate basis within the context of the typical infectious diseases practice. Alternatively, CMS should

provide other terminology and processes that encompass the medical needs of a typical infectious diseases specialist's practice. Specific examples include: 1) new patients who need to be immediately started on antibiotics for infections; or 2) existing patients who require immediate modification of their treatment regimen due to an allergic or other adverse reaction or new circumstances such as a new pathogen or updated culture result.

In many cases, when ID specialists need drugs immediately to prevent complications and/or costly hospital stays (and have no existing inventory), a 24-hour shipping period is not prompt enough. A provision should be included within the CAP final rule to require same day drug deliveries or to allow for immediate drug acquisition when the diagnosing physician can show a clear and present danger to the patient's health and well-being if the drug is not administered immediately. Such a provision could be modeled after the existing "furnish as written" provision, which allows physicians to "obtain a drug under the ASP methodology" in certain situations. Without such a provision, Medicare ultimately will be forced to pay for unnecessary hospital stays for patients that could have been treated more cost effectively in ID physicians' offices. In addition, care must be taken to ensure that whatever mechanism is implemented is of minimal burden to both the physician and patient.

Finally, under claims processing overview, CMS sought comment about how the CAP should be phased-in. IDSA favors a multi-specialty phase-in of the CAP using one or two widely used drug categories. Not only would this approach allow the maximum number of physicians and specialties to become familiar with the CAP, but also, it would allow the vendors to develop experience across multiple specialties and throughout their contracted service areas. We feel that antibiotics represent ideal drugs for an initial phase in of the CAP, since virtually all physicians, regardless of specialty, use them.

CATEGORIES OF DRUGS TO BE INCLUDED UNDER THE CAP

IDSA supports the rule's premise that physicians should have the freedom to opt in or out of the CAP on a category specific basis. We also favor categories that are narrowly configured and align functionally similar drugs. With this in mind, IDSA believes that drug categories should be modeled after the pharmacologic classes established in the United States Pharmacopeia's (USP) drug formulary model guidelines in December 2004. In the case of antibiotics classes, cephalosporins, penicillins, macrolides, and quinolones would occupy their own drug categories. This would allow physicians maximum flexibility to best meet the needs of their patients and the physician's business model.

IDSA also believes strongly that vendors should be allowed to add new drugs to categories during the contract year. The health and well-being of patients, in many cases, depends on physicians' ability to acquire the newest and most effective drugs. However, vendors should not be permitted to substitute or delete drugs throughout the year. Thus, physicians electing to acquire drugs through the CAP will have the assurance of knowing that no substitutions or deletions will be made during the contract year.

COMPETITIVE ACQUISITION AREAS

IDSA favors competitive acquisition areas that will provide for the most efficient and timely delivery of drugs to physicians (and their patients). While statewide areas may work well in densely populated states, an efficient and timely delivery of drugs will be much more difficult in states with smaller populations and/or geographic boundaries. The areas need to be defined such that less densely populated states and/or states with difficult geography are not placed at a disadvantage. Vendors participating in the CAP will most likely have pre-existing shipping networks established in multiple states (since they will have to generate enough volume to justify small profit margins). As such, we feel that competitive acquisition areas that factor in both population density and geographic boundaries will allow for the most timely and efficient delivery of drugs and biologicals.

COLLECTION OF INFORMATION REQUIREMENTS

In the proposed rule, the costs (to physicians) associated with the CAP are dismissed because CMS believes that maintaining separate physical inventories of CAP and non-CAP drugs will not require significant resources. However, the proposed rule does require physicians to maintain a separate electronic or paper inventory for each CAP drug obtained. Additionally, physicians are required to order and file claims for per patient doses of drugs. The requirements to order, track, and file claims on per patient doses of drugs will be both expensive and burdensome for physician practices. There is no way for physicians to recoup these costs. As an alternative to the electronic and paper inventory maintenance requirement, we suggest that CMS track drug utilization through a combination of vendor invoices and the administration claims submitted by physicians to CMS. Invoices from the vendor of drugs shipped to a physician can be matched with the administration claims to allow tracking of drug usage. This would eliminate the costly maintenance of separate electronic and/or paper inventories for CAP drugs and biologicals.

CONCLUSION

IDSA appreciates this opportunity to comment on CMS' Proposed CAP Rule. We strongly believe that infectious diseases physicians need a viable alternative to the flawed ASP methodology for acquiring drugs and biologicals. There are serious problems in the proposed rule and we believe that the final rule should incorporate our changes to better ensure Medicare beneficiaries continued access to life-saving drugs and biologicals in physicians' office setting.

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

Sincerely,



Walter E. Stamm, MD
President

April 26, 2005

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

APR 26 2005

RE: CMS-1325-P – Competitive Acquisition of Outpatient Drugs and Biologicals Under Medicare Part B

Dear Administrator McClellan:

Grifols / Probitas Pharma (Grifols) is a producer of biologic therapies derived from human plasma. These therapies are used to treat congenital and often life-threatening conditions such as hemophilia, immune deficiencies and a variety of other conditions and diseases. The major therapies Grifols produces include:

- Hemophilia clotting factor VIII (FVIII),
- Hemophilia clotting factor IX (FIX),
- Intravenous immune globulin (IVIG), and
- Albumin¹.

We are pleased to provide these comments to the Centers for Medicare and Medicaid Services (CMS or the Agency) on the proposed rule for the competitive acquisition program (CAP) pertaining to outpatient drugs and biologicals under Medicare Part B. 70 Fed. Reg. 10745 (Mar.4, 2005).

In general, the proposed rule offers a workable system for physicians to effectively outsource the commercial aspects of drug and biologic acquisition and payment. However, this system is workable only for those drugs and biologics that routinely are administered in the physician's office. Consequently, Grifols' believes that CAP is inappropriate for plasma therapies such as IVIG and hemophilia clotting factors. As discussed in greater detail below, Grifols believes that the statutory exemption of IVIG from CAP should be codified in CMS regulations and that the Secretary should exercise his discretion to exempt hemophilia clotting factors from CAP.

¹ Albumin is almost exclusively administered in the in-patient setting and therefore will not be addressed in these comments.

CMS Should Codify the Statutory Exemption for IVIG in Regulation

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 PL 108-173 (hereinafter, the MMA) excludes IVIG from the CAP. The MMA specifies that payments to physicians for IVIG furnished after 2005 should be based on the average sales price plus 6% (ASP+6). MMA §303(b). This is different from most other drugs and biologicals for which physicians can either elect to be reimbursed at ASP+6% or acquire them through the CAP. Because the MMA defines a specific payment methodology for IVIG furnished after 2005 (ASP+6%) the statute cannot be read to mean that IVIG is also subject to CAP.

The basic rules of statutory construction lead to the conclusion that physician-furnished IVIG after 2005 is not subject to CAP and instead, is to be paid at ASP+6%. If Congress had intended that IVIG be subject to CAP, it would not have defined a specific payment methodology for it. Instead, the MMA would have remained silent as to the payment rate for IVIG furnished after 2005. IVIG would then have been subject to the provisions of the MMA that define "competitively biddable" drugs and biologics. MMA §303(b), codified at SSA §1847B(2)(A).

Furthermore, the MMA Conference Report confirms that IVIG is excluded from the CAP. It states in relevant part: "[c]ompetitively biddable drugs and biologicals exclude . . . IVIG products and blood products." H.R. Conf. Rep. No. 108-391, at 593. Thus, it is clear both from the MMA construction and the Congressional intent reflected in the Conference Report that IVIG is to be excluded from CAP.

It is imperative that CMS codify this exemption in the CAP regulations. Codifying the IVIG exemption would avoid the unintended consequence of raising uncertainties among physicians and distributors about access and availability of IVIG resulting from confusion about IVIG CAP eligibility. In short, codifying the IVIG exemption from CAP will preclude any confusion about payment rates to physicians for IVIG furnished after 2005.

Even more important is the fact that each brand of IVIG is therapeutically unique with biologic attributes that can affect patient tolerance and therapeutic efficacy. Some of the differences among IVIG preparations include product concentration, infusion rate, and antibody content. In addition, some IVIG preparations may have a higher salt content while others may contain higher levels of sugars. These factors can be important for minimizing the possibility of adverse reactions and maximizing patient response. It is for this reason that doctors often try different IVIG preparations to determine which is most appropriate for the individual patient.

Subjecting IVIG to the CAP would mean that physicians would likely be limited to the brands of IVIG offered by the CAP vendor. This is tantamount to treating all

IVIG brands as therapeutically equivalent, which is clearly not the case. Doing so would have a significant adverse impact on patient care. A 2003 survey of the immune deficient patient community revealed that “nearly half of patients said that they tolerate some products better than others.” The survey also found that 30% of patients had switched products or otherwise altered their course of treatment due to tolerability concerns.² Appreciating the unique nature of each branded IVIG preparation is critical to assuring proper patient care.

CMS should act to assure continuity of care for individuals who rely on IVIG therapy and codify the exclusion of IVIG from the CAP. Accordingly, Grifols requests that CMS revise proposed 42 C.F.R. §414.906(b) to read as follows:

- (b) Exceptions to competitive acquisition.
- (1) *Discretion of the Secretary – Specific competitively biddable drugs, including a category of these drugs, may be excluded from the CAP if the application of competitive bidding to these drugs –*
 - (i) *Is not likely to result in significant savings; or*
 - (ii) *Is likely to have an adverse impact on access to such drugs.*
 - (2) *Excluded from Competitive Acquisition – The following drugs or biologics are specifically excluded from the CAP –*
 - (i) *Intravenous immune globulin (IVIG) furnished on or after January 1, 2006 in accordance with SSA§1842(o)(1)(E).*

Hemophilia Clotting Factors Should be Exempt from the CAP

The stated purposes of the CAP are inapposite to hemophilia clotting factors. Moreover, subjecting hemophilia clotting factors to the CAP would likely have an adverse impact on access to the therapies. Consequently, we request that the Secretary exercise his discretion and authority to exempt hemophilia clotting factors from the CAP by regulation. To wit, we request that proposed 42 C.F.R. §414.906(b) be further amended to list hemophilia clotting factors as a drug or biologic exempt from the CAP.

Inherent in the CAP is the idea that it is intended for drugs and biologics that are primarily administered in the physician office. One of the basic aims of the program is to provide physicians an opportunity to avoid being in the business of drug acquisition. 70 Fed. Reg. 10748 (March 4, 2005). Further, it is intended to reduce the financial burden on physicians. Id. It does this by eliminating the

² Immune Deficiency Foundation, *Treatment Experiences and Preferences of Patients with Primary Immune Deficiency Diseases: First National Survey*, (June 20, 2003) at page 18.

need for physicians to employ working capital to acquire drugs and biologics and avoiding the need for physicians to collect coinsurance from Medicare beneficiaries. Id. Thus, if the CAP were intended to address drugs and biologics other than those primarily administered in the physician office these purposes would be pointless.

Hemophilia clotting factors do not fit within the scope of the CAP principally because they are mostly self administered. While hemophilia patients may visit their physician on an annual basis or as specific health concerns arise, most routine hemophilia care is done through the home-care setting. Patients typically obtain their clotting factor through shipments directly to their home from specialty pharmacies. Often hemophilia patients will supply their own therapy during a doctor visit or for minor physician-office procedures.

Physician offices do not acquire and administer significant quantities of hemophilia clotting factors except in rare circumstances. As such, subjecting clotting factors to the CAP would do little or nothing to advance the stated goals of the CAP: little or no healthcare cost savings would be realized and physicians would not benefit from any meaningful shift in financial burden to CAP vendors.³

Furthermore, including hemophilia clotting factors in the CAP would likely have an adverse impact on access to the therapies. This is because under the proposed rule, CAP vendors are required to offer only one drug or biologic per Healthcare Common Procedures Coding System (HCPCS) code. See proposed §414.908(d)⁴. In the case of clotting factors, more than one branded therapy is included within a single HCPCS code. Under the CAP, a vendor may be required only to provide one of the branded therapies within each HCPCS code and not the other branded therapies within that code. This would have the consequence of denying access to the full range of therapies.

It is imperative that treating physicians and hemophilia patients have access to the full range of branded therapies. Each therapy has unique biological attributes that affect patients differently. For example, one patient may tolerate one brand of therapy well while another therapy may cause an allergic reaction. Moreover, different brands of hemophilia clotting factors are derived from different starting

³ Insofar as the CAP is intended for drugs and biologics administered "incident to" a physician's services (SSA §1861(s)(2)(A)-(B)), hemophilia clotting factors should be exempt from the CAP because they are paid for under a separate provision of the Social Security Act (SSA §1861(s)(2)(I)).

⁴ Although hemophilia clotting factors are not multiple source drugs, the proposed rule does not address the circumstance where more than one single source drug or biologic is included within a single HCPCS code. Instead, the preamble to the proposed rule reiterates that statutory requirement that CMS conduct a competition among CAP vendors for at least one competitive biddable drug and biological within each billing and payment code within each category of competitively biddable drugs for each competitive acquisition area. 70 Fed. Reg. 10751 (March 4, 2005).

materials: some clotting factors are produced from human plasma donations while others are generated from Chinese hamster ovary cells.

In addition, slight variations in production methods and manufacturing techniques, even among products created from the same starting material, result in important biologic and therapeutic differences. The importance of these product differences was recently acknowledged by the Medical and Safety Advisory Committee (MASAC) of the National Hemophilia Foundation (NHF).

Clotting factor therapies are neither pharmacologically nor therapeutically equivalent and vary based upon purity, half-life, recovery, method of manufacture, viral removal & inactivation processes, potential immunogenicity, and other attributes. The characteristics of each product and the resultant product choice for an individual patient require a complex decision making process with the ultimate product being agreed upon by the patient and their respective healthcare provider. It is critical that the bleeding disorder community has access to a diverse range of therapies and that prescriptions for specific clotting factor concentrates are respected and reimbursed.

... The benefit of limiting products to one within a class ... solely for the purpose of cost containment is not supported by present clinical practice or by published data. MASAC Document #159 (February 12, 2005).

MASAC members include some of the world's leading hemophilia treaters. Thus, the importance of assuring access to the full range of therapies by exempting hemophilia clotting factors from the CAP cannot be overstated.

Although the CAP includes a "furnish as written" provision under which a physician who has elected to participate in CAP can obtain a drug or biologic not offered by the CAP vendor when medical necessity requires it is not well suited for chronic care conditions such as hemophilia. 70 Fed. Reg. 10755 (March 4, 2005). Under this scenario, the physician must go outside of the CAP and seek payment in accordance with the standard acquisition and payment systems at a rate of ASP+6%. The physician must jockey back and forth between two drug acquisition and billing systems effectively obviating any ostensible benefit conferred by the CAP. In short, a physician who has elected to use the CAP would have a strong disincentive to then revert back to the standard acquisition and payment methods.

While the "furnish as written" option may be appropriate in rare or exigent circumstances, for chronic care conditions such as hemophilia, physicians would be forced to face the difficult choice of switching patients back and forth between therapies or routinely exercising the "furnish as written" option and foregoing the ostensible benefits of the CAP. Consequently, to maintain the integrity of the

CAP program and to assure unfettered access to the full range of medically necessary therapies, hemophilia clotting factors should be exempt from the CAP.

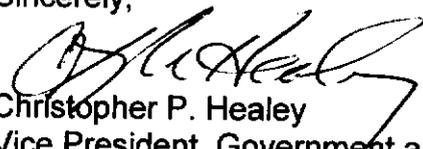
Notwithstanding the "furnish as written" provisions of the CAP, CMS should require CAP vendors to bid on each single source drug or biologic by national drug code (NDC) rather than one drug or biologic per HCPCS code. At present, different single source hemophilia therapies are grouped under one HCPCS code. As discussed above, allowing CAP vendors to bid on only one drug or biologic for each HCPCS code will likely threaten access to those therapies for which the vendor did not bid. With regard to single source drugs or biologics such as hemophilia therapies, this is tantamount to allowing CAP vendors to make medical decisions. Consequently, the only way to assure that physicians and patients have sufficient therapeutic options is to require CAP vendors to bid on each NDC within a HCPCS code containing more than one single source drug or biologic. As such, Grifols urges CMS to amend the CAP regulations to require that CAP vendors bid on every single source drug or biologic by NDC where one or more branded drugs or biologics are included in a single HCPCS code.

Conclusion

Based on the foregoing, Grifols requests that CMS codify in regulation the statutory exemption of IVIG from the CAP. Furthermore, Grifols requests that Secretary Leavitt exercise his discretion under MMA §303(b) to exempt hemophilia clotting factors from the CAP on the basis that the CAP will not lead to significant savings and is likely to have an adverse impact on access to hemophilia therapies.

We hope these comments will assist CMS in developing its final rule for implementation of the CAP. Please contact me if you have any questions regarding our comments.

Sincerely,


Christopher P. Healey
Vice President, Government and Public Affairs

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MARSHFIELD CLINIC

April 26, 2005

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Mark McClellan, MD, PH.D.
Administrator, Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1325-P
Room 445—G
Hubert Humphrey Bldg.
200 Independence Ave
Washington, DC 20201

RE: CMS-1325-P

Dear Dr. McClellan:

On behalf of Marshfield Clinic, a 740 physician, tertiary care, multi-specialty group practice, one of the largest comprehensive health care, research and education systems in the United States, I would like to offer our comments on the proposed rule regarding "Competitive Acquisition of Outpatient Drugs and Biologicals under Part B" as published in the *Federal Register* on March 4, 2005.

Before commenting specifically on the proposed rule I would like to briefly describe the circumstances of cancer care in the Marshfield Clinic service area. I am the chairperson of the twenty-physician medical oncology department at Marshfield Clinic. We serve a very large geographic area of rural Wisconsin. Our oncology physicians are located in six distinct locations and serve a total of ten communities with on-site consultation and chemotherapy services. Several of these sites are relatively low volume but provide considerable convenience for patients that would otherwise have to travel long distances for cancer treatment. The provision of quality oncology care in the outpatient setting, especially in the rural environment requires multiple levels of support, integrated healthcare management systems, and maximum use of information technologies. Supporting oncology programs in smaller, more patient accessible, regional hospitals in an economically viable fashion requires an extensive support system.

Marshfield Clinic's internal analysis of Provisions of this rule yields the following observations:

Overview of the CAP

While we hope that the Competitive Acquisition Program (CAP) will eliminate the financial burden on physicians by providing an alternative means for physicians and group practices to obtain Part B Drugs, we do not expect to participate in the CAP, because we are concerned that such a novel program will not begin to address the needs of comprehensive oncology practices in remote rural areas until some time after the implementation of the program in more densely populated areas. As a conservative medical practice, Marshfield Clinic will wait until the program has demonstrated its viability and reliability before we subject patients to untested and uncertain processes.

We are concerned that a CAP vendor serving a rural area will not rise to the challenge of enabling adjustment to treatment plans on short-term notice, or the needs of treatment without interruption in rural areas without compromising the quality, safety, and efficiency of treatment provided to patients. Treatment interruptions or inadequate service may potentially expose patients to serious medical complications and will impose higher costs due to the necessity of repeat patient visits and potentially increased emergency hospitalizations.

We are also concerned about the potential for uncertain and unsystematic supply-chain processes to increase waste of the drugs acquired, but more importantly, the risk of medication errors by interfering with clinical controls and the communication processes that currently enable physicians, nurses, pharmacists, and technicians to ensure the safety of drugs administered under their direction.

Categories of Drugs to be Included Under the CAP

We recommend that CMS implement Option 3 - the CAP program should be implemented for all Part B drugs furnished incident to a physician's service regardless of specialty. If CMS were to focus the CAP narrowly on oncology drugs alone, all multi-specialty systems of care would have to maintain potentially redundant, costly, and administratively complex systems for the acquisition of drugs furnished by other specialties.

We support provisions that will enable maximum flexibility in the acquisition of high cost drugs under the CAP, as well as the open commercial market for drugs. If a vendor does not offer the complete range of drugs currently utilized, and a physician is required to obtain all of the drugs that he would prescribe or furnish to a patient from the CAP vendor then the patient's treatment options may be compromised. This is an unacceptable outcome.

If a vendor's supply does not include a medically justified treatment option, then the physician would have to resort to "dispense as written" coding specificity within the ASP program incurring additional cost.

If the treating physician has multiple options for the acquisition of drugs, competition among vendors should hold costs down. Provisions to enable the acquisition of drugs from multiple vendors may result in savings to the beneficiary and program. We recommend that physicians and group practices should be allowed to choose the categories of drugs they wish to obtain from the vendor.

Claims Processing Overview

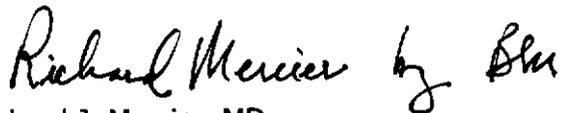
While we believe that the CAP program should be implemented for all Part B drugs furnished incident to a physician's service regardless of specialty, we recommend that CMS not require physicians who participate in the CAP to obtain all categories of drugs from the particular vendor with whom the physician contracts. We believe that the physician or group practice should be allowed to choose the categories of drugs he wishes to obtain from the vendor to assure a competitive selection of drugs that might be provided on a timely basis.

Marshfield Clinic has a comprehensive electronic medical record that includes a complete patient history, problems, vitals, alerts, prevention reminders, appointments, and point of Care decision support including prescriptions and medications. We believe that requiring CAP participating physicians to maintain individual, patient specific inventories of CAP acquired drugs

will increase our costs and make delivery of these therapies to our patients more administratively complex. In addition to the necessity of either maintaining separate physical storage, or maintaining separate electronic or paper inventory for each CAP drug obtained, participating physicians will need to continue with their current supply sources for the drugs they administer to their patients who are covered by commercial insurance, further adding to the administrative complexity.

We appreciate your consideration of our views on these issues.

Sincerely,

Handwritten signature of Richard J. Mercier in cursive script.

Richard J. Mercier, MD
Oncologist/Hematologist

Cc: Frederic P. Westbrook, M.D., President
Reed Hall, Executive Director
Brent Miller, Federal Government Relations Director
Gary Plank, System Director, Pharmacy Services
Donna Andrew, Director, Patient Financial Services,
Don Clark, Director, Clinic reimbursement

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April 26, 2005

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VIA HAND DELIVERY

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

**Re: CMS-1325-P: Medicare Program: Competitive Acquisition of
Outpatient Drugs and Biologicals Under Part B**

Dear Dr. McClellan:

Biogen Idec appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule implementing the competitive acquisition program (CAP) for outpatient drugs and biologicals contained in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). We are a global leader in biotechnology with headquarters in Cambridge, Massachusetts and centers of excellence in San Diego, California and Cambridge. Our significant investment in research and development enable discovery of novel and breakthrough therapies to achieve new standards of care in oncology, neurology, dermatology and rheumatology.

Biogen Idec's products are infused or injected in a variety of settings, including the physician's office. Biogen Idec is hopeful that the CAP will fulfill its removing barriers to beneficiary access by providing an alternative to physician purchase of injected and infused therapies. The drug payment reform provisions of the MMA, including the CAP, appear designed to move CMS closer to its private payor counterparts with respect to acquisition and payment for outpatient drugs and biologicals. We urge CMS to recognize the essential differences between Medicare's elderly and disabled population and that of the private insurance sector that warrant programmatic protections against a market-driven approach to therapeutic choices. Our comments focus on supporting CMS in its efforts toward developing a workable alternative for physicians treating Medicare beneficiaries that enables rather than impedes patient access to the full range of therapies necessary to treat this comparatively fragile and vulnerable patient population.

As further detailed below, Biogen Idec's recommendations include that CMS:

- Permit physicians in any specialty to acquire drugs listed in any category(ies) designated for 2006 phase-in;

- Set initial vendor payment at ASP+6 for drugs and biologicals offered to physicians, but not included in the 2006 bids;
- Require that vendors offer all Part B products within each category; the requirement that at least one drug per HCPCS code be offered is a minimal protection applicable to multiple source products and should not be implemented to restrict access to biologicals or single source drugs;
- Remain flexible with respect to geographic areas that comprise a “region” during phase-in of CAP so that vendors can bid on geographic areas ranging from single-state to national;
- Devise final geographic areas for CAP region purposes that coincide with the geographic regions for Part A and B contractors after contractor reform so that the Part B contractor processing the physician administration claim also processes the vendor drug claim;
- Set initial geographic areas at the State level to accommodate later incorporation into multiple state geographic areas;
- Enable contractual arrangements between CAP vendors and providers that permit providers to minimize paperwork burden and vendors to minimize risk.
- Utilize the phase-in period to assess the need to mitigate risk to CAP vendors of supplying drugs and biologicals for which claims are denied.
- Recognize the lack of program integrity concerns with respect to physician restocking of inventory under CAP and define “emergency” for inventory restocking purposes in a manner that enables physicians to administer necessary therapies to Medicare beneficiaries without undue scrutiny on whether the order preceded administration;
- Ensure that the CAP clerical and inventory burden on physicians is minimal;
- Facilitate meaningful appeals of claim denials by permitting physicians to aggregate the dollar amount in controversy of the administration with that of the supplied drug or biological;
- Provide for partial payments to CAP vendors. The waiver of beneficiary liability for copayment on denied drug claims to CAP vendors strongly supports partial payment to CAP vendors of no less than 20% of the drug payment amount.

Biogen Idec shares CMS’ hope that the CAP will offer a viable option for physicians administering injected and infused therapies to Medicare beneficiaries. We recognize the complexities CMS encounters as it implements MMA reform of drug payment mechanisms and claims processing contractors while initiating the new prescription drug benefit and continuing its efforts to improve claims processing accuracy. The convergence of these reforms represents a far more challenging landscape than would be present with implementing each MMA provision in isolation. Biogen Idec’s comments reflect its efforts to evaluate the proposed rule in the context of overall programmatic reforms. Biogen Idec is also aware of the significant changes that CAP represents to physicians prescribing its products and incorporates concerns voiced by providers contemplating CAP participation.

1. Categories of Drugs to be Included Under the CAP

A. Categories of Drugs To Be Included Under the CAP

CMS presented several options for phasing-in the CAP, including initial implementation of drugs typically administered by oncologists and drugs typical administered by physician specialties that use Part B drugs less frequently. The agency's discussion of its various options illuminated potentially opposing considerations in implementing CAP: the CAP vendor interest in ensuring a hearty physician market for included therapies, and the Medicare program's interest in maximizing potential savings on the one hand; and the benefit of gradual phase-in to identify operational issues, as well as the interest of low-volume injection and infusion specialties in an alternative to procuring expensive therapies on the other.

Biogen Idec expects that many providers are eager for an alternative to the traditional buy and bill requirements for drugs administered incident to a physician's service. Unfortunately, we are also concerned that the initial implementation of the CAP may present clerical and administrative burdens and programmatic difficulties that providers, vendors, and CMS do not fully anticipate. Congress provided for CAP phase-in to enable resolution of these problems prior to full CAP implementation. Biogen Idec recommends that CMS design a CAP phase-in that maintains an even reimbursement landscape within each geographic area (i.e., within each State). Specifically, we recommend that CMS:

- Permit any specialty to elect CAP vendor procurement for the phased-in category or categories;
- Permit physicians to elect between the CAP and payment under Section 1847A of the Social Security Act for each category of competitively biddable drugs, and to choose a vendor on a category-specific basis. Requiring physicians to choose CAP for all products or none does not facilitate programmatic simplicity (contractors must determine that the administering physician made a valid election with respect to each vendor submitting a drug claim), and likely will serve only to limit CAP participation, particularly in the program's early years;
- Enable CAP vendors to respond to provider requests for inclusion of additional products. While the CMS bid for CAP vendor participation would be limited to the listed products, CAP vendors should be encouraged to offer additional products to providers with payment for those products initially set at 106% of the product's ASP for each quarter.
 - CAP vendors will be able to benefit from inclusion of a wide array of products
 - Annual submission by CAP vendor of acquisition costs for any additional products will assist CMS in evaluating bids for these products for future years;
 - Physicians will benefit from utilizing a CAP vendor for most or all physician administered products regardless of specialty;

- This approach will permit CMS to realize increased savings from CAP in future years as non-oncology specialties develop early, positive experiences with CAP

Again, Biogen Idec is acutely aware that physician purchase of therapies can be a significant hurdle to beneficiary access, and expects that CAP will be an important option for physicians. We recognize that to the extent that the CAP program would save Medicare dollars, initial inclusion of oncology products may be desirable. From a patient access and ease of implementation standpoint, however, we expect that an initial focus on non-oncology products may be beneficial. In reviewing the proposed rule, Biogen Idec notes that the list of drugs and biologics most commonly used by oncologists contains several products that are not generally considered anti-cancer therapies. That these products are so frequently administered by oncologists underscores the significant hurdle to beneficiary access arising from Medicare's requirement that physicians purchase and bill for administered therapies. Physicians in non-oncology specialties may be more likely to choose CAP as they have not incorporated the purchase, administration, and billing of drugs and biologicals into their medical practice. As the list of "oncology" drugs illustrates, Medicare beneficiaries with chronic medical conditions requiring injected and infused therapies have frequently had to rely on one provider for prescribing and managing therapies, while another provider (often an oncologist) handled drug administration services. This fragmented care is inefficient from a patient care perspective, increases the number and cost of office visits, and raises the potential for poor compliance, ineffective management of side effects, and lower level of patient satisfaction with medical care. Biogen Idec similarly suggests that, should CMS elect to identify oncology products as its initial CAP category, excluding from initial CAP implementation the listed products that are not generally considered anti-cancer therapies would severely limit non-oncology patient access to providers willing and able to administer necessary therapies. Oncologists for whom CAP is a welcome alternative may cease offering products for which traditional "buy and bill" is required. Similarly, limiting CAP participation to oncologists (or to any other specialty selected for category identification) would perpetuate the inability of beneficiaries with chronic care needs to receive treatment from the physician managing their care plan. It is, therefore, essential that regardless of the specialty or specialties driving category designation, all physicians should have the opportunity to elect CAP participation for any included category

Biogen Idec also remains concerned that many important therapies that may be utilized by physicians prescribing the listed products, as well as by other specialties that would benefit from early CAP inclusion, may not be available under the initial CAP phase-in. For example, Biogen Idec's AMEVIVE is generally administered by dermatologists. The relatively low volume of injections by this specialty does not appear to support initial CAP inclusion from a Medicare savings perspective. While it may not be essential that products such as AMEVIVE be listed as required vendor products, we urge CMS to place patient access paramount in permitting vendor flexibility to implement post-bid inclusion of these relatively low-volume products that will likely remain outside the initial bidding category. Inclusion of these additional products with a payment to vendors equal to the 106% of ASP allowed for physician-purchased therapies would treat these

products on par with new products included in the program and will not impact Medicare's savings from CAP. CMS would receive an incidental benefit from this flexibility in the form of additional data on acquisition cost of a greater breadth of products that would further guide CAP implementation.

b. Preserving Physician Autonomy in Medical Decisions

The success of the CAP in reducing Medicare expenditures for Part B drugs and biologicals will be largely dependent upon its ability to gain and maintain participation from quality vendors, to garner widespread physician acceptance, and to ensure patient access to required therapies. Physicians express a concern that their medical decisions will be reviewed by CAP vendors, and that the CAP option may interfere with their ability to administer all Part B covered products. It is, therefore, essential that CAP include sufficient breadth of products to accommodate the complex medical decisions often required for Medicare's elderly and disabled population. CMS notes in the Proposed Rule that Social Security Act (SSA) section 1847B(b)(1) requires prospective CAP vendors to bid on "at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area" for multiple source drugs¹. Put simply, the MMA sets forth minimal protection to Part B access for multiple source drugs by requiring each CAP vendor to offer at least one drug or biological within each HCPCS code within each CAP category for multiple source products. Biogen Idec urges CMS to recognize that Congress intended this provision as a protection to beneficiary access to multiple source products, and did not intend that it be utilized to constrict CAP inclusion of biologicals and single source drugs.

Similarly, at enactment of the MMA, the HCPCS process was conducted through a non-governmental HCPCS Committee comprised by representatives of CMS and private insurance entities making consensus-based determinations. While the current HCPCS process envisions CMS as decision maker with public input through open meetings, the basis for future HCPCS decisions to grant or decline to grant codes for drugs and biologicals is not clear. Biogen Idec urges CMS to ensure that this newly revised HCPCS process does not present unintended consequences for availability of new drugs and biologicals under CAP.

Biogen Idec requests that CMS clarify that the HCPCS-driven inclusion criteria set up minimal requirements related to multiple source drugs. The CAP program was, however, intended to serve as a means for physicians to acquire the full range of Part B covered products. We ask that CMS clarify that vendors must offer all biologicals and single source drugs within a category regardless of whether or not the products share a HCPCS code. Similarly, while CAP vendors may wish to create formularies similar to those permitted under Part D, the MMA does not allow CMS to approve bids from vendors that exclude covered Part B drugs within a category. Congress clearly intended that CAP offer the full complement of therapeutic options contained under Part B, and that a

¹ 70 Fed. Reg. at 10751.

particular beneficiary's medical care not be influenced by whether or not their physician elects CAP, or the physician's choice of vendor.

2. **Competitive Acquisition Areas (Definition of Competitive Acquisition Areas)**

As noted previously, the convergence of CAP implementation and impending contractor reform greatly complicates CMS' decision on appropriate competitive acquisition geographic areas. Ideally, the CAP would be designed so that vendors and physicians submit claims for drugs and administration services to the same local contractor. This would simplify matching administration and drug claims, streamline appeals, and facilitate predictability with respect to local coverage decisions and other claims processing edits. Current contractor jurisdictions are not sufficiently geographic in nature to act as a template for competitive bidding, e.g., FirstCoast Service Options covers Florida and Connecticut. NHIC's jurisdiction encompasses California and parts of New England.

Biogen Idec understands that contractor reform is currently awaiting implementation, with a potential for 2008 completion. Biogen Idec supports CMS' decision to designate a single carrier for vendor claims processing during the 2006 phase-in. We urge CMS to move toward Part B carrier processing of both physician administration and vendor claims upon contractor reform completion, and suggest that final competitive acquisition areas coincide with regional contractor jurisdiction.

Biogen Idec recognizes that CMS wishes to encourage participation from smaller vendors while avoiding the burden to national vendors of submitting multiple bids. As the agency noted, licensing for specialty pharmacies and vendors operates on a State by State basis. Biogen Idec, therefore, recommends that CMS define CAP areas based upon State boundaries in the initial years of CAP implementation. As the agency implements contractor reform in each of the 15 geographic regions, it can evaluate whether or not to create multiple state regions that coincide with the Part A and B contractor jurisdictions. In any event, Biogen Idec urges CMS to move toward a system through which the Part B contractor processing the physician administration claim also processes the vendor drug claim.

Finally, Biogen Idec recognizes that a CAP phase-in limited to specified geographic areas may be the agency's best option. We suggest that if CMS determines to phase-in CAP in this manner, it should ensure that the initial sample includes both urban and rural areas.

3. **Operational Aspects of the CAP**

Biogen Idec supports CMS in its assertion that it does not intend to restrict physician flexibility in ordering CAP drugs or to impose requirements on physicians for CAP vendor drugs that do not exist for non-CAP vendor drugs. Biogen Idec has received numerous comments from oncologists in particular regarding the administrative difficulties inherent in the CAP proposed rule. For example, in approximately 40% of oncology patients, the intervening time between the office visit during which a chemotherapy course is prescribed and the administration date results in a change in

therapy. Oncologists likely will be discouraged from participating in CAP, or experience frustration and dissatisfaction with the program, if it is not implemented in a manner that permits physicians to respond to changing patient needs with timely therapeutic changes. We urge CMS to recognize the lack of program integrity concerns with respect to physician restocking of inventory through vendor purchases under CAP. From a CMS operational perspective, the requirements of CAP should be satisfied when an electing physician administers an included drug to a beneficiary.

While the MMA language envisions restocking in “emergency” situations, there does not appear to be a programmatic justification for a burdensome and costly review over whether or not a particular situation justified physician use of inventory product rather than advance ordering from the CAP vendor. Similarly, it is unlikely that denial of vendor claims for medically necessary therapies due to application of an emergency standard would further the interests of the vendor, beneficiary, provider, or the Medicare program. The operational requirement that final payment on vendor drug claims are not made until the physician administration claim is processed should act as a sufficient safeguard against any concerns arising from physician use of inventory product. Any regulatory standard that limits physician restocking of inventory will inject uncertainty for providers and vendors, and discourage participation in the CAP. We urge CMS to permit providers and vendors to determine the mechanical processes that work for offered products, as these contracting parties are in the best position to fashion relationships that respond to provider practice realities while mitigating vendor risk. Specifically, Biogen Idec, recommends that CMS presume that an emergency situation exists if a provider chooses to utilize inventory product and restock through a CAP vendor, so long as the prescription number or other required identifier appears on both the administration and drug claim.

4. Claims Processing Overview

Biogen Idec commends CMS on its decision to permit physicians to write a prescription for a therapeutic course rather than for each administration. A workable CAP must not create a burden for physicians beyond that contained with current buy and bill processes. We are concerned, however, that many of the claims processing requirements may present obstacles for providers. Specifically, Biogen Idec understands that many physicians may not currently have the software necessary to include a prescription number on the drug administration claim. We urge CMS to permit vendors to supply the software necessary for exchange of information between vendor and provider, and to fulfill any special requirements for claims submission. Given the substantial governmental interest in ensuring a successful CAP, any software or other assistance from the CAP vendor should not be deemed to have “value” that would trigger an anti-kickback inquiry.

Biogen Idec also notes that CMS will require providers to place the drug HCPCS code on the claim. While it appears that the prescription number will incorporate the HCPCS code, this should be clarified. We assume that CMS will not require physicians to include a line for the drug’s HCPCS code on the claim, as that information will be present in the prescription number. Clearly, vendor consistency in assigning prescription

numbers will be necessary so that the HCPCS code is contained in a specific set of digits within the prescription number on claims and carriers can utilize electronic claims processing.

For the reasons stated above under the heading "Operational Aspects of the CAP," Biogen Idec strongly recommends that CMS not create differential claims processing scrutiny over inventory replacement orders. Post-payment review of claims solely to determine whether or not a specific situation satisfied conditions for emergency drug replacement creates unnecessary programmatic costs that are not justified by a compelling program integrity interest; inclusion of the vendor prescription number on both the administration and drug claim should be a sufficient safeguard.

a. **Claim Denials**

Biogen Idec is concerned that the shift in risk for denied drug claims from the treating physician to the CAP vendor may have an unintended impact on the Medicare program and coverage for drugs and biologicals. The similarity between a CAP vendor and entities such as reference laboratories is striking. In the 1990's, the diagnostic laboratory industry strongly objected to the risk its members incurred in performing tests without knowledge of the beneficiary or the medical documentation supporting medical necessity. Reference laboratories were dissatisfied with physician cooperation in appealing denied claims and in providing medical necessity documentation supporting a laboratory's claim or appeal. While laboratories generally requested and received diagnosis codes that could be matched to local coverage policies, the regional and/or national nature of reference laboratories combined with variability in local written policies and unwritten claims processing edits drove Congressional pressure toward national coverage decisions. This pressure resulted in a set of National Coverage Decisions that were devised through a mandatory negotiated rulemaking process.

Biogen Idec expects that initial CAP implementation will appear relatively smooth. We suggest that CMS closely monitor vendor claim denials. While it may appear sensible to respond to vendor complaints by permitting vendors to decline to fill physician orders based upon LCDs, past denials, or perceived risk, this would cause a shift in therapeutic decision making from providers to vendors, and impel CAP vendors to seek ICD-9 specificity for each competitively biddable drug or biological to achieve uniformity and gain claims payment certainty. LCDs and NCDs can be useful tools for CMS and its contractors to respond to program integrity concerns. The changing standards of care inherent in physician prescribing patterns, however, mitigates against wholesale adoption of NCDs, or even LCDs generated solely to achieve claims processing certainty.

Impending contractor reform and CMS' increased use of Program Safeguard Contractors, including the CERT contractor and upcoming Recovery Audit Contractor demonstration present significant pressures on local contractors to ensure accurate claims processing. It is uncertain whether and to what extent provider claims for administration of CAP drugs will be subject to initial denial for additional documentation, or post-payment denial due to provider non-response to documentation requests or other factors that may not indicate that a CAP drug is not medically necessary. Biogen Idec, therefore, urges CMS to utilize

the phase-in period to monitor vendor claim denials, including post-payment denials. We suggest that any revisions to CAP to mitigate vendor risk be made through a proposed rule with sufficient opportunity for notice and comment from all stakeholders.

a. **Partial Payment**

Biogen Idec supports CMS in devising an appropriate partial payment to CAP vendors. We note that the proposed rule waives beneficiary liability for drug copayments when the claim is denied. Given this waiver of liability, it is appropriate for the designated contractor (or other entity processing CAP vendor claims) to make a partial payment that is no less than the 20% copayment that would be made by the beneficiary. This level of partial payment would not create CAP vendor liability to the claims processing contractor in the event a claim is denied. CMS has historically permitted providers and suppliers to mitigate and distribute risk through contracting mechanisms. CMS should permit CAP vendors to contract with providers in a manner that enables recovery or other accounting mechanisms for product shipped to providers but not administered to a beneficiary.

6. **Implementation of the CAP**

Biogen Idec urges CMS to enable contracting flexibility between CAP vendors and providers that may increase the financial benefit of program participation for vendors and reduce the paperwork burden of participating physicians. For example, physicians commonly procure billing services to eliminate the need to employ additional office staff for claims submission. Provider/vendor relationships that, for example, enable CAP vendors to submit drug administration claims on behalf of physicians would remove this burden from physicians and permit a level of comfort with the vendor that the claim is actually submitted. As billing agent, the vendor would receive timely information in the event that the claim is suspended for medical documentation, or denied. Biogen Idec suggests that CMS explore the vendor/provider relationships that currently exist in the private sector assignment of benefits arrangements to identify aspects of those relationships that further beneficiary care and treatment persistency, alleviate burdens on providers and vendors, and otherwise enable these systems to flourish in the private insurance market.

The successful implementation of the CAP also requires the participation of quality vendors. Because timely and reliable delivery of drugs and biologicals is central to the CAP's operation, we recommend that CMS make bidders' distribution systems a priority in the agency's quality review. To help potential vendors understand the bidding process, we ask CMS to release the utilization data that will be used to form composite bids, and to provide guidance regarding bids for "not otherwise classified" drugs and the use of average sales price (ASP) data in setting CAP prices.

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

Biogen Idec recommends that CMS retain the MMA's utilization of a set of criteria for evaluating vendor bids, rather than to drive selection primarily through the comparison of composite bids. Particularly in its initial years, the CAP may benefit from CMS selection

of vendors with bids below a designated threshold, provided that the vendors with slightly higher bids offer additional customer service capabilities, greater flexibility in distribution, or other advantages.

The MMA requires that CMS identify a single payment amount for each drug in a competitive acquisition area. Biogen Idec understands that CMS is required to implement this provision, yet believe that the CAP may realize greater savings if this requirement were removed through the legislative process. Identification of a single payment amount for each product may discourage participation of vendors able to supply some products at significant discounts if other products cannot be procured and distributed at the single payment rate. The vendor's "bid" then becomes little more than an artificial number that is averaged against other bids but not binding on the vendor. If CMS contractor processes enable vendor-specific payment levels, Biogen Idec suggests that CMS seek a legislative change that permits it to choose vendors based upon composite bids and other factors, but retains the vendor specificity for drug payment at the bid level. We also urge CMS to assure CAP vendors that their proprietary acquisition cost data will remain confidential.

Finally, Biogen Idec suggests that CMS explore whether the CAP would realize greater savings if discounts to vendors were excluded from ASP calculations. If these discounts we will included in ASP calculations, we ask that CMS clarify that it will not utilize vendor bids or other vendor data in ASP calculations. Manufacturer reporting of discounts to all purchasers would incorporate discounts to CAP vendors who are either acquiring product directly from the manufacturer or from a distributor who purchases directly. Manufacturers do not generally exert final control over the price at which a distributor sells its product.

Conclusion

Biogen Idec appreciates the opportunity to comment on the CAP proposed rule. We welcome any questions or additional information that you may have, and look forward to working with you on implementation of this important MMA provision.

Sincerely,



David V. Foster
Vice President, Government Relations

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VIA HAND DELIVERY

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Re: File Code CMS-1325-P; Medicare Program; Medicare Competitive Acquisition of
Outpatient Drugs and Biologicals under Part B: Proposed Rule

Dear Administrator McClellan:

ImClone Systems Incorporated ("ImClone") is pleased to submit these comments in response to the proposed rule on the Competitive Acquisition of Outpatient Drugs and Biologicals under Part B ("Proposed Rule") that was published in the Federal Register on March 4, 2005. 70 Fed. Reg. 10745. ImClone is a biopharmaceutical company dedicated to developing breakthrough biologic medicines in the area of oncology. The Company has utilized the many advances made in the fields of molecular biology, oncology, genomics and antibody engineering to build a novel pipeline of product candidates designed to address specific genetic mechanisms involved in cancer growth and development. The Company's first approved product, Erbitux® (cetuximab), is indicated for the treatment of irinotecan refractory or intolerant metastatic colorectal cancer.

We appreciate the magnitude of the task that the Agency faces in implementing the Competitive Acquisition Program (the "CAP"), and we thank the Centers for Medicare and Medicaid Services ("CMS") for its efforts to implement the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("the MMA"). After carefully reviewing the Proposed Rule and evaluating its implications, we urge CMS to make the following adjustments or clarifications to the Proposed Rule that, we believe, are absolutely critical to the successful implementation of CAP:

1. implement the CAP on a nationwide basis, regardless of how CMS defines geographic areas for bidding or other purposes;

2. introduce the CAP immediately for all specialties so that as many drugs as possible are eligible for CAP bidding or, alternatively, begin implementation with oncology drugs and take all steps necessary to ensure that all oncology drugs are available immediately, regardless of the specialty providing the underlying service; and
3. permit individual physicians practicing in groups to elect whether to participate in the CAP on an individual basis, as group practitioners may come to different conclusions as to how they may best ensure access to necessary drug therapies.

The CAP provides an alternative to the evolving, physician-based average sales price ("ASP") reimbursement methodology. As discussed more fully below, if Medicare beneficiaries are to have access to the full complement of covered outpatient Part B drugs under the new CAP structure, it is imperative that at the outset the CAP be implemented on as broad a basis as possible. This necessity is underscored by the concerns articulated by members of the oncology community that the ASP methodology is not sufficient to cover the costs of providing access to important drug therapies designed and implemented appropriately, CAP represents an opportunity to begin to address these concerns and to help ensure that access is maintained to drug therapies that are absolutely critical to the health of millions of Americans. Unless CMS implements our suggested clarifications and modifications to its proposal, we fear that geographic or clinical segments of the beneficiary population for whom the ASP system is an inadequate option to ensure access will inevitably suffer.

1. Geographic Implementation

CMS should immediately implement the CAP for all geographic areas, without regard to how CMS chooses to divide the country for bidding purposes. The purpose of CAP is to provide an alternative to ASP, so that, in all those communities where physicians are uncertain as to whether they can continue to provide access to drug therapies under ASP, patients will still be ensured access to all Part B drugs. This objective cannot be achieved if CMS does not uniformly implement the CAP across all regions of the country.

The ASP methodology went into effect January 1, 2005. Given the concerns of many physicians that they cannot continue to provide some or all drug therapies under the ASP system, it is important that CMS implement the program as broadly as possible. Delay in implementing the CAP for some communities will risk that patients in those communities will be denied access to needed services. Rural and less densely populated communities, those communities for whom CMS may be tempted to delay implementation of CAP, are the ones that are most in need of the program. Providers in smaller communities, where access was a concern even before the issues created by

the ASP system, are less likely to have the numbers of patients and the economies of scale necessary to be able to provide access to services under an ASP methodology.

We empathize with CMS's concern regarding the logistical issues raised by a nationwide implementation of the CAP, but the nature of the CAP and the critical importance of preserving access to drug therapies mandates that the program be put in place everywhere, as soon as possible.

For purposes of soliciting bids and administering the CAP, CMS may find that it is most appropriate to designate regions. We have no objection to this delineation of geographic areas for financial and administrative purposes. Our concern is simply that, regardless of what geographic segmentation may be best from CMS' perspective, from these perspectives, a nationwide implementation is the only means of assuring uniform beneficiary access to the drugs covered by the CAP, as Congress envisioned. As the Proposed Rule makes clear, CAP is, at its core, an access program, not a cost saving program. Because access is the primary concern, CMS should not discriminate against any community in implementing this badly needed alternative to support the delivery of appropriate and necessary drug therapies.

2. **Designation of Specialties and Categories of Biddable Drugs.**

We also believe that it is critically important for CMS to immediately designate as many physician-administered Part B drugs as possible for inclusion in the CAP. Thus, as part of the initial implementation, CMS should designate categories of drugs covering all drugs and all physician specialties. In the alternative, to the extent that this is not possible, we very much support CMS's proposal to begin with oncology drugs, and we urge CMS to ensure that, in proceeding with oncology drugs, it ensures that all oncology drugs used by all specialties that treat cancer be made immediately available.

We believe that the immediate implementation of the CAP to all drug therapies to be covered by the CAP is the best and the most correct policy for CMS to pursue in order to ensure the access that Congress intended. While we understand CMS does not have any intention to undertake the CAP in any fashion that would work harm to a beneficiary, a phased-in implementation would, as a practical matter, yield disparate benefits for beneficiaries with different clinical needs.

Given the fundamental reluctance of many physicians to participate in the ASP system, delay in designating a drug that is subject to the CAP has the potential to deny beneficiaries access to that drug. If physicians are unable to furnish a drug under the ASP methodology (which is a working assumption of the CAP), and CMS does not include a drug within the CAP, beneficiary access to that drug will, we fear, be severely curtailed. Accordingly, if the CAP is to meet its objectives, CMS should designate as many drugs and categories of drugs as possible for CAP bidding as soon as possible.

used." For the reasons outlined above, we ask that CMS expressly confirm this position in the final rule.

3. Physician Election to Participate in CAP.

The CAP is designed to preserve beneficiary access and promote competition. The proposed rules should be clarified to preserve access and maximize competition by making it easier for physicians to make elections whether to participate in the CAP on an individual basis, or alternatively based on a specialty-by-specialty basis.

As the Proposed Rule is currently written, a group practice that uses a group UPIN to bill Medicare will be required to make an election whether to participate in the CAP that will bind all physicians within that group. While we understand that this approach has its administrative advantages, CAP is supposed to ensure access, and that purpose must be the primary focus for the development of the CAP. Different physicians prefer to use different drugs, even within the same specialty, and – as the Proposed Rule acknowledges -- different specialties use entirely different ranges of drugs. Given the different costs and reimbursements associated with different physicians and specialties, even those practicing together in group practices, if the CAP is going to maximize flexibility for physicians in order to maximize access for beneficiaries, CMS should permit physicians to make the CAP election on an individual basis. More choice for physicians will increase competition and will provide greater potential for patient access.

As the Proposed rule repeatedly makes explicit, the CAP is a voluntary program in which a physician may elect to participate. A physician's election whether to participate has a dramatic effect on that physician's patients, which a physician must consider in deciding whether to participate. Taking the decision whether to participate out of the physician's hands and placing it with the group practice as a whole would distance these patient considerations from the CAP decision.

At a minimum, if CMS is going to institute an effective CAP, it must give physicians the flexibility to make elections on a specialty-by-specialty basis. While the presence of multiple specialties within a group does not impact billing for physician services, it most certainly will affect the desirability of CAP participation.

Because of the very different cost and reimbursement limits faced by different specialties, one specialty in a multi-specialty group might wish to participate in the CAP because of the financial burdens imposed when they "buy and bill" for drugs. Another specialty, that uses a narrower range of drug therapies, however, and, therefore, feels less exposure under the "buy and bill" approach, may be concerned about liability and delivery timing issues associated with the CAP such that they would want to proceed under the ASP methodology. Since Congress made clear that CAP was supposed to increase the options available to physicians in order to encourage and support access

Mark McClellan, MD, PhD

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to drug therapies, we believe that the flexibility that we seek is compelled by the underlying Congressional intent.

The potential for an outcome that is inconsistent with the Congressional intent under CMS's current proposal is clear. Assuming a group consists of four specialties, it would be required to elect whether to participate in the CAP on the basis of the first specialty (i.e., drug category) designated by CMS. It might elect not to participate, only to regret that decision when the next three drug categories are designated at some subsequent point.

A rule that creates these conflicts and requires physicians to make a decision whether to participate in the CAP on the basis of factors external to their particular practice will not promote patient access or competition. Moreover, requiring the CAP election to be made at the group level may have the unintended consequence of creating an incentive for multi-specialty groups to splinter into separate practices, which, though they would be free to make unencumbered CAP decisions, would not provide the integrated care that is in the best interests of patients.

These considerations affect not only physicians, but also Medicare beneficiaries. Patients may be unnecessarily inconvenienced, faced with decisions whether to change doctors, or, worse yet, unnecessarily denied access to Part B drugs, unless our suggestions are adopted. Accordingly, we request that CMS revise the proposed rule to permit physicians within a group practice to elect whether to participate in the CAP on an individual basis, or, at a minimum, a specialty-by-specialty basis.

* * *

Thank you again for the opportunity to participate in the development of these new and important rules. We hope that our comments will assist CMS in crafting final rules that will result in the successful implementation of the CAP.

Sincerely,



Eric K. Rowinsky, MD
SVP & Chief Medical Officer

cc: Leslie Norwalk (CMS)

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RE: CMS-1325-P (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B)

Dear Administrator McClellan:

Amgen appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule regarding the competitive acquisition of outpatient drugs and biologicals under Part B, published in the Federal Register on March 4, 2005 (the Proposed Rule).¹ As a science-based, patient driven company, Amgen is interested in improving access to innovative drugs and biologicals for Medicare beneficiaries. Amgen is committed to supporting programs that achieve the mutual objectives of providing patients with broad access to important medications, maintaining physician decision making authority and providing physicians who are disadvantaged under the new Average Sales Price (ASP) payment system, an alternative method to obtain and to provide drugs and biologicals to patients.

We believe that Medicare payment policy must be designed to assure that patients' access to quality care and services is preserved. The Competitive Acquisition Program (CAP) must ensure Medicare beneficiaries continue to receive drug and biological therapy with products covered under Medicare Part B. In particular oncology patients, an especially vulnerable segment of Medicare beneficiaries, should retain access to necessary treatment. Medicare patients require broad access to the highest quality care and a wide range of biologic therapy. The CAP must be developed to minimize patients' access risks and maximize physicians' opportunities to provide individualized, medically appropriate treatment to patients.

As CMS reviews comments and moves to implement the CAP for Part B drugs and biologicals, Amgen urges CMS to weigh the full range of potential consequences to patient care, especially in

¹ 70 Fed. Reg. 10746 (March 4, 2005).

the oncology setting. Amgen submits comments and recommendations in the interest of ensuring that CMS implements the statute with a priority on the following objectives:

1. The statute should be implemented with safeguards that preserve the physician's prescribing authority. The financial goals of the competitive acquisition vendors should not outweigh the clinical decision-making authority of a physician.
2. Any reform should not disrupt Medicare beneficiaries' access to the most effective and highest quality health care that our system has to offer.
3. The CAP should maintain a primary focus on access to quality of care rather than a focus on cost-containment goals
4. The CAP should not change the foundation of the Medicare Part B system. Patients whose physicians have enrolled in the CAP should not have access to a different set of sole source drugs than those whose physicians do not participate in CAP.

Amgen recognizes that the goal of Section 1847B of the Social Security Act (Competitive Acquisition of Outpatient Drugs and Biologicals) is to provide physicians, who may be disadvantaged by the ASP payment system, another option to acquire drugs and biologicals. We understand also that CMS believes the CAP could allow the government to realize savings from operational efficiencies. However, we are concerned that if not implemented cautiously and appropriately, patients may lose access and CMS may not realize the expected operational savings.

The changes mandated by section 1847B should be executed by CMS with care. Neither physicians, nor CMS and potential vendors will understand fully the actual impact of these changes until after the CAP is implemented. Although a competitive acquisition program was tested in a demonstration project, the scope of the project was limited in geographic area and to certain durable medical equipment products. Hence, CMS has never implemented fully a CAP system. The proposed system has not been tested with drugs and biologics that require special handling due to stability and sterility concerns. In addition, the newly designed and untested claims processing methodology for CAP could cause significant challenges and additional costs for all involved parties – including CMS regional offices, local Medicare Carriers and the Designated Carrier. Patient care could suffer as an unintended consequence of CMS not proceeding cautiously with the implementation of CAP.

Our greatest concern is that the insertion of an intermediary into the prescribing/treatment/payment continuum not be done in a way that interferes with physicians' ability to prescribe and to administer the drug or biological deemed the most medically appropriate for each individual patient. Therefore, CMS must ensure CAP vendors have no incentive and no regulatory pathway by which they can restrict, limit or change a physician's or patient's access to specific drug and biological therapy. The current design of the Part B system allows physicians to have unrestricted access to Medicare covered products when prescribed for medically appropriate reasons. We believe that Congress was clear in its intention to maintain the physicians' ability to prescribe and administer the products they deem most appropriate for individual beneficiaries and we recommend that the Final Rule contain an explicit statement to this effect.

Physicians likely to enroll in the CAP are those unable to purchase Medicare Part B products at or below the quarterly ASP reimbursement rate (e.g., smaller, low-volume providers, many of whom are located in rural areas). These physicians may find it difficult to sustain a financially

viable medical practice under the Part B buy-and-bill model². CAP may be the only viable option by which these physicians may treat Medicare beneficiaries. If the CAP is not implemented with due diligence, some physicians and their patients will have limited options for obtaining access to the Medicare program. We know this is not CMS's intention.

With these critical patient access and physician choice issues as a priority, below we provide recommendations for modifications to the Proposed Rule. Amgen is committed to working with CMS and the medical community to ensure the statute is implemented in a manner consistent with these objectives. We believe CAP, if implemented carefully, can provide an important, new delivery model for Medicare Part B.

SPECIFIC RECOMMENDATIONS

Categories of Drugs to be Included under the CAP

- The CAP initially should include all physician office Part B drugs, for the reasons set out by CMS in the discussion of this option in the preamble of the Proposed Rule. In the preamble, CMS is very clear that vendors would be required to submit bids on all of the HCPCS codes in a category (e.g., all drugs typically administered by oncologists or, as we recommend, all physician-administered drugs) CMS should include this language in the final regulation itself.
- The Final Rule should provide a transparent rationale for how category selection and HCPCS assignment to categories will be performed. The categories themselves or the drugs assigned to a category should not create an actual or a de facto formulary.

The preamble to the Proposed Rule includes a detailed discussion of the statutory provisions defining CMS authority in implementing CAP. Amgen agrees with the agency's interpretation of the statute, including the following key elements:

"Competitively billable drug" should be defined to mean a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Social Security Act. This is the definition in proposed regulation section 414.902, and it should be finalized as proposed.³

Vendors should not be allowed to submit bids on only some of the HCPCS codes in a category of competitively billable drugs.⁴ As discussed below, we believe the statute requires this interpretation, and we urge CMS to include it in the language of the final regulations.

CMS proposes several options for establishing categories and phasing in the CAP. Amgen believes that the simplest solution is to avoid the complexities of a phase in by having a single CAP category including all competitively billable drugs furnished incident to a physician's service. This would require vendors to bid on a wider array of products but would also give them a wider market and allow for more flexibility in designing their bids. As CMS points out in its discussion of this option, it would provide an alternative to all physicians who do not want to be in the drug

² Amgen uses the term "buy-and-bill" to denote the traditional Medicare Part B fee for service reimbursement model in which the provider acquires the product, administers it and receives reimbursement for the drug from CMS

³ 70 Fed. Reg. at 10770.

⁴ Id. at 10751.

purchasing business and would provide also more opportunity for realizing program savings than some other options.⁵

Regardless of the decision about phasing in this program, Amgen believes that it is absolutely essential that CMS hold firmly to its statement in the Proposed Rule preamble that vendors not be able to submit bids on only some of the HCPCS codes in the category. We urge CMS to reinforce this by changing the definition of "bid" in regulation section 414.902 to read as follows:

*"Bid means an offer to furnish each competitively biddable drug within a category of competitively biddable drugs in a competitive area for a particular price and time period."*⁶

Amgen reads the legislative history of the CAP provision of Medicare law as CMS does on this point. Within the HCPCS codes used to define a drug or biological for purposes of this program, there are often multiple National Drug Codes. In the case of multiple source drugs, these codes usually represent the products of different manufacturers. Section 1847B(b)(1) acknowledges this and supports competition by stating that "at least one" of multiple sources within each billing code be included in the competitive bid. The Conference Report accompanying this statutory provision is very clear:

*"The Secretary will conduct a competition among entities for the acquisition of at least one competitively biddable drug or biological that is a multiple source or a single source drug or biological within each billing and payment code within each category for each area. The competition within a HCPCS code for multiple source drugs is intended to produce competitive forces that will lower bid prices for drugs."*⁷

Amgen understands that some vendors are pressing CMS to allow them to create bid packages that would not include every billing and payment code within a category. CMS should continue to state its correct position that the Congress, in order to protect beneficiary access to care, did not intend that physicians using CAP would have access to a smaller number of sole source drugs than those who do not choose CAP.

Competitive Acquisition Areas

- CMS should implement small regions. We recommend state level regions. Additional considerations could include regions aligned to Medicare Part B Contractors or regions at the metropolitan statistical area (MSA). This provides more distributors and specialty pharmacies the ability to participate in CAP and provides CMS the flexibility, if necessary, to phase in the CAP program.
- CAP should be introduced as a pilot, and we believe that it should be phased-in by region. If CMS initiates the program using products that are not widely used across Part B or targets physician specialties that use fewer Part B drugs, CMS may not obtain an accurate understanding of the likelihood of success for a nationwide program that distributes a large number of Part B drugs.

⁵ Id at 10749.

⁶ Id. at 10769 (amended to replace "a" with "each").

⁷ H.R. Conf. Rep. No. 108-391, at p. 594.

Appropriately defining the geographic areas in which a contractor competes for contracts and services accounts could dictate the success of the CAP. We believe it is crucial that the size of the competitive acquisition regions is small for three reasons.

First, CMS may have a greater chance of obtaining more bids – and thus an increased likelihood of a more competitive reimbursement rate – if multiple vendors compete within a region. National regions or four regions would exclude smaller distributors such as specialty pharmacies. These organizations have the skills and resources needed to service small regions; however, they may not have the ability to provide product efficiently to physicians across the United States. CMS may not capture the savings these additional organizations may be able to extract in smaller marketplaces.

Second, distributors capable of providing drug across the United States may provide less prompt service to rural areas and urban areas with low population density. The additional costs a vendor may incur to deliver drugs and biologicals to providers in these geographical areas could be significant. If distributors' losses are greater than their profits, CMS may lose vendors in subsequent years. Ultimately, this would increase CMS's costs by having to source new vendors to meet the two vendors per area requirement. Smaller distributors may have developed processes by which they can deliver product in a timely, cost-effective way to these locations. Excluding smaller, more regional distributors from the bid process could have the unintended consequence of further disadvantaging providers that service geographically dispersed areas.

Third, smaller regions provide both large and small distributors the ability to assess their internal capabilities and bid on the number of regions they can appropriately service. Large distributors could submit the same bid for multiple regions. In addition, smaller regions may afford large distributors the opportunity to test the competitive acquisition distribution model and reimbursement systems on a smaller scale before servicing the entire country. Similarly, smaller distributors that may have believed originally the system too complicated to function efficiently (i.e., beyond their limited geographic region) may expand in subsequent years.

We believe that a competitive acquisition area based on single states may be the best option to ensure bid competition, preserve physician choice and provide optimal access to products and guarantee the most viable contractors obtain the competitive acquisition business.

CAP Bidding Process Evaluation and Selection

- The Final Rule should revise the proposed methodology for calculating bid weights for a HCPCS. CMS should utilize manufacturer reported sales data provided to CMS in conjunction with ASP reporting. These data are more timely than using utilization data.
- The Final Rule should also state that the 1.06ASP bid ceiling rate correlates to the ASP in effect for the quarter in which the bid is generated. Furthermore, the Final Rule should allow CAP payment rates to update quarterly and should require vendors to submit the net acquisition cost information on a quarterly basis. CMS should make every effort to ensure consistency across physician office Part B payment alternatives.
- The Final Rule should state that new products would be reimbursed at 1.06WAC until an ASP payment amount is established. At that time, the product would be reimbursed at 1.06ASP until the vendors submit net acquisition cost information and the CAP payment rates are updated.

The proposed "composite bid" would weigh each "HCPCS bid by the HCPCS code's share of volume (measured in HCPCS units) of drugs in a particular drug category during the prior year. Within each CAP category, the drug weights would sum to one."⁸ We are concerned that the Proposed Rule does not provide sufficient information on how CMS will determine the share of volume for a HCPCS within a category. The methodology must ensure that: i) no HCPCS is advantaged or disadvantaged because of its bid weight or category placement; ii) categories are not created to engineer formularies.

In the example provided by CMS in the Proposed Rule, the oncology category and the most commonly used HCPCS codes within the category were determined by obtaining data associated with Specialty Code 90. This methodology may have excluded products or provided an incorrect weight to certain HCPCS. For example, the additions of Specialty Code 83, Hematology/Oncology, and Specialty Code 98, Gynecological Oncology, may affect the list of drugs in the category.

Utilizing allowed services or allowed charges from the previous year to measure the HCPCS code's share of volume would not base weights on current information. Using the Part B Extract and Summary System 2003 data set for each of the products listed in the Proposed Rule, and weighting it by the allowed services data, one HCPCS code dominates the weighting at 45%. It would take the next 13 HCPCS codes, based on volume, to attain the same percentage. This example suggests that one manufacturer could significantly influence the CAP within a drug category.

Amgen reiterates that it is important for CMS to use consistent methodology and logic across all of Part B drug reimbursement. If the ASP is a key determinant for bids and selection in the CAP process, CMS must have a process that reflects the reality that ASP rates change quarterly. CAP vendors should not be financially advantaged or disadvantaged for three quarters because their bids could not be changed to reflect the current free market. The allowance for quarterly changes would not unduly burden the system with the integration of new products into a CAP category. Physicians participating in CAP should have access to these new products as soon as possible. CAP vendors may be hesitant to distribute new products if they are concerned that they will not have an accurate understanding of their costs for multiple quarters.

CONCLUSION

The implementation of a new payment system for Part B drugs is inherently a complex task, made more so by the implementation timeline and the additional pressures on vendors who may choose to negotiate Medicare Part D contracts as well. To ensure that beneficiaries treated by CAP providers receive individualized treatment, equal access to drugs and biologicals to other Part B beneficiaries, and high quality care, Amgen urges that CMS adopt the recommendations proposed and provide additional guidance on these issues in a final rule.

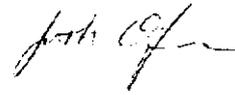
Amgen appreciates the opportunity to comment on the important issues raised in the Rule, and we look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical biological therapies.

⁸ 70 Fed. Reg. at 100761-19762.

Respectfully submitted,



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Re: File Code CMS-1325-P; Medicare Program; Medicare Competitive Acquisition of Outpatient Drugs and Biologicals under Part B: Proposed Rule

Dear Administrator McClellan:

Novo Nordisk appreciates the opportunity to submit these comments on the proposed rule for the Competitive Acquisition of Outpatient Drugs and Biologicals under Part B ("Proposed Rule").¹ Novo Nordisk is a healthcare company and a world leader in diabetes care. The company has the broadest diabetes product portfolio in the industry, and has a leading position within areas such as haemostasis management. We develop, manufacture and market pharmaceutical products and services that make a significant difference to patients, the medical profession and society. One of these products is NovoSeven® - a recombinant Factor VIIa that does not replace Factor VIII or IX, but enables coagulation to proceed in their absence. NovoSeven® can therefore be used by people that have developed a resistance to these factors.

We acknowledge the tremendous effort by the Centers for Medicare and Medicaid Services ("CMS") to implement the provisions of the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("the MMA") that create a new method for furnishing certain outpatient drugs and biologicals to Medicare beneficiaries (the "CAP"). We have thoroughly examined the MMA, the Conference Report on the MMA, and the Proposed Rule, and ask that in issuing a final rule CMS explicitly confirm that blood clotting factors were not intended to be, and will not be, subject to the CAP. If for some reason CMS cannot confirm that position, we ask that CMS exercise its authority to exclude clotting factors from the CAP.

¹ *Federal Register*. Volume 70 (March 4, 2005) p. 10745.

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1. The MMA Does Not Contemplate Subjecting Clotting Factors to the CAP.

As the Proposed Rule reiterates, the CAP is a purely voluntary program that is intended to provide physicians with an alternative to the “buy and bill” model of obtaining drugs to administer to patients. Given concerns that the shift to the average sales price (“ASP”) reimbursement methodology could make it financially infeasible for some physicians to purchase and administer drugs in their offices, Congress created the CAP to assure that patients whose physicians opted out of the ASP methodology would still be able to obtain Part B covered drugs. As the MMA, Conference Report and Proposed Rule consistently indicate, these considerations simply do not apply to the provision of blood clotting factors due to the products’ distinctive manner in which these products are reimbursed and administered. Accordingly, CMS should construe the MMA to exclude clotting factors from the CAP.

As CMS noted in the preamble to the Proposed Rule, while the definition of “competitively biddable drug” might be viewed as including drugs that are not physician administered, such as drugs administered through the durable medical equipment (DME) provision, the structure of the CAP in the MMA is directed solely at physician administered drugs.² Thus, the Proposed Rule would define “competitively biddable drug” to mean “a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act.”³

As the preamble to the Proposed Rule notes, clotting factors have their own statutory benefit category at Section 1861(s)(2)(I) of the Social Security Act (SSA). Therefore, they are covered under Part B not because they are provided “incident to” a physician’s services under Section 1861(s)(2)(A) of the SSA, but rather because of a different statutory mandate.⁴ CMS should construe these two provisions as requiring that blood clotting factors not be considered drugs administered “incident to” physicians services and therefore ineligible for inclusion in CAP. More fundamentally, these products usually are not administered in physician offices.

Furthermore, hemophilia is a very rare condition, affecting only about 18,000 people in the United States.⁵ As a result, hemophilia patients typically receive treatment at hemophilia treatment centers or self-administer clotting factors in their homes, rather than at physician offices.⁶ For these reasons, and because clotting factors are expensive and difficult to store, physicians are not likely to maintain a stock of clotting factors in their offices. Moreover, as discussed below, MMA mandates a special payment for administration of clotting factors for which physicians are not eligible. Therefore, clotting factors are not available to physicians

² 70 Fed. Reg. at 10749.

³ Proposed § 414.902 at 70 Fed. Reg. 10770.

⁴ 70 Fed. Reg. 10749. See SSA § 1861(s)(2)(I).

⁵ National Institutes of Health. National Heart, Lung, and Blood Institute. Accessed at http://www.nhlbi.nih.gov/health/dci/Diseases/hemophilia/hemophilia_what.html, April 18, 2005.

⁶ We are confident that if CMS is able to review the BESS data for clotting factors, such as NovoSeven® (HCPCS Q0187), on the basis of provider type, the utilization data will confirm that physicians rarely administer these products.

under the "buy and bill" model to which CAP is an alternative. It would be inappropriate, and contrary to the intent of Congress, to supply products through CAP that are not available under the "buy and bill" model.

In addition, it would be inconsistent with the fundamental structure of the CAP set forth in the MMA to include clotting factors within the definition of "competitively biddable drugs." It would make no sense to grant physicians the option to opt out of the ASP methodology with respect to clotting factors when physicians have never provided any clotting factors under the ASP methodology or under any other physician office payment methodology. As the Proposed Rule implicitly recognizes, canons of statutory construction do not favor interpretations that would yield absurd results.⁷

The MMA Conference Report confirms that Congress understood that, unlike other Part B drugs and biologicals, clotting factors are not physician-administered. In a section addressing "Items and Services Relating to Furnishing of Blood Clotting Factors," the Conference Report describes "Present Law" and the "Conference Agreement" as follows:

Present Law

Medicare will pay for blood clotting factors for hemophilia patients who are competent to use such factors to control bleeding without medical supervision, as well as the items related to the administration of such factors.

* * *

Conference Agreement

The Secretary is required to review the GAO report on payment for blood clotting factors and provide a separate payment for the administration of these factors. The payment amount may take into account the mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements as well as ancillary supplies and patient training necessary for self-administration. . . . In CY2006 and subsequently, this separate payment amount would be updated by the change in the CPI for medical care for the previous year ending in June.

Conference Report at 597 (emphasis added).

These statements regarding the self-administration of clotting factors without medical supervision succinctly demonstrate Congress' awareness that clotting factors are not physician-administered. Therefore, CMS should not allow clotting factors to be swept into the CAP, a program limited to physician-administered drugs. Moreover, the establishment of payments to

⁷ *United States v. Turkette*, 452 U.S. 576, 580 (1981) (absurd results are to be avoided, and internal inconsistencies in statute must be dealt with).

reimburse Hemophilia Treatment Centers and Home Health Agencies for the mixing and delivery costs associated with providing these factors further contradicts the notion that these products were intended to be physician-administered drugs subject to the CAP. As a result, we ask that CMS confirm that blood clotting factors in general, and NovoSeven[®] in particular, are not "physician-administered" for purposes of this rule. This classification of clotting factors is consistent with both the statutory classification and real world practices regarding clotting factors.

As the Proposed Rule observes, both the MMA and the Conference Report compel the conclusion that the CAP was not intended to apply to products that typically are not physician-administered, such as blood clotting factors. We concur in CMS' reading of the statute, and ask that CMS confirm our reading of the Proposed Rule.

2. In Any Event, CMS Has Substantial Authority to Exclude Clotting Factors From the CAP.

Section 1847B(a)(1)(D) of the SSA grants CMS authority to exclude Part B covered drugs and biologicals from the CAP "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 or biologicals." Were CMS to change the Proposed Rule such that clotting factors were included in the definition of "competitively biddable drug," Novo Nordisk requests that CMS exclude clotting factors in general, and NovoSeven[®] in particular, from the CAP based on both of these criteria.

A. *Inclusion of Clotting Factors in the CAP is Not Likely to Result in Significant Savings*

In the Proposed Rule, CMS proposes to limit the CAP to drugs and biologicals administered "incident to" a physician's service. As noted above, this proposal is based on several factors including statutory language that identifies physicians as the only Medicare providers who may elect to participate in the CAP.⁸ It follows logically that if physicians do not administer clotting factors, including clotting factors in the CAP is unlikely to result in significant financial savings to the Medicare program. As detailed below, the costs and burdens imposed on all parties to the CAP to solicit and evaluate bids for the provision of clotting factors would yield no meaningful savings because essentially no physicians would elect to participate in the CAP with respect to clotting factors.

Because special expertise is required to store, handle, and deliver clotting factors, manufacturers of these products enter into arrangements with highly specialized distributors in order to ensure product integrity until the time of dispensing. Therefore, unlike most other manufacturers of drugs and biologicals, manufacturers of clotting factors likely will have to enter into new distribution arrangements with distributors and CAP vendors in order to make their products available through the CAP. Inclusion of clotting factors in the CAP would effectively create an expensive, unused drug-delivery infrastructure that yields no savings to Medicare.

⁸ *Federal Register*. Volume 70 (March 4, 2005). p 10749-10750.

B. Inclusion of Clotting Factors in the CAP is Contrary to Payment Policies for Clotting Factors in Other Payment Systems and is Likely to Have an Adverse Impact on Access

Historically, Congress has recognized that the administration of clotting factors is associated with significant and unique product-related handling and administration costs (for example, rigid storage techniques). For this reason, clotting factors have been granted separate and special payments under various payment systems. Specifically, clotting factors are covered under Medicare Part B by Section 1861(s)(2)(I) of the SSA, which provides special coverage for hemophilia clotting factors when they are not provided "incident to" a physician's service, because they are so frequently self-administered. In the hospital inpatient setting, Medicare pays separately for clotting factors, reimbursing them at 95% of average wholesale price in addition to the prospective payment amount.⁹

Additionally, in Section 303(e)(1) of the MMA, Congress mandated that CMS reimburse suppliers of clotting factors a separate furnishing fee, in addition to the payment amount for the product itself, recognizing the significant cost associated with their administration.¹⁰ In the rare event that a physician would administer clotting factor in the office setting, the CAP would not provide for those costs and, regardless of whether physicians participate in the CAP, they would not be able to bill for these costs, as recovery of these costs is available only to suppliers of clotting factors (for example, home health agencies and hemophilia treatment centers).¹¹

Therefore, including clotting factors in the CAP would be contrary to Congress' and CMS' historical treatment of clotting factors in other payment systems. Additionally, the unreimbursed costs would place a significant burden on the limited number of physicians who do administer these products, thereby potentially decreasing patient access to this life-saving therapy.

* * *

⁹ *Medicare Claims Processing Manual*. Chapter 17. Section 80.4.

¹⁰ This furnishing fee takes into account the mixing and delivery of clotting factors, including special inventory management and storage requirements, as well as provision of ancillary supplies and patient training. See Conference Report at 597.

¹¹ *Federal Register*. Volume 69 (November 15, 2004). p. 66310-66312.

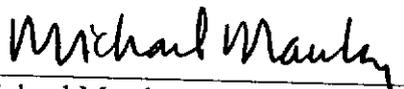
Mark McClellan, MD, PhD

April 26, 2005

Page 6

Thank you again for the opportunity to comment on these new and important rules. We believe that the Proposed Rule correctly excluded clotting factors from the CAP, and we hope that CMS will expressly confirm this position in the final rule.

Sincerely,



Michael Mawby
Chief Government Affairs Officer

cc: Leslie Norwalk (CMS)
Paul M. Rudolf (The Health Strategy Consultancy, LLC)
Anna Spencer (Sidley Austin Brown & Wood)



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April 26, 2005

BY HAND DELIVERY

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Administrator

Centers for Medicare and Medicaid Services

Department of Health and Human Services

Room 445-G

Hubert Humphrey Building

200 Independence Avenue, SW

Washington, DC 20201

APR 26 2005

RE: CMS-1325-P: Proposed Rule, Competitive Acquisition of Outpatient Drugs and Biologicals under Part B, 70 Fed. Reg. 10746 (March 4, 2005)

Dear Administrator McClellan:

The American College of Gastroenterology (ACG) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule relating to the "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B." ACG fully supports Medicare's efforts to provide physicians with more options for purchasing drugs for administration to patients in the physician office setting.

Introduction

The American College of Gastroenterology (ACG) is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers nearly 9,000 physicians among its membership. While the majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists and other specialists in various aspects of the overall treatment of digestive diseases and conditions. The College has chosen to focus its activities on clinical gastroenterology--the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of the College have been, and continue to be educational.

In addition to the College's comments, which follow, we have also reviewed, and wish to endorse, comments submitted to CMS on CMS-1325-P from the American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE).

We applaud the efforts of CMS to implement the competitive acquisition program, and we would like to take this opportunity to provide input and suggestions on a number of provisions in the proposed rule. Our comments are intended to strengthen the competitive acquisition program and ensure that providers and patients alike benefit from this innovative new initiative. Pursuant to the proposed rule, ACG's comments are grouped under the section of the rule to which they refer.

I. Categories of Drugs to be Included Under the CAP

a. Phasing in CAP Drugs by Physician Specialty

ACG agrees with CMS' plan to gradually phase in the competitive acquisition program (CAP) by focusing initially on drugs and biologicals provided "incident to" a physician's office visit and, within this category, drugs commonly prescribed by oncologists. We believe this approach, which focuses on a specialty group characterized by high-volume use of drugs covered under Part B, provides CMS with the greatest opportunity to identify potential program issues and effectively remedy any problems before expanding the program to drugs commonly used by other specialties. A more limited phase-in approach would not be sufficient to allow CMS to adequately gauge the impact of the program and effectively address potential issues prior to implementation of CAP across all Part B drugs. As noted in the proposed rule, oncologists represent the largest portion of expenditures for physician-administered drugs, and therefore it is appropriate to initially phase in CAP by limiting the program to drugs commonly used by oncologists.

After the initial rollout of the program focusing on higher volume specialties, ACG recommends that CMS consider targeting specialties that, historically, have had difficulty obtaining drugs at reasonable prices and could obtain the most benefit from participation in the CAP. While we agree that high-volume Part B specialties provide the best population for the initial CAP phase-in, it is imperative that CMS move swiftly to include specialties that have shown the greatest need to obtain access to reasonably-priced drugs.

Regardless of the method CMS chooses to initiate CAP, ACG stresses that CMS should make every effort during the initial phase-in to prevent potential harmful disruptions in care for Medicare beneficiaries.

b. Drug Categories

ACG recommends that CMS provide detailed information in the final rule on the specific drugs and HCPCS codes that will be included in each CAP category, so that physicians considering participating in CAP will know precisely which drugs will be included in the program. In addition, ACG is concerned that vendors may choose not to participate in the CAP program if the drug categories are drawn too narrowly or in some way disadvantage coverage of lower volume drugs. CMS has just recently changed how Medicare reimburses drugs under Medicare Part B, and the agency has not yet had an opportunity to evaluate how these reimbursement changes will impact access to drug and biological therapies and overall beneficiary care. Therefore, CMS should monitor the market for lower-volume drugs and ensure that physicians have the ability to purchase these drugs either through CAP or through the average sales price (ASP) system at a reasonable cost.

c. Drugs Typically Used by More than One Medical Specialty

There is substantial overlap among Part B drugs administered by various medical specialties, and access to such drugs through the CAP should not be unduly restricted by specialty or diagnosis. The proposed rule states as follows: "It is important to note that, if we choose to phase in the CAP by restricting the program initially to drugs typically administered by members of one specialty, all physicians who administer the drug would still be eligible to elect to obtain these drugs through the CAP and select a vendor of these drugs."¹ ACG is concerned that CAP coverage of specific drugs "typically administered" by specific specialties could inadvertently be interpreted to prohibit or discourage physicians from outside those specialties from taking advantage of the CAP. For example, the proposed rule lists Infliximab as one of the most prevalent drugs administered by oncologists, but gastroenterologists also administer this drug to Medicare beneficiaries as a treatment for Crohn's Disease. Therefore, ACG respectfully requests that CMS clarify in the final rule that all physicians, regardless of specialty, will be able to obtain drugs covered under CAP through the program as of January 1, 2006.

II. Competitive Acquisition Areas

ACG supports implementing a nationwide competitive acquisition area. As noted in the proposed rule, establishing a single national acquisition area would encourage more vendors to participate because they would have access to a single, large pool of potential participating physicians, and they would only have to submit one bid (rather than numerous regional or state bids) to participate in CAP.

III. Claims Processing Overview

a. Requirement of Drug Administration for Reimbursement

CMS interprets the Medicare statute to require verification of physician administration of a drug before final payment can be made. In addition to requiring verification through the claims process, the proposed rule requires that the drug order form must state the anticipated date of drug administration, and that, if not administered, the physician must notify the vendor and reach agreement on how to handle the unused drug.

These drug order and verification provisions are not only burdensome but do not accurately reflect the realities of patient care and could potentially increase costs to the Medicare system. By requiring an anticipated date of administration to order a drug, the CAP program eliminates a physician's option to treat the patient on the patient's initial visit. Because it will take at least one day to acquire a CAP drug after the physician has identified the need for it, the patient will have to return to the physician's office a second time to have treatment the actual treatment administered. In addition, it is not uncommon for a patient's health status to change, necessitating a change in dosage or even the prescription of a drug that is different from the one initially ordered from the CAP vendor. In these scenarios, physicians would be unable to administer the appropriate treatment without ordering new drugs from the CAP and contacting the CAP vendor to determine how to deal with the previously ordered drug. The result is additional burden on physicians to obtain and account for the appropriate drug, additional burden on the beneficiary to receive the

¹ 70 Fed. Reg. 10746, 10750 (March 4, 2005).

appropriate course of treatment, and additional cost to the Medicare program for additional office visits.

ACG recommends that CMS revise the rule to incorporate more flexibility to accommodate these clinical circumstances.

b. Obligation to Obtain Drugs for All Vendor Categories

CMS requested comment on whether physicians must obtain all categories of drugs that a vendor provides, or whether physicians should be allowed to choose the categories of drugs he or she wishes to obtain through CAP.² ACG feels strongly that CAP must be structured to protect physician choice regarding how to procure drugs for administration to patients in the office. The proposed rule provides that a physician choosing to participate in the CAP elects to “acquire that category” from the selected vendor, and that the physician “would not be able to elect to acquire only some of the HCPCS codes in that category from the vendor.”³ While this clearly establishes that a physician participating in CAP must purchase drugs listed in a chosen category from the vendor, it is unclear whether physicians participating in CAP must purchase all CAP categories from that vendor, or whether the physicians may select the categories of drugs they will purchase through CAP. To maximize physician participation in the program, ACG recommends that CMS allow physicians to determine which drug categories to purchase via the CAP program while retaining the ability to purchase other drugs via the ASP system.

c. Administrative Burden

In the proposed rule, CMS rejects physician assertions that the clerical and inventory resources associated with participation in the CAP exceed the clerical and inventory resources associated with buying and billing for drugs under the ASP system. ACG feels that there will be significant additional expenses associated with participation in the CAP, including: (1) maintenance of separate inventories for each beneficiary; (2) additional paperwork requirements, such as collection of data not currently required under the ASP program; and (3) additional work and expense associated with ordering drugs separately for each patient, instead of being permitted to order a supply to of drugs to maintain in the office. CMS should ensure that these additional administrative burdens and practice expenses are immediately considered in revisions to drug administration codes.

d. Prompt Filing of Claims

The proposed rule requires physicians to submit drug administration claims to their carrier within 14 calendar days of the date of administration.⁴ This timeline was not required by the Medicare Modernization Act and will result in enormous burden on virtually all medical practices. While we acknowledge CMS’ concern that vendors can only receive payment once the claim is filed, the regulation in essence only gives physicians 10 calendar days in which to complete all the necessary administrative tasks. We recommend that CMS increase the deadline to 30 calendar days

² 70 Fed. Reg. at 10755.

³ 70 Fed. Reg. at 10751.

⁴ 70 Fed. Reg. at 10755.

from the date of service to allow more time for accurate completion of claim forms and to eliminate an unnecessary burden on physicians participating in the program.

e. Emergency Supplies

Under the proposed rule, physicians can use CAP to re-stock inventories only when: (1) the drugs are required immediately; (2) the physician could not have reasonably anticipated the immediate requirement for the drugs; (3) the CAP vendor *could not* deliver the drugs to the physician in a timely manner; or (4) the drugs were administered in an emergency situation (emphasis added). ACG is concerned that the provisions regarding emergency supplies of CAP drugs are not clear enough and would preclude many scenarios where drugs are needed with short notice. In particular, we are concerned that the definition of emergency situation addresses merely the vendor's capacity to supply the drug on short notice, rather than whether or not the vendor actually supplied the drug. In other words, the rule arguably does not allow a physician to obtain drug from inventory (and then use CAP to re-stock his or her inventories) in circumstances where the vendor fails to deliver the ordered drug. ACG recommends that CMS clarify this in the final rule and protect the physicians' ability to obtain drugs through CAP to re-stock inventories.

f. Beneficiary Co-payment

One of the key elements of the CAP is that it delegates responsibility for collecting beneficiary co-insurance to CAP vendors. ACG is concerned about potential liability issues if a vendor opts not to supply a drug for a patient if that patient fails to make his or her co-payments during the course of treatment. Regardless of any dispute occurring between the vendor and the patient, this dispute does not involve the physicians' services and should not keep a physician from treating a patient. ACG recommends that CMS include in the final rule that a vendor cannot drop a physician from CAP or withhold shipping drugs to the physician due to the inability of the vendor to collect co-insurance from the Medicare beneficiary.

IV. Bidding Entity Qualifications

ACG disagrees with CMS' requirement that a vendor have three years experience in furnishing drugs to Medicare to be eligible for participation in CAP. We believe that vendors are sufficiently qualified to participate in the CAP if they are a registered pharmacy under state law and can provide drugs in a safe and timely manner. We request that CMS revise the proposed rule to require previous experience providing drugs to the Medicare population rather than requiring that vendors actually have experience as a supplier with the Medicare program. Opening up CAP to a greater number of potential vendors should foster innovation, ensure better vendor service to both patients and physician offices, while also providing greater potential for long-term cost savings to the Medicare program.

V. CAP Bidding Process-Evaluation and Selection

CMS is proposing to select vendors based on their "composite bid" that consists of bid prices for the individual drugs listed in a particular CAP category.⁵ CMS also proposes to reject bids

⁵ 70 Fed. Reg. at 10763.

from any vendor that are higher than the weighted ASP for the drugs in that category,⁶ presumably to ensure that the CAP program provides better prices to the Medicare program than those obtained under the ASP methodology. ACG is concerned that by basing the bid policy on the alternative pricing methodology, CMS is undermining the purpose of creating the CAP program in the first place – to create an alternative means of procuring drugs with potential cost savings from negotiating prices lower than ASP. In addition, it is also unclear whether sales to CAP vendors will be included in a manufacturer's calculation of ASP for that drug. If CAP prices are included in ASP, drug manufacturers have little incentive to negotiate below that threshold. ACG recommends that CMS clarify in the regulations that CAP prices are not included in ASP, in order to maximize the benefit of the program.

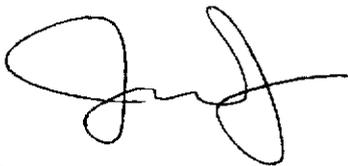
VI. Additional Comments

Due to the complexity of this new program and CMS' requested comments on multiple approaches to several fundamental aspects of the program, ACG asks that CMS issue revised regulations as an interim final rule subject to additional notice and comment.

VII. Conclusion

ACG appreciates the opportunity to comment on the Proposed Rule and respectfully requests CMS to address the aforementioned concerns in any further regulation on the CAP program. In closing, we would welcome the opportunity to meet with you and to respond to any questions you may have regarding our comments.

Sincerely,



John W. Popp, Jr. M.D., FACG
President



Edward L. Cattau, Jr., M.D., FACG
Chair, National Affairs Committee

⁶ 70 Fed. Reg. at 10764.



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April 25, 2005

APR 26 2005

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

Attention: CMS-1325-P

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed Rule

Dear Dr. Mark McClellan:

The American College of Rheumatology (ACR) is an organization of physicians, health professionals and scientists that serves its members through programs of education, research and advocacy that foster excellence in the care of people with arthritis, rheumatic and musculoskeletal diseases. The ACR appreciates the opportunity to comment on selected portions of CMS' Medicare Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed Rule. The College's comments will address concerns related to the following topics:

- Categories of Drugs to be Included Under the CAP
- Competitively Biddable Drugs
- Patient information
- Partial payments
- Administrative burden

Categories of Drugs to be Included Under the CAP

The CAP is an extremely important program for the rheumatology community. The ACR strongly urges CMS to include drugs typically administered by rheumatologists in all phases of the CAP, including the initial implementation. The phase in should be nationwide, rather than restricted to regions. Rheumatologists typically administer a number of drugs suitable for the CAP; for example: cyclophosphamide, hylan GF-20, infliximab, and methylprednisolone. ACR appreciates the alternative to the Average Sales Price (ASP) plus six percent reimbursement system offered by the CAP and will work with CMS and CAP vendors to achieve a successful program.

The proposed rule indicates that although drugs may be restricted to those typically administered by members of one specialty, all physicians who administer the drugs selected would still be eligible to elect to obtain these drugs through the CAP and to select a vendor of these drugs. The rule uses the example of phasing in initially with drugs typically administered by oncologists; participation would not be restricted to oncologists: non-oncologists who prescribe these drugs would still be eligible to elect the CAP and to select a vendor from which to obtain these drugs. The ACR strongly recommends that CMS expand on this in the final rule to make clear that beneficiaries receiving CAP drugs are not required to have a diagnosis related to the selected specialties for the phase in. To expand on the previous example: a rheumatologist would be able to select the CAP vendor offering drugs typically administered by oncologists and order infliximab for the treatment of rheumatoid arthritis even though neither the physician nor the beneficiary are engaged in treatment of cancer.

Competitively Biddable Drugs

The ACR supports physicians being able to select any number of drugs from categories made available by CAP vendors. Particularly at the onset of the CAP, physicians may be reluctant to commit to a new untried system and may seek to test it by choosing one or two drugs. Alternatively, CAP vendors could offer a greater variety of categories, some that include only a few drugs.

The ACR understands the challenges faced by CMS in implementing the CAP. The ACR strongly recommends that CMS test the CAP prior to implementing it, possibly by means of a demonstration project. As a complex new program, the CAP is likely to present obstacles not adequately prepared for in advance. Real-time clinical treatment of seriously ill beneficiaries is a serious concern for ACR in regards to the CAP. A demonstration would allow opportunities to resolve problems on a more manageable scale than will be possible when the CAP is fully implemented.

Patient Information

The rule proposes that physicians include a considerable amount of patient information on the order form, much of which will be included on the claim form. The order form should only require information standard for writing prescriptions, plus the required beneficiary Medicare number for matching drug to claims. Unless the vendor will be making medical decisions, there is no clear purpose in requiring information such as height, weight, date of birth, etc. on the order form. Diagnosis is typically captured on the claim form.

Additionally, if expected date of administration is required on the order form, a generous window should apply to account for the many possible reasons beneficiaries give when rescheduling appointments. ACR recommends that the physician notify the vendor of non-administration if the decision has been made to delay treatment beyond six months, or the beneficiary has failed to initiate treatment within six months.

Partial Payments

The ACR does not object to CMS making partial payments to CAP vendors, as long as doing so does not place additional administrative burden on rheumatologists participating in the CAP.

Administrative Burden

The proposed fourteen day timeframe for submitting drug administration claims represents a drastic change from current submission requirements. The ACR recognizes the need for vendors and CMS to reconcile claims data. However, fourteen business days is too brief a billing period for many rheumatology practices. The ACR suggests that CMS extend the claims submission timeframe to 30 business days.

Under the proposed rule, CMS is not implementing any separate or additional payments to cover resources associated with physician participation in the CAP. The ACR believes the CAP will utilize greater use of clerical and inventory resources than does the ASP system. The ACR strongly supports a pilot or demonstration to assist CMS in assessing the resource costs under the CAP, with the expectation that appropriate modifications will be made as needed to payment for participants.

Additionally, many practices that could benefit from the CAP may not have the software capability to transmit the prescription number electronically. The cost of implementing the necessary upgrades may deter many physicians from participating, particularly since the CAP is an untested program. CMS should support alternate methods of reporting the prescription number, at least until the program is fully implemented (all "phases" complete). For example, CMS could match the drug administration claim with the vendor drug information to confirm administration.

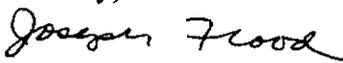
Summary

The ACR appreciates the time and effort CMS has directed towards development of the CAP. The ACR requests that CMS:

- Support inclusion of drugs administered by rheumatologists in all phases of implementation;
- Support phasing in all drugs typically furnished by the selected specialties;
- Expand claims submission timeframe to 30 days;
- Eliminate the electronic submission requirement of the prescription number during the initial phases of the CAP;
- Establish a demonstration to test the CAP prior to implementation;

Thank you in advance for your consideration of these comments. If you have questions or need additional information, please contact Pam Ferraro, Government Affairs Representative, at 202-261-4551.

Sincerely,



Joseph Flood, M.D.

Chairman

ACR Government Affairs Committee



APR 26 2005

April 26, 2005

BY HAND DELIVERY

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
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200 Independence Avenue, SW
Washington, DC 20201

**Re: CMS-1325-P (Medicare Program; Competitive Acquisition of Outpatient
Drugs and Biologicals under Part B)**

Dear Administrator McClellan:

Hoffmann-La Roche Inc. ("Roche"), a research-based pharmaceutical company, submits the following comments in response to the proposed rule implementing provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") that require implementation of a competitive acquisition program for certain Medicare Part B drugs not paid on a cost or prospective payment system basis.¹ We appreciate the work undertaken by the Centers for Medicare and Medicaid Services ("CMS") to implement the MMA and welcome the opportunity to present our suggestions on ways to improve this proposed rule so that it best serves the interests of beneficiaries, providers, and other stakeholders of the Medicare Program.

Our comments will focus on:

- The categories of drugs to be included in the competitive acquisition program;
- Claims processing, in particular the conditions under which physicians may use the competitive acquisition program to re-supply drug inventories in their offices;
- The bidding process, including how drug weights will be calculated and how new drugs will be included in the program; and
- Exclusion of competitive acquisition program prices from manufacturers' calculations of average sales price.

All of our comments are submitted in the spirit of assisting CMS's efforts to preserve beneficiaries' access to appropriate health care items and services. Pursuant to the instructions included in the Notice of Proposed Rulemaking, each comment is set forth under a caption referencing the section of the proposed rule to which that comment relates.

¹ 70 Fed. Reg. 10736 (March 4, 2005).

Categories of Drugs to be Included in CAP

Roche agrees with CMS that the Competitive Acquisition Program, or CAP, should be phased in gradually, covering only selected drug categories and in limited geographic areas, in order to ensure that this new program does not inadvertently obstruct Medicare beneficiary access to drugs and biologicals covered under Part B. CMS has recently implemented major changes to the way that drugs are reimbursed under Part B, as required under the MMA, and the Agency is still in the process of monitoring the impact of these changes on beneficiaries and other Medicare stakeholders. CAP would make further, major changes in how physicians (and ultimately, Medicare beneficiaries) access many important drug and biological therapies covered under Part B. We support CMS's efforts to phase in this new program more gradually, to avoid potentially harmful disruptions in care.

Consistent with this view, we agree with CMS's approach to limit the application of CAP to only Part B drugs provided "incident to" a physician office visit. Physicians rarely dispense certain oral anti-cancer drugs, oral immunosuppressives, oral anti-emetics, and ESRD drugs provided to patients by dialysis facilities, which are covered under Part B by virtue of specific statutory provisions in the Social Security Act. Consequently, it makes sense for CAP to be limited only to drugs that are commonly provided directly to patients by physicians and thus are covered under Part B by virtue of the "incident to" provisions of the statute. Limiting CAP to "incident to" drugs is also consistent with the overall structure of CAP, which is voluntary for physicians.

We note that CMS also has proposed to further limit CAP to drugs typically prescribed by a particular specialty group. In particular, CMS has proposed to limit CAP only to drugs commonly prescribed by oncologists, a specialty characterized by a high volume of Part B drug use. As noted above, Roche supports CMS's approach to phase in the program gradually by limiting the application of CAP to only those drugs typically prescribed by a particular physician specialty group. Roche recommends that CMS phase in CAP more gradually by selecting a lower-volume specialty for the initial implementation.

Roche also recommends that CMS define carefully those drug categories included in CAP, so that physicians understand which drugs are affected. For example, if CMS is going to include in CAP a drug category defined as "drugs typically prescribed by oncologists," the Agency should state whether this category includes drugs that are used off-label for the treatment of cancer, or for cancer supportive therapy, consistent with existing CMS policies regarding the off-label use of cancer drugs. We ask that CMS clarify in the final rule the categories of drugs selected for inclusion in CAP, and provide a specific list of HCPCS codes that are included in those categories.

Roche also supports CMS's proposal that CAP vendors would be required to bid all HCPCS codes associated with a particular drug category. We believe this proposal is consistent with both the provisions of the Social Security Act governing Part B benefits and the intent behind CAP. The statute does not provide the Secretary with authority to force single source drugs within a category to compete against one another for inclusion in the Program. CAP was never envisioned as a mechanism for limiting beneficiary access to otherwise covered Part B drugs. Therefore, we respectfully request that CMS affirm in the final rule Congress's intent to provide Medicare beneficiaries complete access to covered Part B sole source drugs.

Claims Processing Overview

CMS specifically requested comment on whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or whether physicians should be allowed to choose the categories of drugs he or she wishes to obtain through CAP.² Roche agrees that physicians should be permitted to select the categories of drugs that they wish to obtain through a CAP vendor. Physicians may be interested in CAP for certain categories of drugs, but not necessarily for others, and providing physicians with this choice will make it more likely that they will participate in CAP, thereby contributing to the success of the overall program.

Under the MMA, CAP vendors are not permitted to deliver drugs and biologicals to a physician except upon receipt of a prescription or written order for such drugs and biologicals.³ The Secretary is required to establish rules to allow physicians to obtain drugs from a CAP vendor to re-supply inventories of a drug covered under CAP, but only if:

- The drugs are required immediately;
- The physician could not have reasonably anticipated the immediate requirement for the drug;
- The CAP vendor could not deliver the drugs to the physician in a timely manner; or
- The drugs were administered in an emergency situation.⁴

Because even prompt drug delivery from a CAP vendor is likely to take at least one business day, it is possible that CAP will be more costly to the Medicare program because drug administration could now involve two visits to the physician – the first visit to examine and diagnose the patient, which prompts the physician to order the drug, and a second visit to administer the drug. Under the current system, where physicians typically have Part B physician-administered drugs on hand, the evaluation of the beneficiary and the administration of the drug can be taken care of in one visit. Thus, CAP could be more costly to the Medicare program, and more burdensome to beneficiaries, who now must make two visits to the physician to obtain treatment that previously could be obtained in one visit and make a separate, second co-payment for that additional visit.

Roche recommends that CMS create a process in the final rule to allow physicians more liberal use of drugs covered by CAP from existing inventories, to allow physicians to treat a patient with a CAP drug on the day of diagnosis, so that the patient is not required to come back for a second visit. Similarly, physicians should be permitted to use drugs from inventory if the physician is seeing the patient for the first time for a particular problem, or if upon examination of the patient the physician realizes the patient's condition has changed since the drug was ordered, necessitating a different dose of the same drug or a different drug, or if the physician discovers the patient is having an adverse reaction to the existing prescription and promptly needs to be switched to another. Imposing a rule that physicians may only use CAP to re-stock inventories in an emergency is likely

² 70 Fed. Reg. at 10755.

³ Section 1847B((b)(4)(E) of the Social Security Act (2005).

⁴ Id. at Section 1847B(b)(5).



to result in additional burdens on beneficiaries and increased costs to the system, as explained above. CMS should consider adopting a more expansive definition of "emergency" or defining a set of circumstances that *de facto* could not have been reasonably anticipated by the physician, in order to create a construct that works for physicians and patients and still complies with the statutory standard.

In the proposed rule CMS notes that, if for some reason a drug ordered from a CAP vendor could not be administered on the expected date of administration and could be kept safely in the physician's inventory, the physician could generate an order for the drug at the later administration time and just indicate that the drug did not need to be shipped.⁵ (Of course, the vendor could not bill Medicare until the drug had actually been administered, consistent with CAP requirements.) In other words, CMS already has anticipated and created a process to address a circumstance where a physician could use drug inventory to treat a patient, and this circumstance is arguably not an "emergency" by conventional standards. CMS should give additional consideration to the broad range of instances in which physicians would need to use existing inventory to treat a patient, and provide in the final rule for a more expansive set of circumstances or provisions to use CAP to re-stock inventory.

Cap Bidding Process – Evaluation and Selection

The proposed rule sets forth a bidding process whereby prospective CAP vendors submit composite bids for drug categories covered under CAP that are calculated by assigning a weight to each individual drug bid based on the percentage of volume that each drug represents out of the total volume for the category. CMS states that for 2006, this information will be based on claims data from 2004,⁶ but the Agency does not state how this information will get to vendors, or whether it will be publicly available. Because information on the weight for a particular drug included in CAP is critical to potential vendors who will be submitting bids based on this information, as well as to drug manufacturers who will be negotiating with vendors on CAP prices, it is critical that CMS make this information publicly available. Also, because CMS will be using claims data that is nearly two years old to set the weights, the Agency should also clarify in the final rule how it will treat drugs that may be included in CAP but for which there are insufficient claims data.

The MMA provides that new drugs (drugs for which a payment and billing code has not been established) will be reimbursed using the ASP+6% payment methodology.⁷ But the proposed rule is silent on the process for adding new drugs into CAP if those drugs are arguably included in a drug category that is covered by CAP. A new drug that is included in a drug category covered by CAP but is not offered by CAP vendors to physicians participating in the program could be put at a significant competitive disadvantage. Further, beneficiary access to the new product is likely to be hindered if physicians participating in CAP cannot acquire the new drug from the CAP vendor, but the physician can acquire all other drugs in the category through CAP. CMS should clarify in the final rule that new drugs that are covered by a CAP category are required to be provided by CAP

⁵ 70 Fed. Reg. at 10756.

⁶ 70 Fed. Reg. at 10762.

⁷ Section 1847A(d)(2)(A) of the Social Security Act (2005).



vendors as promptly as possible (no later than the second quarter after introduction), and vendors are to be reimbursed by Medicare at ASP +6%, as set forth in the statute.

In the proposed rule, CMS also requests comment on whether it will adjust CAP drug prices more often than annually in cases where a new drug is introduced. Although vendor contracts are for three years, CMS already contemplates making annual price adjustments for all drugs covered by CAP. Because vendors have the option of opting out of CAP once these drug prices are established by Medicare, it seems ill-advised to reset an entire category of drug prices and thereby risk potential mid-year defection of vendors who, after the prices are re-set, evaluate the economics of the contract and opt not to participate. Absent a public health emergency, it does not make sense for CMS to reset prices in the CAP program more often than annually. Roche recommends that CMS make clear in the final rule that new drugs will be reimbursed at ASP +6% until the CAP prices are re-set on an annual basis.

Inclusion of CAP in ASP Calculations

The proposed rule is silent on whether sales to CAP vendors are to be included in a manufacturer's calculation of Average Sales Price, or ASP, for a drug included in CAP. CMS has set a ceiling of ASP +6% for the composite bid for a drug category included in CAP. For this reason, and because CAP prices must include all vendor costs, vendors will have a strong incentive to aggressively push manufacturer drug prices below ASP +6%.

To maximize the capacity of CAP to generate savings for the Medicare program, and to ensure that prices negotiated by manufacturers in CAP do not have unintended ripple effects across other markets, Roche recommends that CMS state clearly in the final rule that drug sales at discounted prices negotiated between manufacturers and CAP vendors for the CAP program be excluded from a manufacturer's calculation of ASP.

The statutory language could be interpreted to allow CMS to exclude CAP sales from calculation of ASP. The statutory provisions establishing the ASP payment methodology state very clearly that the section governing calculation of ASP "shall not apply in the case of a physician who elects" for the provisions governing CAP to apply instead of the ASP provisions for the payment of drugs and biologicals.⁸ Although the MMA states that a manufacturer's average sales price for a drug means "the manufacturer's sales to all purchasers ... in the United States for such drug or biological in the calendar quarter,"⁹ the statute also clearly provides that the provisions governing ASP do not apply where a physician has elected to participate in CAP.¹⁰ In other words, where physicians have elected to participate in CAP, the ASP payment methodology clearly does not apply, and thus the drug sales under the CAP program should not be included in calculation of ASP.

Given the overall purposes of the CAP program, and that the drug prices negotiated between CAP vendors and manufacturers must include all of a CAP vendor's costs for participating

⁸ Id at Section 1847A(a)(2).

⁹ Id. at Section 1847A(c)(1).

¹⁰ Id. at Section 1847A(a)(2).



in the program *and* be below the weighted ASP +6% for the entire category, CMS should affirm or clarify that CAP sales are exempt from ASP in order to avoid frustrating the purposes of the program.

Conclusion

We appreciate this opportunity to submit comments to CMS regarding its proposed rule implementing the competitive acquisition program for certain Medicare Part B drugs. In summary, our recommendations are:

- Phase in CAP gradually -- in limited geographic areas, covering only drugs provided incident to a physician's office visit and, within that category, drugs typically dispensed by a particular physician specialty group;
- Continue to require CAP vendors to bid all HCPCS codes in a drug category covered by CAP;
- Allow physicians to opt in to CAP on drug-category-by-category basis;
- Create a less restrictive, cost efficient process for physicians to use CAP to re-stock office inventories;
- Make information about drug weights used in CAP bids publicly available, and clarify how weights will be calculated for drugs introduced after 2004;
- Require vendors to promptly add new drugs to CAP in order to ensure beneficiary access to all Part B drugs and biologics, and clarify that new drugs are to be reimbursed at ASP +6% until CAP prices are re-set on an annual basis.
- Clarify that drug sales under CAP are excluded from a manufacturer's calculation of ASP.

We hope that CMS will incorporate our suggestions into its final rulemaking and look forward to working with CMS on the issues identified in our comments.

Respectfully submitted,

Michael J. Eging
Executive Director
Public Policy and Federal Government Affairs

APR 26 2005

April 26, 2005

VIA HAND DELIVERY

Centers for Medicare & Medicaid Services
Attn: CMS-1325-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Comments to Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B (File Code CMS-1325-P)

To Whom It May Concern:

PRAECIS PHARMACEUTICALS INCORPORATED ("PRAECIS") respectfully submits the following comments to the proposed rule entitled "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B", published at 70 Fed. Reg. 10745 (Mar. 4, 2005) (File Code CMS-1325-P: the "Proposed Rule"). As an initial comment, we appreciate this effort by the Centers for Medicare & Medicaid Services ("CMS") to implement the complex Medicare Part B competitive acquisition program ("CAP") within the timeframes contemplated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. We believe it is essential to ensure that all Medicare Part B-covered drugs remain accessible to providers for use with beneficiaries who need these products, and we believe that the CAP, properly structured, is one way to further this goal.

I. Background

A. Who We Are

PRAECIS is a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies that either address unmet medical needs or offer improvements over existing therapies. PRAECIS is a small company currently employing less than 200 employees nationally. Our primary revenue stream is currently generated by the sales of Plenaxis® (*abarelix for injectable suspension*), a Medicare Part B-covered drug, approved by the Food & Drug Administration ("FDA") in November 2003, described in greater detail below.

B. Plenaxis*

Plenaxis is indicated for the palliative treatment of men with advanced symptomatic prostate cancer, in whom LHRH agonist therapy is not appropriate and who refuse surgical castration, and have

* These comments are not intended as a promotional communication. PRAECIS encourages anyone reviewing this communication that has not already done so to refer to the approved package insert including BOXED WARNING for Plenaxis (available at www.Plenaxis.com) for more detail regarding the approved Plenaxis indication and important safety information.

PRAECIS

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one or more of the following: (1) risk of neurological compromise due to metastases, (2) ureteral or bladder outlet obstruction due to local encroachment or metastatic disease, or (3) severe bone pain from skeletal metastases persisting on narcotic analgesia. Plenaxis is not indicated in women or children. Plenaxis is administered intramuscularly, incident to a physician's service. It is available currently in a 100mg single-use reconstitution kit (NDC 68158-149-51, J0128).

CMS issued a final national coverage determination memorandum on March 15, 2005, approving Medicare coverage for Plenaxis when used in accordance with its FDA-approved labeling (the "NCD").¹ This NCD is consistent with the PRAECIS' formal request to CMS and with the specifications of the FDA approved label.

Plenaxis is a "GnRH antagonist", and is currently the only prescription drug FDA-approved for men who refuse surgical castration but are not appropriate candidates for "LHRH agonists", a class of hormonal therapies (including, for example, *leuprolide acetate* and *goserelin acetate*) frequently used in prostate cancer treatment regimes. This is because GnRH antagonists and LHRH agonists have fundamentally different mechanisms of action.

Plenaxis is unique and distinguishable from other hormone therapies used in the treatment of prostate cancer such as "LHRH agonists". LHRH agonist treatment initially stimulates production of androgens and gonadotropins, the two types of hormones that cause the production of testosterone. The use of LHRH agonists, therefore, results in significant increases in circulating testosterone. The increase (or "surge") in testosterone production upon the first administration of any LHRH agonist may be substantial, and occurs irrespective of co-administration of anti-androgen therapies (such as *bicalutamide*). Testosterone "surges" can last up to three weeks after the initial administration of the LHRH agonist² and may lead to the exacerbation of prostate cancer and/or its symptoms (sometimes called "flare") in susceptible patients.³ Following this initial stimulatory period, LHRH agonist treatment results in desensitization of GnRH receptors, ultimately resulting in the reduction of testosterone to castrate levels.

In contrast to LHRH agonists, Plenaxis (a "GnRH antagonist") directly blocks the GnRH receptor, shutting down the production of androgens and gonadotropins, and consequently the production of testosterone. Therefore, Plenaxis treatment does not result in a testosterone surge or a resultant clinical symptom flare. Patients who have (1) risk of neurological compromise due to metastases, (2) ureteral or bladder outlet obstruction due to local encroachment or metastatic disease, or (3) severe bone pain from skeletal metastases persisting on narcotic analgesia, should generally not be exposed to the clinical flare associated with LHRH agonists. The FDA-approved labels for the LHRH agonists generally contain

¹ See Centers for Medicare & Medicaid Servs., Decision Memorandum for Abarelix for the Treatment of Prostate Cancer (CAG-00238N), available at < <http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=129> > (Mar. 15, 2005).

² Vallis K, Waxman J. Tumour flare in hormonal therapy. In: Stoll BA, ed. *Endocrine Management of Cancer*. Basel, Switzerland: Karger, 1988:144-152; Thompson IM, Zeidman EJ, Rodriguez FR. Sudden death due to disease flare with luteinizing hormone-releasing hormone agonist therapy for carcinoma of the prostate. *J Urol*. 1990;144:1479-1480.

³ Bruchovsky N, Goldenberg SL, Akakura K, Rennie PS. Luteinizing hormone-releasing hormone agonists in prostate cancer: elimination of flare reaction by pretreatment with cyproterone acetate and low-dose diethylstilbestrol. *Cancer*. 1993;72:1685-1691; Mahler C. Is disease flare a problem? *Cancer*. 1993;72:3799-3802; Fourcroy J. Regulatory history of hormone therapy for prostate cancer. *Molecular Urol*. 1998;2:215-220; Physician's Desk Reference. Montvale, NJ: Medical Economics Company, Inc. 2000.

warnings against use in these patients. It is these patients for whom Plenaxis may be appropriate and for whom Medicare should ensure Plenaxis remains widely available and easily accessible to physicians.

C. The Plenaxis User Safety Program™

For safety reasons, Plenaxis was approved by the FDA with marketing restrictions in November 2003. Only physicians and hospitals that have enrolled in the Plenaxis User Safety (“PLUS”) Program™, based on their signed attestation of qualifications and acceptance of responsibilities, may purchase Plenaxis. The PLUS Program includes, among other elements a physician and hospital pharmacy registry program to enable PRAECIS to keep track of those providers that have enrolled in the PLUS Program in order to restrict distribution to those providers.

II. Comments to Section II.A.2 of the Proposed Rule: “Categories of Drugs to be Included under the CAP”

A. The CAP Should Be Rolled Out for All Drugs Furnished Incident To A Physician’s Service

CMS proposes several “options” regarding categories of drugs to be included in the CAP. PRAECIS supports strongly the proposed option under which all drugs furnished incident to a physician’s service would be included in the CAP from the outset of the program. This option is most consistent with the statute as well as with industry expectations regarding physician drug access options that will be available in 2006. Moreover, this option is most likely to ensure appropriate and efficient access to needed medications, as the proposed “phase-in” options may cause confusion, access problems, and additional administrative burden among physicians, thus hindering patient care.

B. CMS’s Proposal for A Phase-In for Drugs Typically Administered By Oncologists Will Have the Unintended Consequences of Confusing Physicians, Limiting Access to Covered Services and Increasing Administrative Burden on Physician Offices

Under CMS’s proposed option to begin the CAP with a phase-in for “a limited set of drugs that are typically administered by oncologists” (the “**Oncology Option**”), it appears that the drugs to be included in this set would be determined based on previous years’ utilization data. Indeed, in Table 1 of the Proposed Rule, the oncology drugs were selected for inclusion based on the most commonly used HCPCS by Specialty Code 90 in 2003. We note that Plenaxis was not marketed until late January 2004 and that it was not assigned a J-Code until January 1, 2005 (J0128). Therefore, although Plenaxis is an oncology/urology product, there is no way that Plenaxis could be included in the subset of “oncology” products based on a retrospective review of 2003 or 2004 Medicare Claims Data, as it was not available in 2003 and physicians in 2004 were billing using “not otherwise classified” HCPCS codes such as J9999.⁴ Moreover, because Plenaxis is indicated for a relatively small patient population, it is conceivable that it might never appear on a list of most “commonly” used billing codes.

Limiting the Part B drugs available through the CAP as proposed in the Oncology Option may ultimately confuse physicians as to why drugs such as Plenaxis that are indicated solely for use in oncology/urology are not included in the initial CAP as an “oncology drug”. We note that Table 1 includes LHRH agonists such as *leuprolide acetate* (J9217) and *goserelin acetate implant* (J9202). The exclusion of Plenaxis and inclusion of the LHRH agonists in the CAP may have the unintended

⁴ Similarly, in the event that CMS opts to phase-in the CAP in urology (rather than, or in addition to, oncology), another specialty in which Plenaxis is indicated, Plenaxis would be inappropriately absent from a list of “urology” drugs compiled using the same methodology.

consequence of affecting provider's prescribing choices, potentially at the expense of patient care. Physicians may be less willing to take the financial risks necessarily entailed by the "buy and bill" average sales price ("ASP") model on newer and potentially more innovative therapies if they can obtain an older therapy through the CAP.

In light of the numerous changes in Medicare over the past few years, physicians may not fully understand that those oncology drugs not included in the CAP remain reimbursable under Part B. Additionally, access issues might occur if physicians electing the CAP ultimately treat the CAP as a *de facto* formulary, due to their expressed preference not to "buy and bill" under the ASP-based reimbursement system.⁵ Such issues could ultimately affect patient care to the extent they impede physician access to needed medicines.

The Oncology Option may create additional administrative burdens for oncology practices in that they would have to bifurcate their administrative tasks, obtaining certain products through CAP and continuing to "buy and bill" the remaining oncology drugs. A "phase-in" option could increase physicians' office workload, as participating in both the CAP and the ASP-based reimbursement systems (depending on the product) could be confusing and add additional complexity to an already complex billing process. Moreover, as described above, this option could create a bias against newer oncology drugs among CAP-participating offices because of the additional financial risk perceived to be associated with continuing to "buy and bill" such products.

At a minimum, if this option is selected, we recommend using a more accurate method to determine which drugs are "typically administered by oncologist" for purposes of defining this category of products. Defining this category based on previous years' Medicare Claims Data may capture the high volume drugs that have been on the market for some time, but will necessarily hinder newer and/or more specialized therapies such as Plenaxis. Similarly, limiting the category to drugs coded in the "J9's" would not capture many important oncology products, including Plenaxis. An alternative might be for CMS to review the FDA-approved indications for the various Medicare Part B products to assess whether they are appropriately classified as oncology products, and develop a list based on this classification.

As described above, there is a subset of very ill prostate cancer patients who are indicated for treatment with Plenaxis. Plenaxis is the only non-surgical treatment FDA-approved specifically for these patients. PRAECIS believes that the Oncology Option, as set forth in the rule, may impede access to Plenaxis, potentially create confusion among physicians, and create additional administrative burdens, all with potential patient care implications. We further believe that the issues created by the Oncology Option would be present in any "phase-in" approach, including but not limited to a phase-in in urology, and that the most appropriate way to introduce the CAP is as Congress ultimately intended the program to be – for all drugs furnished incident to a physician's service.

III. Comments to Section II.A.3 of the Proposed Rule: "Competitive Acquisition Areas"

A. A National Competitive Acquisition Area Will Be the Most Efficient and Effective Way to Administer the CAP

PRAECIS is a small company with significant resources dedicated to the commercialization of our first FDA-approved product, Plenaxis. Managing purchasing relationships with up to 250 separate CAP vendors will be an expensive and time-consuming process. As described above, Plenaxis is

⁵ We note that current law does not permit CAP vendors to institute a formulary by offering only certain Health Care Common Procedural Coding System codes within a category.

distributed through a restricted distribution network pursuant to the PLUS Program. As part of the PLUS Program, PRAECIS maintains a registry of enrolled physicians and hospital pharmacies that are entitled to purchase Plenaxis, and works with a select group of specialty distributors who facilitate the restricted distribution system and the necessary registry confirmations that such restricted distribution entails. Introducing such a large number of intermediary companies in such a short timeframe could cause significant administrative burden on our resources. Alternatively, working with a handful of national CAP vendors will likely be significantly more manageable, and PRAECIS believes that this approach will be the most efficient and effective way to administer the CAP and ensure the integrity of the PLUS Program.

IV. Comments to Section II.B.2 of the Proposed Rule: "Claims Processing Overview"

A. Vendor's Claims for CAP Drugs Should not be Subject to LCD Edits/Claims Adjudication

The Proposed Rule contemplates that CAP drug administration claims will continue to be submitted to and adjudicated by the physician's local carrier, while drug vendor's claim for the drug would be submitted to the "designated" carrier. Under the Proposed Rule, a determination by the local carrier that the drug administration claim is not consistent with a local coverage determination ("LCD") would cause the drug vendor's drug claim to be denied by the designated carrier.

PRAECIS believes that applying LCDs to CAP vendor drug claims would penalize drug vendors inequitably for decisions that are entirely outside of their control, potentially discouraging their participation in the CAP. We presume that CMS does not plan to grant vendors control over physicians' prescribing practices (something that likely would be inappropriate and impractical for any number of legal and ethical reasons). Therefore, CMS should not penalize vendors that have otherwise complied with their drug fulfillment obligations based on such physician practices (by denying or limiting the vendors' reimbursement to below its cost for the products). This inequity is compounded by the fact that under the Proposed Rule, CAP vendors will have limited appeal rights and limited information with which to appeal drug claims denied or reduced in connection with local carrier adjudication of administration claims. The adjudication of the vendor's drug claim should remain separate from that of the physician's administration claim.

Plenaxis administration has been subject to varying degrees of inconsistent coverage by local carriers, notwithstanding the recent NCD issuance for Plenaxis. Therefore, we recommend that a drug provided by a CAP vendor consistent with an NCD applicable to that drug be covered by the CAP, regardless of the local carrier's determination with respect to the drug administration claim. Additionally, we request clarification in the final rule that the "designated" carrier will not be permitted to apply its own local payment edits to the drug claims it adjudicates nationally.

B. The Proposed Process for Obtaining "Emergency" Drugs Should be Revised

Plenaxis, like many cancer drugs, should be provided on a strict dosing schedule. Physicians who elect to use the CAP should have the ability to adhere to this schedule and respond quickly to any changes in a patient's condition, without delays caused by the CAP ordering process. Under the Proposed Rule, we do not expect that physicians will be able to use the CAP to obtain every drug their patients need when they need it. For example, a physician could not provide a drug obtained through the CAP if the vendor's delivery has been delayed, the patient needs treatment on his first office visit,⁶ or the patient's condition

⁶ We note that Plenaxis is indicated for among other things, a subset of prostate cancer patients at risk of neurological compromise due to metastases. Delay in treatment conceivably might enhance this risk for such patients.

has changed between the time the drug was ordered from the CAP and the scheduled administration. In these cases, we believe the patient must not be sent home to wait for the drug to be delivered. Delaying care could cause the patient's condition to deteriorate and would impose additional cost and inconvenience on the patient. It also would increase costs to Medicare because the physician would likely bill for an additional office visit.

To ensure that patients can receive treatment when they need it, the statute requires CMS to establish rules to allow a physician to treat the patient with a drug from his or her own inventory then order a replacement drug from the CAP vendor.⁷ When a physician exercises this option, CMS proposes to require the physician to demonstrate: (1) the drugs were required immediately; (2) the physician could not have anticipated the need for the drugs; (3) the vendor could not have delivered the drugs in a timely manner; and (4) the drugs were administered in an emergency situation. CMS asks for comment on how to define "emergency situation."⁸ Because this proposal's efficacy will depend on the definition of "emergency situation," we urge CMS to interpret the term broadly to remove potential obstacles to care. In particular, CMS must interpret "emergency situation" to include the following events: (1) the patient arrives for treatment, but CAP vendor has failed to deliver the drug on time or in usable condition; (2) the physician could not have determined which treatment to provide before the appointment; or (3) the patient's change in condition, such as a failure to respond to prior treatment or development of an adverse reaction, requires immediate administration of a different drug.

We also note that the Proposed Rule assumes that physicians have an inventory from which to obtain an emergency product. Physicians who treat primarily Medicare patients and rely on the CAP to supply all of their drugs might not have their own inventory of drugs needed to treat these conditions, and thus could not use the resupply option. In keeping with the CAP's goal of reducing physicians' burdens of purchasing and billing for drugs, we recommend that CMS allow physicians to order an advance supply of these drugs from the CAP vendor. We also suggest that the vendor be allowed to submit claims for the drugs as they are used. This would ensure that the physician has all necessary drugs available to handle these urgent conditions, without having to purchase and bill for them under the ASP-based methodology.

V. Comments to Section II.B.3 of the Proposed Rule: "Dispute Resolution"

The Proposed Rule is not clear with respect to the impact of a successful physician appeal of a drug administration claim on the payment of a previously denied vendor's drug claim. PRAECIS recommends that in the event that a physician successfully appeals a drug administration claim, this determination be linked to the payment of the drug claim, notwithstanding the fact that the timeframes set forth in the proposed rule in which a "match" may be made for a drug claim to be payable will likely have expired by the time the physician's appeals process has been run. This is particularly important given the fact that it appears that under the Proposed Rule, drug vendors will not be able to appeal drug administration determinations, and will have limited appeal rights regarding drug payment determinations. Alternatively, we recommend that CMS consider providing more meaningful appeal rights to drug vendors to ensure their ability to appeal a drug claim denied based on the denial of an administration claim by the local carrier.

⁷ Social Security Act § 1847B(b)(5).

⁸ 70 Fed. Reg. at 10755.

Additionally, CMS does not explain how the Medicare appeals process amount in controversy requirement⁹ will apply to CAP claims. Unless the price of the drug is included in the amount in controversy for appeals of denied drug administration claims, many appeals of administration claims will not meet the \$100 threshold for an Administrative Law Judge hearing. We urge CMS to clarify how the drug claim and the drug administration claim could be aggregated to meet this requirement.

VI. Comments to Section II.C.1 and II.C.2(b) of the Proposed Rule: “Contracting Process-Quality and Product Integrity Aspects”

A. Vendors Should Be Able to Comply with Manufacturer Requirements Pertaining to Restricted Distribution Products

As described above, the FDA approved Plenaxis subject to a risk minimization action plan: the “PLUS Program”. The PLUS Program includes a physician and hospital pharmacy registry program designed to enable PRAECIS to keep track of those providers that have enrolled in the PLUS Program and ensure that only such providers may purchase Plenaxis. Although we recognize that Plenaxis may be unique among many of the Medicare Part B products in that it is subject to a restricted distribution system, we feel it is important to comment that the PLUS Program requires mechanisms to ensure that Plenaxis is only distributed to PLUS-registered physicians and hospital pharmacies. Any CAP vendor should be able to comply with PRAECIS’ requirements that distribution be restricted appropriately (as well as with other manufacturers’ restricted distribution programs to the extent applicable).

VII. Comments to Section II.C.3 of the Proposed Rule: “CAP Bidding Process – Evaluation and Selection”

A. CMS’s Proposal that Vendors Submit “Full Documentation Reflecting [] Purchases, Including Contracts, Invoices, and Other Agreements that Reflect the Actual Purchase Price” Raises Confidentiality Concerns and Increases Unnecessary Paperwork

In the Proposed Rule, CMS outlines a process by which annual adjustments in vendor’s bid prices will be based on changes in vendor’s actual acquisition costs. CMS proposes that to support a request for such a change to a bid price, a vendor should submit “full documentation reflecting [] purchases, including contracts, invoices, and other agreements that reflect the actual purchase price.”¹⁰ PRAECIS is concerned that such a provision requiring complete contract submissions raises issues regarding the confidential and proprietary nature of the information contained therein. It is not clear from the Proposed Rule whether such documentation would be exempt from Freedom of Information Act requests or otherwise treated as confidential by CMS. It is also not clear to what extent such documentation is relevant to the extent it addresses issues not related to CAP pricing. If this provision remains in the final rule, we recommend that the documentation requested by CMS should be limited to those sections of such agreements that directly pertain to pricing and discounts applicable to the CAP. In the alternative, we recommend CMS consider a system by which CAP vendors certify as to accuracy of the price change information submitted, much like pharmaceutical manufacturers do in the ASP reporting context. This latter approach may reduce the administrative burden on CMS by limiting the paperwork that might need to be reviewed (and potentially redacted if FOIA is an issue), provide a more consistent format by which to review pricing changes, and minimize manufacturer and vendor confidentiality concerns.

⁹ 42 C.F.R. § 405.1006.

¹⁰70 Fed. Reg. at 10,765.

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PRAECIS appreciates this opportunity to comment on the Proposed Rule. As the manufacturer of a Part B covered drug, PRAECIS looks forward to the implementation of the CAP and hopes that this program ultimately will simplify access to needed office drugs for physicians and their patients, without limiting access to important and unique products such as Plenaxis. Should you have any questions or wish to discuss any of the issues raised herein further, please contact Kathleen Peterson, Senior Corporate Counsel, at 781-795-4100.

Sincerely,

PRAECIS PHARMACEUTICALS INCORPORATED

By: Kevin F. McLaughlin
Kevin F. McLaughlin
President and Chief Executive Officer

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sanofi aventis

Because health matters

April 26, 2005

BY HAND DELIVERY

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

**Re: CMS-1325-P (Medicare Program; Competitive Acquisition
of Outpatient Drugs and Biologicals under Part B)**

Dear Administrator McClellan:

Sanofi-aventis¹ appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule implementing provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that require implementation of a competitive acquisition program (CAP) for certain Medicare Part B drugs² not paid on a cost or prospective payment system basis (the Proposed Rule).³

Sanofi-aventis is committed to the fight against disease throughout the world. In the new millennium, we have taken up the major challenges of discovering new compounds that are essential to the progress of medical science and launching pharmaceutical products all over the world that constitute real therapeutic progress for patients. Our mission is to discover, develop, and make available to physicians and their patients innovative, effective, well-tolerated, high quality treatments that fulfill vital health care needs. Backed by a world-class research and development organization, we are developing leading positions in seven major therapeutic areas: cardiovascular disease, thrombosis, oncology, diabetes, central nervous system, internal medicine, and vaccines.

¹ These comments are submitted on behalf of Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals, both part of the sanofi-aventis Group.
² We use the term "drug" throughout these comments to refer collectively to both drugs and biologicals.
³ 70 Fed. Reg. 10746 (March 4, 2005).

Administrator Mark McClellan

April 26, 2005

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As a company dedicated to bringing advanced therapies to patients, sanofi-aventis supports the overall goal of the CAP – to ease the administrative burden on physicians of ordering, storing and collecting reimbursement for certain Part B drugs. We have a number of comments and recommendations about the CAP as currently proposed, however. Specifically:

- As intended by Congress, CAP vendors must not be allowed to create formularies.
- In order to maintain prompt beneficiary access to medically necessary treatments, CAP vendors must provide at least one therapy per billing and payment code in a category, and at least one National Drug Code (NDC) for each single source and each brand name therapy within a shared code.
- Vendors should be encouraged to include multiple NDCs for each drug to permit access to appropriate dosing and avoid waste.
- Physicians must be allowed to use the resupply option to provide timely access to care and to minimize costs to their patients and the Medicare program.
- Physicians must be allowed to request an initial supply of drugs from the CAP vendor to use for treating urgent conditions.
- The “furnish as written” requirements should be implemented so as not to limit physician flexibility in prescribing the most medically appropriate drug for the patient.
- Medicare’s current coverage policies, including coverage of medically accepted off-label uses, must apply to the CAP so that physicians can provide the most appropriate therapies to their patients.
- Carriers’ least costly alternative policies should not apply to the CAP.
- CMS should review physicians’ administrative burdens under the CAP, including the information required to be provided in CAP claims, to ensure that they are kept to a minimum.
- CMS must allow physicians to select a different vendor for each category of drugs under the CAP, as required by the statute.
- CMS must use the most recent ASP data, making projections for future changes in rates, when evaluating CAP vendor composite bids.

A more detailed explanation of these concerns, and our specific recommendations for the final CAP rule, are set forth below.

I. Categories of Drugs to be Included under the CAP

Access to and Choice of Drugs under the CAP

The CAP's goal of easing physicians' administrative burdens associated with acquiring and billing for drugs administered to their patients can be met only if physicians can obtain the therapies their patients need through the program. Sanofi-aventis applauds CMS for requiring CAP vendors to bid and make available to participating physicians all of the Health Care Common Procedure Coding System (HCPCS) codes included in a particular drug category covered by CAP.⁴ We understand that CMS is under some pressure to allow CAP vendors to create formularies that could exclude from the CAP many HCPCS codes that contain a single drug. There is no statutory basis for the CAP program to evolve into a formulary-based system, and the creation of formularies would directly contradict Congress' intent to provide physicians an alternate means of obtaining covered drugs for their patients. Furthermore, excluding HCPCS codes that contain a single drug from the CAP could harm patient access to important therapies, particularly in oncology, where we understand that single source drugs are used over 70 percent of the time. Patients' treatment options may be severely limited if these drugs are not available through the CAP. We are vehemently opposed to the imposition of a formulary in the CAP.

The Medicare statute and its legislative history require CAP vendors to offer at least one drug for each billing and payment code within a CAP category.⁵ Because this requirement applies equally to multiple source and single source drugs,⁶ CAP vendors do not have the option of excluding certain codes from the CAP. Sanofi-aventis therefore requests that CMS clearly prohibit CAP vendors from creating formularies. In particular, the final rule must specify that CAP vendors are required to provide at least one formulation of each product per HCPCS billing and payment code in a CAP category. CMS also should encourage vendors to provide multiple NDCs for each drug to allow physicians to choose the best package size for the patient's dosage and to minimize waste.

CMS should further protect beneficiary access to critical therapies under the CAP by requiring vendors to provide at least one National Drug Code (NDC) for each single source and each brand name⁷ product contained in each HCPCS code. A HCPCS code can be used to describe many unique therapies, and sharing a HCPCS code in no way indicates that two or more drugs are interchangeable. In fact, several brand name therapies can be included in a single HCPCS code, even though the therapies are not rated as therapeutically equivalent by the Food and Drug Administration (FDA). Each of these therapies may have different formulations, indications, uses, and effects that make them appropriate for some patients but not for others with the same condition. The Proposed Rule would allow a vendor to provide just one of these therapies, denying

⁴ *Id.* at 10751.

⁵ Social Security Act (SSA) § 1847B(b)(1).

⁶ See H. Rep. No. 108-391, at 594 (2003) (explaining that the Secretary must conduct a competition "among entities for the acquisition of at least one competitively biddable drug or biological that is a multiple source or a single source drug or biological within each billing and payment code within each category for each area").

⁷ By "brand name," we mean a product that does not have a therapeutic equivalent according to the Food and Drug Administration.

participating physicians access to the appropriate therapy for their patients through the CAP. Rather than requiring physicians to use the "furnish as written" option, discussed below, to obtain these therapies, sanofi-aventis recommends that CMS require CAP vendors to provide at least one NDC for each single source and each brand name therapy within each HCPCS code. This requirement would greatly simplify physicians' administrative burdens under the CAP and would help ensure beneficiaries access to the most appropriate therapies.

Finally, if CMS relies on a list of HCPCS codes to define the categories covered by the CAP, the agency will need to ensure that the most current list of codes is used as a reference. In the Proposed Rule, Table 1 – Most Commonly Used HCPCS by Oncologists omits commonly used drugs like oxaliplatin (Eloxatin™) that have been introduced since 2003.⁸ We understand that this table is based on 2003 claims data, and we urge CMS to use the most recent data available when defining categories and to take particular care to ensure that new drugs are included. Because participating physicians will rely on the vendor's list of available drugs when selecting therapies to prescribe to their patients, it is essential that CMS provide vendors and physicians with a complete and up-to-date list of those codes to avoid creating the misimpression that a particular drug within a CAP category is not included. To accommodate beneficiary access to new therapies, sanofi-aventis recommends that CMS require vendors to provide updates of the drugs included in the CAP on a quarterly basis.

II. Claims Processing Overview

Sanofi-aventis appreciates CMS' efforts to simplify claims processing under the CAP. We are concerned that several aspects of the proposed claims processing system conflict with the CAP's goal of easing physicians' administrative burdens associated with purchasing and billing for drugs. We offer the following comments to help CMS achieve these goals while ensuring that Medicare beneficiaries receive care in a timely manner.

A. Use of the Resupply Option to Ensure Timely Access to Care

As proposed by CMS, participating physicians will order drugs for their patients from CAP vendors at least one day before the drug's expected administration. When it created the CAP, Congress recognized that physicians often cannot plan a patient's treatment far enough in advance to order drugs from a vendor. Congress instructed the Secretary to establish rules to allow physicians to obtain drugs from a CAP vendor to re-supply inventories of a drug covered under CAP if:

- The drugs are required immediately;
- The physician could not have reasonably anticipated the immediate requirement for the drug;
- The CAP vendor could not deliver the drugs to the physician in a timely manner; and
- The drugs were administered in an emergency situation.⁹

⁸ 70 Fed. Reg. at 10751.

⁹ SSA § 1847B(b)(5).

Sanofi-aventis urges CMS to recognize the clinical and financial costs of delaying care and implement this requirement with a broad definition of "emergency situation." A patient's condition may change between scheduled visits or the patient may experience an adverse reaction during a drug administration, requiring the physician to alter the planned course of treatment. Instead of requiring the patient to continue to suffer, the CAP should be designed to allow the physician to provide the treatment the patient needs when he or she needs it. A broad definition of "emergency situation" also would lessen the financial cost of care under the CAP by allowing the patient to receive treatment during his or her original office visit. Under CMS' current proposal, care under the CAP could be more expensive than under the average sales price (ASP) reimbursement methodology because patients often would have to return to their physicians' offices at a later date to receive treatment. The beneficiary and the Medicare program would be charged for the extra office visit, and the beneficiary would incur the cost and inconvenience of making a second trip to the physician's office. This may be particularly burdensome in rural areas, where patients have to travel long distances to receive care.

To ensure that beneficiaries receive care when they need it, and to limit the cost of care to the beneficiary and to Medicare, sanofi-aventis urges CMS to define "emergency situation" broadly. Physicians must be allowed to use the resupply option when, for example: (1) the physician could have not reasonably anticipated a patient's need for the drug because the physician is seeing the patient for the first time for a particular problem; (2) upon examination of the patient the physician realizes the patient's condition has changed since the drug was ordered, necessitating a different dose of the same drug or a different drug; or (3) upon examination the physician discovers that the patient is having an adverse reaction or is not responsive to the existing prescription and promptly needs to be switched to another therapy. For example, in oncology, if a certain chemotherapy drug is not working effectively, the physician should be allowed to switch agents immediately to ensure that the patient receives the most benefit from their treatment.

B. Access to Drugs for Use in Urgent Care Situations Under the CAP

Although one of the purposes of CAP is to relieve physicians of the burden of keeping an inventory of Part B drugs in the office, it is clear from the emergency resupply provisions of the rule that CMS expects that physicians will in many cases want to keep an inventory of Part B covered drugs on hand, particularly where those drugs are easily stored and have a reasonable shelf life. Physicians who choose to participate in the CAP and who treat primarily Medicare beneficiaries may not maintain their own stock of drugs, however, and would not be able to obtain the drugs their patients need in urgent situations under the CAP's proposed emergency supply requirements. CMS proposes to require CAP vendors to furnish emergency drug orders on the next day for orders received by the vendor by 3:00 p.m.,¹⁰ but some treatment for some conditions cannot be delayed that long. For example, a patient who presents at the physician's office with possible signs and symptoms of deep vein thrombosis cannot wait until the next day for the CAP vendor to fill an emergency order for a low-molecular weight heparin, such as Lovenox® (enoxaparin sodium). Under the CAP, as proposed, if the physician does not maintain his or her own supply of Lovenox, he or she would have to send the patient to the emergency room for care. Both of these options would increase cost and inconvenience to the patient and the physician, as well as costs for the

¹⁰ 70 Fed. Reg. at 10760.

Medicare program. To facilitate access to drugs for acute conditions, CMS should allow physicians to request from the CAP vendor an initial supply of drugs commonly used in urgent care situations.

C. Use of the "Furnish as Written" Option

As we explained above, it is essential that CAP vendors provide physicians access to a broad range of drugs to meet their patients' unique needs. Although we urge CMS to require CAP vendors to provide a wide choice of drugs, we recognize that there will be instances when a physician prescribes a specific formulation or brand of a drug that is not being furnished by a vendor through the CAP. We thank CMS for proposing a "furnish as written" option to allow physicians to obtain the particular drugs their patients need. We are concerned, though, that the proposal will impose new requirements on physicians that will impede patient access to the most appropriate therapy. For example, CMS proposes to require physicians to use a "furnish as written" modifier to identify claims made under this option to their local carrier. CMS further adds that physician's local carriers will at times conduct post payment reviews of the use of the "furnish as written" modifier, and if the carrier determines that a specific NDC or brand name drug was not medically necessary, the carrier could deny the claim for the drug and the administration fee.¹¹ If the physician chose not to participate in the CAP and bought and billed for the same drug himself, he would not be subject to this review. We believe CMS should not impose requirements on physician prescribing of covered Part B drugs under the CAP that are more onerous than the processes already in place at the local contractor level for determining coverage of these therapies. The "furnish as written" requirements should be written so as not to limit physician flexibility in prescribing the most medically appropriate therapy for the patient.

D. Application of Existing Coverage Process and Policies to the CAP

In addition to providing access to appropriate drugs, the CAP must allow physicians to prescribe those therapies for medically accepted uses. The Proposed Rule clearly requires physicians to abide by local coverage determinations (LCDs) and allows local carriers to review claims for compliance with these policies,¹² but it does not explain whether CAP vendors would perform a similar review before shipping a requested drug. We support Medicare's current statutory and regulatory coverage process, including the requirements for coverage of medically accepted off-label uses of drugs. Physicians must be allowed the same latitude, subject to local carrier review, to prescribe drugs for off-label uses under the CAP as they would have under the current drug acquisition and billing method. Specifically, local carriers must apply the Medicare Benefit Policy Manual's requirement for coverage of off-label uses of anti-cancer drugs and biologicals that are supported by a listing in certain compendia or peer-reviewed medical literature¹³ to drugs obtained through the CAP. CAP vendors and the CAP designated carrier must not impose an additional layer of review before shipping a prescribed drug to a physician. At a recent Practicing Physician Advisory Committee meeting, CMS said the CAP would not modify the existing coverage process

¹¹ *Id.* at 10756.

¹² *Id.*

¹³ Medicare Benefit Policy Manual (CMS Pub. 100-02), ch. 15, § 50.4.5.

and vendors would be required to supply drugs, whether or not they are ordered for off-label uses.¹⁴ We urge CMS to include these statements in the final rule.

E. Least Costly Alternative Policies Should Not Apply under the CAP

We believe it would be unnecessary and impractical to apply carriers' least costly alternative (LCA) policies under the CAP. Because the price for each drug, identified by its HCPCS code, supplied through the CAP will be set through competitive bidding, with a limit on composite bids of 106% of ASP, there is no reason to pay for one drug at another's price. Furthermore, LCA would be extremely difficult to apply in CAP's proposed claims processing system. Under Medicare's regular drug payment methodology, when a physician bills for a drug subject to LCA, he or she can provide an advanced beneficiary notice (ABN) and collect payment from the beneficiary in excess of Medicare's rate. If LCA applied to the CAP, vendors would depend on physicians to provide ABNs, which would be required to allow the vendor to collect the full cost of the drug. It also is unclear how carriers' "grandfathering" or exceptions clauses would be applied under the CAP to protect beneficiary access to the most appropriate therapies. We request that CMS state in the final rule that LCA policies should not apply to the CAP.

F. Physicians' Administrative Burdens Under the CAP

Because one of the objectives of the CAP is to offer physicians a less burdensome means of acquiring drugs for their patients, we recommend that CMS review its proposed administrative requirements to ensure that they are no greater than currently apply. In particular, we believe CMS should re-examine its proposal to require physicians to include a number of pieces of additional information when transmitting written orders for CAP-covered drugs to vendors, including:

- Date of order;
- Beneficiary name;
- Physician identifying information;
- Drug name;
- Strength;
- Quantity ordered;
- Dose;
- Frequency/instructions;
- Anticipated date of administration;
- Beneficiary Medicare information;
- Supplementary insurance information (if applicable);
- Medicaid information (if applicable);
- Shipping address; and
- Additional patient information: date of birth, allergies, Ht/Wt/ICD-9, etc.¹⁵

¹⁴ "Competitive Acquisition Vendors Should Pay Drug Returns – CMS Doctor Panel," *The Pink Sheet*, Mar. 14, 2005, at 25; "CAP Vendors Given Leverage Over Generics, Little Power for Single-Source Drug Prices," *Inside Washington Publisher's Inside CMS*, Vol. 8, No. 5 (March 10, 2005).

¹⁵ 70 Fed. Reg. at 10756.

At a minimum, the information required from physicians ordering drugs through CAP should not be more than what is required for physicians ordering drugs under the current system, except for additional information that is required in order to allow CAP vendors to collect beneficiary co-payment and deductible obligations, a task that currently is performed directly by physicians. For example, the requirement to provide height and weight along with dose appears to be redundant, and the physician should be required to provide the dose only. Physicians should be required to provide only the information needed to allow the CAP vendor to fulfill its obligations as the physicians' pharmacy.

G. Physicians' Choice of CAP Vendors

Finally, physicians must be allowed to select the CAP vendors that offer the best selection of drugs for their practice. CMS asks for comments on whether a physician should be able to choose the categories he or she wishes to obtain from the vendor,¹⁶ although the statute clearly requires the CAP to offer physicians this choice. The statute allows physicians to choose the "contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician."¹⁷ For example, if anticancer and hormonal drugs are in different categories, a physician could choose one vendor to supply anticancer drugs and another to supply hormonal drugs. Requiring a physician to obtain all categories of drugs from a single vendor would severely limit their choices and would reduce competition among vendors. CMS should clarify in the final rule that physicians are allowed to select a different vendor for each category of drugs under the CAP.

III. CAP Bidding Process – Evaluation and Selection

CMS is proposing to select vendors based on a "composite bid," constructed from the bid prices for the individual drugs in the particular CAP category. CMS further proposes to reject a bid from any vendor that is higher than 106% of the weighted ASP for the drugs in that category.¹⁸ In calculating this threshold figure, sanofi-aventis urges CMS to use the most recent ASP data available, making projections for future changes in ASP payment rates as necessary. This will help ensure that potential CAP vendors are not inadvertently excluded from the program, thereby decreasing competition and limiting physician choice of qualified vendors.

IV. Conclusion

In conclusion, sanofi-aventis appreciates CMS' ongoing efforts to implement the various mandates of the MMA, and we ask the agency to consider our recommendations to ensure patient access to important therapies under Part B while these reforms take place. In particular, we ask CMS to:

¹⁶ *Id.* at 10755.

¹⁷ SSA § 1847B(a)(1)(A)(iii).

¹⁸ 70 Fed. Reg. at 10763.

Administrator Mark McClellan

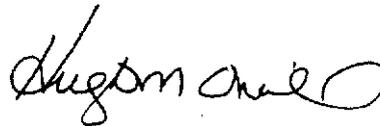
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- Clearly prohibit vendors from establishing formularies for CAP that would result in the exclusion of medically necessary drugs;
- Require vendors to offer at least one therapy per HCPCS code and at least one NDC per single source and each brand name therapy within a shared HCPCS code;
- Encourage vendors to include multiple NDCs for each drug to permit access to appropriate dosing and avoid waste;
- Clarify the resupply provisions to allow physicians to provide timely access to care and minimize costs to patients and the Medicare program;
- Allow physicians to request an initial supply of drugs from the CAP vendor to use for treating emergency conditions;
- Implement the "furnish as written" provisions with a minimal burden on physicians;
- Apply Medicare's current coverage rules, including the requirements for coverage of off-label uses of drugs, to the CAP;
- State in the final rule that carriers' least costly alternative policies should not apply to the CAP;
- Minimize physicians' administrative burdens, including the information required to be provided in CAP claims;
- Clarify in the final rule that physicians are allowed to select a different vendor for each category of drugs under the CAP; and
- Use the most recent ASP data, making projections for future changes in rates, when evaluating CAP vendor composite bids.

Sanofi-aventis appreciates this opportunity to comment on our concerns about the Proposed Rule, and we look forward to working with CMS to protect Medicare beneficiaries' access to life-improving drug therapies. We hope our suggestions will help CMS address these important issues in the final rule. Please contact me if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,



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April 26, 2005

BY HAND DELIVERY

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

Dear Dr. McClellan:

On behalf of Novartis Pharmaceuticals Corporation (Novartis), I appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS's") proposed rule on the Medicare Competitive Acquisition Program (CAP) for Outpatient Drugs and Biologicals Under Part B, published in the Federal Register on March 4, 2005. Novartis Pharmaceuticals Corporation is part of the Novartis Group of Companies, a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. Of particular relevance to this rulemaking, Novartis manufactures and markets drugs in the oncology, ophthalmics, and transplant areas that are covered under Medicare Part B.

We commend you and your staff for your efforts to develop this proposed rule. Novartis' goal is to ensure that patients have meaningful access to pharmaceuticals covered under Medicare Part B. We believe that the CAP has the potential to provide an efficient alternative for physicians to the buy and bill system for physician administered drugs. Our comments on this proposed rule reflect the goal of patient access to care and make suggestions to improve the operation of the program. We are concerned that the bidding process outlined in the proposed rule could create an environment that is economically unstable for vendors and the program. It will be especially difficult for vendors to participate in a cost efficient manner in small volume categories like ophthalmics. We address specific comments in the discussion that follows.

If you have any questions or require clarification on any of our comments, please do not hesitate to contact me.

Sincerely,

Bonnie Washington

**NOVARTIS PHARMACEUTICALS CORPORATION
COMMENTS ON CAP PROPOSED REGULATION**

Categories of Drugs To Be Included Under the CAP

In the proposed rule's discussion of the categories to be included in CAP, CMS acknowledges that the Medicare statute "most closely describes a system for the provision of and the payment for drugs provided incident to a physician's service." 70 Fed. Reg. at 10749. CMS then provides numerous examples within the CAP statute where reference is made solely to physicians, including that only a physician is granted the opportunity to elect CAP. As a result, CMS states that given "our concerns about the clear direction of the statute that the election to participate in this program rests with physicians, we do not believe it is possible to include drugs other than those administered as incident to a physician's service." *Id.* CMS solicits comments on whether the statute can be read to restrict CAP to drugs administered incident to a physician's service.

We believe that, in fact, the best reading of the statute is that only physician administered drugs should be included in the CAP. The CAP cannot apply to drugs and biologicals furnished by Medicare suppliers (e.g., pharmacies), including immunosuppressive drugs for the following reasons:

- a) The application of CAP to pharmacy supplied drugs might have an adverse impact on beneficiary access to such products. For example, inclusion in CAP could deny beneficiaries access to a full range of oral immunosuppressive drugs that are in the same billing code, yet are not therapeutically interchangeable. An example, Neoral (cyclosporine, USP) MODIFIED and Sandimmune cyclosporine, USP are both cyclosporine preparations that share a common HCPCS code but are not bioequivalent nor interchangeable. The proposed rules do provide for the physician to specify "furnish as written" to the CAP provider in certain cases, but the fact that the carriers responsible for claims adjudication may utilize post-payment review when physicians exercise the "furnish as written" option may well serve as an impediment to using the appropriate agent for the individual patient.
- b) The statute does not appear to permit inclusion of pharmacy-furnished drugs in CAP. The language of the statute plainly provides that CAP applies only to drugs that are furnished by physicians. It is only "physicians" that the statute permits to make the election to choose CAP and "physicians" to whom the statute allows CAP contractors to provide products. Elsewhere in the statutory provisions governing Part B drugs, Congress has incorporated the word "supplier" when it intended to address reimbursement for pharmacy provided drugs and it did not do so in the CAP statute. It is reasonable to exclude oral immunosuppressive drugs since the statute provides clear direction that the election to participate in CAP lies with the physician and the included drugs are those administered as incident to a physicians service or procedure.
- c) The intent of the statute was to remove the physician from the drug acquisition and billing process by providing a less burdensome means to obtain drugs. By including oral immunosuppressant medication in CAP, which are currently supplied by pharmacies, CMS would dilute the intent of the statute and only create another layer of distribution and logistic issues. This would defeat the very purpose for the CAP program's existence.

**NOVARTIS PHARMACEUTICALS CORPORATION
COMMENTS ON CAP PROPOSED REGULATION**

- d) Pharmacy furnished drugs do not fit within the CAP construct. CAP is intended for drugs that physicians administer and have historically purchased under the “buy and bill” method. Since pharmacies provide oral drugs (including immunosuppressants) to beneficiaries, physicians have not typically provided or administered such drugs in their offices.

Claims Processing Overview

Definition of emergency situation. Physicians participating in CAP may not always be able to obtain the drugs they need from the vendor in a timely fashion. There may be instances when the doctor must use medications from his own personal stock for a Medicare patient and then replace that drug with one supplied by the CAP vendor later. In the proposed rule, CMS proposes to require the physician to demonstrate the following in these circumstances: (1) the drugs were required immediately; (2) the physician could not have anticipated the need for the drugs; (3) the vendor could not have delivered the drugs in a timely manner; and (4) the drugs were administered in an emergency situation. CMS does not propose a definition of an “emergency situation,” but asks for comment on how it should be defined.

We recommend that CMS apply an expansive definition of “emergency situation.” In order for the CAP to promote patient access to drugs, CMS must allow physicians the flexibility to meet patient needs. The definition of emergency situation should reflect the unpredictable nature of patient care and that delaying care, rather than using existing inventory, would be contrary to the beneficiary’s best interests. Although a physician often can plan a patient’s course of treatment far enough in advance to order drugs through the CAP vendor, he or she cannot always plan ahead for the patient’s adverse reaction to a drug or change in condition since the last treatment. In addition, oncology patients often need supportive care as a result of their chemotherapy treatments and these should be readily available to them. Providing a therapy to address an adverse reaction or a change in the patient’s condition must be included within the definition of emergency situation.

Furnish as written option. CAP vendors must provide at least one drug or biological within each HCPCS code, and CMS proposes that a vendor be required to offer one NDC. As a result, a specific formulation that a patient may need may not be available from the CAP vendor. In those circumstances, CMS proposes to allow physicians to buy those drugs from another source and bill Medicare using the 106% of ASP methodology.

Novartis supports this policy, however, we note it may be confusing and lead to access issues when there are several formulations within a HCPCS code that are not therapeutically interchangeable. We recommend that CMS consider requiring a CAP vendor to offer at least one NDC of each non-therapeutically interchangeable formulation contained within the HCPCS code.

Billing and copayment collection process. In the proposed rule, CMS outlines the process for physicians to submit orders to vendors and to bill carriers for administration fees, and for

**NOVARTIS PHARMACEUTICALS CORPORATION
COMMENTS ON CAP PROPOSED REGULATION**

vendors to bill carriers for the cost of the drugs. This process represents a significant change from the current process and may result in beneficiary confusion regarding their copayments, especially if they are receiving products handled by multiple CAP vendors. We recommend that CMS specify a national standard process for CAP vendors to collect copayments from beneficiaries and notify physicians of the collection. This standard process should provide guidance on how independent charitable foundations that assist low-income beneficiaries with their copayments can interact with CAP vendors. These foundations are an important source of assistance for low-income beneficiaries and we are concerned that this assistance could be interrupted if there is confusion over billing with the CAP vendors.

In addition, we recommend that CMS specify what, if any, information physicians must give to their patients regarding their coinsurance liability at the time of service. Physicians could have the patient sign an ABN, which specifies what drug is being administered in any cases where coverage may be uncertain.

CMS proposes that CAP vendors would not be paid by the carriers until the physician claim for administration has been received and paid. We are concerned about CAP vendors experiencing delays in payment which may create problems for beneficiary access to medications. We recommend that carriers pay CAP vendors when the drug is shipped. This process would eliminate lengthy delays in payment for CAP vendors without creating program integrity issues.

Unused CAP drugs. In the proposed rule, CMS proposes that the physician notify the vendor that a CAP drug was not used and reach an agreement on how to handle the unused drug, consistent with applicable State and Federal law. If the vendor and physician agree that the drug could be maintained in the office and used for another Medicare beneficiary, the physician would generate a new CAP order number at the appropriate time.

CMS did not specify payment how payment for breakage, spillage or interrupted procedures would be handled. We recommend that CMS address this issue in the final rule. We propose that these situations be handled in a manner similar to the current Part B system and that CMS should specify a modifier for physicians who participate in CAP to bill for interrupted procedures and broken vials.

CAP Bidding Process – Evaluation and Selection

Bid Selection. CMS is proposing to select up to the five lowest bidders for a drug category in each area from all bidders that meet quality and financial thresholds. The proposed rule indicates that CMS will not select any bid from a vendor that is higher than 106% of the weighted ASP for drugs in that category, or the “composite bid.”

We are concerned that this methodology creates an environment that is economically unsustainable for CAP vendors, especially in low-volume categories such as ophthalmics. We recommend that CMS should allow flexibility for composite bids in some categories to exceed 106% of the ASP to encourage more vendors to participate in the CAP. Providing price

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COMMENTS ON CAP PROPOSED REGULATION**

flexibility in some categories would improve the overall access to medications without increasing the overall cost of the program to the government.

Adjustment of Reimbursement Amounts. CMS is proposing to update the CAP prices on an annual basis for the second and third years of CAP vendors' contracts based on the vendors' "reasonable, net acquisition costs" for that category.

We recommend that CMS update the CAP reimbursement amounts for vendors on a quarterly basis, parallel with the updates in the ASP system. If CMS does not update reimbursement under both systems on the same timetable, there could be serious discrepancies in payment amounts leading to confusion and access issues.



ABBOTT

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APR 26

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April 26, 2005

Mark B. McClellan, 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

**Re: CMS Proposed Rule on Competitive Acquisition of Outpatient
Drugs and Biological under Part B, 70 Fed. Reg. 10746 (March
4, 2005) [CMS-1325-P]**

Dear Dr. McClellan:

We are writing with several general comments on the Centers for Medicare & Medicaid Services ("CMS") proposed rule regarding the Competitive Acquisition of Outpatient Drugs and Biologicals (CAP) under Medicare part B (the "Proposed Rule"), 70 Fed. Reg. 10,7466 (March 4, 2005).

Abbott first of all, believes that CAP should be implemented in a manner that respects physicians' medical judgment and improves their ability to offer patients the most clinically appropriate drug therapies. We are concerned, however, that because CAP contractors would not be required to provide every National Drug Code ("NDC") associated with a HCPCS code, the CAP contractor's drug selection could effectively limit physician treatment options. Moreover, the proposed rule does not establish strong clinical safeguards to guide CAP vendor drug selection, as it does for Part D drug plans that use formularies. **As CMS drafts the CAP final rule, we recommend that the agency ensure beneficiary access to clinically-appropriate drugs is preserved.**

Secondly, CMS is soliciting comments on several approaches to defining competitive acquisition areas, including nationwide, regional or statewide competitive acquisition areas. **We believe that CMS should carefully phase-in this new program on a state-wide or other limited geographic basis with a limited number of CAP vendors participating. This will enable CMS to**



more manageably address the numerous operational issues that undoubtedly will arise upon implementation.

And finally, we echo the Pharmaceutical Research and Manufacturers of America's (PhRMA's) appreciation for CMS' efforts to work with CAP stakeholders in developing and implementing the program. Given the significant amount of regulatory work that remains before CAP is implemented in January 2006, and the important details concerning CAP implementation that might ultimately be hammered out through subregulatory guidance, we hope that CMS will continue to provide ongoing opportunities for stakeholder input regarding the program, as has been done throughout the Part D implementation process. We believe this approach has fostered constructive dialogue between CMS and stakeholders, and we encourage CMS to adopt a similar collaborative approach as it moves towards CAP implementation. Such an approach will provide CMS with ongoing access to a broad range of information and help ensure the transparency needed to maximize a positive outcome for physicians and patients. We therefore, **recommend that the CAP final rule be issued as an interim final rule with a comment period to provide additional opportunity for stakeholder input.**

Thank you for the opportunity to share our comments on this important proposal. We look forward to a continuing dialogue, and stand ready as a resource for your questions, comments or any additional information to support successful implementation of MMA and the Part D drug benefit.

Sincerely,

Virginia Tobiason
Director, Corporate Reimbursement and Health Policy



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MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

April 26, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

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

Dear Dr. McClellan:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the proposed rule entitled the "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B," as published in the March 4, 2005 *Federal Register*. MGMA recognizes the substantial challenges the Agency faces in implementing the wide-ranging components of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). However, MGMA has several concerns and recommendations related to this proposed rule, as outlined below.

MGMA is the nation's principal voice for medical group practice. MGMA's 19,500 members manage and lead more than 11,500 organizations in which more than 240,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

MGMA has consistently expressed its concern that Medicare reimburse providers appropriately for both the cost of drugs administered in the outpatient setting and the cost of physician administration services. The MMA dramatically altered reimbursement in both of these areas, and MGMA remains extremely concerned about the adequacy of reimbursement levels.

Drug acquisition costs fluctuate daily. Recent research findings that MGMA, the American Medical Association and a number of medical specialty associations conducted regarding the drug reimbursement issue, found that the ability for physician practices to obtain discounts varied widely by specialty, geography and

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other factors. MGMA remains gravely concerned about the adequacy of these payments and the lack of timely notification of payment changes to providers rendering these drugs.

In the 2005 proposed Medicare physician fee schedule, CMS suggested that providers may solve any difficulty in finding drugs at the average sales price plus six percent (ASP+6) rate by joining a group purchasing organization. However, not all specialties have group purchasing organizations and they are not available in all regions where Medicare providers practice. Furthermore, it is an incorrect assumption that all group purchasing organizations can acquire drugs at or below ASP+6. MGMA practice managers report that group purchasing organizations, while helpful, do not all mirror the reimbursement rates set under ASP+6.

The competitive acquisition program (CAP) may offer a viable alternative for providers who are unable to obtain drugs at or below the ASP+6 rates. However, the program must be administered in such a way that it does not further complicate administrative aspects of physician administration of drugs, requires timely delivery of drugs and continues to be appealing to drug vendors. To assist the Centers for Medicare & Medicaid Services (CMS) in making this program a viable option for medical group practices, MGMA offers the following comments and recommendations.

Overview of the CAP

Inclusion of CAP in the calculation of ASP

Although not specifically addressed by the proposed rule, MGMA seeks clarification on how the CAP will influence ASP rates, if at all. We assert that the inclusion of CAP vendor prices in the calculation of the ASP is inappropriate. Only if a CAP vendor is a manufacturer, should the prices fall into the definition of ASP which includes the wholesale and sales price to distributors. Otherwise, the inclusion of the CAP rates in the calculation of ASP would be duplicative.

Definition of participating CAP physician

The definition proposed in the rule under the new 42 CFR 414.902 states that a "participating CAP physician" is a "Medicare physician." We interpret "Medicare physician" to mean a participating MD or DO who has enrolled in the Medicare program. If this is the appropriate reading of the definition, MGMA recommends that CMS revise the definition to clearly state that a "participating CAP physician means a MD or DO who is enrolled in the Medicare program as a participating provider."

However, MGMA cautions CMS that the availability of the CAP should not be limited to participating providers. As previously noted, the CAP can offer physicians treating Medicare patients a viable alternative to taking significant financial risks under the ASP reimbursement mechanism. Additionally, the definition of "selecting physician" in §303(d)(5)(B) of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (42 USC 1395w-3b(d)(5)(B)) has no such limitation. Instead, the category of physicians eligible for participation is open to "a physician who has elected this section to apply and has selected to apply under this section such contractor for such category and area." Therefore, MGMA strongly recommends that CMS clarify that the program is open to all physicians who treat Medicare patients, regardless of their participation status, and that the agency modify the definition in such a way to reflect open enrollment.

Categories of drugs to be included under the CAP

Phase-in implementation

CMS proposed in the rule four different alternatives for phase-in implementation, invited comments on all options outlined in the notice and welcomed alternative suggestions. MGMA respectfully rejects the proposals outlined, as the limitations imposed by them would restrict administrative and programmatic lessons learned to a small category of drugs and/or a single specialty. Alternatively, MGMA recommends that CMS initially make available a full-spectrum of categories of drugs under the program.

This list should include those drugs that many providers have been unable to obtain at rates close to or under ASP+6. MGMA understands that a brief list of approximately 40 codes is being worked on by the Physician Regulatory Issues Team as well as the Office of the Inspector General. This list should be the basis for which drugs would be first offered through the CAP. Specifically, MGMA urges CMS to offer bladder cancer drugs through the CAP, as we have received numerous member reports of difficulty in obtaining these drugs at or below ASP+6.

Category definitions

Specific drug categories were not identified in the proposed rule. Instead, CMS seeks comments on the structure of these categories.

MGMA first recommends that CMS propose a definition for these categories as an interim final rule with comment period. This will afford the public an opportunity to offer further advice and critique. It also addresses the phase-in and permits future comment as the program is incrementally implemented. Additionally, we suggest that the categories be narrowly defined, so that physicians may be able to choose vendors based upon the specific brands that they offer for multi-source drugs.

Off-label uses

The use of drugs purchased through the CAP program for covered off-label uses is not addressed in the proposed rule. MGMA seeks clarification as to whether physicians who intend to use drugs for experimental, clinical trial and other off-label uses covered by the Medicare program will be able to obtain drugs through the CAP system. Additionally, MGMA requests clarification on how code J9999 will be handled for the Medicare covered off-label use of certain drugs to match CAP drug orders and drug administration claims.

Provision of NCDs by vendors

MGMA applauds CMS' proposal that vendors be required to provide CAP prospective doctors with a list of specific National Drug Codes (NDCs) for multi-source drugs. However, the proposal notes that the "information will be provided to physicians who request it no later than the beginning of the election period..." 70 Fed. Reg. 10751. MGMA asserts that it is imperative for a physician to have the list of NDCs that vendors will supply to make their selection of a vendor. Therefore, the list should not be made available upon request. Instead, it should be compulsory and posted to the CMS Website. This requirement should be incorporated into regulatory language of the physician selection of an approved vendor (proposed 42 CFR 414.908(a)), CAP program requirements (proposed 42 CFR 414.908(b)) and Terms of Contract (proposed 42 CFR 414.914).

Competitive Acquisition Areas

MGMA supports the proposed national competitive acquisition area. This approach is consistent with the national ASP model used for Part B drugs. Additionally, supplies used in the calculation for geographic adjustments to the resource based relative value scale are also assessed on a national basis. Specifically, the geographic practice cost indices (GPCIs) assume that medical equipment, supplies and other miscellaneous expenses have a national market and input prices do not vary among geographic areas. For these reasons, MGMA believes that a national competitive acquisition area is consistent with Medicare policy and supports established national drug vendors and distributors.

Consistent with our recommendation, MGMA urges CMS to modify the proposed CFR 414.908(a)(2)(ii) to remove the example of "physician relocates to another competitive area" as an exigent circumstance that would permit a physician to choose another vendor. It is not necessary for a nationally based acquisition area program.

Statutory requirements concerning claims processing

Although the preamble to the notice of proposed rulemaking noted that CMS uses the term "prescription" and "order" interchangeably and interprets it "to include a written order submitted to the vendor," no such definition is included in the proposed rule or current regulation. 70 Fed. Reg. 10753. MGMA recommends that CMS include a definition for "prescription" and/or "order" in the subsequent rule.

Claims processing overview

Incident-to drug limitation

MGMA supports this limitation as part of the phase-in of the CAP program. However, once the program is fully implemented, the CAP should be made available for all categories of drugs, as described in 42 CFR 414.900.

Physician order for whole course of treatment

Many physicians currently order a drug supply sufficient to cover a typical course of treatment for a patient. MGMA appreciates that the CMS proposal permits this type of flexibility to occur. However, the course of treatment may take several months. Many patients do not schedule treatment dates more than a few weeks from the time when a physician orders the drugs. Thus, the flexibility of current drug administration scheduling may not be permitted by the required reporting of the anticipated date of administration at the time of order. Therefore, MGMA recommends that CMS relax the anticipated date of administration to permit doctors to give a "ballpark" date, rather than a strict date of administration.

HIPAA compliance and billing instructions

MGMA appreciates CMS' clear intention to adhere to the transactions and code set mandate established by the Health Insurance Portability and Accountability Act (HIPAA). MGMA looks forward to the timely release of billing instructions which clarify which 837-compliant and CMS-1500 fields physicians should use to identify the prescription number and other required fields for billing CAP drugs and administration services.

Partial payment

In the proposed rule, CMS queries the public whether there is sufficient reason to offer vendors a provisional payment for drugs when a physician has not billed for the drug administration service within 28 days of the anticipated date of administration. As noted above, MGMA remains wary of a strict date of administration due to the nature of a course of treatment and patient schedules. Therefore, MGMA suggests that CMS use the timeline for provisional payment as currently used for Medicare secondary payer (MSP) claims.

The agency makes conditional payment for MSP claims where another insurance company is primary to Medicare when payment is not anticipated within 120 days of the date of service. MGMA believes that this timeline is consistent with Medicare policy and offers both the vendor and physician time to document services and file claims with regional carriers and the CAP designated carrier.

The proposed rule includes a brief explanation of a proposed methodology for partial payment to vendors for drugs supplied but not yet billed by a physician. The proposal notes that "If a physician's claim was not received within 90 days, or the claim was not approved for payment, the initial partial payment made to the vendor would be recouped using CMS overpayment recovery process." 70 Fed. Reg. 10757. The difficulty of the proposed processing system is that vendors will be held responsible for physician claims processing with a deadline of no longer than 90 days for partial payment. As noted above, MGMA does not support a 90-day period and alternatively recommends a 120-day partial payment waiting period.

Emergency situations and resupplying physician stock

CMS proposes that the emergency administration of drugs would be merited under the following scenario: (1) the drugs were required immediately; (2) the physician could not have anticipated the need for the drugs; (3) the vendor could not have delivered the drugs in a timely manner; and (4) the drugs were administered in an emergency situation. These requirements were established in § 303(d)(1)(b)(5) of the MMA.

While this definition would generally permit doctors to administer drugs obtained outside the CAP program in a limited set of emergency situations. Yet, emergency scenarios falling outside of this definition would remain. These situations would arise when a drug is received by a provider to be administered in a timely fashion and the provider questions the integrity and quality of the drug. Alternatively, a physician could have ordered the drug and it is not delivered in a timely fashion. In these circumstances, a physician did anticipate the need for the drug, thus not fitting the demonstrable "emergency situation." MGMA seeks guidance so that the above situations fall into the emergency situation category or a new category for vendor delay and physicians are permitted to use current stock for patients.

MGMA is also concerned with emergency situations where the provider does not have the drug in stock. In these situations, the physician must identify an alternative source where the drug can be obtained immediately. This may be a local distributor or hospital. Depending on the drug, the cost of the immediate transfer may be considerably more than the ASP+6 price; a price that the physician must solely bear under the proposal. Moreover, the CAP replaces a drug which the physician never had in inventory. MGMA recommends that CMS make allowances for drugs that physicians do not commonly keep in stock that are used in emergency situations. In these cases, MGMA suggests that physicians are given an option to restock their inventory or bill for the drug under the ASP+6 system.

MGMA agrees with CMS that a coding modifier would be the best solution to identify drugs that were administered in an emergency situation and require restocking. However, MGMA is concerned that

physicians would be penalized under the "prompt filing" deadline as providers would be required to hold drug administration claims until the CAP vendor sent the replacement drug with the appropriate prescription number. MGMA requests that CMS not apply the "prompt filing" deadline to emergency situations or permit an extension of the deadline such that providers will not be penalized for the time it takes the vendor to fill the order and deliver the drug.

Definition of "timely delivery"

In the 2005 final Medicare physician fee schedule, CMS established a timely delivery standard of "approximately 5 days" for oral cancer and inhalation drugs. 69 Fed Reg 66314; 66337. Using the same rationale as outlined in the final 2005 rule, MGMA recommends that CMS adopt this standard for the CAP in non-urgent situations. However, MGMA requests that CMS make allowances for urgent orders when requested by a physician and require overnight delivery where drug integrity and quality guidelines demand.

Dispense as written orders

MGMA applauds the inclusion of the "dispense as written" (DAW) provision in the proposed CAP rule. This provision is essential for physicians to render appropriate care to Medicare beneficiaries. MGMA suggests that billing for DAW drugs be accommodated through a coding modifier.

Drug category selection by physician

MGMA recommends that categories be defined as narrowly as possible to permit physicians' category selection. However, without knowing how categories will be defined (by specialty, NDS, drug category, etc.), it is difficult to make a recommendation that physicians be required to choose all drugs in a category. Therefore, MGMA recommends that during the phase-in, providers be permitted as much latitude as possible to choose the drugs in which they participate in the CAP and to revisit this issue once the program is fully implemented. Additionally, MGMA urges CMS to publish the next rule as an interim final rule with comment period, so that the public may comment on the final category structure and selection process.

Administrative burden and dispensing fee

The proposed rule states, "We do not believe that the clerical and inventory resources associated with participation in the CAP exceed the clerical and inventory resources associated with buying and billing drugs under the ASP system." 70 Fed. Reg. 10755. MGMA flatly rejects this assertion. Under the CAP as proposed, medical group practices would be required to keep an inventory of CAP drugs and file duplicative claims data to participate. Providers purchasing drugs through the ASP+6 do not carry these burdens.

MGMA has conducted extensive surveys of medical practice costs for more than 50 years. MGMA-collected data indicate that the cost of operating a group practice rose by an average 4.8 percent per year over the last 10 years. In fact, between 2001 and 2003, MGMA data show that operating costs increased more than 10.9 percent. Medicare reimbursement rates for physician services have fallen far short of the increased cost of delivering quality services to Medicare payments and do not capture new administrative burdens such as the keeping of a drug inventory or the filing of duplicative claims data in drug orders.

In the 2005 final Medicare physician fee schedule, CMS recognized the cost related to the dispensing of drugs. As codified in 42 CFR 414.1001, the agency provides supplying and dispensing fees to pharmacies for oral cancer and inhalation drugs. For oral drugs the supplying fee is \$24. 42 CFR 414.1001(a). In

2005, CMS significantly increased the dispensing fees for inhalation drugs, from \$5 a month to \$57 for a 30-day supply and to an \$80 fee for a 90-day supply. 42 CFR 414.1001(c) and (d). Additionally, pharmacies providing drugs to patients during the first month after a transplant are given a \$50 supplying fee. 42 CFR 414.1001(b). It is ironic that CMS recognizes the concern and cost of providing drugs to patients in the context of pharmacies but is unwilling to recognize the cost associated with participation in the CAP program.

MGMA strongly recommends that CMS reimburse providers for the cost associated with the additional administrative burdens mandated by CAP participation. Provider costs will vary by the sophistication of practice claims processing and supply/drug inventory systems. Also, it remains unclear if CAP vendors will be able to receive orders electronically. Nevertheless, there still remains an element of human interaction with the system as providers will need to identify what drugs are received in the mail and when and which patients the drugs are intended for.

MGMA data shows that the average cost per physician for preparing and processing a claim is approximately \$20. MGMA feels confident that this data is similar to that of costs associated with the proposed CAP order which is more like a claim than a prescription as defined by a majority of state laws. Therefore, MGMA recommends that CMS reimburse physicians a dispensing fee of \$20 to compensate physicians for the new burden of keeping an inventory log and filing an order which requires intensive information not required in private drug orders reimbursed under the ASP+6 methodology.

If CMS adopts the changes recommended by MGMA and reduces the requirements of the CAP order, an administrative cost is still associated with keeping an inventory, filing the CAP order and tracking the prescription number. Again, these precise costs are not associated with the ASP+6 system. MGMA theorizes that these costs are approximately \$5, using administrative costs identified in our cost surveys. MGMA recommends that, regardless of the nature of the CAP order, CMS should implement a dispensing fee to compensate CAP physicians for the costs associated with participation in the program.

Prompt claims filing

In the rule, CMS proffers evidence that "75 percent of physician claims are currently filed within 14 days." 70 Fed. Reg. 10755. It is unclear from the explanation whether this data includes hospital outpatient departments and what percentage of the data represents small group practices and solo practitioners. While MGMA data mirrors the CMS finding for large group practices and facility-based physicians, according to MGMA surveys, multi-specialty and small group practices take longer periods to file claims than the average. Therefore, MGMA asserts that a longer timeline must be established to accommodate all practitioners.

The Medicare program currently permits providers to submit claims generally within one year from the date of service. 42 CFR 424.44(a). The proposed rule stipulates that CAP physicians agree to file claims within 14 days of service. The abrupt modification of claims submission deadline from 365 to 14 days is an incredible change that is not substantiated by the arguments and observations of CMS in the proposed rule. For these reasons, MGMA recommends that CMS define prompt claims filing for the CAP to be at a minimum 30 business days from the date of service.

Definition of extenuating circumstances

As noted previously, MGMA strongly believes that providers should be provided a prompt processing period of 14 days, a filing period of 30 days and an extension to 120 days if extenuating circumstances prevent the physician from filing.

"Extenuating circumstances" is already articulated in Chapter 1 §70.7 of the Medicare Claims Processing Manual and 42 CFR 424.44. Generally, MGMA envisions this definition to recognize that where a physician believes that a beneficiary, vendor or administrative error by the Medicare program caused their late filing, physicians be afforded a filing grace period of up to 120 days from the date of service. Administrative error may include misrepresentation, delay, mistake or other action by the Medicare program, or its fiscal intermediaries or carriers or CAP vendors.

Prescription information from physician

The proposed data elements for the CAP order (70 Fed. Reg. 10756) are duplicative to those submitted on a service claim and do not reflect either a drug prescription or drug order. Generally, prescriptions require: (1) date of prescription; (2) patient name; (3) physician identifying information including name, group name, practice address and telephone number; (3) drug, dosage, quantity and refill(s) permitted; (4) patient instructions; (4) DEA/LIC number (if applicable); and (5) signature. Drug orders conducted under the ASP+6 system generally require: (1) physician/group identifying information including name, practice address and telephone number; (2) billing and shipping address; (3) drug, shipment size (vial) and quantity; and (4) DEA/LIC number (if applicable).

As currently proposed, MGMA strongly believes that the requirements are too burdensome and do not reflect current industry standards. Instead, the data elements reflect requirements for the Medicare billing system. The burden of the collection of claims data should be placed on Medicare and not CAP participating physicians. MGMA recommends that many of the data elements sought in the proposed rule be obtained through claims adjudication and not CAP orders. Examples of these elements include: patient date of birth, allergies, height, weight, ICD-9 codes, supplemental health insurance information and Medicaid information.

For payment, many pharmacies require information on insurance. However, these elements are collected directly from the beneficiary. Since this encounter will not occur in the CAP, it is reasonable that the patient insurance number (HIC number) be required in the CAP order.

Specific to the provider identification number, the national provider identifier (NPI) will be available for application beginning in May 2005. MGMA urges CMS to implement the use of the NPI for Medicare programs as soon as possible and to update the CAP order elements no later than the date of NPI compliance in May 2007.

Inventory of CAP drugs

MGMA applauds CMS' observation that separate physical storage of CAP drugs is overly burdensome and not required. However, the requirement that a separate electronic or paper inventory for each CAP drug kept by physicians negates the agency's assertion that there are no new administrative burdens required under the program. "We do not believe that the clerical and inventory resources associated with participation in the CAP exceed the clerical and inventory resources associated with buying and billing drugs under the ASP system." 70 Fed. Reg. 10755.

While MGMA agrees with CMS that the inventory will help medical practices identify stock kept for individual patients, the burden in doing so is new and not required under the ASP+6 model. Therefore, the additional burden must be captured and compensated in such a way that providers are made whole for participating in the program. MGMA again asserts that CAP physicians are reimbursed a reasonable dispensing fee per order as described above.

CAP drugs not administered

In instances where a physician does not administer a drug to an individual patient as ordered, the system must be flexible enough to permit physicians to either keep the drug and transfer it to another Medicare patient or return the drug. Such notification and decision-making should be automated through electronic systems. MGMA looks forward to learning more about the agency's electronic program for notification and communication between providers and CAP vendors. This system should be freely available to providers on a 24 hours a day, 7 days a week basis.

One major concern raised by a number of our members is that of state law in regards to the return of prescription drugs. In certain states (e.g., Florida and Georgia), state law prohibits the return of drugs that are prescribed to an individual patient. Also, some manufacturers prohibit the return of drugs when ordered through a distributor. MGMA is very concerned about the potential conflicts between state law, manufacturer requirements and CAP administrative issues. Specifically, how will CAP vendors deal with drugs that are not administered and physicians that do not have a patient to transfer the order to? If the vendor chooses to have the drug returned to the vendor, will the physician open him/herself to scrutiny under applicable state law? MGMA seeks guidance from CMS on this important issue.

Coinsurance and supplemental insurance billing

The proposed administrative process for vendors to collect coinsurance from beneficiaries follows current system requirements. However, many providers of physician-administered drugs report "bad debt" from beneficiary coinsurance amounts where good-faith efforts to collect the coinsurance from the patient are made but no money is actually collected. Instead, these monies are simply written off. MGMA surmises that potential vendors are not aware of this "bad debt" issue as CMS itself does not have a clear picture of the extent of write-offs physician group practices make in relation to Part B drugs. CMS must make clear to vendors that "bad debt" does exist under the current system, what type of debt collection is permissible and how beneficiaries who do not pay their coinsurance should be handled. MGMA strongly supports the policy that no beneficiary should be excluded from the CAP program due to non-payment of coinsurance amounts.

The greatest concern raised by members of MGMA deals with the billing of supplemental insurance both as primary coverage and Medigap coverage. MGMA seeks clarification whether physicians will be permitted to use the CAP in instances where the physician knows that another insurance plan is primary to Medicare. Also, how will the program handle CAP drugs ordered and administered where the physician did not know that another insurance plan was primary to Medicare? Lastly, what is required from physicians for patients with Medigap insurance?

MGMA seeks clarification of these scenarios and strongly urges the agency to distribute provider and vendor education materials on these instances so that both stakeholders may clearly understand their roles and responsibilities under the program.

In further discussion below, MGMA also seeks guidance on billing for drugs where a physician has reason to believe that the Medicare program will deny benefits. Specifically, whether CAP drugs may be administered and billed to the patient when the physician gives notice of probable denial of coverage.

Physician claims filing for drug administration

The proposed rule requires the administration claim elements: drug HCPCS code, prescription number, and date of service. These fields are reasonable and MGMA supports the proposal if such elements are HIPAA compliant on implementation.

Vendor claims filing for drug reimbursement

MGMA notes that the proposed vendor claim does not include many of the elements proposed in the physician CAP order. Instead, the only data elements are the prescription number, the provider identification number and the expected date of service. MGMA suggest that additional claims fields including patient number (HIC) are necessary and urges the agency to greatly simplify the nature of the drug order since the vendor will not use these elements in their claim to the program.

Dispute resolution

Resolution of vendor's claim

The relationship created between vendors and physicians under the CAP rule is a unique situation where the vendor relies on the successful adjudication and payment of a physician claim. In many ways, this burdens the relationship between the vendor and physician by putting them at odds in the age old conflict over money.

The proposed rule does not identify any safeguards for physicians where a vendor who aggressively seeks payment and pushes the provider into appealing claims. Many providers do not appeal all claims that are denied, focusing instead on claims that can be easily reprocessed. This is increasingly true for small-dollar items and services. Under the CAP, vendors may force physicians into a situation where they are required to appeal claims that they previously had no intention of appealing, even where there is medical necessity and every indication the claim should be covered.

This adversarial arrangement is further burdened by the ability of vendors to recommend suspension of physicians from participation in the program. MGMA recommends that whatever the final vendor loss threshold is, that it be both over a certain dollar amount and a large percentage of orders. Additionally, MGMA suggests that Medicare carriers offer provider education to physicians close to and above this threshold to ensure that they are aware of all Medicare drug administration billing and coding guidelines.

Also, providers should receive ample notice of suspension decisions. The notice should include: the date of the decision, the factor(s) taken into account, the appeal process and the options available to physicians if they are indeed excluded from the CAP program.

Resolution of physician's drug quality and service complaints

It is very helpful that the rule includes clarification that the vendors are the first point of contact for problems with quality and shipment of CAP drugs. It is equally helpful to identify that the designated carrier will act as the third-party in disputes between vendors and physicians for drug quality and shipment problems including timeliness and quantity of drugs ordered.

Resolution of beneficiary billing issues

The rule erroneously states, "If the drug administration claim has been denied, the MSN will reflect a message instructing the beneficiary no deductible or coinsurance may be collected for the drug." 70 Fed. Reg. 10758. This is an over-generalization of the Medicare billing rules, whereby services rendered where a duly proffered and signed advance beneficiary notice (ABN) is obtained, physicians and vendors are able to bill the patient up to the reasonable rate identified in the ABN. This begs the question, may CAP drugs be administered if the physician has reason to believe that Medicare will not cover the service? If so, who is responsible for the notice of drug liability and rate? If not, the final rule and Medicare contractor billing guidance should clearly state that ABNs may not be given to patients with CAP drugs and physicians should not provide CAP drugs to patients where they have a reasonable belief that the program will deny coverage. Additionally, the interim final rule with comment period should clarify how providers should obtain these drugs, if they may not use CAP supplies.

Contracting process-quality and product integrity aspects

Product integrity

Physicians currently work with individual drug wholesalers, distributors and manufacturers to obtain physician administered drugs and have established relationships where they are comfortable with the quality and integrity of the drugs. MGMA is heartened by the safeguards CMS outlines in the proposed rule to ensure product integrity. However, MGMA seeks clarification that where a physician questions the integrity of a drug, that they may return the drug and seek replacement from the CAP vendor without repercussion.

Furthermore, MGMA asserts that the proposed bid of a potential CAP vendor should include potential loss due to product integrity issues that occur during shipment (spoilage) and breakage (spillage) caused during shipping.

CAP bidding process-evaluation and selection

As noted above, MGMA believes additional costs should be included in the vendor bid. They include spoilage and breakage (spillage) that occurs during shipment. MGMA believes that the replacement burden should be on the vendor and these are reasonable costs that occur during the course of normal business practices for drug distribution.

Physician election process

Enrollment in CAP program

As noted previously, MGMA has concerns regarding several of the provider agreements proposed in the rule for CAP physicians. Additionally, MGMA opposes the election period of Oct. 1 to Nov. 15. This deadline is different from the Medicare participation agreement timeline and will confuse physicians. Therefore, MGMA proposes a deadline of Dec. 31 to coincide with the participation agreement election period and that providers be notified when they are approved and enrolled with a vendor. Although this may occur after Dec. 31, providers could bill for drugs under the ASP+6 system until the vendor had processed and acknowledged approval of the physician application.

Vendor leaves program

MGMA opposes the mandate that a physician must stay in the CAP if a vendor leaves the program mid-cycle. Instead, physicians should be given the option to choose another vendor or return to billing the category(ies) of drugs supplied to them by the vendor under the ASP+6 system. Physicians may choose individual vendors on the basis of which specific brand-name drugs they plan to supply under individual HCPCS codes. This option allows physicians to make an educated decision and increases provider satisfaction with the program.

Group practice billing

The proposed rule would mandate that all physicians in a group practice who enroll in the CAP program under the group number must adhere to the participation decision of the group. MGMA supports this recommendation as it simplifies the need to enroll all group practice physicians in the CAP program. However, MGMA seeks clarification where an individual physician in a group practice enrolls in the CAP program under his or her own individual number. Must the group be held accountable to the individual's decision? MGMA believes that the participation decision is on an individual physician level and should not be attributed to a whole group, unless the business as a whole enrolls the entire group under their number in the program.

For example, if a multi-specialty group of 25 physicians enrolls under the group Medicare number, then all physicians are participating in the CAP. Alternatively, if 5 physicians from the group enrolled under their individual numbers, they would be individually enrolled in the CAP but the group (the remaining 20 doctors) would not. All administrative claims for individual participating physicians in a group would be billed under their individual billing number.

New physician participation in CAP

The proposed rule correctly provides an alternative timetable for admission of newly enrolled physicians into the CAP program. MGMA seeks clarification on the definition of "new physician" for the purposes of the CAP program and the triggering event for the 90 days notification timeline. Specifically, are new physicians considered those physicians who have not enrolled in Medicare in that jurisdiction, enrolled in Medicare anywhere or recently graduated and began seeing patients? Also, does the 90 day period commence on the date of enrollment in the Medicare program or some other triggering event?

Vendor and physician education

Provider education is paramount to the successful implementation of the CAP. Following the very uncertain implementation of the ASP system, MGMA strongly urges CMS to publish timely articles and education materials for vendors and physicians. Last year, materials were not yet available on many of the billing nuances of the new system and guidance on coding issues was published well after implementation. Therefore, CMS should work with vendors to test drug order processing system and issue guidance in advance of Jan. 1.

As noted in several studies by the Government Accountability Office (GAO), the information provided by the CAP designated carrier must be correct and timely. Thus far, Medicare contractors have not scored well on this account. MGMA supports the GAO's recommendations and urges CMS to improve the responses to policy-oriented inquiries from providers. Specifically, the GAO recommends that CMS develop: a process to route policy inquiries to staff with the appropriate expertise, clear and easily accessible policy-oriented material to assist carrier representatives and an effective monitoring program

for call centers. MGMA looks forward to collaborating with CMS to educate carriers and medical group practices on the CAP.

Beneficiary education

MGMA applauds CMS' proposals to create and distribute beneficiary education materials on the billing changes they will experience with the CAP program. Specifically, MGMA agrees with the observation that receiving a separate Medicare Summary Notice from a vendor "may cause confusion for the beneficiary because he or she would only know that the drugs were administered by the physician." 70 Fed. Reg. 10767. Materials created and distributed by the agency can and should be made available by participating practices. However, MGMA opposes any provider mandate for the provision of materials to patients receiving CAP drugs.

Currently, practice management systems cannot easily identify patients who are participating in a sub-program of an individual health insurance product. Systems likely would require unique and individual upgrades which are very expensive. Therefore, MGMA welcomes the development of materials for distribution to patients and looks forward to partnering with CMS to aid in the education of physicians on their availability, but opposes any mandate to provide specific materials to beneficiaries receiving CAP drugs.

Regulatory impact analysis

As noted above, the administrative burden to comply with the CAP program is excessive and can easily be decreased by following the recommendations made in this letter. However, additional administrative tasks still remain, all of which are not currently captured in Medicare reimbursement for physician-administered drugs. We urge CMS to revise the regulatory impact analysis and reimburse physicians for the additional burden imposed by participating in the CAP.

Use of CAP vendors for non-Medicare drugs

Currently, medical practices obtain physician administered drugs in batch orders that address treatment needs of both Medicare and non-Medicare patients. MGMA seeks clarification whether physicians will be prohibited from obtaining drugs from CAP vendors for non-Medicare patients through ancillary agreements made directly between the vendor and physician. If CAP physicians may purchase drugs from CAP vendors for non-Medicare patients, what, if any, safeguards must providers show for compliance with federal law. These inquiries also apply to non-covered physician administered drugs therapies.

Participation forms submitted to OMB (OMB Approval No. 0938-Pending)

The physician enrollment form does not clearly outline the process for a group practice enrollment in the CAP. Therefore, MGMA recommends that the form be revised to clearly state how a group practice may enroll on behalf of all physicians and the ramifications of such an enrollment.

Application of e-prescribing rules to Part B drugs

The expansion of the Part D benefit to drugs currently covered by the Medicare system remains a complex aspect of the implementation of the Part D program and the Electronic Prescription Drug Program. Many industry groups, including MGMA, assert that this nexus will result in numerous providers, suppliers and contractors who did not consider themselves to be directly affected by Part D being swept into the program's requirements, including the e-prescribing obligations.

MGMA seeks clarification as to how, if at all, providers will be required to incorporate e-prescribing technologies if ordering drugs currently paid under the Part B program or acquired through the CAP. The proposed rule acknowledges that drugs dispensed by vendors would require a physician's order. This order would include a request for the complete treatment of the patient (multiple doses) and includes the (a) date of order; (b) beneficiary name; (c) physician identifying information, name, practice location, group practice information (if applicable) and Medicare enrollment number; (d) drug name; (e) strength; (f) quantity ordered; (g) dose; (h) frequency/instructions; (i) anticipated date of administration; (j) beneficiary Medicare information/health insurance number; (k) Medicare information; (l) shipping address; and (m) additional patient information including date of birth, allergies, height, weight, diagnosis codes, etc.

As noted above, MGMA recommends that these data elements be greatly simplified. Furthermore, we recommend that CMS ensure that these data elements will be able to be performed within the proposed NCPDP SCRIPT standard. It would be very burdensome if providers are required to submit some of the CAP order through an e-prescribing system and other required data sets through a separate system, either electronic- or paper-based.

Furthermore, the proposed CAP would assign individual Medicare prescription numbers to dispensed drugs used in claims adjudication and payment. CMS should ensure that the NCPDP SCRIPT standard has the ability capture this specific number for Medicare processing.

Lastly, it remains unclear from the proposed CAP regulation, if CAP vendors would be required to use the standards established under the Electronic Prescription Drug Program. It appears that this proposed rule intends to require prescribing physicians and pharmacies/entities of any drug payable under the Medicare program to adhere to the requirements of the Electronic Prescription Drug Program. However, this additional future obligation is not made clear in the CAP regulation, "CAP Vendor Application and Bid Form" or accompanying "CAP Drug Vendor Application Guide" (OMB Approval Pending No. 0938).

MGMA appreciates your consideration of these comments. If you should have any questions, please contact Jennifer Searfoss Miller in the Government Affairs Department at (202) 293-3450.

Sincerely,



William F. Jessee, MD, FACPME
President and Chief Executive Officer