Submitter : Dr. Mariette Austin **Date:** 08/11/2005

Organization : Mariette Austin, PhDMD

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attached file for comments on the proposed CAP ruling.

CMS-1325-IFC-54-Attach-1.DOC

Response to CMS proposal on CAP

CMS does not yet seem to have enough of the specific information with regard to financial performance standards for vendors, creating a pricing metholodology, designing and running a bidding process, providing physicians with adequate opportunity to elect to participate and select a vendor, educate beneficiaries about the program-and the CAP bidding process and vendor selection is currently aiming for a deadline of Fall, 205-with an anticipated effective date of July 1, 2006. I feel that CMS needs to take more time to develop all the above and therefore delay the effective date of CAP until all critical elements are fully developed.

Cancer treatment is complex and poses many risks to patients. Although oncology drugs may be in the same class and category, they are **NOT** interchangeable. Certain drugs may be less effective, or may have different FDA approvals and different indications for use. For example, Procrit and Aranesp, different interferon's, Taxol and Taxotere, anthracyclines (Adriamycin, Daunorubicin, Mitoxantrone, Epirubicin), Velban and Vincristine and Navelbine-and many more. CAP vendors may create formularies that may ignore variations in drug approvals or indications within drug categories. In addition, many treatment regimens are multi-drug, with different dosing of each ingredient-"equivalent" dosing of similar category drugs are **NOT** the same number of milligrams (Velban vs. Vincristine), and the toxicity interactions of similar class drugs can very with the other ingredients-it is therefore **NOT** possible to insert an exchanged ingredient into a published regimen, without potentially compromising either the efficacy of the regimen, or the safety of the regimen. CMS has not yet proposed any minimum standards or safeguards to govern which drugs must be covered by CAP vendors. If vendors a re a llowed t o restrict a ccess o r a re a llowed t o c hange t he d rugs o ffered b y means of formularies, this would compromise cancer care in this county for many patients, and physicians are unlikely to elect to participate in CAP. Therefore, the final CAP rule MUST make clear that formularies are **NOT** permitted!!

Apparently, the physician will be required to submit a written order or prescription to the approved vendor. Each prescription order is to be accompanied by 15 elements of information. This is cumbersome and does not lessen the administrative burden on physicians-but rather, increases the burden dramatically. In addition, the proposed CAP system necessitates that participating physicians maintain individual, patient-specific inventories-therefore complicating inventories immeasurable, and significantly increasing inventory procedure costs. In addition, since roughly one-third of treatments are changed or switch during treatment cycles, there will be a significant waste problem that will increase w aste dis posal costs t o p hysicians a nd increase dr ug r eimbursement c osts t o Medicare. In addition, if a patient needs to change treatment, it is usually necessary to change the treatment on the same day so as not to compromise the management of the patient which is almost schedule-dependent-and not in the best interest of the patient to return in another day or two, in order to obtain a new mixture of drugs, rather than obtain treatment from the physician's current inventory. Delaying treatment and requiring patients to return on another day or wait in order to receive new shipments of drugs acquired through the CAP vendor, is an enormous inconvenience to the patient and a cost

to the practice. Also, such delays in treatment can adversely affect the patients' health and ultimately drive up health care costs. Further, most pharmacy regulations indicate that a drug, once dispensed in a patient's name, may not be returned, reused, or reshelved. Conversion of oncology drug inventories from a single centralized, non-patient specific inventory creates the potential for millions of dollars of "waste" from unused and unusable medications. CAP does not address this issue at all. And furthermore, the costs of drug handling and inventory in outpatient oncology practices run about 12% of total drug purchase expenditures. It is therefore imperative that CAP must recognize and compensate oncologists for the costs of drug handling and inventory. Finally, community oncologists generally are reluctant to refuse to treat a patient who cannot afford to pay a co-payment. Vendors, however, are not ethically or legally responsible for the course of a patient's treatment. If a vendor is unable to collect co-payments from a patient, the current CAP does not prohibit the vendor from stopping delivery of drugs to the physician's office. Allowing vendors to stop delivering drugs to an outpatient setting is likely to endanger patients or force them into more costly in-patient settings for treatment. Further, physicians could be exposed to liability if the physician is unable to complete a course of treatment because a vendor is refusing delivery. Therefore, the final rule must make clear that vendors cannot refuse to deliver drugs because they are unable to collect co-payments.

It is essential that vendors be held to the highest standard for quality and performance. Physicians need to know that when complaints are raised about poor quality and performance that vendors and CMS will take them seriously. It is unrealistic to believe that physicians will participate in CAP if there is no effective process for addressing quality concerns and if they believe they have no recourse if a vendor is not performing as expected. It is also unsettling and contrary to good business practice that physicians are locked into their choice of the CAP vendor for a year regardless of performance and quality. I therefore recommend that CMS develops standard "hold harmless" language for the CAP selection agreement that ensures that participating physicians are held harmless for the negligence and non-performance of CAP vendors. In addition, CMS must make clear that physicians may disenroll from CAP at any time, especially in cases of quality non-performance.

Same day deliveries are feasible, and for some patients necessary. In addition, the duration of the delivery time period must not exceed the drugs' stability, and should be in appropriate shipping containers, appropriate packaging, and on ice if necessary. Vendors should also be required to have the capacity to make same day deliveries when drugs are needed on an emergency basis. At the time the drug is ordered, the physician should receive a commitment from the CAP vendor for a day and time of delivery, and vendors must be held accountable for compliance to that commitment. Therefore, a CAP vendor should be required to demonstrate a history of at least 5 years of delivering each category of drugs for which they submit a bid. In addition, as already described above, CAP providers should **NOT** be permitted to develop formularies for their financial gain-owing to the **SEVERE** impact this would have on the deliver of "standard of care" treatment to patients, based on established protocols, published data, FDA approvals, etc.

Submitter : Dr. Steven Weiss

Date: 08/14/2005

Organization : Northwest Oncology and Hematology Associates

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

I have reviewed the CAP Program and not only do I think that it would not be right for my practice, but I feel it would be bad for cancer care as a whole. This program would greatly increase the inefficiency of office based drug tracking - requiring additional expense out of each practice. Furthermore, as practices go to such programs for some of their patient care, they will gradually be forced to shift all their care to such a program. This would lead to minimal supplies on hand in office and a decreased flexibility to sudden changes in patients needs. It would be extremely difficult to treat a patient if there were a change in his drugs or dosing. Furthermore, removing the collections from the practice would render the system insensitive to the individual patient and could lead to a dehumanizing experience of a needy population. The current level of 'competitive vendors' give sno incentive to make the system more efficient. I would strongly advise shelving this plan and developing a more realistic and flexible alternative.

Sincerely,

Steven Weiss, M.D.

Submitter : **Mrs. Kathleen Bailey**

Organization : **Mrs. Kathleen Bailey**

Category : **Individual**

Date: 08/18/2005

Issue Areas/Comments

GENERAL

GENERAL

August 17, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1372-IFC
PO Box 8013
Baltimore, MD 21244-8013

Dear Sir/Madam:

I 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 my 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 a survivor, I am committed to ensuring that all patients with thyroid cancer have access to the highest quality of care available. Denying access to Thyrogen through the CAP will deny quality of care 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. I do not believe that physicians in private practice are in the position to absorb an expense, risk or administrative responsibility of this magnitude. I do not want thyroid cancer survivors to have their medical treatment and follow-up jeopardized by their inability to gain access to this drug.

I am aware that the ruling to exclude Thyrogen from the CAP pertains to the initial stage of the program only. I 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,

Kathleen Bailey
Thyroid Cancer Survivor

Submitter : Ms. Anne Marie Bicha **Date:** 08/23/2005

Organization : American Gastroenterological Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-57-Attach-1.DOC

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AGA WEB SITE
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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

Submitter : Sheri Dyke **Date:** 08/24/2005

Organization : Sheri Dyke

Category : Individual

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

see attachment

CMS-1325-IFC-58-Attach-1.DOC

Implications for Patient Care

Even though CMS undertook major efforts to address concerned comments about the potential impact of CAP on patient care and quality, elements of CAP still present serious implications.

The timeline for drug delivery is a case in point. In general, CAP vendors will not be required to have product to the ordering physician until 5 pm the next *business* day in an emergency situation and 5 pm on the second *business* day after a routine order is placed, assuming the vendor receives the order before 3 pm 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.

Indeed, the five-day-a week, business day delivery schedule does not bode well for patient care. A patient in the continental US with an emergency discovered at a late afternoon appointment on Friday may 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 pm Friday order to the doctor by 5 pm Tuesday.

In addition, the 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.

Another 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.

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 IFR 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.

Submitter : Dr. Fredric Price **Date:** 08/25/2005

Organization : Pittsburgh Gynecologic Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

This will add a huge problem to my already stressed practice. I may have to shift expenses from patient care to administration, which is certainly not the effect desired by this bill. The most onerous is the additional record-keeping that will be required so that the work increases but not the revenue. Help save community oncology programs.

Submitter : Dr. Michael Lyster **Date:** 08/25/2005

Organization : Dr. Michael Lyster

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I have had the opportunity to review the CAP proposal. I cannot support it.
Cancer care in the United States has become not merely more successful; it has become substantially more efficient and well tolerated by patients. Few patients require inpatient therapy or treatment in hospital-based cancer centers, in contrast to the situation 15 years ago. To rely on outside purveyors of drugs, with the unavoidable increase in complexity and turnaround time will unequivocally reverse that trend.
Most egregious is the option that allows drug suppliers---who have no contact with, nor responsibility to, the patient---to interrupt drug delivery if copayments are not made in a fashion that they deem timely. To not pay one's bills is not the most responsible stance for an individual; it should not carry a death sentence however---which is exactly what such a policy would allow.
This purportedly modest and well-meant proposal will devastate outpatient cancer care, and lead inexorably to higher rather than lower costs----it has uniformly been the case in every region, and every situation that treatment under the auspices of a hospital is always more expensive than treatment in an outpatient community setting.

Michael Lyster, MD
medical oncologist
Melrose Park, Illinois

Submitter : Mrs. Maureen Borawski **Date:** 08/25/2005

Organization : Women's Cancer Center of Central Pa, P.C.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

WHY CAP?? It will not save Medicare any money, small practices will be forced to stop treating chemo patients in their office because of the paper work and inventory issues, and on the top of the list of my priorities THE PATIENTS - how can you even dream of letting a third party with no clue as to the patient's personal or medical issues, decide to stop sending their drugs for non-payment. Do you realize how many patients would not be treated timely now if we waited until payment was received to continue their treatments? Please explore all avenues before implementing this program. I agree and support the comments from COA. Read and discuss their comments, they spell out what the end result would be..... thanks.

Submitter : **Dr. John Peterson** **Date: 08/25/2005**

Organization : **Dr. John Peterson**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I'm a practicing community oncologist in a small town in NC with 75% medicare patients. The CAP program would a very bad policy due to the expense and delay and inconvienience of care. The current system functions and new will likely cause me to close the practice.

Sincerely John Peterson

Submitter : Mrs. DONNA GRAVES **Date:** 08/26/2005

Organization : Ahmad I. Qadri, M. D., P. A.

Category : Individual

Issue Areas/Comments

Background

Background

Physician office manager for 35 years. Oncology hematology office (solo practice, semi rural area) manager for 3 years.

GENERAL

GENERAL

Our office does not have adequate staff to oversee what would be the result of CAP. I don't want to send patients away because the product is not here. I don't want to return product because the protocol changed. I don't want the patient to be denied because they cannot pay the 20% adequately. Oncology has a delivery system that works today. Please keep it that way.

Submitter : Dr. Antonio Gabarda **Date:** 08/26/2005

Organization : Antonio L. Gabarda, MD, PA

Category : Physician

Issue Areas/Comments

Background

Background

CAP

GENERAL

GENERAL

Patients on chemotherapy will drastically be impacted with this legislation. They have to wait for the drugs to be delivered/prepared. It could be waisted since the treatment may not be given due to concurrent illness or low blood counts. Most of the treatment regimen is given on specific schedules. This will be a nigthmare for the physician's office to call the supplier with the right drugs and dose. WE question the quality,efficacy,timeliness of arrival of the drugs as well as dose changes necessary at the time of the patient's visit.

This may end up more expensive than the usual system. The current system is hurting providers already and may shift treatments to the hospitals which will be more expensive.

Thank you.

Submitter : Dr. William Mac Laughlin **Date:** 08/27/2005

Organization : Cancer Spec. of Tidewater

Category : Physician

Issue Areas/Comments

Background

Background

As an oncologist I am quite familiar with the potential impact of the Competative Acquisition Program(CAP), as currently proposed. There are multiple probable negative impacts, and almost no benefits to patient care, or persons being treated with chemotherapy for malignancies.

GENERAL

GENERAL

As above, CAP needs to be fixed and adequateley funded, delayed till this is done, and/or repealed. To do otherwise will create a negative impact on the quality of cancer care for the elderly, and all people affected directly or indirectly by cancer.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

The CAP introduces a new and additional layer of beurocracy, and cost, to the provision of cancer care. Chemotherapy decisions and administration are very complex, important, and have a dramatic impact on patient outcomes and lives. These decisions are currently made by specialized physicians(hematologists and oncologists) with input from patients, and that is the way it should remain. Currently there is absolutely no issue of quality or access to chemotherapy through oncology offices, and their ability to obtain chemothera-peutics from various current suppliers. Thus, there is no medical need or mandate for CAP at all, and it has potential only to hinder oncology care, with no potential, even amongst its proponents, to improve the quality of care. It introduces an additional layer of beaurocracy, and thus true cost, into the current approach to cancer care, while aiming to reduce cost to Medicare. It can accomplish that goal, by definition, only by shifting costs to oncology practices, patients, other insurers, and/or pharmaceutical companies or suppliers.
CAP removes physicians administering chemotherapy one further level from the source of the chemotherapy medications, increasing the chances for mistakes, delays in treatment, drug adulteration and/or substitution by additional added third parties. It thus risks patient safety.
The CAP system is untested, overly rigid in implementation, inefficient, risky for patients, onerous for patients and health care providers, and costly.
IT IS VERY WORRISOME THAT THE INTERIM FINAL RULE ON CAP ENABLES VENDORS TO UNILATERALY STOP DELIVERY OF CHEMOTHERAPY DRUGS IF A PATIENT HAS BEEN UNABLE OR UNWILLING TO MAKE THEIR CO-PAYMENTS. THIS ALLOWS A THIRD PARTY, WHO IS NOT A MEDICAL PROFESSSIONAL, TO WITHOLD POTENTIALLY LIFE-SAVING MEDICATIONS FROM PEOPLE WITH CANCER. CMS, WITH THAT RULE, IS ENABLING THE DISCONTINUATION OF CARE TO ELDERLY PEOPLE WITH LIFE-THREATENING ILLNESSES. THAT RULE SHOULD BE COMPLETELY STRICKEN FROM ANY CAP PROGRAM EVER IMPLEMENTED. [The reponse by CMS to listen, and respond monetarily, to potential (corporate) CAP vendors and their concerns about "bad debt"/unpaid co-payments is interesting, since the oncology community has been talking about this for years without any recognition or favorable response from CMS. Oncology practices, universally, face thousands and thousands of dollars worth of unpaid co-payments by cancer patients(who usually simply do not have the money to make those payments, and would be bankrupt if they tryed to do so) every year, with the amounts rising year after year, and yet they all continue to provide full, high quallity care and chemotherapy to patients, often at an economic loss to their practice.

Regulatory Impact Analysis

Regulatory Impact Analysis

The implementation of CAP has already been delayed 6 months, largely because the vendors, who stand to gain from the system since it gives them more business, balked at its provisions, and would not sign up in sufficient numbers. If even the party most likely to benefit feels CAP is poorly designed, it should be clear that it needs much greater revision, delay, and/or outright repeal. The parties which CMS should be responding to most when delaying and revising CAP are not vendors(middlemen), but those most knowledeable and/or affected by the program, patients and health cre providers in the cancer community.
As an oncologist I recommend, as a first preference, outright repeal of CAP in its current form. If CMS lacks the power to do this, it should ask the required legislative and/or executive entities to repeal the program. If that can not be done, implementation should be delayed further till the programs flaws, which risk harm to cancer patients and oncology practices, are fixed. Since the program is not designed to improve health care outcomes or qualtiy, even indefinite delay will have no negative impact on patients. If implemented, multiple additional protections should be put in place to ensure patient safety, prevent delays or discontinuations or treatment for patients under any circumstances, and adequately fund CAP. CAP is adding another layer of beaurocracy, record keeping, and work to the ways chemotherapy is currently administered, and thus, will certainly, in any form or implementation, add cost to cancer care, not reduce it. Its implementation should, therefore, never be revenue negative or even neutral, but instead it should be adequately paid for by the entity which wants and is requesting it, namely CMS. To do otherwise, takes money out of qualtity and necessary cancer care and shifts it to an untested, burdensome, and economically inefficient drug acquisition system. CC: Honorable Members of Congress

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

CAP is an untested, burdensome, economically inefficient program with no abliity to improve the qualtiy of cancer care. It has already proved difficult to implement, being resisted even by corporate vendors, who stand most to benefit from it. If CMS lacks the authority to fix its deficiencies so that CAP will not hurt patients and cancer care, it should delay implementation indefinitely while asking legislative and/or executive authoritics to make the regulatory revisions required to make the program, at least, inoccous at its worst. The Interim Rule allowing vendors to unilaterlly refuse delivery of potentially life saving chemotherapeutic medications to people with cancer is a terrible provision and should certainally be removed by CMS before even considering implementation.

Submitter : Mr. Theodore Okon **Date:** 08/25/2005

Organization : Community Oncology Alliance

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached.

Thank you.

CMS-1325-IFC-67-Attach-1.DOC

Community Oncology Alliance

Dedicated to high quality, affordable, and accessible cancer care

1101 Pennsylvania Ave., NW
Suite 700
Washington, DC 20004
(202) 756-2258

1790 Kirby Parkway, #101
Memphis, TN 38138
communityoncology.org

August 23, 2005

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

Dear Dr. McClellan:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

Leonard Kalman MD

Dr. Leonard Kalman
President

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

Submitter : Ms. Ann Donovan **Date:** 08/29/2005

Organization : Heartland Hematology-Oncology Assoc

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

With 33 years of oncology experience and as the administrator of a 5 man practice, I find many issues with CAP. 1)Vendor's have the right to stop sending drugs in the event a patient is behind on their payment. Historically, we as oncologist absorbed this loss--before 2005. We could be sued for denying continued treatment because of inability to pay. Vendors having the ability to decide not to send drugs puts the onerous back onto our office when we have no option or recourse. Vendors will have no responsiblity to the patient. Will patients have the ability to sue said vendor? 2) Vendors will have the option to drug replace--Robert Courtney (pharmacist who diluted and replaced ordered drugs with other drugs)did that, and now he is in jail. What medical school did these vendors go to?? Why even have an oncologist if a pharmacist can make a decision to change the formulary? Many patients cannot tolerate one or more of the generic brands available. They are NOT created equal. 3)Delayed treatment. Could be caused by delayed shipment of drug, drug being delivered in inappropriate packaging (which has happened SEVERAL times with at least one of these type of vendors--big name vendor, too), or a change of treatment plan. These patients do not always have the luxury of a few days between treatments--treatment during the cell cycle is critical. 4)The prospect of medicare as a secondary payor has yet to be addressed--if a physician is providing drugs to be billed to a primary insurance such as a BCBS, how do we then bill Medicare if we are in the CAP program. AND, what if, as happens more often as times go by, the primary insurance comes back and says, "OOPPS, sorry, but gee, that insured was being covered under a COBRA plan and oh, by the way, Medicare is primary". We just had this happen to a patient who was treated 12 months ago. How do we then go about getting reimbursed for that drug if CAP is in place? It would really be fraud, don't you think, if we got the drug from CAP then, since the true patient had received the treatment months earlier, utilize that drug for another patient!!? Obviously, no one has walked in our shoes or dealt with the insurance dilemmas we face on a daily basis. 5) Tracking and inventoring these drugs will be very onerous--especially if one mistake is made on entering the px code on the claim. Then no one gets paid.
I could go on and on. Bottom line-I have yet to meet a pharmacy vendor who has any empathy-ethically or morally-for the patient. As having been a "drug replacement" experiment for a major insurance, I can assure you, they could not pull it off--the px vendor kept billing the pharmacy benefit side instead of the medical benefit side. We have not received YET, drug replacement for drugs we already gave the patients from 9-1-02 through 9-30-04. Plus, this major vendor keeps trying to bill our patients for money that is really not due AND THREATENING my patients that if they don't pay, they won't get their drug!!! IF you don't think that this will happen, I feel you are being VERY naive. Maybe this is one reason not many vendors have bid on this whole project. Who, in the government, is going to be the watch dog on this whole show?? Our regional carriers can't handle the new G codes let alone a CAP program.
If the government just does not want to treat cancer patients anymore, they should just come out and tell it like one of my Congressmen told me. "We just can't keep paying for people's bad life styles!" AND, I have witnesses to that conversation-needless to say, I was a bit taken back. You are making it impossible for the middle man, who has always been there for the patient. Do you think that these vendors "just want to do the good thing" and "take care of those poor, unfortunate people"? Baloney-if there wasn't money in it, they wouldn't be doing it-and if there aren't short cuts to take, they will create them. We have taken the best cancer tx in the world and trashed it.

Submitter : **Dr. mark immergut** **Date: 08/26/2005**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

medicare should pay for the treatment of cancer. The cost of treatment should be determined by what is reasonable for the time,liability,educationand years of study that is involved.compare it to a 20 year old line backer who nver completed college who signs with a professional football team.

Submitter : Dr. Jacob Bitran **Date:** 08/30/2005

Organization : Oncology Specialists

Category : Physician

Issue Areas/Comments

Background

Background

The Competitive Aquisition Program (CAP) for chemotherapuetic drugs and biologicals is slated to be implemented in calander year 2006. The implementation of this new program is likely to have a significant impact on both physicians and cancer patients.

GENERAL

GENERAL

The CAP is too risky, too oncrous, too burdensome and too costly. The CAP will likely lead to many wasted chemotherapy doses that will need to sent sent back to vendors due to incurrent illness or low counts that preclude chemotherapy administration. Who will pay for drugs shipped back to the vendor? Finally, allowing a CAP vendor, who is simply ta vendor nothing else, to effectively stop drug delivery based on unpaid co-payments is unconscionable and unethicaL.

Submitter : Ms. Lucinda Long **Date:** 08/30/2005

Organization : Wyeth Pharmaceuticals

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-IFC-71-Attach-1.DOC

#71

Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426

Lucinda E. Long
Vice President, Global Policy and Professional Affairs
484-865-5133 direct

Wyeth

August 29, 2005

BY ELECTRONIC TRANSMISSION

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

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

Dear Administrator McClellan:

Wyeth Pharmaceuticals is pleased to have this opportunity to comment on the Centers for Medicaid & Medicare Services (CMS) interim final rule (IFR) regarding the Competitive Acquisition Program (CAP) for outpatient drugs and biologicals under Part B. Wyeth Pharmaceuticals, a division of Wyeth, is one of the world's largest research driven pharmaceutical and health care companies with leading therapies in the areas of women's health, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology, and vaccines.

Wyeth supports the CMS decision to implement CAP nationally while utilizing one broad drug category that addresses the needs of so many specialty drugs and biologicals. We also appreciate the agency's decision to exclude certain types of biologicals, namely hemophilia clotting factors, and we urge CMS to further confirm its commitment to choice among products for Medicare beneficiaries with hemophilia by stating so in the final CAP rule.

Along similar lines, Wyeth would also like to commend CMS for its efforts to protect access to product of choice by respecting physicians' clinical judgment. Specifically, we support the IFR clarification that CAP vendors cannot require proof of medical necessity and must ship the therapy ordered by the physician. The definition of an "emergency situation" in the IFR further clarifies that it is the

physician who is the best determinant of the most appropriate course of treatment for his or her patients.

Categories of Drugs to be Included in CAP

Wyeth is pleased that CMS provided clarification in the IFR that CAP vendors must provide at least one National Drug Code (NDC) for each Healthcare Common Procedure Coding System (HCPCS) code in the category. We note that this requirement now accurately echoes the statute's instructions to vendors to provide "at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area."[1]

Claims Processing

The CMS improvements to the claims processing provisions of the CAP are to be commended. In particular, Wyeth was encouraged by the agency's efforts to "ensure that the physician's judgment about the appropriate treatment for the beneficiary is primary in the decision-making process."[1] Wyeth supports the CMS definition of an emergency situation as "an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock."[2] This definition allows physicians to access critical therapies/treatments for their patients without the added worry of having to obtain replacement products through CAP.

Medical necessity and having to provide proof before a physician may treat a patient can cause delays in medical care and may disrupt patterns of beneficial

[1] 70 Fed. Reg, at 39039.
[2] 42 CFR § 414.902.

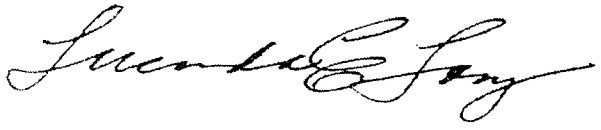
Wyeth

treatment for patients. Wyeth applauds the CMS clarification that CAP vendors cannot make determinations of medical necessity and must ship the therapy ordered by the physician.[3] This clarification protects the beneficiary and provides consistency of process for the physician regardless of whether the product is reimbursed under the Average Sales Price (ASP) methodology or obtained through CAP.

Conclusion

Wyeth thanks CMS for the opportunity to comment on the issues contained in the CAP interim final rule. We strongly urge CMS to ensure the provisions highlighted in this comment letter make the final transition to the CAP final rule, and remain unchanged. We are happy to discuss the issues described in this letter with you or your designees and will provide additional information upon request. If you have any questions please do not hesitate to contact me at (484) 865-5133.

Sincerely,



[3] 70 Fed Reg at 39038-39

Submitter : Dr. Leonard Kosova **Date:** 08/31/2005

Organization : Cancer Care and Hematology Specialists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

The rules as published place an onerous and unreimbursed burden upon physicians which will make it impractical to offer most chemotherapy treatments currently offered in the office setting. We will need to hospitalize many patients for such treatments since there are no alternative facilities in this area. These rules guarantee when taken together with the inadequate reimbursements for nursing care and administration that each physician will essentially be required to subsidize the care of Medicare cancer patients - an unrealistic
scenarioo.

Submitter : Ms. Jennifer Brunkow **Date:** 08/31/2005

Organization : MOHPA

Category : Health Care Professional or Association

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

see attached

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. Steven Ketchel **Date:** 08/31/2005

Organization : Arizona Oncology Associates

Category : Physician

Issue Areas/Comments

Background

Background

Although CAP is designed to help medical oncologsits, it hinders the practice in that patients whose treatment needs to be initiated quickly or changed quickly would not have drugs available to treat them, leaving the oncologist at risk for delivering substandard treatment.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Another sigificant problem is that even if a physician obtains his pharmaceuticals through CAP, there is inadequate reimbursement for the handling of the product when it reaches the office, the shelving of it, the reconstitution of it, the possible waste of it and the administration of it by the nurse with the evaluation and counseling he/she has to to.

Regulatory Impact Analysis

Regulatory Impact Analysis

This is beneficial to allow more constructive comment to be heard so that appropriate changes can be made

Submitter : Mrs. Janet Felps **Date:** 08/31/2005

Organization : Mrs. Janet Felps

Category : Individual

Issue Areas/Comments

Background

Background

Potential Impact on Clinical Research

Today, community cancer care facilities are 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. 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.

GENERAL

GENERAL

please read the background information..

Submitter : Dr. Itra Jaffrey **Date:** 08/31/2005

Organization : Western Slope Oncology Asociates

Category : Physician

Issue Areas/Comments

Background

Background

Asst. Clinical Professor U of Colorado Health Sciences, FACP, Board of Directors Colorado State Medical Society, 30 years of clinical practice as a board certified internist and medical oncologist. Author of numerous articles and lecture and 4 international cancer congresses

GENERAL

GENERAL

This program will result in higher costs to the government, less patients appropriately treated and a general dissatisfaction which will cause many oncologists to stop treating medicare recipients. Particularly in rural areas such as Western Colorado where I practice.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Fails to provide a secure "chain of evidence" from production of a pharmecutical to delivery to a patient. Will incur high cost of unused medications when patients do not receive drugs because of change in clinical status etc.

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

Significant increase in cost.

Submitter : Ms. Lorna Kay **Date: 08/31/2005**

Organization : Cancer Centers of the Carolinas

Category : Other Health Care Provider

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

The timeline for drug delivery is a case in point-the five-day-a week, business day delivery schedule does not bode well for patient care.
the delivery timelines are particularly troubling for oncologists because cancer patients often require unanticipated shifts in their course of therapy
Another major area of concern is drug availability
Concern has also been raised that CAP could compromise patient safety through the potential commingling of patient-specific drug inventories
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
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
the risk of counterfeit drug infiltration could also have a serious impact on cancer clinical research

Submitter : Mr. James Nance **Date:** 08/31/2005

Organization : Mr. James Nance

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The CAP program as proposed by CMS is an idea who's time has come and gone. Most of the major private payors initiated "brown bagging" programs over the last several years. Each of them have discontinued these requirements due to the difficulty in administration, inability to ensure the integrity of the drugs and the difficulty of retaining oncology providers in their networks.
I recognize the need for cost controls. However, requiring private practice physicians to participate in this program is an ineffecient and convoluted approach to the problem.
CMS has been "adjusting" the payments for oncology services back and forth for several years. This constant up and down of payments, the complex formulas used for calculating payments simply makes the whole process of treating patients, billing and collecting for services much more expensive and difficult than necessary.
My major concern is the policies generated from CMS, for all medical specialties is driven more by political interests than any desire to come up with a viable, equitable and UNDERSTANDABLE payment structure.
CMS has created a whole industry for keeping track of the changes that occur in Medicare almost daily, certainly quarterly.
Payment sructures are inordinately difficult to understand and track accurately.
I must believe there are simpler, more straight forward methodologies to contructing fee schedules.
From the private citizen's point of view...this is just another convoluted, make everyone happy (therefore, no one), hard to understand, indirect way to reduce benefits proposal.
Bad idea. Worse for patient care.
I sincerely hope CMS will take a step back and take a harder look at what this proposal will do to local access to cancer care.
This proposal will reduce access either by 1) reduce the number of oncologist nationally by forcing the small practices out of business, or 2) large portion of oncologists terminating their medicare par status.

Submitter : Mr. Keith Krasnigor **Date:** 08/31/2005

Organization : Mr. Keith Krasnigor

Category : Individual

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Potential Impact on Clinical Research.

Today, community cancer care facilities are 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. 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.

Submitter : Greg Graves **Date:** 08/31/2005

Organization : Texas Oncology, PA

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Implications for Patient Care
Even though CMS undertook major efforts to address concerned comments about the potential impact of CAP on patient care and quality, elements of CAP still present serious implications.
The timeline for drug delivery is a case in point. In general, CAP vendors will not be required to have product to the ordering physician until 5 pm the next business day in an emergency situation and 5 pm on the second business day after a routine order is placed, assuming the vendor receives the order before 3 pm 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.
Indeed, the five-day-a week, business day delivery schedule does not bode well for patient care. A patient in the continental US with an emergency discovered at a late afternoon appointment on Friday may 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 pm Friday order to the doctor by 5 pm Tuesday.
In addition, the 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.
Another 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.
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 IFR 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 patients.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Practice Viability

As detailed in comments 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, 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.

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.

Submitter : Mrs. Mary Fruci **Date:** 08/31/2005

Organization : Asheville Hematology & Oncology

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

As a registered nurse delivering chemotherapy and palliative care to cancer patients, I have very serious concerns about the CAP issue. These concerns are related to doubts about product integrity and safety, as well as day to day logistics. I am an active member of the Oncology Nursing Society and an employee of US Oncology. So I have read as much information as I can digest on this issue, and remain unconvinced that this system will ever work in the real world. The additional staff, software, inventory systems, and drug wastage, etc., will most likely eat up and probably surpass any perceived savings. I work in an environment where I have assurances that products I deliver to my patients are unadulterated, undiluted, and kept under optimum storage conditions. I do not want to lose that assurance, nor the ability to share that assurance with my patients. The requirements of such a system as that proposed would be immensely burdensome to those of us down here trying to do the best we can for these people. Most of us truly do want what is best for our patients, but also ourselves, as we are ultimately the ones paying the bill through our tax dollars. But I do not think this currently proposed CAP system will benefit either our patients or those delivering care. I sincerely hope that you will listen to us and allow us to be involved in formulating these decisions and reforms.

Submitter : **Dr. keith logie** **Date: 08/31/2005**

Organization : **CICC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am a medical oncologist in IN. The CAP program contains many provisions making it unusable for the average oncologist.
1. Separate accounting of all CAP drugs from general inventory is a logistical problem.
2. The pharmacist time and supplies are not paid adequately by infusion codes
3. If I start a patient on treatment then the supplier suspends shipment due incomplete payment after 60 days (ie: pt with medicare only with no supplement required to pay 20% not paid by Meedicare) then how can I treat the patient?
4. I have concerns about the suppliers source of medication and potential for counterfit drugs entering the system
5. Waste disposal of residual drugs is my expense
6. I have to stock a supply of drugs to use for emergent treatment of patients if changes on a day by day basis required
7. Submission of billing information cost to 3rd party and inability to make payment arrangements for the indigent.

Submitter : Ms. Susan Van Scoy **Date:** 08/31/2005

Organization : Ms. Susan Van Scoy

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am writing to ask you to please include thyrogen in the upcoming CAP program so it may be available to all thyroid cancer patients. I am a thyroid cancer survivor. After surgery and radiation for initial treatment of thyroid cancer a patient must scan for the results of the RAI tx. They must stay off of their prescribed thyroid medication for about three weeks in order to increase the thyroid stimulating hormone to levels which are greater than therapeutic. The purpose of this is to draw out all that is possible of remaining thyroid tissue and cancer presence so that it is correctly determined whether all thyroid and cancer tissue have been ablated. This process sends the patient into a hypothyroid state which is at best uncomfortable and at worst can produce other worrisome medical symptoms such as heart palpitations and unbearable fatigue. If this initial scan is negative then subsequent scans are often done with thyrogen, which itself raises the TSH to appropriate scan levels without the patient having to stop taking the thyroid medication. This makes the process not only more comfortable but quicker as the process of a thyrogen scan is only a week. I believe that not only is it inhumane to not provide this to all thyroid cancer patients but I also think in the long run it could save money. I know of many fellow thycans who must visit ERs and doctors and receive other tests and medications during their hypo periods for treatment of the side-effects of this temporary but necessary loss of their thyroid medication when thyrogen has not been utilized. Anyone who has had cancer or any other serious disease should also be able to sympathize with the agony of not only having to wait weeks for testing and results of cancer scans but also to do so in a very compromised physical and mental state. Please make thyrogen available to all. Thank you.

Submitter : **Dr. Roy Beveridge** **Date: 08/31/2005**

Organization : **Fairfax Heme Onc**

Category : **Physician**

Issue Areas/Comments

Background

Background

delay of cap

GENERAL

GENERAL

I am worried about many issues with this proposal including:
1. five-day-a week, business day delivery schedule. Pts get chemo 7 days a week in the office and our office is open 363 days per year.
2. I just submitted to JNCCN a review of pharmacy costs -- it is expensive--and we will need to have pharmacists to account for drugs under this proposal for which there is no reimbursement
3. drugs will get co-mingled and the accounting will be onerous
4. there are many last minute adjustments to chemo schedule--which your porposal will not allow for in a busy practice
5. low volume drugs present a significant challenge in your system
6. any errors in system i would be responsible for--i am not willing to accept that risk for these myriad of life-threatening medication errors
7. any accounting error would cause delay to life saving treatment of my patient -- if there is a error currently i will continue to treat and sort error out later, under your system my patient would be at risk till error is completed.
8. your system will cause unde stress to my patient. these people do not need further impediments in obtaining their care.

Submitter : **Ms. Joanne Dennean** **Date: 08/31/2005**

Organization : **thyroid cancer patient**

Category : **Individual**

Issue Areas/Comments

Background

Background

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1372-IFC
PO Box 8013
Baltimore, MD 21244-8013

Dear Centers for Medicare and Medicaid Services:

I am a thyroid cancer patient,and a Medicare beneficiary, and I am writing to request that Thyrogen? (thyrotropin 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 my thyroid cancer treatment, in testing used to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment.

It would reduce the quality of care for the Center for Medicare and Medicaid Services to deny access to Thyrogen through the Medicare Competitive Acquisition Program.

I am concerned that your proposed guidelines will exclude Thyrogen from the CAP. Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Thank you for your help and consideration.

Sincerely yours,
Joanne Dennean
3699 Broadbridge Ave
Stratford, CT 06614
203-375-7059

GENERAL

GENERAL

I am a thyroid cancer patient and a Medicare beneficiary.
Thank you for your time and consideration.

Submitter : Dr. ANTHONY COSCIA **Date:** 08/31/2005

Organization : NORWALK MEDICAL GROUP

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

THE CHANGES IN MEDICARE REIMBURSEMENT OVER THE LAST YEAR HAVE PRODUCED A PROFOUND IMPACT ON WORKFLOW IN CANCER TREATMENT OFFICES. THE ADDITIONAL BURDEN ON ONCOLOGY NURSES AND ADMINISTRATIVE STAFF HAS BEEN ENORMOUS AND HAS LED TO INCREASED COSTS (MORE ADMINISTRATIVE STAFF TIME NEEDED), BILLING ERRORS REQUIRING TIME TO CORRECT, AND MEDICAL ERRORS DUE TO NURSING TIME BEING DIVERTED FROM PATIENT CARE ISSUES TO DEALING WITH ADMINISTRATIVE PROBLEMS. THIS HAS ALSO IMPACTED ON PHYSICIAN WORKFLOW. WE HAVE ALREADY LOST 2 SKILLED CHEMOTHERAPY NURSES WHO ARE LEAVING THE ONCOLOGY FIELD BECAUSE OF THE EVER INCREASING STRESSES THAT ARE BEING COMPOUNDED BY NEW ADMINISTRATIVE DEMANDS. THE CAP PROGRAM PROPOSED FOR JANUARY OF 2006 WOULD ONLY BE A FINAL "NAIL IN THE COFFIN", SO TO SPEAK, AS IT WILL ADD IN ANOTHER CLEARLY OVERWHELMING ADMINISTRATIVE DEMAND THAT WE WILL NOT HAVE THE PERSONNEL TO COPE WITH. AS I HAVE SAID MANY TIMES IN VARIOUS COMMENTS, INSTEAD OF LISTENING TO THOSE OF US WHO DO THIS EVERY DAY, YOU TOOK A BAD SYSTEM (2003 AND BEFORE), MADE IT UNEQUIVOCALLY AND IRRATIONALLY WORSE IN 2004 (ASP PLUS 6%), THEN ATTEMPTED TO CORRECT IT IN 2005 WITH AN IDIOTIC FIX (DEMONSTRATION PROJECT), SO THAT NOW WE HAVE COMPLETE CHAOS, WITH THE POTENTIAL FOR THE ENTIRE SYSTEM TO COLLAPSE UPON ITSELF. THE APPEARANCE OF CAP, WITH ITS CONVOLUTED REQUIREMENTS, WILL BE A KILLER. BESIDES 2 NURSES WHO HAVE RETIRED, I AM ALSO TAKING EARLY RETIREMENT FROM THE FIELD OF ONCOLOGY AS THE BURDENS OF DEALING WITH ALL INSURERS HAVE BECOME TOO GREAT TO DEAL WITH ON A DAY-TO-DAY BASIS.

Submitter : Mr. ASHOK PATEL **Date:** 08/31/2005

Organization : Mr. ASHOK PATEL

Category : Individual

Issue Areas/Comments

Background

Background

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1372-IFC
PO Box 8013
Baltimore, MD 21244-8013

Dear Centers for Medicare and Medicaid Services:

I am a thyroid cancer patient, and I am writing to request that Thyrogen? (thyrotropin 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 my thyroid cancer treatment, in testing used to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment.

It would reduce the quality of care for the Center for Medicare and Medicaid Services to deny access to Thyrogen through the Medicare Competitive Acquisition Program.

I am concerned that your proposed guidelines will exclude Thyrogen from the CAP. Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,

Ashok Patel
2127 East Vista Bonita Drive
PHOENIX, AZ, 85024
Phone: 480-342-8996

GENERAL

GENERAL

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1372-IFC
PO Box 8013
Baltimore, MD 21244-8013

Dear Centers for Medicare and Medicaid Services:

I am a thyroid cancer patient, and I am writing to request that Thyrogen? (thyrotropin 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 my thyroid cancer treatment,

in testing used to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment.

It would reduce the quality of care for the Center for Medicare and Medicaid Services to deny access to Thyrogen through the Medicare Competitive Acquisition Program.

I am concerned that your proposed guidelines will exclude Thyrogen from the CAP. Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,

Ashok Patel
2127 East Vista Bonita Drive
PHOENIX, AZ, 85024
Phone: 480-342-8996

Submitter : **Ms. Maria L. Martinez** **Date: 08/31/2005**

Organization : **El Paso Cancer Treatment Center**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Our patients need their services provided when they are ordered by our Doctors not when CAP say they should be given

Submitter : **Jennifer Schnur** **Date: 08/31/2005**

Organization : **Jennifer Schnur**

Category : **Individual**

Issue Areas/Comments

Background

Background

na

GENERAL

GENERAL

Dear Centers for Medicare and Medicaid Services:

I am a thyroid cancer patient, and I am writing to request that Thyrogen (thyrotropin 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 my thyroid cancer treatment, in testing used to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment.

Denying access to Thyrogen through the Medicare Competitive Acquisition Program WILL reduce the quality of care for the Center for Medicare and Medicaid Services. I am concerned that your proposed guidelines will exclude Thyrogen from the CAP. Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,
Jennifer Schnur

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

na

Regulatory Impact Analysis

Regulatory Impact Analysis

na

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

na

Submitter : **Ms. Joleen Calma** **Date: 08/31/2005**

Organization : **Ms. Joleen Calma**

Category : **Individual**

Issue Areas/Comments

Background

Background

n/a

GENERAL

GENERAL

Dear Centers for Medicare and Medicaid Services:

I am friend of a thyroid cancer patient, and am writing to request that Thyrogen (thyrotropin 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 her thyroid cancer treatment, in testing used to determine whether or not she is free of disease or whether her thyroid cancer has recurred or spread and requires further treatment. Denying access to Thyrogen through the CAP will reduce the quality of care for the Center for Medicare and Medicaid Services as Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,
Joleen Calma

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

n/a

Regulatory Impact Analysis

Regulatory Impact Analysis

n/a

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

n/a

Submitter : **Ms. Beth Shapiro** **Date: 08/31/2005**

Organization : **Ms. Beth Shapiro**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I have just learned that the Medicare Competitive Acquisition Program (CAP)that begins in 2006, excludes Thyrogen (thyrotropin alfa for injection) from the program. As a 47 year old survivor of thyroid cancer (diagnosed in 2000 & treated by surgery and radioactive iodine), I have undergone 2 Thyrogen scans to determine if there is any more cancer. Fortunately, I am clean. I have never had to undergo the more primitive and barbaric way of finding more cancer, ie, off thryoid meds and then RAI scan. The Thyrogen way is so much more humane, efficient and effective. I cannot imagine an elderly person having to go off their meds when such a wonderful alternative is available. Please help them by including Thyrogen on the CAP drug program. I am not too far away from Medicare age. I shudder to think how it would be if I would not be able to undergo the Thyrogen protocol after so many years with it. Thyrogen is truly a blessing to thyroid cancer patients.

Sincerely, Beth Shapiro

Submitter : Ms. Nancy Beegle **Date:** 08/31/2005

Organization : Rocky Mountain Cancer Centers

Category : Other Health Care Professional

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

CAP will create waste and decrease the quality of care provided to patients.

Submitter : **Mr. David Rusch** **Date: 08/31/2005**

Organization : **Mr. David Rusch**

Category : **Individual**

Issue Areas/Comments

Background

Background

NA

GENERAL

GENERAL

Dear Centers for Medicare and Medicaid Services:

I am friend/family member of a thyroid cancer patient, and am writing to request that Thyrogen (thyrotropin 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 her thyroid cancer treatment, in testing used to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment. Denying access to Thyrogen through the CAP will reduce the quality of care for the Center for Medicare and Medicaid Services as Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,
David Rusch

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

NA

Regulatory Impact Analysis

Regulatory Impact Analysis

NA

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

NA

Submitter : Kimberly Law **Date:** 08/31/2005

Organization : Cancer Care Associates

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Even though CMS undertook major efforts to address concerned comments about the potential impact of CAP on patient care and quality, elements of CAP still present serious implications.

The timeline for drug delivery is a case in point. In general, CAP vendors will not be required to have product to the ordering physician until 5 pm the next business day in an emergency situation and 5 pm on the second business day after a routine order is placed, assuming the vendor receives the order before 3 pm 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.

Indeed, the five-day-a week, business day delivery schedule does not bode well for patient care. A patient in the continental US with an emergency discovered at a late afternoon appointment on Friday may 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 pm Friday order to the doctor by 5 pm Tuesday.

In addition, the 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.

Another 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.

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 IFR 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.

Submitter : Dr. Steve McCune **Date:** 08/31/2005

Organization : Northwest Georgia Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

As a community oncologist, I wanted to express dismay and dissatisfaction with the CAP program. It is incredible that we are effectively going to dismantle a proven system for drug delivery for our country's seniors without even a limited testing program. The requirement for a one year commitment to a vendor without the ability to change vendor due to poor performance is troubling. The ability of the vendor to cease shipment of drugs for patients who cannot pay will result in limiting access to critical treatments. This is effectively a way of rationing health care to our nation's seniors and the most vulnerable will be the first to be denied care. The regulatory burdens of maintaining separate drug inventories will almost certainly result in significant cost increases for oncology practices. It is difficult to imagine that the CAP program will result in cost savings for Medicare. The more likely result is that more patient care will be conducted in the inpatient setting which will be far more expensive. Please consider a limited trial project or reduction of the significant administrative burdens associated with this program.

Submitter : **Roxanne Pittman** **Date: 08/31/2005**

Organization : **Roxanne Pittman**

Category : **Individual**

Issue Areas/Comments

Background

Background

I am a thyroid cancer patient, and I am writing to request that
Thyrogen? (thyrotropin 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 my thyroid cancer treatment, in testing used to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment.

It would reduce the quality of care for the Center for Medicare and
Medicaid Services to deny access to Thyrogen through the Medicare
Competitive Acquisition Program.

I am concerned that your proposed guidelines will exclude Thyrogen
from the CAP. Medicare beneficiaries who have suffered from thyroid
cancer need Thyrogen to be included in the Medicare Competitive
Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen
(thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

GENERAL

GENERAL

As a thyroid cancer patient I am using Thyrogen this very week as part of the crucial follow-up of my thyroid cancer treatment, in testing used to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment. I urge you to reconsider your guidelines and include Thyrogen in CAP as soon as possible.
Thank you sincerely for your consideration,
Roxanne Pittman

Submitter : **Ms. Leslie Burnick** **Date: 08/31/2005**

Organization : **N/A**

Category : **Individual**

Issue Areas/Comments

Background

Background

Dear Centers for Medicare and Medicaid Services:

I am a thyroid cancer patient, and I am writing to request that Thyrogen? (thyrotropin 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 my thyroid cancer treatment, in testing used to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment.

It would reduce the quality of care for the Center for Medicare and Medicaid Services to deny access to Thyrogen through the Medicare Competitive Acquisition Program.

I am concerned that your proposed guidelines will exclude Thyrogen from the CAP. Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,
Leslie Burnick

Submitter : Mrs. Julie King **Date:** 08/31/2005

Organization : Medical Oncology Care Associates

Category : Other Health Care Professional

Issue Areas/Comments

Background

Background

see attachment

GENERAL

GENERAL

see attachment

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

see attachment

Regulatory Impact Analysis

Regulatory Impact Analysis

see attachment

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

see attachment

CMS-1325-IFC-98-Attach-1.DOC

CMS-1325-IFC-98-Attach-2.DOC

Practice Viability

As detailed in comments 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, 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.

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.

Submitter : Ms. Jennifer Calabrese **Date:** 08/31/2005

Organization : Ms. Jennifer Calabrese

Category : Individual

Issue Areas/Comments

Background

Background

GENERAL

GENERAL

I am a 28 year old female that was diagnosed with thyroid cancer last year. I urge you to include Thyrogen in the Competitive Acquisition Program of the Centers for Medicare and Medicaid Services.

Without access to thyrogen, patients have to wait weeks for testing while they stop taking their medication. During this time, they feel overwhelming fatigue, have poor concentration, and even experience changes in mood.

With thyrogen, medication can continue uninterupted with no side effects while the patient receives timely testing.

This is too important to thyroid cancer survives (mostly female) who will need testing for the rest of their lives.

Submitter : **Mrs. Huifen Yang** **Date: 08/31/2005**

Organization : **Mrs. Huifen Yang**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1372-IFC
PO Box 8013
Baltimore, MD 21244-8013

Dear Centers for Medicare and Medicaid Services:

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I am concerned that your proposed guidelines will exclude Thyrogen from the CAP. Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,

Submitter : Dr. Leonard Horwitz **Date:** 08/31/2005

Organization : Dr. Leonard Horwitz

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

This makes things very tight financially

Submitter : Dr. Joseph Dudek **Date:** 08/31/2005

Organization : New York Oncology/Hemeatology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Implications for Patient Care

Even though CMS undertook major efforts to address concerned comments about the potential impact of CAP on patient care and quality, elements of CAP still present serious implications.

The timeline for drug delivery is a case in point. In general, CAP vendors will not be required to have product to the ordering physician until 5 pm the next business day in an emergency situation and 5 pm on the second business day after a routine order is placed, assuming the vendor receives the order before 3 pm 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. This is in contrast to "today's"
ability to change a treatment almost immediately to adapt to patient toxicity or a change in the tumor.
Indeed, the five-day-a week, business day delivery schedule does not bode well for patient care. A patient in the continental US with an emergency discovered at a late afternoon appointment on Friday may 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 pm Friday order to the doctor by 5 pm Tuesday.

In addition, the 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.

Another 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.

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 IFR 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.

Submitter : **Dr. John Shields** **Date: 08/31/2005**

Organization : **Alpine Hematology-Oncology**

Category : **Physician**

Issue Areas/Comments

Background

Background

Medical Oncologist in private practice for 25 years, commenting on the CAP program as referenced in the USO letter by Mr. Leo Sands

GENERAL

GENERAL

Not only is CAP not practicable and economically feasible, more importantly, it would both complicate and inhibit patient access to appropriate and timely cancer care.

Submitter : **Dr. linda wilson** **Date: 08/31/2005**

Organization : **Dr. linda wilson**

Category : **Physician**

Issue Areas/Comments

Background

Background

HEME On specialist; solo private practice

GENERAL

GENERAL

I have reviewed the comments and recommendations made by ASCO and agree with them and urge you to honor all aspects.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

no comment

Regulatory Impact Analysis

Regulatory Impact Analysis

no comment

Submitter : Dr. Carlos Rubin de Celis

Organization : Texas Oncology, P.A.

Category : Physician

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

Implications for Patient Care

Even though CMS undertook major efforts to address concerned comments about the potential impact of CAP on patient care and quality, elements of CAP still present serious implications.

The timeline for drug delivery is a case in point. In general, CAP vendors will not be required to have product to the ordering physician until 5 pm the next business day in an emergency situation and 5 pm on the second business day after a routine order is placed, assuming the vendor receives the order before 3 pm 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.

Indeed, the five-day-a week, business day delivery schedule does not bode well for patient care. A patient in the continental US with an emergency discovered at a late afternoon appointment on Friday may 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 pm Friday order to the doctor by 5 pm Tuesday.

In addition, the 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.

Another 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.

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 IFR 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.

Submitter : Ms. Mary Katherine Plakovic **Date:** 09/01/2005

Organization : South Austin Cancer Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Even though CMS undertook major efforts to address concerned comments about the potential impact of CAP on patient care and quality, elements of CAP still present serious implications.

The timeline for drug delivery is a case in point. In general, CAP vendors will not be required to have product to the ordering physician until 5 pm the next business day in an emergency situation and 5 pm on the second business day after a routine order is placed, assuming the vendor receives the order before 3 pm 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.

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Submitter : Ms. Gail Gundling **Date:** 09/01/2005

Organization : THYCA: Thyroid Cancer Survivors Assoc. Inc.

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1325-IFC-107-Attach-1.RTF

#107

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1372-IFC
PO Box 8013
Baltimore, MD 21244-8013

Dear Centers for Medicare and Medicaid Services:

I have been a thyroid cancer patient for 37 years with metastatic disease in my lungs. I am writing to request that Thyrogen (thyrotropin alfa for injection) be included in the list of drugs available through the Medicare competitive acquisition program (CAP) in 2006. I am 66.

The period of hypothyroidism for thyroid cancer patients is nightmarish, some equating it to coming off of heroin. Thyrogen has changed that and allowed us to endure

our diagnosis without the painful and long lasting side effects of medication withdrawal. As a senior citizen this is vital to my health particularly when the need to scan occurs twice in one year. This prevents being hypothyroid for most of the year.

Thyrogen is crucial for the follow-up of my thyroid cancer treatment, in testing used to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment.

It would reduce the quality of care for the Center for Medicare and Medicaid Services to deny access to Thyrogen through the Medicare Competitive Acquisition Program.

I am concerned that your proposed guidelines will exclude Thyrogen from the CAP. Medicare beneficiaries who have suffered from thyroid

cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,

Gail Gundling
18877 N.93rd St
Scottsdale, Az 85255

Submitter : **Michaela Gould** **Date: 09/01/2005**

Organization : **Michaela Gould**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Please include Thyrogen in the CAP Thyrogen? (thyrotropin 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 my aunt's thyroid cancer treatment, in testing used to determine whether or not she is free of disease or whether her thyroid cancer has recurred or spread and requires further treatment.

It would reduce the quality of care for the Center for Medicare and Medicaid Services to deny access to Thyrogen through the Medicare Competitive Acquisition Program.

I am concerned that your proposed guidelines will exclude Thyrogen from the CAP. Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Submitter : **Julie Wohlhuter** **Date: 09/01/2005**

Organization : **Julie Wohlhuter**

Category : **Individual**

Issue Areas/Comments

Background

Background

N/A

GENERAL

GENERAL

Dear Centers for Medicare and Medicaid Services:

I am daughter and friend of two thyroid cancer patients, and am writing to request that Thyrogen (thyrotropin 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 her thyroid cancer treatment, in testing used to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment. Denying access to Thyrogen through the CAP will reduce the quality of care for the Center for Medicare and Medicaid Services as Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,
Julie Wohlhuter

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

N/A

Regulatory Impact Analysis

Regulatory Impact Analysis

N/A

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

N/A

Submitter : **Judy Flack** **Date: 09/01/2005**

Organization : **Patient**

Category : **Individual**

Issue Areas/Comments

Background

Background

I am a recovering thyroid cancer survivor.

GENERAL

GENERAL

Please allow the doctors to use THYROGEN. Many thyroid cancer patients have to have radioactive scans on a regular basis. Normally, in order to do that, they must go off their thyroid hormone replacement for long periods of time. Thus resulting in ill feelings, loss of memory, inability to work and function in their homes. Thyrogen is a drug that can be given during this time which allows the person to function normally and feel good as they prepare for their scan. Please allow the doctors to use THYROGEN for patients preparing for radioactive scans for active thyroid cancer.

Submitter : Michelle Weiss **Date:** 09/01/2005

Organization : Weiss Oncology Consulting

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

In questioning a section of the CMS-1325-IFC I was told to request clarity in the comment forum.

I questioned whether a physician within a group practice could opt out of cap while his partners within the group opted in. I was recently copied on an email from Cecilia Prela, a CMS representative addressing questions related to CAP. Her e-mail states that physicians enrolled in Medicare as a Group Practice MUST join CAP as a group.

?The intent of the physician election section is to emulate the Medicare participating physician process where a Group elects to participate or not to participate, as a Group. If the language is unclear (and it looks like the manager does have questions), for us to be able to respond fully and include the comment as part of the rule making process, we need the comment to be made through the official channel. Would you or the manager be willing to make their comments to the CAP IFC? Comment period closes Sept 6th.?

In reviewing CMS-1325-IFC, I find language which allows one physician within a group to continue with the ?buy and bill? method available through Medicare while the others within the group opt for CAP:

CMS-1325-IFC, page 351, QUOTE:

?a group physician may still ?buy and bill,? even though the group has elected to participate in CAP, as long as the physician bills all of his or her professional services rendered to group patients under his or her own individual PIN. ?

Also included in CMS-1325-IFC, Comments?.

?We think it is unlikely that CAP will cause a significant number of group practices to dissolve because a group physician may still ``buy and bill,?? even though the group has elected to participate in CAP, as long as the physician bills all of his or her professional services rendered to group patients under his or her own individual PIN. Moreover, we believe that physicians choose to practice in a group for many reasons having nothing to do with whether or not a vendor furnishes a particular item or service to patients served by the group (for example, the ability to share overhead costs, coverage duties, and expertise). Under the ``substantially all test?? referenced by the commenter, substantially all of the patient care services of the physicians who are members of the group must be furnished.?

I am requesting clarification and consideration for physicians to be able to make their own, independent decision related to CAP and to not affect the continuity of the group practices.

Submitter : Dr. Marshall S. Flam **Date:** 09/01/2005

Organization : Hem-Onc Medical Group of Fresno, Inc.

Category : Health Care Industry

Issue Areas/Comments

Background

Background

Our group is a 5 man oncology-hematology medical group that draws from approximately 150 miles, bringing patients from the central coast to Fresno. 65% of our practice is Medicare aged patients. We do not anticipate in participating in the CAP Program. Why isn't there a law to keep drug manufacturers from raising prices 3-4 times a year???Amgen has raised their prices 2 times already this year!

GENERAL

GENERAL

The CAP Vendors will participate in this program to make money. Why foster an outside vendor to make the money, when there are so many questions and unanswered questions of implementatuion, when you have ready and willing physicians who have managed the patient drugs successfully for many years? What happens when the CAP Vendor can not continue to supply drugs. In the end, it is the cancer patient that will ultimately be affected by this interference in cancer care. Now, does that appear fair to you?

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

There are no guarantees when a patient enters the office for a office visit with their MD and to receive their chemotherapy treatment that that patient has no toxicities. Our practice must be prepared to "switch" gears without notice and administer a different drug than the patient has received before. A new assessment of the patient's disease and progression of disease is commonplace, a new regimen of drugs for that patient a reality. How could we plan the days before the patient's visit for that change? Medical care, i.e., prescriptions, durable medical equipment, etc. are expensive, how do the CAP vendors expect the Medciare insurance only patient to meet their copays within 45 days....we have copays due for 6-10 months before they are paid. The CAP Program can not be a reality.

Regulatory Impact Analysis

Regulatory Impact Analysis

Don't just delay the CAP Program.....cancel it. It won't work.

Submitter : **Date: 09/01/2005**

Organization :

Category : **Individual**

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Implications for Patient Care

Even though CMS undertook major efforts to address concerned comments about the potential impact of CAP on patient care and quality, elements of CAP still present serious implications.

The timeline for drug delivery is a case in point. In general, CAP vendors will not be required to have product to the ordering physician until 5 pm the next business day in an emergency situation and 5 pm on the second business day after a routine order is placed, assuming the vendor receives the order before 3 pm 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.

Indeed, the five-day-a week, business day delivery schedule does not bode well for patient care. A patient in the continental US with an emergency discovered at a late afternoon appointment on Friday may 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 pm Friday order to the doctor by 5 pm Tuesday.

In addition, the 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.

Another 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.

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 IFR 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 fina

Submitter : Dr. Bruce Gould **Date:** 09/01/2005

Organization : Northwest Georgia Oncology Centers, P.C.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See attachment"

CMS-1325-IFC-114-Attach-1.DOC

#114

August 30, 2005

Dear Dr. McClellan:

Pursuant to the instructions posted in the Federal Register Friday, July 6, 2005/Rules and Regulations, what follows are comments regarding CMS-1325-IFC, Medicare and Medicaid: Outpatient Drugs and Biologicals under Part B; competitive acquisition. This letter is written on behalf of Northwest Georgia Oncology Centers P.C. (NGOC) which represents the interest of fifteen medical oncologists, our staff and our patients.

NGOC commends the decision by CMS to postpone the proposed Competitive Acquisition Program (CAP) bidding process to allow for a through review of comments to the CAP Interim Final Rule.

As stated in our prior comments to CMS submitted on April 24, 2005, we remain concerned that CMS does not fully understand the inefficacies that will result by dramatically changing the drug acquisition process. We are convinced that as currently designed, CAP will have the unintended consequences of increasing cost (both to us and CMS), lowering quality, delaying and/or decreasing access, and creating needless complexity and confusion.

A summary on NGOC's concerns with the proposed CAP program follows:

- Vendor can stop a patient's treatment for non-payment of co-insurance
  The Interim Final Rule allows the CAP vendors the ability to discontinue delivery of cancer drugs for patients who fail to make their co-insurance payments. Allowing a CAP vendor the ability to stop a patient's course of treatment is unacceptable and is a major flaw in the program design.

- Administrative burden to NGOC still a problem
  As proposed CAP will create additional operational burdens and increase our cost of treating our Medicare patients. In 2004, roughly 1,230 (48%) Medicare patients were treated in our six locations. Under the proposed rule NGOC would have to create a separate system for ordering, "prescription" tracking, and maintaining our inventory for almost one half of our patients. Additionally, NGOC would have to develop a new overly burdensome system for providing additional clinical and financial patient specific information to the CAP vendor.

- Likelihood of patients being inconvenienced still a problem
  Due to the complexity of providing cancer treatments, inevitable therapy changes will occur on the day of a patient's scheduled treatment resulting in additional office visits. Patients will also incur additional office visits due to the fact that initial drugs will have to be ordered from the CAP vendor.

- Order Splitting, Re-supply, and Emergencies still a problem
  Due to the complexity and ever changing dynamics in treating cancer patients, issues regarding order splitting, inventory re-supply following an emergency, add another layer of complexity that will result in delayed treatments and increased cost.

- Physician Election Process still a problem
  Under the Interim Final Rule physicians are still locked into their agreement for one year regardless of the performance of their CAP vendor. Physicians must be able to terminate their CAP agreement for cause at any time.

If CMS is committed to implementing the CAP program, NGOC urges CMS to address the many flaws in the program's design, some of which we've addressed above. NGOC also recommends that at pilot program be implemented and tested prior to rolling out on a national basis.

We restate our concern that desire to implement a CAP program (which will require a model that is financially viable for the CAP vendors) will have the unintended consequences of increasing cost (both to us and CMS), lowering quality, delaying and/or decreasing access, and creating needless complexity and confusion.

In conclusion, the best and most cost effective medical care is that in which the drugs are processed and administered in an oncologist's office.

Thank you for your consideration of these important matters.

Bruce Gould M.D.
President and Medical Director

Submitter : Ms. D. Brett Allen **Date:** 09/01/2005

Organization : US Oncology

Category : Health Care Industry

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Product Integrity
MMA 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.

The IFR 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, particularly in light of the tight timelines under which CMS will be allotted for reviewing vendor bids.

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 FDA to move forward with a pedigree requirement nationally. And although many in the distribution industry, under the leadership of the Healthcare Distribution Management Association (HDMA), 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, CMS should 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 by a CAP vendor constitutes a single serious breach of contract that will automatically result in the termination of the vendor?s Part B supplier number and CAP contract.

Submitter : Sheri Ferber-Bradley **Date:** 09/01/2005

Organization : I am a thyroid cancer patient/survivor.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please please do not remove Thyrogen from the list of approved drugs/methods of procedure to help determin if cancer still is present. If you remove this from your list those patients affected will be severely and adversely compromised as they undergo the very difficult process of comming off of the thyroid medication in order to have the scan. The medical community has made great strides in finding a plausable method to scan for cancer. If you remove Thyrogen you will be going backwards decades. Please please...treat these people as you would want to be treated if it were you the dicision directly benefited.

I know you have many areas that are needing cut back. This is NOT one of them.

God bless and give you wisdom as you make your final decisions.

(I am a thyroid cancer survivor myself...I am now a single mom of three...having the scan with out the use of Thyrogen is absolutely unthinkable to me and my family. - in comparison to Thyrogen the other option is in my opinion nothing short of barbaric.

Submitter : Dr. Lance Miller **Date:** 09/01/2005

Organization : Oklahoma Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-IFC-117-Attach-1.DOC

#117

September 1, 2005

Mark McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D. C. 20201

Dear Dr. McClellan:

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

As our previous comments to CMS indicated, the proposed CAP ruling represents a fundamental change in the cancer delivery system. In the absence of any pilot program to test the effectiveness of the CAP, this conceptual new cancer drug delivery system is simply too risky for patients, too burdensome for physicians and too costly to implement.

We have many concerns associated with the implementation of this system. The most important issue that we see is the Vendor's right to stop cancer treatment for non-payment of co-pays. The interim rule gives vendors the responsibility to collect patient co-pays and allows them to stop the delivery of cancer drugs to clinics if the co-payment is unpaid or uncollected. Allowing a CAP vendor, who is not a medical professional and has no relationship to the patient to effectively stop a patient's course of treatment for a life-threatening disease, is unethical and unconscionable.

The CAP program will also place an extreme burden on the patient as they will have to incur additional visits to their oncology clinic because initial drug and therapy changes will have to be ordered from the CAP vendor. This will put an extreme burden on a patient who is already under tremendous health pressures.

The CAP program also places a large administrative burden on oncology clinics. The CAP process requires new claim processing, new tracking requirements and the need to manage two sets of inventories for CAP drugs and non-CAP drugs. These new requirements are not compensated by Medicare and will increase the financial pressures on community cancer clinics, which are already facing a reduced reimbursement for oncology services.

This rule also denies oncologists access to medically necessary drugs by putting a non-medical organization in charge of life saving drugs. This process also denies the oncologist the ability to change and modify drug therapies to fit an individual patient's needs.

Every day cancer patients present with a new set of health issues, that force an oncologist to change their treatment plan. Under the new CAP rules governing when a physician can use CAP acquired drugs to re-supply his or her inventory after an unplanned use or an emergency are very restrictive. Restricting the physician's ability to re-supply their inventories will result in delayed treatments and increased healthcare costs.

The interim rule does not allow physicians to transport medicines. This means that rural oncology clinics throughout the state of Oklahoma will have to hire additional staff and create additional storage capacity to accept, inspect and inventory the CAP deliveries whenever the vendor's shipments arrive, greatly increasing the cost of providing medical care in the rural areas of Oklahoma.

The Interim Final Rule makes clear that once a physician elects CAP, they are locked into this agreement for one year. Given the impact on patient care, physicians must be given the ability to terminate their agreement with a CAP vendor for cause at any given time. Physicians must be given the right to care for their patients in the best way possible and not be tied to rules that do not take into account the care and well being of the patients.

We strongly urge CMS to make changes in the design of the CAP to address the concerns that we have outlined above. Most importantly, given the untested nature of this program, we strongly urge that prior to resuming the bidding process and rollout of the CAP, that CMS undertake a CAP pilot program.

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

The physicians of Oklahoma Oncology appreciate your continued commitment to reform Medicare reimbursement and urge you to consider the well being of all cancer patients. It is imperative that you allow physicians to make the final determination in the care of their patients not a non- medical provider of drugs.

Sincerely,

The Physicians of Oklahoma Oncology.

Submitter : **Edwin Walker** **Date: 09/01/2005**

Organization : **Edwin Walker**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

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

Dear Centers for Medicare and Medicaid Services:

My wife is a thyroid cancer patient, and I am writing to request that ThyrogenA? (thyrotropin 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 her thyroid cancer treatment, in testing used to determine whether or not she is free of disease or whether her thyroid cancer has recurred or spread and requires further treatment.

It would reduce the quality of care for the Center for Medicare and Medicaid Services to deny access to Thyrogen through the Medicare Competitive Acquisition Program.

I am concerned that your proposed guidelines will exclude Thyrogen from the CAP. Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,
Edwin Walker
9/1/2005

Submitter : Ms. Charisse Johnson **Date:** 09/01/2005

Organization : National Association of Boards of Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-119-Attach-1.DOC

#119

nabp
National Association of Boards of Pharmacy
1600 Feehanville Drive • Mount Prospect, IL 60056-6014
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

September 2, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8013
Baltimore, MD 21244-8013

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

The purpose of this correspondence is to provide comments and suggestions concerning the "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B" interim final rule as published in the Federal Register on July 6, 2005. The National Association of Boards of Pharmacy® (NABP®), founded in 1904, represents all of the pharmacy regulatory and licensing jurisdictions in the United States, Guam, Puerto Rico, the Virgin Islands, eight provinces of Canada, two states in Australia, New Zealand, and South Africa. NABP's mission is to serve as the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

Since this interim rule was published for public comment, NABP has received a number of inquiries from states concerning specific provisions of the Competitive Acquisition Program (CAP). The issue that has caused the most concern and confusion among the states is whether or not the "contractor" supplying the drugs and biologicals to physicians is operating as a pharmacy or wholesale distributor.

From NABP's review of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (the Act) provisions and supplementary material, the answer to this query is not readily apparent. It almost appears that the language was particularly vague to allow for some degree of latitude in the operation of "contractors." It may also be that the authors of the Act deferred the matter to the states in the hopes that the states would structure a workable system.

Section 1847 B(b)(2)(A) of the Act clearly requires that the contractor must have sufficient capacity to acquire and deliver drugs in a timely manner within the geographic area, to deliver drugs in emergency situations, and to ship drugs at least 5 days each week. Your agency has also conveyed that it proposed that all CAP contractors "comply with state licensing requirements and be in full compliance with any state or federal requirements for wholesale distributors of drugs or biologics in states that furnish drugs for the CAP." Seemingly, these particular

provisions are direct references to the distribution of drugs and operations that would typically characterize a wholesale distributor.

However, other provisions seem to infer that the CAP contractors perform functions that are traditional to pharmacies. For example, the claim processing statutory requirements mandate that "vendors participating in the CAP bill the Medicare program for the drug or biological supplied, and collect any applicable deductibles and coinsurance from the Medicare beneficiary." Additionally, "the contractor shall not deliver drugs and biologicals to a selecting physician except upon the receipt of a prescription for such drugs and biologicals." The physician is not required to submit a prescription for each individual treatment and may acquire drugs and biologicals from a contractor to "resupply inventories of such drugs and biologicals which are administered consistent with safe drug practices and with adequate safeguards against fraud and abuse" (office use?). An important caveat which occurs at the end of this section reads, "Nothing in this section shall be construed as waving applicable state requirements relating to licensing of pharmacies."

The interim rule also referred to several comments received regarding stringent and high standards for quality and performance in order to attract physicians to the CAP. Sections 1847(b)(2) and 1847(b)(3) of the Act require that approved CAP vendors meet financial and quality of care requirements aimed at assuring the stability and safety of the CAP; Section 1847B(b)(3)(C) of the Act states that the ability to ensure product integrity must be included in the criteria for awarding CAP vendor contracts. Other requirements, such as Section 1847(b)(4)(C) of the Act requires that CAP contractors acquire all drugs and biologics products it distributes directly from the manufacturer or a distributor that has acquired the products directly from the manufacturer.

NABP and its member boards have expressed similar quality concerns with respect to the entire US drug distribution system. In order to address these concerns, NABP convened the Task Force on Counterfeit Drugs and Wholesale Distributors in October 2003. This Task Force produced the updated NABP Model Rules for the Licensure of Wholesale Distributors to assist the state boards of pharmacy in maintaining the integrity of the United States drug distribution system through the regulation of wholesale distributors. The Updated Model Rules are the result of a concerted effort between NABP and other representatives from pharmacy, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit products.

The Task Force also proposed the creation of an accreditation program and clearinghouse for wholesale distributors, a plan that was immediately supported by the Food and Drug Administration, to further combat counterfeit drugs. So in 2004, the Verified-Accredited Wholesale Distributors™(VAWD™) program was established. The VAWD program provides assurance that the wholesale distribution facility being accredited operates legitimately, is validly licensed in good standing, and is employing security and best practices for safely distributing prescription drugs from manufacturers to pharmacies and other institutions. Applicants for VAWD accreditation undergo a criteria compliance review, licensure verification, an inspection, background checks, and screening through NABP's Clearinghouse.

NABP believes that the VAWD accreditation program could play a key role in determining whether or not the CAP vendors adhere to stringent and high standards for quality and

performance. Furthermore, because some of the drugs and biologicals provided under Medicare Part B have shown to be particularly prone to diversion and counterfeiting (ie, Epogen®, Neupogen®, Zofran®, immune globulin), the VAWD accreditation program could serve particularly useful in ensuring the CAP contractor ability to ensure product integrity. States have begun to utilize the VAWD accreditation program to assist with the licensure and inspection of wholesale distributors. In May 2005, Indiana Governor Mitch Daniels signed into law House Bill (HB) 1098, which establishes drug pedigree requirements and requires wholesale distributors to obtain and maintain VAWD accreditation after December 31, 2005. Similarly, Oklahoma Governor C. Brad Henry recently signed into law Senate Bill (SB) 640 and House Bill (HB) 1347, which recognizes the VAWD program and establishes drug pedigree rules.

One of the roles that NABP can assume in the implementation of the Act is to assist the states in establishing uniform interpretations and definitions of the various, and sometimes confusing provisions of this historic legislation. The NABP Executive Committee has authorized the commissioning of a task force to review the relevant provisions of the Act and develop guidelines for the states in key regulatory areas.

Although your agency states in the interim rule that CAP bidding applicants could be a diverse group including wholesale distributors, specialty pharmacy, or group purchasing organizations, it is our opinion that the "contractor" called for in the Competitive Acquisition Areas could be a VAWD-accredited wholesale distributor that contracts with a pharmacy to jointly satisfy all of the relevant provisions. It does not seem likely that an individual pharmacy can serve in this capacity unless the defined Competitive Acquisition Area is limited to the region that can be served by that individual pharmacy. Ultimately, NABP hopes that the Centers for Medicare & Medicaid Services can provide further clarification regarding the types of entities it envisions to provide these services.

If I can provide any additional information, please contact me. Thank you for the opportunity to address this important issue.

Sincerely,

Eleni Z. Anagnostiadis, RPh
Professional Affairs Director

EZA/cj

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary

Submitter : **Date: 09/01/2005**

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Even though CMS undertook major efforts to address concerned comments about the potential impact of CAP on patient care and quality, elements of CAP still present serious implications.

The timeline for drug delivery is a case in point. In general, CAP vendors will not be required to have product to the ordering physician until 5 pm the next business day in an emergency situation and 5 pm on the second business day after a routine order is placed, assuming the vendor receives the order before 3 pm 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.

Indeed, the five-day-a week, business day delivery schedule does not bode well for patient care. A patient in the continental US with an emergency discovered at a late afternoon appointment on Friday may 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 pm Friday order to the doctor by 5 pm Tuesday.

In addition, the 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.

Another 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.

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 IFR 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.

Submitter : **Mrs. Barbara Sickles** **Date: 09/02/2005**

Organization : **Thyroid cancer patient**

Category : **Individual**

Issue Areas/Comments

Background

Background

Medicare program, the Competitive Acquisition Program (CAP)
CMS-1325-IFC

GENERAL

GENERAL

I am a thyroid cancer patient and I am writing to request that Thyrogen be included in the list of drugs available through the Medicare competitive acquisition program (CAP) in 2006. Thyrogen has been used twice for my yearly scans to determine the status of my thyroid cancer and whether or not I would require further treatment.Because I am 70 yrs. of age, Thyrogen has made the preparation for the scans easier, therefore avoiding further health issues relating to being "hypo" as we thyroid cancer patients refer to it. I urge you to reconsider your guidelines. Please include Thyrogen in (CAP) allowing my endocrinologist access to it which will insure that I and other Medicare beneficiaries can receive the highest standard of care for thyroid cancer without the financial and paperwork burdens that otherwise will occur. At this time, I am unsure what the impact of the new Medicare Prescription Drug Program in 2006 will be for me and now to have learned that Thyrogen may be excluded from the (CAP) is quite distressing to me. You may contact me for any further comments, if you wish.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

The proposed guidelines will exclude Thyrogen and 11 other drugs from the list of products to be provided through CAP.

Regulatory Impact Analysis

Regulatory Impact Analysis

Public comment period ends September 6, 2005

Submitter : Mrs. Kathleen Giordano **Date:** 09/02/2005

Organization : Thyca

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Mrs. Kathleen Giordano** **Date: 09/02/2005**

Organization : **Thyca**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1372-IFC
PO Box 8013
Baltimore, MD 21244-8013

Dear Centers for Medicare and Medicaid Services:

I am a thyroid cancer patient, and I am writing to request that Thyrogen? (thyrotropin 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 my thyroid cancer treatment, in testing used to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment. I currently have follow-ups with Thyrogen every 6 months with the use of Thyrogen? (thyrotropin alfa for injection). I have suffered through withdrawal many times, which were 3 months of intrusive, even debilitating, symptoms of hypothyroidism.

It would reduce the quality of care for the Center for Medicare and Medicaid Services to deny access to Thyrogen through the Medicare Competitive Acquisition Program.
I am concerned that your proposed guidelines will exclude Thyrogen from the CAP. Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,
Kathleen M. Giordano
52 Whitson Drive
Newark, DE 19702
(302) 369-0301

Submitter : Mr. Jeffrey Poe **Date:** 09/02/2005

Organization : Rocky Mountain Cancer Centers

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

Background

Background

Implications for Patient Care

Even though CMS undertook major efforts to address concerned comments about the potential impact of CAP on patient care and quality, elements of CAP still present serious implications.

The timeline for drug delivery is a case in point. In general, CAP vendors will not be required to have product to the ordering physician until 5 pm the next business day in an emergency situation and 5 pm on the second business day after a routine order is placed, assuming the vendor receives the order before 3 pm 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.

Indeed, the five-day-a week, business day delivery schedule does not bode well for patient care. A patient in the continental US with an emergency discovered at a late afternoon appointment on Friday may 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 pm Friday order to the doctor by 5 pm Tuesday.

In addition, the 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.

Another 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.

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 IFR 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, vendor collection efforts may adversely affect treatment outcomes for certain financially stressed patients.

GENERAL

GENERAL

Product Integrity

MMA 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.

The IFR 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, particularly in light of the tight timelines under which CMS will be allotted for reviewing vendor bids.

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 FDA to move forward with a pedigree requirement nationally. And although many in the distribution industry, under the leadership of the Healthcare Distribution Management Association (HDMA), 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, CMS should 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 by a CAP vendor constitutes a single serious breach of contract that will automatically result in the termination of the vendor?s Part B supplier number and CAP contract.

Submitter : Dr. Matthew Sulecki **Date:** 09/02/2005

Organization : Dr. Matthew Sulecki

Category : Physician

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

If you read the CAP program description and compare to what we do in the office at present, then you eiher are not too smart or a liar to think that CAPs save money.

Submitter : Mr. Nicholas Opalich **Date:** 09/02/2005

Organization : BioScrip, Inc.

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT"

CMS-1325-IFC-126-Attach-1.DOC

CMS-1325-IFC-126-Attach-2.DOC

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

Dear CMS:

BioScrip welcomes the opportunity to submit our new IFC comments and reincorporation of our original Proposed Comments for participation as a vendor to the Centers for Medicare & Medicaid Services for the Interim Final Rule on the Competitive Acquisition Program "CAP".

Kind Regards,

Nicholas Opalich
BioScrip, Inc.

File Code: CMS-1325-IFC

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 414
[CMS-1325-IFC]

RIN 0938-AN58

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

Agency: Centers for Medicare & Medicaid Services (CMS), HHS.

Action Interim Final Rule.

Comments respectfully submitted electronically by BioScrip to:
http://www.cms.hhs.gov/regulations/ecomments

Interim Final Rule Comments combined with original comments under the Proposed Rule:

Many Physician Associations have commented under the Proposed Rule and Interim Final Rule, that an Administrative burden has been added on them by the CAP, specifically the Oncology community. Other specialties, Gastroenterology, Rheumatology, Infectious Disease and Neurology have significant successful experience with referring Medicare Part B patients to pharmacies, specifically Specialty Pharmacies such as BioScrip.

During the course of a patient's treatment it has always been the responsibility of the Physician or Physician's Office to supply their Pharmacy provider with the necessary information to start the medication treatment for their patients in an alternative setting, such as the Patient's home. Perhaps, given a period of time Specialty Pharmacy providers could promote and/or conceive of a better methodology to handle the process of collecting patient information from the Physician's office. An item, that is not conducive to discuss in the IFC.

Additionally, as our comments indicated below, as submitted during the Proposed Rule period and reincorporated herein for the Interim Final Rule period reflect, that a number of changes should be made to the IFC CAP, particularly in the area of claims administration - throughout areas, that will give rise to various disputes. However, BioScrip strongly suggests that the process of filing, approving and coordinating CAP claims reside with the Vendor's designated carrier and it should be the responsibility of the Designated Carrier to coordinate coverage's with the Physician's Local Medicare Carrier. Leaving it up to the Physician's LCN and the Vendor's Designated Carrier, presently under the IFC are two distinct carriers with two different roles with two different desired outcomes, which will certainly give rise to disputes between the Provider and Vendor. Thus, this process should be streamlined and the incentives should be appropriately aligned between the Physician and the Vendor they choose and the approval process left in the hands of one carrier; the process of matching claims is destined for problems.

However, five specific areas that BioScrip believes are necessary under the CAP are: **1.)** CAP inventory should be maintained, controlled and disbursed by the CAP Vendor; **2.)** All CAP inventory should remain the property of the CAP vendor and stocked by the vendor; **3.)** The process of billing and collections for drugs administered under the CAP should be under the control of the CAP vendor; **4.)** Treatment of wastage and dosage should be consistent with current Part B practices, since we believe the term wastage is being misapplied in the IFC. Presently under Part B, physicians are paid for both products administered to the patient's ad the unadministered product remaining in the vial. Over the years CMS has provided guidance and instruction to this issue and is referred to as wastage that is appropriately billed as part of the treatment. We've provided a number of examples in this response later in the document; **5.)** CAP should be exempt from ASP to encourage pharmaceutical manufacturers to consider CAP specific pricing. As explained throughout this document, with pricing examples provided Manufacturers presently offer

the Oncology physicians a discount through the Physician's GPO, which is below what a distributor or pharmacy would pay and these discounts have been included in CMS quarterly ASP calculations.

This might suggest providing the Physician with an opening CAP order and allow the Physician to pull from this inventory when an infusion is scheduled and administered. As indicated in our opening statement BioScrip is a Medicare Part B Provider and is accustomed to dealing with large and expensive inventories, thus CAP does not pose any new or real threats other than the process of maintaining and control should rest with the Vendor. Although, Physician Cancer Associations on behalf of their Physician constituents, state that they have bought and billed and managed cancer care patients for years is true. Although, an argument could be raised that Physicians might be conflicted under the drug buy and bill program as incentives are not aligned with Practice infrastructure and unable to manage Rx utilization:

- Generic substitutions
- Dosing edits based on lab values and patient status
- Therapeutic interchange
- Unit of use and Rx waste/dose conservation
- Regimen-based prescribing and guidelines dated
- Global outcomes data reporting and metrics
-

BioScrip believes that CMS should consider or adopt some methodology for reimbursement to the vendor and or provider for Patient education and management during infusion cycles. This adds to better outcomes and something that CMS has not focused upon in either the Proposed Rule or Interim Final Rule.

Proposed Claims Processing

Comments:

1. The plan indicates that HCPC codes would be used for vendor claims in addition to our unique identifier, in the form of Rx #. **We would prefer that the claims be submitted with the NDC code and not a HCPC code.** *Medicare was supposed to go to require use of NTSC for pharmacy providers more than one year ago. Use of NTSC versus HCPCS allows CMS and other payers to more accurately determine the exact medication dosage, packaging, and strength dispensed.* The problem with using HCPC codes is that some drugs are dispensed to the patient in different strengths on the same day. (Prograf 5mg and 1mg strengths are a good example of this). While both strengths of the drug have their own unique NDC, they will both carry the same HCPC code which leads Medicare to reject one of the medications, typically the most expensive, as a duplicate service. This practice creates a work-around for the vendors in which the two strengths must be converted to the lower strength and billed with the appropriate units to reflect that actual dosage. By going to the NDC code,

Medicare would greatly improve this process for themselves and the vendors. If need be, we could include the HCPC on the claim record in addition to the NDC.

2. Medicare has published a reference guide or reading Remittance Advice for: Medicare Providers, Physicians, Suppliers, and Billers. This manual speaks loudly to the complexity of claims adjudication by Medicare when the drug and administration are billed together by the Physician. This should identify the need for CMS to make some necessary changes in billing.

3. The Cap Vendor is going to need detailed information on diagnostic and medical status of patients in order to determine if the drug being ordered by the physician is going to be covered by Medicare or not. The CAP vendor's carrier or Designated carrier is not completely involved in this role and process, as most of these kinds of clinical decisions will be left to the Physicians Local Carrier. Presently, the Medicare Intermediaries set the criteria for drug decisions on clinical criteria. This will force the CAP Vendor to have a set of criteria for each regional carrier. Will there be any discussion on how and when we could anticipate Standardization on these types of issues, such as: What will be the means of gathering information from the physician; can we collect this information just one time on each patient and then periodically update, thus trimming this down to just one communication.

4. The plan places the vendor's billing and collection activities at the mercy of the physician's office and their ability to bill on a timely and accurate basis. Specifically:
    a. The vendor is not to submit their claim to Medicare before the physician's expected drug administration date.
    b. Medicare's central claims processing system will not release payment for the vendor's claim until the physician's claim has been received and paid.
    c. If the physician fails to include the vendor's Rx number, the vendor's claim will not be paid.
    d. If the physician's claim is denied because it is not compliant with <u>all</u> of the local coverage determinations (LCD), the vendor's claim will also be denied.
    e. Medicare rules prevent the provider from billing the beneficiary for any patient responsibility until Medicare has made final payment for the services in question. In cases b, c and d, this means that the vendor cannot bill the patient unless and until the physician's claim is paid which will release payment for the vendor's claim.
    f. The physician's CAP agreement would require the physician to submit their claim within 14 calendar days of administration, but does not indicate what, if any, penalty would be used for violations.
    g. CMS should consider allowing a payment incentive to the physician provider in order to submit pharmacy claims rapidly since payment to the CAP vendor is dependent upon timely and correct filing of the pharmacy and administration claim. The CAP vendor's cash flow should not be

negatively impacted by physicians not filing their drug administration claims immediately following the administration. CMS might even consider a late submission penalty on the physician as it shouldn't be left to "dispute resolution" between the physician and CAP vendor.

We suggest that the billing dependency be switched so that the vendor ships the drug and submits a claim for immediate processing and payment by Medicare. Then, the pharmacy's paid claim would be a pre-requisite to paying the physician's claim for drug administration. The pharmacy is paid in this case regardless of whether or not the physician submits a timely and/or accurate claim for their services. This recommendation is consistent with current commercial health plans models; or

Alternatively, the CAP vendor keeps the billing independent with the physician and the pharmacy. The pharmacy will ensure with their audits and audit mechanisms, when the patient executes a signed form with their signature at the physician's office that administration took place at the physician office. That the physician provider is responsible for communicating that the patient signed a form that administration took place and to communicate this back to the vendor via facsimile or some other mode of acceptable communication and prior to any subsequent orders being dispensed that we have received confirmation that the patient did receive the first administration.

5. "Emergency fills", where the physician dispenses out of their on-hand stock which now needs to be replenished, must be billed by the physician and vendor as usual. It is possible to go one step further as the potential exists for the physician to charge full price for all drugs and call them emergencies; and

   We suggest that the physician be able to submit a HCFA for their administration fee as well as the drug at ASP+6 in these cases. Medicare to monitor and deal directly with the physician if they exceed some threshold that would indicate that the physician is abusing this process.

6. We suggest that guidelines should be established regarding inventory control at the physician practice level and the CAP vendor should be the responsible entity to develop and implement the controls that the physician should observe. Having the physician's practice inventory all CAP drugs and pull/replace from a vendor's inventory and then ask the physician to keep track of their inventory is too burdensome and inviting problems. Pharmacy vendor is the specialist at controlling, dispensing, inventorying and shipping drugs.

7. Definition is needed to drive the process around how drugs not administered to a patient are handled. Given that the physician would have placed a drug order with the CAP vendor and there was no drug administration, what happens for

product returns? In these circumstances the CAP vendor would be out: shipping costs, with no means to recoup the cost; uncertain as to the means and methods of how the physician provider initially handled the CAP vendor's drugs; how the drugs may/may not have been appropriately inventoried. This may create many circumstances whereby the CAP vendor may not be able to restock the product in a timely manner or be unable to return the product to the manufacturer. Then the CAP vendor will also be out the actual cost of it's acquisition of the drugs. What happens in these same circumstance(s) when the physician provider is delayed in **notifying** the CAP vendor that drug administration hadn't occurred? We believe that the physician provider be provided with explicit instructions or mandated from CMS that **notification** to the CAP vendor that the drug order hasn't been administered.

8. Current pharmacy practice does not allow for the re-dispensing of a product. If a prescription was filled for a patient in good faith who didn't show up for an administration the CAP vendor would be at risk for the product. How does CMS, the physician and the patient propose to share in the risk of product returns and not place this entire burden on the CAP vendor?

9. Does the physician provider keep the drug in physician's stock for administration and billing to a different patient at a future date? Again, issues of how the physician provider handles and inventories the drug may be called into question.

10. We need to have a better understanding of how CMS proposes to match the claims between the physician and the vendor. Since the CAP vendor's claims are submitted to the designated carrier and the physician claims go to the local carrier. How is this matched as this process was not explained in the Federal Register? It is important to know how this will be completed.

11. Partial payments in certain circumstances may not apply to all situations. Partial payments to vendors would be eliminated in a scenario where reimbursement is not coupled with billing of a physician administration; please reference item #2G. Partial payments add administrative costs to CMS and vendors. Therefore, under these circumstances should not be identified by CMS as a solution for delayed physician administration claims. The CAP program makes the possibility of partial payments available if the physician is slow in submitting a clean claim. Once the physician's claim is received and paid, Medicare would make a "final payment" on the balance of the claim. If the physician fails to submit a claim by 90 days, Medicare would seek to recover the partial payment.

    We suggest that CMS/Medicare monitor the physician and enforces timely claim submission and not do partial payments. . See our comments we suggested underneath item 2G page 2 of this document.

12. What happens to vendor if the physician claims are fraudulent? Example: We received the prescription in good faith from the physician and dispensed in good

faith and the physician billed the administration code fraudulently and we both get reimbursed and the patient never received the medication. To protect CMS and the vendor we suggest that at the time of administration the beneficiary sign an acknowledgement of drug administration and facsimile back to the vendor (See # 2G). This helps eliminate the risk of fraud and minimizes the negative cash flow impact to the vendor.

This is not defined in the program. Will the pharmacy be at risk for future recovery and/or penalty if the physician is submitting fraudulent orders and claims?

13. With respect to the proposed process of collecting copays from beneficiaries, we believe that CMS should offer the physician provider similar language that CMS directed towards the CAP vendor as to when they can collect copays from the beneficiaries. CMS should be aligning the beneficiary copay issue with the physician provider. Thus, the physician provider can't bill or collect upfront for their share of the copay at the time of administration. If the physician does then CMS should allow the CAP vendor the same privilege. CMS should align the physician rule with the proposed rule guiding CAP vendors and when and how they collect copays.

14. A possible suggestion to our comments in item #2. Another way to perhaps approach this issue would be to permit the following scenario: 1.) CAP vendor pharmacy bills CMS designated carrier at ASP + 6% for the drug; 2.) CMS reimburses CAP vendor pharmacy @ASP+6%; 3.) The physician provider is paid for their administration fee **less** their 20% copay plus the 20% copay for the CAP vendor pharmacy claim and allow one provider to bill and collect for copays; 4.) Physician provider collects the full 20% coinsurance for both the drug and the administration from the patient or bills the 20% to a subordinate insurance carrier where the patient has coverage; 5.) Should the physician provider not dispense the drug CMS recoups the pharmacy claim from the physician provider; 6.) what happens if the beneficiary can't or refuses to make their copay, what guidance will CMS provide under the CAP?

15. Will CMS under the CAP permit the Oncologist to use CAP drugs "off label" and will the CAP vendor be held liable for the financial risk of the off-label use and how will this affect the claims process?

16. Oncology private practices have high percentages of underinsured patients and the CAP program could initiate a high enrollment of these patients. Where is this risk going to be shifted under a CAP competitive program, will there be risk sharing?

17. We did not see any coverage or mention about the issues certainly to arise regarding loss of beneficiary insurance coverage during drug administration at the physician's office. What guidance does CMS propose for the CAP vendor and physician involving these types of issues? Will the CAP vendor be permitted to

stop shipments under these circumstances? What other ethical issues may evolve from CAP? What used to be bad debt (underinsured, uninsured, can't pay copay) for the physician practice could become a troublesome issue between the CAP physician and CAP vendor; assuming very tight margins under a biddable concept. Since shifting the bad debt away from the physician practice which could be good for the physician might not be acceptable to the CAP vendor. CMS should update it's guidance regarding this issue.

18. What happens if a CAP physician begins treatment, the vendor ships the drug and the vendor correctly follows all procedures and then the physician submits his/her claim to their local insurance carrier and they deny coverage? What guidance does CMS propose for these types of situations?

Operational Aspects of the CAP

In certain sections of the proposed rule, CMS used the term "prescription" and the term "order" interchangeably. Section 1874B of the Act uses the term "prescription" but does not define it. CMS went on to state, that CMS proposes to interpret the term to include a written order submitted to the vendor. In at least two other sections of the Interim Final Rule and originally in the Proposed Rule CMS interprets that the statute uses the term prescription but does not define it. CMS stated that it believes that Congress intended for CMS to abide by a rigid definition of a prescription. CMS further stated in the Interim Final Rule, that CMS defines the CAP ordering process as a prescription order and will add a definition of the term to the regulations text at 414.902. Then further on, CMS comes back for the purposes of the CAP to define a prescription order as a written order submitted by the physician to the vendor in accordance with requirements of the CAP.

CMS supports the thesis that it intends for the CAP program to be "prescription" driven and "prescription" can only be interpreted as a "prescription written by a physician" and provided that CMS and the CAP proposes to match the prescription order written by the physician submitted to the vendor on a "patient specific and prescription label specific" in order to substantiate that the physician ordered, administered and billed their local carrier in order for the vendor to be reimbursed for the drug.

However, CMS does discuss the issue of licensing throughout the IFC. CMS states that it does not seek to pre-empt State Law. State Laws regarding licensing are different for Wholesalers (Distributors) and Pharmacies. Again, CMS clearly states in certain sections of the IFC that CAP is a "prescription" driven program. Then under the Section headed Licensure, CMS waffles on the issue of licensing and contradicts and conflicts the IFC by stating the following: *"We believe that vendors must operate as distributors in order to participate in the CAP, and we recognize that a natural outgrowth of participating in this program may be that those distributors will need to be licensed as a pharmacy. Regardless, either the vendor, its sub-contractor under the CAP, or both, must be licensed appropriately by each state to conduct its operations under the CAP. Therefore,*

a vendor under the CAP would be required to be licensed as a pharmacy as well as a distributor if a State requires it".

We believe that CMS is clear that its intentions are for the CAP to be prescription driven and should seek to strike any language in the IFC that relates to the word distributor. Since as written the CAP is not a distributor program. If a distributor wants to participate then they should become a licensed pharmacy. However, we believe it is vital and very important to the success of the CAP that CMS clearly distinguishes the terms, order from prescription. This also effects issues of wastage since unless CMS redefines this issue and benchmark it against current Part B practices regarding wastage, then wastage as written in the IFC conflicts the Physician and the CAP Vendor, gives rise to fraud and abuse and anti-kickback issues. Last, State Pharmacy Law does have very clear guidelines/laws on waste and reuse of product once a patient label has been applied to a vial. That negates returning unused product back to the Pharmacy.

Since the CAP is a national distribution program - Specialty Pharmacies are in the best position to service the CAP program. The reason for this is because most Specialty Pharmacies are currently licensed as Medicare Part B contractors and licensed Medicaid Providers. Additionally, Specialty Pharmacies currently contract with all of the Medicare DMERC carriers, know how to bill Medicare, have the infrastructure to bill Medicare & Medicaid seamlessly. Most of the top Specialty Pharmacies currently interface on a daily basis with thousands of Medicare & Medicaid patients and must work efficiently with the Patient's Physician. In BioScrip's case with its 32 National Licensed Pharmacies supports its endeavors through routine sales calls supported by its National Field Sales force. Additionally, BioScrip is one of the very few Specialty Pharmacies based in the United States with a successfully integrated Community Oncology Pharmacy program. This National Sales Force is an added asset when it comes time to enroll Physicians in the CAP because BioScrip is already calling on the most likely Physicians who will enroll in the CAP and can successfully support CMS and consistently provide education to the Physician. In summary, current Part B Providers already functionally serve CMS Part B Benefit.

CAP Program Rx Logistics support the Specialty Pharmacy Model since Specialty Pharmacies currently serve the Patient's Home and the Physician's/Patient's Office and will provide a successful transition from CAP to PDP to MA-PDP to Designated Carrier for Part B Drugs to the Physician's Local Carrier Medicare Part A&B. It will be very difficult for other types of providers to scale up rapidly to the point of being able to service CAP patients and Physicians in the manner in which Specialty Pharmacy currently functions extremely well.

Categories of Drugs to be Included under the CAP

CMS needs to recognize this:

1. Pharmaceutical Manufacturers drive significant Physician Group Purchasing discounts not extended to distributors or specialty pharmacies. Additionally, when CMS calculated its ASP for the 181 drugs covered under the Interim Final Rule the discount extended to the Physicians were included and therefore those that didn't received these exclusive discounts are effected negatively under the CAP. Of the 181 drugs approximately 6 branded drugs formulate 65% of the purchasing volume and the expected bidders, distributors and pharmacies will lose money before the program begins because of the pricing relationship between the Pharmaceutical Manufacturer and the Physician GPO. We suggest that these discounts to the Physician trade not be included in the calculation of ASP or CMS should require the Pharmaceutical Manufacturer to include or recognize the CAP vendors as a distinct and a new Class of Trade.

- **Examples**
- Anzemet 100 mg vial – 00088-1206-32 Price (AWP) $173.16; Price (WAC) $144.30; Physician Cost $54.87; and
- Aloxi .25mg/5mL SDV – 58063-0707-25; Price (AWP) $324.00; Price (WAC) $270.00; Physician Cost $166.36

2. CMS Pricing Transparency: ASP = Provider Drug Margins controlled:

COG at ASP (Inelastic as 90% of reporting GPO discounts)	**$1.00**
Medicare Maximum Allowable @ASP +6%	**$1.06**
Medicare Reimbursement 80%	**$0.85**
20% patient co-pay	**$0.21**
Bad Debt = Conservative 10% of patient co-pays	**$0.02**
Billing and Collection costs @3%	**$0.03**
Income before SG&A	**$0.01**

*** Reporting sources MMA legislation and CMS ASP web site**
ASP = Total Manufacturers Sales at Net/Total Units Sold includes volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargeback's and rebates.*

3. Oncology ASP Rx Economics

Eloxatin ASP reimbursement	**$3,086.62**
Physician Average Cost	**$2,901.42**
CMS Reimbursement 80%	**$2,469.32**
Patient 20% Copay Resp.	**$ 617.20**
• Historical Copay collection 50%	$308.65
• Historical 2nd Insurance Collection 25%	$154.32
• Estimated Copay collection	$426.97
• Balance received for drug reimbursement	$2,932.29
Net drug Profit	**$30.87**
Assume 3% Billing and AR	**$92.60**

4. These significant discounts have contributed to the high percentage of physicians that purchase drugs and make profits on the spread between their cost and what CMS has been reimbursing; thus the reason for ASP pricing methodology and CMS need to put controls in place.

5. For the highest utilized Medicare Part B drugs like Aranesp, physicians have represented the largest / majority purchasers of the products; thus, when CMS calculates ASP based on pricing net of all discounts and rebates, it comes out extremely low - much lower than a pharmacy's cost- because most of the sales for these drugs take place at the physician level at the discounted pricing.

6. Under the CAP it is feasible that the pharmaceutical manufacturers might bundle products used by the oncologist. This event may build uncertainty into the CAP vendor's product costs.

The fact that CMS is asking for bids in the range of ASP+6 demonstrates the lack of understanding and/or recognition of the drug pricing that physicians have benefited from vs. other classes of trade, as well as an unreasonable expectation that non-physicians can still be profitable at these reimbursement rates; quality of care also being an issue under the CAP.

We understand that CMS is attempting to rectify this under new policies under the CAP however the specialty pharmacy industry must look to its pharmaceutical partners for assistance. At this point in time we do not know how the drug industry will react, whether to shift/not shift the discounts formerly enjoyed by the Oncology physician community, in a separate class of trade, for the competitive benefit and new market realities of ASP pricing.

CAP Bidding Process- Evaluation and Selection

We have indicated in **section one** "Claims Processing" that these comments pertain to Composite Bid Price through the use of HCPC codes instead of using the CAP vendor's NDC code:

The plan indicates that HCPC codes would be used for vendor claims in addition to our unique identifier, in the form of Rx #. ***We would prefer that the claims be submitted with the NDC code and not a HCPC code.*** *Medicare was supposed to go to NDC codes a year or so ago. The problem with using HCPC codes is that some drugs are dispensed to the patient in different strengths on the same day. (Prograf 5mg and 1mg strengths are a good example of this). While both strengths of the drug have their own unique NDC,* they *will both carry the same HCPC code which leads Medicare to reject one of the medications, typically the most expensive, as a duplicate service. This practice creates a work-around for the vendors in which the two strengths must be converted to the lower strength and billed with the appropriate units to reflect that actual dosage. By going to the NDC code, Medicare would greatly improve this process for themselves and the vendors. If need be, we could include the HCPC on the claim record in addition to the NDC.*

Essentially, HCPC codes by therapeutic class will report volume but not necessarily the actual usage by treatment unit, since no HCPC code exists for certain treatments and prescriptions. However, in many cases the vendor will have an NDC code. We believe that instead of HCPC codes for the purposes of composite bid price should reflect and report usage by NDC code.

Example: Solution (Aranesp) J0880

For the purposes to best understand how composite bid price selection is applied by CMS as illustrated in Tables 2, 3 and 4 on page 10763 of the Federal Register we need to know the following: 1.) CMS needs to define what a Volume Unit consists of; 2.) Clarify by HCPC what dosage is represented by the volume of units indicated; 3.) How many numbers of orders have occurred by HCPC code.

We have a 70 Kg patient whose been prescribed Aranesp for **chronic anemia** the physician provider will prescribed 31 mcg. **moderate anemia** patient will receive a prescription for 52.5 mcg and the **oncology induced anemia** patient is prescribed 157.6 mcg. However, as illustrated in CMS tables the HCPC the code offered could apply to all 3 patient examples.

Aranesp Solution can be ordered as follows:

25 mcg/mL; 40 mcg/mL; 60 mcg/mL; 100 mcg/mL; 150 mcg/mL; 200 mcg/mL or 300 mcg/mL. As you can determine none of the prescribed unit volumes fell into the HCPC code provided. The CAP vendor in order to determine bid prices under the ASP model and to further become blended into a composite bid could benefit by having CMS provide the following information:

1. If the volume unit is equal to mcg then the CAP vendor needs to know what the number of orders are; or

2. If the volume unit is equal to vials then the CAP vendor needs to know the number of orders and the amount paid to the physicians; or

3. If the volume unit is equal to orders then the CAP vendor needs to know the amount paid to the physician.

One additional concern that the CAP vendor would have is that in some circumstances depending on dose prescriptions and what was the volume of unit provided by the CAP vendor, is that the physician provider could in the above patient example use the vendor's supply for more than one CAP patient or for the benefit of private pay patients. We have no way of knowing that the physician provider actually will use that supply for 1 or more CAP qualified patients and we are uncertain as to how CMS proposes how should the physician notify the CAP vendor when he/she places their next order with the CAP provider, that leftover product was able to be used on more than one CAP patient and not used by the physician provider for the benefit of his private pay patients. This issue circles back to the product return issue as well as the physician provider inventory issue.

4. ASP Calculations:

- Aranesp AWP – 33.64%
- Procrit AWP – 31.74%
- Neupogen AWP – 27.30%
- Carimune AWP – 43.84%
- Lovenox AWP – 30.80%
- Remicade AWP – 23.35%
- Zofran AWP – 44.14%
- Anzemet AWP – 37.41%
- Cytoxan AWP – 54.84%

5. CMS Pricing Transparency: ASP = Provider Drug Margins controlled:

COG at ASP (Inelastic as 90% of reporting GPO discounts)	**$1.00**
Medicare Maximum Allowable @ASP +6%	**$1.06**
Medicare Reimbursement 80%	**$0.85**
20% patient co-pay	**$0.21**
Bad Debt = Conservative 10% of patient co-pays	**$0.02**

Billing and Collection costs @3%	**$0.03**
Income before SG&A	**$0.01**

*** This model makes no assumptions for timely or untimely billing for infusion administration by the Physician. The longer a physician goes outside the allotted 14 day billing period increases the risk to the Vendor.**

*** Reporting sources MMA legislation and CMS ASP web site**
ASP = Total Manufacturers Sales at Net/Total Units Sold includes volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargeback's and rebates.*

Competitive Acquisition Areas

National Competitive Acquisition Area as outlined in the Federal Register on page 10762 states that under this option defines NCAA as follows: the competitive acquisition program would require participating vendors to offer competitively biddable drugs and Biologicals to physicians in any State within the United States, as well as the District of Columbia, Puerto Rico, and the U.S. territories. In other words, there would only be a single national competitive area. Bidders that seek to compete in a national competitive acquisition area would need a national network of distribution points that could serve physicians in a timely manner with products that are properly stored and shipped.

Comment:

How does CMS propose to choose what a successful CAP vendor's national network of distribution points looks like? How many are necessary and in what locations would they be deemed necessary to carry out the functions of a national competitive bidder?

We agree with the definition of the national competitive acquisition Area. However, we would ask CMS to consider that should the CAP vendor demonstrate that it meets or exceeds the various national distribution points to serve physicians in a timely manner, that CMS would leave it up to the CAP vendor to choose the most cost effective means throughout its network to distribute drugs in a timely manner or choose a single national distribution location. We believe that once the successful CAP vendor operationalizes a single national distribution location, that it can deliver biddable drugs in a timely manner to all physicians anywhere who elected CAP participation.

Dispute Resolution

We do not agree that the physician provider should have exclusive control of the claims process (See "Claims Processing Review Comments") which entails the ordering process as well as the need for the physician provider to match his/her claims with the CAP vendor's NDC # and prescription number. Presently worded, the CAP vendor will not be a party to the process. Our concern is that CMS should mandate language and guidelines

that provide the CAP vendor the opportunity **to not** serve a physician provider that is seriously negligent or erroneously behind in filing their respective claims appropriately and on time. Essentially, the CAP vendor could be out thousands of dollars and not resolve the issues of the physician provider is just negligent in it's business practices or just doesn't not have to means to create a new business environment to meet the demands of the CAP program.

In the Interim Final Rule did not specify a time frame for the dispute resolution process to take place between the CAP Vendor, Physician and the CAP vendor's Designated Carrier and CMS.

CAP Contracting Process

Subcontracting

CMS stated that it did not agree that the statutory requirement that states payments be made directly to the approved CAP vendor would preclude the vendor from subcontracting with another drug distributor or pharmacy. Currently, the larger drug wholesalers have divisions that separately distribute drugs to the Physicians office. These same distributors' more than likely service and have under contract all of the retail pharmacy, long term care pharmacy, and infusion pharmacy and specialty pharmacy trade. They buy directly from the Manufacturers. Additionally, some of the larger drug distributors distribute drugs to the Oncologist and even operate Group Purchasing Organizations. I would like clarification from CMS whether or not could the large distributors sub-contract with a specialty pharmacy to be their CAP provider provided that no conflicts of interest exist. Please provide examples of what would be a conflict of interest between a drug distributor and one of its clients such as a specialty pharmacy?

What if one of the larger drug distributors served the physician office trade and served them under contract, but does not provide the necessary services to compete as a Pharmacy under the CAP, then decides to participate in the CAP but does so through a sub-contract to another client who is a specialty pharmacy and a customer of the distributor. In this case the large drug distributor has both the Physician Office as a client and a Specialty Pharmacy as a client; is this a conflict of interest?

Competitive Acquisition Program (CAP) for Medicare Part B Drugs Bidding Forms

Providers such as BioScrip are classified as "Specialty Pharmacy Providers". BioScrip has over 30 distribution and specialty pharmacy locations located throughout the United States, including a central Specialty Pharmacy and Mail Fulfillment center. Each location has filed either an 855B or 855 DMEPOS enrollment form. Currently BioScrip is a contractor to Medicare and DMERCs as well most State Medicaid Programs.

Question/Clarification: BioScrip intends to bid nationally and include all of its locations to service the CAP Program, How many 855 (B) applications does BioScrip need to complete?

Submitter : Dr. Gail Wright **Date:** 09/02/2005

Organization : Florida Cancer Institute

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Implications for Patient Care:

Even though CMS undertook major efforts to address concerned comments about the potential impact of CAP on patient care and quality, elements of CAP still present serious implications.

The timeline for drug delivery is a case in point. In general, CAP vendors will not be required to have product to the ordering physician until 5 pm the next business day in an emergency situation and 5 pm on the second business day after a routine order is placed, assuming the vendor receives the order before 3 pm 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.

Indeed, the five-day-a week, business day delivery schedule does not bode well for patient care. A patient in the continental US with an emergency discovered at a late afternoon appointment on Friday may 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 pm Friday order to the doctor by 5 pm Tuesday.

In addition, the 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.

Another 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.

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 IFR 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 forego treatment earlier in their course of therapy when the possibility of a successful treatment outcome may be higher. Finally, the stress of collection pressures could adversely affect treatment outcomes for financially stressed patients.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Product Integrity:

MMA 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.

The IFR 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, particularly in light of the tight timelines under which CMS will be allotted for reviewing vendor bids.

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 FDA to move forward with a pedigree requirement nationally. And although many in the distribution industry, under the leadership of the Healthcare Distribution Management Association (HDMA), 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, CMS should 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 by a CAP vendor constitutes a single serious breach of contract that will automatically result in the termination of the vendor?s Part B supplier number and CAP contract.

Submitter : Mrs. Catherine Swanson **Date:** 09/02/2005

Organization : Mrs. Catherine Swanson

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Cancer medicine is very and expensive. It could mean the difference between life or death. I think it should be decided to keep the coverage.

Submitter : Mr. Craig Wheeler **Date:** 09/04/2005

Organization : Chiron Corporation

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-129-Attach-1.DOC

#129

CHIRON

September 4, 2005

Via electronic mail

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

Re: **Comments on CMS-1325-IFC: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B"**

Dear Dr. McClellan:

Chiron Corporation is pleased to have the opportunity to comment on the Interim final rule ("the rule") published by the Centers for Medicare and Medicaid Services (CMS) to implement the competitive acquisition program (CAP) of section 1847B of the Social Security Act, as amended by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). 70 Fed. Reg. 39022 (July 6, 2005).

Chiron is a leading biotechnology company with businesses in biopharmaceuticals, vaccines, and blood testing. Chiron develops and manufactures innovative therapies for the treatment of cancer and infectious diseases. Chiron is located in Emeryville, CA with research and manufacturing facilities around the world.

While Chiron supports the CMS decision to take time to perfect the program, we are hopeful that it can be implemented based on the revised schedule the agency has announced, without additional delay. We believe that the CAP represents an important option for physicians who would prefer not to directly purchase Part B medicines under the Average Sales Price System (ASP). Many physicians have reported that the ASP reimbursement system in some cases reimburses for drugs and biologicals below physician acquisition cost for those products. The CAP is an even more important alternative for these physicians and presents an important protection for patients who would otherwise lose access to particular Part B drugs or be forced to change physicians or seek care in other settings.

As a result of these important roles of the CAP program, Chiron is quite concerned about the exclusion from the CAP of the single indication orphan products, including our own product Proleukin® (aldesleukin, interleukin-2, J9015) which provides treatment for patients with certain types of cancer. We urge CMS to include single indication orphans in the CAP as soon as possible. Because of the low volume usage of the single indication orphans, physicians administering these products are often faced with higher administrative and handling costs than other products, increasing the likelihood that 106% of ASP will not cover their acquisition and handling costs.

The agency has long recognized the importance of the single indication orphan products, providing special protections for these products in the Hospital Outpatient Prospective Payment System (HOPPS) to ensure that patients with rare diseases have adequate treatments available. These protections were codified by the Congress in the MMA but were initially undertaken voluntarily by CMS. It seems ironic that the special rule applying to these products under the CAP will serve to exclude the products from the program—denying physicians an important option for delivering them to patients and potentially harming patient access to single indication orphans. Chiron urges CMS to protect patients with rare diseases by reconsidering the decision to exclude single indication orphan drugs from the CAP. One positive benefit flowing from the agency's recent decision to delay implementation of the CAP is that this problem can be addressed prior to the implementation of the program. We hope that the final rule released later this year includes CAP coverage to provide for these important products to patients.

In order to ease any burden of covering single indication orphans, we believe that vendor bids for single indication orphan products should not be capped at 106% of ASP. If a limitation must be imposed, vendor "reasonable net acquisition cost" could be used. If CMS continues the policy of the interim final rule of collecting acquisition information from vendors in order to provide updates to bids under the program in the later years of initial contracts, vendors should be well positioned to report this information to CMS. Alternatively, a higher percentage of ASP could be used to cap bids for single indication orphan products.

Another alternative available to the agency is to base inclusion under the program for single indication orphans on the tests applicable to other products, rather than singling orphan products out for exclusion. Proleukin®, for instance, is sold through normal distribution channels and does not require especially onerous handling requirements. Thus, we do not believe that covering it would present an undue burden for vendors who have the capability to meet all of the other requirements of the CAP.

Whatever option the agency chooses, we hope that it extends CAP coverage to most of the single indication orphan drugs. These products represent important therapies for the patients who use them and should not be arbitrarily excluded from the program.

In conclusion, Chiron congratulates CMS on the steps it has taken to implement the CAP but believes that the program would be significantly improved by including the single indication orphans. We urge CMS to take make this important improvement to the program, which we believe will provide important protections for patients with rare diseases.

I thank you for your attention to this important issue. Representatives of Chiron are available to discuss this issue in more detail with your staff.

Sincerely,

Craig A Wheeler

Craig Wheeler
President, Chiron BioPharmaceuticals

Submitter : Dr. Sanjiv Modi **Date:** 09/05/2005

Organization : Joliet Oncology Hematology Associates Ltd.

Category : Physician

Issue Areas/Comments

Background

Background

Implications for Patient Care

Even though CMS undertook major efforts to address concerned comments about the potential impact of CAP on patient care and quality, elements of CAP still present serious implications.

The timeline for drug delivery is a case in point. In general, CAP vendors will not be required to have product to the ordering physician until 5 pm the next business day in an emergency situation and 5 pm on the second business day after a routine order is placed, assuming the vendor receives the order before 3 pm 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.

Indeed, the five-day-a week, business day delivery schedule does not bode well for patient care. A patient in the continental US with an emergency discovered at a late afternoon appointment on Friday may 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 pm Friday order to the doctor by 5 pm Tuesday.

In addition, the 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.

Another 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.

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 IFR 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 fina

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GENERAL

See above

Regulatory Impact Analysis

Regulatory Impact Analysis

See above

Waiver of Delayed Effective Date

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See above