

Submitter : Mary Lyman
Organization : Utah Cancer Specialists
Category : Other Health Care Professional

Date: 07/20/2005

Issue Areas/Comments

GENERAL

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This letter is in response to Interim Final Ruling outlining implementation of the Competitive Acquisition Program. We would appreciate consideration of our comments.

Following is a list of problems associated with CAP implementation:

- 1) While CMS has made concessions concerning emergency availability, the physician will need to maintain a constant stock of drug in order to treat patients. This defeats the purpose of CAP by helping to relieve physicians from the financial and administrative burden of drug acquisition.
- 2) Physician offices will have to maintain additional space and staff to implement the CAP drugs.
- 3) UCS has multiple sites with some sites only open one or two days per week. Receipt of CAP drugs at these sites is problematic and will delay patient care. CAP rules do not allow receipt of drug at one location and transfer to the treatment location.
- 4) The billing criteria and paperwork will increase at the physician level.
- 5) Patients will need to return to the clinics for treatment after their physician visit. This increases patient visits.
- 6) Patients will have to pay double co-pays; one to the physician office and one to the CAP vendor. This increases patient burdens. Additionally, patients who do not send their co-pays to the vendors in a timely manner may not receive needed drug for treatment on time.
- 7) Physician practices will accept the responsibility of another entity getting paid. It is clearly the physician's responsibility to prove justification and documentation in the event a vendor is denied payment for drugs furnished.
- 8) Physicians who elect to participate in CAP will have to maintain two separate systems for purchasing and inventorying drugs.
- 9) This issue of who pays for drug waste has not been effectively addressed.
- 10) The cost of implementing CAP in physicians is not reimbursed, therefore making the program too burdensome for physicians.

Sincerely,

Mary Lyman
Director of Clinical Services
Utah Cancer Specialists

Submitter : Walt Moyer
Organization : Utah Cancer Specialists
Category : Individual

Date: 07/20/2005

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Walt Moyer
CEO
Utah Cancer Specialists

Submitter : Dr. Graydon Harker
Organization : Utah Cancer Specialists
Category : Physician

Date: 07/20/2005

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Utah Cancer Specialists

Submitter : Dr. donald wender

Date: 07/21/2005

Organization : shoa

Category : Physician

Issue Areas/Comments

GENERAL

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I am quite concerned that we will be making a giant step in the wrong direction in our ability to deliver cancer chemotherapy.

**Provisions of the Interim Final Rule
With Comment Period**

Provisions of the Interim Final Rule With Comment Period

I am quite concerned about two main issues. One is that patients expect to be treated the day they are seen. I don't see this as being able to occur with the proposed system. I think this will be a giant step backwards in cancer care. I am also concerned about how timely drugs will be shipped and certainly see a impending disaster in cancer care delivery.

The second issue regards adequate reimbursement for chemotherapy administration. I still think the costs of this are not really addressed. The cost of storage of drugs and training and maintaining equipment and more importantly staff are not accounted for.

Submitter : Mr. Ted Okon

Date: 07/27/2005

Organization : Community Oncology Alliance

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

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Please see attached.

CMS-1325-IFC-15-Attach-1.DOC

Community Oncology Alliance

Dedicated to high quality, affordable, and accessible cancer care

July 27, 2005

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

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

Dear Dr. McClellan:

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

The Community Oncology Alliance (COA) represents community oncology practices across the United States — real doctors treating real patients afflicted with the life threatening disease of cancer. The mainstay of cancer treatment is drug therapy. Cancer drugs are very potent — indeed, many are toxic. For practicing community oncologists, the acquisition of drugs needed to treat patients is critical to successful cancer treatment. We must not only have confidence that we are able to acquire the drugs that we trust, know, and need, but that they will be delivered at the right time and in the right amount for our patients — including patients who struggle financially and may be unable to keep up with co-payments.

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

Unlike the current system that is time-tested and patient safe, the CAP system is new and has never been attempted in community oncology, even on a pilot basis. Given that we are dealing with cancer treatment, oncologists must approach CAP with caution and will want assurances that adequate safeguards are in place should something go wrong. While we are mindful that CMS did make some changes in the Interim Final Rule to address physician concerns raised in response to the proposed rulemaking, major concerns remain. Indeed, overall, we believe that absent fundamental changes and piloting, most community oncology practices will conclude that CAP is simply too risky for patients, too burdensome for physicians, and too costly to implement. Our major concerns are summarized below.

Increased Administrative Burden

While Congress intended CAP to relieve physicians from the financial and administrative burden of the drug acquisition business, the Interim Final Rule actually imposes significant new administrative burdens on physicians and subjects them to increased monitoring and surveillance. Among other things, physicians must do the following:

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Vice President:
Frederick M. Schnell, MD
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Secretary:
Linda Bosserman, MD
California

Treasurer:
John Ogle, CPA
Tennessee

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Connecticut

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Lance Miller, MD
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Carol Murtaugh
Nebraska
Ricky Newton
Virginia
William Nibley, MD
Utah

Lee Schwartzberg, MD
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Frank Senecal, MD
Washington
Robert Smith, MD
South Carolina
Michael Sullivan
Washington

Kurt Tauer, MD
Tennessee
Annette Theis
Florida
Mark Thompson, MD
Ohio
Steve Tucker, MD
California

- Order drugs by individual prescription number
- Provide extensive patient specific information to the vendor so that the vendor can bill CMS
- Wait the necessary amount of time for ordered drug to arrive before treating
- Maintain individual paper, electronic, or physical drug inventories for each patient
- Report actual dose documentation to the vendor
- Provide follow-up information to the CAP vendor each time a planned dose or treatment changes
- File claims within 14 days of drug administration
- File appeals of denied claims and assist the vendor in prosecuting its appeals
- Provide information to the vendor to help with the collection of coinsurance payments
- Track dose specific prescription order numbers per drug
- Add modifiers to drug claims for “furnish as written” or “emergency private stock use” orders.

No compensation is provided to the physician to reimburse the practice for these additional administrative costs; however, if a physician fails to meet the deadline for filing claims, the vendor can file a complaint and initiate an investigation that can result in the physician’s termination from the program.

In light of the increased burden to physicians, CMS must make sure that physicians are adequately informed of all CAP administrative requirements before a CAP election is executed. Unfortunately, unless physicians are relieved of the administrative burdens associated with CAP or are compensated for the time and expense required of the program, physician participation in CAP may be too low to make the program viable.

Access to Medically Necessary Drugs

CAP vendors are not required to provide every NDC code for each CAP HCPCS code. To accommodate orders for drugs not provided by the vendor, the rule provides that physicians will be allowed to obtain medically necessary drugs in “furnish as written” cases. However, CMS states that this provision is to be used rarely and may trigger compliance reviews if used too often. CAP vendors will also be permitted to switch drugs when a particular formulation is in short supply.

While we understand that CMS hopes that market forces will encourage CAP vendors to provide an array of NDC codes for each CAP HCPCS code, physicians must have confidence that vendors will provide all or substantially all medically necessary drugs and will also provide newer drugs as they become available. Restricting physicians’ access to medically necessary drugs will not encourage enrollment in CAP. Further, it will force physicians to maintain and operate two acquisition programs, one for CAP and a second inventory for drugs not available or restricted under CAP.

Drug Deliveries, Order Splitting, Emergencies

The Interim Final Rule provides that CAP vendors must make routine deliveries within two business days of transmittal of an order; emergency deliveries must be made within one business day. While physicians will be permitted to place an order for a beneficiary’s entire course of treatment at one time, the CAP vendors, at their discretion and with notice to the physician, may split orders into different shipments. If drugs are needed immediately, physicians may use CAP acquired drugs to resupply their own inventories, but only if (1) the drugs are needed immediately, (2) the physician could not have anticipated the need for the drugs, (3) the approved CAP vendor could not have delivered the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

Again, CMS states that the emergency resupply provisions should be used only rarely. The delivery time frames, coupled with the restrictive criteria for emergency resupply, fail to acknowledge the realities of community cancer care. On a daily basis, patients present with health status changes that can lead to unplanned and unanticipated changes in treatment that may not constitute an emergency. Nevertheless, if the rules for allowing physicians to resupply their inventories with CAP drugs are not changed, patients who present with health status changes will be forced to reschedule their appointments, delaying treatment and increasing costs to the practice. Statistically, 25% to over 30% of

patients presenting for treatment will have a health status change resulting in drug dosage or medication alterations, a frequency that is inconsistent with the CMS expectations of “only rarely.”

Impact on Rural Clinics

The resupply restrictions will have a particularly harsh impact on low-income patients and those who live in rural areas and must travel great distances, at great expense, to get care. Rural clinics are further impacted by the prohibition against physicians transporting medications. If drugs can only be delivered to the site where they will be administered, additional staffing and storage will be required at satellite sites to ensure that someone is on site to accept, inspect, and inventory deliveries whenever the vendors “delivery of choice” truck arrives.

Physician “Lock-In”

The Interim Final Rule makes clear that once a physician elects CAP, they will be locked into their agreement for one year. While physicians may be terminated from the program if they fail to comply with administrative requirements, physicians do not have the right to opt out of the program even if they are dissatisfied with the performance of the CAP vendor or find the operational/financial burdens of compliance with the program to be overwhelming to their practice.

The lock-in provision, coupled with the lack of a meaningful, structured process for complaints about quality, means that physicians will be captive consumers, unable to walk with their feet. This raises two concerns. First, before making a CAP election, physicians must be able to weigh the risks and benefits of CAP participation. Making an informed choice means they must have access to complete, unbiased, and accurate information about CAP operations and the products and services offered by each vendor. Given the short time frame allowed for consideration of CAP election, CMS must do more to ensure that physicians are properly educated and informed about CAP before they make an election. We are recommending that CMS require CAP vendors to provide physicians with a disclosure form and to certify that they have accurately disclosed all program features including administrative requirements, technical/software requirements, penalties, restrictions on delivery, transporting of drugs, etc.

Second, absent the ability to terminate a CAP election, vendors will be serving a captive customer base and will have little incentive to respond promptly to concerns about quality. Given the potential impact on patient care, we believe that physicians must be able to terminate a CAP election agreement for cause at any time.

Vendors’ right to stop shipment for non-payment of co-pays

If a patient fails to pay a co-payment after 45 days, a CAP vendor may refuse further shipments to the CAP physician for that patient, unless the patient requests cost sharing assistance. If such assistance is requested, the CAP vendor has certain defined responsibilities including a requirement to refer the patient to a bona fide charity, implement a reasonable payment plan, or provide for a full or partial waiver. If the patient is referred to a charity, the CAP vendor may refuse to ship drugs if the past-due balance is not paid *in 15 days* after the postmark date of the vendor’s written notice to the patient containing the referral. Vendors may also stop shipment of drugs if a patient is more than 15 days late with a payment under a payment plan.

The ability of a CAP vendor to unilaterally stop shipment of drugs for non-payment of co-pays is extremely disturbing to community oncologists. Stopping shipment literally means that a course of cancer treatment will be interrupted or will end. Unlike oncologists, CAP vendors have no relationship to the cancer patient and no ethical or legal obligation to provide treatment. Yet, rather than make it difficult for vendors to stop shipment, CMS has created a rule that actually makes it relatively painless to stop shipments of drugs that are needed to treat life threatening illnesses. Specifically, under the Interim Final Rule, vendors may, but are not required, to provide information to the patient about cost-sharing assistance. There is no requirement that a patient or a physician receive notice about a pending cut off and there are no appeal rights. Further, the time frames for obtaining charitable assistance and for allowing a vendor to stop shipment for non-compliance with a payment plan are ridiculously short.

Our experience tells us that those most affected by these rules will be disproportionately poor and elderly. Some may even be entitled to cost-sharing assistance through Medicaid. In short, CMS' rule fails to adequately protect Medicare beneficiaries. Either patients will get sicker or be forced into more costly hospital settings, or they will die. In summary, allowing vendors, who are not medical professionals and who have no relationship to the patient, to have the authority to effectively stop a patient's course of treatment for a life threatening disease is unethical and unconscionable. No oncologist will be able to sign a CAP vendor agreement if this provision is allowed to stand.

Dispute Resolution

If a CAP vendor is not providing satisfactory service to the physician, the physician's recourse is first, to address it through the CAP vendor's grievance process and second, raise the issue through an alternative dispute resolution process administered by the designated carrier and CMS. In alternative dispute resolution, the designated carrier will review the CAP vendor's performance and potentially recommend termination of the approved CAP vendor's contract. A recommendation to terminate a CAP vendor's contract must be reviewed by CMS and is subject to the CAP vendor's right to reconsideration and informal and formal hearing procedures. The Interim Final Rule does not specify a time frame for this process, nor does it provide the physician with interim relief pending the final resolution of the dispute.

Oncologists treat patients with life threatening illnesses. If a community oncologist experiences problems with a drug vendor, he or she requires immediate relief. Community oncologists must have the ability to opt out of CAP pending resolution of disputes and CMS needs to specify time frames for each stage of the dispute resolution process.

Extra Costs Introduced

Because we deliver cancer care on a daily basis, we are confident in coming to the conclusion that CAP will introduce significant additional costs to Medicare, and therefore, American taxpayers. These costs will include waste (patient treatment changes), administrative and shipping charges of CAP vendors, and the profit of CAP vendors. Introducing a middleman — especially one put between the physician and the patient — will only increase costs. Additionally, CAP vendors will not write off bad debt, as community oncologists do. They will likely deny drugs to the patient, if the patient cannot find financial assistance.

Conclusion

In the past year, community oncology practices have had to expend precious time and resources to absorb what were fundamental changes to Medicare reimbursement for cancer care. Now, we are being asked to consider a conceptual, entirely new, and untested system of delivering drug treatment. Especially given the critical nature of cancer treatment, we are extremely concerned that this system is being introduced nationwide without any analyses and testing. Additionally, as designed, CAP is not the type of patient-centric treatment delivery system that has been designed around the needs of patients, as well as the realities of delivering oncologic treatment and care. Rather than put the needs of patients first, CAP is designed to ensure that CAP vendors are able to capture market share and make money on the most profitable drugs. Absent safeguards to ensure patient access to medically necessary drugs and provision of high quality services to physicians, the CAP program unfortunately falls far short of being a viable alternative acquisition program.

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

Again, we thank you for the opportunity to comment on CAP and welcome the opportunity to work with CMS to reform Medicare reimbursement such that it retains the hallmarks of community oncology — quality, accessible, and affordable cancer care.

Sincerely,

A handwritten signature in cursive script that reads "Leonard Kalman MD". The signature is written in dark ink and is positioned above the typed name.

Dr. Leonard Kalman
President