Submitter : **Ms. Kelli McClure** **Date: 08/04/2005**

Organization : **Ms. Kelli McClure**

Category : **Pharmacist**

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 : **Dr. Mark Moskowitz** **Date: 08/04/2005**

Organization : **Florida Cancer Specialists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am a medical oncologist; 75% of my very busy practice consists of medicare patients. The CAP program will devastate how my patients are treated. I just can't happen. It will lead to unacceptable drug waste since a significant number of patients cannot receive their treatment as scheduled due to intercurrent illness or low blood counts and it will also increase the number of visits unnecessarily since patients will have to come in on one day for a visit and the next day for chemotherapy. Many of these people don't have cars or have limited mobility; they can't do multiple visits. And please, who will pay for the waste drug? The vendor? CMS? I am also concerned with the potential hazard of spoilage and even adulteration. As the system stands, I am completely responsible for what my patient gets. I like it that way. If the drug comes in a brown bag from some vendor, who knows what the patient is getting? I can't personally vouch for it.

Submitter : **Dr. Roy Beveridge** **Date: 08/04/2005**

Organization : **Inova Fairfax Hospital**

Category : **Physician**

Issue Areas/Comments

Background

Background

CAP would seriously impact patient access.

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.

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GENERAL

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Imposition of CAP would impact patient access. I urge its imposition be eliminated

Submitter : **Dr. Bichlien Nguyen** **Date: 08/04/2005**

Organization : **New Hope Hematology-Oncology Consultants**

Category : **Physician**

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.

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Submitter : **Mrs. Patricia Westbrook** **Date: 08/04/2005**

Organization : **US Oncology/Texas Oncology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

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GENERAL

GENERAL

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.

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Waiver of Delayed Effective Date

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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. Gail Bender-Gabel** **Date: 08/04/2005**

Organization : **US Oncology**

Category : **Individual**

Issue Areas/Comments

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Submitter : **Mr. Jim Clarke** **Date: 08/04/2005**

Organization : **North Bend Medical Center - Oncology**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

I cannot recomend CAP to our 3 Oncologists because the cost of implemenation in there practice would require at least one additional full time person to track orders and inventory, maybe two. We would require addition refrigeration and storage areas. These cost have never been addressed in the rules. The other major concern is artifical boundary created by inserting a vendor between the Dr., his staff, and patient. Patient care and service is subject to delivery dates, copayment, and treatment chances. These are very important issues to patient with cancer. Without significant changes in CAP, there is little or no way I can support CAP as proposed. Thank you.

Submitter : Carolyn Kirk **Date:** 08/04/2005

Organization : US Oncology

Category : Individual

Issue Areas/Comments

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Submitter : **Dr. Elizabeth Kent** **Date: 08/04/2005**

Organization : **Kansas City Cancer Center**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Background

Background

As a medical oncologist who now has one year of private practice under my belt, having recently completed training, I am amazed at the struggles that patients and medical oncologists face in receiving/providing quality oncology care. It is hard enough, on a day to day basis, to provide to patients the care that they need. Time allotted to spend with patients is short, insurance coverage is often grossly inadequate, out-of-pocket costs are prohibitive . . . the list goes on and on. The changes that are happening with Medicare and CMS only compound these problems, and will likely result in many medical oncologists closing their offices, thus further restricting access to good care. The CAP program is, thus far, the most damaging idea that CMS has come up with. Our ability to provide patients with timely care is grossly compromised, as is our ability to ensure that the drugs we provide are safe. Please, do not make our jobs, or the plight of patients, more difficult.

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Submitter : **Eric Kiefer** **Date: 08/04/2005**

Organization : **Eric Kiefer**

Category : **Individual**

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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. Joni Landes** **Date: 08/04/2005**

Organization : **Dr. Judy Schmidt MD PC**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

As an oncology nurse for 16 years, I am alarmed at the current climate in reimbursement for oncology practicioners. The CAP program is an attempt to lower costs by creating a single vendor. CAP vendors will have no relationship to the patients. They will be able to unilaterally stop shipment of medicines. THat can and no doubt will inevitibly effect therapies that are dependent on a timed schedule in order to work. IT could cost people their chance of cure. The program also has the liklihood of limiting the choices of therapies for patients. New drugs will not be quickly available.If care is compromised, Medicare will end up paying more in emergency hospitlaizations for those whose care has been delayed or compromised.Please consider dropping the CAP program. You never know, you might be the one it affects, not just the lo-income patient.

Submitter : **Dr. Thom as Fisher** **Date: 08/04/2005**

Organization : **San Antonio Tumor and Blood**

Category : **Physician**

Issue Areas/Comments

Background

Background

I am a medical oncologist and provide chemotherapy to my patients in the office. The most recent regulation changes have hit very hard and our group has been continuing to look at ways to cut cost including closing sites of service to reduce personell. So far we have not been able to find ways to substantially affect these changes.

GENERAL

GENERAL

We will have to participate with CAP, just as we have been forced to accept the changes that have been made with the MMA. This will increase our costs dur to loss of scaling economies, and more importantly decrease access to patients. The vendors do not have to face the patient and tell them that the drug will not be sent because the cannot pay their 20%. Who gets sued by the patient who cannot get care?
Finally, I am tired of the fight. You (the legislation) will do what you will and this cannot be stopped. I also realize that you (as individuals) are only doing your job - one that I would not want. So with this I finish, wishing you (as individuals) all the best and wish for you good fortune and health as these processes take on their own lives.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

The provisons of the rule that are concerning are a) the all or none approach to CAP, b) increasing the costs of care and, c) decreasing access to care, with associated treamtent delays.
It would be wonderful to not have to deal with aquisitions, but we will have to have aquisitions to provide services to our non medicare patients. If we institute CAP, the administrative costs will increase without any hope of increased reimbursement.
Also, under CAP guidelines, patients CAN be refused care by the vendor. Most of my patient's cannot afford their co-payments and thus we have set up payment plans etc to assist them, so as to allow treatment. CAP will prevent this and patients will not get drug if they cannot pay the copayments for chemo.

I anticipate that any savings to our group from cap will be off set by increases in administrative costs. ASP will be squeezed out as it is already a money loosing proposition.

Thus I feel that the current CAP guidelines will a) decrease the access to care, b) increase the administrative costs as there will be a substantial reduction of economies of scale in aquistion (ASP currently and CAP vs ASP), and c) Prevent timely treatment, by increasing the number of patient visits to the physician by requiring a blood work vist and then a visit to the physician.

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

I have no doubt that any regulatory analysis will be irrelavant. The changes will be bad for patient care because it will increase the barriers to care. Any administrative step during a care process is a barrier.

Submitter : **Date: 08/04/2005**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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 : **Dr. Bichlien Nguyen** **Date: 08/04/2005**

Organization : **New Hope Hematology-oncology consultants**

Category : **Physician**

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Practice Viability

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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 : **Dr. Joseph Muscato** **Date: 08/04/2005**

Organization : **Dr. Joseph Muscato**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

This rule is very detrimental to the care of patients with cancer. The rule seems to imply that oncologists can predict weeks or months ahead how someone will respond to chemotherapy. Patients will often come for appointments with a progression of their cancer and need a change in therapy. The CAP will delay necessary treatment and be very harmful to our rural patients who will have to travel long distances again to be treated. Dose reductions will also lead to wasted drugs in a massive way, and discontinuation of therapy will leave unused drugs in large amounts in the physician's office. The CAP program will not work and will waste huge amounts of money.

Submitter : **Ms. Jan Merriman** **Date: 08/05/2005**

Organization : **Minnesota Oncology Hematology, P.A.**

Category : **Pharmacist**

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Hello,
I have worked in the outpatient oncology pharmacy field (private practice) for 8 years, and oversee pharmaceutical inventory procurement/management and the admixture/administration of chemotherapy to our patients in our infusion rooms. We have 7 clinic sites and treat up to 60 patients per day at 4 of those sites. Each patient receives 4-8 drug doses per treatment visit, and about half of our drugs are supplied in multidose vials, which is much more efficient use of drug than single dose vials - less waste. Doses are not usually an 'even' number of vials.
About a third of patients get their drug regimen changed during a course of treatment.
If we were to participate in the CAP program, I cannot imagine the enormous complexity of trying to order/stock and track drug supplies for each individual Medicare patient, in addition to maintaining and managing our own clinic stock of drugs for managed care patients. We would have shelves full of bags or boxes of drug supplies for each patient - split between both room temp and refrigerated for each patient(about half of our oncology drugs are refrigerated), and would need to remember to use the drug supply for that particular patient rather than from our clinic stock. When therapy changes (1/3 of patients) we would need to waste the previous regimen's drugs and order the new regimen, and make the patient go home and come back in a few days when the new supply comes in. You cannot legally use drugs dispensed for one patient on another patient - it would also have already been paid for by the first pt's insurance coverage, so would be double billing for the same supply if reused.
It is expensive to dispose of hazardous drug waste; we have to contract with a separate waste hauler and it is about $1000 per pick up. The haz waste volume would increase dramatically with CAP due to changes in therapy and excess stock, not to mention the remainder of drug in the partial vials from that patient's therapy that cannot be used on another patient.
It would take alot more administrative time for staff to order each patient's drug supply each month, recieve it, and ensure we have it in stock before the patient is scheduled to receive it.
I feel CAP would result in higher overall drug costs due to the wasted drug from changed regimens and drug waste from single dose vials, result in higher expenses for hazardous drug disposal from same, result in higher practice costs for staff to order/manage it, need more space to store all the indiviaual supplies of drugs and keep it organized, and potential for using clinic stock mistakenly for Medicare pts.
medicare could save many dollars by changing some of the billing units for some of the oncology drugs such as Hycamtin (topotecan), Fludarabine, and others since these drugs are stable and we wouldn't have to bill the entire vials to the patients.

Please reconsider this program and allow us to spend the time and energy on taking care of our patients rather than managing a very complicated procurement system that I doubt will result in savings in the end.

thank you,
Jan Merriman, RPh, BCOP

Submitter : **Dr. Robert Robles** **Date: 08/05/2005**

Organization : **Diablo Valley Oncology and Hematology Medical Grp**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-IFC-32-Attach-1.DOC

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

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Submitter : **Mrs. Judith Morrison** **Date: 08/05/2005**

Organization : **Oncology Hematology of Lehigh Valley**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

Cap is a no-win for oncology offices as well and the vendors. It should be carefully thought about before it surfaces again. It will take a lot of money for very little gain.

Submitter : **Dr. ANTHONY COSCIA** **Date: 08/05/2005**

Organization : **NORWALK MEDICAL GROUP**

Category : **Physician**

Issue Areas/Comments

Background

Background

I AM A MEDICAL ONCOLOGIST WITH MORE THAN 30 YEARS OF PRACTICE EXPERIENCE. I AM INTIMATELY INVOLVED IN THE FINANCES OF OUTPATIENT MEDICAL ONCOLOGY AND CHEMOTHERAPY. THE IMPACT OF THE MMA OF 2003 HAS, IS, AND WILL CONTINUE TO OVERWHELM THE RESOURCES AVAILABLE IN THE US TO CARE FOR CANCER PATIENTS.

GENERAL

GENERAL

THE AMOUNT OF NURSING AND PHYSICIAN TIME THAT HAS HAD TO BE DEDICATED TO THE NEW MEDICARE CODES FOR 2005 HAS UNEQUIVOCALLY TAKEN THEIR TIME AWAY FROM PATIENT CARE IN ORDER TO DEAL WITH THE BUREAUCRATIC MEDICARE REQUIREMENTS. THE PROPOSED NEW CAP PROGRAM FOR JANUARY OF 2006, WHICH COULD HAVE BEEN AN ECONOMIC SALVATION FOR MANY PRACTICES IF PROPERLY STRUCTURED, INSTEAD HAS TURNED INTO ECONOMIC CHAOS THAT NO PRACTICE CAN AFFORD TO PARTICIPATE IN. THE AMOUNT OF STAFF AND PHYSICIAN TIME THAT WOULD HAVE TO BE DEDICATED TO MANAGING THE CAP PROGRAM WOULD OVERCOME VIRTUALLY ANY ONCOLOGY ORGANIZATION, NO MATTER HOW LARGE OR WELL ORGANIZED. AND TO FORCE THIS ADDITIONAL (UNCOMPENSATED) WORKLOAD ON AN ALREADY VANISHING BREED (CHEMOTHERAPY NURSES) WOULD DESTROY ONE OF THEIR GREAT VALUES TO OUR PATIENTS - INDIVIDUALIZED ATTENTION AND COMPASSION - AS THEIR TIME WOULD RAPIDLY BE CONSUMED BY THEIR NEED TO MEET NUMEROUS AND EVER INCREASING REGULATORY REQUIREMENTS. YOU NEED TO STOP AND THINK, AND GET INPUT FROM THE PEOPLE WHO DO THIS WORK EVERY DAY, AND NOT JUST LISTEN TO REMOVED STATISTICIANS WHO KNOW NOTHING OF THE REAL WORK OF OFFICE MEDICAL ONCOLOGY. IN YOUR ATTEMPTS TO RECTIFY A BAD SYSTEM (IN EFFECT IN 2003 AND BEFORE), THE MMA OF 2003 DEVISED AN INCOMPREHENSIBILY STUPID SYSTEM THAT WAS NOT ECONOMICALLY VIABLE; THE FISCAL IDIOCY OF WHAT HAD BEEN DONE WAS QUICKLY REALIZED, AND IN DECEMBER OF 2003 A QUICK FIX, THE DEMONSTRATION PROJECT, WAS HASTILY PUT INTO PLACE. WHILE IT DID HELP ALLEVIATE THE ECONOMIC BURDEN PLACED UPON US BY MMA, IT INHERENTLY MAKES NO SENSE. SO YOU TOOK AN ADMITTEDLY BAD SYSTEM, FIXED IT WITH A REALLY IRRATIONAL FIX, THEN CORRECTED THIS ERROR BY AN EQUALLY DUMB DEMONSTRATION PROJECT - AND NOW YOU ARE PROPOSING THE CAP PROGRAM WHICH MAKES EVERYTHING ELSE YOU'VE DONE LOOK LIKE SMALL POTATOES. SOME ONE IN YOUR ORGANIZATION NEEDS TO GET REAL!!! WHAT A SHAME TO THINK OF HOW MUCH PROFESSIONAL (DOCTORS, ETC) AND LEGISLATIVE/EXECUTIVE (YOURS) TIME HAS BEEN WASTED OVER THE LAST 3 YEARS BECAUSE NO ONE TRUSTED US TO GIVE YOU HONEST ANSWERS AS TO HOW TO FIX THE SYSTEM PROPERLY AND PERMANENTLY. I AM FRANKLY EXHAUSTED BY THE AMOUNT OF MY PROFESSIONAL TIME THAT HAS BEEN DEVOTED TO TRYING TO ENSURE PROPER REFORM OF THE MEDICARE REIMBURSEMENT SYSTEM; IT HAS CERTAINLY CONTRIBUTED TO MY DECISION FOR EARLY RETIREMENT NEXT SUMMER FROM A FIELD I HAVE TRULY ENJOYED FOR OVER 30 YEARS. I CANNOT BUT COME TO THE CONCLUSION THAT MANY INDIVIDUALS, PHYSICIANS AND NURSES, WILL BE LEAVING THE ONCOLOGY FIELD EARLY BECAUSE OF THEIR FRUSTRATION WITH EVER-MOUNTING ADMINISTRATIVE RESPONSIBILITIES AND THE ABSENCE OF ANY SENSE THAT ANYONE OUT THERE IS LISTENING AND INTERESTED IN REALLY FIXING THE SYSTEM.

Submitter : **Miss. Donna Clark** **Date: 08/05/2005**

Organization : **Cancer Centers of the Carolinas**

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

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.

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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. Matthew Sulecki** **Date: 08/05/2005**

Organization : **UPMC Cancer Centers**

Category : **Physician**

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

I am a community oncologist. Our practice has already lost millions this year on ASP+6, and CAP will be a nail in the coffin. It ultimately will raise patient care costs. Why not incentivise us to deliver quality?

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.

Please go against CAP. Thank you.

Submitter : **Kathi Dunsmore** **Date: 08/05/2005**

Organization : **Premier HealthCare Associates, Inc**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Practice Viability

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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. Deborah Buenting** **Date: 08/05/2005**

Organization : **Carolina Gyn Oncology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CAP raises major concerns for our practice. We do not feel we would be able to manage the administrative burden on labor and cost to accomodate such a plan. This plan increases the burden of inventory control and billing systems. Our fear is that we will not be able to continue to administer chemotherapy in our office any longer. Currently the demonstration project has made it possible to continue treatment, but even with the demo project, some drugs can't be administered in the office because of the financial impact.

Submitter : **Mr. Douglas Burk** **Date: 08/05/2005**

Organization : **Hematology Oncology Consultants, Inc.**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Background

Background

Practice Administrator for 6 years with a three doc, 20 employee Hem/Onc private practice.

GENERAL

GENERAL

There seems to be way more questions than answers at this point. We are convinced that our practice could not choose to participate and stay in the patient treating business.
Patients treatment plans change so frequently based on un forseen health changes that just the increase in wasted drug would be costly. As a small practice we would need to hire additional Pharmacy staff just to Accept,inspect and track the additional inventory. These people are not cheap nor is the space neccessary to house the inventory. We would also be loosing the revenue we do generate at the ASP +6 now, (about 2%) which would also probably cause staff layoff.

We feel in it's current form CAP is a very bad idea that will cripple the current community cancer tratment practices. If these patients must in stead go to a hospital for care the overall treatment cost will be far higher.

thank you,
Douglas Burk

Submitter : **Dr. Joel Grossman** **Date: 08/05/2005**

Organization : **Naples Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I have a great concern about CAP. Actually, I have many concerns, but I would like to focus on the major one. It might be obvious, but it should be restated that while most physicians are also businessmen, few businessmen are physicians. By that, I mean to emphasize the role of the physician as being the ombudsman for the patient. The physician is responsible for guiding a patient to the best possible medical care. As a physician, when treating the indigent or underinsured for me this often means doing a lot of extra work speaking with insurance companies, filling out forms, begging phamaceutical companies, accepting protrated payment plans or far less (if any) payment, etc. etc. to make sure every possible avenue to get a patient appropriate care is taken. Community oncologists have been doing this for a long time and have been doing it well.

Businessmen, quite frankly, do not concern themselves with such issues.

Know you this:
When you take the financial aspect of chemotherapy out of the hands of the physican you will be decimating cancer care for a significant proportion of the population. When people get behind on their medical bills, as they do very very frequently, your CAP vendors will just cut them off and there won't be diddlysquat that I or other medical oncologists will be able to do about it. Before you implement this system, make sure that you are comfortable with this outcome and with the other byproduct of CAP--that you will be inconveniencing EVERY medical oncologist and cancer patient.

Oncologists have already made it very clear they have no interest in this program; however, the current very flawed system of drug reimbursement may force us all into it...if ASP + 6% is less than acquisition costs, then we all will have to do it, although I suspect most of us will just leave medical oncology practice altogether.

Thank you.

Submitter : **Date: 08/05/2005**

Organization : **Texas Oncology, P.A.**

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

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 : **Dr. Basel Dabas** **Date: 08/06/2005**

Organization : **Dabas cancer Institute**

Category : **Physician**

Issue Areas/Comments

Background

Background

We are striving to care for the cancer patients. and last thing we need now is complicantions and hendrence to our efforts.

GENERAL

GENERAL

Please extend the demonstration progect, cancel the CAP and increase funds for cancer care to help us continue our noble mission of taking care of cancer patients.

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 : **Ms. Ann Bise** **Date: 08/06/2005**

Organization : **Missouri Cancer Associates**

Category : **Other Technician**

Issue Areas/Comments

Background

Background

I work in a rural physician's office oncology clinic.

GENERAL

GENERAL

Please keep health care available for our patient population.

Submitter : **Dr. Karen Roden** **Date: 08/07/2005**

Organization : **Louisiana Oncology Associates**

Category : **Physician**

Issue Areas/Comments

Background

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Implications for Patient Care

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GENERAL

GENERAL

Please consider these comments so that our patients can continue to receive good oncology care.

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.

Regulatory Impact Analysis

Regulatory Impact Analysis

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.

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

Practice Viability

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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 : **Dr. Joel Lamon** **Date: 08/04/2005**

Organization : **Southwest Cancer Care Medical Group**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am a medical oncologist in a single specialty group (Hematology and Medical Oncology). I have been in community practice for 21 years and I believe I have considerable insight into the delivery of complex out of hospital care for cancer and blood diseases. My group has prided itself in being innovative and flexible with regard to delivering cancer care and that has included drugs being delivered to our office for administration. I am very familiar with the problems that can arise regarding timely and acurate care, as well as attempting to control excess administrative costs. We have been very careful in implementing these arrangements and they have been limited and we have local responsible people for complaints and immediate action for problems.

Your might think that my group could easily embrace the proposed CAP system. That is not the case. To say it is flawed is an understatement. It is proposed for one purpose and that is to limit payment to physicians for appropriate care. You are putting into place unfunded mandates for administrative work and physician and nursing time to coordinate care in a currently efficient outpatient activity with intentionally limited hours of operation.

What is your goal? If you wish to spend less, then ration care and drugs. Don't ration by inconvenience.

We do not intend to participate in the CAP program. We have been and will continue to expend considerable energy in assessing the costs of treating a variety of conditions. Our ability to maintain the status quo regarding cancer treatment for Medicare beneficiaries is seriously challenged by the dramatic changes in reimbursement scheduled for 2006 and beyond(I will not comment on the absurdity of including drugs in the volume performance measurement calculations). To participate in the proposed CAP program doesn't just eliminate cost of drug aquisition and potential profit. It also will add considerable variable costs to care of your beneficiaries.

Regarding profit...that is not a dirty word. You are not just paying for drugs as an isolated service...you are paying for a complete package of care that you insist on unbundling. When you order pizza in for lunch, do you ask for line item billing for sauce, dough, cheese, oven time and facility overhead? You obviously are aware that the isolated components are cheaper than the completed product? To extend the analogy; business advisors would recommend abandoning a business in which added value to the components of the product could not be recognized.

Making up for a loss on individual services by increasing volume of services is absurd and may only be observed in medical practices that don't yet know their costs.

CAP is a myopic and seriously flawed concept.

Joel M. Lamon, M.D., F.A.C.P.

Submitter : **Mrs. Alison Williams** **Date: 08/05/2005**

Organization : **Peachtree Hematology '&' Oncology Consultants, PC**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Under CAP, the vendors will have too much control over the selection '&' delivery of drugs. What if the patient can not pay the co-insurance on their drug, will the drug be withheld causing the patient to progress further? How will a change in treatment plan be handled by CAP vendors? As it is now oncologists are able to provide the drugs needed at a moment's notice. These patients cannot wait for the CAP vendors to deliver the drugs when a change in disease status dictates a change in treatment plan.

Submitter : **Dr. Kirti Jain** **Date: 08/08/2005**

Organization : **Ashland Bellefonte Cancer Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

MMA act has significantly reduced payment for drugs to physician outpatient clinics. Still some offices have managed to keep their doors open in anticipation of some relief.

CAP program will completely demolish the cancer care in an outpatient setting in this country. No one knows for sure, how this program will be adminsitered. Who will be responsible for the stability of the drug? Who will mix the drugs? Today we administer drugs even though we may or may not get the 20% of the payment. We work in an extremely rural area where patients often have to choose between food and their medical care. Will these CAP vendors be as sensitive to our patients' needs? I doubt it. Medicare has taken one more step backwards towards a point where access to quality cancer care will be seriously jeoparadized. I have talked to my colleagues, some of whom have already made plans to retire or join a hospital. I think Medicare should have talked to the patients and asked them as to where they would like to be treated? At least our patients prefer an outpatient clinic where they dont have to spend hours filling out the paper work everytime they come in for a treatment. CAP program will prove to be another nail in what is fast becoming a coffin for cancer care in this country.

Submitter : **Mr. Arden Ensminger** **Date: 08/08/2005**

Organization : **Breastlink Medical Group, Inc.**

Category : **Other Health Care Professional**

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

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Submitter : **Ms. Ramona Semanko** **Date: 08/08/2005**

Organization : **Minnesota Oncology and Hematology, PA**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

Practice Viability

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Submitter : **Dr. Torrey Whitworth** **Date: 08/08/2005**

Organization : **The Center for Cancer Care and Research**

Category : **Pharmacist**

Issue Areas/Comments

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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.

Also, 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.

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.