1020 First Avenue
PO Box 61501
King of Prussia, PA 19406-0901
Tel: 610-878-4583
www.zlbbehring.com

AUG - 9

ZLB Behring

August 3, 2005

The Honorable Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

ATTN: (CMS-1325-IFC) Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B, Interim Final Rule with Comment Period

Dear Dr. McClellan:

ZLB Behring is a leading researcher and manufacturer of life-saving biotherapeutics such as blood clotting factors to treat bleeding disorders, including hemophilia and Von Willebrand disease; intravenous immune globulin (IVIG), which is used in treating conditions such as immune deficiencies; and alpha$_1$-proteinase inhibitor, used to treat alpha$_1$-antitrypsin deficiency, which is commonly referred to as genetic emphysema. We have also submitted to the FDA a Biologics License Application for a new subcutaneous immune globulin that could be especially helpful in patients with venous access issues. These therapies are created by either pooling and manufacturing donated human blood plasma into lifesaving therapies or through recombinant DNA technology.

Thank you for allowing ZLB Behring the opportunity to comment on the interim final rule regarding implementation of the Competitive Acquisition Program (CAP) for Medicare Part B. We believe that CMS correctly used its authority in determining which therapies to include and not include within the initial implementation of CAP. The consideration that CMS applied to covered therapies derived from human plasma and recombinant analogs is especially appreciated, as the agency recognized their unique attributes in treating rare conditions for chronic disease populations. By not including blood clotting factor, alpha$_1$-proteinase inhibitor and immune globulins within the CAP, CMS will preserve access to these life-saving therapeutics. On behalf of ZLB Behring, I would like to briefly comment on each of our therapies as they relate to CAP.

Blood Clotting Factors

Blood clotting factors were not included within the implementation of the CAP program. This will positively result in the estimated 1100 Medicare beneficiaries with hemophilia having continued access to the multiple brands of therapy within a class. The different brands of

clotting factor within a therapeutic class are not all of the same composition and beneficiaries react differently to the specific brands. ZLB Behring applauds CMS' decision in addition to the provision requiring that a proposed rule be issued should CMS decide at some point in the future to include blood clotting factors within CAP.

Intravenous Immune Globulin (IVIG)

CMS correctly did not include IVIG within the CAP and stated that should the agency decide to include at a later date, similar to clotting factor, it would issue a proposed rule. The MMA statutory language precludes CMS from including IVIG within CAP. As the interim final rule points out,

> *"Many of these commenters also argued that IVIG is implicitly excluded from the CAP by section 1842(o)(1)(E)(ii) of the Act (section 303(b)(1)(E)(ii) of the MMA), which provides that the payment for IVIG "in 2005 and subsequent years" is the amount determined under the ASP system".*

Immune Globulins

ZLB Behring commends CMS for determining that other immune globulins will not be included within CAP at this time. While the agency did reserve the right to include immune globulins at a later date, we request that CMS maintain this exclusion. As previously indicated, ZLB Behring plans to introduce a subcutaneous immune globulin to the United States market in the near term. We believe this therapy will be an innovative step in the advancement of immune globulin for treating individuals who have difficulty tolerating traditional methods of administering immune globulin. ZLB Behring believes that by not including IVIG within CAP, Congress intended to ensure access to immune globulin therapy for conditions like immune deficiency and not solely the intravenous delivery method. Excluding IVIG but not the subcutaneous form of therapy (should the decision ever be made to phase immune globulins into CAP) would disadvantage access to a new and improved approach in treatment that could benefit segments of the immune deficient population. Therefore we request that CMS maintain the exemption for immune globulins and treat them identically to IVIG.

Alpha$_1$-Proteinase Inhibitor

Lastly, CMS also correctly decided to not include single indication orphan drugs, such as alpha$_1$-proteinase inhibitor, within CAP. CMS correctly surmised that CAP could pose access problems for these orphan therapies. While CMS reserves the right to incorporate these therapies during the later stages of CAP implementation, such a step would only create access difficulties for alpha$_1$-proteinase inhibitor. As the CMS response to public comments rightfully notes:

> *"The latter group of orphan drugs poses much more severe access issues than other orphan drugs precisely because their use is generally limited to relatively rare orphan indications".*

According to the Alpha 1 Foundation, approximately 2800 individuals in the United States have been diagnosed with alpha$_1$-antitrypsin deficiency, approximately 40% of who are Medicare beneficiaries. With such a limited number of beneficiaries, CAP would not result in substantial savings compared to ASP plus 6% and would only create access problems. Further, the CAP vendor may not have the ability or desire to provide access to all three available brands, each of which have unique properties, for such a small population. CMS made the right choice in not including single indication orphan therapies such as alpha$_1$-proteinase inhibitor within CAP.

The Biotechnology Industry Organization (BIO) has made a request that CMS reconsider and incorporate the single indicated orphan therapies within CAP. However, BIO has requested that alpha$_1$-proteinase inhibitor be excluded from such a request. Unlike the other single indication orphan therapies, alpha$_1$-proteinase inhibitor is the only therapy with multiple brands within its HCPCS code. CAP does not require that all brands within a therapeutic grouping be provided, despite the need for access to all three brands of alpha$_1$-proteinase inhibitor in order to determine the most suitable treatment for each individual patient. Should CMS consider the request of BIO, we would ask that alpha$_1$-proteinase inhibitor remain distinct and not be included within CAP, as CMS has already correctly determined.

Impact on Supply and Patient Access

The plasma therapeutics industry is unlike pharmaceuticals. It has high material and manufacturing costs and this, combined with other economic forces, has resulted in major consolidations, including companies going out of business or being sold. The industry provides therapies for small populations that have serious genetic disorders and require chronic care. Because CAP could result in some therapies in a therapeutic class not being covered and also would concentrate purchasing power in CAP bidders, this would exacerbate this situation and would further reduce the ability of manufacturers to provide therapies.

One only need look at the history of vaccines where low prices, high manufacturing costs, liability concerns and lowered reimbursement resulted in the great reduction in the number of US vaccine providers. This must be avoided for plasma therapeutics by having reimbursement policies that recognize the unique and delicate nature of plasma therapeutics manufacturing and supply.

Conclusion

CMS' decision not to incorporate plasma therapies and their recombinant analogs within CAP will help preserve access to these rare disease therapies. The agency's consideration of public comments is reflected within the interim final rule and is greatly appreciated. The actions of CMS will both aid in the successful implementation of the CAP program and benefit beneficiaries reliant on therapies that are not ideally suited for the program.

Future actions regarding CAP and other CMS reimbursement actions need to recognize the special nature of plasma protein therapeutics manufacturing, distribution and administration of these life-saving therapies.

Should there be any questions or if we may be of assistance, please feel free to contact either Patrick Collins (610-878-4311) or myself. Your consideration of comments in the formulation of policies is greatly appreciated.

Sincerely,

Dennis Jackman
Senior Vice President, Public Affairs

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AUG 22 2005

J. Woody Sistrunk, M.D., PLLC
Thyroid Disease and Endocrinology
1151 North State Street
Medical Arts West, Suite 601
Jackson, Mississippi 39202

AUG 22 2005

Diplomate, American Board of Internal Medicine (ABIM)
Diplomate, ABIM Subspecialty of Endocrinology
Fellow, American College of Endocrinology
Member, American Thyroid Association

Phone (601) 948-7313
Fax (601) 949-6058

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

To Whom It May Concern:

As one of the only thyroidologists in Mississippi who follows many Medicare patients with thyroid cancer, I would ask for your consideration of Competitive Acquisition Program for the distribution of Thyrogen (thyrotropin alpha) for diagnostic evaluation of Medicare patients with thyroid cancer.

Serving in Mississippi is rewarding, but patients are severely limited by financial constraints. With most of the Medicare-age patients having significant co-morbidities such as cardiovascular disease, hyperlipidemia, and cerebrovascular disease, making a patient hypothyroid can at times cause a significant amount of morbidity and mortality. As a physician in an underserved area, I simply cannot afford to cover Thyrogen dose costs for every Medicare patient that I carefully follow.

I have personally had a Medicare recipient who became blind from the complications of profound hypothyroidism in while undergoing thyroid cancer evaluation.

Please give strong consideration to the inclusion of Thyrogen in Competitive Acquisition Program. This would allow Medicare recipients to receive the latest standard of care in thyroid cancer management.

I would be more than happy to personally testify to the importance of this decision. Please feel free to call me.

Respectfully,

J. Woody Sistrunk, M.D.

NATIONAL PATIENT ADVOCATE FOUNDATION

A National Network for Healthcare Reform

August 22, 2005

AUG 2 2 2005

Centers for Medicare and Medicaid Services
Attn: CMS-1325-IFC
P.O. Box 8013
Baltimore, Maryland 21244-8013

Re: CMS–1325–IFC: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B - Interim Final Rule

To Whom It May Concern:

The National Patient Advocate Foundation (NPAF) is a non-profit organization dedicated to improving access to health care services through policy reform. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive counseling and case management services from our companion organization, the Patient Advocate Foundation (PAF), which specializes in mediation for access to care, job retention, and relief from debt crisis resulting from diagnosis with a chronic, debilitating or life-threatening disease. From July 1, 2003 to June 30, 2004, PAF received 3.2 million requests for information and/or direct professional intervention in the resolution of access disputes. The majority of our cases deal with the diagnosis of cancer.

On behalf of the people with cancer that we serve, we are writing to respond to the Centers for Medicare and Medicaid Services (CMS) interim final rule regarding the Competitive Acquisition Program (CAP) for drugs and biologicals under Medicare Part B.

Terms of Contract

Although NPAF appreciates several of the changes CMS made to the interim final rule regarding extended payment plans, we continue to be concerned that the rule does not adequately address the problems associated with a CAP vendor that cuts off drug delivery to patients that fail to meet cost-sharing obligations. NPAF remains unsure about how low-income Medicare beneficiaries, especially those with extraordinary medical needs, will fare under the CAP payment provisions. In the proposed rule, NPAF noted its concern about the potential for CAP vendors to stop providing drugs to patients who do not remit coinsurance payments in a timely manner. Unfortunately, since patients do not have any interaction with CAP vendors, they will not associate the supplier with the care they have been receiving in the physician's office.

NPAF is concerned that the way in which the contracting provision is currently structured is harmful to any low-income beneficiary that requires timely access to drugs. The interim final rule allows CAP vendors to stop shipping drugs for patients who have not paid billed cost-sharing amounts within 45 days after the postmark date on the bill, unless the patient has contacted the vendor about the payment problem. And while the vendor is required to provide information about payment options to those struggling with cost-sharing obligations, we believe many patients, especially those requiring multiple medications, would likely have difficulty in keeping up with any kind of a payment plan.

As we noted earlier, patients being treated for cancer face tremendous economic hardship as a result of the high cost of their care. Patients with mounting medical costs face deductibles and coinsurance payments for drugs and professional services that are not covered by secondary insurance, but also custodial, transportation and other unanticipated expenses associated with their care.

And while the interim final rule acknowledges that CAP vendors could elect to waive coinsurance obligations, it is not clear whether the vendors would choose to write off any of these co-payments, or cut off beneficiaries from their drug supply. As with the proposed rule, NPAF suggests that CMS require vendors to develop procedures for assessing financial need and waiving cost-sharing for non Medicaid eligible beneficiaries with incomes up to 150 percent of the federal poverty level and partially waiving cost-sharing on a sliding scale for beneficiaries with incomes between 150 and 250 percent of the federal poverty level.

CMS suggests that beneficiaries be referred to charitable foundations that provide cost-sharing assistance to Medicare beneficiaries; however one of the most viable sources of charitable assistance to low-income individuals – charitable foundations of pharmaceutical manufacturers – would not be eligible to provide drugs under this rule. Without assistance from these foundations, there is very limited premium assistance available from other organizations, and we hope patients are not given the impression there is an untapped source of charitable giving available for this purpose.

Except for help from charities, the only solution offered by CMS for beneficiaries who require cost-sharing assistance is one that shifts the burden to the patient's physician. And unfortunately, the only remedy provided to the physician is that he may resign from CAP and provide the patients their drugs under the *buy and bill* model. If a physician chooses to leave the CAP program because one or more patients is losing access to drugs, he loses access to CAP for all of his patients for the remainder of the year.

NPAF would be interested in hearing from CMS what specific guidance will be available to beneficiaries on the co-payment collection process – especially for beneficiaries being treated for a life-threatening disease.

Timely Delivery of CAP Drugs

NPAF is concerned about the delivery timeline as it currently exists in the interim final rule, especially as it impacts people with cancer. As stated in our response to the proposed rule, people with cancer often require unanticipated shifts in their course of therapy, depending on tumor response and patient condition during therapy. For patients, it is critical that physicians can provide the right therapy at the right time.

NPAF also recommended that CMS liberalize emergency replacement and resupply procedures for physicians that select CAP. The interim final rule does not address many of our concerns. Specifically, in light of state pharmacy limitations on the ability of CAP practices to redirect unused drugs that have been dispensed for another patient, when a change is needed in a patient's course of therapy there usually will be a multiple day delay in the patient's treatment.

Our reading of the interim final rule suggests that timelines for product delivery described in the interim final rule may be more burdensome than they appeared in the proposed rule. In the bulk of the country, CAP vendors will not be required to have product to the ordering physician until 5 p.m. the next business day in an emergency situation and 5 p.m. on the second business day after a routine order is placed, assuming the vendor receives the order before 3 p.m. vendor's local time. Practically speaking, physicians will have to reschedule patients with emergency needs two days later. Non-emergency patients could not be scheduled any sooner than three days after their original appointment. Unfortunately, a patient in the continental U.S. with an emergency need discovered at a late afternoon appointment on Friday would have to wait for a Wednesday appointment to be treated with a drug supplied through the CAP vendor since one business day delivery would only require the CAP vendor to get the 3 p.m. Friday order to the physician by 5 p.m. Tuesday. The five to seven business day delivery schedule for the Pacific Islands will obviously pose tremendous access and clinical obstacles to Medicare beneficiaries.

Under the current rule, patients will have to schedule multiple trips to their physician's office to receive treatment. And for patients who are too sick to come to a physician's office, the CAP rule does not provide physicians with the option of taking drugs to a patient's home for their administration in the home setting. Some exception process to the prohibition against physicians moving CAP drugs from one location to another must be developed to permit house calls when medically necessary. It is our hope that CMS will reconsider a 5-day business week for CAP operations to allow for better patient access to their treatment regimens. Changes must be made to ensure quicker routine and emergency deliveries even if those changes require lifting the ASP + 6% aggregate ceiling on acceptable CAP bids.

Drug Availability

Another major area of concern for NPAF is drug availability. Under the interim rule, the drugs available under CAP are limited to 181 products. Moreover, CAP vendors may supply only one drug per HCPCS code. Although the drug list constitutes 85 percent of Part B drugs based on spending, it leaves out over 250 products covered under Part B. By eliminating low volume products from the scope of CAP, CMS has left CAP physicians responsible for buying and billing for just those drugs for which they are least likely to be able to obtain discounts, further impacting patients' access to drugs.

CAP does not appear to be a complete solution for oncologists. The decision to exclude drugs that must be billed using a miscellaneous HCPCS code (along with orphan drugs, controlled substances and oral anti-cancer and anti-emetic drugs) also impact oncology. The exclusion of drugs billed on miscellaneous codes means that CAP physicians will have to resort to different purchasing practices to provide their patients with the newest therapies and could undermine access to treatment options for patients who have failed to respond to old-line treatment regimens.

Potential Impact on Clinical Research

NPAF is concerned about the potential harmful impact that CAP could have on clinical research. Most cancer trials involve adding a test drug to a standard treatment regime. As a result, patients in the control arm receive the current standard of care and those in the test arm receive the current standard of care plus the test drug. Under the National Coverage Determination, when Medicare beneficiaries enroll in a clinical trial, the standard of care drug use in both the control and the test arms will be reimbursable. If the control drug called for by a particular protocol is not one that a physician's CAP vendor provides, that physician may not be able to enroll Medicare patients in the trial.

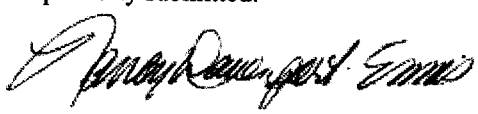
Product Integrity

NPAF is also concerned about the possible risk of counterfeit drug infiltration, and the serious impact it could have on cancer patient care in general and on clinical research. Under the carefully developed protocols of clinical trials, every effort is made to isolate research from any external factor that could alter the outcome. In the case of a CAP practice, a trial participant who has unintentionally administered a counterfeit drug would likely be removed from the trial. If evidence of the infiltration is found only after the clinical phase, a substantial portion if not all of the data gleaned from the trial could be jeopardized.

MMA requires CAP vendors to buy the drugs they dispense directly from the product's manufacturer or from a wholesaler that buys the product directly. This provision is designed to address the grave threat posed by counterfeit drugs. While this is a good provision, we have to note the lack of oversight, and perhaps too great a reliance on the state regulatory process, in order to ensure CAP vendors comply with this requirement.

NPAF would like to thank CMS for the opportunity to offer comments on the final CAP program rules. If you require additional information, please don't hesitate to call me at (202) 347-8009.

Respectfully submitted:



Nancy Davenport-Ennis
CEO
National Patient Advocate Foundation

Medical Imaging Contrast Agent Association

ORIGINAL 7

AUG 3 1 2005

August 25, 2005

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

Re: CMS-1325-IFC
Comments on Competitive Acquisition for Medicare Part B Drugs -- Contrast Drugs

Dear Dr. McClellan:

The Medical Imaging Contrast Agent Association (MICAA) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) on the interim final rule for competitive acquisition for Medicare Part B Drugs (70 Fed. Reg. 39,022 (Jul. 6, 2005)). MICAA represents manufacturers of contrast agents, which are agents used in diagnostic imaging tests, such as x-ray, CT, MRI and echocardiography. MICAA has worked closely over the years with CMS on Medicare coverage, coding and payment policies for contrast agents and related diagnostic imaging services, including, most recently, working with CMS to expand the number of HCPCS codes for contrast drugs and Medicare coverage policy for low osmolar contrast drugs.

In our comments to the proposed rule, MICAA requested that CMS either exclude contrast agents altogether from the competitive acquisition program ("CAP") or exclude contrast agents from CAP during the initial stages of CAP implementation. MICAA believed that the exclusion of contrast agents from CAP was appropriate given the limited use of these drugs in the physician office setting and recent changes to their coding and payment structures.

We support CMS's announcement in the interim final rule that it will not include contrast agents under the CAP during the initial stage of program implementation. We believe that CMS's decision makes good policy sense and will help reduce physician confusion about the CAP as the program becomes operational. In future years, as CMS reconsiders whether to include contrast agents in CAP, we request that CMS continue to recognize the unique characteristics of these drugs. Among other things, given the fact that contrast agents are neither interchangeable nor identical, CMS should encourage CAP vendors to include a broad array of

agents in the CAP that may be represented by a single HCPCS code, even if such inclusion is not expressly required under the CAP regulations.

MICAA appreciates this opportunity to submit comments to CMS and would welcome the opportunity to meet with CMS to discuss these issues in greater detail. Please feel free to contact MICAA'S Reimbursement Counsel: Gordon Schatz (202) 414-9259 or Gail Daubert (202) 414-9241.

Sincerely,

Jane Majcher
Jane Majcher

Jay Schafer
Jay Schafer

cc: William Thorwarth, M.D. (American College of Radiology)
Pamela Kassing (ACR)

AMERICAN GASTROENTEROLOGICAL ASSOCIATION

4930 Del Ray Avenue • Bethesda, Maryland 20814-2513
301-654-2055 • Fax 301-654-5920 • member@gastro.org

AUG 31 2005

August 23, 2005

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

RE: 2005 Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Interim Final Rule

Dear Doctor McClellan:

The American Gastroenterological Association (AGA) is the nation's oldest not-for-profit medical specialty society, and the largest society of gastroenterologists, representing more than 14,000 physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system.

The AGA appreciates that CMS has published the Competitive Acquisition of Outpatient Drugs and Biologicals rule (CAP) as an interim final rule allowing for a second comment period. We also commend CMS for delaying the implementation of the CAP until July 2006 until all issues have been resolved to make this program a viable alternative for physicians, vendors and CMS. The interim final rule makes a number of improvements based on comments received by the AGA and numerous other organizations. AGA, however, still has a few issues for reconsideration that we feel CMS has not adequately addressed.

First, the interim final rule retains the requirement that physicians submit the drug administration claim to their carriers within 14 calendar days that was not a requirement in the law. There is no precedent of a 14-day time frame for any other Medicare services. As we indicated in our proposed rule comments, we believe a 14-day time frame will be unduly burdensome on smaller and rural practices. We again recommend that CMS change this timeframe to 30 calendar days, with the acknowledgement that practices which currently submit within a 14-day time frame will likely continue to do so. A 30-day

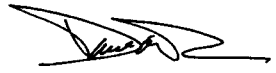
time frame would alleviate the burden on those practices that do not have the capability of meeting a 14-day time frame.

Second, in the interim final rule, CMS maintained its position that the CAP requirements will not place any additional burden on physician practices. As we indicated in our previous comments, AGA disagrees with CMS on this assessment. We believe participation in the CAP program will add significantly to the administrative costs of providing infusion services to patients in their office setting. These added costs flow from the need to maintain a dual ordering and inventory system, the need to match the physician's and the vendor's bills, formulary limitations, and the potentially burdensome rules dealing with the disposition of unused drugs. We recommend again that CMS consider establishing an administrative service fee, possibly through creation of a G code, to be paid to physicians who enroll in the CAP to offset some of these added costs.

Lastly, as CMS works to implement the CAP program, we recommend that it also exercise its authority to remove physician-administered drugs from the sustainable growth rate system (SGR), retroactive to the SGR base year. This will help address one of the largest flaws in the SGR system contributing to projected negative physician payment updates through 2012.

Thank you for consideration of our comments on the CAP interim final rule. If we may provide any additional information on our comments, please contact Anne Marie Bicha, AGA Director of Regulatory Affairs at 301-654-2055, ext. 664 or abicha@gastro.org.

Sincerely,



David A. Peura, M.D.
AGA President

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AUG 31 2005

PROVIDENCE
HOSPITAL AND MEDICAL CENTERS

Member of St. John Health System

30055 Northwestern Highway, Suite 150
Farmington Hills, MI 48334-3226
248-865-4150
Fax 248-865-4151

August 17, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1325-IFC
PO Box 8013
Baltimore, Maryland 21255-8013

Dear Sirs:

On behalf of the Michigan Chapter of the American Association of Clinical Endocrinologists, we request that Thyrogen (thyrotropin alfa for injection) be included in the list of drugs available through the Medicare competitive acquisition program (CAP) in 2006. It is our position that permitting physicians the option of using a CAP vendor to obtain Thyrogen is important in providing access to the drug, and to avoid compromising the level of care available to Medicare beneficiaries who have suffered from thyroid cancer.

Early diagnosis and regular lifelong monitoring comprise effective treatment and management of well-differentiated thyroid cancer. Administration of Thyrogen has become a well recognized standard of practice in the follow-up management of thyroid cancer patients. As responsible physicians we are committed to providing all of our patients with the highest quality of care available. Denying access to Thyrogen through the CAP forces us to continue participation in the drug acquisition business with its associated financial risk and significant administrative burdens. Requiring medical professionals to assume these burdens where other options exist will not enhance the quality of care provided to thyroid cancer patients who are Medicare beneficiaries.

The current wholesale price for Thyrogen is approximately $1,390.00. The Medicare allowable rate will cover the purchase price of the drug *if* the $278.00 co-insurance is successfully collected. This is often a difficult and very time consuming task. Physicians in private practice are not in the position to absorb an expense, risk or administrative responsibility of this magnitude and should not be in the untenable position of jeopardizing the financial viability of their practice in order to provide the appropriate quality of care.

We are aware that the ruling to exclude Thyrogen from the CAP pertains to the initial stage of the program only. We urge you to reconsider this approach and include Thyrogen in the vendor

bid process as soon as possible. Allowing physicians to access Thyrogen through the competitive acquisition program will ensure that Medicare beneficiaries' access to the highest standard of thyroid cancer care is not compromised by financial considerations.

Very truly yours,

Sheldon S. Stoffer, M.D., F.A.C.P.,
Co-Chair, Michigan Chapter.
American Association of Clinical Endocrinologists.

SSS/ds

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UnitedHealthcare®
A UnitedHealth Group Company

5901 Lincoln Drive Edina MN 55436

AUG 31 2005

August 16, 2005

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

Re: UnitedHealthcare comments on: **Federal Register** / Vol. 70, No. 128 / pages 39022-39102, July 6, 2005, Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B.

Dear Sir or Madame:

UnitedHealthcare respectfully submits the following comments on the in reply to your invitation to comment on the above referenced **Federal Register** publication.

Please feel free to contact me if you have questions or require additional information.

Sincerely,

Steven Affield

Steven Affield
UnitedHealth Networks, a UnitedHealth Group Company
5901 Lincoln Drive, MN012-S204
Edina, MN 55436
(952) 992-5252
Fax: (952) 992-4320
steven_d_affield@uhc.com

Enclosure: One original and two copies

CC: Robert Holman, Director, Fee Schedule Administration

UnitedHealthcare Comments

Comment 1 General Overview of CAP (Experience of private insurers with similar models):

UNITEDHEALTHCARE comments: UNITEDHEALTHCARE has implemented a Chemotherapy Drug Management program that has not resulted in patient inconvenience. It is an external drug vendor acquisition sourcing tactic that is transparent to patients.

UnitedHealthcare's Chemotherapy Drug Management program has similarities to CAP. CAP could increase physician practice administrative burden to by requiring physicians to carry out different sets of payer-specific external drug vendor procedures for non-Medicare payers. CMS may consider facilitating payer industry external drug vendor procedure standardization to minimize physicians' administrative burden.

Comment 2 Categories of drugs under the CAP (Potential future CAP expansion to DME and pharmacy drugs):

UNITEDHEALTHCARE comments: UNITEDHEALTHCARE supports CAP expansion to include all CMS drug and biological categories. In practice the rationale for differentiating between the three CMS categories is not clear.

Comment 3 Categories of drugs under the CAP (Exclusion of certain drug types):
The following orphan drugs are not initially included in CAP and CMS welcomes comments about whether these drugs should be included during later stages:
J0205 (Injection, Alglucerase, per 10 units);
J0256 (Injection, Alpha 1-proteinase inhibitor, 10 mg);
J9300 (Gemtuzumab ozogamicin, 5mg);
J1785 (Injection, Imiglucerase, per unit);
J2355 (Injection, Oprelvekin, 5 mg)
J3240 (Injection, Thyrotropin alpha, 0.9 mg);
J7513 (Daclizumab, parenteral, 25 mg);
J9010 (Alemtuzumab, 10 mg);
J9015 (Aldesleukin, per single use vial);
J9017 (Arsenic trioxide, 1 mg);
J9160 (Denileukin diftitox, 300 mcg); and
J9216 (Interferon, gamma 1-b, 3 million units)

UNITEDHEALTHCARE comments: UNITEDHEALTHCARE supports including orphan drugs in CAP. Their inclusion in CAP would expand access to these drugs because not all physicians are able to acquire them on their own for office administration.

Comment 4 Categories of drugs under the CAP (Excluding diagnostic imaging contrast agents):
CMS has initially excluded diagnostic imaging contrast agents.

UNITEDHEALTHCARE comments: UNITEDHEALTHCARE agrees with excluding diagnostic imaging contrast agents from CAP.

Comment 5 Categories of drugs under the CAP (Excluding immune globulin):

CMS will not include blood clotting factors or IVIG within the initial single drug category. These products are commonly used in emergency situations, and therefore poorly suited for ordering and billing procedures contemplated by CAP.

UNITEDHEALTHCARE comments: Excluding immune globulin would omit a major medical expense component. The emergency administration rationale offered for excluding immune globulin is not clear because emergency infusion of these products typically occurs in the outpatient hospital setting while CAP is a physician office initiative. UNITEDHEALTHCARE supports inclusion of immune globulin in CAP for non-emergency use.

Comment 6 Categories of drugs under the CAP (Excluding unlisted codes):
Regarding excluding Not Otherwise Classified (NOC) codes including J3490, J3590, J7199, J7599, J7699, J7799, J9999, and Q0181. Unlisted drug codes represent a shifting collection of miscellaneous, unrelated products. It is not feasible for potential CAP vendors to develop meaningful bids on unlisted codes given that the codes represent disparate products and that the specific drugs assigned to these codes are subject to ongoing change.

UNITEDHEALTHCARE comments: The rationale offered for excluding unlisted HCPCS codes is not clear given Medicare carrier procedures for pricing unlisted drug codes. Medicare carriers require, when submitting a claim for an unlisted code, the drug name and dosage to be entered in block 19 on the CMS 1500-claim form or electronic equivalent. Unlisted drug code coverage is limited to the list of drugs and payment allowances for Medicare Part B NOC drugs posted at the CMS web site associated with the drug name and dosage entered in block 19. NOC payment allowances are in turn based on (National Drug Codes) NDCs that map to the drug name and dosages. Because Medicare unlisted drug pricing is based on drug name and description on the CMS list of NOC covered drugs, and this list is presumably mapped to NDCs, drug vendors are capable of submitting meaningful CAP bids for them.

Comment 7 Ordering CAP Drugs (Concerns about vendor drug delivery causing treatment delay):
CMS comments stated that the drug ordering process outlined will make it difficult for physicians to treat a patient on the patient's first visit, which will necessitate at least a one day treatment delay.

UNITEDHEALTHCARE comments: These statements are confusing because, for most chemotherapy patients, infusion is delivered at a later follow-up appointment arranged during the initial visit. In light of usual practice a one day delivery standard seems appropriate for most patients.

Comment 8 Proposed claims processing and operational overview (CAP procedures apply even if Medicare is secondary payer):

CMS comments stated that a beneficiary's additional coverage may have an effect on when or from whom an approved CAP vendor receives payment but the requirements under CAP will not be different.

UNITEDHEALTHCARE comments: If CAP procedures govern the primary payer for patients with secondary Medicare coverage, UNITEDHEALTHCARE opposes that requirement on the basis of the primary payer's need to manage its own coverage.

Comment 9 Restricting Physicians to one vendor (Initially, all CAP drugs are in a single category which limits physician choice):
In the initial stage of CAP physicians are effectively restricted to one vendor because there is only one drug category and one vendor area. If there were additional categories, then physicians will be allowed to select the categories of drugs that they will obtain from the CAP and it will be possible to select a different vendor for each drug category.

UNITEDHEALTHCARE comments: UNITEDHEALTHCARE agrees with the concept of a single CAP drug category inclusive of all CAP drug codes. A single drug category minimizes CAP physician administrative burden.

Comment 10 Requirements for group practices (medical groups are either entirely in or out of CAP participation):
Physicians billing under a group billing number will need to reach agreement among themselves on whether to participate in CAP and which vendor to select. CAP administration is based on the group practice PIN.

UNITEDHEALTHCARE comments: UNITEDHEALTHCARE agrees with CAP election at the medical group practice rather than individual physician level.

Comment 11 Concerns about economic conflicts of interest:
Comments stated concern about conflicts of interest that might influence vendors to steer market share toward one drug over another in response to contract discounts and rebates.

UNITEDHEALTHCARE comments: Provided that CAP is structured so that the role of drug vendors is limited to filling physician orders as prescribed, CAP vendors are not in a position to steer market share.

Comment 12 Claims Processing Methodology (Matching claims based on prescription number):
The "designated carrier," Noridian, verifies drug administration by matching the prescription number on the vendor's claim to the prescription number on the physician drug administration claim. Physicians must file drug administration claims within 14 days.

UNITEDHEALTHCARE comments: UNITEDHEALTHCARE questions the added administrative burden of matching physician and vendor claims by prescription number. The new "prescription number" claim processing procedure may be difficult to track,

prone to error, and may hinder CAP participation. UNITEDHEALTHCARE recommends basing physician drug administration to vendor drug claim match on physician claim date of service.

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7475 Lusk Boulevard
San Diego, CA 92121
T (858) 457 2553 F (858) 457 2555

August 22, 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

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

Dear Administrator McClellan:

Elan is a neuroscience-based biotechnology company that is focused on discovering, developing, manufacturing and marketing advanced therapies in neurology, autoimmune diseases, and severe pain. On December 28, 2004, we received FDA approval for our newest product, PRIALT® (ziconotide **intrathecal infusion**), which is indicated for management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or IT morphine. PRIALT® is neither an opioid nor a controlled substance.

PRIALT® is intended for intrathecal delivery using a programmable implanted variable-rate microinfusion device or an external microinfusion device and catheter. Depending on the site of service and the drug's method of delivery, PRIALT® may be billed through the Medicare intermediaries as a hospital outpatient service, through the Medicare carriers as an "incident to" physician service, and through the DMERCs under the DME benefit.

We would like to take this opportunity to comment on certain aspects of Interim Final Rule CMS-1325-IFC, "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B" (the "Interim Final Rule") published in the *Federal Register* on July 6, 2005.[1] The Interim Final Rule describes an alternative distribution model for Part B drugs designed to give physicians a choice between buying and billing for the drugs and biologicals (henceforth "drugs" for simplicity) they administer to their patients or having those drugs dispensed and billed to the program by a Medicare contractor selected

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

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through a competitive acquisition program ("CAP"). Authority for the CAP can be found in Social Security Act § 1847B, as added by Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") §303(d).

Elan is strongly supportive of the goals of the CAP. We want to commend CMS for its efforts toward developing the program. We believe that many physicians who use our products will welcome the opportunity to obtain the drugs they need to treat patients in their offices without having to assume the inventory and collection risks associated with buying and billing for drugs furnished as an "incident to" physician service so long as the administrative changes necessitated by the CAP are manageable.

We applaud CMS' decisions to make the CAP available to all physician specialties and to include an expansive list of drugs in the initial phase of the program. We are appreciative of the clarity that the Interim Final Rule brings to questions about vendor formularies and the applicability of local coverage rules. The positions CMS has taken on these issues are conducive to broader acceptance of the CAP in the physician community. At the same time, the new provisions on Advanced Beneficiary Notices and CAP vendor appeal rights in the Interim Final Rule should improve the attractiveness of the program to potential vendors.

We are disappointed that CMS has decided to suspend bidding on the CAP program,[2] but we appreciate the complexity of the CAP development task. Ensuring a program design that is workable from the perspectives of vendors and physicians is paramount. We remain hopeful that CMS will be able to move forward with the CAP in accordance with the timeline set forth in its suspension notice. We encourage CMS to use the delay to reconsider the comments submitted by Elan and many others in response to the Proposed Rule about the implications of placing an ASP + 6% aggregate reimbursement limit on the CAP. We also believe the CAP would benefit from further refinements designed to address physician concerns. Certainly, reports about the CAP in the trade press shortly after the Interim Final Rule was published suggested that a significant proportion of physicians would reject the program as overly burdensome and disruptive to current office practices. Significantly shortening the drug delivery times detailed in the Interim Final Rule would be a welcome step in the right direction.[3] We remain convinced that enhanced physician reimbursement for pharmacy handling costs and/or the added administrative expenses associated with drug ordering, vendor coordination, rapid claims filing, and increased claims appeal activities under the CAP also may be appropriate.

To assist the agency fine-tune its plans for CAP and thereby better ensure continued patient access to needed Part B therapies in the face of the reimbursement cuts physicians

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2 http://www.cms.hhs.gov/providers/drugs/compbid/cap_08032005.pdf

3 In an informal survey conducted by Part B News between July 5-11, 47% of physician practices said that waiting for delivery of CAP drugs would affect the operation of their practices in a "major way" and an additional 38% foresaw a "moderate-to-medium effect" on practice operations.

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face under ASP+6%, we offer the following recommendations for making the CAP more attractive to potential bidders and more accommodating to the needs of physicians and the patients they treat. We have also provided additional information about PRIALT® to clear up any misconceptions about the appropriateness of the product for inclusion in the CAP. In the interest of efficiency, we have not repeated comments we offered in response to the Proposed Rule even though we encourage CMS to reconsider our recommendations that it chose not to incorporate in the Interim Final Rule in light of its decision to rework and enhance the design of the CAP over the next six to twelve months.

I. "Incident To" Drugs Administered by Intrathecal Pump

Elan is extremely pleased that CMS has concluded "in principle that opioid medications administered intrathecally through implanted variable-rate infusion devices could be included under the CAP, when they are administered by physicians in their offices incident to their services."[4] We assume the "in principle" limitation was included only because controlled substances have been deemed inappropriate for the initial phase of the CAP. Similarly, we assume the "opioid" limitation merely reflects the reality that the majority of such pain medications are scheduled drugs, not an intention on CMS' part to exclude non-scheduled intrathecally administered pain medications from the CAP. We recognize that at least one non-opioid medication approved for intrathecal treatment of spasticity – Baclofen (J0475) – has been included in the list of CAP drugs in Addendum A. Though Baclofen is indicated for the management of severe spasticity, according to the USPDI, Baclofen is also useful in relieving flexor spasms and concomitant pain. Another non-opioid medication commonly used intrathecally to treat severe chronic pain, Clonidine Hydrochloride, was also included in the list of CAP drugs. That said, to eliminate any potential for confusion on the part of physicians offering intrathecal therapy who are considering a CAP election or on the part of CAP vendors who are choosing new products for addition to their approved drug lists, Elan urges CMS to state expressly in the Final Rule that non-scheduled pain medications designed for intrathecal administration are suitable for inclusion in the initial phase of CAP.

Elan also would appreciate it if CMS would correct the mischaracterization of PRIALT® in the Interim Final Rule as an opioid medication.[5] PRIALT® is neither an opioid nor a controlled substance. In fact, the drug is indicated for individuals who are intolerant of intrathecal morphine. A careful reading of CMS's response to the comment that contains the mischaracterization suggests the agency understands the true nature of PRIALT®. However, we are afraid that, absent an explicit clarification in the Final Rule, some physicians and CAP vendors might not realize that PRIALT® is not a controlled substance and that, because it is not, it can be provided by CAP vendors. But for the fact

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4 70 *Fed. Reg.* 39028.

5 70 *Fed.Reg.* 39028 ("One commenter asked about the status of opioid medications administered intrathecally through implanted variable-rate infusion devices (for example, PRIALT®.")

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that PRIALT® has not yet been assigned a HCPCS code, the product would have qualified for the Addendum B list under a threshold requirement that Medicare allowable charges in an office setting must be at least $50,000 a year. In fact, PRIALT® exceeded that target during the first quarter of 2005. Moreover, we expect PRIALT® to be assigned a HCPCS code this fall. Because a CAP program that is as expansive as possible will benefit physicians and improve patient access to important therapies, we strongly urge CMS to expand the list of drugs in Addendum B when it publishes the Final Rule to include suitable new products like PRIALT® that will be assigned HCPCS codes during the bidding suspension.

II. Procedures for Adding Newly Introduced Products

We appreciate the rationale for excluding drugs from the CAP that must be billed using one of the miscellaneous HCPCS codes.[6] We recognize that one implication of this decision is that drugs introduced too late to have an assigned HCPCS code at the time of CAP bidding cannot be included in the single drug category list of products subject to the composite bid methodology (e.g., drugs listed in Addendum A). Similarly, drugs without an assigned HCPCS cannot be accommodated in a listing of newer products for which too little utilization data exists to permit the weighting required for drugs in the composite bid pool (e.g., for 2006, those drugs listed in Addendum B).

Because we suspect that some physicians who have elected the CAP may be reluctant to return to the buy-and-bill model to obtain newly introduced products for their patients, we applaud CMS for including a process in the Interim Final Rule for vendors to add products with newly assigned HCPCS codes to the list of drugs they will ship to physicians. We hope the agency is correct in its assumption that market forces will push vendors to make newly introduced products available promptly. We suspect, however, that beneficiary access would be better served – or at least served with more certitude – if CMS would make new product additions mandatory beginning the quarter after claims data establish that allowable charges for a new product that otherwise meets the criteria for inclusion in the CAP have reached the $50,000 minimum annual threshold.[7] We strongly encourage CMS to codify such a provision when it promulgates the Final Rule.

We also urge CMS to give CAP vendors the flexibility to add otherwise suitable new products to their approved products lists on a voluntary basis before utilization levels reach the $50,000 threshold. Providing this flexibility would allow CAP vendors to anticipate the needs of their physician customers and could, thereby, foster improved beneficiary access. For example, it is not hard to imagine that some physicians in specialties that historically have not billed for substantial quantities of "incident to" drugs might choose CAP because the launch of a potentially breakthrough product targeting their patient base seems imminent. In this situation, the very pressures that motivated the

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6 70 *Fed. Reg.* 39030.

7 70 *Fed. Reg.* 39032.

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CAP selection might deter these physicians from using the buy-and-bill model until they could get the new product from their CAP vendor, thus impeding early beneficiary access to the new therapy.

Regardless of whether CMS is willing to accept our recommendation to make certain new drug additions to CAP mandatory, the agency should spell out the criteria that it intends to apply before it approves vendors' proposals for voluntary additions to their approved drug lists and provides for payment for the newly added drugs at the next quarterly update. Neither the regulations nor the preamble to the Interim Final Rule clearly define how CMS will "determine that the new drug is appropriate for inclusion on the approved CAP vendor's approved list." At a minimum, the Final Rule should declare expressly that CMS would apply the same criteria that it used to identify the select list of drugs introduced in 2004 or after and in including in CAP through Addendum B. Ideally, CMS should add a step to the approval process to weigh more subtle access issues as well and, if necessary, to waive the $50,000 minimum threshold for vendors who have affirmatively asked to take on a still low-volume product that holds great promise for Medicare beneficiaries. Since the rationale for the threshold was to "lessen the inventory burden for vendors,"[8] granting such waivers pursuant to a vendor's request would not be inconsistent with the decision tree established to identify the drugs designated for inclusion in the CAP in the Interim Final Rule.

III. Updates to Include Products Recently Assigned HCPCS Codes

Inevitably, a number of new products will be assigned HCPCS codes between now and the time when the provisions of the Final Rule will be drafted. CMS should update the list of drugs in Addendum B to the Final Rule to include those new drugs deemed suitable for CAP that meet the criteria established in the Interim Final Rule for integrating relatively new products with assigned HCPCS into the program. We recognize that it is not common for CMS to add new products to fee schedule rules between the proposed and final rule stage, but the unexpected suspension in the implementation of CAP and the market-based nature of this new, never-before-tried drug delivery system favor a break from traditional patterns in this instance. Not to do so would be inconsistent with beneficiary access and with CMS's stated intent of designing a CAP program that is workable and attractive to both physicians and vendors.

IV. Reimbursement for Discarded Drugs from Single-Use Vials

We are concerned that an overly aggressive interpretation of the requirement under MMA §303(d) prohibiting payments to CAP vendors for "wastage, spillage, or spoilage" could make the CAP too unattractive to prospective bidders. Based on CMS's responses to questions posed at the Special Open Door Forum for prospective vendors held July 8, 2005, we understood the agency intended to limit reimbursement for drugs dispensed

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[8] 70 *Fed. Reg.* 39032.

from the smallest available single-use vial to the amount actually administered to a patient, rounded up to the closest full HCPCS code unit of measure, even if product remaining in the vial after treatment must be discarded for safety reasons. Elan disagreed with that approach.

We are pleased that CMS has already rethought its position and posted an FAQ on its website aligning single-use vial wastage policies under CAP with those applicable to physicians operating under the buy-and-bill model. We urge CMS to affirmatively state in the Final Rule that Medicare Claims Processing Manual, Chapter 17 "Drugs and Biologicals" § 40 applies to CAP. That manual provision states:

> The CMS encourages physicians to schedule patients in such a way that they can use drugs most efficiently. If a physician must discard the remainder of a vial or other package after administering it to a Medicare patient, the program covers the amount of drug discarded along with the amount administered. NOTE: The coverage of discarded drugs applies only to single-use vials. Multi-use vials are not subject to payment for discarded amounts of drug.

We are encouraged by CMS' commitment in the FAQ to provide more guidance on ways physicians and CAP vendors can work cooperatively to control waste. We hope the Final Rule will contain significantly more detail about approaches to waste minimization under CAP. It is clear that concerns about the financial implications of the MMA prohibition against reimbursing vendors for waste must be resolved to make CAP a viable option.

V. Provisions to Address Concerns Unique to Compounded Drugs

The current structure of the CAP may disincentivize physicians who offer pain management therapy from selecting the program simply because of the carve-out of controlled substances from the list of drugs deemed appropriate for the initial round. For those physicians offering pain management services who may still see benefit in the CAP, the program, as structured, may impose an additional hurdle that could prove insurmountable. That hurdle relates to the prescribing of compounded drugs that include one or more drugs from the list of products included in the initial phase of the CAP. Since a physician participating in the CAP cannot be reimbursed under the buy-and-bill payment system for a drug on his or her CAP vendor's approved list of products, it appears that physicians selecting the CAP could be left without a way to obtain full payment for compounded drugs that include one or more of the CAP products unless CMS takes corrective action.

CMS could begin to rectify the situation by including a provision in the Final Rule that would permit CAP physicians to be paid for any compounded drug under the buy-and-

bill model,[9] regardless of whether the compound contains a component on the list of drugs included in the CAP or even components exclusively from the CAP list, unless the physician's vendor could provide the required compounding services. Absent additional reimbursement for compounding services, we suspect that few, if any, CAP vendors would be willing to admix compounded drugs from their approved drug list given the ASP + 6% composite payment limitation of the CAP, the unreimbursed pharmacy costs that would be associated with preparing and dispensing compounded drugs, and, to the extent that state law permits CAP vendors to operate with only a wholesaler license, the legal barriers to engaging in compounding.

In addition, CMS must add provisions in the Final Rule loosening the restrictions on transporting CAP drugs[10] and – since the majority of physicians do not have the safety equipment necessary to compound highly toxic products in their offices – providing for adequate physician payment for subcontracted compounding pharmacy services. Such a provision will be essential when CAP physicians prescribe a compounded product that contains both controlled substances and one or more non-scheduled drugs from the CAP vendor's approved list. We know of no statutory or regulatory impediment to including provisions in the Final Rule that would permit CAP vendors to ship drugs to a compounding pharmacy for subsequent delivery to a CAP physician. The preamble to the Interim Final Rule acknowledges this fact, saying "[a]lthough the statute allows us to provide for the shipment of drugs to other settings under certain conditions, we did not propose to implement the CAP in alternative settings at this time."

We recognize that the 2006 Physician Fee Schedule would likely be the proper regulatory vehicle for accomplishing the payment reforms needed to permit separate physician reimbursement for compounding pharmacy services under the CAP. We plan to address this issue in our comments on that rule along with our concerns about (1) confusion surrounding buy-and-bill reimbursement amounts for infusion drugs carved out of the ASP + 6% methodology under the MMA and (2) the inadequacy of current payment levels for procedures associated with drug administration by intrathecal pump. In the meanwhile, we urge CMS to work with the DEA to resolve the concerns that caused it to deem controlled substances inappropriate for the initial phase of the CAP. We feel strongly that making adequate pain management therapy options available to beneficiaries will require making compounded drugs – including those containing controlled substances – available through the CAP because, in our experience, many pain management physicians are unwilling to take on the administrative burden and financial

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9 We are not endorsing the current poorly developed, often inconsistent local reimbursement policies for compounded drugs under the buy-and-bill model (or under the DME benefit). We fully intend to submit comments on the 2006 Physician Fee Schedule Proposed Rule articulating our concerns and making recommendations for the development of a more appropriate national payment methodology for compounded drugs.

10 70 *Fed. Reg.*39047 ("[W]e will require that physicians must have CAP drugs shipped directly to the location at which they plan to administer them. The physician may not transport CAP drugs from one location to another."); 42 C.F.R. §414908((a)(3)(x).

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risk of purchasing compounded products for their Medicare patients under the current poorly defined and ill-structured buy-and-bill system applicable to such products.

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We appreciate the opportunity to comment on the Interim Final Rule and we hope our suggestions will help CMS structure the Final Rule in ways that will make the CAP attractive to a sufficient number of bidders and a workable option for all physicians who furnish Part B drugs to their patients as an incident to service. We again urge you to reconsider our comments on the Proposed Rule as you work to refine and improve the attractiveness of the CAP to potential vendors and potential physician participants. In addition, as we have explained above, CMS should take steps to facilitate further the timely addition of new products to the CAP and, consistent with this goal, should update the list of Addendum B drugs before it promulgates the Final Rule to include suitable new products assigned HCPCS codes since the Interim Final Rule was drafted. CMS should provide guidance to physicians and vendors about practical, effective waste minimization strategies under CAP. CMS also must address concerns unique to compounded drugs in the Final Rule; otherwise, physicians offering pain management therapies will be effectively precluded from availing themselves of the advantages of CAP for those non-scheduled drugs included in the initial phase of the program. Finally, we urge you to appropriately characterize PRIALT® in the Final Rule, ideally by including it as an addition to Addendum B.

If you have any questions about our comments or would like to discuss issues we have raised further, please do not hesitate to contact me.

Sincerely,

Nick Poulios, PhD

Nick Poulios
Vice President
Pricing & Reimbursement
Elan Pharmaceuticals

SEP - 6 2005

September 1, 2005

Mark McClellan, MD, Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1325-IFC
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave SW
Washington, DC 20201

Susan Slaton
Director, Reimbursement
6 West Belt
Wayne, NJ 07470
Telephone: (973) 305-5374
Fax: (973) 305-4440

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

Dear Administrator McClellan:

Berlex Laboratories appreciates the opportunity to comment on CMS-1325-IFC Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B as published in the Federal Register on July 6, 2005.[1]

Berlex Laboratories, the U.S. affiliate of Schering AG Germany, is a pharmaceutical company producing, developing, and marketing specialized medicines in the areas of female healthcare, oncology, central nervous system disorders, and diagnostic imaging. For the past twenty-five years, Berlex has worked to make important treatments available to Medicare beneficiaries.

Our comments regarding CMS-1325-IFC Medicare Program; Competitive Acquisition of Outpatient Drugs Under Part B, referred to in this comment letter as "Interim Final Rule" center around eight key areas:

- We support CMS selection of a single broad category containing 169 drugs and biologics, and the 12 new therapies for inclusion under the CAP.[2]

[1] 70 Fed. Reg. 39021.
[2] Id. at 39030.

- We are pleased that beneficiaries will retain access to all drugs available under the CAP, as CMS has issued clarification that CAP vendors do not have the authority to offer only certain HCPCS codes in the category.[3]
- Additionally, we applaud CMS for excluding imaging agents under CAP due to concerns about implementation.
- We encourage CMS to reexamine the exclusion of orphan drugs under CAP as this may create access issues for beneficiaries with rare diseases.
- We encourage CMS to create a mechanism so that new FDA approved products are immediately available under the CAP.
- We support CMS's utilization of a mechanism to update single prices for CAP drugs and biologics to the mid-point of calendar year 2006 by the Producer Price Index for prescription preparations.
- We endorse CMS's clarification that CAP vendors can not make determinations of medical necessity.
- We request CMS provide an explicit position on discarded and wasted drugs under CAP in a Final Rule.

Each comment above is discussed in detail below.

Beneficiary Access to Drugs and Biologics Furnished Under CAP

Beneficiary access to drugs and biologics furnished under CAP is the most critical issue to consider during implementation of CAP. The Interim Final Rule clarified the creation of a single category of 169 drugs and biologics, plus 12 new therapies, for inclusion in the initial CAP category. We support this broad category, as it provides an extensive range of products that will provide Medicare beneficiaries access to most drugs and biologics. Additionally, we are pleased that CMS explicitly stated in the Interim Final Rule that CAP vendors must provide at least one NDC for each HCPCS in the category.[4] This will continue to protect beneficiary access to drugs and biologics furnished under CAP.

A. Support for Exclusion of Imaging Agents

We support CMS's decision to exclude imaging agents under CAP.[5] We agree that the recent changes in coding and payment for imaging agents pose special implementation concerns. Contrast agents could be represented in several categories, such as LOCM, HOCM, or MR contrast agents. If these drugs are to be included in competitive acquisition at all, they must first be placed in an appropriate category. Multiple categories would be needed as the features of these products vary widely.

MMA also authorizes CMS to exclude from competitive acquisition a drug or class of drugs if the application of competitive acquisition to the drug(s) is not likely to result in

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[3] Id. at 39034.
[4] Id.
[5] Id. at 39029.

significant savings or it is likely to have an adverse impact of access to such drugs.[6] The classification of many contrast drugs under one HCPCS code has the effect of lowering the ASP and thus achieving cost savings. The marginal savings from competitive acquisition, relative to the newly determined ASP, will not be significant. **We understand CMS will consider including imaging agents in the future as the program is refined[7], however, we request that CMS allow stakeholders to submit comments prior to future inclusion of imaging agents under CAP.**

B. Request to Reexamine Exclusion of Orphan Drugs

We encourage CMS to reexamine the exclusion of CMS designated orphan drugs from CAP. We believe that the exclusion of CMS designated orphan drugs will further impede beneficiary access to therapies for rare diseases. The intent of CAP is to improve access to drugs and biologics by reducing the physician cost associated with acquiring these products; therefore, exclusion under CAP is contradictory. Orphan drugs are specifically the types of therapies that pose the most challenge under the current ASP reimbursement methodology.

Due to the low demand, orphan drugs are costly to manufacture and costly for physicians to keep in inventory. These costly but rarely utilized drugs are precisely the types of therapies that physicians are most burdened with their associated acquisition and payment collection, and would be the types of drugs for which CAP might be ideal. **We therefore request that CMS reconsider the exclusion of orphan drugs under CAP in order to ensure the beneficiaries retain access to these important life-saving therapies.**

C. Request Immediate Inclusion of New Products Under the CAP

We are pleased CMS is requiring CAP vendors to provide the 12 new drugs and biologics as listed in Addendum B.[8] This is the first step in ensuring that Medicare beneficiaries have access to the newest innovative therapies. However, we request that CMS continue to provide beneficiary access by creating a mechanism to require that CAP vendors provide new drugs under the CAP program upon FDA-approval.

The addition of § 414.908(a)(3)(xii) as outlined in the Interim Final Rule[9] allows CAP-participating physicians to purchase non-CAP products, such as products without HCPCS codes, under the ASP methodology.[10] We are concerned that CMS is not mandating that CAP Vendors add new FDA approved products immediately. Under the current Interim Final Rule, new products may not be available under CAP for a period of up to three years. This policy denies access to the newest available therapy to beneficiaries who seek care from a CAP participating physician.

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[6] SSA § 1847B(b)(1) and 70 Fed. Reg. 10749.
[7] Id.
[8] 70 Fed. Reg at 39102.
[9] Id. at 39086.
[10] Id. at 39075.

The current HCPCS coding process results in a period of as long as a year until a new product received a HCPCS code.[11] Until a HCPCS code is awarded, a generic Not Otherwise Classified (NOC) Code is used. This delay will further postpone the inclusion of new drugs under the CAP program. Additionally, once a new HCPCS code is awarded the CAP vendor has the option of providing the product through the CAP.[12] Since vendors will be chosen based on the comparison of the composite bid to the 106% of the weighted ASP for the drug category, there is no incentive for CAP vendors to include newly approved products under the CAP.

Unless CAP vendors are required to provide products billed under the NOC codes and any recently FDA approved products, Medicare beneficiaries will not be able to access new, potentially life-saving drugs. **We request CMS create provisions that require CAP vendors to provide new FDA-approved drugs in a timely manner so that Medicare beneficiary access to new therapies is not compromised.**

D. Clarification Regarding Determinations of Medical Necessity

We are pleased that CMS provided clarification that CAP vendors are not allowed to make determinations of medical necessity and should provide the therapy as ordered by the physician.[13] Medical decision making is the sole responsibility of the healthcare provider. CAP vendors should not have any discretion or interference with this decision making. Simply, vendors should only serve as the conduit to the drug and dispense the specific NDC as ordered by the physician.

Additionally, CAP is not intended to modify the existing coverage process for drugs and biologics. Medicare's current polices for off-label utilization of drugs and biologics ensure beneficiary access to critical therapies. This practice creates improved standards of care and provides the beneficiary with timely access to innovative therapies. Under these policies, Medicare Contractors have the flexibility to provide coverage of off-label uses. Under the current system, coverage is available when supported by acceptance in selected drug compendia, supported by clinical research as published in select peer-reviewed clinical journals, or where the Contractor has determined the use to be generally medically accepted, safe and effective for a particular use.[14]

This clarification helps to ensure that there is consistency in coverage across both the CAP and the current ASP reimbursement mechanisms to Medicare physicians. **By using the jurisdiction of the local Medicare Carriers, beneficiary access to approved and accepted indications of drugs is protected.**

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[11] Due to the timing of HCPCS applications, the delay in obtaining a permanent HCPCS code can exceed one year. Based on HCPCS application obtained at http://www.cms.hhs.gov/medicare/hcpcs/.
[12] 70 Fed. Reg. at 39075.
[13] Id. at 39039.
[14] Medicare Policy Manual. CMS Publication 100-02, §50.4.5.

E. Clarification of Payment for Wasted and Discarded Drugs

The Final Interim Rule did not address the issue of wasted or discarded drugs. However, in response to questions raised at the Open Door Forum on July 8, 2005, CMS clarified the expectation "that vendors will be able to bill the program for unused drugs under the CAP program in a similar fashion if physicians and vendors act in good faith with respect to the ordering and use of the drugs."[15]

Additionally, in the same document CMS states "Generally speaking, under the Average Sales Price system, a physician is able to bill the program for unused drugs if the physician acted in good faith with respect to the ordering and use of the drugs."[16] **While these comments provide needed guidance on the appropriateness of billing for wastage, we encourage CMS to provide in the CAP Final Rule clarification and documentation as referenced under stature to apply the long-standing Part B drug and biological policy[17] uniformly in the physician office, regardless of whether a physician participates in CAP.**

F. CMS Intent to use Producer Price Index to Update Bid Price

The Proposed Rule raised questions regarding the use of the composite ASP in the bidding process. In many cases, ASP can fluctuate as much as 10 percent per quarter as purchase price changes. If CMS used third quarter 2005 ASP payment rates to evaluate a potential bid, the current actual price a CAP vendor may purchase the product for may not correspond with third quarter ASP. In determining the 2005 payment rates for separately billable drugs furnished under dialysis facilities, CMS used the Producer Price Index in order to update prices from 2003 to 2005.[18] Due to the fluidity of ASP, we are pleased CMS considered a mechanism to make projections on the effect on ASP when a product has experienced a price adjustment.

In the Interim Final Rule, CMS will update prices from the period in which CAP bidding begins to the period in which prices will actually be in effect for the CAP program. CMS will use changes in the Producer Price Index (PPI) for prescription preparations over the same period to update the bid prices to the midpoint of program implementation[19]. This approach may result in CAP prices being somewhat higher than ASP prices during the first half of program implementation.

While we commend CMS for creating a mechanism to update prices, the frequency of the update is inadequate. **We encourage CMS to use the most recent quarter ASP available and develop a mechanism to allow CAP Vendors to account for**

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[15] "Response to CAP Vendor Questions: available at http://www.cms.hhs.gov/providers/drugs/compbid/capquestions081005.pdf

[16] Id.

[17] SSA § 1847B(a)(3)(A)(ii)

[18] 69 Fed. Reg. Nov 15, 2004 66236, 66231.

[19] 70 Fed. Reg. at 39074.

manufacturer price adjustments in a timely manner so that CAP Vendors are not penalized in the event that the composite ASP exceeds current ASP.

Conclusion

Berlex appreciates the opportunity to provide comment to the Interim Final Rule. Additionally we commend CMS for delaying the implementation of the program while considering key stakeholder comments.[20] In summary, we recommend that CMS consider the following changes when drafting the Final Rule:

- We request that CMS allow stakeholders to submit comments prior to future inclusion of imaging agents under CAP before implementation.
- We request that CMS reconsider the exclusion of orphan drugs under CAP in order to ensure the beneficiaries retain access to these important life-saving therapies.
- We request that CMS create provisions that require CAP vendors to provide new, FDA approved drugs in a timely manner, so that Medicare beneficiary access to new therapies is not compromised.
- We encourage CMS to provide in the CAP Final Rule clarification and documentation under stature to apply the long-standing Part B drug and biological policy regarding discarded or wasted drugs.
- We encourage CMS to provide a system that allows for price adjustments for CAP vendors in the event the composite ASP exceeds the current ASP.

If you have any questions about our comments, please contact Susan Slaton at 973-305-5374. Thank you for your consideration of the above comments.

Sincerely,

Susan I. Slaton
Director, Reimbursement
Berlex Laboratories

[20] http://www.cms.hhs.gov/providers/drugs/compbid/cap_08032005.pdf

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

SEP - 6 2005

September 1, 2005

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

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

These comments are submitted by the American Society of Clinical Oncology ("ASCO") in response to the interim final rule establishing the Competitive Acquisition Program ("CAP") for Medicare Part B drugs and biologicals, which was published in the Federal Register on July 6, 2005. ASCO is the national organization representing physicians who specialize in the treatment of cancer. Our members administer chemotherapy and other drugs covered by Part B and are very interested in the CAP.

ASCO appreciates the changes that CMS made in response to comments by ASCO and others on the proposed rule. The changes provided important clarifications and improvements. We have a few comments on the interim rule.

Patient Coinsurance

ASCO is very concerned about provisions in the interim rule that permit vendors to terminate the provision of drugs for patients who have not paid their coinsurance within 45 days. Although the rule does require vendors to consider alternatives, such as establishing a payment plan or referral of the patient to a charitable organization, ultimately the vendor has the right to terminate a patient's access to drugs.

We believe that this harsh rule will be a major impediment to oncologists' participating in the CAP. Cancer patients will look to their oncologists, not the drug vendor, if their drug supply, and therefore also their treatment for a life-threatening condition, are terminated. Oncologists will have no effective response for them and will likely avoid this situation by not enrolling in the CAP.

CMS should address this issue in some other manner. Oncologists currently are required to absorb the cost of any unpaid coinsurance, and vendors could reasonably be placed in the same position. The interim rule's decision that cancer patients who cannot pay their coinsurance should simply go without treatment is not a tenable and humane resolution of this issue.

Payment for Administrative Costs

In our comments on the proposed rule, we pointed out that physicians participating in the CAP will incur significant administrative costs beyond those that would be incurred under the buy and bill system. CMS responded that physicians should weigh those costs against the benefits of the CAP when considering whether to participate but declined to provide any additional payment.

The lack of payment for the additional administrative costs involved will, we believe, significantly discourage CAP enrollment. Since implementation of the program has been delayed, ASCO recommends that CMS commission a study to quantify the extra administrative costs involved. Based on the results of such a study, CMS may conclude that an additional payment is appropriate to facilitate CAP enrollment.

Prohibition on Moving Drugs Between Offices

The regulations prohibit physicians from transporting CAP drugs from one practice location to another (42 C.F.R. § 414.908(a)(3)(x)). This prohibition was added in response to comments from prospective vendors that were concerned about possible spoilage or breakage that could occur in such a move and about the possibility of liability if deteriorated drug were administered to patients. (70 Fed. Reg. at 39047) CMS noted that drugs are sometimes administered to patients in their homes and asked for comment on how the vendor concerns about product integrity could be accommodated with home administration.

ASCO believes that the prohibition on transporting drugs between practice locations should be rescinded. Oncologists, especially those serving rural areas, often use satellite offices on an intermittent basis, such as one day a week. The oncologist traveling to a satellite office may carry the drugs for the patients scheduled for chemotherapy that day. It may not be possible for drugs to be shipped directly to the satellite office because it is unoccupied at times or because the regular occupants are not oncologists familiar with handling drugs. The prohibition on transporting drugs may make it impossible for oncologists administering chemotherapy in satellite locations to enroll in the CAP.

We do not believe that transporting drugs from one practice location to another presents a special risk that warrants its prohibition. Oncologists and their staffs are very knowledgeable about maintaining drug integrity. They must routinely handle and store large quantities of drugs properly. In the case of oncology, transporting drugs to satellite offices is much more important that carrying drugs to patient homes for administration there, which CMS has acknowledged should be accommodated. Transporting drugs from one office to another can be safely managed and should not be barred.

Specifying the Estimated Date of Drug Administration

When ordering a drug from the CAP, the physician is required to specify the estimated date of administration. In the preamble to the interim rule, CMS states that it will allow the date to be stated as a range of up to seven days. (70 Fed. Reg. at 39040) The 7-day time period was selected because drugs are often administered on a weekly basis, and the 7-day period was intended "to provide the physician with flexibility to shift the specific date of administration of needed drugs within a specified period without overlapping the next treatment period."

One purpose of the estimated date of administration apparently relates to the requirement for the physician to notify the vendor when a drug is not administered. (42 C.F.R. § 414.908(a)(3)(vi)) Although the regulation itself does not specify when the duty to notify the vendor arises, the preamble suggests that the notification must take place if the drug is not administered on the previously specified expected date of administration. (70 Fed. Reg. at 39048)

ASCO supports CMS's decision to allow flexibility in estimating the expected date of administration. Plans for administering drugs to cancer patients are often modified based on the patient's condition.

For purposes of notifying the vendor that a drug has not been administered, we believe that more flexibility should be allowed. For example, if a patient's condition does not permit the administration of chemotherapy on a scheduled day, it would not be uncommon to reschedule the chemotherapy session for the same day a week later. This 8-day delay would apparently require the physician to notify the vendor that the drug had not been used on schedule.

We question whether the CAP vendors and physician-enrollees would be well served by a requirement for communicating information about relatively short delays in drug administration. It certainly would be a burden on the physician, and if the drug is still scheduled to be used for the patient, the information would seem to be of no value to the vendor.

We believe that rule should be modified to require the physician to notify the vendor only when there will be a significant delay in administering the drug to the patient or when the drug is not expected to be administered to the patient at all.

Patient Support Activity

Patients may have questions for CAP vendors relating to billing, payment schedules, and other matters. The regulations do not include any clear requirement for the vendors to have a responsive patient support function that will answer patient questions. Rather, the regulations appear to require only that vendors have procedures to resolve "complaints" and "inquiries about drug shipments." (42 C.F.R. § 414.914(f)(3)) ASCO is concerned that if the vendors do not have an easily accessible and responsive mechanism for answering all patient inquiries, patients will turn to their oncologists for answers, and oncologists will not be in a position to assist them.

Therefore, ASCO recommends that the regulations include specific requirements for vendors to maintain a mechanism, such as a call center, adequately staffed and available for extended hours to respond to patient issues.

Vendor Sale of Physician-Identified Data

In our comments on the proposal, ASCO asked whether the vendors would be permitted to sell data on drug use that included physician identifiers. If so, we suggested that vendors should be required to disclose their policies so that physicians could take them into account in deciding whether to participate in the CAP and in selecting a particular vendor.

In responding to the comments, CMS stated that vendors would need to comply with HIPAA privacy requirements with respect to patient-specific data, but the issue of physician-specific data was not addressed. We believe that data on drug use by specific named physicians would not be subject to restrictions under HIPAA if it did not contain patient identifiers. ASCO therefore renews its request that CMS state its policy on whether vendors can sell physician-specific data and, if so, that vendors should be required to disclose those policies.

Thank you for the opportunity to submit these comments.

Sincerely,

John V. Cox, DO
Chair, Clinical Practice Committee

Robert T. Woodburn, M.D.
Pimpa J. Tara, M.D.
Virginia Tan Tabib, M.D.
Cheryl Morgan-Ihrig, M.D.
M. Muthusamy, M.D.

M. Y. Ali, M.D.
J. P. Sanghvi, M.D.
B. Keralavarma, M.D.
G. Sloan, M.D.

Cancer Health Treatment Centers, P.C.

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Practice Limited to Hematology and Medical Oncology

August 31, 2005

CMS-1325-1FC
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Sir:

Enclosed you will find final comments relating to the Interim Final Rule, (IFR) on the Competitive Acquisition Program (CAP).

Patient Care

A major area of concern is drug availability. Under the IFR, the drugs available under CAP are limited to an identified list of 181 products, and even then CAP vendors may supply only one drug per HCPCS code. Although the drug list constitutes 85% of Part B drugs based on spending, it leaves out over 250 products covered under Part B. Moreover, CMS acknowledges that CAP will only cover "most of the drugs with access problems under ASP+6%." With low-volume products excluded, CAP physicians will have to buy and bill those drugs for which they are least likely to be able to obtain discounts, further impacting access to drugs. Further, the exclusion of drugs billed on miscellaneous codes could undermine access to advanced treatment options for patients who have failed to respond to old-line treatment regimens.

Concern has also been raised that CAP could compromise patient safety through the potential commingling of patient –specific drug inventories. The traditional physician prescription and pharmacy dispensing process has long played an essential role from a patient safety perspective. However, any commingling of patient prescriptions under CAP could lead to life-threatening medication errors.

The timeline for drug delivery presents serious implications. In general, CAP vendors will not be required to have product to the ordering physician until 5:00 p.m. the next business day in an emergency situation and 5:00 p.m. on the second business day after a routing order is placed, assuming the vendor receives the order before 3:00 p.m. vendor's local time. Practically speaking, physicians will have to reschedule patients with emergency needs at least two days later, and non-emergency patients may not be scheduled any sooner than three days after their original appointment.

Practice Viability

Neither CAP nor buy-and-bill will be sustainable for many oncology practices if reimbursement for drug administration services remains inadequate to cover their costs. When factoring in the additional administrative costs physicians face if they elect to participate in CAP, the risks to practice viability become even greater.

Based on detailed analyses utilizing current information on 2006 payment policy, community cancer care faces substantial losses beginning January 1, 2006. Absent legislative or regulatory change, several critical sources of support will end on December 31st; the symptom management demonstration program is scheduled to end at that time, the drug administration transition factor of 3% will fall to zero, and the physician fee schedule will be cut by 4.3 percent.

As a result of these factors and the chronic underpayment of oncology drug administration services, the projected impact for all of community oncology is a loss of more than $420 million—assuming every penny of coinsurance is collected (which never happens). If, by contrast, half of all coinsurance is collected, the sector wide impact is projected to be in excess of $830 million next year. This translates into an estimated loss of $1,425 per Medicare beneficiary or over $530,000 for a typical 5-physician oncology practice.

Sincerely,

Charles L. Kleinschmidt
Administrator

CLK/jes

PHARMACEUTICALS INC.

September 6, 2005

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

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") interim final rule ("IFC") regarding the Competitive Acquisition Program ("CAP"), published in the Federal Register on July 6, 2005. 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.

TAP also submitted comments to the proposed rule published in the Federal Register on March 4, 2005. Although some of our comments were addressed in the IFC, we remain deeply concerned about the application of the Least Costly Alternative ("LCA") policy to the CAP and believe it will compromise the attractiveness of the CAP to both vendors and physicians.

"Ordering the CAP Drugs"

In the interest of seeing this program succeed, improving both its efficiency and its appeal to vendors and physicians, TAP urges CMS to reconsider the application of LCA to the CAP. The IFC states, "We are implementing the CAP initially through a single, broad drug category and a single,

national competitive acquisition area; therefore, because leuprolide is subject to LCA policies in all carrier jurisdictions, its inclusion in the current CAP drug category would have the effect of requiring vendors to supply the drug at the cost of goserelin in each instance in which a participating CAP physician orders it, regardless of the price established for leuprolide under the bidding and single price determination processes ... and regardless of the geographic location (and local carrier jurisdiction) of the participating CAP physician." It appears that CMS excluded Lupron in an effort to protect the vendors against the application of the LCA policy within the CAP. However, the current solution disregards a number of factors which remain problematic for vendors, and lessens the desirability for physician participation by excluding the preferred and most widely used prostate cancer therapy from the CAP.

First, the IFC states that, "every carrier has applied an LCA policy to injectable forms of leuprolide." However, at this time, not all Medicare carriers have adopted the LCA policy, nor do those that adhere to it uniformly apply the 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. Furthermore, as the ASPs for these products change on a quarterly basis, it is not unlikely that prostate cancer therapies other than goserelin could become the least costly agent. In fact, over the course of the last three quarters of ASP reporting, three different prostate cancer products served as the least costly agent. 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 physicians and patients may suffer the unintended consequence of limited access to therapy.

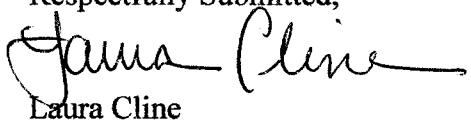
More importantly, the LCA policy goes well beyond the scope of simply leuprolide and goserelin alone. CMS included a number of prostate cancer therapies in the CAP, specifically triptorelin pamoate, leuprolide acetate implant, and abarelix injection, each of which is also included in a number of local carriers' LCA policies. . For example, the local Medicare carriers Noridian, Palmetto of SC, NHIC of New England, HGSA, Cahaba, BC/BS of Arkansas, and the three carriers of NY state, covering a total of twenty-seven states have either already included triptorelin pamoate in their LCA policies or have effective dates for its inclusion before the year's end. This means that this product and others are also subject to payment at the level of the least costly agent in the class. Additionally, by the time CMS implements the CAP in July of 2006, it is likely that those carriers with LCA policies will have rolled in most of the products in the LHRH class. Therefore, vendors will not have relief from managing their costs and administration as they relate to the LCA policy. The best way to alleviate the problem would be to remove the LCA policy from the CAP.

Conclusion

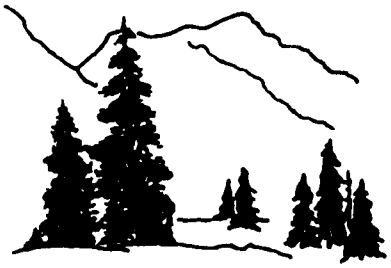
In summary, TAP continues to be concerned that the application of LCA to the CAP will greatly interfere with the success of this program. The inconsistencies inherent in the application of the policy by the local carriers, and the policy's dependence on changing quarterly ASPs to determine the least costly agent will complicate CAP operations. Furthermore, the fact that many local carriers have extended their LCA policies to a number of the prostate cancer products included in the CAP means that vendors must bid on this drug class without knowing how much they will be reimbursed. In order to make the CAP most attractive to vendors and physicians, and to ensure patient access to appropriate prostate cancer treatment, TAP strongly recommends that CMS prevent the LCA policy from applying to the CAP and consider including in the program the most widely used therapy to treat this disease.

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,



Laura Cline
National Manager
Government Affairs



ALPINE HEMATOLOGY-ONCOLOGY
DIPLOMATES OF AMERICAN BOARD OF INTERNAL MEDICINE
AND SUBSPECIALTY BOARD OF MEDICAL ONCOLOGY
236 W. SIXTH STREET, SUITE 400
RENO, NEVADA 89503

OFFICE (775) 329-0873 • FAX (775) 329-1026

JOHN A. SHIELDS, M.D.
STEVEN A. SCHIFF, M.D.

August 31, 2005

Centers for Medicare of Medicaid Services
Dept. of Health and Human Services
Att: CMS-325-IFC
P.O. Box 8013
Baltimore, Maryland 21244-8013

Re: CMS-1325-IFC

Dear Sir:

As a practicing oncologist in Reno, Nevada, let me express my strong opinion that the impact of CAP on my patient flow is going to seriously impede the efficient delivery of appropriate oncologic care. In our office we are usually making decisions on an as needed basis as far as who gets treated with what drugs and at what doses. To anticipate the needs of the cancer patient 24-48 hours in advance will produce delays which I feel will subtract from the quality of care.

I hope you will consider these comments in your deliberations.

Sincerely,

Steven A. Schiff, M.D.

SAS/flm

17

Genentech
IN BUSINESS FOR LIFE

SEP - 7 2005

1399 New York Avenue, NW
Suite 300
Washington, DC 20005
(202) 296-7272
FAX: (202) 296-7290

September 6, 2005

Sent electronically

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

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

Dear Dr. McClellan:

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

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

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

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

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

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

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

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

Policies Genentech Supports in CAP IFR

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

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

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

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

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

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

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

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

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

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

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

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

Policy Changes Needed to Ensure Successful CAP Implementation

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

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

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

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

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

Although the IFR allows CAP-participating physicians to purchase non-CAP products through the traditional "buy-and-bill" method, such a requirement is inconsistent with the overall intent of

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

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

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

Coding and Billing for New Products under CAP

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

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

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

Payment for New Products under CAP

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

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

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

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

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

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

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

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

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

Conclusion

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

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

Sincerely,

Walter Moore
Vice President, Government Affairs

cc: Herb Kuhn, Director, Center for Medicare Management

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SEP - 7 2005

Privileged and Confidential

August 29, 2005

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

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

Dear Dr. McClellan:

Priority Healthcare Corporation (Priority), a specialty pharmaceutical distributor and specialty pharmacy services provider, is pleased to submit comments in response to the interim final rule for the competitive acquisition program (CAP) of outpatient drugs and biologicals. Priority supports the Centers for Medicare and Medicaid Services' (CMS) efforts to implement the CAP program and achieve the policy goals of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) in a manner that best serves the interests of beneficiaries, providers, taxpayers and the healthcare system as a whole.

Priority understands that optimal patient care and convenience are primary goals of Congress and CMS, and strongly supports that position. We further believe that the final business model should be sensitive to the needs of the physician community and be operationally efficient and economically sustainable for participating vendors. Furthermore, we support CMS in its position that the community physician office setting is the right place to provide most of the drugs covered under this rule with appropriate compensation for administration and delivery of high quality care.

In these comments, Priority seeks to ensure that the CAP program regulations promote convenience, optimal patient care, appropriate reimbursement for physician offices, as well as fair compensation and risk mitigation for CAP vendors. Additionally, we seek to ensure the

250 Technology Park
Lake Mary, FL 32746
(800) 892-9622
Fax: (800) 932-2684
www.priorityhealthcare.com

integrity and availability of products through a logistically sound and operationally efficient distribution model by appropriately allocating risk among all parties, based upon what each party can directly control.

In addition to the comments and suggestions herein, Priority, as a member of the Specialty and Biotech Distributors Association (SBDA), also supports their comments, on behalf of that industry, and the portion of Priority's business which resides in that service segment.

Introduction to Priority Healthcare

As you may know, Priority Healthcare has been very active in collaborating with CMS on the impact of the Interim Final Rule. In all our interactions we have found CMS to be willing to listen and to incorporate our thoughts and comments to the extent practicable and allowed by law. We appreciate that very much and have written the comments below in the same thoughtful and deliberate manner in which we have approached the agency these many months.

As both a specialty distributor (distribution of specialty and biotech drugs to physician offices, clinics, etc. in their "bulk" form, non-patient specific), and a specialty pharmacy (provision of pharmacy services for specialty and biotech products on a patient specific basis, to the physician's office or directly to the patient's home), Priority is uniquely positioned to meet the requirements of the CAP program for CMS, participating physicians and beneficiaries. We also believe that we possess the required experience and knowledge to be able to consult with CMS in the development of the final rule and operation model.

Unlike most other pharmaceutical distributors, Priority has extensive capabilities and experience as a licensed medical services provider. Priority manages medical billing and payment for its services from health plans, and also counsels patients on health plan benefits. Priority provides a range of clinical services in conjunction with its pharmacy services, including 24/7/365 nursing and pharmacy support, that define a comprehensive program of specialty pharmacy care. To this end, Priority has developed our Caringpaths clinical programs based on core criteria and utilization management protocols specific to best practice standards that are both drug and disease specific. Our Caringpaths care management therapeutic programs help to ensure that patients and physicians are successfully managing these therapies and lead to successful outcomes. Additionally, Priority is an experienced provider of other related patient and physician office support services that include metric based compliance tracking, electronic medical record integration and disease treatment management programs, all of which are a testament to our experience working to build best in class specialty pharmacy programs.

Priority is also distinguished from other pharmacies as we have extensive expertise in logistics and cost effective distribution systems, augmented by our clear focus and expertise in the specialty channel. Therefore, Priority has significant insight into this market and is uniquely qualified to offer input to CMS on the CAP program, and to work with CMS to craft the type of solution that meets all of the aforementioned objectives.

Comments

Claim Adjudication Risk

Under the interim final rule as proposed, CAP vendors must wait until the proposed date of administration before they can submit a claim for reimbursement to the designated carrier. If the drug was not administered or the dose that was administered is different from that which was distributed to the physician, the physician by rule must contact the vendor and communicate this information in order to prevent an incorrect/invalid claim from being submitted to the designated carrier. This is problematic from many perspectives. Providers of pharmaceutical services are customarily entitled to payment after a drug has been delivered. Updated information from the physician regarding dose or date of administration is often unlikely to be communicated, even when warranted.

Billing delays that are incurred waiting for the administration date to pass will materially and adversely affect the provider's costs. Priority's experience in the commercial and current Medicare market dictates that it is unrealistic to expect that the physician's office will communicate this information to the vendor in a timely manner. Most offices do not possess the required staff to coordinate such activities. The vendor has limited knowledge and little way of knowing when and what to bill CMS. The only way the vendor can truly know is for them to place a follow-up call to the physician's office for each claim prior to billing the designated carrier. This follow-up activity adds costs and further lengthens the time in which the vendor will receive payment.

Regarding situations in which the drug is never administered, the interim final rule allows the drug to be used for another Medicare beneficiary. It indicates that the vendor and physician need to work out the required administration and paperwork to make that happen. It also refers to State Law having precedence over the distribution of product. CMS needs to understand that these two statements will often conflict with each other and not allow the necessary resolution to take place. This is only a pharmacy concern and does not apply if the drug is distributed to the physician under a distribution license.

It is our belief that if the vendor in good faith received a valid prescription order from the physician and shipped that order to the physician, they should be paid for the drug. In the case of the drug not being administered, the final rule should have allowances that are hassle-free and economically neutral to both the physician and vendor. The goal would be to eliminate unnecessary administrative activities and significantly cut down on returns. The details of this should be spelled out in the physicians' contract with both CMS and the Vendor.

In the final rule, CMS should develop an operational model that does not burden the physician's office with more administrative functions than they currently have the capacity to handle. Secondly, the CAP vendor should not be penalized for circumstances that are totally outside of their control. CMS should consider many of the commercial practices that are in use today, both from a "Buy and Bill" and "Pharmacy Administration/Adjudication" standpoint.

Credit Risk

Under the interim final rule, the CAP vendor's claim must be matched to the physician's claim before a bill for coinsurance or deductible can be generated. This situation turns the collection of beneficiary co-payments into a potential economic loss for the vendor. Our extensive experience shows that every day that transpires without collecting a co-payment significantly impairs the vendor's ability to realize the full price of the product, with the risk of non-collection being another cost factor that must be considered by CMS and CAP vendors. Placement of this credit risk on the CAP vendor places an undue burden upon them and therefore makes the program such a high risk that participation may be untenable.

Detailed (in Attachment A) is a timeline that hi-lites cash flow as it relates to the CAP interim final rule. As depicted, even when everything works correctly, the CAP vendor will not receive full payment for product until 90 days from the time the drug was distributed to the physician's office. The case worsens when the beneficiary is not meeting their co-payment obligation. What also must be considered is that the vendor most likely purchased the product from the manufacturer approximately 10 to14 days prior to shipping the drug, thereby further eroding cash flow.

Therefore credit risk is particularly high in light of CMS' unwillingness to allow vendors to reasonably confirm coverage and collect copayments at the time the product is dispensed. Priority believes that CMS does possess the ability to take further action on this issue under the Secretary's demonstration authority. "The Secretary has been given the authority under sections 402(a)(1)(B) and 402(a)(2) of the Social Security Act Amendments of 1967 (Pub. L. 90-248), as amended, to develop and engage in experiments and demonstration projects to provide incentives for economy, while maintaining or improving quality in provision of health services -(69 Fed. Reg. 66236,66308 – Nov. 15, 2004).

Specifically, we recommend that the vendor be able to exercise the right not to ship product in circumstances where it is clear that an ABN has not been provided or no means have been agreed upon to ensure the collection of copayments. These issues need to be addressed to reduce the financial risk of the current program design to acceptable levels.

Other than the obvious economic efficiencies that this model promotes, it also allows the vendor to work closer and sooner with the beneficiary in order to capitalize and take advantage of "Patient Assistance" programs and/or establish individual payment plans that will meet the needs of the beneficiary over the course of therapy.

Distribution Risk

The risk of loss due to logistical factors makes the potential downside of CAP so significant that it prohibits participation in the program. Neither the CAP vendor nor the physician has sufficient financial capacity to absorb losses related to logistical changes. The program needs to address returns in such a fashion that relieves both the CAP vendor and the physician from costs associated with losses due to factors not within the scope of the services they have successfully provided to Medicare beneficiaries. We touched upon some of these issues earlier in our comments.

Other significant risks that need to be addressed in this section are as follows:

a.) Excess Drug – (example: Physician orders dosing based on HCPCS code but the vendor has to supply the product in the manufacturers' packaging which is associated with the NDC number)

The interim final rule indicates that the vendor can only be reimbursed for the amount of drug that is administered as compared to the amount the vendor is forced to ship to the physician.

Unless CMS allows vendors to ship product in amounts different than the manufacturers' packaging (NDC number), we strongly believe that the vendor's reimbursement should be based on the manufacturer's packaging and not on the dose administered, similar to the way it is handled today in the "Buy and Bill" model.

However, Priority is pleased that CMS has recently issued guidance providing more clarity concerning the issue of billing for unused portions of drugs. That guidance indicates that "good faith" efforts to avoid wastage and utilize the appropriate amount of drug for a beneficiary will allow the CAP vendor to recoup the full cost of the drug product. Priority appreciates CMS' modification and believes it should affirm this policy in the final rule.

b.) Forced Distribution – (example: CAP vendor knows that a prescription order is inconsistent with a local coverage determination (LCD) but must still ship drug fully knowing or suspecting based on past clinical precedent that the product will not be reimbursed).

We know from experience that if a physician determines a patient in Texas needs Erbitux, for example, off-label for head and neck that the Trailblazer medical director will deny the claim if the head and neck indication is not in compendia. Three other carriers act in the same manner with no deviation. In this situation, the vendor should not have to assume the risk. CMS should amend its current stance to say that local coverage determinations are to be adhered to under the CAP program and allow the vendor to exercise the right not to ship product. If the physician decides to maintain the prescribed drug regimen then we believe the best way to handle this is for CMS to treat it as a "Furnish as Written" exception and let the physician buy the drug and bill CMS under the "Buy and Bill" protocol. This way the physician has full control over the situation and is able to execute their clinical expertise.

We also believe that with today's technology, and the fact that there are seventeen (17) local carriers with as many sets of rules on reimbursement, CMS should seriously consider implementing a real time system answer (similar to the way Pharmacy Benefit Managers (PBMs) handle prior authorizations and medical necessity requests) to this complicated and complex area.

c.) Pharmacy versus Distribution

When implementing a national program such as CAP, there should be no confusion regarding the type of license(s) a CAP vendor must obtain and utilize in order to fully perform its' obligations. Secondly, all "gray areas" of confusion regarding national versus state requirements need to be defined.

We encourage CMS to take a position as to the specific program and licensure requirements a CAP vendor needs to exercise. However, before doing so, CMS needs to fully comprehend the differences between a "Pharmacy" and "Distribution" model and all of the associated costs (operational, returns, etc..) since they differ significantly between models.

An example of this is that many states do not permit pharmacies to accept returns from patients except under specific circumstances such as when the product is returned in a properly labeled and sealed manufacturer's package or if customized units are individually sealed and part of a closed-drug delivery system.[1] The Food and Drug Administration (FDA) also recommends that pharmacists not accept return of drug products once they have left his or her possession.[2]

The interim final rule suggests that the issue of returns should be addressed between the physician and the pharmacy. However, this may not be feasible under various state pharmacy laws. Such a policy is inconsistent with today's practices and would render the CAP model untenable from a cost-management perspective.

Other Important and Pertinent Areas to Address:

1) Inclusion of CAP Prices in the ASP calculation

Since CMS has expressly forbidden the use of formularies in the CAP program, and seems to indicate it would frown on payor cost management tools such as step therapy or fail first policies, vendors have very little negotiating leverage with the manufacturers of proprietary products other than those situations in which the HCPCS code has multisource products associated with it. Whatever negotiating leverage they do have is further diminished by including negotiated CAP prices in the drug's ASP. This becomes a significant disincentive for many manufacturers and is very difficult, if not impossible for them to have a good business reason as to why they should offer CAP vendors discounted pricing.

In our analysis, we found that much of the initial CAP pricing offered by manufacturers exceeded that for which physicians could purchase the identical product today. In some cases, the CAP price was greater than ASP + 6%. However, we were certainly not at all surprised by these results.

Priority does believe that CMS possesses the regulatory discretion to exempt CAP from the computation of Average Sales Price ("ASP"). Congress very specifically created two separate payment structures because it wanted to provide physicians with a meaningful choice of how they were reimbursed for drugs.

Our perspective regarding CMS' discretion on this issue is derived from several statutory provisions. First, as we have articulated previously, CMS' demonstration

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[1] Fla. Admin. Code Ann. r. 64B16-28.118 (2005) (prohibiting returns by patients except for unused portions of a unit dose package dispensed to in-patients in a closed delivery system and if the drug is individually sealed and properly labeled); Md. Regs. Code tit. 10, § 10.34.10.07 (prohibiting returns to a pharmacy's stock of previously sold product unless the product is properly labeled and sealed or, in the case of a unit dose, the pharmacist determines the product to have been handled in a manner that preserves the strength, quality, purity, and identity of the drug).

[2] FDA Compliance Policy Guide § 460.300 (CPG 7132.09).

authority is broad and would permit the Agency to implement the CAP program without incorporating ASP prices. The Social Security Act permits CMS "to determine whether, and if so which, changes in methods of payment or reimbursement...including a change in negotiated rates, would have the effect of increasing the efficiency and economy of health services..."Social Security Act, 42 U.S.C. 1395b-1. As exempting CAP negotiated prices from ASP calculations would represent a change in negotiated rates and would arguably increase the efficiency of health services, CMS possesses the ability to effectuate this change.

In addition to this demonstration authority, CMS should also find support for its authority to exempt CAP bids from ASP prices from the plain language of the MMA. According to Section 1847(a)(1)(B), the "Secretary shall establish categories of competitively biddable drugs and biologicals. The Secretary shall phase in the program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate.

2) One Drug Category

Although we believe CMS initially created the One (1) Drug Category as a means to simplify the program, we believe CMS should consider revisiting the complete economic ramifications behind that decision. Implicit in CMS' decision to reduce the number of available drugs under CAP from 440 to 181 is that cost-efficiencies will not be realized by the Program for small volume or inexpensive drugs. In fact, a CAP vendor would lose money on every shipment of these less expensive drugs. We therefore recommend that the Agency exclude an even wider class of inexpensive and low-volume drugs from the bidding process. Inexpensive and low-volume drugs represent a fixed cost to the CAP vendor that make it considerably more difficult to comply with the Agency's aggregate bidding cap of ASP + 6%. CAP simply cannot save money for the Medicare Program if a vendor is required to undertake shipping costs for a product when it may cost more to send the product to the physician than the vendor will realize from Medicare.

We therefore ask CMS to consider including only the high dollar claim drug categories in the initial program launch. After a successful launch, CMS could consider excluding these other specialties for the duration of the program or establish a minimum payment amount per claim and include all currently proposed drugs and specialties. Another option for CMS is to establish multiple drug categories of which vendors can select those they are interested in bidding on. We do not have a problem, as was posited by the biotechnology companies, with inclusion of orphan products in the CAP program; so long as they fit into the high dollar claim categories previously discussed.

3) Supplemental Insurance

In the interim final rule, CMS states that approximately 80% of Medicare beneficiaries have some form of supplemental insurance (i.e. Medicaid, Medigap, etc.) that will reimburse the CAP vendor for the remaining 20% of the drug cost. What CMS may not recognize is that no one vendor is in network with 100% of these supplemental insurers. In fact, even in the best case scenario, vendors will be in-network 75% of the time. The situation worsens when you consider that distributors in general are not contracted with supplemental insurers.

Another classic example for CMS to recognize is the case of "dual-eligibles". Many states do not award a Medicaid license to a provider unless that business entity meets specific eligibility requirements. Therefore, this reality presents an additional risk to CAP vendors in many states.

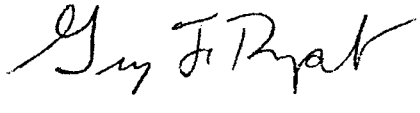
Some Medicaid agencies (such as the State of Texas) require a physical presence in the state (or a border state) before the provider may be enrolled. Many commercial plans limit contracting to specific providers. In each case, secondary reimbursement under the terms of coverage may not be available to the CAP vendor.

4) Addition of New NDCs

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

In closing, Priority Healthcare wishes to express again its interests in assisting CMS in a successful implementation of the CAP program and its commitment to CMS to give serious consideration to becoming a CAP vendor. We welcome the opportunity to come in and discuss any of this information at a face-to-face meeting. We hope our suggestions will help CMS address these important issues in the final rule. Please contact Mike LaBrecque R.Ph., MBA at 407-804-8179 if you have any questions regarding our comments. Thank you again for this continuing opportunity to work with CMS to improve the mechanics of this very important program for Medicare physicians and beneficiaries.

Respectfully submitted,

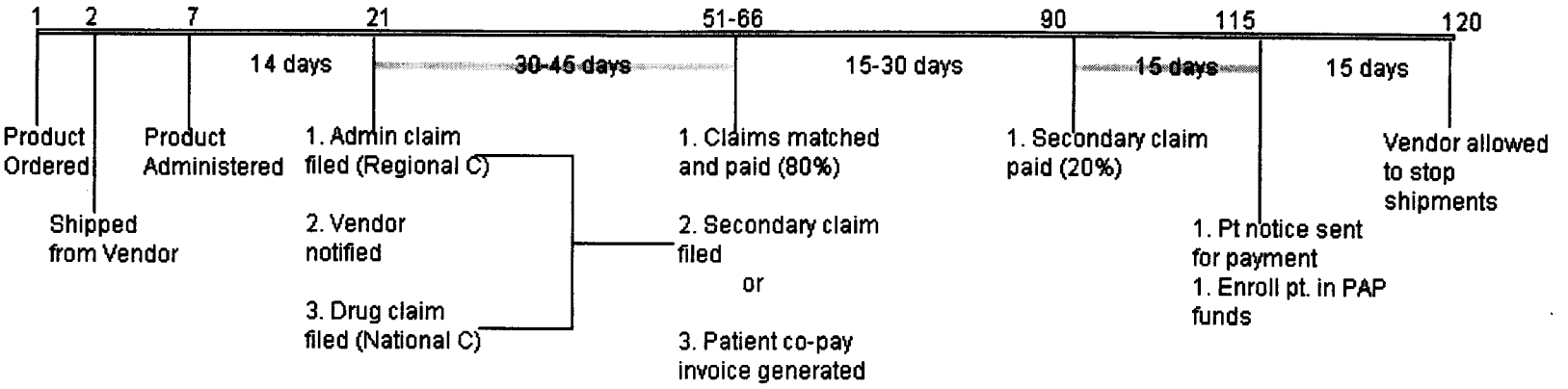


Guy Bryant
Executive Vice President & General Manager, Distribution Services

Attachment

CAP Vendor Cash Flow
Time and Risk Analysis

Attachment A



Therapy

On-therapy | Off-therapy | On-therapy | Off-therapy | On-therapy | Off-therapy | On-therapy

Risk Points:

1.Claim is not filed within 14 days
2. Claim filed improperly

1. Delay
2. Denial
3. Dependency on Dr. appeal

1. Secondary denial
2. PHC out of network of secondary insurance
3. Pt does not pay
4. Pt receives additional product

1.Pt does not pay
2.Pt received additional product

1.Pt does not pay
2.Pt received additional product

eyetech

3 Times Square, 12th floor • New York, New York 10036
Telephone: 212 824.3100 • Fax: 212 824.3101
www.eyetech.com

August 30, 2005

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

RE: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals, Fed. Reg., Vol. 70, No. 128, July 6, 2005 [CMS-1325-IFC]

Dear Dr. McClellan:

Eyetech Pharmaceuticals, Inc. is pleased to have the opportunity to provide comments on the Competitive Acquisition Program (CAP) Interim Final Rule. As noted in our previous comments submitted on April 26, 2005 for the CAP Proposed Rule, Eyetech is a biopharmaceuticals company with a focus on the development of therapeutics to treat diseases of the eye. We continue to enthusiastically support the CAP and its implementation; and we share the perspective that the CAP will lead to less administrative burdens for physicians and the Centers for Medicare & Medicaid Services (CMS), and will provide greater convenience and access to therapies for beneficiaries.

We were pleased to learn that the CAP Interim Final Rule clearly established ophthalmology as an initial component to the implementation of the CAP. We encourage CMS to ensure that ophthalmology is maintained as part of the initial phase-in of the CAP, regardless if other physician specialties are included or excluded in the Final Rule. Eye disease treatment with pharmaceuticals is a rapidly advancing field and will only develop further as the elderly population increases and the onset of eye diseases, such as macular degeneration, become more commonplace. By including ophthalmology in the CAP, CMS has addressed a serious and increasing need for its beneficiaries and providers.

In the Proposed Rule comments submitted by Eyetech, we expressed our objections to include the CAP prices in Medicare ASP calculations. We understand the statutory limitations that CMS must consider in the development of this policy issue, however, we would like to reiterate our view that the CAP prices should be excluded from ASP calculations. Further, CAP-negotiated prices should be excluded from the calculations for Medicaid AMP or Best Price, 340B, FFS and other government programs pricing. Ambiguity on this issue may discourage manufacturer participation in the CAP or reduce the savings CAP could potentially achieve for the Medicare program and beneficiaries. We, therefore, urge CMS to adopt the position that the CAP-negotiated prices will not be included in ASP or other government program pricing.

The Interim Final Rule contained a list of drugs that would be included in the initial category for the phase-in of the CAP. Given the recent announcement regarding the delay on the CAP bidding process, Eyetech encourages CMS to reassess the drugs to be included in the initial phase of the CAP. It is imperative for beneficiaries to receive the best available therapies; and

therefore, it is critical that CMS reconfigure the list of qualified drugs to include those that are now eligible based on the adjusted timeline.

Eyetech, in discussions with the American Academy of Ophthalmology and a major Pharmacy provider would be willing to support a limited roll-out of CAP to the Ophthalmology area alone. We believe such an approach would offer CMS the opportunity to meet the January 1, 2006 deadline and provide a reasonably sized "test" to evaluate the strengths and weaknesses of the CAP program. Focusing initial implementation on Ophthalmology would also assure that CAP is launched with a limited number of prescription products and with physicians who are supportive of the concept and are not currently large purchasers of part-B covered items. With the changes suggested related to the CAP prices and the initial drug list noted in the proceeding paragraphs, we think it is possible to pull together a working group comprised of the key stakeholders to enable CMS to move forward. This group could meet with CMS regularly to reevaluate the issues and concerns that have led to some of the issues raised in the comment period as well as identify the issues that may arise during this "trial" period

Eyetech is once again grateful for the opportunity to provide its views on these important issues for the CAP. We are enthusiastic to support the implementation and development of this initiative. Please consider our company a resource as CMS progresses with its policy decisions and Final Rule for the CAP.

Thank you for your consideration of our comments.

Sincerely,

Pat Barnett
Director of Reimbursement and Health Policy
Pharmaceuticals, Inc.

CMS competitive Acquisition Program (CAP) Interim Final Rule Comment

File Code: CMS – 1325-IFC

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

SEP - 7 2005

As an employee in a community oncology practice the practical implementation of the CAP program concerns me. CMS needs to realize that Medicare patients are not the only patients we care for. The actual implementation of the CAP program would force a physician's office into maintaining two inventory systems. The CAP program would govern the ordering of drugs for Medicare patients on a per patient basis and then for our Commercial (non-Medicare) patients we would have a separate inventory system for ordering and supplying their drugs. The implementation of the CAP program itself introduces significant administrative burdens on the physician practice, but even more so because the CAP program creates an environment that two inventory systems must be maintained. Currently, we buy the drugs we need for all patients, whether Medicare or Commercial, and store them accordingly. Under the CAP program we would order the drugs we need from a CAP vendor on a individual patient basis and then have to store the drugs separate for each patient. Then we would have to order drugs for our Commercial patient as we currently do but we would have a separate storing method and place the keep those drugs separate from our CAP drugs. I think CMS needs to realize that implementing the CAP program not only affects the Medicare patient but the entire physician practice patient population. Depending on the size of a practice, implementing the CAP program may force a physician's office to have to hire an employee just to maintain an inventory system for all patients. Otherwise you are taking current staff time away from patient care ultimately affecting the quality.

Thank you for allowing me this forum to express my concerns.

Respectfully,

Liza Owens

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SEP - 7 2005

J. Michael Carroll, M.D., P.C.
Internal Medicine, Hematology and Oncology

J. Michael Carroll, M.D.
Jacqueline A. Cox, M.D.
W. Wm. Andrew Cox, M.D.
Nancy Schupp, A.N.P.

1640 Cowles, Suite 1
Fairbanks, Alaska 99701
Phone (907) 452-4768
Fax: (907) 452-1009

August 29, 2005

Department of Health and Human Services
Attn: CMS-1325-15C
P.O. Box 8013
Baltimore, Maryland 21244-8013

Dear Sirs:

I am writing with regard to my concerns over the CAP Vendor Program for chemotherapy drugs. I understand that this has been put on hold for six months.

As a practicing oncologist in Northern Alaska, there are many unique features about practicing oncology in Alaska that would be adversely affected by the proposed CAP Program. Examples include the fact that patients frequently come from long distances (100 to 250 miles) by the highway system or by air taxi scheduled services from the villages. Having to return to their communities or villages and then return for chemotherapy because of not receiving chemotherapy medications in a timely fashion would, needless to say, be a great burden on these patients who live at great distances. This would add considerable expense to the Medicaid / Medicare system and, as a result, an indirect expense to the government program for healthcare.

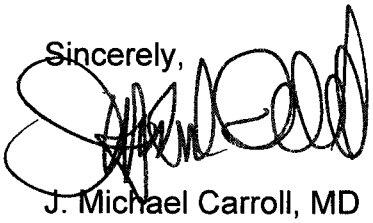
I am furthermore concerned with patients who have difficulty meeting their co-payments. This could result in patients needing to go to the hospital for chemotherapy. This offers considerable inefficiency and burdens the already overwhelmed hospital system.

Frequently, patients receive Medicare-covered treatments that are unscheduled but are not in the emergency category. Examples are the use of Erythropoietin agents and granulocyte colony stimulating factors. It is very difficult to predict the dosing and schedule of these medications in this setting, and dealing with the CAP Vendor Program would be exceedingly difficult.

Finally, the bureaucratic burden of keeping each patient's medications allocated and separate and, if necessary returned, adds to the administrative costs for community-based practice of oncology. My impressions are that I would probably have to add one additional full-time employee to deal with the CAP issues of ordering drugs, keeping track of their administration and making sure that any unused drugs were properly returned.

As the regulations are currently proposed, I am reluctant to sign up with a CAP Vendor Program.

Sincerely,



J. Michael Carroll, MD

JMC:rjs
R:08/30/2005 rjs
3976349

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SEP - 7 2005

Mr. and Mrs. Jett D. Thomas
103 Chesapeake Drive
Vallejo, California 94591-7207

02 September 05

Centers for Medicare + Medicaid Services
ATTN: CMS-1325-IFC
po box 8013
Baltimore, MD 21244-8013

Dear Centers for Medicare + Medicaid Services;

We are friends of Jo Walker, a thyroid cancer patient, and we are requesting that Thyrogen (thyrotopin alfa for injection) be included in the list of drugs available through the Medicare competitive acquisition program (CAP) in 2006.

Thyrogen is crucial for the follow up of Jo's thyroid cancer treatment, in testing used to determine whether or not she is free of the disease of if the cancer has recurred or spread.

We are concerned that your proposed guidelines will exclude Thyrogen from the CAP. Jo and many other Medicare beneficieries who suffer from thyroid cancer need Thyrogen to be included in the CAP.

We urge you to reconsider your guidelines. Please include Thyrogen in CAP as soon as possible.

Sincerely yours

Jett D Thomas
Mildred D. Thomas

e-mail; jettmilly@webtv.net

Johnson & Johnson

KATHLEEN A. BUTO
VICE PRESIDENT
HEALTH POLICY
GOVERNMENT AFFAIRS & POLICY

1350 EYE (I) STREET NW
WASHINGTON, DC 20005-3305
(202) 589-1000
FAX: (202) 589-1001
kbuto@corus.jnj.com

September 2, 2005

By Hand Delivery

Mark B. McClellan, MD
Administrator, Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Attn: CMS-1325-IFC
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Dear Dr. McClellan:

On behalf of Johnson & Johnson (J&J) operating companies, we are providing the following comments in response to the Interim Final Rule (IFR) issued by the Centers for Medicare and Medicaid Services (CMS) regarding implementation of the Competitive Acquisition Program (CAP) for Part B drugs and biologics published in the Federal Register on July 6, 2005.[1]

J&J is the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical and medical devices and diagnostics markets. J&J has more than 200 operating companies in 57 countries around the world employing approximately 109,000 employees and selling products in more than 175 countries. The fundamental objective of Johnson & Johnson is to provide scientifically sound, high quality products and services to help heal, cure disease and improve the quality of life. Of particular relevance to this rulemaking, J&J operating companies manufacture and market some of the most important drugs and biologics covered under Part B of the Medicare program, including PROCRIT® (epoetin alfa), REMICADE® (infliximab), RISPERDAL CONSTA® (risperidone) and NATRECOR® (nesiritide).

J&J has long believed that the CAP can help ensure patient access to important therapies while offering an alternative for physicians to the current "buy and bill" system under

[1] 70 Fed.Reg. 39021.

which physicians purchase the drugs, collect the beneficiary coinsurance and bill the Medicare program for drug reimbursement. We commend CMS for instituting several policies in the IFR that promote Medicare patient access to Part B drug therapies including (1) the creation of a single broad category of drugs that includes mental health products and complex biologics and (2) the nationwide implementation of the program that will allow physicians and their Medicare patients in all parts of the country to have access to the CAP. Given these positive aspects of the CAP IFR, we were disappointed to learn that CMS has planned a 6-month delay in the implementation of the program from January 1 to July 1, 2006.

While it is likely that CMS will work in this interim period to make the program more attractive to the vendor and physician community, we urge CMS to continue to make patient access to medical therapies the paramount goal of the CAP program. **Specifically, we urge CMS not to scale back the number and scope of products included in the CAP and to maintain the national rollout of the program for 2006. We also urge CMS not to delay the initial implementation of the program any later than July 1, 2006 as providers especially in the mental health and rheumatology fields would like to utilize CAP at its earliest possible date.** As CMS stated in the IFR, "it is important to provide an alternative to the 'buy-and-bill' method of drug acquisition for physicians as widely and quickly as possible."[2] We therefore urge CMS not to delay implementation of the program any longer than July 1, 2006.

Our specific comments and recommendations follow. As requested by CMS, we have identified the specific "issue identifier" that precedes the section of the IFR on which we are commenting.

I. Categories of Drugs to Be Included Under the CAP

A. Number of NDCs Provided by the Vendor In a HCPCS Code. CMS stated in the IFR that it would not require vendors to provide every National Drug Code (NDC) associated with a HCPCS code.[3] While we understand that CMS is trying to promote competition and minimize the administrative and financial burden of the CAP vendor, we are concerned that this policy could have negative implications for patient access and overall quality of care if applied in all situations. We think that CMS should institute two general exceptions to this policy described below before final implementation of the CAP.

J&J Recommendation: We recommend that vendors be required to provide all NDCs within a specific HCPCS code in the following two situations:

1. *CAP vendors should be required to bid on all NDCs within a HCPCS code if they are unit doses of the same single-source medication.* For example, if a single-source drug or biologic has three NDCs to describe three different unit strength doses within the same

[2] Id. at 39035.
[3] Id. at 39034.

HCPCS code, a vendor could theoretically bid on and provide only one dosage level to the physician under the current CAP rules. Under such a scenario, the CAP vendor could choose to bid on and provide only the lowest dosage strength of a given product. In this case the physician may be offered only a 25 mg dose of a given product described by a specific NDC, but some of his patients may be in need of larger 75 mg doses. There is the potential that the physician would have to inject the drug three times to appropriately treat the patient. This obviously would have negative implications for quality of care for the patient. While the physician could theoretically obtain other NDC formulations of the product through the "furnish as written" policy, we believe that physicians should not be forced to take on this additional administrative burden just to obtain the correct dosage of a product covered under the CAP program. We strongly recommend that CMS remove this possibility by requiring the vendor to supply all NDCs describing different dosing levels for the same single-source drug within the HCPCS code. This requirement should add no more than minimal administrative and financial burden on the CAP vendor. Accordingly, CMS should take the requested action in the interest of patient welfare as described above.

2. *Vendors should be required to provide the NDCs of branded single-source drugs described by the same HCPCS code.* CMS wisely rejected comments to establish drug formularies under the CAP. As the agency indicated in the IFR, "[w]e are not accepting the recommendation that vendors be permitted to establish drug formularies by offering drugs from only some of the codes included in a category. The statute expressly requires that for multiple source drugs, a competition be conducted for the acquisition of at least one drug per billing code within the category."[4] We agree that the statute expressly requires competition for multiple source drugs, but does not create such a structure for single-source products. We believe that all single-source products should be offered the same status under the CAP regardless of whether they have their own unique HCPCS code or share them with other branded products.

Requiring each CAP vendor to bid on at least one NDC for each single-source drug and biological in a category would ensure that Medicare beneficiaries have access to the brand that works best for them. Single source drugs are unique products that should be carried by each CAP vendor in order to ensure patient access to them. We believe that it is essential that each patient receive the specific brand that is best suited for his or her condition so that patient treatment options are not dependent upon a physician's CAP decision. This recommendation would not add significant administrative or financial burden on CAP vendors given that there are very few examples of similar single source drugs covered under CAP that are described by the same HCPCS code.

B. Inclusion of New Drugs and Biologicals in the CAP. We commend CMS for requiring CAP vendors to bid on and provide the 12 new drugs and biologicals listed in Addendum B,[5] including "Risperidone, long-acting" (J2794) otherwise known as RISPERDAL CONSTA®. Psychiatrists operating at Community Mental Health Centers

[4] Id. at 39034.
[5] Id. at 39102.

(CMHCs) support the CAP and hope to use the program as a way to offer patient access to this important new therapy.

However, we were disappointed that the IFR did not have an explicit provision to require vendors to bid on and provide other new Part B drug therapies likely to be introduced over the initial three-year CAP contracting period. While CMS encourages vendors to add new drugs to the program beyond the initial list in the single category, it does not require them to do so.[6] As a result, physicians electing the CAP program may not be able to access the newest therapies through the CAP unless the vendor agrees to offer such products. ~~To obtain the newest therapies, P~~physicians may be forced to devote financial resources to obtaining such products through the "buy-and-bill" acquisition model. In addition, CAP-enrolled physicians who must purchase these newer non-CAP products directly from wholesalers and distributors will likely be extremely low volume purchasers. As a result, such physicians may be forced to pay higher prices for the same product(s) as larger volume practices that continue to buy-and-bill for all their drug purchases.

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J&J Recommendation: CMS should require vendors to bid on and provide new Part B therapies by no later than the next calendar quarter following FDA approval. These therapies should be reimbursed to the CAP vendors under the methodology created in section 1847A of the Social Security Act until the next vendor bidding cycle. Newer products should be treated comparably to the 181 drugs in the single drug category so that physicians electing CAP can have full access to the newest technology without having to revert back to the "buy-and-bill" system.

C. Future Drug Categories. For the initial roll-out of CAP, CMS has established a single drug category consisting of 181 drugs and biologicals representing approximately 85 percent of physicians' Part B drugs by billed charges. The agency indicates in the IFR that it plans to phase-in multiple drug categories in future years "probably defined around the drugs commonly used by physicians' specialties (for example, urology, rheumatology)"[7] as CMS refines the program.

J&J Recommendation: We look forward to working with the agency on developing new categories under the CAP. We strongly recommend that CMS maintain a broad category structure to ensure adequate vendor interest for all therapeutic areas in future years. For example, if CMS structured the product categories too narrowly so that very few Part B products would fall into a single specialty category (e.g. psychiatry), vendors may have little interest in bidding on the products if they proved to be insufficiently profitable. As CMS states in the IFR, the broad single drug category will increase the interest of potential vendors by making it more likely that "the fixed costs of being a vendor can be covered across the broad array of Part B physician-administered drugs that are included..."[8] While multiple categories may be necessary in future years, we strongly

[6] Id. at 39075
[7] Id. at 39030.
[8] Id. at 39030.

recommend that CMS structure them broadly enough to maintain sufficient vendor interest in all therapeutic specialty categories.

II. Competitive Acquisition Areas

Subcontractor Responsibilities. CMS has established a single, national distribution area for the initial stage of CAP. Given that there will be a maximum of only five vendors selected to participate in the program, it is highly likely that vendors will need to employ subcontractors to adequately fulfill drug distribution responsibilities in all 50 States, the District of Columbia, Puerto Rico and the U.S. territories. While we support the national implementation of the CAP in 2006, we are concerned about the possibility of product counterfeiting or other product integrity issues with the use of vendor subcontractors in such a broad geographic region. For this reason, we welcome CMS's decision to require subcontractors to comply with all the requirements binding on the CAP vendor themselves, including those relating to product integrity.[9] We also appreciate that CMS holds CAP vendors accountable even for the acts of its subcontractors.[10] We request, however, certain additional safeguards described below.

J&J Recommendation: We believe that CAP vendors should have an obligation to expressly include in their agreements with their subcontractors a covenant binding on the subcontractor to comply with all rules applicable to CAP vendors, including those rules regarding product integrity and drug pedigree set forth in 42 C.F.R. §§ 414.906(a)(4) and 414.914(c)(1). The subcontractor agreement should also include that the Department of Health and Human Services (DHHS) is a third party beneficiary to these agreements with the right to enforce any of the provisions relating to CAP program compliance. The agreement would also need to specify that DHHS should have access to all books and records relating to CAP program compliance.

III. Claims Processing Overview

A. Payment of Coinsurance by Medicaid. The IFR establishes a number of procedures and requirements that the vendors must first address before refusing to make further shipments of drugs to physicians for individual beneficiaries due to non-payment of coinsurance.[11] For most dual eligible beneficiaries, state Medicaid plans will be responsible for the coinsurance for patients receiving their Part B drugs from physicians enrolled in CAP. As CMS is aware, individual state Medicaid plans can have differing policies on the appropriate level of Medicare Part B coinsurance for dual eligible beneficiaries. This inconsistency among the States may be confusing to some vendors in determining when a dual eligible patient in CAP has met his or her coinsurance obligations.

J&J Recommendation: We request that CMS confirm that CAP vendors cannot refuse to make shipments of CAP drugs on behalf of dual eligible beneficiaries when a State

[9] 42 C.F.R. § 414.914(f)(9); 70 Fed. Reg. 39022, 39060.
[10] 42 C.F.R. § 414.914(f)(9).
[11] 42 C.F.R. § 414.914(h).

Medicaid program has upheld its statutory obligations relating to coinsurance payments. For certain dual eligible beneficiaries, State Medicaid programs can limit coinsurance payments to the extent that any such payment, when combined with Medicare payments, equals the amount of reimbursement payable under the State Medicaid program.[12] Accordingly, a State Medicaid program may deem a CAP vendor to be paid in full even if it has received either no coinsurance payment or a reduced payment from the State. Beneficiaries have no liability beyond the State's payment.[13] Thus, CMS should clarify that the State's adjudication of a claim for payment of an outstanding coinsurance amount is final. CAP vendors have no continuing right after the State's adjudication to seek payment from the beneficiary of any purported remaining balance pursuant to 42 C.F.R. § 414.914(h)(2). The State's claim adjudication should preclude the CAP vendor from pursuing any action that would ultimately lead to the CAP vendor's refusal to make future shipments of CAP drugs on behalf of the beneficiary. In order to account for any shortfall in financing to the CAP vendor, CMS may need to take these variable co-payments into account in making payment adjustments to the CAP vendors' administrative costs.

To facilitate the processing of these claims for coinsurance for dual-eligible beneficiaries, J&J recommends that CMS direct Noridian, the designated CAP carrier, to update their claims process systems so that claims can be automatically crossed over from Noridian to the relevant state Medicaid program. This will permit the speedy processing of claims by Medicaid programs for dual-eligibles and allow CAP vendors to submit a single claim for such patients, when automatic cross-over is permitted by the Medicaid program in question.

B. Waiting Period Before a Vendor Can Withhold Delivery of Drug for Non-Payment on Coinsurance. Under the provisions of the IFR, vendors must provide information, when requested by patients, on sources of cost-sharing assistance available to beneficiaries. This assistance can include a referral to a bona fide and independent charitable organization. If the beneficiary requests cost-sharing assistance and the vendor refers the patient to a bona fide independent charitable organization for assistance or offers a payment plan, the vendor must wait an additional 15 days from the postmark of the approved CAP vendor's response to the beneficiary's request for cost-sharing assistance. If at the end of the 15-day period the vendor has not received a cost-sharing payment from the charitable organization or the patient, the vendor may refuse to ship additional drugs to the physician on behalf of that patient. [14]

J&J Recommendation: CMS should extend the time the CAP vendor must wait before discontinuing provision of drug after which the patient has requested assistance and the vendor has provided patients with a referral to third-party. If a patient requests assistance, and if they are referred to a third-party for assistance, they should be provided greater than 15 days to assemble required materials, submit the materials and have the

[12] Social Security Act, § 1902(n)(2).
[13] Social Security Act, § 1902(n)(3)(A).
[14] 42 C.F.R. § 414.914(g).

application for assistance reviewed and approved and finalized. We propose that time requirement should be a longer period of time (e.g. 30 to 45 days) to permit patients to appropriately respond and gather information and submit materials required by various assistance organizations. It is not unreasonable to expect that Medicare beneficiaries in need of financial assistance will need additional time beyond 15 days to navigate the administrative requirements necessary to receive third-party assistance under the new CAP program in 2006 and receive approval and funding from these organizations.

C. Option for Physicians to Opt Out of CAP for Non-Delivery of Drug. The IFR permits CAP physicians to opt out of the single category in the CAP program all-together in 2006 "in instances where a beneficiary has failed to meet his or her obligation to pay coinsurance or deductible for a drug and the vendor has refused to continue providing the drug..."[15]

J&J Recommendation: CMS should clarify that in the situation highlighted above where a vendor has refused to continue providing the drug for a specific beneficiary who has failed to meet his or her cost-sharing obligations, that the physician should instead be afforded the opportunity to seek reimbursement for that specific beneficiary under the Average Sales Price (ASP) plus six percent methodology. However, the physician should still be able to remain in the CAP program for his or her other patients that do not have difficulties meeting their cost-sharing obligations through their own financial means or through secondary insurance. It seems extreme to force physicians to withdraw completely from the new CAP program as a result of cost-sharing difficulties related to one specific patient. Physicians in this situation would face the Hobson's Choice of either abandoning the one financially needy patient or incurring the financial exposure entailed in returning to the purchase of drugs under Section 1847A of the Act. CMS should not put physicians in this position.

D. Payment for Discarded Drugs. The IFR appears to create a new and inconsistent policy that conflicts with long-standing CMS policy on discarded drugs set forth in the Claims Processing Manual. CMS states that "[s]ince the CAP statute authorizes us to pay the approved CAP vendor only upon administration of the drug, any discarded drug (or drug that is considered waste) will not be eligible for payment."[16] However, we are encouraged to see that CMS has since clarified its position and legal interpretation of the CAP statute given the recent "Question & Answer" (Q&A) statement posted on the CMS website. "Generally speaking, under the Average Sales Price system, a physician is able to bill the program for unused drugs if the physician acted in good faith with respect to the ordering and use of the drugs. We expect that vendors will be able to bill the program for unused drugs under the CAP program in a similar fashion if physicians and vendors act in good faith with respect to the ordering and use of the drugs."[17]

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[15] 70 Fed. Reg. at 39053.
[16] Id. at 39063.
[17] See "Response to CAP Vendor Questions," posted at http://www.cms.hhs.gov/providers/drugs/compbid/capquestions081005.pdf

J&J Recommendation: We commend CMS for clarifying its position in the recent Q&A. We recommend that CMS modify the regulations governing the CAP program to reflect the position in the Q&A posting above to avoid any further confusion for vendors and physicians.

E. Administrative Burden – Need for A Physician Management Fee Under CAP. CMS declined requests it received in the prior comment period to establish a management fee reimbursement for physicians electing the CAP to offset some of the additional costs providers will face under the new program. In stating its rationale for declining such requests CMS stated that "[a]lthough we agree that a physician may have to make some adjustments in his or her practice in order to comply with the requirements under the CAP, we believe that the relief of the financial burden of purchasing the drugs and billing Medicare for these drugs will be a substantial improvement and benefit for many physicians."[18]

This statement assumes that certain efficiencies will accrue to physician practices due to anticipated elimination of certain functions or activities under CAP. However, CAP does not materially reduce the administrative resources associated with the following activities:

- Actual administration of the therapy;
- Billing for the drug administration; and
- Collection of coinsurance for the drug administration.

In addition, CAP requires additional activities that do not occur under the buy and bill model. These include:

- Individualized ~~purchasing~~order entry vs. bulk order entry today;
- Additional discussions with patients regarding their second bill from the CAP vendor, and communication of related patient-specific information;
- Potentially maintaining a duplicative and parallel procurement systems in addition to established purchasing processes;
- Increased vial tracking tasks to comply with CAP provisions; and
- Increased administrative processes associated with use of a replacement or alternative vial (e.g., as in the event of a patient failing to show up for an appointment).

In addition, the CAP imposes a significant change for some practices by establishing "just-in-time" (JIT) processes as explained below. Under CAP, the vendor is required to deliver the drug for administration to each individual patient in two business days from the date of that patient's administration. This type of order fulfillment is known as "just-in-time" inventory management.

[18] 70 Fed. Reg. at 39049.

JIT purchasing is the purchase of goods or materials (the CAP drugs in this case) such that delivery immediately precedes demand or use.[19] It is an accepted cost accounting fact that JIT inventory management incurs certain incremental costs. Such increased incremental costs include:

- Ordering costs per purchase order under JIT;
- Materials requirements planning (i.e., coordination of separate purchasing processes for materials and supplies associated with drug administration);
- Incoming materials inspection and tracking; and
- Inventory stockouts (i.e., management of inventory shortfalls and delays).

In summary, a CAP JIT inventory system in the physician's office will require additional inventory and clerical resources.

J&J Recommendation: CMS should establish a management fee for physicians who participate in the CAP to offset some of these added JIT and other related costs as a result of participating in the program. We also plan to submit a similar comment as part of our comments on the 2006 Physician Fee Schedule proposed rule.

IV. CAP Bidding Process – Evaluation and Selection

Composite Bid: Products with Multiple HCPCS Codes. The IFR establishes a "composite bid" process to evaluate bid prices submitted by prospective CAP vendors. The composite bid will weight a vendor's bid price for each CAP drug by the relative utilization of its HCPCS code in 2004 compared to all other CAP covered HCPCS codes in the category. Addendum A of the IFR lists the assigned relative weights for each HCPCS code within the single drug category. For example, the HCPCS code for PROCRIT® (Q0136) is assigned the highest relative weight for all CAP drugs of 0.2489891.

We note that several single-source drugs and biologicals in the single category have multiple HCPCS codes with considerably different relative weights depending on 2004 utilization for the code. We are concerned that the composite bidding structure described in the IFR could provide an incentive for gaming of the bids for products with multiple HCPCS codes. Consider an example of a single-source product under CAP that has two HCPCS codes to describe different dosage strengths: HCPCS code *JXXX* has a dosage of 1 mcg and has a relative weight of 0.15 and code *JYYY* has dosage of 10 mcg and a relative weight of 0.05 (See table below). Under this scenario, vendors could potentially bid significantly higher amounts on a per dosage unit for the lower weighted HCPCS code *(JYYY)* compared to the higher weighted HCPCS code *(JXXX)*. In the scenario described in the table below, vendors could bid $10 for code *JXXX* or $10 per mcg unit. Alternatively, the vendor could bid $120 for code *JYYY* or $12 per mcg unit.

[19] C. Horngren, et. al. *Cost Accounting: A Managerial Emphasis*, 8th ed. Englewood Cliffs, NJ: Prentice Hall (1994) 840.

This practice could help allow the vendor to meet the overall ASP plus six percent weighted-average bid, but result in a significantly higher median bid and reimbursement on a per unit basis for the lower-weighted HCPCS code. Such an action by even one winning CAP vendor could have an impact on the eventual median bid of a given drug, especially if only three vendors are eventually selected to participate in the program. Upon implementation of the CAP program vendors could potentially encourage physicians to utilize the HCPCS-code with the lower composite bid relative weight that has the higher per unit reimbursement rate.

Drug	HCPCS	Dosage	Weight	Bid for HCPCS Code	Per Unit (mcg) Bid
A	JXXX	1 mcg	0.15	$10	**$10**
A	JYYY	10 mcg	0.05	$120	**$12**

J&J Recommendation: CMS should require vendors to submit consistent "per unit" bids on single-source drug and biologic products with multiple HCPCS codes. This would remove the potential for vendors to have different per unit bids for HCPCS codes with differing relative weights and prevent the gaming scenario described above.

Conclusion: J&J appreciates the opportunity to submit comments and recommendations to CMS. We look forward to working with you and your staff to ensure that Medicare beneficiaries have meaningful access to Part B drugs and biologics under the CAP. If you have any questions related to these comments, please contact Greg White at 202-589-1040.

Sincerely,

Kathy Buto
Vice President, Health Policy

Congress of the United States

U.S. House of Representatives

COMMITTEE ON WAYS AND MEANS
1102 LONGWORTH HOUSE OFFICE BUILDING
(202) 225-3625
Washington, DC 20515-6348
http://waysandmeans.house.gov

September 6, 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:

Thank you for suspending the vendor bidding process for the Competitive Acquisition Program (CAP) for Medicare covered Part B drugs as you develop the final rule for the program (CMS-1325-IFC). As we have discussed, the program is an important and critical option physicians should have at their disposal to foster appropriate clinical decisions without regard to financial considerations related to the purchase of the drugs they administer. That is why we both understand the final rule governing the program must balance the interests of CAP vendors with the needs of patients and physicians.

To make the program viable and robust, I suggest several changes to the rule that are consistent with Congressional intent:

1. CAP prices should be excluded from the calculation of average sales price (ASP).

2. Treatment of new products should be revised such that participating physicians have access to the latest drugs and biologicals.

3. Unused product should be treated the same under ASP and CAP.

4. CAP vendors should be allowed to specifically subcontract with physicians to collect coinsurance at the point of drug administration.

I strongly encourage you to make these changes in the final rule.

CAP/ASP Interaction

In the interim final rule, CMS intended to include CAP prices in the calculation of ASP. This decision was directly contrary to Congressional intent and would have threatened to defeat the entire program.

As you are aware, the two House Committees with jurisdiction over Part B of Medicare worked for many years to reform the seriously flawed average wholesale price (AWP) reimbursement system for drugs. As a result, two different and separate structures were incorporated into the Medicare Modernization Act (MMA, P.L. 108-173), in order to provide physicians a choice of programs. In writing the legislation, Congress very specifically created these two separate payment structures, and provided the Secretary with sufficient flexibility to ensure that both programs could be implemented independently. If CAP prices were included in the ASP calculation, manufacturers would have little incentive to provide discounts to vendors, as it would reduce ASP reimbursement. Therefore, allowing CAP prices to be included in the calculation of the ASP threatens to undermine both programs and prevent their successful implementation.

In fact, under Section 1847A (ASP), CAP reimbursement for drugs and biologicals do not apply to physicians who elect payment for drugs and biologicals under ASP. The provision specifically states that CAP shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) of section 1847B. Likewise, Section 1847B (CAP) states that section does not apply in the case of a physician who elects section 1847A to apply. Thus, Congress always intended for the two programs to operate independently.

In addition, the Social Security Act permits CMS "to determine whether, and if so which, changes in methods of payment or reimbursement... including a change in negotiated rates, would have the effect of increasing the efficiency and economy of health services..." (42 U.S.C. 1395b-1). As exempting CAP negotiated prices from ASP calculations would represent a change in negotiated rates and would arguably increase the efficiency of health services, CMS could effectuate this change.

As I noted in my April 26 letter to you, it would truly be ironic if the Secretary's flexibility provided for in the legislation were used to defeat the creation of these two new programs by inappropriately linking the two structures together in a way that was never intended.

New Products

CMS proposes reimbursing new drugs and biologicals during a CAP vendor's contact through a "buy-and-bill" process where the physician would be financially liable and reimbursed for the product. This is completely counter to the entire purpose of the CAP program whereby Congress sought to eliminate financial incentives to administer one therapy over another. In addition, such a structure will discourage the coverage of

new drugs and biologicals at the same time Congress is trying to encourage their use for the obvious benefit of patients.

If not fixed, the CAP program will be the only venue in which new products are not made available to Medicare beneficiaries upon approval. Physicians opting to participate in CAP should not be forced to go outside of the program to buy newer products.

I suggest reimbursing CAP vendors for new products (unless there are multiple products within a procedure code (HCPCS)) at ASP + 6 percent (or at wholesale acquisition cost + 6 percent) until ASP data are gathered and reported, just as new products are treated under the ASP payment methodology. Vendors should be allowed to bill for new products using the same miscellaneous codes available to physician offices under buy-and-bill. Both changes will ensure consistency between the physician offices and CAP settings, ensuring patients and providers have equal access to products upon approval.

Unused Product

CMS responded to the question of whether a CAP vendor could file a claim for an unused portion of drug through a sub-regulatory question and answer document posted on the CMS website. CMS responded that approved CAP vendors would likely furnish drugs and interact with physicians in a manner that will minimize unused drug. Under the Average Sales Price system, a physician is able to bill the program for unused drugs if the physician acted in good faith with respect to the ordering and use of the drugs. CMS stated that CAP vendors would also be able to bill the program for unused drugs in a similar fashion if physicians and vendors act in good faith with respect to the ordering and use of the drugs.

Because this is such an important issue, I believe CMS should definitively state in the final rule, rather than a sub-regulatory document, that CAP vendors would be allowed to bill the program.

Collection of Coinsurance

CAP vendors should be allowed to specifically subcontract with physicians to collect coinsurance at the point of drug administration. The statute is quite clear that coinsurance may not be collected prior to drug administration. The statute does not prohibit collection of beneficiary coinsurance obligations at the time of drug administration.

Because I expect CAP vendors and physicians – the CAP vendor's client – to work harmoniously, there is reason to allow contractual arrangements for the collection of beneficiary coinsurance at the time of drug administration. This would promote efficiency and reduce effort collecting cost sharing obligations after a drug is administered. It would also likely reduce CAP vendor bids that would lower beneficiary

cost sharing, promote efficiency and save taxpayer dollars. While this provision was not explicit in the interim final rule, I encourage CMS to make it explicit in the final rule.

Promoting the success of the CAP program is our shared goal. The changes I have outlined here will go a long way in ensuring a robust alternative that offers physicians a real choice in how they interact with the Medicare program when treating beneficiaries.

Should you have any questions, or wish to discuss this further, please do not hesitate to contact me.

Best regards,

Bill Thomas

Bill Thomas
Chairman

WMT/jcw

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September 6, 2005

Mark McClellan, MD, 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-IFC

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

Dear Dr. 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; Interim Final Rule. The College's comments will address concerns related to the following topics:

- Categories of drugs to be included under the CAP
- Patient information
- Administrative burden

Categories of Drugs to be Included Under the CAP

As mentioned in the ACR's comments on the CAP proposed rule, the CAP will be a very important program for rheumatologists. The ACR was pleased to see in the Interim Rule that drugs typically administered by rheumatologists will be included in the initial implementation and CAP will be implemented nationwide. However, CMS still has not expressly stated that beneficiaries receiving CAP drugs are not required to have a diagnosis directly related to the specialty of the treating physician. For 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. The ACR reiterates its request that CMS expressly affirm this understanding.

Patient Information
The ACR appreciates CMS' plan to issue billing instructions with guidance about the appropriate fields on the agency's electronic and paper claim form. The ACR requests that such guidance expressly confirm that physicians entitled to submit paper bills under HIPPA may continue to do so under CAP.

The ACR also commented previously on CMS' required date of administration. While the ACR appreciates CMS' willingness to allow physicians to report a range of expected administration dates, we believe the seven-day timeframe the interim final rule provides is far too limiting given the vicissitudes of physician office scheduling practices. Physicians typically are unable to predict potential rescheduling demands. In fact, many physicians – particularly in rural areas – have more than one outpatient office, and, thus, may not be readily available to so rapidly reschedule a patient who cancels a scheduled appointment. Because the seven-day window could impose a significant and unavoidable administrative burden on physicians, the ACR recommends CMS expand the administration date to 60 days.

Administrative Burden
The ACR reiterates our previous assertion that the 14-calendar day timeframe for submitting drug administration claims will be a drastic change for physicians across the country. Accommodating this requirement would represent an unreasonable hardship for some physicians. The ACR believes that a more reasonable timeframe for submission would be 30 business days, particularly since there will be no beta testing to work out any unforeseen problems and no supplemental payments for the additional clerical and inventory resources.

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

- Clarify that beneficiaries receiving CAP drugs are not required to have a diagnosis directly related to the specialty of the treating physician;
- Confirm that physicians entitled to submit paper claim forms under HIPPA can continue to do so;
- Expand the expected drug administration timeframe to 60 days; and
- Allow 30 business days for submitting drug administration claim forms.

Thank you in advance for your consideration of these comments. If you have questions or need additional information, please contact Bret Koplow, PhD, JD, ACR Government Affairs Representative, at (202) 457-5242.

Sincerely,

Joseph Flood

Joseph Flood, MD
Chairman
ACR Government Affairs Committee

ACP
AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

SEP -6 2005

September 6, 2005

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 303-D
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code: CMS-1325-IFC; Comments on the Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals under Part B; Interim Rule

Dear Dr. McClellan:

The American College of Physicians (ACP), representing over 119,000 doctors of internal medicine and medical students, is pleased to submit comments on the interim final rule "Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals under Part B." ACP continues to appreciate the efforts of the Centers for Medicare and Medicaid Services (CMS) to develop an alternative to the current practice of physicians buying and billing for drugs under the average sales price (ASP) system.

The College also wants to commend CMS for choosing to release the Competitive Acquisition Program (CAP) rule as an interim final rule rather than a final rule. As an interim final rule, physicians, patient advocates and vendors have had an extended opportunity to provide public comment prior to the actual roll-out of the CAP. CMS can only benefit from this additional input in its goal to implement a quality program; particularly a program embarked upon without any pilot testing or direct previous experience to ensure its effectiveness.

The College is limiting its comments to a follow-up of the general, basic concerns regarding the CAP previously conveyed to you in our comments on the proposed rule dated April 25, 2005. Currently, there is only limited interest among our members regarding this program. The College believes that the way CMS has addressed the following issues in this interim rule and will address them in the final rule will have a significant affect on increasing internist's and subspecialist's interest in the CAP program.

1. The requirement for physicians to bill claims within 14 calendar days of the date a drug acquired through the CAP was administered.

   The College is disappointed that the interim final rule continues to maintain a 14-day requirement for submitting drug administration claims under the CAP. We continue to

believe that this requirement would impose an excessive burden in many practice settings. As a result, practitioners will have less interest in the program. The College requests that a 30 business day period to bill claims be adopted in the final rule. This time period better meets the needs of the typical practice, and at the same time recognizes the needs of the vendors who must wait for the claims to be submitted in order to bill CMS for the drugs.

2. The decision not to make a separate payment to physicians for the clerical and inventory resources associated with participation in the CAP program.

   The interim final rule continues to reflect the position that the clerical and inventory resources associated with participation in the CAP do not exceed the corresponding resources associated with the ASP program. Thus, CMS is not proposing any separate or additional payment to cover the clerical and inventory resources associated with participation in the CAP. The ACP continues to disagree with this position.

   More specifically, we believe the CAP program will require the use of more clerical and inventory resources than under the ASP system from such activities as needing to include additional information on drug order forms, having to repeatedly acquire drugs linked to each patient as opposed to more bulk purchasing, having to return drugs that are not administered, and having to appeal --- or provide information in support of a vendor's appeal --- a larger number of denials solely to ensure that the vendor receives payment. These increased administrative burdens without adequate compensation make the CAP program a non-starter for many practices; particularly the smaller ones. We would prefer that you provide an additional payment to cover these additional administrative costs for CAP participation. At a minimum, we urge you to collect appropriate data to determine the actual administrative cost of participating in this program and implement necessary payment modifications as indicated

3. The requirement that a physician must acquire <u>all drugs listed in a category</u> from a chosen vendor to participate in the CAP.

   The interim final rule indicates that the CAP program will be implemented initially with vendors offering to supply a single drug category consisting of a broad range of 169 drugs commonly administered incident to a physician's service. As in the proposed rule, physicians must agree to acquire from the chosen vendor all drugs for their Medicare patients listed in the category to participate in the CAP. The College continues to believe that this "all-or-none" requirement will deter practitioners from participating in the CAP.

   The College was pleased to see that CMS did extend the exceptions to the "all-or-none" rule by adding the "furnished as written " provision under which the physician may bill under the normal ASP system in situations when it is medically necessary for a patient to receive a specific formulation of a drug not available from the approved CAP vendor.

The more leeway a physician has to choose which drugs to acquire through CAP, the more interest the program will have to the physician. This principal should be kept in mind when developing further drug categories to include under the CAP. For example, many physicians are only interested in participating in CAP for those drugs that pose access problems under the ASP system. A category inclusive only of those drugs would be of interest to many of our members.

4. The availability of adequate patient protections related to vendors' collection of applicable co-payments and deductibles.

   The College was concerned that the issue of adequate patient protections surrounding vendors' collection of applicable co-payments and deductibles was not adequately addressed in the proposed rule. The College was pleased to see that the proposed rule was modified to include a provision requiring vendors to provide information on sources of cost-sharing assistance to beneficiaries. The fact that the vendor must offer assistance through a referral to a bona fide and independent charitable organization, the implementation of a reasonable payment plan, and/or a full or partial waiver of the cost-sharing amount under certain conditions significantly helps beneficiaries to meet their deductable/copayment obligations and maintain their access to needed medications .

The ACP appreciates this opportunity to comment on the interim final CAP rule. Please do not hesitate to contact Neil Kirschner on the ACP staff at 202 261-4535 and nkirschner@acponline.org if you have any questions regarding the submitted comments.

Sincerely,

Joseph W. Stubbs, MD/BB

Joseph W. Stubbs, MD, FACP

26.

SEP - 6 2005

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

September 6, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-IFC
Room 445-G

Phase-in implementation

MGMA is pleased by the phase-in adoption of a wide category of drugs. However, we continue to recommend that the drug list should include those drugs that many providers have been unable to obtain at rates close to or below the average sales price plus six percent. MGMA understands that the Physician Regulatory Issues Team (PRIT) and the Office of the Inspector General developed a brief list of drugs in this category. Since the list was not disclosed in the interim final rule, it is unclear how many drugs were included from this list. MGMA suggests that CMS identify specific drugs on the PRIT list in the final rule and explain why drugs were or were not included in the phase-in category.

Categories of drugs to be included under the CAP

information is required for follow-up orders as a national standard and strongly suggests that the information be the minimum necessary and simplified as much as possible.

Drug vendor's prescription order process

The interim final rule states that "CAP vendor[s] will contact the designated carrier by telephone to verify that the beneficiary has current Part B coverage." 70 Fed. Reg. 39042. MGMA is frustrated by this statement due to the availability of the 270/271 electronic transaction under the Health Insurance Portability and Accountability Act that can easily facilitate this inquiry. MGMA recommends that CMS quickly adopt this transaction system-wide to enable cost-effective implementation of the CAP.

Administrative burden and dispensing fee

The proposed CAP rule stated, "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. This position is mirrored in the interim final rule, "Although we agree that a physician may have to make some adjustments in his or her practice in order to comply with the requirements under the CAP, we believe that the relief of the financial burden of purchasing the drugs and billing Medicare for these drugs will be a substantial improvement and benefit for many physicians." 70 Fed. Reg. 39049. MGMA flatly rejects this assertion. Under the CAP as defined in the interim final rule, medical group practices will be required to keep a tracking inventory of CAP drugs and file duplicative claims data to participate. Providers purchasing drugs through the average sales price model do not carry these burdens.

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. As noted in our previous comments, 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. Nevertheless, there still remains an element of human interaction with the system since providers need to identify what drugs are received in the mail, which patients the drugs are intended for and the dispensing date.

Drug administration

According to MGMA surveys, multi-specialty and small group practices take longer periods to file claims than the average. Therefore, MGMA continues to assert that a longer timeline must be established to accommodate all practitioners.

As previously noted, the Medicare program currently permits providers to submit claims generally within one year from the date of service. 42 CFR 424.44(a). The interim final 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.

Beneficiary coinsurance

In our comments on the proposed CAP rule, MGMA sought clarification as to whether vendors were aware of the need for financial assistance for the numerous Medicare beneficiaries who are financially unable to meet their coinsurance for physician-administered drugs. The comprehensive discussion of this issue is a step in the right direction, however, CMS has adopted a dangerous public policy position whereby the agency has failed to address the current problem in the fee-for-service drug reimbursement model and left patients to the assistance of CAP for-profit vendors. The agency noted that you "seek comment on additional provisions that we should use to define these processes to protect the vendor and the beneficiary." 70 Fed. Reg. 39053. MGMA submits the following observations.

MGMA believes that CMS itself does not have a clear picture of the extent of write-offs physician group practices make in relation to Part B drugs. We are encouraged by the customer-friendly requirements that the interim final rule adopts for vendor bids and this may offer CMS a glimpse into the "bad debt" world of Part B providers. However, CMS is jeopardizing patient care by allowing vendors to exclude patients based on their non-payment of coinsurance. "[I]n the case of a beneficiary who fails to satisfy his or her cost-sharing obligations for CAP drugs ordered by a particular participating CAP physician, we will allow the vendor to refuse to make further shipments to that physician for that beneficiary." 70 Fed. Reg. 39053.

MGMA strongly rejects this policy and asserts that no beneficiary should be excluded from the CAP program due to non-payment of coinsurance amounts. And while it is helpful to allow a physician to withdraw from the program if a vendor excludes a patient, this does not address the underlying issue of coinsurance "bad debt." MGMA urges CMS to begin to investigate and address this issue for Part B providers, and recommends that CMS revise 42 CFR 414.914(h) so that vendors may not exclude a patient based on their ability to pay and subsection (9) be withdrawn.

Implementation of the CAP

Participating CAP physician election process

The interim final rule would mandate that if one physician in a group practice enrolls in the CAP program, all physicians in the group must adhere to the participation decision of the individual. This highly discriminatory policy places solo practitioners in a much better position than group practices when it comes to evaluating CAP enrollment. MGMA believes that the participation decision should be determined on an individual physician level and should not be attributed to a whole group.

Also of significance, this is the only Medicare enrollment decision where the decision of an individual provider binds the entire group practice. Medicare participation is made on an individual basis and may be billed under a group number. Thus, MGMA strongly recommends CMS withdraw the group practice provision found in 42 CFR 414.908(a)(4).

Vendor and physician education

MGMA strongly urges CMS to publish timely articles and education materials for vendors and physicians. Also, CMS should work with vendors to test drug order processing system and issue guidance in advance of Jan. 1. MGMA looks forward to collaborating with CMS to educate carriers and medical group practices on the CAP.

Beneficiary education

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. This mandate continues to be an unfunded requirement of the CAP that discriminates against participating providers making it a less attractive option than the average sales price drug model. This burden should be the responsibility of the Medicare program and CAP vendors and not providers. MGMA urges CMS to withdraw the provisions of 42 CFR 414.908(a)(3)(xi).

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.

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

27.

EPSTEIN BECKER & GREEN, P.C.

ATTORNEYS AT LAW

1227 25TH STREET, NW, SUITE 700
WASHINGTON, DC 20037-1175
202.861.0900
FAX: 202.296.2882
EBGLAW.COM

SEP - 6 2005

CARRIE VALIANT
202 861 1857
CVALIANT@EBGLAW.COM

MARCI HANDLER
202 861 1382
MHANDLER@EBGLAW.COM

September 6, 2005

VIA HAND DELIVERY

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

Re: Medicare Program - Competitive Acquisition of Outpatient Drugs and Biologicals under Part B, Interim Final Rule with Comment Period
CMS-1325-IFC

Dear Dr. McClellan:

This letter is submitted in response to the interim final rule with comment period (the **"Interim Regulations"**) published by the Centers for Medicare and Medicaid Services (**"CMS"**) on July 6, 2005 with regard to the Medicare Program's competitive acquisition of outpatient drugs and biologicals under Part B (CMS-1325-IFC) (hereafter the **"CAP Program"**). We submit these comments on behalf of a client interested in participating in the CAP Program as a vendor of Medicare Part B drugs and biologicals. Overall, we submit that CMS takes certain positions in the Interim Regulations that will inhibit CAP vendors from supplying drugs to Medicare beneficiaries to the full extent of their capabilities from both a quality and cost-saving perspective. Distributors can easily meet or exceed CMS timely delivery standards and ensure the timely provision of drugs to meet patients' changing needs through tested, available and cost-saving distribution technology, so long as CMS modifies the Interim Regulation within the limits of its statutory authority, as described below. If CMS declines to modify the Interim Regulations in the areas discussed below, the result will be that Medicare beneficiaries may be adversely affected and treated in a disparate manner.

Our comments to the interim regulations are as follows:

1. **Order and Ship/Delivery Timing Requirements.**

CMS should confirm that a CAP vendor's obligation to supply drugs to a physician upon receipt of a prescription order is not meant to limit the use of ordinary commercial sales and financing mechanisms commonly used by vendors to deliver drugs, provided such mechanisms can ensure product integrity and meet other CAP Program requirements. We are concerned that the Interim Regulations' provisions dictate the timing and order of events required to supply CAP Program drugs in an unnecessarily restrictive manner, which is not required by the statute. The core statutory requirement is that CAP vendors "deliver" drugs upon receipt of a CAP Program prescription order. CMS has the authority to confirm that "delivery" is intended to be construed broadly and that the CAP Program does not dictate the use of any particular method for delivery of CAP Program drugs.

There is nothing in the CAP Program statute that dictates how the delivery of drugs should occur. The statute states only that a CAP vendor shall not ***"deliver"*** drugs and biologicals to a physician except upon receipt of a prescription. Social Security Act (**"SSA"**) §1847B(4)(E) (emphasis supplied). The Interim Regulations state that the CAP vendor/CMS contract must state that CAP vendor will "***supply*** CAP drugs upon receipt of a prescription order" from a CAP participating physician." 42 C.F.R. §414.914(f)(8) (emphasis supplied). The preamble to the Interim Regulations (at p. 39047) discusses the statutory standard that "the approved CAP vendor shall not ***deliver*** drugs to the physician except upon receipt of the prescription order and such necessary data as may be required by the Secretary. . ." (emphasis supplied). The preamble (at p. 39045) also states that ". . . the statute requires that the approved CAP vendor may not ***provide*** drugs to a participating CAP physician unless the physician submits a written prescription order to the approved CAP vendor" (emphasis supplied). Similarly, the preamble at p. 39036, middle column states, "the vendor may not ***provide*** drugs to a physician participating in the CAP unless the physician submits a written order or prescription, and any other data specified by the Secretary, to the vendor" (emphasis supplied). The Interim Regulations also dictate certain timeframes for routine (generally 2 business days) and emergency (generally 1 business day) delivery timeframes (*see* 42 C.F.R. §414.902).

Our concern is that a highly literal reading of the Interim Regulation and preamble provisions suggests that CMS intends to prohibit CAP vendors from initiating physical transfer of CAP Program drugs to physicians until *after* the CAP vendor has received a prescription order from the physician. As this approach is not dictated by statute, we urge CMS to confirm that there may be various legally acceptable ways to accomplish "delivery" of drugs upon receipt of a prescription order and that the CAP Program is not directing the sequence or mechanics of how such delivery is to be accomplished, provided statutory standards are met.

For example, Blacks' Law Dictionary discusses several different modes of legally sufficient delivery, including absolute, conditional, actual and constructive delivery. According to Blacks, delivery means more than merely transfer of possession. Only "absolute" delivery is completed upon transfer of possession. It also is legally possible to have "conditional" delivery,

which is not complete upon the transfer of possession, but is only completed upon the happening of a specified event. Similarly, it is possible to have "constructive" delivery, which takes place when goods are set apart, notice given to the person to whom they are to be delivered, and the conduct of the parties is consistent with a change in the "nature of the holding."

The Uniform Commercial Code also contemplates varying methods of delivery that do not necessarily involve change of possession of goods. Specifically, the Uniform Commercial Code §2-103 defines "delivery" of goods as "the voluntary transfer of physical possession ***or control*** of goods" (emphasis supplied). Similarly, the Uniform Commercial Code contemplates "delivery . . . made without moving. . . goods" (UCC § 2-401). "Tender of delivery" requires only that "the seller put and hold conforming goods at the buyer's disposition and give the buyer any notification reasonably necessary to enable the buyer to take delivery" (UCC § 2-503).

We see nothing in the statute that would preclude a CAP vendor from accomplishing "delivery" of CAP drugs through conditional, constructive, or some other mode of delivery other than "absolute" or "actual" delivery upon receipt of a written order (*i.e.*, other than actual transfer of possession of the goods). To the extent alternate delivery mechanisms can be accomplished pursuant to available distributor technology and consistent with state law, CMS should allow their use. Such an approach does not pose any risk to product integrity, since the products will come from the same distribution source and be subject to the same quality standards irrespective of the timing of shipment vs. prescription order and can be accomplished in a more cost-effective manner, thereby potentially resulting in lower CAP vendor bid prices. Medicare has been paying physicians for Part B drugs for years where the drugs have been purchased and stored by physicians in their offices prior to administration to patients, and we see no reason why the CAP Program provisions for direct billing by CAP vendors should affect this scenario.

Any narrower definition of the CAP vendor's "delivery" obligations will unnecessarily hamper physicians' practice of medicine, impose unnecessary additional administrative obligations on physicians who participate in the CAP Program, potentially harm patients, and result in disparate treatment of Medicare beneficiaries. We fail to understand why non-CAP Program patients are assured access to needed drugs in their physician's offices at all times, but CAP Program patients must wait until after a CAP drug prescription order is sent to the vendor and the drug is shipped to the physician (except in strictly defined emergencies). This new process is sure to be more cumbersome and will entail some degree of delay over the current practice and fails to take into account a patient's unique medical condition, which frequently requires on-the-spot changes to proposed treatment. We are concerned that this creates unnecessary risk to patient care and that it will increase the administrative burden on physicians.

CMS has acknowledged as much in its request for comments on providing more rapid order turnaround, particularly in urgent situations and specifically for ways in which to avoid unnecessary express shipping situations. (See 70 Fed. Reg. at 39046.) So long as alternate delivery mechanisms can be utilized, there should be no reason that CAP vendors cannot meet the pressing needs of Medicare CAP beneficiaries without resorting to unnecessarily cumbersome and expensive express or same-day shipping.

The legislative history to the CAP Program supports our position. The Conference Agreement provisions state that "[i]n no way do conferees intend the requirements for the competition program to impair a patient's access to health treatment as a result of changes in the patient's health status . . ." Joint Explanation Statement of the Committee of Conference at page 595. We find no rational basis for mandating the timing and order of events for delivering drugs to a physician's office for use for Medicare CAP Program beneficiaries versus other patients. CMS interference with traditional commercial notions of sales and sales financing under state law is not compelled by the statute. Just as CMS has declined to interfere with state law governing the licensure of pharmacies, so should CMS decline to interfere with state law concepts of sales, delivery, and the like.

Request

We respectfully request that (1) CMS modify the regulation and accompanying preamble text to use in a consistent manner the word "delivery" as it is set forth in the statute, rather than to use the words "supply" or "provide" which have a different meaning than term "delivery" in the statute; and (2) CMS specifically confirm that CAP vendors can accomplish "delivery" of CAP drugs in any legally acceptable manner under state law.

2. <u>Title.</u>

CMS should eliminate references in the preamble to the Interim Regulations stating that a CAP vendor must retain title to the drugs until the moment of administration to a beneficiary, and, moreover, the final regulation should confirm that title to the drug is irrelevant for CAP Program purposes.

Neither the statute nor the Interim Regulations dictates that the CAP vendor must retain title. The statute speaks only to "acquisition" and "supply" of drugs, not title, and requires only that a CAP vendor "acquire all drugs and biological products it distributes directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer." Thus, it is chain of custody, not chain of title, that is relevant for CAP Program purposes.

Nevertheless, the preamble to the Interim Regulations references in two places that the CAP vendor will retain title until the drug is administered. First, the preamble states that "[u]nder the CAP, the approved CAP vendor retains title to the drug, even after it is shipped to the physician, which may make it more difficult to ensure compliance with the special rules for controlled substances." 70 Fed Reg. at 39028. Second, the preamble states that CAP vendors are financially responsible for the shipping costs associated with the return of drugs, and "the approved CAP vendor retains title to the drug until it is administered." 70 Fed Reg. at 39062. This CMS position on title was restated in CMS's recent response to CAP vendor questions posted on the website (dated 8/11/2005) where it is stated that "[t]he CAP vendor maintains ownership of the drug until it is administered to the Medicare beneficiary."

We point out that this title restriction is inconsistent with preamble language at p. 39060, which states that CAP vendors are not precluded from subcontracting with another drug distributor or pharmacy, provided the entity meets all of the approved CAP vendor requirements and the subcontract is divulged in the CAP vendor's application. Subcontracting with another entity to furnish CAP drugs necessarily implies that title to CAP drugs may reside in an entity other than the CAP vendor.

Further, from a program policy perspective, the technicality of "title" is not relevant to CMS's focus on product integrity. Dictating title does not ensure product integrity. So long as the CAP vendor can meet the statutory standard that a drug is delivered in the form obtained directly from the manufacturer or a distributor who obtained the drug directly from the manufacturer, that it is not administered to anyone other than the designated beneficiary and that no claims are submitted to Medicare until the time of administration, then the requirements and goals of the CAP Program are met, regardless of who has had technical legal title during the course of a CAP drug's passage from manufacturer to patient. The CAP vendor still would retain responsibility for product integrity and shipping as required by the CAP Program at all points during this passage.

Limiting who has title unnecessarily restricts drug vendor shipment and financing models that otherwise can meet applicable requirements. Further, there are a variety of financing and shipping arrangements used by the pharmaceutical industry where technical legal title may reside for some period of time outside of the vendor. This would include, for example, consignment arrangements, bailment arrangements, warehousing arrangements, and similar forms of secured and other commercial sales and sales financing transactions governed by the Uniform Commercial Code and state law. For example, a CAP vendor may wish to sell a quantity of drugs to a physician (*i.e.*, title would transfer to the physician) pursuant to a contractual arrangement whereby the physician agrees to hold certain units aside for CAP Program use which are released only after the physician sends a written order to the vendor and a specific CAP patient assignment of the drugs is made.

Request

We submit that CMS has the administrative discretion to clarify the issue of title. We respectfully request that CMS eliminate title restrictions in the final regulations and confirm that title to CAP drugs is irrelevant for CAP Program purposes provided a vendor can meet the other elements of the Program.

3. <u>Physician Stock Resupply/Emergency Drug Replacement.</u>

The Interim Regulations decline to permit an alternative method for emergency drug replacement that involves maintaining drugs in a physician's inventory, citing program integrity and drug diversion concerns. Yet, Medicare already covers and pays for drugs maintained as physician inventory and will continue to do so under the Medicare Modernization Act. Again, CMS should not unduly restrict through the CAP Program regulations drug delivery and administration mechanism that have been in place and functioning for many years. This is

especially so in light of CMS's acknowledgement that the present configuration may not be sufficient to meet urgent needs of patients and accommodate last minute changes in patient drug protocols.

In addition, CMS should clarify that no physical segregation of drugs by physicians is required by the CAP Program. The Interim Regulations state that a physician may acquire drugs under the CAP Program to resupply his or her "private inventory" only in certain emergency situations where drugs are required immediately, the need for the drugs could not have been anticipated and the CAP vendor could not deliver the drugs in a timely manner (which is defined as one business day for all U.S. areas, with the exception that the time frame is extended to 5 business days for the Pacific Territories). *See* 42 C.F.R. §414.906(e). These regulatory requirements suggest that a physicians' stock of drugs be segregated into "CAP supply" and "private inventory." Yet, CMS also states separately that physical segregation of inventory is not required, only separate electronic or paper inventory (see preamble at p. 39048).

Request

We request clarification that (1) the only requirement under the CAP Program is for paper or electronic tracking of inventory, and that no physical segregation of inventory is required, regardless of whether a physician uses private inventory for CAP purposes in authorized circumstances; and (2) CMS reconsider its position that physician inventory can be used only for emergency purposes.

4. Coinsurance Collection.

CMS should clarify that the CAP Program allows a CAP vendor to make arrangements with a physician's office to act as the vendor's agent in collecting copayments on behalf of the vendor, provided such arrangements are structured in light of other federal and state fraud and abuse laws. This will enable CAP vendors to collect coinsurance in a cost-effective manner, and with bad debt kept to a minimum, thereby potentially lowering the CAP vendor's bid price.

The statute clearly requires the CAP vendor to take responsibility for collect coinsurance and deductibles ("collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsibility of such contractor and shall not be collected unless the drug or biological is administered to the individual involved." SSA §1847B(a)(3)(A)(ii)). The statute also states that "payment. . . and related amounts of any applicable deductible and coinsurance. . . shall be conditioned upon the administration of such drugs and biologicals." SSA §1847B(a)(3)(A)(iii). Further, the statute authorizes the collection of coinsurance and deductibles "in a manner similar to the manner in which the coinsurance and deductible are collected for durable medical equipment under this part." SSA §1847B(e)(3). The preamble to the Interim Regulation further acknowledges "that Medicare allows for the collection of coinsurance at the time a service is delivered." 70 Fed. Reg. at 39052. Nevertheless, the Interim Regulation, at §414.906(a)(3) (p. 39094) states, "The approved CAP vendor collects applicable deductible and coinsurance with respect to the drug furnished under the CAP only after the drug is administered to the beneficiary." The preamble states that "since the approved

CAP vendor is not present at the time the drug is administered the vendor is unable to bill the beneficiary at that time." 70 Fed. Reg. at 39052. The legislative history states that "[g]enerally, these coinsurance and deductible amounts will be collected by the contractor that supplies the drug or biological . . ." Conference Report at p. 596. Congress's use of the word "generally" suggests that it recognized that other arrangements (*e.g.*, subcontracting for this function) may be permissible.

None of these provisions dictates who can mechanically perform the task of coinsurance collection, or precisely when in the sequence of time such collection may occur. Rather, the provisions merely state that "responsibility" for coinsurance collection rests with the CAP vendor and coinsurance cannot be collected "unless" the drug is administered and "conditioned upon" the drug's administration. These provisions plainly contemplate coinsurance collection through arrangements by the CAP vendor with the physician's office at the time of drug administration. The use of a subcontractor arrangement to collect coinsurance does not affect CMS's latitude in determining who is responsible for collecting the coinsurance. The use of contracted agents to carry out a contractor's obligations is a widespread practice, provided the contractor remains ultimately liable for the performance of the functions and the arrangements do not violate any other applicable law.

In this regard, the preamble expressly states as follows: "This interim final rule does not prohibit approved CAP vendors and physicians from entering into a contract or agreement governing their arrangements for the provision of CAP drugs or other items or services" so long as the arrangements do not violate the Stark Law, the Anti-Kickback statute or any other federal or state laws or regulations governing billing or claims submission. 70 Fed. Reg. at 39050. The preamble also states that "[t]his interim final rules does not prohibit approved CAP vendors and physicians from entering into a contract or agreement governing their arrangements for the provision of CAP drugs or other items or services. . ." provided the parties ensure that their arrangements comply with Stark and the federal anti-kickback statute (preamble at p. 39050). Thus, the preamble contemplates the possibility that physicians would be subcontracted agents to CAP vendors in appropriately structured arrangements. CMS should clarify in the final regulations that arrangements between CAP vendors and physicians who elect to participate in the CAP Program to collect CAP patient coinsurance and deductible amounts on behalf of the CAP vendor are permissible if structured in light of the Stark Law, the Anti-Kickback statute or any other federal or state laws or regulations governing billing or claims submission.

Request

CMS should clarify that CAP vendors may contract with physicians for collection of coinsurance and deductibles on behalf of the vendor, consistent with fraud and abuse laws.

5. <u>Waste.</u>

We request clarification that the regulations reference to costs of "wastage, spillage or spoilage," which may not be taken into account in establishing a CAP vendors bid price, refers solely to waste, spills or spoils in drugs not administered to the beneficiary once the drug is

delivered to the physician's office, but not product that is destroyed in transit or otherwise wasted at the distribution level. We recognize that the statute states that a vendor's bid price shall include the costs of dispensing (including shipping) and management fees, but shall not include costs related to the administration of the drug or biological or wastage, spillage or spoilage. SSA §1847B(6)(B). The Interim Regulation uses similar language. No definitions for what constitutes "wastage, spillage or spoilage" are provided in the statute or regulations.

We read this preclusion on waste costs in the bid price as reflecting the Program's concern that unused products not be billed to Medicare. On the other hand, the statute specifically allows for costs of shipping to be included in the bid price. Shipping of products necessarily includes a certain amount of wastage for the product, which is an expense of the business that manufacturers and distributors ordinarily account for and include in their price determinations for the cost of doing business. Therefore, we suggest that the reference to "wastage, spillage or spoilage" be limited to the waste, spills or spoiling that may occur after the product is delivered to a physicians' office.

Request

CMS should clarify that wastage, spillage or spoilage of drugs delivered to physicians but not administered to beneficiaries should be excluded from vendors bid prices, but that the cost of product lost or destroyed in transit or otherwise at the distribution level may be included in the bid price.

6. <u>Licensure.</u>

CMS should clarify certain aspects of the CAP Program that could affect CAP vendor licensure, as explained below. In order to avoid unnecessary confusion or disincentives for potential vendors to participate in the CAP Program in light of state pharmacy laws, CMS should clarify that the sole purpose of the required CAP Program physician prescription order is to facilitate the CAP vendor's responsibility for billing and collection of applicable copayment and deductibles, and that the CAP Program prescription order is not intended by the CAP Program to constitute or substitute for the physician's prescription or order that otherwise may be required for the CAP drugs under other state and/or federal laws.

The statute is silent on exactly what licenses a CAP vendor must maintain. The Interim Regulations state only that a CAP vendor must "[m]eet applicable licensure requirements in each State in which it supplies drugs under the CAP." 42 C.F.R. §414.914(f)(5). Although CMS appears to defer to state law, the preamble warns that state licensing laws that may preclude vendors from operating in states must be taken into account (preamble at p. 39035) and that CAP vendors must comply with state licensing requirements in all cases (preamble p. 39037). The preamble goes on to state that vendors must operate as distributors in order to participate in CAP (preamble at p. 39066) and that nothing about the CAP Program should be construed as waiving applicable state requirements relating to licensing of pharmacies. (preamble at p. 39066). The preamble also states, however, that CMS recognizes that "a natural outgrowth of

participating in this program may be that those distributors also will need to be licensed as pharmacies . . ." (preamble at p. 39066).

We believe that clarification on this matter would be helpful, in light of our research of retail pharmacy laws in the fifty states (and territories), to ensure that the CAP Program requirements do not unnecessarily trigger any additional state law requirements that otherwise do not apply to the vendor activities contemplated by the CAP Program. Specifically, we are concerned that some state pharmacy regulators could take the position under their state laws that a CAP vendor's delivery of CAP drugs to a physician specifically in response to a CAP Program prescription order in the format dictated by the CAP Program triggers the "dispensing" of drugs by the CAP vendor, for which a state retail pharmacy license for the CAP vendor is required. To the contrary, most states' physician dispensing laws are designed to address both the current Part B practice as well as CMS' proposed CAP Program. Such an approach then could give rise to "depot" issues under state laws that prevent pharmacies from delivering patient-specific prescriptions to a physician's office for subsequent administration to a patient.

Contrary to the preamble at p. 39047, we do not read the statute as requiring patient-specific prescription orders. The CAP Program statute contemplates delivery "directly to the selecting physicians and not directly to individuals . . ." "upon receipt of a prescription" for such drugs and biologicals. The statute specifically states that it does not "require a physician to submit a prescription for each individual treatment." Nothing in the statute, therefore, requires a beneficiary-specific prescription and the term "prescription" is undefined. A common definition for the term prescription is a "written order . . . for the preparation and administration of medicine or other treatment" (The American Heritage® Stedman's Medical Dictionary Copyright © 2002, 2001, 1995 by Houghton Mifflin Company), which also is not necessarily patient-specific.

Distributors of drugs covered under the Medicare Program have been operating in compliance with state licensing laws for years, and we see nothing in the statutory requirements for the CAP Program that should require additional pharmacy licenses for the same distribution channels that existed previously to the CAP Program

Request

CMS should clarify that: (1) vendors in the CAP Program need to comply with applicable state laws, however, the requirements of the CAP Program are designed to provide information solely for CAP vendor billing purposes and not to affect the legal channels for distribution of drugs for Medicare beneficiaries; and (2) patient-specific billing information required by the CAP Program can be provided by the physician to the CAP vendor after administration to the patient "to facilitate collection of applicable deductible and coinsurance" (see 42 C.F.R. 414.908(3)(v)).

7. Certification.

The certification section of the CAP Program vendor application needs to be amended or clarified to make clear that the certifications relating to compliance and licensure take effect as of the time when items and services are first furnished by a CAP vendor under the Program.

Specifically, the certifications at sections B (performance of activities) and D (compliance with wholesale distributor laws) of paragraph (3) on the Certifications page are written using future tense language, while the certification at section C (licensure) is written with present tense language. The certification at section C (licensure) needs to be amended to enable CAP vendors to bid while in the process of establishing the licensed infrastructure necessary for compliance.

The certification at section B (performance) states that the organization and its subcontractors and affiliates "shall be able to perform activities" in compliance with CAP program requirements. The certification at section D (compliance with wholesale distributor laws) states that the organization and its subcontractors and affiliates "will be in full compliance" with state and federal requirements for distributors. We read these certification to state, appropriately, that as of the time that the vendor starts to supply drugs and perform the activities required under the CAP Program, it will be in compliance with these requirements.

In stark contrast, the certification at section C (licensure) states that the organization "meets" all applicable state licensing requirements and its subsidiaries and affiliates "meet" all applicable requirements. We read this potentially to require a certification of compliance at the time the application is submitted, not at the time the services start to be furnished under the CAP Program. Given the novelty surrounding each of each of the states' pharmacy laws interplay with the CAP Program requirements, many bidders are likely to need time to work through the intricacies with various of the states' Boards of Pharmacy. It is more important that vendors have all required licenses as of the start of CAP Program services, not at the time of application. Further, for applicants who determine the need for additional licensure, there is nothing in the statute or Interim Regulations that precludes giving them time after they have submitted an application to complete this process.

Request

CMS should clarify or revise this section on grounds that requiring state licensing compliance as of the application submission will unnecessarily preclude vendors from applying to participate who have not completed all requisite state licensure processes.

* * *

We thank you in advance for your consideration of these comments. Please do not hesitate to contact us if you have questions or think we can provide further assistance.

Sincerely,

Carrie Valiant

Marci Handler

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AstraZeneca

Stephen D. McMillan
Director Government Reimbursement
Federal Government Affairs
Tel 202 350 5577
Fax 202 350 5510

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September 6, 2005

By Hand Delivery
Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Rec'd by TFM
SEP 6 2005

Re: Comments on Interim Final Rule with Comment Period: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B, 70 Fed. Reg. 39,022 (July 6, 2005) [CMS-1325-IFC]

Dear Dr. McClellan:

AstraZeneca (encompassing AstraZeneca Pharmaceuticals LP and AstraZeneca LP) ("AstraZeneca") is pleased to submit comments on the Interim Final Rule with Comment Period (the "Interim Final Rule", 70 Fed. Reg. 39,022 (Jul. 6, 2005)) issued by the Centers for Medicare & Medicaid Services ("CMS") to implement the Competitive Acquisition of Outpatient Drugs and Biologicals under Medicare Part B. We appreciate this opportunity to share our views on this important component of the reforms included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").

AstraZeneca is one of the world's leading pharmaceutical companies, with a strong commitment to developing treatment options for debilitating diseases and improving patient lives. In keeping with this commitment, AstraZeneca manufactures several drugs that are reimbursed under Medicare Part B and will be included in the Competitive Acquisition Program ("CAP"). We support the development and implementation of the CAP in a manner that provides open access to drugs, ensures continuity of patient care, and includes only Food and Drug Administration ("FDA") approved safe and effective medications.

The following comments address a number of specific program design considerations raised in the Interim Final Rule. We are available to provide additional information about any of these items or answer any questions you may have.

I. Drugs Included Under the CAP

A. CMS should explicitly state in the Final Rule that only drugs approved by the FDA will be covered and reimbursed under the CAP.

AstraZeneca recommends CMS explicitly state in the Final Rule that Medicare drug coverage under the CAP is limited to drugs approved by the FDA, consistent with Social Security Act § 1861(t). This would help ensure the safety and efficacy of drugs furnished to Medicare beneficiaries under the CAP and discourage CAP vendors from substituting cheaper but untested and potentially dangerous products, such as certain pharmacy-compounded drugs, for FDA-approved products. While it is not currently included under the CAP, Medicare covers AstraZeneca's Pulmicort Respules®, the only FDA-approved inhaled corticosteroid for nebulization – under HCPCS code J7626. We are aware that Medicare is currently reimbursing (perhaps unknowingly) compounded budesonide inhalation solutions when these drugs are billed using HCPCS code J7626. These compounded solutions are not FDA-approved generic equivalents of Pulmicort Respules®, are not proven to be clinically equivalent to Pulmicort Respules® and are not guaranteed to be manufactured in a sterile environment in compliance with FDA regulatory requirements. Since a similar issue could arise under the CAP with respect to the drugs that are currently included in the CAP, we recommend that CMS protect Medicare beneficiaries from potentially ineffective, or even dangerous, medications by explicitly limiting CAP drugs to only those that are FDA-approved.

B. CAP vendors should be required to provide a broad range of NDC codes within a HCPCS code to allow for appropriate treatment options considering drug dosing, indication and individual patient tolerance for mode of administration and/or formulation.

Under the Interim Final Rule, a potential CAP contractor would be required to bid on all HCPCS codes included within a drug category. However, CMS is proposing that a CAP vendor would be required to provide only one National Drug Code ("NDC") associated with a HCPCS code. This decision is in tension with CMS's recognition that physician and patient decision-making regarding the use of the most appropriate drugs in specific individual circumstances must be maintained.

CMS can provide open access to drugs under the CAP by ensuring that physicians, not CAP vendors, remain responsible for clinical decision-making. The role of CAP vendors will be to ensure that physicians have timely access to drugs required by their patients through procurement and distribution of drug products and the management of Medicare and beneficiary reimbursement. By law, CAP vendors cannot make formulary-style or other coverage determinations, and thus cannot be given the authority to restrict or otherwise influence prescribing decisions. AstraZeneca has concerns about giving a vendor discretion to choose which individual drugs within a HCPCS code the vendor will provide. This discretion would essentially allow CAP vendors to establish a formulary without providing any of the beneficiary safeguards CMS has established for Part D drug plans that use formularies (e.g., the creation of a pharmaceutical and therapeutic committee that includes practicing physicians and/or pharmacists, formulary decisions must be based on scientific data and standards of practice, etc.). Additionally, if physicians cannot receive most medically appropriate drugs through the CAP, or are required to go through a cumbersome process to obtain needed drugs outside of the CAP framework, it will undermine incentives for physicians to participate in the CAP and jeopardize the success of the program.

We therefore recommend that CAP vendors be required to provide a broad range of NDC codes within a HCPCS code to allow for appropriate treatment options considering drug dosing, indication and individual patient tolerance for mode of administration and/or formulation. All NDC codes included within a certain HCPCS code are not identical, and patients can respond differently to different manufacturer products, different mechanisms of action, and different formulations of the same drug. CMS must ensure that the new CAP does not disrupt Medicare beneficiaries' ongoing medical treatments or prevent physicians from prescribing the most appropriate formulations of a needed drug. Medicare beneficiaries often experience multiple medical conditions. This requires medication regimens that must be carefully developed and adjusted to address possible adverse drug interactions and to maximize health benefits to patients. The CAP should be implemented in a manner that does not force beneficiaries to change successful medication therapies due to the establishment of narrow drug categories and onerous requirements to obtain drugs outside of the CAP. Accordingly, CAP vendors should not be permitted to restrict physicians' choices of the most medically appropriate products. Oncologists and urologists commonly administer dosages specific to diseases, tumor size and/or patient weight. For example, for a patient diagnosed with locally advanced prostate cancer who decided to receive radiation therapy, a physician may decide to administer one unit of ZOLADEX® (goserelin acetate implant) 3.6 mg for four consecutive months as part of a combined androgen blockade regimen to achieve the required dosing for that indication. In contrast, for a patient diagnosed with metastatic prostate cancer, a physician may choose to use a series of ZOLADEX® 10.8 mg injections. For a patient diagnosed with advanced breast cancer, a physician may use a 3.6 mg dosage.

Moreover, the Interim Final Rule indicates that CMS will not provide any payment for any discarded drug or any drug that is considered waste. We commend CMS for indicating in the "response to CAP vendor questions" that it will refine the wastage provisions in the Final Rule. We also believe, however, that physicians who have a choice of only one NDC within a HCPCS code may actually be forced to order a larger dose than necessary, which could potentially leave vendors unable to receive any payment on that portion of the dose that was not used and not considered reasonable wastage by providing additional NDC codes as necessary. We believe that physicians will be able to provide patients with appropriate therapies without significant and inappropriate wastage as well.

Under the Interim Final Rule, if a CAP vendor does not contract to furnish a drug or particular formulation of a drug, the physician would be able to obtain and be reimbursed for the product under the ASP system only if the drug is "medically-necessary." In these cases, the physician would be instructed to place a "furnish as written" modifier on his or her claim form and bill his or her Medicare carrier for the drug and the administration fee. If the carrier determined that the physician had not complied with furnish as written requirements and 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. While CMS states that physicians would be able to obtain drugs

outside of the CAP if medically necessary, we believe vendors providing only certain NDC codes per HCPCS category raises administrative hurdles for physicians and could result in (1) physicians choosing less medically-appropriate drugs in order to avoid "buying and billing," (2) significant wastage when physicians order larger dosage forms than needed, or (3) physicians choosing not to participate in the CAP so that their medical choices are not compromised. Thus, the one NDC per HCPCS minimum could significantly jeopardize continuity of care for beneficiaries, eliminate patient choice in their treatment regimen, result in formulary-style determinations, increase program costs for unused portions of drugs, and undermine treatment options. To avoid or limit these implications, we recommend CMS expand this requirement to a broad range of NDC codes within a HCPCS code to allow for appropriate treatment options considering drug dosing, indication and individual patient tolerance for mode of administration and/or formulation.

II. CAP Bidding Process

A. Manufacturer prices made available under the CAP should be included in the calculation of average sales price.

AstraZeneca supports the inclusion of manufacturer prices made available under the CAP in the calculation of ASP and requests that CMS confirm that manufacturer prices made available under the CAP should be included in the calculation of ASP in the Final Rule. Based on the definition of ASP in the MMA, we believe manufacturer prices offered under the CAP must be included in ASP calculations. We note that the definition of ASP in the MMA contains very few exceptions to the calculation methodology and prices offered under the CAP are clearly not included among them. Further, CMS's exclusion of manufacturer prices offered under the CAP from the calculation of ASP would be inconsistent with CMS's current ASP calculation methodology.

The ASP methodology relies upon a market-based approach in order to adequately reflect the market price of a product after taking into consideration price concessions in primarily all market settings. AstraZeneca believes the inclusion of manufacturer CAP prices in the calculation of ASP would encourage physician participation in the CAP because there would be no financial incentives or disincentives based on a particular ASP price driving the decision of whether to participate in CAP. Exclusion of CAP prices from ASP could result in a situation where the ASP is no longer an accurate reflection of a product's market price which would potentially impact reimbursement both within and outside of CAP.

III. Claims Processing

A. CAP vendors should be required to make reasonable collection efforts prior to discontinuing to supply drugs for a particular patient.

The Interim Final Rule permits a vendor, in certain circumstances, to discontinue supplying drugs for a particular patient when the patient fails to meet cost-sharing obligations. We commend CMS for requiring the vendor to provide the patient with

information on available payment assistance options to ensure that patients with limited means can be assured access to needed therapies. In addition to this safeguard, CMS should work with OIG to set forth guidelines as to how a manufacturer patient assistance program can support underinsured Medicare Part B beneficiaries that cannot meet their financial obligations with their treatments. Such programs would ensure continuity of care and cause less disruption for patients receiving treatment for potentially terminal illnesses.

Further, we recommend that CMS require that vendors must make and document reasonable collection efforts prior to the discontinuation of drugs for a particular patient. Specifically, the guidance provided on reasonable collection efforts in the hospital setting should be reiterated for purposes of the CAP.

IV. Clarification Requests

A. CMS should provide guidance in the Final Rule regarding what will constitute "bona fide" services in fee-for-service arrangements between CAP vendors and manufacturers.

AstraZeneca requests that CMS provide guidance in the Final Rule concerning the types of "bona fide" services CAP vendors will be permitted to provide manufacturers in exchange for administrative fees. Specifically, AstraZeneca would like CMS to provide guidance on the classification of services such as prompt payments, inventory management and storage, distribution, data collection, chargeback management, deduction management, membership fees, consolidation of distribution fees and case management services including compliance and medication management programs. Many services that were previously performed by distributors as part of the distribution service are now being offered as separate services requiring additional fees. We request that CMS apply the same criteria applicable to the treatment of administrative fees in traditional "buy and bill" transactions to the treatment of administrative fees for purposes of the CAP. This would require manufacturers to include administrative fees in the calculation of ASP if they ultimately affect the price actually realized by the CAP vendor.

AstraZeneca also requests that CMS include strong safeguards in the Final Rule to protect against CAP vendors trying to influence product utilization based on vendors' ability to negotiate fee-for-service arrangements with manufacturers. Failing to provide appropriate safeguards may result in vendors, rather than physicians, determining access to medications. Therefore, we recommend that CMS prohibit vendors from influencing product utilization when a manufacturer declines to enter into additional fee-for-service arrangements or enters into a limited fee-for-service arrangement. Further, we recommend that CMS include all of the services a vendor may provide including any services furnished pursuant to a fee-for-service arrangement in its reporting requirements.

B. CMS should provide additional guidance in the Final Rule regarding the definitions of emergency use and inventory provisions.

AstraZeneca requests that CMS provide additional guidance in the Final Rule concerning the definitions of emergency use and inventory provisions. The Interim Final Rule provides that physicians participating in CAP are permitted to use medicines from their own inventory to Medicare patients when all of the following requirements are met: the product is required immediately, the physician could not have reasonably anticipated the need, the vendor could not have delivered the drug on time, and the medicine was administered in an "emergency" situation. "Emergency" is defined for purposes of CAP as those times when in the physician's clinical judgment, immediate treatment is required.

AstraZeneca wants to make sure patients are able to receive the medication they need, when they need it. If physicians are faced with an immediate need that does not rise to the level described above, they may resort to prescribing a less medically appropriate drug outside of CAP if the first choice drug in CAP is not immediately available. An immediate need can result when a cancer patient presents with anemia or neutropenia that is identified during an office visit that requires treatment. Requiring another office visit solely for administration of medication adds cost to the health care system by way of unnecessary office visits and needlessly exposes patients to delays in treatment.

Furthermore, restrictions on quick access to CAP medications may also cause increased emotional strain on patients. For example, patients may be subject to additional emotional distress if they have to wait for treatment after finding out their cancer has just come out of remission just because their situation may not be classified as an emergency. Overly tight restrictions on emergency access will also cause increased hardship on patients in rural areas who must travel significant distances in order to receive their medication as well as disabled patients dependent on specialized forms of transportation. In order to prevent these problems, CMS should expand emergency use and inventory provisions in such a way that allows deference to a physician's professional judgment to stock inventory and furnish drugs in situations of immediate need to ensure all patients have access to the medications they need when they need it.

V. Future of the CAP

A. The CAP should be expanded in the future to include other Part B drugs.

AstraZeneca supports CMS's decision to limit the CAP initially to drugs furnished incident to a physician's service. We believe this limitation in the early stage of the CAP will simplify distribution mechanisms, education and outreach efforts, and other administrative issues as the new program is implemented and operational issues are refined.

Going forward however, CMS should consider expanding the CAP to include other Part B FDA-approved drugs. This should include DME-administered drugs, such as respiratory products, and other statutorily-referenced drugs. In addition to fulfilling the statutory language that the CAP covers Part B drugs generally, inclusion of such drugs offers the potential for further savings to the Medicare program because CAP

vendors presumably would be able to negotiate competitive prices on all Part B drugs. Moreover, additional Part B suppliers, including small DME companies, would be able to take advantage of the administrative simplifications offered by the CAP, including the opportunity not to collect beneficiary copayments or negotiate individual drug purchases. AstraZeneca recognizes that the inclusion of expanded categories of drugs will necessitate CMS to consider certain operational changes, such as the parameters for DME suppliers and pharmacies electing to contract with CAP vendors. Therefore, AstraZeneca recommends that CMS consider what future refinements will be necessary to expand CAP coverage to additional categories of drugs as the CAP is being implemented and provide a timeline for such consideration.

B. Additional stakeholders should be involved in the new drug approval process under CAP.

Pursuant to the Interim Final Rule, vendors can petition CMS to include new drugs no sooner than the first fiscal quarter following FDA approval and HCPCS code assignment. To ensure patient access and protect physician choice, we request that CMS extend the new drug approval process to any stakeholder – physicians, manufacturers, patients and/or patient advocacy groups. In addition, we recommend that stakeholders be permitted to petition CMS for inclusion of a particular drug following FDA approval only and not limit the inclusion of a new drug following the assignment of a unique HCPCS code. Current Medicare coverage provisions permit coverage of a new drug under an existing code or the miscellaneous code when coding and coverage requirements are met; therefore restricting inclusion under CAP to only those drugs assigned a unique HCPCS code would be inconsistent with existing Medicare practices and potentially limit beneficiary access to new therapies.

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Again, AstraZeneca appreciates the opportunity to share our views on this important regulation. We look forward to working together to implement the CAP in a way that promotes high-quality care for Medicare beneficiaries while improving the administration of the Medicare program. Please do not hesitate to contact me at 202.350.5577 or by electronic mail at Stephen.S.D.McMillan@AstraZeneca.com if you have any questions or need further information about these comments.

Sincerely,

Stephen McMillan
Director, Government Reimbursement

PPTA
Plasma Protein Therapeutics Association

September 6, 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-IFC (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B)

Dear Administrator McClellan:

The Plasma Protein Therapeutics Association (PPTA) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) interim final rule with comment period regarding the competitive acquisition program (CAP) for outpatient drugs and biologicals under Part B, published in the Federal Register on July 6, 2005 (IFC). PPTA is the association that represents the commercial producers of plasma-derived and recombinant analog therapies (collectively, "plasma protein therapies"). These therapies are used by millions of people to treat a variety of diseases and serious medical conditions. PPTA members produce over 80% of the plasma therapies for the United States market and more than 60% worldwide. Some of the critical therapies produced by PPTA members include: blood clotting factors for people with hemophilia and other bleeding disorders, intravenous immune globulin (IVIG) used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitors (A1PI) used to treat people with alpha-1-antitrypsin deficiency, also known as genetic emphysema.

PPTA shares Congress' recognition that the CAP is not appropriate for all drugs and biologicals and extends its appreciation to CMS for not including blood clotting factors or alpha-1 proteinase inhibitors in the first phase of the program. The Association urges CMS to adhere to the decision to protect access to blood clotting factors and alpha-1 proteinase inhibitors by not including them in subsequent phases of the CAP. PPTA respectfully disagrees with CMS on the basis for excluding IVIG as a matter of an election versus a mandate from Congress. The Association does not believe CMS has discretion to include IVIG in the CAP during the initial phase or in the future. We request that CMS clarify the statutory exemption of IVIG in the final rule. A more detailed discussion follows.

147 Old Solomons Island Road · Suite 100 · Annapolis, MD 21401 USA
tel: 202.789.3100 · 410.263.8296 · fax: 410.263.2298 · e-mail: ppta@pptaglobal.org · www.pptaglobal.org
PPTA Offices in Washington · Annapolis · Brussels · Tokyo

A. Categories of Drugs To Be Included Under the CAP

1. Statutory and Regulatory Exclusions

Statutory Exclusions

PPTA notes that Congress has excluded certain products from the CAP, yet the proposed and interim final rules appear not to acknowledge these exclusions. For example, both rules seem to suggest that intravenous immune globulin (IVIG) is subject to the CAP by noting that blood and blood products (not including IVIG) are excluded.[1] However, SSA § 1842(o)(1)(E)(ii) states that "in 2005 and subsequent years, the amount of payment provided under section 1847A" (i.e., ASP plus 6%) is how Medicare pays physicians and supplier that furnish IVIG. The Conference Report to the MMA confirms that IVIG is excluded from the CAP – "[c]ompetitively biddable drugs and biologicals exclude . . . IVIG products and blood products."[2] It does not follow that CMS adhered to the Conference Report language by excluding blood products in the proposed rule and IFC but failed to recognize the same exemption for IVIG. PPTA believes that Congress' intent is very clear and that CMS needs to explicitly identify the exclusion of IVIG from the CAP in the final rule.

Regulatory Exclusions

In addition to these statutory exclusions, Congress recognized that some drugs and biologicals may not be appropriate to include in the CAP because patient access to them likely would suffer under competitive bidding. Specifically, SSA § 1847B(a)(1)(D) authorizes the exclusion from the CAP of any drugs and biologicals for which competitive bidding is not likely to achieve significant cost savings or is likely to have an adverse impact on access. However, CMS states in the IFC that they do not intend to rely "at this time" on the Secretary's authority under 1847(a)(1)(D) of the Act to exclude competitively biddable drugs and biologicals from the CAP on the grounds that including those drugs or biologicals would not result in significant savings or would have an adverse impact on access.

PPTA contends that Congress gave the Secretary exclusionary authority to use for exceptional cases just like blood clotting factors and alpha-1 proteinase inhibitors. Patients rely on plasma protein therapies to replace critical proteins that their bodies do not naturally produce. Including blood clotting factors and A1PI in the CAP would likely have had a significant adverse impact on individuals with hemophilia and other bleeding disorders and with alpha-1 antitrypsin deficiency because the CAP requires contractors

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1 Id. at 10749.

2 H.R. Conf. Rep. No. 108-391, at 593.

to furnish just one product per billing and payment code within each category. It is highly unlikely that vendors will voluntarily choose to provide more than one brand per category to serve the small patient populations treated by plasma protein therapies. This could be especially troublesome if a patient is under the care of a general practitioner who is not familiar with their rare disease or or the unique properties of all the available therapies and therefore chooses a vendor who does not offer a broad range of plasma protein therapies.

The key issue is that currently, there are multiple products bundled within each of the five Healthcare Common Procedure Coding System (HCPCS) blood clotting factor codes, and all three A1PI products are packaged within a single HCPCS code, even though none of the products are therapeutically equivalent and each are recognized as single source biologics. Single source drugs and biologicals3 including plasma protein therapies are not rated as therapeutic equivalents in the Orange Book and have not otherwise been found pharmaceutically or bioequivalent by the FDA. Given the individual differences in clinical response to biological agents, these treatments do not lend themselves to a one-size-fits-all approach. Each brand has a unique effect on the patient, and efficacy, allergic reactions, development of inhibitors, and response times can vary from patient to patient. Though many patients may respond to a particular manufacturer's product, other patients with the same diagnosis do not. (See Attachment A.) PPTA believes it is absolutely imperative that patients have access to the most effective treatment for their individual condition and commends CMS' recognition of this by not including plasma protein therapies in the CAP.

2. Intent of the Program

In addition to an exclusion based on access concerns, blood clotting factors should also be excluded from the CAP on the grounds that they are primarily administered in the home, not by a physician in the physician's office.4 PPTA is very pleased by CMS' reaffirmation in the IFC that "...given the clear direction of the statute that the election to participate in this program rests with physicians, it is not advisable to include drugs other than those administered as incident to a physician's service as part of this program".

As stated in the proposed rule, "Section 1847B of the Act describes a program that will permit physicians to elect to obtain drugs from contractors rather than purchasing and billing for those drugs themselves." As explained above, PPTA asserts that the statute most closely describes a system for the provision of and the payment for drugs provided

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3 Under the definition applied in SSA § 1847A(c)(6)(D), a single source drug or biological is: (I) a biological or (II) a drug which is not a multiple source drug and which is distributed under a new drug application approved by the Food and Drug Administration. We have included this definition in our proposed regulatory text.

4 Given that clotting factor can be covered under SSA § 1861(s)(2)(I), rather than as an "incident to" drug, and that CMS is focusing on "incident to" drugs for CAP, the alternate coverage basis for clotting factor provides another reason to exclude it from CAP.

incident to a physician's service. For example, the mechanisms described in the statute include the following:

- Only physicians *(and not pharmacies)*, are expressly given an opportunity to elect to participate in the CAP.
- Physicians who elect to obtain drugs under the CAP make an annual selection of the vendor through which drugs will be acquired and delivered to the physician under Part B.
- Payment for drugs furnished under the CAP is conditioned upon drug administration.
- The submission of information that will be used by the vendor for collection of cost sharing applies to physicians.
- The primary site for delivery of drugs furnished under CAP is the physician's office.
- The statute requires the Secretary to make available to physicians on an ongoing basis a list of CAP vendors.

For people with hemophilia who self-infuse in the home, there would be no physician to submit a claim upon administration and therefore vendors would not be able to get reimbursed by Medicare or to charge the beneficiary or a third party insurer for any applicable deductible or coinsurance. In addition, the proposed structure of the CAP for emergency replacement situations and the appeals process are designed for physician-administered drugs and will not work effectively for the majority of patients who get their blood clotting factor delivered to their home through specialty pharmacies, homecare companies or hemophilia treatment centers (HTCs). The emergency re-supply issue is especially important for individuals with hemophilia because without access to the appropriate blood clotting factor in the event of an accident or injury, people with hemophilia bleed internally, causing severe joint damage and potentially fatal outcomes. For all of the above reasons, PPTA thanks CMS for agreeing that blood clotting factors are poorly suited for the normal ordering and billing procedures contemplated by the CAP statute.

In addition, if plasma protein therapies are included in the CAP, we expect that physicians would have to use the "furnish as written" option frequently. It makes more sense, therefore, to exclude them from the CAP than to require physicians to routinely use the "furnish as written" (FAW) option. CMS did not intend for the FAW provision to be employed by physicians on an on-going basis for a particular therapy for a particular beneficiary. Patients who rely on plasma protein therapies have chronic illness and usually require lifelong treatment.

PPTA understands that the Biotechnology Industry Organization (BIO) is recommending in their IFC comments that CMS include single indication orphans in the CAP. However BIO fully supports PPTA's position regarding the importance of excluding alpha-1

proteinase inhibitors from the CAP. Like PPTA, BIO members recognize that the small, fragile patient population with alpha-1-antitrypsin deficiency needs to have assurance that they will have access to the brand of therapy best suited for their condition chosen in conjunction with a physician and not by a CAP vendor. PPTA requests that regardless of whether CMS decides to exclude or include the other single indication orphans, you will adhere to the decision in the IFC to exempt A1PI.

Conclusion

PPTA appreciates this opportunity to comment on the IFC, and we look forward to continue working with CMS to protect Medicare beneficiaries' access to life-sustaining plasma protein therapies. We are grateful that CMS has recognized the unique and fragile nature of patients treated by plasma protein therapies by not including them in the first phase of the CAP. That said, PPTA asks CMS to recognize Congressional intent by identifying explicitly that IVIG is statutorily excluded from the CAP and to exercise the discretion to permanently exclude blood clotting factors and alpha-1 proteinase inhibitors.

We hope our suggestions will help CMS address these important issues in the final rule. Please contact Anna Weinstein at 202-789-3100 x 2116 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Julie Birkofer

Julie Birkofer
Executive Director, North America

Attachment A

Product	Gammar-P I.V.	Gammagard S/D	Ivegam EN	Polygam S/D	Gamimune N S/D 10%	Flebogamma 5%
Manufacturer	ZLB Behring	Baxter Corp/BioScience Division	Baxter Corp/BioScience Division	Baxter Corp/BioScience Division	Talecris	Grifols
Form	Lyophilized	Lyophilized	Lyophilized	Lyophilized	Liquid	Liquid
Viral Inactivation Process	Pasteurization	Solvent detergent	PEG; trypsin	Solvent detergent	Incubation pH 4.2 plus solvent detergent	Heat pasteurization (60 degrees C, 10 h); PEG; precipitation
IgA Content	<50 mcg/mL	<2.2 mcg/mL	<10 mcg/mL	<2.2 mcg/mL	170 mcg/mL	<0.05 mg/mL
IgG Content	>98%	≥90%	≥95%	>90%	≥98%	>99%
Sugar Content	5% Sucrose	2% Glucose	5% Glucose	2% Glucose	None	Sorbitol
Sodium Content (at 5% concentration)	0.5%	0.85%	3 mg/mL	0.85%	Trace	<3.2 mEq/L
pH (after reconstitution)	6.4-7.2	6.4-7.2	6.4-7.2	6.4-7.2	4.0-4.5	5-6
Product Half-Life	40 days	37.7±15 days	23-29 days	37.7±15 days	21 days	37.5 days
Product Shelf Life	24 months	24 months	24 months	36 months	36 months	24 months
Storage	≤25 degrees C; do not freeze	≤25 degrees C; do not freeze	2 - 8 degrees C, do not freeze	≤25 degrees C	2 - 8 degree C, do not freeze	<25 degrees C; protect from light
Reconstitution time	<20 minutes	<5 minutes at room temp; >20 minutes if cold	≤10 minutes at room temp	Within minutes	NA (liquid solution)	NA (liquid solution)
Osmolality	5% 309 mOsm/L 10% 600 mOsm/L	5% 636 mOsm/L 10% 1,250 mOsm/L	~240 mOsm/L	5% 636 mOsm/L 10% 1,250 mOsm/L	274 mOsm/L	342-350 mOsm/L
Method of Preparation	Cohn-Oncley, pasteurization, ultrafiltration	Cohn-Oncley, ultrafiltration, ion-exchange, chromatography, solvent detergent treatment	Cold ethanol, PEG, trypsin	Cohn-Oncley, ultrafiltration, ion-exchange, chromatography, solvent detergent treatment	Cohn-Oncley, pH 4.25 + low salt; solvent detergent treatment	Cohn-Oncley; PEG precipitation; ion-exchange chromatography; heat pasteurization

SEP -2 2005

August 30, 2005

Dr. Mark McClellan
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, SW
Washington, DC 20201

Re: CMS-1325-IFC

Dear Dr. McClellan:

The July 6, 2005 *Federal Register*[1] included the publication of Interim Final Rule CMS-1325-IFC, "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B." We would like to take this opportunity to again provide our perspectives on this important regulatory effort. Before doing so, however, we would like to commend the Agency for the time and attention that has clearly been given to this complex issue, as well as to the many opportunities we have had to speak with Agency officials about this program.

Consistent with our discussions with Agency officials, we wish to focus our comments on the paramount concerns of patient care, clinical research implications, product integrity, and practice viability.

Implications for Patient Care

Review of the Interim Final Rule evidences that the Agency has undertaken significant efforts to address concerns raised with respect to the Proposed Rule regarding the potential impact of the Competitive Acquisition Program (CAP) on patient care and quality. Nevertheless, we believe that elements of CAP still present serious implications.

Indeed, the additional details provided in the Interim Final Rule about CAP shipping processes causes the timelines for product delivery to appear even more troubling. For example, CAP vendors operating in the continental U.S. will not be required to have product to the ordering physician until 5:00 pm the next *business* day in an emergency situation and 5:00 pm on the second *business* day after a routine order is placed, assuming the vendor receives the order before 3:00 pm vendor's local time. Practically speaking, physicians will have to reschedule patients with emergency needs at least *two* days later. Non-emergency patients could not be scheduled any sooner than *three* days after their original appointment.

The implications of this proposed timetable could be serious. For example, a patient with an emergency need discovered during a late afternoon appointment on Friday would have to wait for a Wednesday appointment to be treated with a drug supplied through the CAP vendor since one business day delivery would only require the CAP vendor to get the past-3:00 pm Friday order to the doctor by 5:00 pm Tuesday. Further, CMS notes that emergency orders are not intended to be used routinely, but rather only in situations where the patient's need for the drug cannot be accommodated under routine delivery time

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1 70 *Fed. Reg.* 10745 (March 4, 2005).

frames. The Agency suggests referring patients to hospital outpatient departments for therapy if CAP delivery delays are problematic, but that gives rise to the potential for higher beneficiary co-pay percentages or beneficiary inconvenience.

These delivery timelines are particularly troubling for oncologists because cancer patients often require unanticipated shifts in their course of therapy, depending on tumor response and patient condition when he or she presents for therapy. In light of state pharmacy limitations on the ability of CAP practices to redirect unused drugs that have been dispensed for another patient, when a change is needed in a patient's course of therapy there usually will be a multiple day delay in the patient's treatment.

Finally, the five-to-seven business day delivery schedule for the Pacific Islands appears to pose significant clinical risks. In addition, it may serve to reinforce the concern expressed by many that CAP may be about controlling Medicare costs, not about providing quality patient care to all of the program's beneficiaries.

Another major area of patient care concern is drug availability. Under the Interim Final Rule, the drugs available under CAP are limited to an identified list of 181 products, and even then CAP vendors may supply only one drug per HCPCS code. Although the drug list constitutes an estimated 85 percent of Part B drugs based on spending, it leaves out over 250 products covered under Part B. Moreover, CMS acknowledges that CAP will only cover "most of the drugs with access problems under ASP+6%." With low-volume products excluded, CAP physicians will have to buy and bill those drugs for which they are least likely to be able to obtain discounts, further impacting access to drugs. Further, the exclusion of drugs billed on miscellaneous codes could undermine access to advanced treatment options for patients who have failed to respond to old-line treatment regimens.

Concern has also been raised that CAP could compromise patient safety through the potential commingling of patient-specific drug inventories. The traditional physician prescription and pharmacy dispensing process has long played an essential role from a patient safety perspective. However, any commingling of patient prescriptions under CAP could lead to life-threatening medication errors.

Finally, patient care can be severely impacted by the CAP vendor's right to cut off delivery of drugs for patients who fail to meet their cost-sharing obligations. Under the IFR, CAP vendors may stop shipping drugs for patients who have not paid billed cost-sharing amounts within 45 days after the postmark date on the bill unless the patient has contacted the vendor about the payment problem. Although the Interim Final Rule provides for notification, waiver, and limited postponement, the impact on patients could be significant. Many patients are unable to cover the full cost of their coinsurance, exposing potentially tens of thousands of patients to treatment cut-off. Likewise, increased collection effort pressures from CAP vendors could drive more cancer patients to choose to forego treatment earlier in their course of therapy when the possibility of a successful treatment outcome may be higher. Finally, the stress of vendor collection effort pressures could adversely affect treatment outcomes for certain financially stressed patients.

Potential Impact on Clinical Research

As you know, community cancer care facilities today serve as a vital source of both treatment and access to clinical research. According to patient encounter data compiled by the U.S. Centers for Disease Control and Prevention, an estimated 83.4 percent of all cancer treatment encounters occurred in non-hospital facilities like physicians' offices and community clinics throughout the 1990s. This large patient population has enabled clinical trials to accrue the patients needed to support ongoing research, with a majority of all clinical trial participants now also coming from non-hospital settings.

In light of the importance of community cancer care to clinical research, anything that could undermine patient access to community facilities or their operations could therefore have a significant and negative impact on the nation's clinical research. This consideration is especially important in light of the fact that physician reimbursement for publicly sponsored clinical research is currently not adequate to cover the cost of trial work.

As practice reimbursement shrinks, either under ASP+6% or CAP, the ability of oncologists to absorb the cost of offering patients who have not responded to traditional therapy access to trials in the community setting could be seriously compromised. So too could the efforts begun under the National Coverage Decision on Clinical Trials to ensure the enrollment of more Medicare beneficiaries in clinical trials testing new treatments for diseases common among the elderly. Such a result would dash the hopes of many Medicare cancer patients and undermine the evolution of scientific knowledge specifically focused on the patient population most likely to develop cancer.

Most cancer trials involve adding a test drug to a standard treatment regime. As a result, patients in the control arm receive the current standard of care and those in the test arm receive the current standard of care plus the test drug. Under the NCD, when Medicare beneficiaries enroll in such a clinical trial, the standard of care drug used in both the control and the test arms will be reimbursable. If the control drug called for by a particular protocol is not one that a physician's CAP vendor provides, that physician may not be able to enroll Medicare patients in the trial because the physician will have no ability to obtain and bill for the control drug unless CMS amends the CAP rule to allow such drugs to be provided under the furnish-as-written option.

In addition, the risk of counterfeit drug infiltration could also have a serious impact on cancer clinical research. Under the carefully developed protocols of clinical trials, every effort is made to isolate the research from any external factor that could alter the outcome. In the case of a CAP practice, a trial participant who is unknowingly administered a counterfeit or adulterated drug would likely be removed from the trial. If evidence of the infiltration is found only after the clinical phase, a substantial portion if not all of the data gleaned from the trial could be jeopardized.

Product Integrity

The Medicare Modernization Act requires CAP vendors to buy the drugs they dispense directly from the product's manufacturer or from a wholesaler that buys direct. This provision is designed to address the grave threat posed by counterfeit drugs. US Oncology applauded this requirement in its comments on the proposed rule but noted the lack of oversight procedures needed to ensure CAP vendors comply with this requirement. The Interim Final Rule appears to suffer from the same deficiency.

Indeed, the Interim Final Rule relies heavily on a vendor credentialing process that focuses on financial data and vendor experience in the drug distribution business. In addition, it requires CAP vendors to include "language with shipping material stating that the drug was acquired directly from the manufacturer or that the vendor possesses verification that the drug was acquired directly from the manufacturer and has been acquired in a manner that is consistent with the statutory requirements." CMS supplements these attestations with state regulation of the CAP vendor as a licensed wholesaler and, perhaps, as a licensed pharmacy, routine Medicare provider enrollment monitoring, carrier statistics, complaint monitoring, breach of contract sanctions if the vendor fails to honor product integrity requirements, and the threat that CAP vendors could be required to present pedigree documents upon request. None of these oversight tools seems sufficient to guarantee the integrity of drugs shipped under CAP, however.

Wholesaler and pharmacy licensing laws have not historically restricted the supply sources of licensed entities. Florida has begun to enforce a requirement for paper pedigrees under its authority to license prescription drug wholesalers and a few other states are preparing to do the same, but the Florida pedigree requirement is limited to a defined list of drugs with a high risk of counterfeiting. Meanwhile, the majority of states are waiting for the U.S. Food and Drug Administration to move forward with a pedigree requirement nationally. And although many in the distribution industry are working hard to stem the tide, radiofrequency identification devices and electronic pedigrees are not yet an affordable reality and paper pedigrees remain easy to forge.

As a result, we recommend that the Agency establish standards for CAP vendors akin to the DMEPOS supplier standards and provide for routine survey requirements under the interim final rule. CMS should also ensure that auditors from the designated CAP carrier or other appropriate CMS contractor make frequent, randomly timed, unannounced site inspections of CAP vendors and their subcontractors to review purchase contracts, shipping documents and other records that establish the chain of custody of drugs delivered to CAP physicians. CMS also should establish and broadly disseminate information about the procedure that CAP physicians should follow to report a suspected delivery of counterfeit drugs. That procedure must incorporate rapid timelines for the investigation and resolution of the report. A web-based quality reporting system akin to that operated by CMS for nursing homes and home health agencies should also be implemented to alert the physician and patient communities to the quality, service, solvency and other performance accomplishments and shortfalls of CAP vendors.

Finally, CMS should clarify that one substantiated instance of the purchase or distribution of a counterfeit drug constitutes a serious breach of contract that will automatically result in the termination of the vendor's Part B supplier number and CAP contract.

Practice Viability

As detailed in the comments we submitted regarding the CAP Proposed Rule, neither CAP nor buy-and-bill will be sustainable for many oncology practices if reimbursement for drug administration services remains inadequate to cover their costs. When factoring in the additional administrative costs physicians face if they elect to participate in CAP, we believe the risks to practice viability become even greater.

Based on detailed analyses utilizing current information on 2006 payment policy, we project that community cancer care faces substantial losses beginning January 1, 2006. Absent legislative or regulatory change, several critical sources of support will end on December 31st: the symptom management demonstration program is scheduled to end at that time, the drug administration transition factor of 3 percent will fall to zero, and the physician fee schedule will be cut by 4.3 percent.

As a result of these factors and the chronic underpayment of oncology drug administration services, the projected impact for all of community cancer care is a loss of more than $420 million, assuming every penny of coinsurance is collected – which never happens. If, by contrast, three-quarters of all coinsurance is collected, the sector wide impact is projected to be in excess of $625 million next year.

Simply exiting the buy-and-bill system does not relieve practices of these losses, of course, since a major source of the shortfall is the drug administration services underpayment. Instead, practices opting to participate in CAP will experience a net loss on every Medicare patient due to this underpayment. Adding to the financial strain the practice will experience are the additional and as-yet uncompensated costs of pharmacy services and the administrative functions required of CAP practices.

With respect to pharmacy services, CAP practices will continue to engage in a wide range of important and costly activities including: drug receipt and recording, inventory management, drug preparation, and hazardous waste disposal. In the Hospital Outpatient Prospective Payment System (HOPPS) proposed rule, CMS acknowledged the expense of these activities when it observed that "the handling costs for drugs, biologicals, and radiopharmaceuticals ... are not insignificant as [these] medications ... generally require greater pharmacy preparation time...." As a result, while CMS collects data for two years to further define the HOPPS costs, 2% of ASP will be added to drug payments set at ASP+6% to reimburse hospitals for these handling costs, making effective HOPPS reimbursement for drugs with separate APCs ASP+8%.

No such reimbursement currently exists for physician offices, however, making CAP-related pharmacy costs an unreimbursed loss to the practice.

In addition, the multitude of issues raised in the "Burden on Physician" section of US Oncology's Proposed Rule comments appears to remain. CAP practices will need to engage in order placement processes that involve the submission of substantial detailed information. Software systems may need to be revised to accommodate this requirement. Claims denials must be appealed by the practice on behalf of the CAP vendor. Follow-up tracking and enhanced safety systems will be needed to prevent medication errors under CAP. And the IFR even adds a new burden in that CAP physicians will be expected to secure Advance Beneficiary Notices (ABNs) when CAP vendors ask them to because of concerns about coverage denials or lowest cost alternative issues.

Each of these activities will impose real costs to CAP practices, costs that are not offset by any form of administrative compensation to anyone participating in the CAP program.

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In closing, we wish to thank you again for this opportunity to provide these comments. We are grateful for the opportunity to engage in substantive discussions and practice site visits with CMS officials and continue to stand ready should you have any questions about the issues, concerns, suggestions and data analyses discussed above.

Sincerely,

Leo E. Sands
Chief Administrative Officer
and Executive Vice President