

Submitter : Mr. James Middleton
Organization : Summit Pointe
Category : Health Care Professional or Association

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

April 25, 2005

Dear Members of the CMS:

Thank you for this opportunity to present my comments on the proposed program for drug acquisition under the Medicare Modernization Act (specifically, CMS-1325-P).

Having served for a local community mental health agency for seven years, I have seen the results when continuity of care is compromised. Not only does the patient suffer the consequences of abrupt discontinuation of drug therapy, but the ultimate cost is pressed upon the area's health care infrastructure with additional hospitalization costs and extended use of tightly-budgeted resources and personnel.

I am, therefore, thankful that the Competitive Acquisition Program does not make use of a potential option barring mental health drugs. The final rule, however, could go further to assure that the phasing in of coverage for mental health patients moves in tandem with the proposed timetable of January 1, 2006. In addition, the creation of a category for mental health drugs should include long-acting antipsychotic agents; and, since so many already-challenged patients abandon therapy when co-payment processes are perceived as unduly elaborate, that these processes are made as consumer-friendly as possible.

The existing challenges for patient compliance are frequently perceived as heroic. The benefits of smoothing the paths for mental health care are equally great.

Again, thank you for your time.

I remain,

Sincerely,

Jim Middleton, BS, RPh, MCTE

Consultant Pharmacist

Submitter :

Date: 04/25/2005

Organization : Infectious Diseases Society of America

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1325-P-302-Attach-1.DOC

Submitter : Mr. Mike Moseley
Organization : Division of Mental Health
Category : State Government

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : Dr. Jerry J. Ransom
Organization : OmniSYS, Inc.
Category : Health Care Industry

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1325-P-304-Attach-1.DOC



P.O. Box 8489, 2824 Terrell Road, Suite 602 • Greenville, TX 75404-8489 • Phone: 903.455.0461 • Fax: 903.455.7910

April 25, 2005

The Honorable Mark McClellan, MD, Ph.D.
Administrator
The Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 20201

Via Electronic Mail

Attention: CMS-1325-P

Re: Comments on Proposed Rule: Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B CMS-1325-P (42 C.F.R. Part 414) (70 Fed. Reg., March 4, 2005)

Dear Dr. McClellan:

OmniSYS, Inc. submits the following comments from a healthcare technology perspective as one of the highest volume submitters of Medicare Part B claims nationwide. OmniSYS will apply its practical experience and domain expertise to develop a web-based management system that incorporates all of the "claims processing" functionality outlined in the Proposed Rule.

The system will e-capture physician's orders and beneficiary information including eligibility verification, deductible status and supplemental payor information; verify medical necessity across Local Carriers; coordinate electronic billing of "Designated" and "Local" carrier claims; post and reconcile electronic remittance for collection of coinsurance and/or coordination of supplemental payor benefits; process payment adjustments; and, perform inventory management if required. OmniSYS regularly submits claims to Local Carriers and Durable Medical Equipment Regional Carriers (DMERC's) for over 17,000 providers nationwide.

As such, OmniSYS elected not to comment on specific sections of the Proposed Rule that address certain patient, provider, formulary or payor issues. Rather, our comments are reflective of issues that affect development of processes, which in aggregate will comprise a comprehensive, secure and scaleable system that reduces the cost of healthcare through the application of technology.

Specific OmniSYS comments to follow:

1. Competitive Acquisition Areas (p 10752-10753). OmniSYS' web-based client-server tool will be secure, scaleable and ubiquitous and, as such, deployable across national or regional markets. The determination of Competitive Acquisition Geographic Areas should be independent of claims processing approaches or the technology applied.
2. Statutory Requirements Concerning Claims Processing (p 10753). Overpayments and adjustments are currently submitted to the various Medicare Carriers via a variety of customized, carrier-specific paper forms. As a part of this program, OmniSYS recommends that Medicare adopt electronic standards for processing overpayments and adjustments.

"Reducing the Cost of Healthcare Through Technology."

3. Claims Processing Overview (p 10754-10757). The Proposed Rule is inconsistent with regard to billing criteria for physician's services and drugs. There are significant differences between Local Coverage Determination Policies (i.e. Medical Policies) related to medical necessity. As currently proposed, reimbursement for physician's services will be based on Local Carrier Rules; reimbursement for drugs will be based on Designated Carrier Rules. While the Proposed Rule addresses "Local Coverage Determination", it is not specific as to whether the "Local" or "Designated" policy will apply when there are differences – essentially, will Local Carrier Determinations always "trump" Designated Carrier Determinations. This issue should be clarified in the Final Rule.
4. Claims Processing Overview (p 10754-10757). OmniSYS suggests that National Drug Code (NDC) should be included as part of the information exchanged between the Physician and Drug Vendor. As discussed in the Proposed Rule, a single HCPCS frequently represents multiple drugs (i.e. multiple NDC's). Within the drug industry, NDC uniquely identifies the drug as well as its package size and strength, which may be required to identify specific billing codes (HCPCS), affix billing code modifiers or calculate appropriate billing units.
5. Claims Processing Overview (p 10754-10757). OmniSYS agrees that physician's orders should apply to an entire course of treatment even if the physician's order is fulfilled via "appropriately spaced shipments" identified by separate prescription numbers for each shipment. In addition, it should be possible for physicians to modify the course of treatment as required.
6. Claims Processing Overview (p 10754-10757). OmniSYS is concerned that patients (particularly seniors) will view the administration of services as a "single event" and, as such, will be confused when billed separately for drugs and physician's services, which may affect the collection of deductibles and coinsurance associated with these claims. OmniSYS recommends that the Secretary adopt procedures for submitting claims for drugs and physician's services in tandem in order to mitigate beneficiary confusion and possible "race conditions" related to claims payment.

Please contact the undersigned or Ms. Heather Benzi at 800.448.6891 if you have questions or suggestions regarding these recommendations. We appreciate the opportunity to submit these comments from a claims processing perspective.

Respectively submitted,

Jerry J. Ransom, Ph.D.
President – CEO
OmniSYS, Inc.
800.448.6891

jerry_ransom@omnisys-inc.com
heather_benzi@omnisys-inc.com

Submitter : Ms. Lynn Clark
Organization : Mental Health Association in Texas
Category : Consumer Group

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

Mental Health Association in Texas
1210 San Antonio Street, Suite 200
Austin, Texas 78701
512/454-3706 512/454-3725 FAX
Molly Van Ort, Board Chair
Lynn Lasky, LMSW, President

April 25, 2005

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

Dear Dr. McClellan:

On behalf of the Mental Health Association in Texas, I am writing to you regarding the Center for Medicare and Medicaid Services' (CMS') proposed regulation [CMS-1325-P] to establish a Competitive Acquisition Program (CAP) for medications covered by Medicare Part B. We are particularly interested in the impact this regulation will have on access to mental health medications and encourage you to include mental health medications in the list of medications covered by the CAP program as of January 1, 2006.

Unfairly, Medicare imposes more restrictive limits and much higher out-of-pocket costs for mental health care than for the care of other illnesses. Of particular concern is the 50 percent co-payment that applies to Part B coverage of outpatient mental health services, instead of the usual 20 percent required for other outpatient care. This unequal and unfair barrier to treatment for individuals with mental illness under the Medicare program is inconsistent with growing and widespread recognition that mental illnesses are real and can be severely debilitating without treatment.

As you know, mental illness affects a very large segment of the Medicare population, but with the discriminatory restrictions and added costs imposed on mental health treatment under this program, few receive the treatment they need. Some 20 percent of older Americans and 40 percent of those on Medicare because of a disability, face mental illness. Yet, all too often they struggle with this disease alone, without treatment and support. In fact, research indicates that two-thirds of those who need mental health care do not receive it. This lack of care has tragic consequences as illustrated by the fact that older adults have the highest rate of suicide in the country, accounting for 20 percent of suicide deaths.

This high co-payment requirement for mental health services has also impeded access to certain types of mental health medications covered by Medicare Part B such as injectible anti-psychotic medication. Overly complex and confusing reimbursement policies for this type of medication have caused physicians to discontinue use of it for financial reasons instead of therapeutic reasons. The heightened risk of non-reimbursement associated with this type of medication also discourages physicians from offering it to consumers who may benefit from it.

Mental health disorders require highly individualized treatment and mental illnesses vary greatly in their symptoms and effects on consumers. In prescribing mental health medications, physicians must take into account myriad factors including past treatment history, likely responses to side effects, other medications currently being taken, any co-morbidities (which are common among individuals with mental illness), and overdose safety, given the heightened risk of suicide. As a result, in order to receive effective treatment, consumers need access to the full array of treatment options.

Again, we encourage you to include mental health medications in the list of medications covered by the CAP program as of January 1, 2006. The inclusion of these medications in the CAP program would conform with the recommendation by President Bush's New Freedom Commission on Mental Health. Thank you for your consideration of our views.

Sincerely,

Lynn Lasky Clark, LMSW
President and CEO

Submitter : Mrs. Denise Paretti
Organization : Mrs. Denise Paretti
Category : Individual

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1325-P-306-Attach-1.DOC

April 25, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-8010

Attention: CMS-1325-P

To Whom It May Concern:

I have grave concerns about the proposed CAP Rule and what effect it would have on community based cancer centers.

Oncology is unlike any other field in the medical profession. Not only does it require highly trained physicians, it also requires highly trained personnel: ie., nurses, assistants, and professional clerical personnel to administer to critically ill patients.

Oncology drugs have to be delivered in a safe manner to insure their viability. To have chosen vendors does not allow our physicians to have choices over what drugs they would use to treat individual patients. It would be at the sole discretion of vendors to decide between generic or name brand. The rule states we could order entire regimens for patients; however, the vendor would decide if it would be divided into separate shipments. Most oncology patients have changes in their clinical situation on a regular basis. In these situations, I believe the CAP rule would allow shipment of the appropriate drugs to be delayed which could cause physical harm to patients.

I know physicians have a choice to stay with ASP. However, ASP is not what it should be. I feel it needs to be reevaluated also before allowing physicians to make their choice of the two programs.

Many practices in community setting will have to close their doors under the CAP Rule which would lead to only hospital access for patients. This would be a step backwards as patients do not want to be hospitalized for any type of treatment.

Please consider taking more time to reevaluate the proposed rule. Remember it is the patient who will lose. Any consideration for not implementing this rule is greatly appreciated.

Sincerely,

Denise Parette

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Dr. Renwick Goldberg
Organization : Coastal Cancer Center
Category : Physician

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1325-P-307-Attach-1.DOC

April 25, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-8010

Attention: CMS-1325-P

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Please consider taking more time to reevaluate the proposed rule. Remember it is the patient who will lose. Any consideration for not implementing this rule is greatly appreciated.

Sincerely,

Denise Paretti

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

April 25, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Attn: CMS1325-P

Dear CMS,

I would like to thank you for the opportunity to comment on the Competitive Acquisition Program. I am a practicing medical oncologist in the South Carolina and I don't believe the proposed Competitive Acquisition Program is will serve the patients best interest in a community based cancer treatment facility.

Treatment for patients who are diagnosed with cancer requires flexibility. Often medication dosing adjustments and/or complete change in medications need to be made immediately due to patient's toxicities of treatment. The CAP program does not allow for this flexibility of making important decisions regarding treatment for patients with life threatening cancer. Based on the proposed CAP rule, there would be delays in making therapeutic changes, The vendor would need to be contacted to have new medications shipped to our office to provide appropriate treatment changes which causes time delays for treatment which can be critical for patient's with debilitating and life threatening cancer.

I feel the billing system and ordering process will be cumbersome. It is very unclear in the process of the vendor supplying a drug which is not administered to the patient on the expected date of treatment where as the physician is to notify the vendor and "reach an agreement on how to handle the unused drug consistent with applicable state and federal law". I see no vehicle for the handling of waste disposal and cost of keeping the drugs viable, either in the doctor's office or potential return shipment to the vendor. This problem of a supplied drug not used will be a significant issue for practicing oncologists throughout the country.

The billing system rules in regard to vendors working with physicians in making sure claims are submitted in a timely manner are very unclear in a situation where chemotherapy drugs are very costly. I would be concerned with vendors not providing appropriate drugs to the physician in a timely manner to best treat their patients. Also, there is no coverage for patients who do not have secondary co-pay insurance with the proposed CAP rule.

Overall, I feel that the Competitive Acquisition Program is cumbersome, burdensome to practices and staff, and will be a detriment to the quality of care that has been established throughout the country in community cancer care. In the Myrtle Beach area of South Carolina we have created an outstanding community cancer care program to allow life saving treatment for patients with malignant diseases.

Thank you for the opportunity to comment on the proposed program. I cannot recommend use of the Competitive Acquisition Program. There clearly needs to be more time spent on this program inn working out mechanisms for optimal drug delivery and treatment for patients requiring therapy for life threatening malignancies. I feel that patients should not be penalized for changes in the drug delivery system as under the proposed CAP rule provided by CMS.

Sincerely,

Renwick N. Goldberg, M.D.
Coastal Cancer Center
8121 Rourk St
Myrtle Beach, SC 29572
843-692-5000
www.coastalcancercenter.com
BV/cjc

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Dr. Paul Greenberg

Date: 04/25/2005

Organization : Dr. Paul Greenberg

Category : Physician

Issue Areas/Comments

1-15

Overview of the CAP

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement.

As a result, 2005 Medicare reimbursement for cancer care services is considerably higher than pre-MMA rates. However, total reimbursement will drop dramatically on January 1, 2006, when the demonstration project is scheduled to end and the drug administration transitional factor will be zeroed out.

It has been calculated that the impact of these changes will translate into a \$940 underpayment for drug administration services per Medicare beneficiary. Put another way, 2006 Medicare reimbursement for patient care services will cover only an estimated 50.09% of drug administration costs.

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who choose to give up the traditional buy-and-bill model and select the CAP model instead. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

CMS expects CAP to appeal to those physicians who do not want to be in the drug procurement and drug coinsurance collection business? [70 Fed. Reg. 10750]. Indeed, statements made by CMS and CAP's Congressional authors all reinforce the notion that CAP is intended to be an option that physicians may choose to adopt in place of the current buy-and-bill model. According to the MMA Conference Report produced by Congress, "Conferees intend this choice to be completely voluntary on behalf of the physicians?" [H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)].

And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even greater should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services which will fall well below the cost of providing drug administration services.

In light of the reimbursement shortfall that looms on January 1, 2006, many cancer care specialists will face a very different choice than the one that Congress intended: continue to offer cancer care services to seniors (under buy-and-bill or CAP) and incur a significant net loss? or discontinue offering chemotherapy services to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

Congress has clearly stated its intent that patient access to community cancer care must be preserved because it is the source of convenient, cost-effective care for more than 4-out-of-5 American cancer patients. If CMS intends to abide by this intent, it must take additional steps to align Medicare reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Contracting Process-Quality and Product Integrity Aspects

Issue Identifier: Contracting Process ? Quality and Product Integrity Aspects

In an effort to ensure the stability of CAP, MMA directs CMS to require CAP vendors to meet standards for quality, service, financial performance and solvency that include appropriate procedures for the resolution of physician complaints and grievances. Unfortunately, the statute offers few specifics regarding these standards, and the proposed rule does not define all of the standards to which the vendors will be held. As it has done in the DMEPOS Supplier manuals, CMS should issue CAP guidance that defines measurable quality, service, financial performance and solvency standards.

With respect to Quality and Service Standards, I believe CMS should focus on standards related to shipment errors (e.g., wrong drug or dose; wrong quantity; damaged packaging; inadequate refrigeration; counterfeit product, etc.) and timely deliveries, both for routine and emergency deliveries. I also believe that the required physician call centers need to operate a minimum of 12 hours per day and that call management standards should tightly limit ring time, hold time, and dropped calls.

When it comes to Clinical Standards, I applaud CMS's decision to make the local carriers the arbiters of coverage and medical necessity decisions. In oncology, drugs can be extremely expensive, compendium-supported off-label usage is statutorily mandated, and off-label usage supported by peer-reviewed literature is also commonly reimbursed. As a result, CMS is right not to place decisions about coverage and medical necessity in the hands of vendors.

I am concerned, however, about the administrative burden on physician practices that will result from the CAP Election Agreement's requirement that physicians appeal all denied drug administration claims. The proposed rule provides no guidance on how many levels of appeal the physician must pursue, but the draft Election Agreement requires appeal through the reconsideration level. For clarity, we urge CMS to include this limitation in the final rule. The burden of appealing every denied drug administration claim is heightened by the pending changes in the claims appeal process that become effective on May 1, 2005. Given the magnitude of those changes, CMS should require the CAP vendor to request clinical literature from drug manufacturers needed to support appeals of drug administration denials.

I am also concerned that the proposed rule ignores the significant risk that physicians could face litigation over adverse drug events due to drugs provided by a CAP vendor. I strongly urge CMS to require CAP vendors to indemnify physicians for all costs, including reasonable attorney's fees, associated with the defense of all such actions where the physician is ultimately exonerated. The indemnification may be prorated if the physician is found to be partly liable and there is a rational basis for apportioning costs between the CAP vendor and the physician.

With respect to Financial and Solvency Standards, I commend CMS's decision to assess CAP bidders using Federal Acquisition Regulation (FAR) criteria, adopt FAR business integrity and conflicts of interest standards, and review third-party information on the structure and effectiveness of CAP bidders' internal control systems. The proposed rule does not specify how CMS will ensure ongoing compliance with vendor performance requirements, however, so CMS should issue a detailed guidance document, require CAP vendors to report key performance statistics quarterly, and consider imposing contractually defined financial penalties for sub-par performance in addition to the imposition of False Claims Act liability that vendors face.

Claims Processing Overview

Issue Identifier: Claims Processing Overview

I am concerned that the proposed rule's delivery standards could pose a significant risk of increased financial and clinical costs to cancer patients. Today, cancer care practices routinely maintain a drug inventory to meet their patients' treatment needs. This has enabled practices to accommodate changes in patients' treatment plans without requiring the patient to return for therapy on another day. Under CAP, however, this level of service could be difficult if not impossible to maintain.

If chemotherapy sessions must be rescheduled to wait for the delivery of the drug(s) that patients need, they will face additional coinsurance obligations for the repeat physician services. In addition, patients will face other financial burdens in the form of higher transportation costs and additional missed time from work. This situation may also mean missed work time and reduced productivity for family members and other caregivers who must bring beneficiaries to the rescheduled treatment sessions.

I recognize that Social Security Act 1847B(b)(5) and the proposed rule permit physicians to receive replacement product from their CAP vendors for drugs taken from the physician's inventory. Even if CAP physicians had a sufficient inventory to draw from, this option appears too narrowly tailored to save most patients from having to undertake a return trip and bear the cost of an additional coinsurance payment. Specifically, the use of the replacement program is limited to situations where the physician builds a record to demonstrate all of the following to the local carrier: (1) the drugs were required immediately, (2) the physician could not have anticipated the patient's need for the drugs, (3) the CAP vendor could not deliver the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

There are a few glaring problems with the inventory replacement option. First, neither the statute nor the proposed rule defines "emergency." Moreover, neither the proposed rule nor the preamble discussion explains what a physician would have to show to justify immediate need or how the local carrier will assess whether the physician could have anticipated the patient's drug needs sufficiently far in advance to permit delivery via the CAP vendor. Aside from the risk that the claim for replacement drug will be denied by the local carrier, the administrative burden of building this record may discourage many physicians from using the inventory replacement option. The inventory replacement option also raises the question about whether commercial insurers are being asked to subsidize a portion of the drug costs for Medicare beneficiaries in CAP, since Medicare would not be paying a physician for the ordering, financing, inventorying and handling costs associated with drugs borrowed from the practice's inventory.

I am even more concerned about what this option could mean for patients, since it is not at all clear that oncology practices will be able to maintain full inventories after the implementation of CAP. Depending on their patient bases, the range of drugs that some practices would need for Medicare beneficiaries may not be the same as the drug inventory that the practice would stock for commercial patients. Moreover, if CAP encourages the proliferation of mandatory vendor imposition (MVI) programs among commercial carriers, it is likely that some practices may stop maintaining drug inventories altogether.

In sum, patients may be forced to pay both a financial and clinical price for treatment disruptions due to CAP, potentially exposing them to medical complications and increased emergency hospitalizations in addition to repeat visits and higher cost-sharing obligations.

Contract Requirements

Issue Identifiers: Contract Requirements

The World Health Organization estimates that 6% of all drugs distributed in the world are counterfeit and some observers believe it to be as high as 12%. Since most counterfeit drugs in the US enter the chain of commerce through the secondary market, I applaud Congress' decision to require CAP vendors to acquire all of their drugs directly from the manufacturer or from a wholesaler that buys direct.

Product integrity is about more than blocking the distribution of counterfeit goods, however. That is why I am concerned that the Proposed Rule's provisions could jeopardize product integrity and violate state licensing laws.

I suspect that CMS may not have thought through licensing and product integrity issues because it seems to have concluded that CAP vendors should be licensed as wholesalers but not as pharmacies. Indeed, many provisions in the Proposed Rule and the entire discussion of product integrity in the preamble focuses on wholesale distributors.

I am convinced that CAP vendors must be licensed as pharmacies, however. The statute does not expressly define the class of trade of a CAP vendor and 1847B(b)(4)(C) could suggest that Congress viewed CAP vendors as wholesalers. And yet, Social Security Act 1847B(b)(6) seems to take a different position, stating that nothing in Social Security Act 1847B shall be construed as waiving applicable State requirements relating to licensing of pharmacies. CAP vendors must be licensed as pharmacies because they will accept patient-specific written orders for prescription drugs from physicians, assign prescription numbers to those orders, interpret the orders, presumably making generic substitutions as appropriate and permissible under applicable State law, and then transfer dispensed drugs to the prescribing physician for administration to the patient. This patient-specific transfer amounts to "dispensing" a drug under state pharmacy practice acts and because CAP vendors dispense, they are practicing pharmacy and must be licensed accordingly.

Since CAP vendors must operate as licensed pharmacies, some of the operational aspects of CAP seem unworkable or in need of retooling. For example, state pharmacies laws do not permit a pharmacist to assign different prescription numbers to successive fills of a single prescription. Rather, prescription refills are

CMS-1325-P-308

always dispensed under the prescription number assigned to the original written order. A new prescription number is assigned only when a new written order is received. These practices are inconsistent with the prescription numbering system described in the preamble to the Proposed Rule.

Another critical problem is posed by CMS's proposal for dealing with CAP drugs that cannot be administered to the beneficiary for whom they were prescribed. Most state pharmacy laws prohibit the restocking of unused drugs after they have been dispensed. By establishing a process for the restocking and use of previously-dispensed drugs, however, the proposed rule appears to put the physician in the position of aiding and abetting the violation of these state pharmacy laws. In fact, none of the laws of which I am aware allow dispensed product to be redirected to another patient without going back to the dispensing pharmacy first.

Redirecting unused drugs dispensed by a CAP vendor from the intended recipient to another patient could expose physician practices to tort liability. Physicians participating in CAP will therefore need indemnification from CAP vendors when reuse decisions about drugs belonging to the vendor, not the physician, are made based on discussions with the CAP pharmacist. CMS should build requirements for appropriate indemnities into the final rule.

Submitter : Mr. Phillip Saperia
Organization : The Coalition of Voluntary Mental Health Agencies
Category : Other Association

Date: 04/25/2005

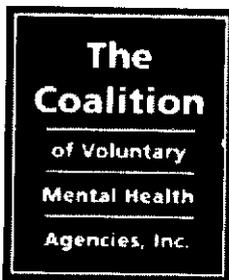
Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-309-Attach-1.DOC



90 Broad Street
New York, NY 10004
Phone 212.724.1600
Fax 22.742.2080
mailbox@cvmha.org
www.cvmha.org

April 25, 2005

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

Dear Sir/Madam,

I am writing regarding the proposed rulemaking published in the March 4, 2005 Federal Register concerning the "Medicare Competitive Acquisition Program" (CAP) for Part B drugs. We strongly support the proposed rule which has tremendous potential to benefit individuals with severe and persistent mental illnesses for whom injectable medications are life-saving. The rule would relieve many providers of the financial risk and administrative burdens associated with filing and tracking claims. We want to ensure that Part B address the needs of our community behavioral health providers

The following comments are submitted on behalf of our 120 behavioral health provider members in the New York City area.

- Include psychiatric drugs in the CAP program.
- Include psychiatric drugs in Phase I. It is important that CMS include psychiatric drugs in the initial stages of CAP to alleviate barriers to access inherent in the current system.
- Inclusion of a Mental Health Drug Category. It is important that CMS create a category that includes mental health drugs, including long-acting injectable antipsychotics.
- Preventing discontinuation of therapy by vendors by defining a reimbursement process that adequately addresses the handling of co-pays and other payment issues that could threaten the continuity of therapy.

CAP has the potential to bring new psychiatric therapies into wider use and to significantly improve the quality of care for some of the

vulnerable people in our society. We urge you to include coverage of antipsychotic injectable medications in the drug categories that compose the initial phase of CAP implementation.

Sincerely,

A handwritten signature in black ink, reading "Phillip A. Saperia". The signature is written in a cursive style with a long horizontal flourish at the end.

Phillip A. Saperia
Executive Director
The Coalition of Voluntary Mental Health Agencies, Inc.

Submitter : Mrs. Joan Grimes
Organization : Urological Associates of Southern Arizona
Category : Other Health Care Professional

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

I am the practice administrator for eleven urologists in Tucson, Arizona. My doctors are VERY concerned about the proposed CAP that will become effective January 1, 2006. I offer the following issues of concern regarding this legislation:

--It seems premature to roll out this new program without having tested the program on a smaller scale. It is certain that logistical problems will occur and it would be desirable to have these ironed out prior to implementation.

--CAP does not pay the physician for any additional administrative costs to maintain separate claims, develop and file patient care plans, appeal denials, provide the CAP vendor with patient billing information and track inventory though it is obvious that there will be additional staff time allocated to these activities.

--The new law allows CAP vendors the opportunity to appeal to CMS for additional compensation to cover their inventory/acquisition costs above and beyond what they will be paid for the drugs. This seems inherently unfair since there is no opportunity for the physicians to obtain a similar recovery.

--Physicians are required to declare their participation in CAP before they know what the new quarterly ASP rates are going to be. A more fair way to conduct enrollment in CAP would be to fix the ASP pricing for one full year so that everyone understands the financial impact for CAP participation. This further prevents financial risk to the physicians mid-year as ASP pricing changes quarterly.

--Physicians are faced with a lose-lose situation financially. If they opt into CAP they cannot leave for one full year. If they experience problems with the vendor or experience additional administrative costs they are not allowed to return to the ASP+6% program for 12 months. If they opt for the ASP+6% program, the ASP pricing (which will be adjusted quarterly) is likely to be reduced due to the purchasing power of the CAP vendors. So, the ASP could drop below the physician's acquisition cost before there is an opportunity to opt out in to the program. Either way, Congress is asking the physician to be financially at risk for this new program.

--CMS is also contemplating another 4.3% reduction in fees for 2006. We are approaching the point where office overhead expenses are going to exceed practice revenue. The problem is compounded when most other managed care contracts are linked to the CMS fee schedule. These are go out of business strategies and many physicians will be forced to close their practices to Medicare enrollees.

There is already a projected shortage of urologists as our population ages. Urologists already took a 10% cut in drug reimbursement for 2005 which was NOT made up for with general increases in the remaining fee schedule. Urologists generally treat prostate cancer using androgen suppression therapy. We are approaching the point where castration may offer the least costly option. Is it the intent of Congress to legislate treatment options for Medicare enrollees? What would constituents think if their only choice for prostate cancer was castration? I believe that Congress needs to evaluate the CAP position very closely before implementing this program on a widescale basis. Thank you.

Submitter : Mr. Marcus Elliott
Organization : Wenatchee Valley Medical Center
Category : Health Care Provider/Association

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-311-Attach-1.DOC

Wenatchee Valley Medical Center, established in 1940, is a multi-specialty group practice with a regional focus and a commitment to serve patient needs by providing the highest quality healthcare and services in an atmosphere of concern that works to ensure patient safety. With 172 physicians and 35 mid-level practitioners providing comprehensive medical and ancillary services, we are the third largest multi-specialty clinic in the Pacific Northwest. Our physicians provide primary care to area residents and also draw patients from throughout the region for specialty care.

The rural heartland of the Pacific Northwest is an unusual place to find a state-of-the-art medical center. Wenatchee Valley Medical Center, with its seven locations, serves an area of roughly 12,000 square miles, a region larger than the state of Maryland.

Wenatchee Valley Cancer Treatment Center is an integral part of this organization. Its goal is to provide state of the art care accessible to the 240,000 persons in Central Washington. WVCTC is comprised of four Hematology/Oncology Physicians, two Radiation Oncologists, two Nurse Practitioners, and six General Surgeons. There are three clinic sites each supported by a specialized RN staff to provide case management and infusion services. We diagnosed and treated over 1100 new cases of cancer, with over 13,000 patient visits and over 6000 infusion/chemotherapy treatments.

We agree that the current system needs reform however, a reduction in Medicare payments for chemotherapy drugs without recognizing the longstanding underpayment of essential direct patient care services will result in reimbursement for services at rates less than the actual cost of providing patient care. If enacted these provisions will cut Medicare funding for cancer care by over 30 percent. The impact will be a significant disruption in the cancer care delivery system, including access to basic cancer care services that remained viable this year because of the Quality of Care Demonstration Project.

In its implementation of the Medicare Modernization Act of 2003 (MMA), Congress and the Centers for Medicare and Medicaid Services (CMS) has sought to adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Our comments today focus on the implementation of the Competitive Acquisition Program (CAP) for 2006. This program was developed to allow the oncology physician to opt out of the drug purchasing, inventory, and billing components of a complicated and expensive process in providing and overseeing patients in cancer treatment.

We do not endorse the CAP or ASP provision of Congress's MMA. These are a few of the issues that must be addressed:

- Patient Safety
- Patient access to service
- Viability of oncology practices
- Timely delivery and administration of medications
- Formulary control by Vendors
- All Medicare Part B drugs in initial rollout of CAP
- ASP combined with low reimbursement for administration
- The loss of the Quality of Care Demonstration Project
- Delays in diagnosis and treatment
- Burdensome physician, pharmacy, and nursing requirements with no recourse for Vendor shortcomings
- Uncompensated costs of drug handling and inventory management

If CMS institutes the CAP program as written by the end of November 2005 we will have to decide if we will continue to be at risk for drug inventory and reimbursement or sign a one year binding contract with a vendor chosen by CMS for our region. Neither CMS nor Congress has recognized that the viability of either of these two choices depends upon the adequacy of reimbursement for drug administration services. Unless changes are made, we like many oncologists will face a loss under the buy-and-bill model and a loss that will be even greater should they opt to participate in CAP. This is because the only reimbursement received under CAP is drug administration – which will fall well below the cost of providing drug administration services. If this is allowed it will cause us to re-evaluate services and populations of patients to whom we provide services.

It was not Congress's intent to decrease access to care but if these valuable services are not provided in community cancer centers such as ours then the cancer patients and their families will have no choice but to travel to hospitals in a few regional facilities to receive care. This will surely impact care by delaying diagnosis and treatment. This will also increase the economic burden on patients and families as they will have to take more time away from work to transport and care for loved ones away from home.

Again, if CMS intends to avoid this effect then it must take additional steps to align reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006

Physician Fee Schedule must be published. As a result, we urge CMS to extend the quality demonstration project while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy

We also understand that the design and implementation of a CAP for part B drugs is an enormous undertaking. Cancer drugs are highly sophisticated and volatile substances, many of which are time and temperature sensitive and must be mixed and delivered with great care to ensure patient safety. The drug infusion process requires skilled clinical professionals to mix and administer the chemotherapy and closely monitor patient reactions. These services will suffer if the quality of drug handling is not monitored to the highest degree and patient safety may be adversely affected if we are forced to reduce the number of trained oncology nurses in order to maintain a viable practice. We suggest that instead of diving into a national CAP involving all Part B drugs used in "incident to" services, CMS should begin with a regional or national test involving a limited set of drugs that are typically administered by a physician specialty that uses drugs less intensely than oncology. This would allow CMS to refine its application and vendor selection procedures and its quality and service requirements, correct glitches in CAP upgrades to its claims processing systems, work out handling issues stemming from state regulations, assess and adjust for changes in practice expenses attributable to CAP, and complete the work needed to better match the reimbursement rates for drug administration services to actual costs for the various specialties before CAP is universally implemented.

We are also concerned that CAP vendors will have the authority to establish formularies and these formularies will be driven by price and not established treatment processes or clinical effectiveness. When it comes to Clinical Standards, we applaud CMS's decision to make the local carriers the arbiters of coverage and medical necessity decisions. In oncology, drugs can be extremely expensive, compendium-supported off-label usage is statutorily mandated, and off-label usage supported by peer-reviewed literature is also commonly reimbursed. As a result, CMS is right not to place decisions about coverage and medical necessity in the hands of vendors.

Under the proposed rules, CAP participating oncologists are prohibited from using CAP-acquired drugs and biologicals to re-supply their inventories unless:

- 1) The drugs are required immediately;

- 2) The oncologist could not have anticipated the need for the drugs;
- 3) The vendor could not have delivered the drugs in a timely manner;
- 4) The drugs were administered in an emergency situation.

In situations where a scheduled treatment for a patient does not happen as planned because the patient's needs have changed, the patient's appointment will have to be rescheduled pending shipment and delivery of a new CAP "order". As mentioned our patients may come hundreds of miles for treatment. We have concerns regarding the delay in treatment and the inconvenience to the patient and family this will cause particularly with the fragile status of many of the patients for whom we provide care. To ask them to return when the drug is available has major implications for care. For those practices that enroll in the CAP we would suggest additional requirements be implemented for drug delivery to the clinic site by MMA requiring CAP vendors to deliver ordered drugs within 24 hours, 7 days a week rather than the "timely delivery" requirement leaving much interpretation by the vendor.

A primary goal of CAP is to give oncologists an alternative way to acquire drugs without the cost and burden of purchasing them and seeking reimbursement through the Medicare claims process. Yet, to participate in CAP, an oncologist must:

- Sign an election form that commits the oncologist to order drugs via a written prescription for each individual patient;
- Submit Medicare claims within 14 days of the date of drug administration that includes
 - The name and HCPCS code of the drug administered
 - The prescription number for each drug administered, and the date of service;
- Provide information to the vendor regarding patients to help the vendor collect applicable deductibles and coinsurance;
- Notify the vendor when a drug is not administered;
- Agree to submit an appeal accompanied by all required documentation necessary to support payment if the participating CAP oncologist's drug administration claim is denied.

Oncologists receive no payment or compensation for any of these services. Clinics incur costs associated with drug handling and inventory management. If one adds these to the additional uncompensated costs of ordering, tracking, and filing CAP claims, pursuing appeals and sharing information with vendors to help them collect and it becomes clear that we, who are already facing a reimbursement shortfall, will experience further reimbursement

erosion as a result of CAP and may be unable to continue providing patient care.

If we elect to participate in CAP we will be "locked-in" the program and the vendor for one year. We will not be able to leave CAP unless the approved vendor ceases to participate in the program or they do not meet the criteria established by the Secretary of Health and Human Services. If we have a concern about our vendor's performance, the proposed rule states that the recourse is to file a grievance with the vendor. If the grievance isn't resolved then it can be escalated to the carrier. Concerns about quality and service, however, are not grounds for terminating service with the vendor but, the vendor may appeal to the designated carrier and request that we be investigated, which may lead to exclusion.

We are also concerned that CAP vendors may be permitted to "cut-off" patients who fail to make timely coinsurance payments. This is a provision that community cancer centers have always had to make. In sum, patients may be forced to pay both a financial and clinical price for treatment disruptions due to CAP, potentially exposing them to medical complications and increased emergency hospitalizations in addition to repeat visits and higher cost-sharing obligations, and thus jeopardize patient safety.

If this legislation passes every cancer patient will be directly affected. The increased burden of providing care to under-funded Medicare Patients will cause us to take measures to preserve the viability of our clinic.

In Summary we feel that the CAP program is ill conceived and that Congress could not have foreseen or predicted the long-term ramifications to:

- Patient safety.
- Timely delivery and availability of drugs for patient care.
- The ability for the patient and family to receive care within their own community.
- Forced regionalizing of Oncology Care centers and chemotherapy.
- The amount of drug waste produced with the individual inventories of medications.
- The increased burden placed upon the physician and their staff.
- Drug reimbursement under ASP with no reimbursement for treatment planning and pharmacy facilities.
- The absence of the Quality of Care Demonstration Project.

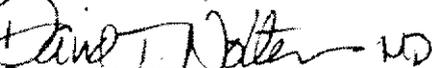
The mission of Wenatchee Valley Medical Center is to provide our patients with the highest quality healthcare in a friendly and caring atmosphere.

We have communicated our above concerns regarding the proposed CAP program and the impact it will have on patients and their families fighting this disease in our communities. We ask you to consider these concerns and make improvements to the program before the consequences of this legislation create an environment in which we are unable to fulfill this mission.

Signed,

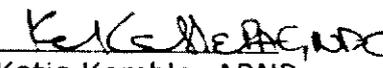

Sareena Malhi, MD


Prabhas Mittal, MD


David Notter, MD


David Weber, MD, Chairman


Julie Smith, MD


Katie Kemble, ARNP

CMS-1325-P-312

Submitter : Ms. Sonya Hohm
Organization : Arizona Oncology Associates
Category : Health Care Professional or Association

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1325-P-312-Attach-1.DOC

Issue Identifier: Overview of CAP

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement.

As a result, 2005 Medicare reimbursement for cancer care services is considerably higher than pre-MMA rates. However, total reimbursement will drop dramatically on January 1, 2006, when the demonstration project is scheduled to end and the drug administration transitional factor will be zeroed out.

It has been calculated that the impact of these changes will translate into a \$940 underpayment for drug administration services per Medicare beneficiary. Put another way, 2006 Medicare reimbursement for patient care services will cover only an estimated 50.09% of drug administration costs.

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who choose to give up the traditional buy-and-bill model and select the CAP model instead. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

CMS expects CAP to appeal to those physicians "who do not want to be in the drug procurement and drug coinsurance collection business" [70 *Fed. Reg.* 10750]. Indeed, statements made by CMS and CAP's Congressional authors all reinforce the notion that CAP is intended to be an option that physicians may choose to adopt in place of the current buy-and-bill model. According to the MMA Conference Report produced by Congress, "Conferees intend this choice to be completely voluntary on behalf of the physicians" [H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)].

And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even *greater* should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services – which will fall well below the cost of providing drug administration services.

In light of the reimbursement shortfall that looms on January 1, 2006, many cancer care specialists will face a very different choice than the one that Congress intended: continue to offer cancer care services to seniors (under buy-and-bill or CAP) and incur a significant net loss...or discontinue offering chemotherapy services to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

Congress has clearly stated its intent that patient access to community cancer care must be preserved because it is the source of convenient, cost-effective care for more than 4-out-of-5 American cancer patients. If CMS intends to abide by this intent, it must take additional steps to align Medicare reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Submitter : Ms. Sonya Hohm
Organization : Arizona Oncology Associates
Category : Health Care Professional or Association

Date: 04/25/2005

Issue Areas/Comments

1-15

Contracting Process-Quality and Product Integrity Aspects
see attached

CMS-1325-P-313-Attach-1.DOC

Issue Identifier: Contracting Process – Quality and Product Integrity Aspects

In an effort to ensure the stability of CAP, MMA directs CMS to require CAP vendors to meet standards for quality, service, financial performance and solvency that include appropriate procedures for the resolution of physician complaints and grievances. Unfortunately, the statute offers few specifics regarding these standards, and the proposed rule does not define all of the standards to which the vendors will be held. As it has done in the DMEPOS Supplier manuals, CMS should issue CAP guidance that defines measurable quality, service, financial performance and solvency standards.

With respect to Quality and Service Standards, I believe CMS should focus on standards related to shipment errors (e.g., wrong drug or dose; wrong quantity; damaged packaging; inadequate refrigeration; counterfeit product, etc.) and timely deliveries, both for routine and emergency deliveries. I also believe that the required physician call centers need to operate a minimum of 12 hours per day and that call management standards should tightly limit ring time, hold time, and dropped calls.

When it comes to Clinical Standards, I applaud CMS's decision to make the local carriers the arbiters of coverage and medical necessity decisions. In oncology, drugs can be extremely expensive, compendium-supported off-label usage is statutorily mandated, and off-label usage supported by peer-reviewed literature is also commonly reimbursed. As a result, CMS is right not to place decisions about coverage and medical necessity in the hands of vendors.

I am concerned, however, about the administrative burden on physician practices that will result from the CAP Election Agreement's requirement that physicians appeal all denied drug administration claims. The proposed rule provides no guidance on how many levels of appeal the physician must pursue, but the draft Election Agreement requires appeal through the reconsideration level. For clarity, we urge CMS to include this limitation in the final rule. The burden of appealing every denied drug administration claim is heightened by the pending changes in the claims appeal process that become effective on May 1, 2005. Given the magnitude of those changes, CMS should require the CAP vendor to request clinical literature from drug manufacturers needed to support appeals of drug administration denials.

I am also concerned that the proposed rule ignores the significant risk that physicians could face litigation over adverse drug events due to drugs provided by a CAP vendor. I strongly urge CMS to require CAP vendors to indemnify physicians for all costs, including reasonable attorney's fees, associated with the defense of all such actions where the physician is ultimately exonerated. The indemnification may be prorated if the physician is found to be partly liable and there is a rational basis for apportioning costs between the CAP vendor and the physician.

With respect to Financial and Solvency Standards, I commend CMS's decision to assess CAP bidders using Federal Acquisition Regulation (FAR) criteria, adopt FAR business integrity and conflicts of interest standards, and review third-party information on the structure and effectiveness of CAP bidders' internal control systems. The proposed rule does not specify how CMS will ensure ongoing compliance with vendor performance requirements, however, so CMS should issue a detailed guidance document, require CAP vendors to report key performance statistics quarterly, and consider imposing contractually defined financial penalties for sub-par performance in addition to the imposition of False Claims Act liability that vendors face.

Submitter : Dr. Stephen Volk
Organization : Oncology/Hematology of Lehigh Valley PC
Category : Physician

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

The competitive acquisition program in Oncology is poorly thought out and untested. Having elderly, sick patients making two trips instead of one (or perhaps four instead of five) so they can be seen by the doctor one day and get their blood count and then return the next day to get their chemotherapy is definitely going to adversely affect patient care. For many of these ill patients, or those that are transported from nursing homes, the travel is a significant burden. It adds to their overall weakness and may diminish their nutritional intake because of the time spent travelling and the increased fatigue. There will be angry patients, not to mention their care givers having to take off an extra day of work demanding to know why they can't get their treatment once they are already in the office. Many of these patients travel a long way to come to the office (30 to 50 miles or more). There will be great confusion in the office as, say, on a Tuesday we will have the Monday patients coming back for their treatments, Tuesday patients coming for their exams, drug treatments being delivered to the office for some patients while other non-Medicare patients are also vying for time in the chemo chair to get their treatments. Is there any payment for handling the logistics of all this? Plans for unused drugs have not been made (what if Mrs. X comes on Monday for her exam, is deemed ready, the drugs are ordered and delivered on Tuesday but Mrs. X doesn't show up because of any one of a number of potential problems from illness, to car trouble, to weather problems, etc). This plan is unworkable, was not given much forethought nor ANY testing, and is going to cause chaos in the delivery of healthcare to patients receiving treatment for cancer in community oncology offices and clinics. Also, members of congress are going to be besieged with angry constituents once this plan is put into effect. One trip to a working oncology office would demonstrate that this competitive acquisition program as it pertains to Oncology is going to be disastrous to the patients and the cancer care providers.

Submitter : Dr. Joseph Parks
Organization : Department of Mental Health
Category : State Government

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir,

Psychiatric medications in general and long-acting injectable and anti-psychotic medications in particular should be included in phase 1 of the Competitive Acquisition Program. Long-acting injectable anti-psychotic medications have consistently shown superiority in reducing symptoms and in preventing hospitalization when compared to oral formulations. In most states these medications can be obtained either through Medicaid or through Medicare part B. With the implementation of the Medicare Modernization Act in 2006 these essential medications will only be available through Medicare part B for dual eligible persons. Many of the prescribers of these medications either operate their own small-office practice or work and small organizations for whom cash flow in the buy and then bill process will be a significant burden. Additionally it's important to include in the rules for the Competitive Acquisition Program a process of notification and time to adjust treatment in instances where the competitive acquisition vendor feels it is necessary to stop provision of the drug due to nonpayment of co-pays or other reimbursement issues. Persons with psychotic illness are not always organized in their finances or their paperwork. Stopping their medication abruptly without notification to the prescribing physician and allowing time to correct the oversight can lead to expensive and even life-threatening medical consequences due to recurrence of illness. Thank you for the opportunity to comment. Sincerely yours, Joseph Parks M.D. Medical Director, Missouri Department of Mental Health

Submitter : Dr. James Parker
Organization : Jefferson-Blount-St Clair Mental Health Authority
Category : Physician

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

My comments are re: the proposed Competitive Acquisition Program (CMS-1325-P). I am the Medical Director for the noted agency. We provide intense community (outpatient) treatment to the Seriously Mentally Ill (SMI) in our Region of Alabama. Many of these SMI persons are unable to comply with oral psychiatric medications due to the severe nature of their diseases. Other SMI persons are unwilling to comply with oral medications for a variety of reasons. The use of long-term injectable medications are essential for these SMI citizens to remain stable. Should these medications be included under the proposed rule, many of these SMI persons will eventually require inpatient treatment, which is the most expensive form of Psychiatric treatment. Please change the rules of this proposal so that access to long-term injectable antipsychotic medications will not be limited.

Thank you,

James E. Parker, M.D., FAPA
Medical Director

Submitter : Ms. Joyce Wilde
Organization : NAMI - Ventura County
Category : Individual

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

As President of the Ventura County chapter of the National Alliance for the Mentally Ill, I'd like to request that medications used to treat mental illness be considered as part of the CAP program.

Submitter : Dr. olukemi wallacwe
Organization : healing hands oncology
Category : Physician

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-318-Attach-1.PDF

CMS-1325-P-318-Attach-2.DOC

Analysis of Issues Raised by Proposed Rule Implementing the Medicare Competitive Acquisition Program (CAP)

Prepared by the Community Oncology Alliance

April 19, 2005

This document is provided as a service by the Community Oncology Alliance (COA) to community cancer clinics. It is intended to help community cancer clinics better understand the Competitive Acquisition Program (CAP) mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). CAP, which is designed as a cancer drug replacement program, is also referred to as MVI (Mandatory Vendor Imposition).

On March 4, 2005, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule implementing CAP for Medicare Part B drugs. The CAP program was established by the MMA and is intended to provide physicians with an alternative way of obtaining Medicare Part B drugs. Under CAP, beginning January 1, 2006, physicians who choose to participate in CAP will obtain Medicare Part B drugs from vendors who have been selected through a competitive bidding process. Under CAP, vendors, not physicians, are responsible for billing Medicare carriers and collecting beneficiary co-payments.

According to CMS, while CAP *may* provide opportunities for Federal savings to the extent that aggregate bid prices are less than 106 percent of the average sales price (ASP), an important goal of CAP is to eliminate the financial burden on physicians by providing an alternative means for physicians to obtain Part B drugs. In other words, CAP is supposed to provide an alternative for physicians who do not want to be in the business of acquiring and billing both Medicare and patients for cancer drugs. **This analysis, however, identified a number of serious concerns regarding CMS' approach and the program's proposed structure and operations that may render the program unworkable for oncologists.** We also are concerned that CMS may be rushing to promulgate a final rule and implement a new program without adequate opportunity for input from affected stakeholders and for public comment as required by the Administrative Procedures Act (APA).

The following analysis is organized into sections that coincide with the sections discussed in CMS's preamble to the proposed rule. It summarizes COA's major issues, concerns and recommendations and is intended to help you formulate your own individualized comments. All comments are due to CMS no later than 5 p.m. on April 26, 2005 and must reference file code CMS -1325-P. Comments may be submitted electronically to <http://www.cms.hhs.gov/regulations/ecomments>, or mailed (one original and two copies) to: Centers for Medicare and Medicaid Services, Department of Health and Human Services, Attention: CMS -1325-P, P.O. Box 8010, Baltimore, MD 21244-8010.

For questions or comments, contact Dianne Kube at dianne.kube@att.net.

I. General Overview of CAP [If you choose to comment on these issues, CMS requests that you caption your comments “Overview of the CAP.”]

A. Implementation Tasks and Timetable

The MMA provides that CAP is to be effective on January 1, 2006. Prior to issuance of the proposed rule, CMS engaged in several activities to help the agency design and implement CAP. Specifically, CMS hired a contractor to obtain basic information, develop alternative proposals, and consult with stakeholder groups. CMS also conducted one Special Open Door Listening Session on April 1, 2004, established an electronic mailbox, and issued a Request for Information, which yielded 15 responses. Nevertheless, as noted below, the proposed rule suggests that CMS is still very much in the information gathering stage and is still deliberating various options regarding basic program operations. As a result, the proposed rule lacks specificity regarding a number of key program requirements.

Beyond the need to identify key program requirements, CMS has identified a laundry list of activities that must be completed prior to CAP’s effective date, including designating or developing quality, service, and financial performance standards for vendors; creating a pricing methodology; designing and running a bidding process from solicitation through contract award; providing physicians with an opportunity to elect to participate and select a vendor; educating beneficiaries about the program; and conducting other activities specified in the statute and described in the proposed rule. In reality, however, the CAP bidding process and the selection of vendors must be completed by fall, 2005, which is the beginning of the first annual election period.

Comment: With only eight (8) months before CAP’s effective date, and less than five (5) months before the beginning of the first annual election period, COA is concerned that CMS does not have adequate time to deliberate and reach closure on key program requirements *and* complete all of the tasks necessary to initiate CAP. Furthermore, CMS’ interest in broadly soliciting input on very basic issues at this stage in the CAP implementation process suggests that CMS lacks sufficient information and understanding of the drug acquisition process and its impact on community cancer care and the delivery of cancer treatment to formulate viable proposals for the CAP program.

Recommendation: While we are cognizant that Congress decreed that CAP should be effective on January 1, 2006, we strongly urge CMS to take the time it needs to fully understand how CAP can best be structured to attain Congress’ objectives and benefit physicians without compromising access to drug therapies and treatment. Further, to ensure an effective launch with adequate vendor and physician participation, CMS must delay the effective date of CAP to such a time.

II. Phase-in Options [If you choose to comment on these issues, CMS requests that you caption your comments “Categories of Drugs to be included under the CAP.”]

A. Categories of Drugs to be Included in CAP

The MMA provides some flexibility in the development of CAP by giving the Secretary of the Department of Health and Human Services (HHS) the authority to select appropriate categories of drugs and appropriate geographic areas for the program. CMS proposes three phase-in options:

Option 1 – Under Option 1, CMS would initially implement CAP for a limited set of drugs that are typically administered by oncologists. Drugs typically administered by other specialties would be included over the next few years. CMS believes that one advantage of this approach is that it allows CMS to focus implementation efforts on one specialty with a more homogeneous set of concerns and issues. Also, by limiting the targeted drugs to those typically administered by oncologists, the physician education process would be streamlined and potentially more effective. Finally, oncologists use a high proportion of the physician-administered drugs that could be included under CAP, therefore making the program more attractive to potential vendors. A potential downside is that a focus on oncology drugs may be too narrow and would deprive other physicians of the opportunity to participate.

Option 2 – Under Option 2, CMS would choose a limited set of drugs that are typically administered by one or more physician specialties that use Part B drugs less intensively. Such an approach would allow operational issues to be addressed more gradually, but may restrict the potential benefits of the program. Further, a restricted approach may not elicit sufficient response from potential vendors.

Option 3 – Under Option 3, CAP would be implemented for all Part B drugs that are furnished incident to a physician's service regardless of specialty.

CMS states that it is not proposing any particular option at this time but is actively considering all of these options and is encouraging recommendations on other approaches for further analysis. CMS further states that it may adopt one of the options described above, or an option brought to its attention through the comment process, in the final rule. Importantly, the categories that are established for physicians to select will be the same categories that would be open for bids of potential vendors. Thus, for example, if a category embracing all drugs typically administered by oncologists is established, vendors would bid on all HCPCS codes contained in the category and a physician who elects to participate in CAP would be electing to acquire that category from the vendor.

Comment: CMS' approach violates the Administrative Procedures Act requiring that agencies must publish a notice of proposed rulemaking in the Federal Register that provides interested persons with an opportunity to participate in the rule making through submission of written comments. 5 U.S.C. § 553. It is well established that a notice of proposed rulemaking must provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully.¹ Here, CMS has made no specific

¹ Florida Power & Light Company v. U.S., 846 F.2d 765, 269 U.S. App. D.C. 377 (CADC 1988), cert denied 109 S.Ct 1952, 490 U.S. 1045, 104 L. Ed. 2d 422.

proposal regarding the phase-in of CAP. Instead, CMS has offered three options and is seeking additional ideas from interested entities. While CMS' interest in soliciting new ideas is appreciated, contrary to CMS' own statement, it cannot adopt a proposal without giving the public the opportunity to comment on it.

Recommendation: Once CMS has decided what "phase-in" approach it will take, a second notice must be published in the Federal Register to allow for public comment before the proposal can be adopted as a final rule.

B. Allowing Vendors to Limit Availability of Drugs within Categories (i.e., formularies)

While vendors will be required to bid on all HCPCS codes within a category, (e.g. drugs used by oncologists), CMS is proposing that vendors not be required to provide every National Drug Code associated with a HCPCS code.² In effect, this gives a vendor permission to establish a formulary by choosing which drugs it will make available through CAP.

Comment: Cancer treatment is complex and poses many risks to patients. Although oncology drugs may be in the same class and category, they are not fungible. Active ingredients, for example, may be similar, but inactive ingredients may act quite differently when combined with other drugs in a complex, multi-treatment regimen. Certain drugs may be less effective or more costly to administer (e.g., the drug takes extra time to reconstitute, or fails to mix properly — leaving particulate matter and needed treatment, at the bottom of the bag instead of in the patient). Furthermore, different drugs within the same class or category can have different FDA approvals and different indications for use. A prime example is Procrit and Aranesp. For certain types of treatments, some may consider these drugs to be interchangeable; however, the drugs are different because each drug has a different indication for use. Similarly, interferon drugs, while in the same category, also have different indications and FDA approvals.

When a health insurer or prescription drug plan limits access to drugs through a formulary, certain safeguards generally are required to ensure that patients are assured access to medically necessary drugs and that formularies are not overly restrictive or driven solely by pricing. For example, under Medicare Part D, formularies must be developed by Pharmacy and Therapeutics (P&T) committees. Formularies must also be non-discriminatory and must provide for exceptions and appeals. Finally, prescription drug plan sponsors are prohibited from making certain formulary changes and if formulary changes are made, plans must provide notice or a one-time supply to assist the beneficiary through transitions.

Unlike Medicare Part D, however, CMS has not proposed any minimum standards or safeguards to govern which drugs must be covered by CAP vendors within a designated category of drugs. If vendors are allowed to restrict access or are allowed to change the drugs offered without notice to the participating physicians, physicians are unlikely to

² Although this proposal is discussed in the preamble to the proposed rule, it is not included in the actual text of the proposed rule.

elect to participate in CAP. For those that do elect to participate, if formularies become too limited, they will be forced to resort to “dispense as written” specificity for drugs and work outside of CAP through the ASP program, incurring cost and additional effort on all sides. (See additional comments below regarding CAP Operations.) Finally, we note that while CMS states in the preamble to the proposed rule that, upon request, vendors will be required to provide potential physician participants with specific information about the NDCs within each HCPCS code that it provides and that this information must also be disclosed to CMS as part of the bidding application, the proposed rule contains no such provisions.

Recommendation: The final rule must make clear that formularies are not permitted. Further, the final rule should provide that during the annual election period and upon request thereafter, a CAP vendor must fully disclose each drug that the vendor will make available pursuant to its CAP contract. In addition, vendors must be prohibited from making any changes in the list of drugs available through CAP within 90 days of the annual election period or, after the expiration of 90 days following the election period, without 90 days advance written notice to all participating physicians. Finally, physicians should have the right to opt out of CAP should a vendor fail to make proper disclosures or fail to make drugs available that the physician determines are medically necessary for the treatment of his/her patients.

C. Exclusion of Drugs

Section 1847B(a)(1)(D) of the Act gives the Secretary authority to exclude competitively biddable drugs and biologicals from CAP on grounds that including those drugs and biologicals would not result in significant savings or would have an adverse impact on access to those drugs and biologicals. While the preamble to the proposed rule states that CMS has made no findings regarding these two issues at this time, and the rule merely tracks the statutory language without elaboration, neither the preamble nor the rule identify how CMS intends to monitor either savings or adverse impact on access.

Comment: CAP is a new and untested acquisition program for Part B drugs — a significant percentage of which are drugs to treat cancer. Timely, clinically effective treatment is critical to cancer care and in its absence, death is likely. CMS does not know what impact CAP will have on access to oncology drugs or oncology practices. Further, CMS does not know whether CAP will actually produce cost savings.

Recommendation: Given the high stakes involved, we believe it is imperative that CMS commit to and identify a methodology for monitoring how CAP affects the impact on oncology practices, including access to treatment and whether there is any impact on cost.

III. Competitive Acquisition Areas [If you choose to comment on these Issues, CMS requests that you caption your comments “Competitive Acquisition Areas.”]

The law authorizes the Secretary to establish appropriate geographic regions or “competitive acquisition areas” within which to conduct CAP competitions. Competitive acquisition areas constitute the geographic boundaries within which entities will compete for contracts to provide competitively biddable drugs. The size of the geographic area will be a crucial factor in determining the number of entities that bid for and ultimately are awarded contracts.

CMS has proposed several basic options for defining the competitive acquisition area. These include: (1) establishing a national competitive acquisition area, (2) establishing regional competitive acquisition areas; and (3) establishing statewide competitive acquisition areas. According to CMS, a large, national acquisition area is attractive to vendors because it is less administratively burdensome and offers the greatest opportunity to gain market share. At the same time, however, a large acquisition area would likely discourage smaller regional drug distributors from participating in CAP, thereby reducing competition. Sub-national regions offer an opportunity to implement CAP in stages, bringing one region into the program at a time. This approach might permit CMS to work out problems in the early stages that would be important to gaining physician and vendor participation. A state approach is attractive because it uses clearly defined geopolitical borders that coincide with current vendor licensing requirements. A state-based approach could also support a geographic phase in of the program.

Comment: CMS is considering all of the above options and is also soliciting additional ideas. While all of the proposed options have merit, the biggest problem with CMS’ approach is that CMS may violate the APA should it adopt a proposal that has not been published and subjected to a period of public comment.

Recommendation: Once CMS has decided how to define a “competitive acquisition area,” a second notice must be published in the Federal Register before the proposal can be adopted as a final rule.

IV. Operational Aspects of CAP [If you choose to comment on these issues, CMS requests that you caption your comments “Statutory Requirements Concerning Claims Processing.”]

A. Physician Responsibilities and Burden

Under the proposed rule, 42 C.F.R. §414.908, physicians will be given the opportunity to select an approved CAP vendor on an annual basis. Physicians must complete and sign a CAP election agreement. In addition, the physician will be required to submit a written order or prescription to the approved vendor. CMS is proposing that each drug order be accompanied by the following information:

* Date of order

- * Beneficiary name
- * Physician identifying information
- * Drug name
- * Strength
- * Quantity ordered
- * Doses
- * Frequency/instructions
- * Anticipated date of administration
- * Beneficiary Medicare information/Health insurance (HIC) number
- * Supplementary Insurance info
- * Medicaid info
- * Shipping address
- * Additional patient info: date of birth, allergies, Ht/Wt/ICD-9 etc.

CAP participating physicians must also provide information to the approved vendor to facilitate collection of applicable deductibles and coinsurance, notify the vendor when a drug is not administered, agree to file a “clean” Medicare claim within 14 days of the date of drug administration that includes the name and HCPCS code of the drug administered, the prescription number for each drug administered, and the date of service, and agree to submit an appeal accompanied by all required documentation necessary to support payment if the participating CAP physician’s drug administration claim is denied. Physicians will also have to maintain a separate electronic or paper inventory for each CAP drug obtained.

No provision is made to compensate the physician for any of the above activities. Yet, if a vendor is not paid on claims, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician and if the problem persists, the vendor may ask the carrier to investigate the physician’s performance and recommend the suspension of the physician’s CAP election agreement. While the proposed rule does provide for reconsideration and appeal of a physician’s exclusion, if the carrier’s decision is ultimately upheld, “CMS publishes a final reconsideration determination against the participating CAP physician in the Federal Register.” Proposed 42 C.F.R. § 414.916(b).

Comment: The CAP process creates a dramatic and operationally significant change in how physicians acquire Medicare Part B drugs. When ordering from a non-CAP vendor, physicians stock a single, centralized, inventory. CAP requires each practice to order drugs and track inventory on a prescription basis for each patient, track the date of administration, bill claims within 14 calendar days of administration and share information with vendors to assist them in collecting co-payments.

For a program that was designed to get physicians out of the drug acquisition business, CAP does little to lessen the administrative burden on physicians. In fact, we believe that it increases the burden. At the same time, it strips physicians of any claim to payment. Moreover, the reward for signing on as a non-paid agent of the vendor potentially is investigation and a public pronouncement of exclusion from the program.

Recommendation: CMS must restructure CAPS' proposed claims process and tracking requirements to significantly reduce the administrative burden on physicians.

B. Written Order or Prescription

The statute (MMA) provides that the contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. The statute further provides that this section does not require a physician to submit a prescription for each individual treatment, or change a physician's flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or course of treatment.

For purposes of CAP, CMS has chosen to interpret the term "prescription" to include a written "order" submitted to the vendor. CMS states its intention not to restrict a physician's flexibility when ordering drugs from a CAP vendor or to require that a physician participating in CAP would order drugs differently from a CAP vendor than he or she would a non-CAP vendor.

Comment: As proposed, a CAP "vendor" will supply pharmaceuticals to a physician's office for a particular beneficiary (patient). The "vendor" then submits a claim with a prescription number for the pharmaceutical agent to a designated carrier. That claim must be matched to a claim filed by the physician that shows the date of administration by the physician. This is not a typical supplier arrangement but rather describes the "filling" or dispensing of a "prescription" for a specific patient.

There are two problems with this approach. First, Federal and state laws make clear that only a licensed pharmacist may dispense a prescription. Second, requiring CAP participating physicians to maintain individual, patient-specific inventories will further increase costs substantially to physicians. Based on the fact that approximately one-third of treatment regimens are switched during the treatment cycle, there will be a significant waste problem that will increase waste disposal costs to physicians and increase drug reimbursement costs to Medicare.

Recommendation: It is clear that the statute (MMA) very specifically uses the word "prescription," which cannot be loosely interpreted by CMS to mean an "order."

C. Order Splitting

CMS proposes allowing the physician to place an order for a beneficiary's entire course of treatment at one time but allow the vendor to split the order into appropriately spaced shipments. According to CMS, the vendor would create a separate prescription number for each shipment and the physician would track each prescription separately and place the appropriate prescription number(s) on each drug administration claim.

Comment: It is unclear how CMS could authorize a vendor to split a shipment of pharmaceuticals needed to treat a patient without the express consent of the physician who orders the drugs. How does the vendor know how to “appropriately” space shipments? Further, allowing the vendor to split shipments creates additional administrative burden for the doctor.

Recommendation: Vendors should be prohibited from splitting shipments unless approved by the physician who orders the drugs.

D. Inventory Resupply

CMS has proposed that drugs acquired under the CAP may be used to resupply inventories but only if the physician can demonstrate all of the following to the Secretary: (1) the drugs are required immediately, (2) the physician could not have anticipated the need for the drugs, (3) the vendor could not have delivered the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

Comment: The standard for allowing physicians to resupply inventories with CAP drugs is too onerous and does not take into consideration certain common reasons why a CAP drug may not have been used. About one-third of the time, a scheduled treatment for an oncology patient does not happen as planned. This may be due to scheduling issues or, more commonly, the patient’s needs change and an alternative regimen is indicated. In most cases, such changes cannot be categorized as “emergencies.” Yet, it is highly unreasonable and very costly to require a patient, who has already been examined and tested, to return in another day or two, in order to obtain a new mixture of drugs, rather than obtain treatment from the physician’s inventory. The resupply rules will be especially difficult for rural oncology clinics where patients in debilitated health must travel long distances to obtain treatment. Delaying treatment and requiring patients to return on another day or wait long hours in order to receive new shipments of drugs acquired through the CAP vendor, is an enormous inconvenience to the patient and a cost to the practice. More importantly however, delaying treatment can adversely affect patients’ health and ultimately drive up health care costs.

Recommendation: Physicians should be permitted to resupply their inventories if any one of the four conditions is applicable.

E. Unused Drugs

CMS proposes that, if for some reason, the CAP-acquired drug cannot be administered to the beneficiary on the expected date of administration, the physician would notify the vendor and reach an agreement on how to handle the unused drug, consistent with state and federal law.

Comment: CMS’ proposal ignores the fact that most pharmacy regulations indicate that a drug, once dispensed in a patient’s name, may not be returned, reused, or reshelfed. The conversion of oncology drug inventories from a single, centralized, non-patient specific

inventory to a patient-specific, individualized inventory creates the potential for millions of dollars of “waste” from unused and unusable medications.

Recommendation: We understand that the requirement that a vendor only provide drugs to a participating CAP physician prohibition based upon a prescription is statutory. Nevertheless, we urge CMS to work with Congress to address impediments to a viable CAP program.

F. Uncompensated Costs

One of the goals of CAP is to reduce the financial burden of drug acquisition on physician practices. However, as long as chemotherapy and other therapies to treat cancer are incident to a physician’s services, physician practices will still incur costs associated with drug handling and inventory. The preamble to the proposed rules, for example, states, “the drug and prescription number would be shipped to the physician and would be maintained until the date of drug administration.” However, no provision is made to compensate the physician for these costs.

Comment: At a recent MedPAC meeting, MedPAC staff identified the costs of drug handling and inventory in the hospital outpatient setting at 26% to 28% of drug costs. Oncology practices have long maintained that drug handling and inventory costs run about 12% of total drug purchase expenditures. While the CAP program does not eliminate these costs for oncology practices, physicians are not compensated for these costs under any other fee schedule.

Recommendation: CMS must recognize and compensate oncologists for the costs of drug handling and inventory.

G. Furnish as Written

CMS proposes that when a CAP participating physician has determined that it is medically necessary to use another brand of product within the HCPCS or a product with an NDC that is not being furnished by the vendor, that the physician be allowed to bill for the drug under ASP. The physician would place a “furnish as written” modifier on his or her claim form and bill the Medicare carrier for the drug and the administration fee.

Comment: We support the CMS proposal to permit physicians to obtain a drug under the ASP methodology in “furnish as written” cases when medical necessity requires that a specific formulation of a drug be furnished to the patient and the vendor has not been contracted to furnish a specific formulation of a drug or product defined by the product’s NDC number. However, we are concerned that physicians are still subject to post payment reviews and carrier determinations that a specific NDC number was not medically necessary. This process takes the medical decision-making completely out of the physician’s hands, yet it is the physician who holds the responsibility and the liability for the quality and effectiveness of drugs used for patient care, and has access to the full information.

Recommendation: CMS must make clear that “furnish as written” orders are reviewed under the same standards and process used under Medicare Part B for non-CAP drug acquisitions.

H. Physician Choice of Drug Categories

CMS is seeking comments on whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or whether the physician should be allowed to choose the categories of drugs he wishes to obtain from the vendor.

Comment: CAP vendors may create formularies that are inconsistent with the physician’s preferred medical practice, or may ignore certain variations in drug approvals or indications within categories. Oncology care is so complex that without the flexibility to deselect certain categories, quality and patient access risks increase dramatically. Furthermore, promoting choice will increase competition among vendors and should have a positive impact on quality and price.

Recommendation: COA strongly recommends that physicians be given a choice of which categories of drugs to obtain from a particular CAP vendor. There is no basis for implementing formularies.

I. Collecting Beneficiary Co-payments

The statute requires that the vendor bill Medicare and the beneficiary, and that the beneficiary may not be billed until after the drug has been administered to the beneficiary by the physician, who has filed a claim for the drug administration. CMS is proposing that the vendor be allowed to bill the beneficiary and/or his or her third party insurance after drug administration has been verified by matching the physician claim with the vendor claim using the prescription number, and final payment is made by the Medicare program.

Comment: Despite the impact on cash flow, community oncologists generally are reluctant to refuse to treat a patient who cannot afford to pay a co-payment. Vendors, however, are not ethically or legally responsible for the course of a patient’s treatment. If a vendor is unable to collect co-payments from a patient, nothing prohibits the vendor from stopping delivery of drugs to the physician’s office. Allowing vendors to stop delivering drugs to an outpatient setting is likely to endanger patients or force them into more costly in-patient settings for treatment. Further, physicians could be exposed to liability if the physician is unable to complete a course of treatment because a vendor is refusing delivery.

Recommendation: The final rule must make clear that vendors cannot refuse to deliver drugs because they are unable to collect co-payments. Alternatively, if CMS does allow vendors to stop delivering drugs, this must be made very clear to physicians during the CAP election period that the vendor may suspend treatment to any patient not paying

their co-insurance. Additionally, physicians must be permitted to immediately opt out of CAP and obtain drugs through the ASP system in any single case where a vendor has decided to not ship drug(s) for a patient not paying the Medicare co-insurance.

V. CAP Contracting Process [If you choose to comment on issues in this section, CMS requests that you caption your comments “Contracting Process-Quality and Product Integrity Aspects.”]

A. Vendor Quality Control

Sections 1847B(b)(2)-(3) of the MMA makes clear that vendors must meet financial and quality of care requirements aimed at assuring the stability and safety of CAP. The statute also provides that vendors have sufficient capacity to acquire and deliver drugs within a geographic area, to deliver drugs in emergency situations, and to ship drugs at least five days a week. The MMA also requires that the criteria for awarding vendor contracts include the vendor’s ability to ensure product integrity. CMS correctly notes in the preamble that physicians would be reluctant to participate in CAP if they have little confidence that CAP vendors would be reliable and provide quality CAP products. The preamble further states that CMS seeks to “define a set of overall financial and quality standards that would ensure that reputable, and experienced vendors are chosen to participate in CAP and states we propose that CMS be allowed to suspend or terminate a vendor’s contract if the vendor falls out of compliance with any of these quality requirements.”

Unfortunately, the proposed rule does not identify those standards. Rather, the proposed rule states only that CMS will select approved vendors based upon certain criteria including but not limited to the “ability to ensure product integrity,” “financial performance and solvency,” and “record of integrity and the implementation of internal integrity measures.” Proposed rule at 42 C.F.R. § 414.908(b).

On the other hand, proposed rule 42 C.F.R. §414.916(d) provides that issues regarding quality and service that relate to the vendor’s performance raised by the participating CAP physician are treated through the vendors own internal grievance process. If the approved vendor does not resolve a quality issue to the participating CAP physician’s satisfaction, the participating CAP physician may escalate the matter to the designated carrier. Unlike the unpaid physician who is subject to investigation and exclusion, CMS merely provides that the “designated carrier attempts to develop solutions that satisfy program requirements and the needs of both the participating CAP physician and the approved vendor.” Proposed 42 C.F.R. §414.916(d).

Comment: Vendors are being paid to delivery highly volatile and, at times, toxic drugs to physicians who need them to treat critically ill patients. It is essential that vendors be held to the highest standard for quality and performance. Physicians, who will be dependent on the vendors to obtain these drugs, need to know that when complaints are raised about poor quality and performance that vendors and CMS will take them seriously. It is unrealistic to believe that physicians will participate in CAP if there is no

effective process for addressing quality concerns and if they believe they have no recourse if a vendor is not performing as expected. It is unsettling and contrary to good business practice that physicians are locked into their choice of the CAP vendor(s) for a year regardless of performance and quality.

Recommendation: CMS must strengthen the rules pertaining to quality and performance standards of vendors and clarify the procedures that will be used to investigate allegations involving the poor performance of vendors. Vendors who fail to perform should be subject to investigation and sanction, up to and including exclusion from the program.

We also recommend that CMS develop standard “hold harmless” language for the CAP election agreement that ensures that participating physicians are held harmless for the negligence and non-performance of CAP vendors.

Finally, CMS must make clear that physicians may disenroll from CAP at any time, especially in cases of quality non-performance.

VI. Bidding Entity Qualifications [If you choose to comment on these issues, CMS requests that you caption your comments “Bidding Entry Qualifications”].

A. Vendor Experience and Capabilities

Under the proposed rule, 42 C.F.R. § 414.908(b)(1)(iv), vendors are expected to show a history of delivering Part B injectable drugs for at least 3 years.

Comment: Oncology drugs are complex medications/chemicals, with strict parameters for handling and storage. Experience with other drugs does not guarantee successful experience with oncology drugs, and the risks and liability for Medicare patients and physicians is too great to allow inexperienced vendors the responsibility of handling oncology and cancer-related supportive care drugs.

Recommendation: A CAP vendor should be required to demonstrate a history of at least 3 years of delivering each category of drugs for which they submit a bid.

B. Timeframes for Routine and Emergency Shipment

CMS is seeking comments on how to define timely delivery for routine and emergency drug shipments. CMS is proposing that routine shipments of drugs furnished under CAP would occur within one or two business days. However, the duration of the delivery time period must not exceed the drugs stability in appropriate shipping containers and packaging. CMS also proposes that emergency drug orders be furnished on the next day for orders received by the vendor before 3 p.m. (vendor’s local time). CMS is seeking comments on the feasibility of providing same-day deliveries received for emergency situations.

Comment: Same day deliveries are feasible and necessary.

Recommendations: Vendors should be required to have the capacity to make same day deliveries when drugs are needed on an emergency basis. At the time the drug is ordered, the physician should receive a commitment from the CAP vendor for a day and time of delivery, and vendors must be held accountable for compliance to that commitment.

CMS must make clear that physicians may disenroll from CAP at any time, especially in cases of delivery non-performance.

C. Conflicts of Interest

The CMS proposal sets forth a code of conduct for CAP vendors, and identifies a conflict of interest as being “where a drug vendor, its representative, or contractor provides a product or service for a Medicare provider or beneficiary and the drug vendor, representative or contractor has a relationship with another person, entity product or service that impairs or appears to impair the drug vendor’s or contractor’s objectivity to provide the Medicare covered product or service.”

Comment: The creation of formularies for the purpose of steering market share toward one drug in a category over another in response to contracting discounts and rebates would appear to meet this definition of conflict of interest. If physicians are required to acquire drugs within categories as defined by the CAP vendor, and the CAP vendor offers only a limited selection of the possible drugs, the CAP vendor has restricted the availability of drugs for its financial gain, and to the detriment of access to care for Medicare beneficiaries and their physicians.

Recommendation: Formularies should not be allowed.

VII. CAP Bidding Process – Evaluation and Selection [If you choose to comment on these issues, CMS requests that you caption your comments “CAP Bidding Process – Evaluation and Selection.”]

A. Composite Bid Process

CMS proposes employing a composite bid process. The composite bid would be implemented in two steps. First, bidders would have to demonstrate that they meet certain quality and financial thresholds. Second, each bidder would submit its bid constructed by weighing each HCPCS bid by the HCPCS code’s share of volume of drugs in a particular drug category during the prior year. The calculated composite bid would be equal to the average price per HCPCS unit for drugs in that category. CMS would then select up to five bidders, based upon price, for a drug category in each competitive acquisition area. However, CMS would not select any bid for a category that is higher than 106 percent of the weighted ASP for the drugs in that category.

Comment: As proposed, the bid process automatically eliminates drugs that are not obtainable at significant savings to the Medicare program. The result is that only the cheapest and possibly least usable versions of a drug in a category will be made available through CAP vendors.

Recommendation: CMS must revise the bid process to avoid a race to the bottom, where price considerations trump quality and efficacy concerns. Given physician's choice and the ability to "walk with their feet" should help make vendors more sensitive and responsive to quality concerns.

B. Drug administration, waste, spillage, and spoilage

The bidding process also specifically excludes recognition of any costs related to the administration of the drug or wastage, spillage, or spoilage in submitted bids.

Comment: Wastage, spillage, and spoilage are part of the cost of treating cancer patients with drug products that are highly toxic and unstable.

Recommendation: While we recognize that the exclusion of drug administration costs, wastage, spillage, and spoilage are statutory, CMS must adjust payments to physicians for services to more accurately reflect their costs.

VIII. Physician Election Process [If you choose to comment on these issues, CMS requests that you caption your comments "Physician Election Process."]

Pursuant to proposed 42 C.F.R. § 414.908, physicians will be asked to make an election and select a qualified CAP vendor on an annual basis by October 1. Once selected, the physician will only be able to go to another vendor if the approved vendor ceases to participate in CAP, or other exigent circumstances defined by the Secretary such as when the CAP physician relocates to another competitive acquisition area or leaves a group practice that is participating in CAP.

Comment: While the statute does provide for an annual election, nothing in the statute requires or supports the use of a "lock-in" period for physicians. CMS must be mindful that vendors would be inclined to charge higher rates to their captive customers if a lock-in period is required, while physicians are unlikely to sign up for the program if they cannot leave it at will. This is a new, untested program. If physicians develop serious concerns about the vendor, or the program, or unanticipated costs of supporting the program, as small businesses with a low capacity for financial risk, they need the flexibility to depart.

Recommendation: CMS must make clear that physicians may disenroll from CAP at any time.

IX. Beneficiary Education [If you choose to comment on this section, CMS requests that you caption your comments “Beneficiary education.”]

Beneficiaries are likely to be confused by the CAP program. CAP co-payment collection policies also may lead to denials and reduced access to care for some Medicare cancer patients. To educate beneficiaries, CMS is proposing to develop a beneficiary-focused fact sheet, and to update existing materials, to reflect these changes. The fact sheet would be available for physicians who elect to participate in the CAP to provide to beneficiaries at the time of service. CMS seeks comment on the administrative burden associated with this activity. CMS is not proposing any additional options for specific outreach to beneficiaries.

Comment: Patients rely on their physicians to guide them through the treatment process, and any confusion regarding billing or disruption of care will send patients immediately back to the physician office with a variety of physical, financial, medical, and psychosocial issues.

Recommendation: CMS should conduct outreach and beneficiary education to patients receiving treatment under Medicare Part B.

X. Physician Application Process

CMS is estimating that physicians will need 15 minutes each to fulfill the application requirements.

Comment: At COA, we believe the decision process will actually be far more complicated and take much longer than 15 minutes. As stated elsewhere in the CMS proposed rule, practices will need to evaluate the costs of purchasing and acquiring drugs under the ASP option, and compare the costs of acquiring drugs under the CAP program, plus evaluate discrepancies between the drugs now selected for patient care and whatever specific drugs are carried under the CAP vendor formulary – and assess any relevant issues for patient care and operational burdens. The CMS proposed rule assumes that physicians must maintain a separate electronic or paper inventory for CAP drugs, but reality dictates that a physically separate inventory will also be needed, with all the attendant costs.

Recommendation: CMS should revise its estimate to reflect the additional time it will take physicians to evaluate CAP. CMS must fully analyze the application requirements and administrative costs by conducting a test with real community oncology practices and reporting back on the results.

XI. Regulatory Impact Analysis

For purposes of the RFA, physicians and non-physician practitioners are considered small businesses if they generate revenues of \$8.5 million or less. According to CMS, there are in excess of 20,000 physicians and other practitioners that receive Medicare payment for

drugs. These physicians are concentrated in the specialties of oncology, urology, and rheumatology. Of the physicians in these specialties, approximately 40 percent are in oncology and 45 percent are in urology. CMS was unable to draw any specific conclusion regarding the impact of this proposed rule on physicians because it depends on what drugs they provide to Medicare beneficiaries, whether the drugs will be included in the CAP program, and whether the physician chooses to obtain drugs through CAP.

Comment: While we agree that certain impacts are dependent on how individual physician's react to the program, their own practices, and on information that is not yet known, we believe that overall, CAP will reduce reimbursement to oncologists, increase administrative and pharmacy costs, and ultimately affect access to treatment as more clinics are forced to close and send their patients to more costly hospital settings. Physicians who feel compelled to participate in CAP will find they will need to absorb more uncompensated costs including unreimbursed drug handling and inventory costs and the increased administrative burden of the new ordering and claims processing system. In sum, the burden to the physician and the related costs actually increase under CAP due to the need for separate inventory management and running of concurrent inventories — both for staff and facility resources.

Recommendation: CMS should do a complete impact analysis that both examines and quantifies the true cost of CAP to a community oncology practice and also quantifies the overall impact of CAP on the delivery of cancer care in this country.

Submitter : Dr. Michael Repka
Organization : American Academy of Ophthalmology
Category : Health Care Professional or Association

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-319-Attach-1.DOC

April 25, 2005

Tel. 202.737.6662
Fax 202.737.7061
<http://www.aao.org>

via Electronic Mail

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

Federal Affairs Department

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

Dear Dr. McClellan:

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the proposed rule for Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B. The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active medical practice in the United States. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule.

The Academy has been and remains supportive of the development of a Competitive Acquisition Program (CAP) program for Part B drugs, as enabled by section 303(d) of the Medicare Modernization Act. The Academy views the proposed CAP as a unique opportunity to stabilize the cost of drugs to physicians and commends CMS for its efforts in implementing this option. We have long supported imposition of a program which would allow physicians to be taken out of the process of purchasing and storing drugs and which will instead allow them access to the drugs needed to treat their patients in a timely manner.

The Academy has several comments regarding the implementation, administrative burdens, breadth, and publicity of the program. We would like to take this opportunity to highlight some of our concerns and praise regarding the proposed rule.

Categories of Drugs to Be Included Under the CAP

The structure currently proposed for implementation of the CAP program would benefit the practice of ophthalmology by allowing our physicians to get out of the business of purchasing and storing drugs. The Academy is interested in the implementation of a CAP program that will benefit both physicians and beneficiaries. However, this will only work if CMS is careful to structure the drug categories in a way that is beneficial to individual specialties. The Academy does not support the proposal to include only one specialty in the initial phase-in or to limit phase-in to physician specialties that use the same drugs.

We believe that limiting the phase-in to one specialty and/or class of drugs would not result in data that is useful in expanding the program to all physicians.

It is important that CMS evaluate the impact of the program on several physician specialties with varied numbers and classes of drugs subject to coverage under the CAP. The Academy favors an approach that includes several specialties and would like to be considered for inclusion. In our opinion these results can best be achieved through implementation of the CAP system on a national level across specialties.

Implementation at a national level would better assess the overall impact of the CAP system on drug pricing and acquisition as opposed to a regional implementation which has the continuing potential of creating inaccurate data regarding drug pricing and access. Implementation could initially include several specialties, each with differing numbers of drugs that are interested in procuring them through the CAP program.

In order to achieve the best results the Academy would urge CMS to include those specialties in the initial phase of implementation that are vested in the success of the program. For instance, ophthalmology has long been a proponent of a system that would create fair and stable pricing among drugs used in the treatment of patients with Age-related Macular Degeneration (AMD). There are currently two drugs on the market, Visudyne and Macugen, to treat this condition.

Visudyne was delivered in the physician's office as part of photodynamic therapy 106,664 times in 2003. There were an additional 5,394 bilateral treatments using the drug. Visudyne is typically provided to each involved eye 5.5 times over a two year period. The service is delivered in the physician's office setting 92% of the time. Macugen is delivered to each involved eye nine times in the first year and seven times during the second year. This drug is administered in the physician's office over 99% of the time. Macugen received FDA approval in 2004. Volume is not known at this time but is expected to exceed that of Visudyne in 2005. The Academy has worked with the manufactures of both drugs, Pfizer-EyeTech (Macugen) and Novartis (Visudyne), to establish fairer pricing for the drugs under the ASP program. Both manufacturers have expressed an interest in participating in the CAP program. National imposition of CAP using a drug category for AMD drugs would produce high-volume data that could be used to evaluate the efficacy of the program.

The Academy further recommends that drugs in the CAP be subdivided by specialty and drug type. This would allow CAP participating physicians to obtain the drugs they need. For instance, an ophthalmologist could elect to purchase AMD, antibiotic, antiviral, or glaucoma drugs under the CAP program. The Academy believes that this method would encourage more vendors to participate in the CAP (for example one vendor might win the bid to provide ophthalmic antibiotics while another might provide glaucoma drugs). In the alternative the Academy would encourage CMS to cover all drugs administered by two or more specialties. We are concerned that an approach that uses a comprehensive list of drugs will create data tracking difficulties and could impair physicians' ability to continue purchasing drugs under the ASP system.

The Academy urges CMS to consider several other factors regardless of the system used to phase in the CAP. This includes clarifying vendor liability for covering all drugs listed in a CAP drug category during the contract period. CMS should also prohibit vendors from suspending coverage for drugs within an approved CAP category during a contract period. The Academy recommends that CMS clearly state that any CAP participating physician utilizing a drug that is on an approved CAP list, regardless of whether it appears on the CAP list for their particular specialty, can procure the drug. This is especially important for specialties, like ophthalmology, that use drugs that are utilized by other specialties such as oncology.

Competitive Acquisition Areas

The prices of drugs fluctuate depending upon region of the country. Differences in procurement costs create drug access problems among medical specialties and among physicians practicing within specific specialties. To prevent this problem from persisting under the CAP, the Academy would urge CMS to initially phase-in the program using a national competitive acquisition area. The benefits of nationwide implementation would best be gleaned by including drugs which are nationally distributed by a limited number of manufacturers in the initial phase-in. Implementation on a national level would also enable CMS to understand the issues which might arise with vendors who are remote from physician offices where the drugs are administered. The drugs used to treat AMD would be appropriate for national implementation.

The proposed rule does not mention modifying the vendor-approved drug list during the contract period. New drugs may be developed during the course of a three-year vendor contract. Vendors may also attempt to replace or discontinue coverage for a drug during the contract period. In order to prevent problems regarding access to drugs, the Academy urges CMS to implement a requirement prohibiting vendors from removing drugs covered by the CAP contract during the contract period. CAP vendors should only be permitted to expand an existing list of covered drugs to include additional drugs during the three-year contract period. These provisions would ensure that physicians have access to the most cutting edge drug treatments for their patients while also protecting physicians and their patients from being forced to use drugs that may not produce the most desirable results.

Statutory Requirements Concerning Claims Processing

In order to prevent additional and onerous administrative costs the Academy urges CMS to institute a claims method that eliminates redundancy in the provision of information at the drug ordering and claim phases. As a first step the Academy would recommend that the emergency prescription exception be expanded to allow physicians to get the drug at either the ASP or the CAP vendor rate, in cases where the drug was covered under the CAP.

The proposed rule is silent regarding the method for co-pay collection on behalf of dually eligible patients. The Academy urges CMS to address this issue in the final rule by either incorporating a method whereby the vendors have the ability to bill Medicaid or by sanctioning a physician's right to file a claim with Medicaid under the ASP system.

Claims Processing Overview

The Academy believes that the methods spelled out by CMS regarding emergency dispensing as well as the "furnish as written" option will be helpful in alleviating additional work in cases where emergencies and special formulations of drugs are needed. We would urge CMS to give examples and/or more clearly define what is meant by emergency situations. For example, CMS might consider clearly stating that an emergency situation is one in which immediate treatment is required to address the patient's presenting symptoms or complaint or other appropriate language. The Academy also recommends that CMS consider allowing doctors to provide drugs using the emergency or "furnished as written" option in instances where the vendor is unable to deliver a requested drug within a specified time frame.

The Academy also urges CMS to re-consider its position regarding the administrative burden of participating in the CAP. There will likely be additional work associated with the submission of drug orders and claims using the methods outlined in the proposed rule. The proposed rule requires physicians to compile and submit more detailed information when placing a drug order than would traditionally be required by a manufacturer. Certain information being requested as part of the drug order is not necessary or appropriate including: patient date of birth, allergies, height, and weight. Compiling and submitting this additional information, on the front end of a drug order will require more staff time and higher administrative costs. Developing and maintaining a separate tracking system for CAP drug orders and claim submissions will cause physicians to incur additional administrative costs. The Academy believes that some of the administrative burden, associated with the CAP, could be reduced if physicians were permitted to submit drug orders via fax and if vendors were required to provide bar coded and/or scanned tracking numbers for each drug dispensed once they received the drug order.

We would also urge CMS to allow physicians 30 days to submit claims for drugs that have been administered in the absence of evidence that the time and burden associated with claims submission is greatly diminished under the CAP system.

Ophthalmology on occasion uses drugs in which wastage is used to treat indigent beneficiaries. This wastage is included in the dose ordered for the paying beneficiary and the remainder is used to treat the indigent patient at no cost to them or Medicare. It is very important that the new system of billing and procuring drugs under CAP include a mechanism for continuing to report and use the wastage associated with some drugs. Without being allowed to use wastage, indigent patients would go without necessary treatment.

The Academy would appreciate CMS's clarifying the process and/or procedure to be used if a drug is damaged during shipping, prior to, or during administration. We would recommend that a modifier be developed indicating that the drug was not administered due to damage. Responsibility for the drug should remain with the vendor because they are responsible for the drug until administration. We would encourage CMS to implement a system whereby a vendor could receive partial compensation, at a minimum, in cases where an unstable and/or short shelf-life drug is ordered and cannot be administered.

The drug order delivery times set forth in the proposed rule are sufficient for ordering drugs whose need can be anticipated far in advance. However the Academy is concerned that the method for ordering emergency and other unanticipated drugs may greatly compromise the ability of patients to get prompt treatment. We are even more concerned that the inability to provide immediate treatment may lead to the failure of some patients to get any treatment for their conditions. A patient who presents for a routine exam could be diagnosed with a problem that requires immediate or very prompt treatment. This patient would be greatly inconvenienced by having to return to the office two days after an initial appointment to obtain medication that under ordinary circumstances would be kept on site as part of the physician's inventory.

The Academy urges CMS to allow physicians to order a small inventory of drugs, which could be stored in the office for patients who are expected to receive treatment within a fixed span of time (i.e. three to six months), instead of requiring identification an expected administration date. The Academy recommends that CMS allow physicians to place orders on either a monthly or quarterly basis. While we realize that this is only feasible with regards to stable drugs with a shelf life that could accommodate in-office storage we believe that this is the only way to effectively and timely treat patients. Without such a provision physicians will be constantly placed in the position of borrowing drugs from their private pay inventory for emergency use and/or dispensing drugs and having to bill under ASP. Under this proposal physicians would still be held accountable for tracking the drugs once shipped and submitting appropriate claims following administration.

The Academy also recommends that CMS allow physicians to place an order based on expected use in a Medicare patient. Under this system, the vendor would generate bar code/tracking numbers for the medication that are not specifically linked to a patient. For instance, a physician could order five doses of Visudyne for patients being treated for AMD. The physicians would in turn use the doses, which will have a pre-assigned tracking number in the vendor database, on any qualifying Medicare patient who meets the criteria for AMD treatment. This process not only eases administrative burdens, but it also allows physicians and vendors to avoid the additional paperwork associated with re-allocating drugs ordered for one patient and used in another because of emergencies or other unforeseen circumstances.

Lastly, all other drug administration codes received increased payment over the last two years to offset the costs for inventory maintenance and drug administration. However, the infusion code for Visudyne is bundled into CPT code 67221 and received no increase in practice expense payment for the infusion despite having the same practice expense inputs for the infusion as 90780, *Intravenous infusion for therapy/diagnosis administered by the physician or under their direct supervision for up to one hour*. CPT code 67221 also includes the use of an expensive laser, a dedicated room and second skilled clinical staff member. We urge CMS to rectify this inequality.

Physician Election Process

While the Academy understands the requirement that a physician participating in the CAP sign a one-year contract, we recommend that CMS include a provision whereby

physicians who are involved in unsatisfactory vendor relationships can terminate the CAP contract and use the ASP. This provision is needed to resolve situations involving vendors who do not meet the requirements of their CAP contract (i.e. failing to provide drugs in a timely fashion, failing to provide the drugs requested, providing adulterated or improper dosages of the drug requested, etc.).

The Academy also urges CMS to incorporate a provision in the rule which states that vendors are required to accept all physicians who elect to participate in the CAP. The Academy recommends inclusion of another provision stating that under no circumstances is a physician's CAP contract to be terminated based on the inability of the vendor to collect co-payments from one or more of the physician's patients. This provision is needed to protect physicians and their other patients.

Lastly, the Academy would like CMS to clarify whether non-participating physicians who treat Medicare patients will be eligible to participate in the CAP.

Beneficiary Education

The Academy believes that the transition to CAP billing may create tremendous confusion among beneficiaries and is pleased that CMS has anticipated and made plans to address this possibility. The Academy supports CMS's proposal to develop a fact sheet which physicians can distribute to patients who will be receiving drugs through the CAP. The Academy recommends that the CMS-authored fact sheet be developed as a template with sections that could be customized by each CAP participating physician to list the drugs that he/she will be procuring through the program as well as the name and address of the vendor. This will enable physicians to provide their patients with one comprehensive document regarding the drugs whose co-pay will be directly billed to the patient by the vendor.

Conclusion

It is our hope that CMS will give serious consideration to the Academy's recommendations regarding the proposed CAP rule. The Academy anticipates that the CAP can be effectively implemented and looks forward to being involved in the program's phase-in. Again, the Academy would like to thank you for providing us with the opportunity to comment and looks forward to CMS's response.

Sincerely,



Michael X. Repka, M.D.
Secretary for Federal Affairs

Submitter : Dr. Gregg Eure
Organization : Dr. Gregg Eure
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

I do not believe the proposed solutions for prostate cancer drug therapy are in the best interest of the patient or the cost control of medicine. These options will only create an extra, burdensome level of unneeded administration. It will provide an opportunity for another, third party, business venture to profit at the sake of patients' best interests. There will be no incentive for the patient to receive the most appropriate care. It will add another level of frustration for patients who are facing a difficult fight against cancer. I encourage you to put the treatment decisions concerning prostate cancer treatment back in the place where they belong, i.e. between the patient and his physician. Thank you.

Submitter : Dr. Kert Sabbath
Organization : Medical Oncology & Hematology, PC
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

I am extremely troubled that CAP will be implemented without any testing or analysis of what is a radical change in the cancer care drug delivery system. The current drug delivery system developed by community cancer care is a time-tested, proven system. It is extremely effective and efficient in providing treatment to Americans battling cancer. To substitute this proven delivery system with a concept that has not been tested is very dangerous. It makes no sense to introduce a radically new system without adequate study or demonstrations that it works.

Some specific concerns we have about CAP as currently structured are as follows:

- * As a practice we would be locked into the drug vendor you chose for an entire year, regardless of vendor adherence to quality, delivery, etc.
- * Patients will be inconvenienced and have to return for treatment (new or switched) because drugs will have to be ordered.
- * Multiple vendors may be supplying drugs that go into a treatment regimen, thus creating a logistical nightmare.
- * Community cancer clinics currently maintain one drug inventory. CAP will produce multiple inventories, possible individual patient inventories.
- * Aspects of CAP appear to violate pharmacy laws.
- * CAP will produce additional administrative burden, which we doubt will be compensated for by Medicare.

We are extremely concerned that CAP introduces a middleman between the sacred patient/physician relationship, because it will be the vendor dealing with the patient for the Medicare co-insurance drug payment. Patients who cannot afford to pay the co-insurance will most likely be sent by the vendor to a collection agency or forced to pay up front. This removes the current safety net that community cancer clinics provide to their patients who have financial difficulties.

On a very practical level, CMS has not addressed the bad debt that community cancer clinics carry relating to co-insurance payments that are not covered. No commercial vendor is going to float these payments as community cancer clinics are forced to do on behalf of their patients.

This would represent a seismic shift in cancer care at a time when the system is very precarious.

Please do not institute this change.

Yours truly,

Kert D. Sabbath, MD
203 755 6311

Submitter : Dr. Rama Sudhindra
Organization : Southern Oncology Hematology Associates
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

From my understanding of CAP, I believe this program will create un-needed burden on patient, poor quality care, confusion from possible multiple vendors and chaotic inventory management in private office like mine. The system will only create administrative burden, higher cost to practices and drain on medicare system. LET US NOT FORGET THAT THESE ARE REALLY SICK PATIENTS AND ALL OF US NEED TO MAKE SURE THAT WE DO NOT FURTHER INCONVENIENCE THEIR CARE. As is this year in ASP world, a lot of our patients have been forced to undergo treatment else where, escalating the cost for a poor quality care.

Submitter : Mrs. Bethany Barfield
Organization : Hematology-Oncology Associates
Category : Health Care Industry

Date: 04/26/2005

Issue Areas/Comments

1-15

Claims Processing Overview

I am concerned that the proposed rule's delivery standards could pose a significant risk of increased financial and clinical costs to cancer patients. Today, cancer care practices routinely maintain a drug inventory to meet their patients' treatment needs. This has enabled practices to accommodate changes in patients' treatment plans without requiring the patient to return for therapy on another day. Under CAP, however, this level of service could be difficult if not impossible to maintain.

If chemotherapy sessions must be rescheduled to wait for the delivery of the drug(s) that patients need, they will face additional coinsurance obligations for the repeat physician services. In addition, patients will face other financial burdens in the form of higher transportation costs and additional missed time from work. This situation may also mean missed work time and reduced productivity for family members and other caregivers who must bring beneficiaries to the rescheduled treatment sessions.

I recognize that Social Security Act 1847B(b)(5) and the proposed rule permit physicians to receive replacement product from their CAP vendors for drugs taken from the physician's inventory. Even if CAP physicians had a sufficient inventory to draw from, this option appears too narrowly tailored to save most patients from having to undertake a return trip and bear the cost of an additional coinsurance payment. Specifically, the use of the replacement program is limited to situations where the physician builds a record to demonstrate all of the following to the local carrier: (1) the drugs were required immediately, (2) the physician could not have anticipated the patient's need for the drugs, (3) the CAP vendor could not deliver the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

There are a few glaring problems with the inventory replacement option. First, neither the statute nor the proposed rule defines "emergency." Moreover, neither the proposed rule nor the preamble discussion explains what a physician would have to show to justify immediate need or how the local carrier will assess whether the physician could have anticipated the patient's drug needs sufficiently far in advance to permit delivery via the CAP vendor. Aside from the risk that the claim for replacement drug will be denied by the local carrier, the administrative burden of building this record may discourage many physicians from using the inventory replacement option. The inventory replacement option also raises the question about whether commercial insurers are being asked to subsidize a portion of the drug costs for Medicare beneficiaries in CAP, since Medicare would not be paying a physician for the ordering, financing, inventorying and handling costs associated with drugs borrowed from the practice's inventory.

I am even more concerned about what this option could mean for patients, since it is not at all clear that oncology practices will be able to maintain full inventories after the implementation of CAP. Depending on their patient bases, the range of drugs that some practices would need for Medicare beneficiaries may not be the same as the drug inventory that the practice would stock for commercial patients. Moreover, if CAP encourages the proliferation of mandatory vendor imposition (MVI) programs among commercial carriers, it is likely that some practices may stop maintaining drug inventories altogether.

In sum, patients may be forced to pay both a financial and clinical price for treatment disruptions due to CAP, potentially exposing them to medical complications and increased emergency hospitalizations in addition to repeat visits and higher cost-sharing obligations.

Dispute Resolution

According to the preamble to the Proposed Rule, CMS believes that CAP will not significantly increase the administrative burden on physicians. As a result, CMS has concluded that the payment for clerical and inventory management services that is bundled into the drug administration codes should be adequate to cover the practice expenses which physicians will incur under CAP. This is unrealistic for a number of reasons, including the following:

First, CAP practices will have to implement and operate a second, separate ordering process for CAP drugs to transmit patient-specific drug orders that include demographic and clinical information. The ordering system under the buy-and-bill model is much simpler because aggregate orders based on practice usage are placed with wholesalers. Buy-and-bill ordering does not involve the review of individual patient charts nor does it require input of substantial amounts of data for each vial of drug requested from the wholesaler.

Second, CAP will increase the demands on oncology practices for pharmacy management services. Changes in individual treatment plans will have to be closely monitored so that new prescriptions can be sent to the vendor in timely fashion. The job of ensuring that drugs are given to the right patient and that patient-specific drug supplies provided in multi-dose vials have not expired or passed stability deadlines before the entire vial is used will be more complicated because the time that any particular multi-dose vial must be maintained and monitored will increase. The increases in complexity of required pharmacy management services will also increase the risk of medication errors.

A study of oncology pharmacy costs by the University of Utah on behalf of the Global Access Project suggests that the average cost of these services per dose of chemotherapy preparation is already \$36.03. Since the current level of pharmacy services costs is not captured in the practice expense component of payments for drug administration services, the new costs imposed by CAP will be both additive and uncompensated.

Third, CAP will likely increase hazardous waste disposal costs substantially due to complications regarding the redirection, in the physician's office, of unused drug dispensed for one patient to another patient. Waste handling costs will also be higher under CAP due to the increased likelihood that a drug designated for a particular patient will pass its expiration or stability deadline before all of the vial can be finished. As a result, total waste quantities could quickly exceed levels allowable for routine disposal, thereby adding even greater costs.

Fourth, CAP physicians will face much higher claims administration costs. CAP requires Medicare claims for drug administration services to be filed within 14 days of the drug administration service. This represents an increased burden since the Proposed Rule acknowledges that only about 75% of claims currently are filed

within this timeframe and since claims processing software will need to be upgraded. Further, CAP physicians will be unable to make a cost-benefit decision about the value of appealing a claim denial for drug administration services. Instead, physicians could be forced to appeal all denials in a process that requires all the evidence needed to support the appeal to be collected and submitted.

Given the management, inventory control, drug preparation, paperwork, integrity assurance, and other necessary new or enhanced functions that will face physicians selecting CAP, CMS should establish a new HCPCS code for pharmacy management services to compensate physicians. To address the hazardous waste disposal problem, CMS should also require each CAP vendor to subcontract with properly licensed and permitted hazardous waste haulers and disposers to pick up from physicians discarded drugs dispensed by the vendor and to destroy those drugs in accordance with applicable federal,

GENERAL

GENERAL

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement.

As a result, 2005 Medicare reimbursement for cancer care services is considerably higher than pre-MMA rates. However, total reimbursement will drop dramatically on January 1, 2006, when the demonstration project is scheduled to end and the drug administration transitional factor will be zeroed out.

It has been calculated that the impact of these changes will translate into a \$940 underpayment for drug administration services per Medicare beneficiary. Put another way, 2006 Medicare reimbursement for patient care services will cover only an estimated 50.09% of drug administration costs.

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who choose to give up the traditional buy-and-bill model and select the CAP model instead. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

CMS expects CAP to appeal to those physicians who do not want to be in the drug procurement and drug coinsurance collection business? [70 Fed. Reg. 10750]. Indeed, statements made by CMS and CAP's Congressional authors all reinforce the notion that CAP is intended to be an option that physicians may choose to adopt in place of the current buy-and-bill model. According to the MMA Conference Report produced by Congress, "Conferees intend this choice to be completely voluntary on behalf of the physicians? [H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)].

And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even greater should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services which will fall well below the cost of providing drug administration services.

In light of the reimbursement shortfall that looms on January 1, 2006, many cancer care specialists will face a very different choice than the one that Congress intended: continue to offer cancer care services to seniors (under buy-and-bill or CAP) and incur a significant net loss?or discontinue offering chemotherapy services to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

Congress has clearly stated its intent that patient access to community cancer care must be preserved because it is the source of convenient, cost-effective care for more than 4-out-of-5 American cancer patients. If CMS intends to abide by this intent, it must take additional steps to align Medicare reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Submitter : Maureen Lowry
Organization : Consultants in Medical Oncology
Category : Nurse

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

There are many issues of concern with this program. I truly believe that patients will feel the hardship of this program. This program will delay treatments for patients, and increase their number of visits to physicians and clinics. A delay in treatment can compromise a patients response to therapy. These patients are dealing with a life threatening disease and should never have to "wait for a delivery" to start their treatment of cancer.

From a clinic standpoint, this will cause an increase in staff time, ordering and managing inventory for each patient, which I am sure will not be compensated for. Aside from inventory management, patient's appts will need to be re-scheduled continuously based on shipments. Statistics have shown that a delay in treatment puts every patient at risk for a recurrence of their cancer. Even 2-3 days per cycle can have an impact.

Another issue is being locked into a vendor for an entire year. Having no choice in the matter promotes no follow through on the vendor's part. Delivery delays, inadequate turn around time, splitting shipments up at their discretion, and adherence to quality are just a few issues that I am concerned with.

The final outcome from this program will be the deterioration of outpatient chemotherapy treatments. I have worked in Oncology Nursing for 18 years and have seen many changes. The change to the outpatient delivery system has been remarkable for our patients. They enjoy a much better quality of life, spending more time at home than in the hospital. The use of this program will force the outpatient clinics to have patients admitted to the hospital for their treatments. This will increase the cost of cancer care astronomically. Our cancer patients deserve better than this! We need to move forward into the future, not return to days of old.

If you have ever had a family member with the diagnosis of cancer, you will surely understand our outrage with all of these changes. As nurses we have been taught to always put our patients first. I hope you will put them first also.

Submitter : Dr. John Ellerton
Organization : Cancer Consultants
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-325-Attach-1.DOC

April 25, 2005

CMS

Re: CMS-1325-P

As a member of a small oncology group I must protest most strenuously the proposed regulations. To say that there is no change in administrative costs must refer to CMS's costs not ours.

Several years ago our practice had occasion to deal with an HMO that delivered drugs on a per patient basis. Keeping track of these drugs and accounting for their disposition was a nightmare. And now, we are expected to do this on a grand scale.

My small suggestions:

1. Allow us to choose which drugs we contract for—do not make it all or none.
2. Allow us to opt in and out several times a year. Once a year is a bureaucratic nicety but is difficult in practice.
3. Make the transfer of drugs to patients easy. Ie: if we do not use for one patient easily transfer to another. This is another argument for allowing us to choose which drugs to contract for. It is easier to keep an inventory of frequently used drugs, than order on a patient by patient basis.
4. Insulate us from the disputes the supplier will have with patients. These are inevitable, especially over co-pays. The companies cannot be allowed to cut off patients with co-pay problems.
5. Pay us an administrative fee per patient who participates in the program; say fifty dollars per treatment day.

I will not be the first to opt in. In fact, I doubt we will participate the first year. It is too complicated.

John A. Ellerton MD, CM FACP
Cancer Consultants
#110
2020 W. Palomino Ln.
Las Vegas, NV 89106
702-384-0808

Submitter : Dr. J Sherman
Organization : CIU
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement.

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CMS-1325-P-327

Submitter : Dr. Rebecca Cody
Organization : Coastal Cancer Center
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-327-Attach-1.DOC

April 25, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

ATTN: CMS1325-P

Dear CMS,

As a practicing medical oncologist, I would like to thank you for the opportunity to comment on the Competitive Acquisition Program. I believe that the proposed Competitive Acquisition Program does not serve a patient's best interest and detracts from quality of care.

This system as designed is extremely cumbersome. It does not allow for flexibility of same day treatment decisions for non-emergent situations. This inflexibility detracts from the overall quality of care by limiting the options for patients with cancer. Specifically, treatment decisions cannot be made in a timely fashion and subsequently require a built-in delay of several days for changes in therapy. This will ultimately lead to long-term delays in care for patients. Furthermore, this system does not allow appropriately for the dosage reductions that are frequent in cancer therapy. Additionally, it is unclear as to who pays for unused chemotherapy that is wasted through no fault of anyone's (e.g.: unexpected death or a natural disaster such as we have with hurricanes in our area).

The billing system and the ordering process are cumbersome. Coverage of indigent care becomes a difficult issue, in so far as who covers the cost of the chemotherapy. The administrative work caused by the system is an unfunded mandate from the government. The payment coverage of denials of claim processes as well as the appeals process is not clear.

In general, this system does not allow flexibility of same day treatment decisions for non-emergent patients, and overall detracts from the quality of care by limiting the options of patients with a built-in delay.

I do not recommend the implementation of the Competitive Acquisition Program's implementation. More time needs to be spent to work out the mechanisms so that patients are not penalized.

Sincerely,

Rebecca D. Cody
Coastal Cancer Center
8121 Rourk St.
Myrtle Beach, SC 29572
RDC/cjc

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Dr. Carol Bogdan
Organization : Coastal Cancer Center
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-328-Attach-1.DOC

April 25, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

ATTN: CMS1325-P

Dear CMS,

I appreciate the opportunity to comment on the Competitive Acquisition Program. As a practicing medical oncologist, I believe that the proposed Competitive Acquisition Program does not serve a patient's best interest and detracts from quality of care.

This system as designed is extremely cumbersome. It does not allow for flexibility of same day treatment decisions for non-emergent situations. This inflexibility detracts from the overall quality of care by limiting the options for patients with cancer. Specifically, treatment decisions cannot be made in a timely fashion and subsequently require a built-in delay of several days for changes in therapy. This will ultimately lead to long-term delays in care for patients. Furthermore, this system does not allow appropriately for the dosage reductions that are frequent in cancer therapy. Additionally, it is unclear as to who pays for unused chemotherapy that is wasted through no fault of anyone's (e.g.: unexpected death or a natural disaster such as we have with hurricanes in our area).

The billing system and the ordering process are cumbersome. Coverage of indigent care becomes a difficult issue, in so far as who covers the cost of the chemotherapy. The administrative work caused by the system is an unfunded mandate from the government. The payment coverage of denials of claim processes as well as the appeals process is not clear. Furthermore, the "acceptable threshold" for denials of a physician's services is also unclear.

In general, this system does not allow flexibility of same day treatment decisions for non-emergent patients, and overall detracts from the quality of care by limiting the options of patients with a built-in delay.

Thank you for the opportunity to comment on this proposed program. I do not recommend its implementation. More time needs to be spent to work out the mechanisms so that patients are not penalized.

Sincerely,

Carol A Bogdan, M.D.
8121 Rourk St
Myrtle Beach, SC 29572
CAB/cjc

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Dr. Neeraj Mahajan
Organization : Coastal Cancer Center
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-329-Attach-1.DOC

April 25, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Attn: CMS1325-P

Dear CMS,

I appreciate the opportunity to comment on the Competitive Acquisition Program (CAP). As a practicing medical oncologist, I believe the Competitive Acquisition Program is inappropriate for patients in the community and does not serve their best interests in terms of treatment for cancer.

Patients who are diagnosed with cancer requiring chemotherapy need to have flexibility with their treatment. Some patients need to have dosing adjustments made immediately. Some people have toxicities of treatment requiring immediate changes in the actual drugs that are administered for their specific malignant diagnoses. The CAP program does not allow for this flexibility of making very important treatment decisions for patients with life threatening cancer. Based on the proposed CAP rule, there would be delays in making therapeutic changes, so that the vendor would have to be contacted to have new drugs shipped to our office to provide appropriate treatment changes for their cancer therapy. This delay in therapy can be very critical in terms of taking care of patients with debilitating and life threatening cancer.

The billing system also appears cumbersome, as well as the ordering process. If a drug is supplied by a vendor and it is not administered to the patient the rule states "on the expected date of administration" the physician would notify the vendor and then "reach an agreement on how to handle the unused drug consistent with applicable state and federal law". This statement is unclear and there is no vehicle for handling waste disposal and the cost of keeping the drugs viable, either in the doctor's office or potential reshipment back to the vendor. The problem of a supplied drug that is not used is going to be a significant issue throughout the country for practicing oncologists.

As far as the billing system, the rule states that vendors must work with physicians in terms of making sure claims are submitted timely and that there will be a vehicle for dealing with grievances, both from the physician, as well as the vendor. This is very unclear in a situation where chemotherapy drugs are very costly. We would be most concerned with vendors not providing appropriate drugs to the physician in a timely manner to best treat their patients. There is no coverage for indigent care, i.e. patients who do not have secondary co-pay insurance with the proposed CAP rule.

Overall, I feel that the Competitive Acquisition Program is cumbersome, confusing, and inconvenient and will be a detriment to the quality of care that we have established throughout the country in community cancer care.

I do not recommend use of the Competitive Acquisition Program. There clearly needs to be more time spent on working out mechanisms for optimal drug delivery and treatment for patients requiring therapy for life threatening malignancies. Patients should not be penalized for changes in the drug delivery system under the proposed CAP rule provided by CMS.

Sincerely,

Neeraj Mahajan, M.D.
Coastal Cancer Center
8121 Rourk St
Myrtle Beach, SC 29572
843-692-5000
www.coastalcancercenter.com
NM/cjc

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Mrs. Deanna Cochran, CPA
Organization : Mrs. Deanna Cochran, CPA
Category : Other Health Care Professional

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-330-Attach-1.DOC

April 22, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-8010

Attention: CMS-1325-P

To Whom It May Concern:

As an employee in a community based oncology practice, I feel that the proposed Competitive Acquisition Program (CAP) Rule for Medicare would place an enormous burden on oncology practices. The reasons I feel this way are as follows:

1. Increased costs for storing and maintaining inventory for which no reimbursement will be received.
2. Much more paperwork will be involved since records must be maintained for each patient's drugs – increased workload on practice staff.
3. Even if the practice opts not to sign up with CAP, the system of ASP will be affected. There are many services and costs that are not reimbursed which add increased expenses to the practices.

Thank you for allowing me to express my thoughts and concerns to you regarding the CAP Rule. I ask that you take time and reevaluate the effects of this program.

Sincerely,

Deanna Cochran, CPA

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Dr. Rob Hornstra
Organization : UMKC Dept of Psychiatry
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

Please include Mental Health medications as soon as possible. This area is probably the lowest cost area to the system, for the greatest positive impact.

Submitter : Lorrie Kaplan
Organization : National Home Infusion Association
Category : Health Care Professional or Association

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-332-Attach-1.PDF



National Home Infusion Association
Providing solutions for the infusion therapy community

April 25, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

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

Dear Dr. McClellan:

The National Home Infusion Association (“NHIA”) submits these comments on the proposed rule to implement the new Competitive Acquisition Program (“CAP”) for certain Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis, as published in the Federal Register on March 4, 2005.

NHIA is a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in home care and outpatient settings. Our members include independent local and regional home infusion pharmacies; national home infusion provider organizations; and hospital-based home infusion organizations. Generally, infusion pharmacies can be defined as pharmacy-based, decentralized patient care facilities that provide care in alternate sites to patients with either acute or chronic conditions. Currently, NHIA has 1,800 members.

¹ Throughout these comments, our references to “home infusion therapy” pertains to parenteral drugs, which are prescription drugs and biologics administered through catheters and/or needles, provided in a patient’s home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular.

NHIA strongly urges the Centers for Medicare and Medicaid Services ("CMS") to limit the scope of the CAP to Medicare Part B drugs administered "incident to" physician's services, which we believe was Congress' principal intent when it established the program in the Medicare Modernization Act ("MMA"). Furthermore, NHIA would like to express its concern that the CAP's design, in practice, will exclude independent infusion pharmacies from participating as vendors. Physician access to infusion drugs under the CAP probably will have to come from another source. These issues are discussed in greater detail below.

NHIA Urges CMS to Follow Congress' Intent and Limit the Scope of the CAP to Those Part B Drugs Administered "Incident To" a Physician's Services, Particularly for the Initial Phase(s) of the Program.

The CAP, as designed by Congress in Section 1847A of the Social Security Act, appears to be intended to provide physicians with the opportunity to elect annually to obtain drugs from one of a few, select vendors or to purchase Part B drugs and seek reimbursement independently. Numerous elements of the program, as CMS notes in the proposed rule, demonstrate that Congress designed the CAP for physician acquisition of drugs. For example, physicians are the only provider expressly given the opportunity to acquire drugs under the CAP, and the statute explicitly conditions payment for drugs upon administration of the drugs in the physicians' offices.

The Conference Agreement for the MMA similarly describes the CAP as a program designed for the acquisition of drugs administered incident to a physician's services. The conferees state that the CAP "should reduce administrative and inventory costs for physicians," (Conf. Agmt. at 157.) and the description does not reference any other provider type as a potential participant in the program.

CMS also acknowledges in the proposed rule that the CAP is designed for drugs administered incident to a physician's services, stating "[t]he statute, therefore, most closely describes a system for the provision of and the payment for drugs provided incident to a physician's service." (70 Fed. Reg. 10749.) Despite the statutory definition for "competitively biddable drugs" that includes other types of Part B drugs, the statutory language, program design and conference agreement all reflect Congress' intent that the CAP be limited to drugs administered incident to physician's services.

NHIA recommends that CMS follow Congress' intent and limit the scope of the competitive acquisition program for Part B drugs to those drugs administered incident to a physician's service. At the very least, CMS should limit the CAP to drugs administered incident to a physician's services in the initial phase(s) of the program so that CMS can properly review and assess the program's cost-savings as well as its ability to provide appropriate beneficiary access to these medications.

Independent Infusion Pharmacies are Unlikely to be Able to Participate as Vendors in the CAP.

The CAP is intended to produce savings for the Medicare program by increasing competition among businesses that supply Part B drugs to physicians. The vendors must provide "competitively biddable drugs" at prices that are equal to or lower than the applicable ASP payment rate in order for the vendor to be able to compete for a contract with Medicare, and vendors that submit bids that exceed the ASP payment rate likely will not be awarded a contract under the CAP. Under these circumstances, it is unlikely that infusion pharmacies could participate in the CAP program.

Infusion drug payment rates set at ASP + 6% often do not cover even the independent infusion pharmacies' drug acquisition costs. It is for that reason, in part, that Congress exempted infusion drugs covered under the durable medical equipment benefit from the ASP provisions in the MMA. Infusion drugs provided to physicians' offices, however, are reimbursed at the ASP-based rate, and the design of the CAP also would foster payment rates that are lower than these infusion pharmacies' acquisition costs.

Infusion pharmacies also are subject to numerous state licensing requirements as well as industry standards that aim to ensure and protect the quality of the product. The USP 797 practice standards for pharmaceutical compounding-sterile preparations reflect the industry standards that infusion pharmacies must satisfy. These costs, which are not reflected in the ASP payment rate and also are not acknowledged under the proposed CAP, also could impede independent infusion pharmacies' participation in the program.

Since ASP-based rates often fall short of infusion therapy acquisition costs, and certainly are less than the costs of acquisition plus the professional services required to compound an infusion drug in a manner consistent with applicable quality standards, there is little likelihood that an infusion pharmacy could bid significantly lower than ASP + 6% to participate in the CAP. Essentially, the existing design of the CAP will prevent independent infusion pharmacies from participating in the program because the bids these pharmacies would have to submit would be inadequate to cover costs of participation – including drug acquisition costs and necessary overhead expenses.

* * *

We welcome the opportunity to discuss these and other issues with CMS at any time. Please do not hesitate to contact me at (703) 838-2658.

Sincerely,



Lorrie Kline Kaplan
Executive Director

::ODMA\PCDOCS\WSH\351525\1

Submitter : Mrs. Linda Richards
Organization : Cancer Care Associates, P.c.
Category : Other Health Care Professional

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

In December of 2003 DIMA became Federal law. A provision under that law calls for the establishment of a Competitive Acquisition Program (CAP) which is intended to be a cancer drug replacement program. I oppose CAP for the following reasons:

- 1- CAP eliminates competition. It takes CMS out of the negotiation process with pharmaceutical vendors. This country is founded on competition. Multiple reasons can be cited for the current healthcare crisis. Competition is not one of them.
- 2- Oncology Practices are locked into 1 year agreements with the "preferred" CAP vendor. No recourse has been drafted related to vendor quality of drug (counterfeits have occurred) and service. Does CMS want to risk court battles accusing it of eliminating "due process"?
- 3- Multiple inventories will need to be handled in the oncology practice. CAP drug orders are specific to an individual patient. If a patient's health status changes and they cannot receive the drug on the scheduled day, the oncology practice must keep that drug until the patient can receive. Chemotherapy drugs have limited "shelf lives". Who will incur the costs of un-used drug? The CAP vendor?
- 4- CAP will create a burdensome claims processing. The CAP vendor will bill CMS for the drug and the oncology practice will bill for the Administration of that drug. Sounds simple, it is not. Who reconciles these 2 claims from different addresses? Along with the standard demographic information practices normally submit to CMS, they now must include a Prescription Number, any information that will help the vendor collect monies, and agree to submit an appeal along with the drug CAP vendor to help the vendor get paid. Why should the practice help in these areas? This is duplication of efforts. We are doing all this just to get our administration codes reimbursed as well as the Evaluation and Management codes?
- 5- Cancer patients receive multiple drugs during chemotherapy administration. What if the "preferred" CAP vendor does not supply all these drugs? What if they split an order? Again the costs of inventory management will increase for the oncology practice.

CAP will introduce middle-men into the patient/physician relationship, they are called pharmaceutical companies & distributors. They will be the ones asking patients for money and sending patients to collection agencies. Our practice has never sent a patient to collection. We write off hundred's of thousands of dollars each year due to patient bad debt. Has CMS quantified this number?

We all want a solution. Eliminating competition and implementing a solution that has not been fully thought out is not the final answer. I urge CMS to continue to talk with physicians, manufacturers, distributors, patients and insurers to obtain factual data. Work with the "stakeholders" to improve access to chemotherapy treatments. Delay CAP implementation until all of the preceding issues can be resolved.

Sincerely,

Linda Richards

Submitter : Dr. David Decker
Organization : Cancer Care Associates, PC
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

The Center for Medicare and Medical Services Proposed Medical Acquisition Program mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 is yet another potential barrier to Medicare patients expecting to receive quality care in the office of a community oncologist. In Medicare's attempt to further control costs, the Competitive Acquisition Program will significantly interfere with the ability of Medicare recipients to receive cancer care in the offices of community oncologists. The CAP program was clearly written by bureaucrats who do not understand the potential consequences.

1. CAP vendors will have the authority to establish formularies. These formularies will undoubtedly be driven by cost-effectiveness and not clinical effectiveness; therefore, it is possible that treatments are chosen based on financial considerations and not clinical considerations.
2. CAP vendors will be prohibited from delivering drugs and biologicals to participating oncologists except upon receipt of a written prescription. This will essentially result in more paperwork concerning patient-specific inventory. Drugs may be ordered and subsequently not used because of change in the patient's condition. This results in potential waste of unused medications and delays in treatment.
3. CAP participating oncologists will be prohibited from using CAP-required drugs and biologics to resupply their inventories unless four specific requirements are met. In a situation where a scheduled treatment for a patient does not happen as planned because the patient's condition has changed, the patient's appointment will have to be rescheduled pending shipment and delivery of a new CAP order. This is certainly extremely inconvenient for ill patients who require a change in medication. Additionally, the oncologist's practice incurs the added costs of drug handling and inventory management of the unused drug.
4. There is no provision for the emergency delivery of drugs. Patients who need the emergency delivery of drugs will evidently need to wait one or two business days.
5. There appears to be a lack of vendor responsibility in the proposal. Concerns about quality of service do not appear to be grounds for terminating the oncologist's election to acquire drugs from a vendor. Essentially, the patient is locked into a 1-year CAP election.
6. There are multiple administrative issues with the CAP program. These administrative issues will result in the community oncologist's office spending more time with paperwork and less time caring for patients. These uncompensated costs include ordering, tracking, and filing CAP claims. The claims process is burdensome. To participate in CAP, an oncologist must sign an electronic form that commits the oncologist to order drugs via a written prescription for each individual patient; submit Medicare claims within 14 days of the date of drug administration that includes the name and HCPCS code of the drug administered, the prescription number for each drug administered, and the date of service; provide information to the vendor regarding patients to help the CAP vendor collect applicable deductibles and coinsurance; notify the vendor when the drug is not administered; and agree to submit an appeal accompanied by all required documentation necessary to support payment if the participating CAP oncologist drug administration claim is denied. Oncologists receive no payment or compensation for any of these services.

CMS should do a complete impact analysis that both examines and quantifies the true costs of CAP to a community oncology practice and its overall impact of CAP on the delivery of cancer care in the community.

In short, CAP is bad medicine and bad economics. It risks patient care, imposes extra costs and liability on private oncology practices and will cost CMS (Medicare) more money.

Submitter : Mr. Rick Jones
Organization : Little Rock Cancer Clinic
Category : Physician

Date: 04/25/2005

Issue Areas/Comments

1-15

Overview of the CAP

No where in this document did I see any discussion of what will happen when (not if) a beneficiary cannot/does not pay the deductible/co-insurance to the vendor. CMS must stipulate in great detail what the program will do regarding this issue. Does the vendor have the option of denying shipment based on non-payment? If so, then the vendor is creating a barrier to treatment that does not now exist. Also, since CAP is offering physicians the opportunity to escape the burden of collecting deductibles & co-insurances, is it offering us the opportunity to escape the burden of trying to enroll beneficiaries in patient assistance programs and drug reimbursement programs? This should be spelled out precisely and clearly in the rules. CAP vendors will have all beneficiary demographics and medical information from physicians, so the vendor should also be responsible for enrolling beneficiaries into assistance programs.

Bidding Entity Qualifications

Prospective CAP vendors should have a minimum of 2 years experience delivering the all the drugs in the category for which they are going to bid. The nature of each individual drug (even drugs in the same class) are so different that the vendor must have knowledge and experience in handling them. Physicians and beneficiaries must have the confidence in the quality of the drug itself, and in the proper handling of that drug during storage & shipment. There is no substitute for experience.

As to delivery schedules, the requirements as stated are sufficient with the exception of the lack of same day deliveries. There are rare occasions where this is necessary, and it is possible to arrange same day delivery, so it should be written into the rule that this is available as necessary.

Contracting Process-Quality and Product Integrity Aspects

We physicians must see strong, precise language in this rule requiring CAP vendors to maintain the highest levels of quality and performance of delivering drugs. The language must also be strong and precise as to the procedures for complaints (by either physicians or vendors) and how complaints will be investigated and followed through to resolution by CMS, vendors, and physicians. Without high quality standards and clear-cut steps to resolve complaints in writing, we cannot consider enrolling in the CAP program. Also, should an adverse event occur to the detriment of a beneficiary due to vendor negligence (or error of any kind), the vendor & CMS should be held liable, not the physician. This should be spelled out in the rule as well.

Lastly, should a physician become dissatisfied (for any reason) with their CAP vendor, the physician should be allowed to disenroll at any time. We suggest a letter from the physician to CMS & CAP vendor giving 90 notice of disenrollment. The physician should not be locked into a contract for an entire year if dissatisfied with their CAP vendor.

Categories of Drugs to be Included under the CAP

"The ACT further authorizes the Secretary to exclude competitively biddable drugs and biologicals from the competitive bidding system if the application of competitive bidding to such drugs and biologicals-1) Is not likely to result in significant savings; or 2) Is likely to have an adverse impact on access to such drugs.

If a large national supplier cannot acquire drugs at a rate low enough to result in significant savings, then CMS should be required to immediately review its allowables for increased payments for all drugs in that category because physicians are surely taking a loss.

Isn't this "Cherry Picking?" You will include only those categories that will save you money...what part of health care is this? Using this exclusion allows CMS/vendors to provide the category that is financially advantageous (to them) while leaving the financially burdensome categories to the physicians. If you plan to give physicians the ability to get out of the purchasing and co-insurance/deductible collection business, then do it all the way. We are not likely to participate in CAP on a part-time basis. If CMS cannot decide, then I suggest you include ALL potential categories. If this program is going to save money and lighten the load for physicians, then by all means do not discriminate...give all physicians the opportunity to enroll.

Statutory Requirements Concerning Claims Processing

This time frame is acceptable to our practice methods for billing drugs, however, in some situation for some providers this may be too short a time frame. Maybe 21-28 days should be considered as an acceptable time frame for filing a clean claim.

Claims Processing Overview

Physicians choosing to enroll in CAP should be required to obtain all categories of drugs under the CAP program. Just as CMS should not be able to pick and choose those most beneficial (financially) to them, so physicians should not be able to pick and choose. You are either in the program or not. If physicians doesn't want to be in the drug purchasing and deductible/co-insurance collection business, then enroll in CAP and be all the way out.

CMS states "We do not believe that the clerical and inventory resources associated with participation in the CAP exceed the clerical and inventory resources associated with buying and billing drugs under the ASP system." And CMC goes on to say that there no proposal to make a separate payment to physicians for the clerical and inventory resources associated with participation in CAP.

At this time we have an automated inventory system with 1 inventory. As we dispense drugs the system monitors the decreased levels of drugs, and once the level reaches a pre-set (by us according to our usage history) level, the system AUTOMATICALLY files an electronic order with our vendor. This is the case for about 95% of our drug orders. We don't have to collect ANY demographics and give them to our vendor. The machine orders the drugs, our vendor ships them, we put them back into inventory on arrival.

CMS is proposing INDIVIDUAL inventories for EACH patient & Date Of Service (DOS). Example: If we have 100 Medicare patients who are receiving treatment weekly, then we have 100 INDIVIDUAL inventories times the number of treatments the vendor decides is reasonable to deliver. Suppose the vendor decides a 3 week supply is best, then we will receive and have to enter into our inventory system 300 INDIVIDUAL patient inventories, each one by a different prescription number. Then we will be required to keep each of these 300 inventories separate from all others, and upon dispensing the meds enter the CORRECT prescription numbers back into the inventory system for EACH drug. Then that information must be CORRECTLY transferred to the billing department who must then CORRECTLY enter ALL PRESCRIPTION NUMBERS FOR ALL DRUGS GIVEN. Also, not discussed is the time required to gather all the demographic and medical information out of each patient records in a fashion quickly and easily disseminated to the vendor. At this time we do not have to perform ANY of these function. EACH additional step is an opportunity for errors to occur. EACH time a prescription number must be keyed is an opportunity for an error to occur

which will cost much more administrative time (for physicians, vendors & CMS) to detect and correct. **CMS MUST PAY FOR THIS ADDED TIME BURDEN TO PHYSICIANS AND ADMINISTRATIVE STAFF.** Just collecting the demographic & medical information required to place an initial order for a patient could take between 15-30 minutes. This is for each patient that is new to the vendor.

All of these added procedures will add time to the process of dispensing drugs. The nurses will have to take several additional minutes for each patient encounter finding the exact drugs for that DOS, then entering the prescription numbers into the inventory system, then double checking to be sure there are no errors.

Lastly, many other payers follow Medicare's lead, and will institute similar programs. Actually, some national payers already have tried, or are in the process of trying now. So we physicians will in fact have SEVERAL inventories...CMS, numerous other payers, and then our own. Given that CMS is in the lead here, it is incumbent on you to build a system that either makes life as we know it SIMPLER, or else PAY for the burdens you are adding.

Dispute Resolution

As written, this section is absurd. The vendor can complain to CMS about a physician and require a physician to be counseled, and possibly even terminated from CAP, yet the physician has no such rights if dissatisfied with the vendor. CMS is sorely mistaken if you believe physicians will EVER allow a VENDOR to have such control over their practice AND THE WELFARE OF THEIR PATIENTS. Physicians will not participate in CAP without the exact same opportunities for redress of errors/complaints as every other participant in this program.

Competitive Acquisitions Areas

Same as the "Categories of Drugs" above. Since CMS has no preference, then open CAP up to all physicians practicing under the CMS system. No favorites, no cherry picking, no discrimination. Institute a program open to all specialties in every area of the country.

GENERAL

GENERAL

The CAP program's proposed objectives are good ones, and can offer a benefit to providing cost-effective health care to CMS beneficiaries. However, this rule, as written, is so generic and non-specific that it is not satisfactory. We suggest that CMS evaluate all comments received, determine their specific program objectives and rules for each of the sections outlined, and then resubmit this for further comment and evaluation by all interested parties.

Also, as discussed in the "Background" section, part D "Competitive Acquisition Program (CAP) is the statement "The competitive acquisition program may provide opportunities for Federal savings to the extent that aggregate bid prices are less than 106 percent of ASP. This rule also states that there is no expected savings through the CAP program for beneficiaries. How is it that the Federal government and vendors can reap a profit, but the beneficiaries get nothing? We propose that after a set level of savings is achieved by the CAP program as stated in these rules (such as 3 or 5%) to CMS, that future savings (or at least a part of them) are passed on to beneficiaries in the form of lowered co-insurance due.

Submitter : Mrs. Sandra Johnson
Organization : Option Care Specialty Pharmacy
Category : Health Care Professional or Association

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

CMS-1325-P-337

Submitter : Mr. Phillip Lubitz
Organization : NAMI NEW JERSEY
Category : Other Association

Date: 04/26/2005

Issue Areas/Comments

1-15

Overview of the CAP

See attached comments

CMS-1325-P-337-Attach-1.DOC

CMS-1325-P-337-Attach-2.DOC



NAMI NEW JERSEY

*1562 Route 130
North Brunswick, NJ 08559
(732) 940-0991
Fax (732) 940-0355*

April 26, 2005

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

Dear Dr. McClellan:

On behalf of NAMI NEW JERSEY, I am writing to you regarding the Center for Medicare and Medicaid Services' (CMS') proposed regulation [CMS-1325-P] to establish a Competitive Acquisition Program (CAP) for medications covered by Medicare Part B. We are particularly interested in the impact this regulation will have on access to mental health medications.

We continue to be dismayed by the fact that Medicare imposes more restrictive limits and much higher out-of-pocket costs for mental health care than for the care of other illnesses. Of particular concern is the 50 percent co-payment that applies to Part B coverage of outpatient mental health services, instead of the usual 20 percent required for other outpatient care. This unequal and unfair barrier to treatment for individuals with mental illness under the Medicare program is inconsistent with growing and widespread recognition that mental illnesses are real and can be severely debilitating without treatment. The 50 percent co-pay represents a tax on mental health care that is grounded in stigma.

As you know, mental illness affects a very large segment of the Medicare population, but with the discriminatory restrictions and added costs imposed on mental health treatment under this program, few receive the treatment they need. Some 20 percent of older Americans and 40 percent of those on Medicare because of a disability, face mental illness. Yet, all too often they struggle with this disease alone, without treatment and support. In fact, research indicates that two-thirds of those who need mental health care do not receive it. This lack of care has tragic consequences as illustrated by the fact that older adults have the highest rate of suicide in the country, accounting for 20 percent of suicide deaths.

This high co-payment requirement for mental health services has also impeded access to certain types of mental health medications covered by Medicare Part B – such as injectible anti-psychotic medication. Overly complex and confusing reimbursement policies for this type of medication have caused physicians to discontinue use of it for financial reasons instead of therapeutic reasons. The heightened risk of non-reimbursement associated with this type of medication also discourages physicians from even offering it to consumers who may benefit from it.

As you know, mental health disorders require highly individualized treatment. Mental illnesses vary greatly in their symptoms and effects on consumers. In prescribing mental health medications, physicians must take into account myriad factors including past treatment history, likely responses to side effects, other medications currently being taken, any co-morbidities (which are common among individuals with mental illness), and overdose safety, given the heightened risk of suicide. As a result, in order to receive effective treatment, consumers need access to the full array of treatment options.

Thus, we encourage you to include mental health medications in the list of medications covered by the CAP program as of January 1, 2006. The inclusion of these medications in the CAP program would conform with the recommendation by President Bush's New Freedom Commission on Mental Health that "[a]ny effort to strengthen or improve Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services."

Thank you for your consideration of our views. If you have any questions, please contact me at (732) 940-0991.

Sincerely,



Phillip Lubitz, MSW
Director of Advocacy Programs
NAMI NEW JERSEY

A NEW JERSEY NON-PROFIT CORPORATION

AFFILIATE of NAMI - THE NATIONS VOICE ON MENTAL ILLNESS, ARLINGTON, VA.



NAMI NEW JERSEY

1562 Route 130

North Brunswick, NJ 08559

(732) 940-0991

Fax (732) 940-0355

April 26, 2005

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

Dear Dr. McClellan:

On behalf of NAMI NEW JERSEY, I am writing to you regarding the Center for Medicare and Medicaid Services' (CMS') proposed regulation [CMS-1325-P] to establish a Competitive Acquisition Program (CAP) for medications covered by Medicare Part B. We are particularly interested in the impact this regulation will have on access to mental health medications.

We continue to be dismayed by the fact that Medicare imposes more restrictive limits and much higher out-of-pocket costs for mental health care than for the care of other illnesses. Of particular concern is the 50 percent co-payment that applies to Part B coverage of outpatient mental health services, instead of the usual 20 percent required for other outpatient care. This unequal and unfair barrier to treatment for individuals with mental illness under the Medicare program is inconsistent with growing and widespread recognition that mental illnesses are real and can be severely debilitating without treatment. The 50 percent co-pay represents a tax on mental health care that is grounded in stigma.

As you know, mental illness affects a very large segment of the Medicare population, but with the discriminatory restrictions and added costs imposed on mental health treatment under this program, few receive the treatment they need. Some 20 percent of older Americans and 40 percent of those on Medicare because of a disability, face mental illness. Yet, all too often they struggle with this disease alone, without treatment and support. In fact, research indicates that two-thirds of those who need mental health care do not receive it. This lack of care has tragic consequences as illustrated by the fact that older adults have the highest rate of suicide in the country, accounting for 20 percent of suicide deaths.

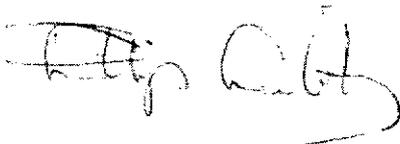
This high co-payment requirement for mental health services has also impeded access to certain types of mental health medications covered by Medicare Part B – such as injectible anti-psychotic medication. Overly complex and confusing reimbursement policies for this type of medication have caused physicians to discontinue use of it for financial reasons instead of therapeutic reasons. The heightened risk of non-reimbursement associated with this type of medication also discourages physicians from even offering it to consumers who may benefit from it.

As you know, mental health disorders require highly individualized treatment. Mental illnesses vary greatly in their symptoms and effects on consumers. In prescribing mental health medications, physicians must take into account myriad factors including past treatment history, likely responses to side effects, other medications currently being taken, any co-morbidities (which are common among individuals with mental illness), and overdose safety, given the heightened risk of suicide. As a result, in order to receive effective treatment, consumers need access to the full array of treatment options.

Thus, we encourage you to include mental health medications in the list of medications covered by the CAP program as of January 1, 2006. The inclusion of these medications in the CAP program would conform with the recommendation by President Bush's New Freedom Commission on Mental Health that "[a]ny effort to strengthen or improve Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services."

Thank you for your consideration of our views. If you have any questions, please contact me at (732) 940-0991.

Sincerely,



Phillip Lubitz, MSW
Director of Advocacy Programs
NAMI NEW JERSEY

A NEW JERSEY NON-PROFIT CORPORATION

AFFILIATE of NAMI - THE NATIONS VOICE ON MENTAL ILLNESS, ARLINGTON, VA.

CMS-1325-P-338

Submitter : Dr. Beth Karlan
Organization : Society of Gynecologic Oncologists
Category : Health Care Professional or Association

Date: 04/26/2005

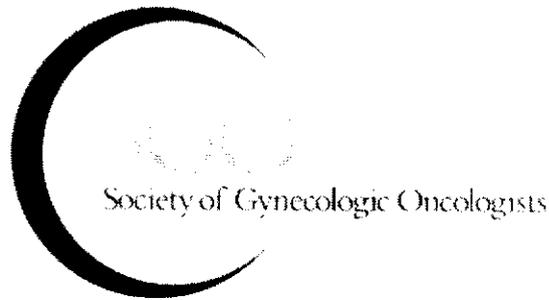
Issue Areas/Comments

GENERAL

GENERAL

The Society of Gynecologic Oncologists wishes to submit formal comments on CMS-1325-P - Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologics. Please see attachment that is submitted in Word format. We will follow with the original letter and two copies.

CMS-1325-P-338-Attach-1.DOC



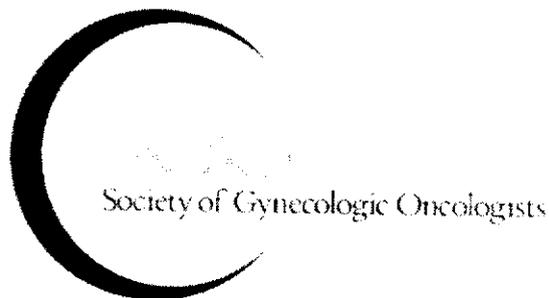
April 25, 2005

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

Dear Dr. McClellan:

The Society of Gynecologic Oncologists (SGO) appreciates the opportunity to offer comments on the proposed Competitive Acquisition Program (CAP) for Medicare Part B Outpatient Drugs and Biologics. A majority of our members provide office-based chemotherapy to patients with gynecologic malignancies. Consequently, this proposed program would have a significant impact on our patients and our member physicians. Our primary goals in responding to this proposed rule are to insure access to the highest quality of cancer care for our patients. In reviewing the CMS proposal, we have identified numerous issues that present obstacles to quality cancer care and may increase the costs to deliver this care.

1. **Drug delivery:** How the drug(s) are delivered will significantly alter the processing costs for physician practices (vials vs. premixed) as well as projected waste, inventory, resupply, and emergency acquisition. CAP vendors also will have authority to establish formularies which may limit the choice of deliverable drugs, that may be determined by costs rather than effective or appropriate indications. What provisions will be made for participating physicians to utilize drugs not found in vendor established formularies?
2. **Quality and Quantity:** How can the treating physician insure the quality and quantity of the delivered medications, especially if the medications are delivered premixed by the vendor? What recourse does the treating physician have if they believe or suspect that the quality or quantity is unacceptable? If the physician has concerns about the delivered medications, are they allowed to substitute drugs obtained through another vendor while they investigate the issue with the designated vendor?
3. **Dosage Adjustments:** If the calculated drug dosage should differ between the date of the order and the date of administration, how will the adjustment be made and what will be the process to communicate this change to the vendor? Does the patient have to return for another clinic visit after the vendor makes the dose adjustment, or will the physician have the ability to make the dose adjustments in some other manner?



4. **Waste Management**: How should excess drugs for a given patient on a given day be managed? Should the unused excess medication be wasted? Can the excess be sent back to the vendor? Who will be financially liable for the delivered excess medication?
5. **Claims Processing**: How can the physician and patient be assured that the vendor is submitting the bills for the drugs correctly? What would be the appeals process if mistakes are identified? What will vendors do with Medicare beneficiaries who are unable to pay the co-payments due on the ordered medications? Do the vendors have the right to deny delivery of drugs to patients who make only partial payments? What appeals process is available to patients with limited financial resources?
6. **CAP vendor contract**: Commitment to the program for an entire year is unacceptable. We understand that stability of customers is important to the vendors. Nevertheless, if the physicians and/or physician groups find the program to be unworkable, what recourse will they have if the relationship with the vendor remains unsatisfactory? How will medication orders to the vendors be accomplished? How quickly can orders be changed when needed? What if the vendors are not able to deliver medications on time?
7. **Un-reimbursed Pharmacy/Processing Costs**: There is considerable anxiety that the drug administration fee reimbursement may not cover all the costs of maintaining an OSHA-compliant infusion center, employment of oncology-certified nursing staff, and the added administrative costs such as maintaining a separate patient and drug specific inventories, plus the added burden of assisting vendors with denials of payment by the regional Medicare carriers.
8. **Program Goals**: How does the current proposal improve access to quality patient care? We are concerned that some physicians may conclude that they can no longer afford to offer office-based chemotherapy to Medicare beneficiaries in the environment suggested through the CAP proposal and/or with current methods of drug delivery. Consequently, these patients are likely to be referred to hospital-based infusion centers that are more expensive and these hospital-based infusion centers may become overwhelmed by patient volume.

The Society of Gynecologic Oncologists recommends that CMS consider the following modifications/additions to its proposal:

1. Adopt a two-year transition after the introduction of the CAP during which individual physicians and physician practice groups would have greater flexibility to opt in or out for periods less than one year.
2. The transition period would involve intense monitoring of the CAP by CMS regarding the effectiveness of the program including quality and access to care and added costs associated with program administration, pharmacy processing, and drug waste.



Society of Gynecologic Oncologists

3. Physicians and groups that choose to participate in the CAP should be offered increased reimbursement for the drug administration codes to compensate for the increased work of record keeping and other administrative details. For example, physicians would need to develop a separate new system for monitoring drug inventory that is different than that used for patients covered under other insurance plans. This could be accomplished with the addition of special modifiers attached to the drug administration codes that identify participants in the CAP.
4. An appeals process should be developed so that physicians who experience problems with the quality and delivery of the drugs through their designated vendor can seek rapid redress of the problem, either through CMS or the regional carrier.
5. A fallback system is necessary in case the designated vendor does not adequately fulfill their obligations to the patient or physician. This would include the ability of the physicians to revert back to the standard “acquire and bill” system without penalty if patient care and/or access is endangered due to problems with the vendor.
6. During the transition, we recommend that CMS adopt a vendor system that is maximally responsive to the physicians and groups. In the initial stages of the CAP, the vendors should cover the smallest reasonable geographic region (e.g., one state or several adjoining states). We are very concerned that vendors who cover very large geographic regions may not be adaptable to unique local problems (such as mountainous or rural areas) where timely delivery may be difficult or expensive.
7. We recommend that the CAP vendors absorb the costs of returning drugs, or unusable drugs, and that the vendors must be willing to advance credit for drugs when patients are unable to make the required co-payments.
8. Composite bid analysis and establishment of payment rates of drugs based upon composite bids from vendors should not be part of the CMS proposed adjustment to Medicare reimbursement rates, and should in no way affect the ASP + 6% rates established by other criteria.
9. We recommend that the CAP vendor be willing to provide drugs for “off label” use when the medical literature supports the indication, and that the vendor use the established CMS process for determination of medical necessity. We are concerned that vendors will not be amenable to provide drugs “off label”, since these drugs may not be reimbursed without going through a formal appeals process.
10. We recommend that CMS phase in the CAP with the fewest number of drugs possible. CMS could choose either the most expensive drugs or the most frequently used drugs as a trial run. Either way, the initial trial period would provide a meaningful test of the costs and effectiveness of the CAP.
11. We recommend that CMS include in the reimbursement to physicians and physician groups a product preparation fee (i.e., a pharmacy fee) if the drugs require reconstitution prior to administration.



Society of Gynecologic Oncologists

In its current form, the CAP proposal has very little that would be attractive to physicians who offer office-based chemotherapy. Although it is possible that the CAP might offer cost savings to the Medicare program, it is not obvious how these benefits would result in improved access to care, improved quality of care, or decreased costs to the Medicare beneficiary. Just as importantly, we are skeptical that SGO members would embrace such a complex program that may not yield significant benefits to our patients and may likely increase the physicians' costs for drug administration. We fear that the net effect may result in shifting many Medicare beneficiaries from office-based services to hospital-based programs that are already overwhelmed and more expensive.

The Society of Gynecologic Oncologists is committed to working in partnership with CMS to provide access to quality oncology care for our patients with gynecologic malignancies. We hope that our comments are viewed as positive steps to improving the cancer care for a large segment of the patient population that we serve. We would appreciate the opportunity to work with CMS in this regard. Please feel free to contact us if you have questions about our recommendations or wish to work further with us.

Sincerely,

Beth Karlan, M.D.
President, Society of Gynecologic Oncologists

Gary Leiserowitz, M.D.
Chair, Coding Committee

Carol Brown, M.D.
Chair, Government Relations

John V. Brown, MD
Chair, Clinical Practice Committee

Submitter : Dr. Anne Bauer

Date: 04/26/2005

Organization : Mass. Society for Prevention of Cruelty to Childre

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

As a psychiatrist working with low income clients, some of whom do not have insurance - I would like to see psychiatric medications included in CAP. And this would include long acting injectible antipsychotic medications. Thank you for your consideration

Submitter : Dr. Mariette Austin
Organization : Dr. Mariette Austin
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

1-15

Overview of the CAP

CMS does not yet seem to have enough of the specific information with regard to financial performance standards for vendors, creating a pricing methodology, designing and running a bidding process, providing physicians with adequate opportunity to elect to participate and select a vendor, education beneficiaries about the program -- and the CAP bidding process and vendor selection is currently aiming for a deadline of Fall, 2005 -- with an anticipated effective date of Jan 1, 2006. I feel that CMS needs to take more time to develop all the above, and therefore delay the effective date of CAP until all critical elements are fully developed.

Bidding Entity Qualifications

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

Categories of Drugs to be Included under the CAP

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

Statutory Requirements Concerning Claims Processing

Apparently, the physician will be required to submit a written order or prescription to the approved vendor. Each or prescription order is to be accompanied by 15 elements of information. This is cumbersome and does not lessen the administrative burden on physicians -- but rather, increases the burden dramatically. In addition, the proposed CAP system necessitates that participating physicians maintain individual, patient-specific inventories -- therefore complicating inventories immeasurably, and significantly increasing inventory procedure costs. In addition, since roughly one-third of treatments are changed or switched during treatment cycles, there will be a significant waste problem that will increase waste disposal costs to physicians and increase drug reimbursement costs to Medicare. In addition, if a patient needs to change treatment, it is usually necessary to change the treatment on the same day so as not to compromise the management of the patient which is almost schedule-dependent -- and not in the best interest of the patient to return in another day or two, in order to obtain a new mixture of drugs, rather than obtain treatment from the physician's current inventory. Delaying treatment and requiring patients to return on another day or wait in order to receive new shipments of drugs acquired through the Cap vendor, is an enormous inconvenience to the patient and a cost to the practice. Also, such delays in treatment can adversely affect the patients' health and ultimately drive up health care costs. Further, most pharmacy regulations indicate that a drug, once dispensed in a patient's name, may not be returned, reused, or reshelfed. Conversion of oncology drug inventories from a single centralized, non-patient specific inventory to a patient-specific individualized inventory creates the potential for millions of dollars of "waste" from unused and unusable medications. CAP does not address this issue at all. And furthermore, the costs of drug handling and inventory in outpatient oncology practices run about 12% of total drug purchase expenditures. It is therefore imperative that CAP must recognize and compensate oncologists for the costs of drug handling and inventory. Finally, community oncologists generally are reluctant to refuse to treat a patient who cannot afford to pay a co-payment. Vendors, however, are not ethically or legally responsible for the course of a patient's treatment. If a vendor is unable to collect co-payments from a patient, the current CAP does not prohibit the vendor from stopping delivery of drugs to the physician's office. Allowing vendors to stop delivering drugs to an outpatient setting is likely to endanger patients or force them into more costly in-patient settings for treatment. Further, physicians could be exposed to liability if the physician is unable to complete a course of treatment because a vendor is refusing delivery. Therefore, the final rule must make clear that vendors cannot refuse to deliver drugs because they are unable to collect co-payments.

Contracting Process-Quality and Product Integrity Aspects

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

Submitter : Dr. William Mooney
Organization : Oregon Hematology Oncology Associates
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

I completely disagree with the proposed competitive acquisition program CAP.

1. You are locked into a CAP vendor for one year.
2. CAP vendors can establish formularies
3. CAP vendors are prohibited from delivering drugs and biologicals to a participating oncologist except upon receipt of a written prescription. This means that orders placed and filled under CAP are specific to a particular patient and the CAP participating oncologist must maintain an electronic or paper, patient specific inventory for each patient. Individual inventories also create potential for millions of dollars of 'waste' from unused and unusable medications.
4. There will be patient inconvenience and inventory resupply problems
5. There are no emergency provisions
6. There will be very burdensome claims processing
7. Vendors may have oncologists investigated and excluded.
8. If an oncologist places an order for a patient's entire course of treatment at one time, the CAP vendor is permitted to split the order into different shipments without the oncologist's authorization.
9. There will be quality control problems and a lack of vendor responsibility.
10. The pharmacy costs are un-reimbursed - further addition to the reimbursement shortfall.

Submitter : Mr. Steven Cosler
Organization : Priority Healthcare Corp.
Category : Health Care Industry

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-342-Attach-1.DOC



April 25, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1380-IFC
P.O. Box 8010
Baltimore, MD 21244-1850

Dear Dr. McClellan:

Priority Healthcare Corporation (Priority), a specialty pharmaceutical distributor and specialty pharmacy services provider, is pleased to submit these comments in response to the proposed rule for the competitive acquisition program (CAP) of outpatient drugs and biologicals under Part B ("proposed rule").¹ Priority supports the Centers for Medicare and Medicaid Services' (CMS) efforts to implement the CAP program and seeks to implement the policy goals of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) in a manner that best serves the interests of beneficiaries, providers and taxpayers.

Priority understands that optimal patient care and convenience is the ultimate goal of Congress and CMS, and strongly supports that position. Furthermore, we support CMS in its position that the community physician office setting is the right place to provide most of the drugs covered under this rule with appropriate compensation for administration and delivery of high quality care.

In these comments, Priority seeks to ensure that the CAP program regulations promote optimal patient care and convenience, appropriate reimbursement for physician offices, as well as fair compensation and risk mitigation for CAP vendors. Additionally, we seek to ensure the integrity of products through a logistically sound and operationally efficient distribution model. Finally, we are committed to ensuring compliance with all applicable state and federal laws, as well as appropriately allocating risk among all parties, based upon what each party can directly control.

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

¹ "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B," 70 Fed. Reg. 10,745-10,773 (Mar. 4, 2005).

Introduction to Priority Healthcare

Throughout the past year, we have had the privilege of meeting with many CMS representatives in both formal and informal settings to discuss the CAP program. In these meetings we discussed the uniqueness of our company and proposed model or models with Herb Kuhn, Director of the Center for Medicare Management (CMM), Don Thompson, Amy Bassano, and others within the Centers for Medicare and Medicaid Services (CMS). Through these interactions we feel we have a strong understanding of where CMS wants to take the CAP program, and have provided CMM with our initial impressions of the draft rule, gleaned from interactions with our customers, physicians, health plans, and pharmaceutical manufacturers. The comments within this document are a more thoughtful and deliberate reflection of our concerns as we hope to continue our dialogue with you and your staff as final preparations are made to launch this important program.

As both a specialty distributor (distribution of specialty and biotech drugs to physician offices, clinics, etc. in their "bulk" form, non-patient specific), and a specialty pharmacy (provision of pharmacy services for specialty and biotech products on a patient specific basis, to the physician office or directly to the patient's home), Priority is uniquely positioned to meet the requirements of the CAP program for CMS, physician participants and patients.

Unlike pure distributors, Priority has extensive capabilities and experience in reimbursement services, claims processing and adjudication services. Priority also provides clinical services, including 24/7/365 nursing and pharmacy support, that define comprehensive specialty pharmacy care. To this end, Priority has developed our Caringpaths clinical programs based on core criteria and utilization management protocols specific to best practice standards that are both drug and disease specific. Our Caringpaths care management therapeutic programs help to ensure that patients and physicians are successfully managing these therapies and lead to successful outcomes. Additionally, Priority is an experienced provider of other related patient and physician office support services that include metric based compliance tracking, electronic medical record integration and disease treatment management programs, all of which are a testament to our experience working to build best in class specialty pharmacy programs.

Priority is also distinguished from pure pharmacies as we have extensive expertise in logistics and cost effective distribution systems, augmented by our clear focus and expertise in the specialty channel. Therefore, Priority has significant insight into this market and is uniquely qualified to offer input to CMS on this proposed program, and to potentially work with CMS to craft the type of hybrid solution that may best fit your requirements.

One of the issues that CMS must reconcile within its final rule, is whether vendors are to be distributors (under state wholesaler/distributor licensure), or pharmacies (under state Board of Pharmacy licensure). This distinction is critical to ensure vendor adherence to all appropriate state and federal laws. Our assumption, based on the patient specific requirements of this program, is that pharmacy licensure is required, along with the 3 year experience requirement as outlined in the proposed rule.

Comments

Adjudication Risk

Under the proposed model, CAP vendors must wait until the physician's claim for drug administration is submitted before they can submit a claim for reimbursement. This is problematic from both a time value of money perspective and for the potential adjudication risk. While the time value of money is clearly an economic cost, the greater risk is that the CAP vendor may be penalized for untimely or inaccurate submission of the administration claim, a circumstance that is completely out of the control of the CAP vendor.

Credit Risk

Additionally, under the existing rule, the CAP vendor's claim must be matched to the physician's claim before a bill for coinsurance or a deductible can be generated. This situation is further exacerbated with respect to the collection of beneficiary co-payments. Every day that transpires without collecting a co-payment significantly impairs the contractor's ability to realize the full price of the product, with the risk of non-collection of these co-payments being another cost factor that must be considered by CMS and CAP vendors. Placement of this credit risk on the CAP vendor would place an undue burden upon the vendor and therefore make the program such a high risk that participation may be untenable. We feel that CMS needs to allow the CAP vendor to collect the coinsurance and deductible at the time of pharmacy dispense. In the traditional pharmacy revenue model, a service is performed and revenue is earned based upon the standards set by the state's pharmacy laws for supplying medication to patients. Once the pharmacy has met the lawful definition of "dispense," it has earned its revenue. Services should be billable and payable at the point that the service is performed, both for the physician and the pharmacy vendor. If this cannot be accomplished, CMS needs to otherwise protect the CAP vendor from this potential loss.

Distribution Risk

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

Many states do not permit pharmacies to accept returns from patients except under specific circumstances such as when the product is returned in a properly labeled and sealed manufacturer's package or if customized units are individually sealed and part of a closed-drug delivery system.² The Food and Drug Administration (FDA) also recommends that pharmacists not accept return of drug products once they have left his or her possession.³

² Fla. Admin. Code Ann. r. 64B16-28.118 (2005) (prohibiting returns by patients except for unused portions of a unit dose package dispensed to in-patients in a closed delivery system and if the drug is individually sealed and properly labeled); Md. Regs. Code tit. 10, § 10.34.10.07 (prohibiting returns to a pharmacy's stock of previously sold product unless the product is properly labeled and sealed or, in the case of a unit dose, the pharmacist determines the product to have been handled in a manner that preserves the strength, quality, purity, and identity of the drug).

³ FDA Compliance Policy Guide § 460.300 (CPG 7132.09).

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

Conclusion

Given that aggregate CAP bids must be submitted at a pricing level under ASP plus six, every burden placed on CAP contractors must be carefully considered. As it stands today, there are significant risks for potential CAP vendors that CMS needs to address in the final rule. Absent any changes to the proposed rule, Priority would most likely not be able to participate as a CAP vendor. Priority appreciates your consideration of these comments and welcomes the opportunity to contribute to the development of a final rule that meets the objectives of Congress and CMS.

Steven D. Cosler
President & Chief Executive Officer

DCI 763873v.1

Submitter : Mrs. Nancy Beebe
Organization : NAMI Virginia
Category : Individual

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

Following are a number of issues that would be of importance:

- 1) Inclusion of Psychiatric Drugs
- 2) Inclusion of Psychiatric Drugs in Phase I
- 3) Inclusion of Mental Health Drug Category
- 4) Ensure Rule Prevents Discontinuation of Therapy by Vendors

Submitter : Ms. Cynthia Kresge
Organization : Cancer Care Associates
Category : Physician Assistant

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

I don't feel that implementation of this program will benefit patients who are receiving cancer care. Imposition of mandatory vendors will slow down the treatment process, require extra visits from patients who will have to wait for their drugs to be ordered, and potentially increase the cost of delivering care if meds can not be used due to unexpected changes in therapy.

Many of our patients rely on family and friends to bring them for their appointments and caregivers will have to take more time from their work schedules to bring in their family members, especially if we have to order drugs individually for patients and have them come back to receive treatment once drugs are received. Also, the process of stocking drugs for individual patients will require significantly more space and book keeping than our current inventory system of acquiring and maintaining a drug supply.

Overall I think this is poor legislation and disagree with its implementation, both from a consumer and a user perspective.

Submitter : Dr. Wayne Creelman
Organization : Michigan Psychiatric Society
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

Michigan Psychiatric Society
271 Woodland Pass
Suite 125
East Lansing, MI 48823
mps@mpsonline.org

April 26, 2005
Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

Dear Administrator McClellan:

The Michigan Psychiatric Society (MPS) is a state medical specialty society representing psychiatrists in Michigan and a district branch of the American Psychiatric Association (APA). We are submitting comments pertaining to CMS-1325-P, the proposed rule for acquisition of drugs and biologicals, under 42 C.F.R. Part 414, published in the Federal Register on March 4, 2005, with the title, 'Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B.'

Among the members of MPS are psychiatrists who treat publicly funded patients in Community Mental Health Centers (CMHC), many of these patients are Medicaid-Medicare dual eligibles, who will be receiving new pharmaceutical coverage under Medicare. Psychiatrists in Michigan's CMHCs are serving a subset of patients who have serious mental illness and whose response and/or adherence to treatment may be significantly enhanced by a relatively new form of an anti-psychotic drug, risperidone, now available as a long-acting injectable medication.

This product has been utilized for Medicaid beneficiaries in our state with good clinical results, however, the acquisition process under Medicaid has been a physician 'buy and bill' arrangement that has been difficult for many of our Community Mental Health Centers to operationalize. This is impeding access to a potentially cost-effective outpatient treatment.

When we became aware of the Medicare proposal for the competitive acquisition program (CAP) for injectables under Part B, we were initially very pleased with the model. In fact, we have been pursuing similar processes for our state Medicaid program. However, we learned that psychotropic medications are not necessarily included in the first phase of the CAP program. In addition, we have learned that the initial design of the program raises some significant concerns regarding potential administrative burdens as well as due process concerns in the proposed dispute resolution provisions.

The American Psychiatric Association, in its written comments on the proposed rule, outlined important concerns for the physician community, as well as proposed remedies and simplification measures. We at MPS hope that the goals of CMS' acquisition proposal can be accomplished within the framework of the APA's proposed corrective solutions. We believe that the inclusion of psychotropic medications in the CAP is of utmost importance to allow access to important treatment for Medicare beneficiaries.

Thank you for the opportunity to submit these comments.

Sincerely,

Wayne L. Creelman, MD
President

Submitter : Ms. Lori Webb
Organization : Ms. Lori Webb
Category : Individual

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-346-Attach-1.DOC

April 21, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-8010

Attention: CMS-1325-P

“RE: Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals under Part B”

To Whom It May Concern:

Thank you for the opportunity to comment to CMS on the Medicare Competitive Acquisition Program which is scheduled to begin 01/01/06.

“An Overview of the CAP Rule”

I have lived in South Carolina for the last 2 years. In this time I have been working for the local cancer center in Horry County. I have been in the medical field for the last 8 years but the changes I have seen in Oncology have been costly and unproductive to the physicians. I work on a day to day basis with oncology patients and have also experienced having a close family member who passed away from cancer. I am very concerned with the Competitive Acquisition Program. In reading the proposed information I believe the proposal is subject to the following flaws:

1. The proposed rule states that this could save the physician time and paperwork. However, according to the CAP Rule, it will be the provider's responsibility for getting the patients signed up with a vendor, supplying demographic information, etc., which will require an increase in staff and workload.
2. Patients could have a longer wait for treatment due to demographic, insurance, regimen treatment information, etc., to be supplied to a vendor and the vendor delivers the chemotherapy medications to the practice.
3. When the physician orders the drugs for the Medicare patients, these drugs are going to have to be kept in a separate inventory because most physicians also see patients that have commercial insurance, not just Medicare patients.
4. Our office is located in a tourist area of South Carolina. We have many patients that live in the North during the summer and come here during the winter. Have you considered how this is going to affect them? Again, according to CAP, it will be the responsibility of the provider and staff to gather necessary information for the patient and vendor and to prescribe to vendor for delivery so this patient can continue regular treatment.

5. Also, when patients are getting two separate bills for the service, they are going to become very confused. Again the responsibility of explaining this to the patients will fall on the physicians and staff.
6. We would expect the vendor to not hold any shipment due to an outstanding bill that the patient may have with the vendor. Will the vendor notify the physician as to why drugs are not being sent for a specific patient? This cost of administrative duties for these issues will ultimately be the provider's.
7. I am concerned that this proposal could force patients to opt out of crucial and life altering treatment.

I am proud of the Oncology practice that I am associated with, as we are compassionate, caring and committed to excellent patient care. We provide our patients with daily comforts locally so that they maintain productive and happy lives. I fear that maintaining our level of excellence in providing care for our patients may be compromised under the proposed CAP rule.

Again, I would like to thank you for taking the time to hear my concerns and hope that you will be a part of our effort to maintain our level of excellence in patient care.

Sincerely yours,

Lori M. Webb
Location Supervisor
Coastal Cancer Center

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Dr. Todd Kliewer
Organization : Oklahoma Society of Clinical Oncology
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-347-Attach-1.DOC

April 26, 2005

attach#347

Mark B. McClellan, M.D., Ph.D.
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS -1325-P
P.O. Box 8010
Baltimore, MD 21244-8013

Re: Comments on the Proposal for Competitive Acquisition of Outpatient Drugs and Biologicals Under Medicare Part B

Dr. McClellan:

I am writing on behalf of the membership of the Oklahoma Society of Clinical Oncology regarding CMS-1325-P (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B) which was published in the Federal Register on March 4, 2005. OSCO represents the majority of medical and radiation oncologists throughout the state. OSCO has several concerns regarding this program, and, these comments are organized by the subjects specified in the notice.

General Overview of CAP:

OSCO does not support a "hurried" effort to enact an untested program. Most physicians and practices within the state do not fully understand the ramifications of the CAP program. This is understandable since CMS itself has not clarified multiple issues regarding the basic structure of the program. Since it is now almost May of 2005, we feel that five to seven months is not sufficient time to organize and establish a completely new and "theoretical" pharmaceutical provision program especially when **CMS has no data to actually support any cost savings by implementing the program.**

Categories of Drugs to be included in CAP:

To begin, once again, seven months is insufficient time to seriously consider any theoretical approach to medication inclusion within the CAP program and then to allow sufficient public comment.

Next, the establishment of formularies is potentially dangerous regarding appropriate management of oncological conditions. Chemotherapeutics are typically not interchangeable, and, certainly, medications within a certain class may have different FDA approved indications. If physicians have to work outside of the CAP program to provide appropriate chemotherapeutics due to vendor enforced formularies, the CAP program would in effect prove to be of no worth except to increase healthcare cost and endanger the lives of patients.

Importantly, any provision regarding potential vendor inventory must allow physicians the ability to evaluate the vendor's inventory both prior and subsequent to a relationship with that vendor. A physician should also have the right to discontinue a relationship if the vendor fails to make proper disclosures or will not allow the proper treatment for any specific patient based upon formulary.

Statutory Requirements Concerning Claims Processing:

First, there is no provided compensation for required services the physician must provide in order to assist the vendor (insurance and beneficiary information, appeal documentation, pharmaceutical tracking). This includes a significant amount of paper/electronic work not

currently performed by physicians' offices. For a system established to disentangle my member physicians from the pharmaceutical business; it, in fact, creates a significant administrative burden upon practices that is not reimbursed. The "reward" is to act as an unpaid agent of the vendor with significant liability and potential CAP exclusion without due process.

Second, costs will increase as physicians are compelled to maintain patient specific inventories. Medication waste and thus overall cost will also increase with unplanned chemotherapy changes and unavoidable delays.

Third, potential split shipments will disturb appropriate chemotherapeutic administration and timing. This will interfere with regimen efficacy, and, it will have a severe negative impact upon the amount of time a patient spends within the office environment thus increasing administrative cost.

Fourth, it is inappropriate and unethical for physicians to be potentially liable for negative outcomes if a vendor refuses to provide medication due to lack of patient co-pay payment. It is also unethical for patients to begin a chemotherapeutic treatment program and then be denied completion of therapy due to financial concerns. Vendors are not legally or ethically responsible for a patient's therapy; therefore, their denial of medication due to personal economics is a real possibility.

CAP Contracting Process:

CMS has not established standards of quality to which approved chemotherapy vendors must adhere. This lack of such standards places both patients' lives and physicians' practices at significant risk. Both physicians and patients need to believe that CMS will seriously investigate independently any questions regarding quality control, not leave the issue to the vendors own internal grievance process. It is both unsettling and unprecedented that practitioners would be "locked" into such a system on an annual basis without realistic expectations regarding quality and performance. It is beyond comprehension that CMS would be willing to place patients' lives at risk in such a system.

Bidding Entry Qualifications:

Physicians and patients have the right to expect very timely arrival of ordered medications. CMS must be prepared for a large financial loss due to chemotherapy wastage unless it necessitates same day delivery.

Beneficiary Education:

Current and future Medicare patients must be appropriately educated regarding the impact of MMA upon oncology and the administration of chemotherapeutics prior to January of 2006. It is unethical to "surprise" beneficiaries with substantial debt, substandard care and medication quality, and even denial of timely therapy after a lifetime of paying into the system. A "fact sheet" is insufficient, and, physicians will not be reimbursed for their time in patient education.

The following is a brief summation of the problems with the CAP program.

1. Mandatory annual vendor enrollment with limited ability to leave a specific vendor regardless of quality or performance.
2. Vendor imposed formulary establishment based upon pharmaceutical costs rather than patient welfare.
3. The establishment of multiple patient specific pharmaceutical inventories within a practice with the concomitant increase in administration cost and burden.
4. Increase in drug wastage and inappropriate delays to patient treatment schedules.
5. Lack of provision for timely treatment under emergency circumstance. Cost will increase as patients are admitted to hospitals in order to provide therapy.

6. Increased costs to the individual physician practices that will not be reimbursed in the form of burdensome claims processing.
7. Although no provision is made to compensate for increased administrative burden, vendors can request participant investigation or exclusion based upon failure to file timely claims or pursue appeals. Hypocritically, if a physician complains regarding a vendor's behavior, the claim is overseen by the vendors own internal grievance process.
8. Vendor's may inappropriately split orders into separate shipments. This will increase administrative cost and potentially interfere with patients' therapy.
9. There are no current standards for a vendor's product or performance, and, individual participants cannot change a vendor based upon the above criteria.
10. Pharmacy costs for inventory storage and handling are un-reimbursed despite the development of individual patient inventories. Other uncompensated costs include drug ordering and tracking, filing CAP claims, pursuing appeals, and sharing information with vendors in order to facilitate remuneration. With practices already facing dangerous financial shortfalls, we predict a serious oncology dilemma within the near future.

I speak for the entire membership of the Oklahoma Society of Clinical Oncology when I offer sincere concern regarding the implementation of the CAP program. **This program is unprecedented and unproven without any proof that it will actually result in any cost savings.** In its current state of development, it will place an increased financial burden upon patients and physician practices thus seriously impeding the effective quality administration of cancer care. Thank you for the opportunity to comment on this matter and for your sincere consideration of the problems outlined.

Sincerely:

Todd Michael Kliewer, MD
Cancer Treatment Center of Oklahoma
President, Oklahoma Society of Clinical Oncology

Cc: Representative John Sullivan
Representative Dan Boren
Representative Frank Lucas
Senator Jim Inhofe
Senator Tom Coburn
President George W. Bush

Submitter : Ms. Mary Jo Carden
Organization : Transplant Pharmacy Coalition
Category : Pharmacist

Date: 04/26/2005

Issue Areas/Comments

1-15

Overview of the CAP

See attachment

Categories of Drugs to be Included under the CAP

See attachment

CMS-1325-P-348-Attach-1.PDF

CMS-1325-P-348-Attach-2.PDF

CMS-1325-P-348-Attach-3.PDF

April 26, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS -1325-P
P.O. Box 8010
Baltimore, MD 21244-8013

Re: Comments on the Proposal for Competitive Acquisition of Outpatient Drugs and Biologicals Under Medicare Part B

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Sincerely:

Todd Michael Kliewer, MD
Cancer Treatment Center of Oklahoma
President, Oklahoma Society of Clinical Oncology

Cc: Representative John Sullivan
Representative Dan Boren
Representative Frank Lucas
Senator Jim Inhofe
Senator Tom Coburn
President George W. Bush

Transplant Pharmacy Coalition

April 25, 2005

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

Re: CMS-1325-P, Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Medicare Part B; Proposed Rule (70 FR 10746 *et. seq.*)

I. INTRODUCTION

The Transplant Pharmacy Coalition (TPC) is pleased to provide comments on *Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals under Medicare Part B; Proposed Rule*. TPC is a coalition of eight specialty transplant pharmacies that are both independently owned and public companies. The members of the coalition are Amber Pharmacy (Omaha, NE); Bioscrip, Inc. (formerly Chronimed, Inc; Minneapolis, MN); Echo Drugs (Flushing, NY); F&M Specialty Pharmacy (New Orleans, LA); PharmaCare, Inc (Lincoln, RI); Skyemed Pharmacy (Pompano Beach, FL); Transcript Pharmacy (Jackson, MS); and Two Thousand Ten (2010) Pharmacy (Los Angeles, CA). These companies supply immunosuppressant medications and associated, necessary pharmacy services to approximately 30% of all US organ transplant recipients and approximately 40% of Medicare Part B beneficiaries who have received an organ transplant. *Attachment 1* provides a complete listing of TPC member companies and contact information.

TPC's comments focus on the impact of the competitive acquisition program ("CAP") from the perspective of specialty transplant pharmacies. TPC supports the Centers for Medicare and Medicaid Services' ("CMS") assertions made throughout the Preamble of the proposed rule that CAP is intended primarily for medications administered in conjunction with a physician office visit. As these comments demonstrate, immunosuppressant medications for preventing organ transplant rejections are generally dispensed through specialty transplant pharmacies and not through administration in a physician's office. Therefore, TPC supports CMS' interpretation that the CAP should be limited to those medications administered "incident to" a physician services and that the Secretary should use its statutory authority to exclude immunosuppressants.

The current system using average sales price (ASP) plus 6% plus a pharmacy supplying fee is not perfect, but it represents a better option than CAP to ensure that transplant recipients maintain continued access to immunosuppressant medication through a pharmacy (or through pharmacies) of a patient's choice. Rather than changing this system, CMS should focus on ensuring that pharmacies can purchase immunosuppressants at costs below reimbursement rates and receive an appropriate supply fee to provide the special services necessary for transplant patients.

Maintaining the current system allows beneficiaries continued access to Part B medications through TPC members and other pharmacies that provide these medications. TPC member pharmacies have developed relationships with patients, their care team and caregivers because of the unique ability to manage the medication therapy of transplant patients. Social workers and nurses from transplant centers work closely with patients to assist them in selecting a specialty transplant pharmacy that will meet their individualized needs. However, the ultimate decision to use a pharmacy rests with the patient.

Patients should be able to continue to select the pharmacy that best serves their pharmaceutical dispensing and medication management needs. Requiring physicians to select the pharmacy on behalf of the patient interferes with the independence of patients to make these choices and their freedom of choice under the Medicare law.

The CAP program is also unnecessary for immunosuppressant medications because the ASP pricing methodology meets the objectives of controlling Medicare Part B costs of pharmaceuticals. Only a limited number of immunosuppressants exist and most are single source products. TPC is currently working with CMS regarding the possibility of establishing more J-codes representing different strengths of each immunosuppressant. If successful, this system will provide even more transparency for tracking immunosuppressant pricing and utilization.

TPC recommends that if CMS implements the CAP program for immunosuppressants it must consider the special pharmacist and pharmacy services necessary to serve the needs of transplant patients. These services, outlined Section II below, include the ability to provide direct patient care by pharmacists and assurances that the pharmacy can stock immunosuppressant medications to ensure timely receipt by patients. CMS should also ensure that patients have continued access to pharmacies that meet their specific needs. Finally, CMS should ensure that pharmacies receive adequate supply fees to cover costs associated with additional pharmacy, pharmacist and Medicare billing services.

TPC would like to thank representatives from CMS and the Department of Health and Human Services (HHS) for their willingness to address our concerns regarding Medicare Part B billing and coverage for immunosuppressant medications. TPC looks forward to continue working with CMS as it works to refine payments for Medicare Part B pharmaceuticals that strike an appropriate balance between ensuring transplant

patients' access to appropriate medications and pharmacist services at adequate reimbursement rates while controlling costs paid by the Medicare program and patients.

II. BRIEF OVERVIEW OF SERVICES PROVIDED BY SPECIALTY TRANSPLANT PHARMACIES

Specialty transplant pharmacy costs to supply medications to transplant patients include a higher level of services when compared to providing other outpatient medications. These services include:

- Direct patient care through pro-active pharmacist contact;
- Expeditious processing and turnaround of medication orders;
- Direct Medicare billing and coordination of benefits on behalf of transplant patients, lowering costs to Medicare beneficiaries; and
- Maintaining expensive immunosuppressant medications in stock to ensure timely receipt when needed by beneficiaries.

III. TPC COMMENTS TO SUPPORT EXCLUDING COVERAGE OF IMMUNOSUPPRESSANTS UNDER CAP

A. CATEGORIES OF DRUGS TO BE INCLUDED IN CAP (SECTION I(A)(2))

1. CMS' Interpretation of MMA Only Supports Inclusion of Medications Administered by a Physician in Conjunction with an Office Visit

In section II(A)(2) of the proposed rule, CMS indicates that a reasonable interpretation of Section 1847B of the Social Security Act (the "Act") favors CAP for intravenous and injectable medications administered in conjunction with a physician's service. TPC agrees with this interpretation. Immunosuppressant medications would be properly excluded under this interpretation. Immunosuppressants are oral, solid dosage forms taken by transplant recipients multiple times a day on an outpatient basis. These medications are not intravenous, intramuscular or in any other form commonly administered in a physician's office.

2. Secretary Should Use Authority to Exclude Certain Classes of Medications by Excluding Immunosuppressants

As CMS describes in Preamble section II(A)(2), the Secretary has authority to exclude medications from CAP that will not result in cost savings for the program or that will result in access problems if included in CAP. TPC supports exclusion of immunosuppressants from CAP based upon both of these reasons.

The ASP pricing methodology system has been effective in reducing the cost of immunosuppressants to the Medicare program and for beneficiaries. *Attachment 2* provides a comparison of first quarter and second quarter 2005 ASP prices for the eight most commonly prescribed immunosuppressant agents. In most cases, ASP remained the same or decreased between the first and second quarters. In some cases, ASP prices are below the acquisition cost for TPC members. If prices are further reduced, then access problems could arise because the costs associated with acquiring, handling and maintaining an inventory of these expensive medications will outweigh the cost of providing them.

As described previously, transplant patients use immunosuppressants on an outpatient basis and generally receive these medications from a pharmacy specializing in providing to transplant patients. Beneficiaries select a pharmacy with the advice and assistance of the health care team, including social workers, case workers, and nurses responsible for managing their care health before and after discharge from the hospital.

In most cases, the physician responsible for overseeing the care of transplant patients is a transplant surgeon. Unlike oncologists and other physicians whose practice routinely involves administration of medications in an office setting, transplant surgeons generally do not administer medications in the office setting. The transplant surgeon continues managing and overseeing the transplant patient on a regular basis. However, requiring these physicians to participate in CAP would change their practice model by imposing additional administrative burdens, including selecting a contracted vendor to provide immunosuppressant medications. This situation represents a needless administrative burden because it is more efficient for patients to receive medications through a specialty transplant pharmacy. If immunosuppressants are included under CAP, access could be limited because many transplant surgeons might be unwilling to participate in the program.

CAP could also violate patient access to medications under the Medicare program's freedom of choice provision under §1802(a)(23) of the Act. The freedom of choice provision allows any individual enrolled in the Medicare program to select health care services from any institution, agency or person qualified to participate in the program.

In a situation where a patient receives an injection or other medication treatment in the physician's office, the patient's freedom of choice is in the selection of the physician. Immunosuppressant medications are intended for dispensing and administration on an outpatient basis; therefore giving the patient the freedom to choose any

pharmacy that participates in the Medicare program to provide these medications. Any change in this provision could violate the patient's freedom to choose a pharmacy provider for these medications.

3. Statutory Definition of "Competitively Biddable Drugs" Properly Excludes Immunosuppressants

In Preamble section II(A)(2), CMS seeks comments regarding whether the definition of "competitively biddable drugs" properly includes only those medications administered "incident to" a physician service. TPC believes that CMS' interpretation of this definition is correct based upon the description of the CAP program in the Act. TPC further supports CMS' assessment that because CAP is based physician administered medication, immunosuppressants and other medications not administered incident to a physician's service should be excluded.

IV. Summary and Conclusions

TPC again thanks CMS and HHS for the opportunity to comment on the CAP proposed rule. TPC reiterates its support for excluding the immunosuppressant medications from CAP because of reasons cited by CMS in the Preamble and in these comments. TPC looks forward to continuing to work with CMS to improve the current system that allows patients to select a specialty transplant pharmacy that serves their needs. TPC believes that CMS' efforts are best directed to ensuring that beneficiaries continue to have the choice to select the pharmacy that can best provide for their needs. TPC urges CMS to continue working with the industry to ensure that reimbursement rates and pharmacy supply fees are fair and equitable for Medicare beneficiaries, the Medicare program, and specialty transplant pharmacies.

If you have questions concerning these comments, please contact Dumbarton Group & Associates, LLC, TPC's Washington representation, Mary Jo Carden (Mcarden@dumbartonassociates.com; 202-744-2773) or Leigh Davitian (ldavitian@dumbartonassociates.com; 202-669-7114).

Sincerely,

Mary Jo Carden, RPh, JD
On behalf of the Transplant Pharmacy Coalition

Attachment 1
Transplant Pharmacy Coalition
Member and Contact Information
As of April 2005

Amber Pharmacy

4,000 transplant patients
Bill Kaplan, Sr.
President & Chief Executive Officer
10004 S. 152nd Street
Omaha, NE 68138
888-370-1724

Bioscrip (Formerly Chronimed, Inc.)

10,000 transplant patients
Tony Zappa, PharmD
10900 Red Circle Drive
Minnetonka, MN 55343
800-444-5951

Echo Drugs

1,200 transplant patients
Boris Mantell
Chief Executive Officer
7035 Parsons Boulevard
Flushing, NY 11365
718-591-1040

F&M Specialty Pharmacy

725 transplant patients
Ian Edwards
President & Chief Executive Officer
631 Lakeland East Drive
Flowood, MS 39232
601-939-9353

PharmaCare, Inc.

10,000 transplant patients
Greg Weishar
President & Chief Executive Officer
695 George Washington Highway
Lincoln, RI 02865
610-783-0242

Gregory S. Kaupp, Attorney
Consultant to PharmaCare
761 Gulph Road
Wayne, PA 19087

610-783-0242

Skyemed Pharmacy

50 patients

Deepak (Dee) Ranade

1960 North Federal Highway

Pompano Beach FL 33062

954-426-3330

Transcript Pharmacy, Inc.

250 transplant patients

Todd Barrett

President & Chief Executive Officer

Cliff Osbon

2506 Lakeland Drive, Suite 201

Flowood, MS 39232

(601) 420-4041

Two Thousand Ten Pharmacy

2,800 transplant patients

Louis Wong

2010 Pharmacy

Wilshire Boulevard

Los Angeles, CA

213-483-5910

**Transplant Pharmacy Coalition
CAP Comments**

**Attachment 2
2005 Quarter 1 and Quarter 2 Comparisons of ASP for Immunosuppressants**

J-Code	Drug Description	Reference Drug(s)	Strength	Q1 2005 ASP Per Unit	Q2 2005 ASP Per Unit
J7500	Azathioprine oral	Generic	50 mg	\$0.190	\$0.211
J7502	Cyclosporine oral	Generic	100 mg	\$3.900	\$3.869
		Neoral	100 mg	\$3.900	\$3.869
		Gengraf	100 mg	\$3.900	\$3.869
J7506	Prednisone oral	Generic	5 mg	\$0.220	\$0.232
J7507	Tacrolimus oral	Prograf	1mg	\$3.310	\$3.307
J7515	Cyclosporine oral	Generic	25 mg	\$0.990	\$0.975
		Neoral	25 mg	\$0.990	\$0.975
		Gengraf	25 mg	\$0.990	\$0.975
J7517	Mycophenolate mofetil oral	Cellcept	250 mg	\$2.510	\$2.454
J7518	Mycophenolic acid	Myfortic	180 mg	\$2.420	\$2.418
J7520	Sirolimus oral	Rapamune	1mg	\$6.730	\$6.728

Submitter : Dr. Harry Barnes
Organization : Montgomery Cancer Center
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

The proposed Competitive Acquisition Program (CAP) is a new intrusion on medical oncology practices. Many practices treat a large number of patients and in an essence are like a mini hospital. The encumbrance of having to order drugs for specific patients without the ability to adjust drug dosage and frequency for changing clinical scenarios makes this whole idea unworkable for all but the smallest of oncology practices. In addition, the fact that there is no payment for the administrative burden is totally unacceptable. Handling unused drugs is also ill defined and potentially a serious issue. The CAP program would be unworkable in our practice and I suspect many other large oncology practices.

My recommendation would be not to implement this and to proceed with the development of fair and adequate reimbursement to the oncologists for pharmaceuticals and services.

I would be more than happy to discuss any of these issues at length. Please let me know if I can be of further assistance.

Sincerely,
Harry M. Barnes, MD

Submitter : Ms. Judy Dunnahoe
Organization : Hematology-Oncology Associates of Houston
Category : Health Care Professional or Association

Date: 04/26/2005

Issue Areas/Comments

1-15

Overview of the CAP

The two choices available in 2006, the buy and bill model with reduction of the ASP +6% now in effect ,or the CAP model when coupled with the end of the demonstration project and the loss of the remaining 3% transition on administration codes will result in this practice having to provide drug administration at below cost. The estimated cost of drug ordering, storage, wastage and inventory is an estimated 26% of the total cost. We have worked very conscientiously in our practice to lower our costs for drugs and all hard costs in an effort to maximize our efficiencies to enable us to provide the best standard of care at the lowest cost possible. Either of these alternatives could result in a crisis situation for providing care to Medicare beneficiaries which at this time make up 35% of our practice.

Claims Processing Overview

Recognizing that the proposed rule would allow physicians to receive replacement product from their CAP vendor for drugs taken from the physician's non-CAP inventory, that again is a time intense process with the physician having to prove the drugs were required immediately, the physician could not have anticipated the need, the CAP vendor could not deliver the drugs in a timely manner and the drugs were administered in an emergency situation. Another level of service that should be recognized in administration fees due to the time involved to build this record to prove emergency situation. What if the "emergency" drug is denied by Medicare, who bears the cost?

Bidding Entity Qualifications

CMS should place great emphasis on vendor's competence in patient-centric drug management services, in billing, claims processing, coordination of benefits and collections. Since vendors will be acting as a pharmacy by filling patient specific prescription orders they should be licensed pharmacies as well.

Competitive Acquisitions Areas

Regarding CMS request for comments on the 'feasibility of providing same day deliveries for orders received for emergency situations' and on the definition of 'emergency' - Many times patients have a change regimen after seeing the physician on the day of treatment. This change can be minor, adding Activace to de clot a port, a patient who needs hydration unexpectedly prior to treatment, etc. However, if treatment were delayed due to these minor problems, then the situation could be considered an emergency. I strongly urge CMS to define timely delivery for emergency drug shipments to within 24 hours of order and to specifically define the term emergency.

Statutory Requirements Concerning Claims Processing

Apparently CMS believes that CAP will not significantly increase the administrative burden on physicians. Perhaps not on physicians, but most certainly on oncology nurses who are tasked with providing the care as well as, in many smaller practices such as ours, with ordering and inventorying drugs. The added requirement when ordering drugs of providing patient specific demographic and clinical information, the added burden of separate inventory for CAP provided drugs and drugs for private patients, the remaining cost of supplies, i. e. Huber needles, tubing, butterflies, etc., do not appear to have been completely analyzed by CMS. I would request that CMS establish a new HCPCS code for pharmacy management services to compensate for these time intense requirements.

Categories of Drugs to be Included under the CAP

Unlike the DMEPOS acquisition project, if a CAP vendor were to stint on quality or operate with multiple medical errors, the impact on beneficiaries would be significant at best and life altering at least. CMS should begin with a regional or national test involving a limited set of drugs, typically administered by a specialty that uses those drugs less intensely than oncology, allowing for a 'learning curve' before implementing the project in a 'life and death' specialty like oncology.

Contracting Process-Quality and Product Integrity Aspects

CMS must establish standards for quality, service, financial performance and solvency for CAP vendors prior to physicians having to choose buy and sell model or CAP model and publish those standards both for vendors and physicians. This would enable physicians to make a better informed decision. Regarding quality and service standards CMS should focus on shipment errors such as wrong drug or wrong dose, damage in shipping, inadequate refrigeration, counterfeit products, etc. Vendor call centers should be available at least 12 hours per day since many clinics operate either early morning and/or late evening to accommodate patient needs. Some standards should also be established for the ring time, hold time and dropped calls, that ultimately could greatly add to the cost for the physician. Who would bear the burden of possible litigation over adverse drug events due to drugs provided by a CAP vendor? The physician must not be expected to stand alone. The proposed rule at this time has no guidance on how many levels of appeal the physician must pursue on denied drugs. I urge CMS to include this limitation in the final rule. Regarding financial and solvency standards I would hope CMS would require CAP vendors to report key performance statistics quarterly and consider financial penalties for subpar performance, allowing the physician to opt out prior to the one year contract for subpar performance.

Cap Bidding Process-Evaluation and Selection

Bad debt will pose a major financial challenge to a CAP vendor. Traditionally most of the bad debt incurred by physicians is for Medicare patients with no supplemental coverage. Will a CAP vendor pursue patient assistance programs for qualified patients? At what point will a CAP vendor deny shipment of drug for a non-paying patient? Will the CAP vendor have the ability to assess indigence and be willing to waive coinsurance in those instances where a patient is not Medicaid eligible? If the reimbursement to CAP vendors should prove too low to attract qualified bidders, what is the alternative? Would under qualified bidders be accepted with the potential of providing inadequate services and potential patient harm?

Submitter : Ms. Beth Patrick

Date: 04/26/2005

Organization : DeKalb Community Service Board

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please consider CAP for mental health injectible drugs, beginning 1/1/06. There is a lot of confusion with the current system. This presents barriers to treatment to the Medicare dual eligible consumer. If the CAP is put in place, it would improve access to care for this particular consumer class. Currently, we have not been able to offer this medication to all of these consumers due to reimbursement delays.
Thank you very much for your consideration of the mental health population.

Submitter : Mr. Billy Taylor
Organization : National Association of Chain Drug Stores
Category : Health Care Professional or Association

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

Please accept the attachment on behalf of the National Association of Chain Drug Stores.

CMS-1325-P-352-Attach-1.RTF

April 26, 2005

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

Subject: Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed Rule, RIN 0938-AN58

To Whom It May Concern:

The National Association of Chain Drug Stores (NACDS) is writing to provide comments on the proposed rule regarding the competitive acquisition of outpatient drugs and biologicals under Part B of the Medicare program, herein after referred to as the "CAP" program. This CAP program would give physicians the opportunity to obtain certain Medicare Part B drugs from an entity or entities under contract with the Centers for Medicare and Medicaid Services (CMS), in lieu of purchasing and administering the drug, and being reimbursed at the current rate of ASP plus 6 percent.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

NACDS represents over 200 retail chain community pharmacy companies that operate about 35,000 pharmacies and provide about 71 percent of the 3.2 billion prescriptions dispensed nationwide. Our membership consists of traditional community pharmacies, supermarket chains with pharmacies, and mass merchandise retailers. Our members are major suppliers of Medicare Part B oral and inhalation drugs to Medicare beneficiaries, which include immunosuppressive drug, oral cancer drugs, and oral anti-emetic drugs.

MMA Directs CAP Program to Physicians, Not Suppliers

The Medicare Modernization Act (MMA) clearly states, as CMS has articulated in the proposed regulation, that participation in the CAP program is at the physician's discretion. That is, it is the physician (not the supplier) elects to participate in the Part B CAP program each year. As a result, CMS states explicitly that "at this time we are proposing to incorporate only drugs incident to a physician's service into the CAP."

NACDS supports this conclusion, even though the statute does allow CMS to consider including these other Medicare Part B oral and inhalation drugs in the CAP program. However, we believe that any effort to bring DME drugs and statutorily covered drugs into the CAP will violate one of the central provisions of this section of the statute. Moreover, any effort to remove pharmacies from the patient care equation in order to satisfy this portion of the statute, for example by having physicians dispense oral cancer drugs, will result in a reduction in Medicare beneficiaries' quality of care.

(703) 549-3001

Fax (703) 836-4869

www.nacds.org

Thus, we are in agreement with CMS that the CAP program should be focused exclusively on physician-administered Part B drugs.

We are particularly concerned that inclusion of these drugs in this CAP program could create serious quality of care issues for Medicare beneficiaries that have serious medical conditions. The beneficiaries who require the types of drugs typically provided under Part B, such as cancer patients and transplantation patients, are very ill and often are receiving numerous other prescription medications. As a result, these Medicare Part B medications are most appropriately provided by community retail pharmacists. These pharmacists would be able to provide important comprehensive medication management services to the beneficiary regarding all their drug therapy regimens. We believe that CMS should take into account the important patient care role played by pharmacists for Medicare beneficiaries, and not implement any programmatic changes that would remove the pharmacist from the patient care process.

In fact, there are several important patient care and logistical challenges to any form of CAP program for Medicare Part B drugs that are traditionally supplied through retail pharmacies.

Comments on “Categories of Drugs to be Included under the CAP”

Application of Proposed CAP System to Oral Part B Drugs: The system proposed for the physician CAP program in the final regulation, if extended to oral and inhalation drugs, would imply that physicians would be dispensing these oral drugs from their office. This would mean that physicians would have to be interested in dispensing these oral drugs from their offices, and have the systems and structures in place to dispense these oral drugs from their offices. Only a very small number of physicians dispense oral medications from their offices, and most Medicare beneficiaries are not accustomed to obtaining such medications from their physician’s office.

Moreover, based on the structure of the current CAP program, payment for these drugs is based on “administration” by the physician of the drugs. Part B oral and inhalation drugs are not typically “administered” by the physician. They are “dispensed” by the retail pharmacy to the patient based on a physician’s prescription. The patient then “self administers” the oral medication. Thus, this reinforces the fact that these oral and inhalation drugs should not be included in CAP.

Under CAP as applied to oral drugs, the physician would have to be able to anticipate the beneficiary’s oral medications needs in terms of correct drug and dosage before they came to their office. This is often difficult to do, given the changing therapeutic nature of the conditions that are most commonly treated with Part B drugs: cancer and prevention of organ rejection. That is because the CAP program, as envisioned, requires that the physician has already ordered the drug from the contractor before the beneficiary comes to the office for the prescription. If the physician ordered a drug that was no longer the correct drug for the beneficiary – either because they need a higher dose or a different drug to treat the medical condition – the physician would likely have to write a prescription for the correct drug for filling at the local pharmacy anyway.

Therefore, instead of requiring the preordering of an oral drug that might be appropriate for the beneficiary, the use of the traditional retail pharmacy would give the physician a broader range of drugs and dosage forms based on the changing nature of the beneficiary's medical condition.

Dispensing of Part B drugs through physicians offices might also inconvenience the beneficiary, who may or may not be also obtaining other physician services (such as injection or infusion drugs) at the same time they may need to return to the physician's office to obtain a refill on a Medicare Part B oral medication. This would mean that the beneficiary could have to make a special trip to the physician's office when they needed an oral medication, rather than the local pharmacy. The physician could call in the Part B medication to the local pharmacy, while the beneficiary would have to travel to the physician's office under the CAP program. This could also increase costs to Medicare because it is possible that the cost to Medicare of the physician's office visit would be higher than the supplying fee cost of the retail pharmacy supplier.

Most important, dispensing of these oral Part B drugs through the physician's office can compromise Medicare beneficiaries' quality of care. That is because the physician may not know the other drugs the beneficiary is taking for other chronic medical conditions. The beneficiary's pharmacist, however, would know this information, making it more likely that the pharmacist would be in the position to detect and avoid any potential drugs interactions or quality of care issues that might result from the drug prescribed by the physician. The pharmacist is also in a better position to manage the beneficiary's total drug therapy.

In addition, individuals taking the Part B drugs are likely to be very sick individuals with other chronic medical conditions. As a result, additional education and training is needed to help these beneficiaries properly understand how to take immunosuppressive and oral cancer drugs. Pharmacists need to take time with these patients to assure that they understand the complexities of using these drugs, which often require adjustments to the beneficiary's regimen during the early stages of use.

CMS has recognized the need for these important professional services, and their importance to overall health care outcomes, by providing higher supplier fees for these immunosuppressive drugs. It is unlikely that the physicians have the time to provide these services in their office, nor are these services conducive to being provided by mail order firms. Thus, for the many statutory reasons cited by CMS in the proposed regulation, as well as the patient care and logistical reasons listed here, CMS should not adopt the physician dispensing CAP model for oral and inhalation Part B drugs.

Use of a Stock Replacement Program for Oral Part B Drugs: There are other potential scenarios under which Medicare Part B could theoretically create some form of "competitive bidding" program for Part B oral drugs. Either one, however, would require an overly broad interpretation of the statute. Neither option would provide that the physician make the required "choice" to opt into the Part B CAP program. Nevertheless, we present these options here, as well as describe the difficulty in implementing them.

Under another scenario, CMS could create a stock replacement program for retail pharmacies and other Medicare Part B suppliers of these drugs. Under this scenario, a entity or entities contracting with CMS could theoretically negotiate for prices lower than ASP plus 6 percent with the manufacturers of a group of competitively-biddable drugs as designated by CMS, including drugs dispensed by Part B suppliers. In this system, the beneficiary would bring the Medicare Part B prescription to the retail pharmacy, which would simply bill Medicare for the supply fees, but not receive payment for the drug product. The pharmacy would dispense the Part B drug ordered by the physician from existing stock, but the CMS contractor would send replacement stock to the pharmacy for the Part B drug dispensed.

Such a program could create significant administrative and operational challenges for community pharmacies. Under current practice, pharmacies typically carry a wide range of different dosage forms and strengths of brand and generic drug products, but tend to consolidate these purchases from a single or limited number of generic suppliers to maximize their purchasing leverage in the marketplace. Under a stock replacement program, the vendor or vendors that have might be supplying these drugs may or may not be the same generic suppliers used by the retail pharmacy.

Requiring pharmacies to monitor the use of Part B CAP products separately from their existing stock, especially when the CAP contractor is not the retail pharmacy's contractor, would be administratively burdensome. This would require that pharmacies either maintain a complex system of dual inventory for Part B drugs, or create a "virtual electronic inventory" system for their pharmacies for a select number of Part B drugs, many of which are generically available. Pharmacies do not have the capability to maintain separate inventories of stock in their pharmacies. Shelf space is limited, and pharmacies do not want to be in a position of potentially mixing different stocks of Part B drugs. A so-called "virtual" inventory tracking system is not easy to maintain, and is costly. Moreover, there are issues relating to appropriate ordering, shipping, mixing stock and lot numbers, returns, recalls, and program integrity that would have to be addressed.

In addition, while many NACDS members are small regional chains that operate only in one or a few states, we have many members that are large multi-state operators as well. To the extent that CMS contracts with multiple suppliers for a retail-based CAP program, it could make it even more difficult for a single chain operator across multiple states a region to track a duplicative or "virtual inventory" program under which they are receiving Part B drugs from multiple CAP suppliers. Retail pharmacies generally only stock one generic manufacturer's product, so any program that disrupts the generic purchasing power of a chains retail buying group could significantly affect a pharmacy's overall acquisition costs for generics.

The potential for savings under this scenario is also limited. The program is predicated on the ability of Medicare Part B to save money under this CAP program. Given that CAP contractor cannot use formularies under the program, it is not clear how much savings would be generated beyond the ASP+6 percent system for branded drugs. For generics, retail pharmacies already are very prudent purchasers of generic drugs. To the extent that CMS further squeezes generic margins, it may result in fewer generic competitors and higher prices for Part B drugs.

We would suggest that CMS determine the cost and benefit of a Part B CAP system for retail dispensed Part B drugs.

Use of a Single or Multiple Specialty Pharmacy Contractor for Part B Drugs: Under another potential scenario, CMS might contract with one or more specialty suppliers to provide Part B oral and inhalation drugs to Medicare beneficiaries. Such a program would also require an overly broad interpretation of the statute, and we do not agree that CMS has the authority to implement such a program.

Under this approach, a beneficiary (or the beneficiary's physician) might send their Part B prescription to a specialty pharmacy supplier who would then mail the prescription to the beneficiary's home. Given that this CAP program begins in 2006, which means that a Medicare beneficiary could be obtaining some of their prescription medications from a Part B CAP supplier as well as some of their medications from the new Medicare Part D prescription drug plan that they have selected.

There is no guarantee – in fact it is highly unlikely – that the Part B specialty CAP contractor would have all the information about the other drugs that the beneficiary was taking, or vice versa. Thus, we believe that the same quality of care issues that would exist under the physician-dispensing model would also exist under the specialty-supplier model.

This will result in fragmented quality of care since neither the CAP specialty contractor nor the Part D PDP will know the total medication regimen of the patient, unless this can be coordinated through the beneficiary's local retail pharmacy. This scenario would argue against including Part B drugs in a specialty pharmacy CAP program because, unless the specialty supplier and the PDP are the same, neither of them can bridge the actual information gap. Only the beneficiary's current retail pharmacy will know all the medications being taken by the beneficiary. Moreover, beneficiaries should not have large quantity of these very potent medications delivered to their home and then have to rely on "telephonic" professional service to help them manage their condition. Face to face contact is critical in maintaining life and health for individuals taking cancer drugs and immunosuppressives.

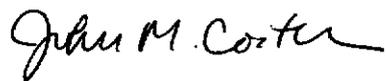
Finally, it is likely that many if not all of the Part B oral and inhalation drugs will be transferred to the new Medicare Part D program within the next few years. While requiring a change in current law to achieve this, consolidation of these programs would make sense from both an operational level and patient care level. Thus, it would seem to be an unnecessary waste of resources to establish a CAP program for oral drugs under Part B when they will likely be subsumed under the new Part D program in a relatively short period of time.

Conclusion

NACDS agrees with CMS that the CAP should be directed exclusively toward physician-administered drugs. Including other Part B drugs is contrary to a central provision of the statute and has the potential to reduce the quality of care that Medicare beneficiaries now receive.

We appreciate the opportunity to provide comments on the competitive acquisition program.

Sincerely,

A handwritten signature in black ink that reads "John M. Coster". The signature is written in a cursive style with a long, sweeping underline.

John M. Coster, Ph.D., R.Ph.
Vice President, Policy and Programs

Submitter : Ms. Jessica Combs
Organization : Suncoast Center For Community Mental Health Inc.
Category : Social Worker

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

Our agency would like make comment about the ability to bill medicare "part D" for psychiatric medications that are taken by injection. Currently, our agency is being asked to submit money up front to later be reimbursed by medicaid for IM drugs like Risperdal Consta. It would be beneficial for our clients if this was able to be billed through the pharmacy, like other medications, and like the medications that will become a part of the "part D" program. This would allow for easier access for our clients, and the ability to have a continuity of care that they are sometimes in danger of losing. It is, of course, absolutely necessary that these medications are included in the plan at some level, even if there is a phaseing in of the different medications. The sooner this can happen the better. We all know the costs of a day spent in the hospital, and psychiatric hospitals are just as costly. If clients do not receive the medications they need in the time frame they need them, it is very likely that client will require very costly hospitalization, that will eventually be paid for by Medicare. Please consider these issues when making decisons about the Competitive Acquisition Program.

Submitter : Dr. Sara Augustin
Organization : DeKalb Community Service Board
Category : Pharmacist

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

I believe that CAP should include mental health injectible drugs. It would facilitate access for Medicare consumers. The process right now is very cumbersome, which limits the ability of providers to give access to these drugs. Please include this medication in the initial phase of 01/01/06. Thanks for your consideration of this issue.

Submitter : Ms. Cece Dorough
Organization : Men's Health Network
Category : Health Care Industry

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

Men's Health Network (MHN), on behalf of men and their health care providers, appreciates this opportunity to comment on the CMS proposed rule regarding the Competitive Acquisition Program (CAP), published in the Federal Register on March 4, 2005 (the Proposed Rule).

The Men's Health Network is dedicated to ensuring that men of all ages, especially those most vulnerable including older men and men who suffer disproportionately from certain diseases and conditions, have access to the care, treatment, and prescription drugs they need and deserve. As such, our overall concern in regard to the launching of the CAP program is preserving patient access and quality of care.

CMS-1325-P-355-Attach-1.DOC

CMS-1325-P-355-Attach-2.DOC

April 26, 2005

By Electronic Delivery

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

Re: Comments on CMS-1325-P: Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Dear Administrator McClellan:

Men's Health Network (MHN), on behalf of men and their health care providers, appreciates this opportunity to comment on the CMS proposed rule regarding the Competitive Acquisition Program ("CAP"), published in the Federal Register on March 4, 2005 (the "Proposed Rule").

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Claims Processing Overview

Of particular concern to us is the fact that prostate cancer drugs represent the only class of drugs to be subjected to the LCA policy at this time, thereby unfairly targeting a disease state that disproportionately affects African American men. If a physician chooses the CAP and the LCA policy is still in place, payment rates will not adequately cover the costs of all FDA approved prostate cancer therapies. Without proper safeguards, CAP may inappropriately be combined with the LCA policy – if LCA is enforced, providers may not have access to all drugs available under the CAP – **potentially limiting patients' access to the full range of FDA approved prostate cancer therapies**. Providers may be forced to change their patients' therapy and/or consider other treatment options. Decisions about prostate cancer therapy should be made based on the best interests of patients – not on payment formulas that won't even cover the costs of all appropriate drugs.

Also of concern to us is the fact that the vendor will have authority to impose substitution and dosing restrictions. **Patients may be forced to switch therapies and strengths**. Vendors may not offer access to all current therapies and patients may be forced to switch their drug or dose. Here vendors determine their own coverage and they may limit what they are willing to send out.

CAP Bidding Process – Evaluation and Selection

Vendors would be required to supply a drug for each of the HCPCS J-codes identified, but in the case of multiple-source drugs, they would only be required to supply one manufacturer's version. **Physicians may be forced to change a patient's therapy based on drugs available.**

Drug Delivery

Proper safeguards must be put in place to ensure CAP does not place undue administrative burdens on physicians and patients. When ordering drugs from the vendor, providers must submit a written order for patients, which will include a treatment and delivery schedule. This structure does not account for individuals who may obtain the drug from multiple locations, such as "snowbirds", thus **creating additional paperwork and possible confusion among providers – this will negatively affect patient care.**

Beneficiary Education

The CAP does have potential for significant confusion among beneficiaries, and CMS must take extra care to ensure there is ample information readily available to patients impacted by this program. Of even greater concern, however, is the handling of those patients who would normally need assistance covering the expense of their co-pays. Physicians typically play a direct role in identifying patient assistance programs for these vulnerable individuals, and it is unclear how this assistance would be offered under the CAP. Patients will now deal with large vendors instead of their physicians' office for co-insurance and collections. This means physicians will lose control over the collection process and the vendor may aggressively pursue the patient for coinsurance collection. **The CAP program could also negatively affect the most vulnerable patients.** The vendor will not have an incentive to screen indigent patients for referral to patient assistance programs, thus creating a possible interruption in care and an undue financial burden to the patient. CMS must come up with a way to deal with these vulnerable communities.

Please contact me or Jimmy Boyd, Executive Director, at 202-543-6461, to discuss any questions you may have about our comments on this proposed rule.

The Men's Health Network appreciates your consideration of these recommendations.

Sincerely,



Cece Dorough, MSW
Manager

April 26, 2005

By Electronic Delivery

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

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Also of concern to us is the fact that the vendor will have authority to impose substitution and dosing restrictions. **Patients may be forced to switch therapies and strengths**. Vendors may not offer access to all current therapies and patients may be forced to switch their drug or dose. Here vendors determine their own coverage and they may limit what they are willing to send out.

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Beneficiary Education

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Please contact me or Jimmy Boyd, Executive Director, at 202-543-6461, to discuss any questions you may have about our comments on this proposed rule.

The Men's Health Network appreciates your consideration of these recommendations.

Sincerely,



Cece Dorough, MSW
Manager

Submitter : Dr. Matthew Layton
Organization : Spokane Mental Health
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1325-P-356-Attach-1.DOC

April 26, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Part B Competitive Acquisition Program, Categories of Drugs to be Included under CAP

Dear Dr. McClellan:

Thank you for the opportunity to comment on the proposed rule recently issued by the Centers for Medicare and Medicaid Services (CMS) that addresses implementation of the Competitive Acquisition Program (CAP). I am writing in strong support of this program, as it has tremendous potential to benefit individuals with severe and persistent mental illnesses for whom injectable medications can help maintain adherence to drug regimens, treatment that is life-saving and essential to successful rehabilitation outcomes. We urge that injectable antipsychotic medications be included in the initial phase of CAP implementation.

Advantages of Injectable Psychiatric Medications

In 2003, the final report of the President's New Freedom Commission on mental health declared that recovery – helping individuals overcome the disabling aspects of mental illnesses – is the overarching goal of the U.S. mental health system. Addressing the means for attaining this goal, the report stated, “To achieve the promise of community living for everyone, new service delivery patterns and incentives must ensure that every American has easy and continuous access to the most current treatments and best support services.” In implementing the CAP program, CMS has an opportunity to make a significant contribution to fulfilling the goals of the federal New Freedom Initiative by facilitating patient access to important psychiatric medications.

Patient noncompliance with psychotropic medication regimens is similar to that for patients who take medications for somatic illnesses. A review of the literature has found that most patients probably only take 33 – 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a sizeable percentage are wholly noncompliant.¹ For people with schizophrenia and severe mood disorders, noncompliance with medications often results in the relapse of acute symptoms, frequently resulting in negative outcomes such as rehospitalization, loss of employment/housing, and suicide. These negative consequences for the patient are compounded by a parallel negative impact on the service delivery system: costs escalate as outpatient treatment is stymied, the use of emergency facilities increases, and hospital stays are more frequent and longer.

¹ Morris LS, Schulz RM. Patient compliance—an overview. *J Clin Pharm Ther* 1992, 17:283-95.

The use of injectable antipsychotics has been recognized as an important, evidence-based practice that addresses the noncompliance of many with schizophrenia. In addition, injectable formulations of newer, atypical antipsychotic medications show tremendous promise in addressing the issue of partial compliance among people with mental illnesses. These newer medications are injectable, but do not have the side effect profile of older injectable psychotropics that consumers found objectionable, including lingering pain after the injection, sedation, and Parkinsonian and other neurological problems that often required additional medications to treat the side effects. While a number of the new injectable medications are currently in development (including an antidepressant), one new depot antipsychotic, an injectable form of risperidone, has been employed successfully in community-based settings for about a year, and it has shown great promise in treating schizophrenia.

The Schizophrenia Patient Outcomes Research Team (PORT) treatment recommendations, considered one of the most important practice guidelines for the treatment of schizophrenia, find that the older injectables are an important therapy for schizophrenia, stating that depot injectables should be “strongly considered for persons who have difficulty complying with oral medication...” The emerging evidence for the use of risperidone long-acting injection seems to indicate that the new injectable antipsychotics may offer significant clinical advantages to the older depot injectables, in addition to addressing the issue of noncompliance. Compliance is a significant issue in the treatment of schizophrenia, with 50 – 70 percent of all patients being only partially compliant in the first two years of treatment. A survey of studies found that noncompliance was associated with a risk of relapse that is 3.7 times greater than that for compliant patients.²

Studies have found that the use of long-acting injectable risperidone is associated with fewer and shorter hospitalizations³ and improved functioning and quality of life.⁴ Given the promise of these new injectable medications to improve outcomes for patients and reduce healthcare costs, and the recognition of the use of injectable depot medications as an evidence-based practice, we believe that CMS should make consumer access to injectable antipsychotic medications an urgent priority. As other new injectable psychotropics become available, we suggest that CMS prioritize efforts to enhance consumer access to these drugs.

Current Obstacles Faced by Providers Using Injectable Psychiatric Medications

Unfortunately, community mental health centers (CMHCs) and other multi-service community providers, which serve a large number of people with severe mental illnesses that are eligible for both Medicaid and Medicare, face serious obstacles in providing injectable medications. As safety-net providers, CMHCs are very often heavily burdened treatment settings that lack sophisticated information technology and a sufficient level of administrative staffing. For example, to provide the new injectable antipsychotic risperidone to patients, CMHCs must first

² Fenton WS, Blyler CR, Heissen RK. Determinants of medication compliance in schizophrenia. *Schizophr Bull.* 1997, 637-651.

³ Leal A, Rosillon D, Mehnert A et al. Healthcare resource utilization during 1-year treatment with long-acting injectable risperidone. *Pharmacoepid Drug Safety*, 2004, 13: 811-816.

⁴ Nasrallah HA, Duchesne I, Mehnert A, et al. Health-related quality of life in patients with schizophrenia during treatment with long-acting injectable risperidone. *J Clin Psychiatry* 2004, 65:531-536.

purchase the medication, and then seek reimbursement from both Medicare (which makes only partial payment for mental health drugs) and Medicaid. Providers then bear the administrative burden of tracking the claims and the financial risk of receiving incomplete payment from one or both payers. This burden has become an impediment to expanding access to this medication to the full range of patients who could benefit from it. In some cases, CMHCs will only provide the medication to patients that are solely Medicaid beneficiaries. When injectable antipsychotics are included in the Medicare CAP program, this substantial impediment will be removed, as providers would have the option to obtain the medications from a drug vendor that will handle reimbursement from Medicare. Helping providers expand access to this medication will bring great benefit to our patients with schizophrenia.

From a brief review of the proposed rule, it appears that CMS may view oncology medications as the primary medication category to be included in the initial phase of CAP. CAP also has the potential to bring new psychiatric therapies into wider use and to significantly improve the quality of care for some of the most vulnerable people in our society – helping to “achieve the promise” of the New Freedom Initiative for people with psychiatric disabilities. We urge you to include coverage of antipsychotic injectable medications in the drug categories that compose the initial phase of CAP implementation.

Sincerely,

Matthew E. Layton, M.D., Ph.D.
Medical Director, Spokane Mental Health
Clinical Associate Professor, University of Washington Psychiatry
Adjunct Associate Professor, Washington State University Pharmacy

Submitter : Dr. Robert Schwert
Organization : Robert C. Schwert, DO, PC
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

1-15

Overview of the CAP

The current CAP model will have a negative impact on patient care here in rural northern Michigan. It is an inflexible system that does not deal with the realities of patient care. It places more burdens on very sick patients and their caregivers who must return on another day when changes in treatment are necessary, when drug orders don't arrive on time, or when product integrity is questioned.

It places additional administrative burdens on physician offices who will now have to manage not one drug inventory, but multiple inventories, probably individual patient inventories. In light of the reimbursement shortfall that looms in 2006, important decisions need to be made now about offering cancer care services to seniors. At this point, my choice is to incur a significant net loss to treat Medicare beneficiaries, or to discontinue offering chemotherapy services to that patient population.

Contracting Process-Quality and Product Integrity Aspects

With respect to Quality and Service Standards of CAP vendors, I believe CMS should focus on standards related to shipment errors (e.g., wrong drug or dose; wrong quantity; damaged packaging; inadequate refrigeration; counterfeit product, etc.) and timely deliveries, both for routine and emergency deliveries. I also believe that the required physician call centers need to operate a minimum of 12 hours per day and that call management standards should tightly limit ring time, hold time, and dropped calls.

Another administrative burden that concerns me is the requirement for physicians to appeal all denied drug administration claims. With respect to Quality and Service Standards, I believe CMS should focus on standards related to shipment errors (e.g., wrong drug or dose; wrong quantity; damaged packaging; inadequate refrigeration; counterfeit product, etc.) and timely deliveries, both for routine and emergency deliveries. I also believe that the required physician call centers need to operate a minimum of 12 hours per day and that call management standards should tightly limit ring time, hold time, and dropped calls.

Claims Processing Overview

The use of the replacement program is limited to situations where the physician builds a record to demonstrate all of the following to the local carrier: (1) the drugs were required immediately, (2) the physician could not have anticipated the patient's need for the drugs, (3) the CAP vendor could not deliver the drugs in a timely manner, and (4) the drugs were administered in an emergency situation. The huge administrative burden of building this record will discourage me from using the inventory replacement option.

Dispute Resolution

Contrary to CMS belief, CAP will significantly increase the administrative burden on physicians. CAP practices will have to implement and operate a second, separate ordering process for CAP drugs to transmit patient-specific drug orders that include demographic and clinical information. The ordering system under the buy-and-bill model is much simpler because aggregate orders based on practice usage are placed with wholesalers. Buy-and-bill ordering does not involve the review of individual patient charts nor does it require input of substantial amounts of data for each vial of drug requested from the wholesaler. Given the management, inventory control, drug preparation, paperwork, integrity assurance, and other necessary new or enhanced functions that will face physicians selecting CAP, CMS should establish a new HCPCS code for pharmacy management services to compensate physicians.

Competitive Acquisitions Areas

Key issues relating to Competitive Acquisition Areas are the service requirements for CAP vendors. It is estimated that approximately one-third of treatment plans must be modified on the day of treatment due to changes in a patient's health status. The unavailability of drugs needed on the day of treatment would pose a significant burden on patients who would have to return another day for treatment. This burden can be particularly severe in rural areas such as where patients may have to travel long distances to receive cancer care.

Categories of Drugs to be Included under the CAP

The implementation of a CAP for Part B drugs should be undertaken with a cautious approach. Although CMS has managed two CAP for limited types of DME and POS in limited geographic markets, it has never organized and run a CAP on a national or even regional scale. The complexity of and flexibility necessary to manage chemotherapy regimens goes far beyond what is required to implement the DMEPOS CAP's.

Contract Requirements

The World Health Organization estimates that 6% of all drugs distributed in the world are counterfeit and some observers believe it to be as high as 12%. While Congress' decision to require CAP vendors to acquire all of their drugs directly from the manufacturer or from a wholesaler that buys direct is a good step toward product integrity, it falls short of the mark. Product integrity is about more than blocking the distribution of counterfeit goods. That is why I am concerned that the Proposed Rule's provisions could jeopardize product integrity and violate state licensing laws.

I suspect that CMS may not have thought through licensing and product integrity issues because it seems to have concluded that CAP vendors should be licensed as wholesalers but not as pharmacies. Indeed, many provisions in the Proposed Rule and the entire discussion of product integrity in the preamble focuses on wholesale distributors. I believe CAP vendors must operate as licensed pharmacies because they will accept patient-specific written orders for prescription drugs from physicians, assign prescription numbers to those orders, interpret the orders, presumably making generic substitutions as appropriate and permissible under applicable State law, and then transfer dispensed drugs to the prescribing physician for administration to the patient. However, some of the operational aspects of CAP seem unworkable or in need of retooling. For example, state pharmacies laws do not permit a pharmacist to assign different prescription numbers to successive fills of a single prescription. Rather, prescription refills are always dispensed under the prescription number assigned to the original written order. A new prescription number is assigned only when a new written order is received. These practices are inconsistent with the prescription numbering system described in the preamble to the Proposed Rule.

Most state pharmacy laws prohibit the restocking of unused drugs after they have been dispensed. In fact, none of the laws of which I am aware allow dispensed product to be redirected to another patient without going back to the dispensing pharmacy first. Redirecting unused drugs dispensed by a CAP vendor from the intended recipient to another patient could expose physician practices to tort liability. Physicians participating in CAP will therefore need indemnification from CAP vendors when reuse decisions about drugs belonging to the vendor, not the physician, are made based on discussions with the CAP pharmacist. CMS should build requirements for appropriate indemnities into the final rule.

Submitter : Ms. Theresa Toler
Organization : Ms. Theresa Toler
Category : Nurse

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-358-Attach-1.DOC

April 21, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-8010

Attention: CMS-1325-P

To Whom It May Concern:

I was a nurse in the VA system for more than 10 years. Even though I love treating veterans, the VA system is a difficult system in which to work. In order to keep down costs, patients had to endure long waits for appointments, limited access to care, and limited choices, especially with the pharmacy. I now work in the private sector with an oncology group that treats every patient that walks through our door. The new Medicare rules are difficult, but the CAP rule would be a disaster.

“Statutory Requirements Concerning Claims Processing”

The CAP rule would do to oncologists what the cost of malpractice insurance has done to obstetricians. If unable to provide quality care to our patients, smaller offices would be forced to close some, if not all, of its valuable services. Oncologists do not control chemotherapy drug costs—the major pharmaceutical companies have that control. The inventory control under the proposed CAP rule would be a nightmare. We would have to increase staff to be able to process the extra work for filing, inventory, and to report minor changes in administration of chemotherapy while at the same time dealing with a decrease in revenue.

“Impact on Beneficiaries”

I personally want a qualified oncologist to make medical decisions with me should the need ever arise – not a government employee. As I experienced within the VA system, political “rules and regulations” dictated medical care instead of board certified physicians. The proposed CAP rule would have the same affect on oncology care by limiting choices for both the physician and the patient.

Our main objective is to deliver quality oncology care to people that truly need exceptional services. If that is also your objective, then the proposed CAP rule should be abolished.

Terri Toler,
Clinical Coordinator
Coastal Cancer Center

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Mr. Nick Opalich
Organization : BioScrip, Inc.
Category : Health Care Industry

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1325-P-359-Attach-1.DOC

File Code: CMS-1325-P

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 414
[CMS-1325-P]

RIN 0938-AN58

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

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

Action Proposed rule.

Comments submitted electronically to:
<http://www.cms.hhs.gov/regulations/ecomments>

Proposed Claims Processing Overview

1. The plan indicates that HCPC codes would be used for vendor claims in addition to our unique identifier, in the form of Rx #. **We would prefer that the claims be submitted with the NDC code and not a HCPC code.** Medicare was supposed to go to NDC codes a year or so ago. The problem with using HCPC codes is that some drugs are dispensed to the patient in different strengths on the same day. (Prograf 5mg and 1mg strengths are a good example of this). While both strengths of the drug have their own unique NDC, they will both carry the same HCPC code which leads Medicare to reject one of the medications, typically the most expensive, as a duplicate service. This practice creates a work-around for the vendors in which the two strengths must be converted to the lower strength and billed with the appropriate units to reflect that actual dosage. By going to the NDC code, Medicare would greatly improve this process for themselves and the vendors. If need be, we could include the HCPC on the claim record in addition to the NDC.
2. The plan places the vendor's billing and collection activities at the mercy of the physician's office and their ability to bill on a timely and accurate basis. Specifically:
 - a. The vendor is not to submit their claim to Medicare before the physician's expected drug administration date.
 - b. Medicare's central claims processing system will not release payment for the vendor's claim until the physician's claim has been received and paid.

- c. If the physician fails to include the vendor's Rx number, the vendor's claim will not be paid.
- d. If the physician's claim is denied because it is not compliant with all of the local coverage determinations (LCD), the vendor's claim will also be denied.
- e. Medicare rules prevent the provider from billing the beneficiary for any patient responsibility until Medicare has made final payment for the services in question. In cases b, c and d, this means that the vendor cannot bill the patient unless and until the physician's claim is paid which will release payment for the vendor's claim.
- f. The physician's CAP agreement would require the physician to submit their claim within 14 calendar days of administration, but does not indicate what, if any, penalty would be used for violations.
- g. CMS should consider allowing a payment incentive to the physician provider in order to submit pharmacy claims rapidly since payment to the CAP vendor is dependent upon timely and correct filing of the pharmacy and administration claim. The CAP vendor's cash flow should not be negatively impacted by physicians not filing their drug administration claims immediately following the administration. CMS might even consider a late submission penalty on the physician as it shouldn't be left to "dispute resolution" between the physician and CAP vendor.

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

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

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

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

4. We suggest that guidelines should be established regarding inventory control at the physician practice level and the CAP vendor should be the responsible entity to develop and implement the controls that the physician should observe. Having the physician's practice inventory all CAP drugs and pull/replace from a vendor's inventory and then ask the physician to keep track of their inventory is too burdensome and inviting problems. Pharmacy vendor is the specialist at controlling, dispensing, inventorying and shipping drugs.
5. Definition is needed to drive the process around how drugs not administered to a patient are handled. Given that the physician would have placed a drug order with the CAP vendor and there was no drug administration, what happens for product returns? In these circumstances the CAP vendor would be out: shipping costs, with no means to recoup the cost; uncertain as to the means and methods of how the physician provider initially handled the CAP vendor's drugs; how the drugs may/may not have been appropriately inventoried. This may create many circumstances whereby the CAP vendor may not be able to restock the product in a timely manner or be unable to return the product to the manufacturer. Then the CAP vendor will also be out the actual cost of it's acquisition of the drugs. What happens in these same circumstance(s) when the physician provider is delayed in **notifying** the CAP vendor that drug administration hadn't occurred? We believe that the physician provider be provided with explicit instructions or mandated from CMS that **notification** to the CAP vendor that the drug order hasn't been administered.
6. Current pharmacy practice does not allow for the re-dispensing of a product. If a prescription was filled for a patient in good faith who didn't show up for an administration the CAP vendor would be at risk for the product. How does CMS, the physician and the patient propose to share in the risk of product returns and not place this entire burden on the CAP vendor?
7. Does the physician provider keep the drug in physician's stock for administration and billing to a different patient at a future date? Again, issues of how the physician provider handles and inventories the drug may be called into question.

8. We need to have a better understanding of how CMS proposes to match the claims between the physician and the vendor. Since the CAP vendor's claims are submitted to the designated carrier and the physician claims go to the local carrier. How is this matched as this process was not explained in the Federal Register? It is important to know how this will be completed.
9. Partial payments in certain circumstances may not apply to all situations. Partial payments to vendors would be eliminated in a scenario where reimbursement is not coupled with billing of a physician administration; please reference item #2G. Partial payments add administrative costs to CMS and vendors. Therefore, under these circumstances should not be identified by CMS as a solution for delayed physician administration claims. The CAP program makes the possibility of partial payments available if the physician is slow in submitting a clean claim. Once the physician's claim is received and paid, Medicare would make a "final payment" on the balance of the claim. If the physician fails to submit a claim by 90 days, Medicare would seek to recover the partial payment.

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

10. What happens to vendor if the physician claims are fraudulent? Example: We received the prescription in good faith from the physician and dispensed in good faith and the physician billed the administration code fraudulently and we both get reimbursed and the patient never received the medication. To protect CMS and the vendor we suggest that at the time of administration the beneficiary sign an acknowledgement of drug administration and facsimile back to the vendor (See # 2G). This helps eliminate the risk of fraud and minimizes the negative cash flow impact to the vendor.

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

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

12. A possible suggestion to our comments in item #2. Another way to perhaps approach this issue would be to permit the following scenario: 1.) CAP vendor pharmacy bills CMS designated carrier at ASP + 6% for the drug; 2.) CMS reimburses CAP vendor pharmacy @ASP+6%; 3.) The physician provider is paid for their administration fee less their 20% copay plus the 20% copay for the CAP vendor pharmacy claim and allow one provider to bill and collect for copays; 4.) Physician provider collects the full 20% coinsurance for both the drug and the administration from the patient or bills the 20% to a subordinate insurance carrier where the patient has coverage; 5.) Should the physician provider not dispense the drug CMS recoups the pharmacy claim from the physician provider; 6.) what happens if the beneficiary can't or refuses to make their copay, what guidance will CMS provide under the CAP?
13. Will CMS under the CAP permit the Oncologist to use CAP drugs "off label" and will the CAP vendor be held liable for the financial risk of the off-label use and how will this affect the claims process?
14. Oncology private practices have high percentages of underinsured patients and the CAP program could initiate a high enrollment of these patients. Where is this risk going to be shifted under a CAP competitive program, will there be risk sharing?
15. We did not see any coverage or mention about the issues certainly to arise regarding loss of beneficiary insurance coverage during drug administration at the physician's office. What guidance does CMS propose for the CAP vendor and physician involving these types of issues? Will the CAP vendor be permitted to stop shipments under these circumstances? What other ethical issues may evolve from CAP? What used to be bad debt (underinsured, uninsured, can't pay copay) for the physician practice could become a troublesome issue between the CAP physician and CAP vendor; assuming very tight margins under a biddable concept. Since shifting the bad debt away from the physician practice which could be good for the physician might not be acceptable to the CAP vendor. CMS should update it's guidance regarding this issue.
16. What happens if a CAP physician begins treatment, the vendor ships the drug and the vendor correctly follows all procedures and then the physician submits his/her claim to their local insurance carrier and they deny coverage? What guidance does CMS propose for these types of situations?

Overview of the CAP

BioScrip believes bid pricing should be bid on all drugs used by Oncology physician specialty under the CAP and phased-in on a national phase-in basis to Oncology at the inception of the CAP program. This enables all the participants to debug the program and work out known or unknown efficiencies. To the extent that the same drugs are used by another physician specialty other than Oncology we would agree to add those physician providers under and during the national phase-in program. This could include Urology and Internal Medicine.

Categories of Drugs to be Included under the CAP

The following drug Darbepoetin Alpha injection (Aranesp- HCPC J0880), listed on page 10751 of the Federal Register as one of the most commonly used codes by oncologists. Based on ASP methodology published in April 2005 by CMS, the maximum allowable reimbursement rate per unit of 5mcg is \$16.12 (equivalent to ASP+6). BioScrip's takeaway from the Federal Register is ASP+6 would be the expected bid range from BioScrip for CMS/CAP. **However, cost per unit is approximately \$20.72.**

CMS needs to recognize this:

1. The prices that manufacturers have been offering to the oncologists / physician class of trade are significantly discounted; pharmacies have not been extended these same pricing advantages.
2. These significant discounts have contributed to the high percentage of physicians that purchase drugs and make profits on the spread between their cost and what CMS has been reimbursing; thus the reason for ASP pricing methodology and CMS need to put controls in place.
3. For the highest utilized Medicare Part B drugs like Aranesp, physicians have represented the largest / majority purchasers of the products; thus, when CMS calculates ASP based on pricing net of all discounts and rebates, it comes out extremely low - much lower than a pharmacy's cost- because most of the sales for these drugs take place at the physician level at the discounted pricing.
4. Under the CAP it is feasible that the pharmaceutical manufacturers might bundle products used by the oncologist. This event may build uncertainty into the CAP vendor's product costs.

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

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

CAP Bidding Process- Evaluation and Selection

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

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

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

Example: Solution (Aranesp) J0880

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

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

Aranesp Solution can be ordered as follows:

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

- 1.) If the volume unit is equal to mcg then the CAP vendor needs to know what the number of orders are; or
- 2.) If the volume unit is equal to vials then the CAP vendor needs to know the number of orders and the amount paid to the physicians; or
- 3.) If the volume unit is equal to orders then the CAP vendor needs to know the amount paid to the physician.

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

Competitive Acquisition Areas

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

Comment:

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

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

Dispute Resolution

We do not agree that the physician provider should have exclusive control of the claims process (See "Claims Processing Review Comments") which entails the ordering process as well as the need for the physician provider to match his/her claims with the CAP vendor's NDC # and prescription number. Presently worded, the CAP vendor will not be a party to the process. Our concern is that CMS should mandate language and guidelines that provide the CAP vendor the opportunity to not serve a physician provider that is seriously negligent or erroneously behind in filing their respective claims appropriately and on time. Essentially, the CAP vendor could be out thousands of dollars and not resolve the issues of the physician provider is just negligent in it's business practices or just doesn't not have to means to create a new business environment to meet the demands of the CAP program.

Submitter : Mrs. Kristi Dearing

Date: 04/26/2005

Organization : Weems Community Mental Health Center

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

I would just like to voice our support of the Competitive Acquisition Program. This program will benefit our consumers greatly. Working for a community mental health center, I see daily the problems individuals face in accessing treatment particularly in the areas of obtaining medications and in transportation. Weems works to help individuals as much as possible in these areas by utilizing all resources available. So we would very much appreciate any program that would ultimately help those we serve.