

Submitter : Dr. Judy Ognibene
Organization : Eastern State Hospital
Category : Physician

Date: 04/21/2005

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

As a psychiatrist at a large state mental health facility in Kentucky, I am dismayed that many of my Medicare/Medicaid patients are not able to obtain their prescribed antipsychotic medication, particularly long acting injectable Risperdal Consta, due to technicalities in the current reimbursement system. As a result, these patients quickly relapse leading to recidivism and increased tax payer dollars spent on costly hospitalization. I implore CMS to include psychiatric drugs in Phase I of the Competitive Acquisition Program and include in Part B a Mental Health Drug category which would allow pharmacy benefits for long acting injectable antipsychotic medications. The system savings in the long run will far outweigh the cost of maintaining these patients on their medication as stable outpatients.

Submitter : Dr. Howard Zipin
Organization : Bux-Mont Oncology
Category : Physician

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

CAP is bad medicine. It risks patient care, imposes extra costs and liability on community cancer clinics, and will cost Medicare more money.

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.

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

You are 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.

Submitter :

Date: 04/21/2005

Organization : Cumberland River Reg. MH/MR Bd., Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

As a Behavioral Health Care Provider, we would like to encourage the Center for Medicare Services to provide coverage for medications to treat psychiatric disabilities. Individuals with psychiatric disabilities deserve the same benefits as those seeking physical health services. If anti-psychotic medications are not included in the formulary, these individuals may be denied the appropriate prescribed drug treatment needed.

Submitter : Dr. David Kraebber
Organization : Dr. David Kraebber
Category : Physician

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

The Competitive Acquisition of out patient drugs is entirely unusable. The program will cost each physician more to obtain and administer the drug than on the current system. There are numerous unanswered questions about delivery, which drugs will be available, waste or loss, vendors responsibility, and pateints who are part time in a given region. Unless mandated I can see no reason why any physician would chose this system, and if mandated I personally would stop providing this class of medicaions to patients.

Sincerely, David M KRaeber, MD

Submitter : Ms. Jane Majcher
Organization : GE Healthcare
Category : Drug Industry

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment".

CMS-1325-P-155-Attach-1.DOC

GE Healthcare

| April 25, 2005

Deleted: April 21, 2005

VIA E-MAIL

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

ATTN: File Code CMS-1325-P, "Drugs Furnished Incident to a Physician Service" and "Phasing in CAP by Physician Specialty"

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

Dear Administrator McClellan:

GE Healthcare appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding the implementation of a competitive acquisition program (CAP). GE Healthcare is a unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging, information technologies, medical diagnostics, patient monitoring systems, disease research, drug discovery, and biopharmaceuticals. Worldwide, GE Healthcare employs more than 42,500 people committed to serving healthcare professionals and their patients in more than 100 countries.

We agree with CMS' assessment that it is not possible to include drugs other than those administered as "incident to a physician's service" as part of the CAP at this time. Because of this, we recommend that CMS implement the CAP program through a phasing process beginning with a single specialty for which drugs are compounded and ordered through a prescription for each patient dose. Limiting the process to one specialty such as oncology, may offer a more effective approach to the implementation of the CAP. We recognize that CMS indicated that singling out drugs typically administered by one physician specialty may prove to be too narrow to effectively identify all issues or concerns for other specialties. However, we believe that the complexity of a specialty such as the oncology drug administration process would set forth a solid foundation for other physician specialties to phase into the CAP over time. Further, we believe that implementing the CAP to a broader range of drugs at this time may prove to be overwhelming to the physician community.

General Electric Company
Amersham plc
101 Carnegie Center
Princeton, NJ 08540
U.S.A.

T : (609) 514-6701
E : jane.majcher@ge.com



GE Healthcare

Thank you for providing the opportunity to comment on these important issues. Should you have any additional questions or wish to discuss further, please contact me at (609) 514-6701 or via email at jane.majcher@ge.com.

Sincerely,

Jane Majcher
Director, Reimbursement
Medical Diagnostics

General Electric Company
Amersham plc
101 Carnegie Center
Princeton, NJ 08540
U.S.A.

T: (609) 514-6701
E: jane.majcher@ge.com



Submitter : Mrs. dolores meals
Organization : andrews & patel assoc
Category : Other Health Care Professional

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

1. what will happen with patients who do not pay their co-pay or deductible for their drugs or patients do not have a secondary payor to cover the 20%? will the cap vendor stop sending the drug?
2. what will happen to drugs that are ordered and then cancelled by the physician due to the need to change therapies on the patient?
3. if a cap vendor is out of a drug and cannot deliver it for the specified therapy date, what will happen?
4. is there going to be a monetary (\$) increase to the drug administrations to help cover the increased cost to physicians to administer the cap policies per patient?
5. who pays for the return of drugs from the physician office to the vendor?

Submitter : Dr. James Atkins
Organization : southeastern Medical Oncology Center
Category : Physician

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

The drug procurement program is equivalent to you going to McDonalds to have a hamburger. when you get there you tell them that you have brought your own hamburger and you want them to cook it and use your bun, but you want them to take liability for the quality of the hamburger that you are bringing and that it won't make them sick, and that it is not contaminated, has been stored at the appropriate temperature and is safe to eat.
I hate to say it but you must be nuts. ja

Submitter : Mrs. Denise Smith
Organization : PA Oncology Hematology Assoc
Category : Health Care Professional or Association

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

I have been working in outpatient oncology as a nurse for almost 7 years now. For about 5 years, I have been involved with the contracting and drug purchasing. I also work closely with the billing department. The recent changes over the last 2 years have greatly affected the office and the patients. I now find myself and other staff members spending much more time doing insurance related things such as precerts and following up on drug replacement instead of spending time with the patients and their families. Or working extra hours to follow up on these things. If competitive acquisition goes through, it will be the demise of cancer care as we know it. There are many services made possible such as nutrition and social work support because of profit from drug therapy. There is a lot of time that I spend with the patient that is not covered providing teaching, emotional support, helping with patient assistance programs, filling out disability forms just to name a few.

There is also the issue of ethical treatment. How can we tell a patient they are no longer responding to therapy, but we can not change the treatment until they receive their new medication in the mail. Who wants to wait to start fighting the cancer again?

Please reconsider this bill. For the sake of all of the patients, maybe your family members someday, who will be affected in the long run.

Submitter : Renae Lilly
Organization : Renae Lilly
Category : Individual

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-159-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 am writing to you regarding the newly proposed competitive Acquisition Program (CAP) Rule for Part B drugs beginning January 1, 2006. I am strongly against this and I would like to explain why I feel this way.

I have been employed with a community cancer clinic for several years in South Carolina. I have noticed constant changes in the oncology field over these years. I feel that CMS unfairly looks to physicians as the cause of the high cost of chemotherapy drugs when in reality the high costs are relayed to physicians by the pharmaceutical companies.

“Statutory Requirements Concerning Claims Processing”

The CAP rule that you have proposed will not help the physician as you say. It may cause their practices extreme financial hardship or the physician will eventually not accept Medicare. Physicians that opt into this plan, whether opposed or not, will have to expend great resources just to get this process started. They will have to add significant staff just to keep up with inventory, storage, prescription numbers, etc.; not to mention the chaos.

“Impact on Beneficiaries:”

Where does the concern for the patient come in? If the community cancer clinics close their doors, where will they go for treatment? The answer is the hospital. Would this save money? No. Will it be the result of better patient care? No. Will it be better for the patient and their care givers? No.

Please reconsider the CAP rule for the cancer patient. It could be you as the patient in the future.

Thank you for your attention.

Renaë Lilly

RL/bb

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Ms. Susan Milkowich
Organization : Pennsylvania Oncology Hematology Asso
Category : Nurse

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

I hope that bill does not pass. It would inhibit patients treatment protocols and perhaps jepodize the curative effectiveness. If a patient comes in for treatment and it is not working and the doctor changes the treatment, the patient will have to wait perhaps weeks for their chemo drugs to arrive. I dont know about you but I would want my treatment imediately, not waiting while the cancer spreads and grows.....VOTE NO TO DOCKET CMS 1325 P.

Thank You
Susan Milkowich, RN
Oncology Nurse

Submitter : Mrs. Barbara Smart
Organization : Peachtree Hematology Oncology Consultants
Category : Other Health Care Professional

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs,

I am the administrator of a 5 physician oncology group. We oppose the new CAP program on the following grounds:

Patient care and staff time- patients treatments change on a regular basis, if we have received the drug in advance of the treatment day then it may not be the treatment that is required that day. We would then have to reorder and have the patient return when we get the new drug. Oncology patients are very compliant about their treatment. This would cause them added undue stress. It would increase our costs of staff time to reschedule visits; added nurse time to assess on two different days.

Storage- we do not and do not anticipate having the space required to store a variety of individual drugs.

Consequently, we do not plan to use the program.

Thank you for your consideration.

Barbara J. Smart, CMPE

Submitter : Mrs. Cheryl Hodges
Organization : Drs. Forte Schleider & Attas, Pa
Category : Other Health Care Professional

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

Our practice will not participate with the CAP program and believe it to be unreasonable do to the following reasons.

- 1) There is much room for error when seperating, ordering and storing individuals medications. This adds additional risk to our practice. We currently use a trusted vender, who ships the medications we order as we order them. We have a drug inventory system (Lynx) that keeps track and properly controls the climate of the stored drugs. This is of grave concern as our staff will be administering drugs shipped from unknown vendors. Our Nurses are very uncomfortable with this issue. We do not have the resources to maintain multiply inventory systems.
- 2) This will create additional work time for our staff which we are not compensated for.
- 3) Often times patients treatments are changed on the day they are supposed to be treated. We will not be able to accommodate these patients who are already tapping out strength and travel resources(many rely on others to provide transportation as they are too sick to drive)
- 4) This will force us to use one vendor. Unfair.
- 5) Cancer patients are often patients who have limited financial resources. They are ill and many cannot hold down a job while treating. We are faced with the challenge of juggling a patient with limited resources and payment plans, how will this program affect our ability to treat the unfortunates?? Is anyone thinking of that?

Submitter : Dr. Kenneth Miller
Organization : Arthritis Associates of CT/NY
Category : Physician

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-163-Attach-1.RTF

April 13, 2005

CMS

Dear Sir:

I am writing this letter as a practicing rheumatologist and as the president of Connecticut Rheumatology Association, which is a professional organization representing many of my colleagues in our state. I am expressing our concerns regarding the proposed Competitive Acquisition Program (CAP). I have multiple concerns, which I would like to express in this letter. Currently, infusion products are being billed through the patients' Medicare and secondary insurance as part of our administrative process in this office. In the proposed CAP, the vendor would do this billing. However, multiple responsibilities would still fall on our office including the need for inventory of drug per patient. We would need to provide claim status for the vendor to collect payment. There are issues with the quality of standards for the vendors, and whether we would have the ability to switch vendors if that becomes a problem. There is a concern about whether fractured billing would be of confusion to our patients. Currently, an issue with the payment for infusion products, and specifically Remicade, has affected multiple physicians all over the country, and Connecticut as well, on an ongoing basis. The intended 6% markup to cover acquisition costs and administrative costs in acquiring and billing for this product has not been realized in multiple locales. It turns out the 6% markup is based on the prior quarter and on the best available price, which is often given to large utilizers, such as HMOs. Consequently, the reimbursement is essentially flat and does not provide any cushion to cover these costs. I do feel that this needs to be rectified on an immediate basis. The physician's office is the patient-preferred setting to provide infusion medicines. It is also the safest and most cost-effective setting. CMS must be sensitive to the relationship between fair reimbursement and preserving access for patients. I think any movement towards a CAP program must be voluntary, and the average selling price calculations for practices that are currently doing billing should be adjusted to reflect the 6% incremental reimbursement above acquisition cost as soon as possible.

Thank you for your consideration.

Sincerely,

Kenneth A. Miller, M.D.

KAM:jed
V4633-ID77775

CC: Representative Nancy Johnson

Submitter : Dr. James Radford, Jr.
Organization : Hendersonville Hematology and Oncology
Category : Physician

Date: 04/21/2005

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

For physicians attempting to practice up-to-date but evidence-based medicine, formularies will reduce the quality of care provided to patients.

Statutory Requirements Concerning Claims Processing

I would anticipate that the administrative burden on my office/staff would increase, not decrease.

There should be no specific requirements regarding inventory resupply.

Vendors should be required to provide drug irrespective of payment expectation or history, or physicians should be able to go outside the CAP system anytime the CAP vendor declines to provide the ordered drug, for any reason.

Physicians and their staff should be held harmless for mistakes/deficiencies of the vendor.

Cap Bidding Process-Evaluation and Selection

How am I to be compensated for the time and resources expended in ordering and inventorying drugs on a patient-specific basis, and for the additional costs incurred whenever a planned treatment is delayed, cancelled, or switched?

Physicians should be allowed to disenroll or switch vendors at any time.

GENERAL

GENERAL

I cannot believe that there are any circumstances under which I would be willing to enroll in a program which will reduce my treatment scheduling flexibility, possibly decrease my patient's treatment options, increase my administrative burden, and lock my into a year-long relationship with a vendor which will thereafter have little or no incentive to provide satisfactory service. Any circumstance which might lead me in desperation to consider this will lead me first to send my patients to the hospital for treatment.

Submitter :

Date: 04/21/2005

Organization : American Association of Clinical Endocrinology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-165-Attach-1.DOC



American Association of Clinical Endocrinologists

1000 Riverside Avenue • Suite 205 • Jacksonville, Florida 32204 • Phone: (904) 353-7878 • Fax: (904) 353-8185 • <http://www.aace.com>

April 20, 2005

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1325-P

To Whom It May Concern:

The American Association of Clinical Endocrinologists (AACE) appreciates the opportunity to comment on the Part B Competitive Acquisition of Outpatient Drugs [CMS-1325-P], as stated in the Centers for Medicare and Medicaid Services' (CMS) proposed rule. Although AACE is supportive of the Part B Competitive Acquisition of Outpatient Drugs, we recommend the initial phase of implementation be expanded to include the following drugs:

Drug/Treatment	Route of Administration	Use
Sandostatin LAR	intramuscular-monthly	Acromegaly
Thyrogen	intramuscular-usually 1-2 days	Thyroid Cancer, multi-nodular Goiter
Radioiodine I-131	Oral-one dose	Hyperthyroidism multi-nodular Goiter
Cortrosyn	intravenous-one dose	Diagnosis of Addison's disease, pituitary suppression
Aredia (pamidronate) (zoledronic acid)	intravenous	Paget's disease and hypercalcemia
Zometa	intravenous	Osteoporosis

AACE strongly supports the inclusion of these drugs, and feels that doing so will not only prove to be both more cost effective to the Medicare program but also very beneficial to the day to day operation of the physician's practice.

AACE requests CMS' favorable consideration of this recommendation. We appreciate the opportunity to address this important issue and are pleased to have been able to contribute to this important effort. Should you have any questions regarding the information provided in these comments, please do not hesitate to contact the AACE office at 904-353-7878 x-142.

Sincerely,

Carlos Hamilton Jr., MD, FACE
President

- cc: AACE Board of Directors
- AACE Managed Care and Third Party Relations Committee
- Donald Jones, AACE CEO
- Chris Welch, AACE Deputy CEO
- Shelley Garrett, AACE Director of Socioeconomic and Member Advocacy

Submitter :

Date: 04/21/2005

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please stop the regulations. This legislation would create more hassle and work for us and our patients. You've cut the profit. Don't increase the hassle of the administration

Submitter : Ms. Barbara Dykes
Organization : Virginia Prostate Cancer Coalition
Category : Consumer Group

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

Comment follows and is also attached.

April 21, 2005

Centers for Medicare and Medicaid Services
Attn: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

Re: Comments on the Medicare Competitive Acquisition Program (CAP) for Part B Drug Coverage proposed rule

I am writing on behalf of the Board of Directors of the Virginia Prostate Cancer Coalition, a non-profit organization dedicated to making prostate cancer an urgent priority for the medical, patient, and policymaking communities. We represent the prostate cancer patient community in the Commonwealth of Virginia. This year alone it is projected that 5,080 men will be diagnosed with prostate cancer and 660 men will die from it in our state.

Our review of the proposed regulation to implement the Part B drug Competitive Acquisition Program (CAP) mandated by the Medicare Modernization Act raised some concerns about patient care and clinical appropriateness that we would like to share as part of the public comment period. These concerns center around patient and physician choice concerning treatment decisions and continuity of care.

First, it is our understanding that doctors may choose only one CAP vendor to obtain all their Part B drugs and that vendors need only supply one drug per HCPCS J-code required. In the case of multiple-source drugs, this could mean that patients are limited to only one manufacturer's version. There are distinct differences between versions of the same drug, and patients and their physicians should not be forced to either change their existing therapy, or choose a drug that is not appropriate for them.

We note that CMS is proposing an exception that would allow physicians to buy a drug under the ASP-system if medical necessity requires a specific formulation not supplied by the vendor; however, this will create additional administrative burdens on already over-burdened physician offices.

Secondly, the vendor has the authority to impose substitution and dosing restrictions. Again, patients should not be forced to change therapies and strengths.

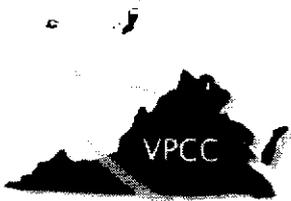
Finally, the Least Costly Alternative (LCA) policy is currently imposed by the Virginia Medicare carrier on prostate cancer hormone therapies. If LCA is allowed to continue on top of the CAP system, payment rates may actually fail to cover the costs of all FDA-approved prostate cancer therapies. There is no incentive for CAP vendors to carry any product other than the least costly one. Once again, the full array of clinical choices must be available to both the patient and his physician.

Thank you for your consideration of these views in the interest of prostate cancer patients on Medicare. We look forward to a review of the final regulation when it is available.

Sincerely,

Barbara Dykes, Chair

CMS-1325-P-167-Attach-1.DOC



Virginia Prostate Cancer Coalition

10804 Anita Drive, Mason Neck, VA 22079

April 21, 2005

Centers for Medicare and Medicaid Services

Attn: CMS-1325-P

PO Box 8010

Baltimore, MD 21244-8010

Re: Comments on the Medicare Competitive Acquisition Program (CAP) for Part B Drug Coverage proposed rule

I am writing on behalf of the Board of Directors of the Virginia Prostate Cancer Coalition, a non-profit organization dedicated to making prostate cancer an urgent priority for the medical, patient, and policymaking communities. We represent the prostate cancer patient community in the Commonwealth of Virginia. This year alone it is projected that 5,080 men will be diagnosed with prostate cancer and 660 men will die from it in our state.

Our review of the proposed regulation to implement the Part B drug Competitive Acquisition Program (CAP) mandated by the Medicare Modernization Act raised some concerns about patient care and clinical appropriateness that we would like to share as part of the public comment period. These concerns center around patient and physician choice concerning treatment decisions and continuity of care.

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We note that CMS is proposing an exception that would allow physicians to buy a drug under the ASP-system if medical necessity requires a specific formulation not supplied by the vendor; however, this will create additional administrative burdens on already over-burdened physician offices.

Secondly, the vendor has the authority to impose substitution and dosing restrictions. Again, patients should not be forced to change therapies and strengths.

Finally, the Least Costly Alternative (LCA) policy is currently imposed by the Virginia Medicare carrier on prostate cancer hormone therapies. If LCA is allowed to continue on top of the CAP system, payment rates may actually fail to cover the costs of all FDA-approved prostate cancer therapies. There is no incentive for CAP vendors to carry any product other than the least costly one. Once again, the full array of clinical choices must be available to both the patient and his physician.

Thank you for your consideration of these views in the interest of prostate cancer patients on Medicare. We look forward to a review of the final regulation when it is available.

Sincerely,

Barbara Dykes, Chair

Submitter : Dr. Karen Fields
Organization : Cancer Healthcare Associates
Category : Physician

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

Please see attached Word document

CMS-1325-P-168-Attach-1.DOC

CMS-1325-P-168-Attach-2.DOC

CHA
CANCER HEALTHCARE ASSOCIATES

AN AFFILIATE OF THE CANCER THERAPY & RESEARCH CENTER INSTITUTE FOR DRUG DEVELOPMENT

April 21, 2005

Dr. Mark McClellan
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

File Code: CMS-1325-P

Dear Dr. McClellan:

On behalf of the Cancer Healthcare Associates (CHA), a community physician group practicing in San Antonio, Texas, we are pleased to comment on the proposed rule published in the Federal Register of March 4, 2005 to implement the competitive acquisition of outpatient drugs and biologicals under Medicare Part B. In addition to providing a wide range of specialty oncology care, we engage in medical education and clinical research with the Cancer Therapy and Research Center and the University of Texas Health Science Center in San Antonio.

CHA is supportive of giving physicians the opportunity to relinquish the business of drug acquisition as well as the associated financial and administrative responsibilities. We commend the efforts of the Centers for Medicare and Medicaid Services (CMS) to provide physicians with an alternative procurement and payment system for Part B drugs. The proposed competitive acquisition program (CAP) represents a good start in the development of a new drug procurement system that balances a competitive framework with the need to ensure drug safety, quality, and access.

However, as CMS proceeds with finalizing the CAP, we encourage the agency to give careful consideration to protecting patient care and patient access to drugs, especially for cancer patients. Perhaps more than any other patient population, cancer patients often require the immediate availability of their chemotherapy regimens. It is critical that their drug treatment is not hampered in any way since a disruption or delay could be life threatening.

With these concerns in mind, we urge CMS to adopt the recommendations outlined below for improving the CAP. Our recommended CAP modifications are necessary in order for oncologists and other physicians participating in the program to be able to continue delivering optimum patient care in the timeliest manner.

General

Under the proposed rule, CMS generally defines the scope of work for CAP drug vendors to be drug acquisition and delivery to participating physicians. The agency is silent on the matter of whether these vendors also would be given the responsibility for mixing and preparing different drug agents to create a final drug, as is often undertaken to produce chemotherapy treatments.

CHA recommends that CMS excludes the mixing and preparation of drug agents from the scope of work of CAP vendors.

Many drug agents requiring additional preparation are fragile in that they need particular storage, handling, and equipment. The actual mixing and preparation must be performed by specially trained staff. As a result, these activities now typically take place under the supervision of physicians in specialized facilities so as to guarantee that neither drug safety nor drug quality is compromised. It is unclear whether CAP drug vendors would have the capability and resources to undertake the mixing of these special drug agents. We are very concerned that dangerous drug errors would result if this work was delegated to vendors lacking experience with these drug agents or having inadequate facilities. Not only could errors delay important patient care, they could cause serious harm to patient health. For cancer patients, nothing would be worse than knowing that their medical care was at risk. The preparation of drug agents, consequently, should remain firmly in the purview of facilities proven to be experienced with such work rather than being delegated to CAP vendors. We strongly recommend that CMS specifically excludes the mixing and preparation of drug agents from the responsibilities of vendors awarded CAP contracts.

Categories of Drugs to be Included under the CAP

According to CMS, drugs administered by oncologists account for the largest portion of Medicare Part B physician-administered drug expenditures. Many of the potential benefits of the CAP (e.g., savings) thus would be contingent on including such drugs in the program. One option being contemplated by the agency involves limiting the scope of the CAP initially to drugs typically administered by oncologists. Drugs furnished by other specialties would be phased into the program in the future.

While we understand CMS' interest in initially restricting the CAP only to drugs commonly administered by oncologists, we have concerns about the implications of this option for cancer patients and their physicians. The CAP is an entirely new program advancing a different approach for procuring Part B drugs. CHA anticipates that operational issues would emerge in the beginning phases of the CAP's implementation, compelling CMS to make both minor and major changes to the program once it was already underway. If the CAP initially included only drugs typically furnished by oncologists, this means that oncologists would bear the brunt of any early operational problems interfering with drug delivery and access. Their patients would end up being at risk for delayed treatment, a frightening prospect for individuals who are in an

extremely fragile state of health. Given the absolute necessity for cancer patients to receive timely drug therapy, we recommend that CMS puts in place a contingency plan for cases in which the CAP confronts ongoing operational challenges that impede drug delivery to oncologists and jeopardize access to drugs for cancer patients. Such a contingency plan might include permitting oncologists to revert temporarily to the existing system in which they directly purchase drugs and are paid under the average sales price methodology until problems with the CAP were resolved.

We are very supportive of CMS' proposal for "furnish as written" cases in which medical necessity calls for specific National Drug Codes (NDC) or Healthcare Common Procedure Coding System (HCPCS) brands that are not supplied by the selected vendors of CAP physicians. Although the proposed rule requires vendors to supply all of the HCPCS codes contained in the drug categories for which they have CAP contracts, they are not required to supply every NDC associated with a HCPCS code. Vendors, in effect, would be allowed to establish drug formularies for CAP physicians that may not contain certain NDCs or HCPCS brands.

This has the potential to be very detrimental to patient care by denying access to critical drugs. The NDCs or HCPCS brands available through a vendor may not necessarily be the most clinically effective or appropriate drugs for patients. Even though CMS proposes that vendors be required to inform potential CAP physician participants about the specific NDCs that they would be able to supply, different patient drug needs may emerge over time following a physician's election into the CAP. There is the strong possibility that patients would need drugs in the future different than what the vendor could supply. CAP physicians could be forced into the difficult position of substituting less effective drugs from the vendor formularies for better performing drugs, thereby compromising the quality of care delivered as well as patient health. Patients either would need to accept the vendor formulary restrictions or leave their physicians since the proposed rule binds CAP physicians to the program for a minimum of one year. Neither option would be in the best interests of patient health or well-being. Cancer patients especially would suffer additional health risks if their oncologists did not have the ability to provide them with the best chemotherapy regimens. These patients often have longstanding relationships with their oncologists through which the oncologists have gained detailed knowledge about their medical needs and history. Our patients, and others like them, have developed a trust in their oncologists to provide them with the best care in a consistent and reliable way. Consequently, many cancer patients probably would be compelled to remain with their physicians even if they could not receive the drugs optimally suited for their treatment. The lack of access to the most clinically effective drugs could undermine their chances for full remission and recovery.

CMS takes a major step in preventing these potential problems by permitting CAP physicians, in cases of medical necessity, to procure from non-CAP sources those NDCs or HCPCS brands not available from CAP vendors, bill Medicare for them with a "furnish as written" modifier, and subsequently receive reimbursement for the drugs according to the average sales price methodology in place for non-CAP physicians. We urge CMS to retain this option in the final rule implementing the CAP. It is vital for ensuring that patients have access to the drugs they need. Furthermore, we encourage CMS to consider putting in place a requirement and process for a CAP vendor to supply any NDC or HCPCS brand not included in the vendor's original

formulary if the physician deems that the specific formulation is medically necessary. While the "furnish as written" option helps to alleviate the possible lack of access to certain drugs under the CAP, physicians would need to expend time and resources to execute this option without any guarantee that they would be able to acquire the necessary drugs for their patients in a timely manner. Physicians participating in the CAP should be able to rely on the program to satisfy most of their drug needs. Otherwise, CHA's physicians and others would have little reason to participate in the CAP.

Statutory Requirements Concerning Claims Processing

The statute requires a CAP physician to submit a written order to the vendor in order to receive the requested drug(s). It further specifies that physicians participating in the CAP would not be required to submit a written order for individual treatments of a drug. Instead, the statute and the proposed rule preserve physician discretion to submit an order for a single treatment or an order for a course of treatments. CHA is very supportive of this approach. To be able to provide the most appropriate and timeliest care, physicians under the CAP need the flexibility of having ready access to multiple treatments of a drug based on the medical needs of their patients. Moreover, giving physicians the opportunity to submit one order for an entire course of treatments would reduce the administrative burden of CAP participation as well as eliminate needless redundancy in ordering. This is particularly true for cancer treatments in which a course of chemotherapy often involves the same drug being administered to a patient in the same dose over an extended period of time. Not only would the submission of identical orders for individual treatments of a drug be administratively redundant, the time and resources spent on this would divert valuable staff attention away from direct patient care. From the vendor perspective, allowing a single order to be placed for an entire course of treatments likewise would be less burdensome for them while promoting more efficiency in the drug ordering process. This is because vendors would have fewer orders to review and fulfill. Therefore, physicians, their patients, and vendors all benefit from physicians having the flexibility to order an entire course of drug treatments.

Claims Processing Overview

As discussed earlier, the statute requires a CAP physician to submit a written order to the vendor in order to receive the requested drug(s). In the Preamble discussion of the proposed rule, CMS explains that, "The order transmitted between the physician and the drug vendor may occur in a variety of HIPAA-compliant formats, such as by telephone with a follow-up written order." We understand this to mean that a physician would not be required to submit a written order immediately but could begin the drug ordering process with a telephone order and then follow-up with a written order. CHA strongly supports this general approach and further recommends that CMS permits a drug order to be initiated via either telephone or fax, with a formal written order to be submitted shortly thereafter.

Allowing a telephone or fax order to trigger the drug ordering process would be important for enabling vendors to fulfill drug orders with the greatest possible speed. CMS proposes a number of information elements that must be included in a written order. Physician offices may require some time to collect and write this information, potentially resulting in a delay in submitting the written order to the vendor. If a vendor were required to have a written order in hand before it could begin the process of fulfilling the drug request, then even a minor delay in the physician's

submission (or the vendor's receipt) of the written order would slow down the drug's delivery and, ultimately, delay administration of the drug to the patient. For cancer patients, even a short delay could be detrimental to their health. A process in which a telephone or fax order would be sufficient notification for the vendor to start work on fulfilling the drug order would help expedite the delivery of drugs and the subsequent provision of patient care. Because a written order would follow shortly thereafter, the vendor would have the opportunity to verify the order before final shipment was made. Our recommendation of permitting a drug order to be initiated via telephone or fax, to be followed later by a formal written order, would allow CMS to ensure the ready availability of drugs for patients, to enhance the efficiency of the drug ordering process, and to maintain the process' overall safety.

CHA also encourages the agency to consider establishing a comprehensive electronic drug ordering system in the future for CAP physicians and vendors. The system should allow physicians to access a secure website, submit electronic orders, and track shipments. Such a system would facilitate even greater efficiency and speediness in the delivery of drugs.

We are extremely concerned about a provision in the proposed rule that would allow a vendor to split a single drug order placed for a patient's entire course of treatments into multiple shipments. An entire course of treatments may take place within a very limited period of time. This is frequently the case with chemotherapy in which a chemotherapy regimen usually is administered over five to ten days. Therefore, it is often essential for a physician to have ready access to an entire course of treatments in order to provide the necessary uninterrupted patient care. The separation of a course of drug treatments into different shipments creates the opportunity for some of the drug treatments to be delayed in their delivery. This could cause harmful disruptions in patient therapy. CHA recommends that CMS prohibits vendors from splitting drug orders for entire courses of treatments into multiple shipments. Instead, the agency should require every vendor to ship an entire course of treatments in a single shipment so as to safeguard the continuity of patient care.

Bidding Entity Qualifications

CHA supports CMS' proposed requirement for potential vendors to be licensed in each State in which they would operate under the CAP. State licensure provides further assurance that CAP vendors are complying with important safety, quality, financial, and operational standards. We agree that potential vendors should supply state licensure information to CMS at the time they apply for CAP contracts so that only licensed vendors are considered for contract awards. We encourage the agency to undertake the appropriate measures to verify that vendors are licensed and remain licensed throughout their contract terms. Physicians participating in the CAP would have neither the ability nor the resources to confirm that vendors were licensed. The responsibility for verifying state licensure should lie with CMS due to the fact that the agency has full authority over the evaluation and selection of CAP vendors.

CAP Bidding Process—Evaluation and Selection

Because the proposed rule specifies that potential CAP vendors would need to include all drug shipping and handling costs in their bid prices submitted to CMS, this suggests that the agency would assume all of these costs and that physicians participating in the CAP would not be held responsible for them. CHA strongly supports CMS bearing the shipping and handling costs for

drugs delivered under the CAP. It would not make sense for CAP physicians to pay such costs since the vendors, not the physicians, would be under contract with CMS and receive Medicare reimbursement for all aspects of drug procurement and delivery.

Beneficiary Education

With respect to the agency's inquiry about the administrative burden of requiring physicians to provide to their Medicare patients a CMS-developed CAP fact sheet, we do not believe that such a requirement would impose a heavy administrative burden on physician practices. A standard fact sheet, in our view, would greatly aid CHA in informing our Medicare patients about the CAP. However, it would be important for the fact sheet to be developed by CMS rather than by individual physician offices. Asking each physician practice to develop a fact sheet would pose too great of an administrative burden as well as result in potentially inconsistent information being disseminated about the program.

Regulatory Impact Analysis

CMS alludes in its impact analysis of the proposed rule to various benefits that physicians might reap by participating in the CAP. Among them is the expectation that the CAP would yield savings for physicians. These savings, according to the agency, partially would be attributable to a reduction in the costs that physicians presently incur for storing drugs and negotiating with individual drug suppliers. CMS notes that additional savings would come from CAP vendors assuming sole responsibility for collecting drug deductibles and coinsurance from patients, as the statute requires. Because physicians electing to participate in the program would no longer need to expend resources in this area, the costs they bore in the past for performing those activities would be entirely eliminated.

Although physicians electing to participate in the CAP might enjoy a decrease in some of their overhead costs, it is equally feasible that their participation would lead to an increase in their acquisition costs for any drugs not included in the CAP. Physician groups probably would not be able to rely on the CAP to obtain all of the drugs they require. It is clear from the proposed rule that the CAP would only include drugs furnished incident to a physician's service. Even then, not every drug meeting this criterion would necessarily be included in the CAP. The drugs available under the CAP would depend on the vendors selected by CMS and how the agency ultimately decides to phase-in the program. As a result, physician practices participating in the program likely would find it necessary to continue to procure some drugs directly from their own suppliers. In the absence of the CAP, each physician group usually has attempted to procure all of its drugs from one or two suppliers. This purchasing strategy enables our group as well as others to leverage volume price discounts. However, with the advent of the CAP, physician groups would only be purchasing drugs not included in the CAP, a substantially smaller volume of drugs. There is a good chance that they subsequently would lose part of their ability to obtain volume price discounts. CAP physicians thus would end up incurring higher acquisition costs for their non-CAP drugs. This would hold especially true for small practices, medium-sized physician groups, and individual practitioners, all of whom have experienced difficulty in the past in securing the price discounts typically available to larger physician groups. As a mid-sized oncology group, CHA intends to consider this issue in its deliberations about participating in the CAP. We expect that potentially higher prices for non-CAP drugs would affect the CAP

election decisions of other physician groups too. We ask that CMS keeps this issue in mind as it examines the impact of the CAP on physicians and finalizes the program.

On a related note, CHA believes that the CAP could also negatively affect Medicare beneficiaries. If physician practices were unable to absorb higher costs for non-CAP drugs, there is a possibility that these costs would be passed directly on to their patients. Alternatively, physician groups may take the undesirable step of no longer making those particular drugs available as treatment options. Patient access to care, in either case, would be severely compromised. We urge CMS to evaluate this issue as well before final implementation of the CAP.

CHA thanks CMS for the opportunity to share our views of its proposed competitive acquisition program. We appreciate your consideration of our comments and recommendations as you proceed with implementing the CAP. We strongly believe that our recommendations would enhance the CAP's operations and protect patient care. Our cancer patients, as with patients everywhere, deserve nothing less than unimpeded access to the treatment and quality care they need.

Sincerely,

Karen K. Fields, M.D.
President, Cancer Healthcare Associates

CHA
CANCER HEALTHCARE ASSOCIATES

AN AFFILIATE OF THE CANCER THERAPY & RESEARCH CENTER INSTITUTE FOR DRUG DEVELOPMENT

April 21, 2005

Dr. Mark McClellan
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

File Code: CMS-1325-P

Dear Dr. McClellan:

On behalf of the Cancer Healthcare Associates (CHA), a community physician group practicing in San Antonio, Texas, we are pleased to comment on the proposed rule published in the Federal Register of March 4, 2005 to implement the competitive acquisition of outpatient drugs and biologicals under Medicare Part B. In addition to providing a wide range of specialty oncology care, we engage in medical education and clinical research with the Cancer Therapy and Research Center and the University of Texas Health Science Center in San Antonio.

CHA is supportive of giving physicians the opportunity to relinquish the business of drug acquisition as well as the associated financial and administrative responsibilities. We commend the efforts of the Centers for Medicare and Medicaid Services (CMS) to provide physicians with an alternative procurement and payment system for Part B drugs. The proposed competitive acquisition program (CAP) represents a good start in the development of a new drug procurement system that balances a competitive framework with the need to ensure drug safety, quality, and access.

However, as CMS proceeds with finalizing the CAP, we encourage the agency to give careful consideration to protecting patient care and patient access to drugs, especially for cancer patients. Perhaps more than any other patient population, cancer patients often require the immediate availability of their chemotherapy regimens. It is critical that their drug treatment is not hampered in any way since a disruption or delay could be life threatening.

With these concerns in mind, we urge CMS to adopt the recommendations outlined below for improving the CAP. Our recommended CAP modifications are necessary in order for oncologists and other physicians participating in the program to be able to continue delivering optimum patient care in the timeliest manner.

General

Under the proposed rule, CMS generally defines the scope of work for CAP drug vendors to be drug acquisition and delivery to participating physicians. The agency is silent on the matter of whether these vendors also would be given the responsibility for mixing and preparing different drug agents to create a final drug, as is often undertaken to produce chemotherapy treatments.

CHA recommends that CMS excludes the mixing and preparation of drug agents from the scope of work of CAP vendors.

Many drug agents requiring additional preparation are fragile in that they need particular storage, handling, and equipment. The actual mixing and preparation must be performed by specially trained staff. As a result, these activities now typically take place under the supervision of physicians in specialized facilities so as to guarantee that neither drug safety nor drug quality is compromised. It is unclear whether CAP drug vendors would have the capability and resources to undertake the mixing of these special drug agents. We are very concerned that dangerous drug errors would result if this work was delegated to vendors lacking experience with these drug agents or having inadequate facilities. Not only could errors delay important patient care, they could cause serious harm to patient health. For cancer patients, nothing would be worse than knowing that their medical care was at risk. The preparation of drug agents, consequently, should remain firmly in the purview of facilities proven to be experienced with such work rather than being delegated to CAP vendors. We strongly recommend that CMS specifically excludes the mixing and preparation of drug agents from the responsibilities of vendors awarded CAP contracts.

Categories of Drugs to be Included under the CAP

According to CMS, drugs administered by oncologists account for the largest portion of Medicare Part B physician-administered drug expenditures. Many of the potential benefits of the CAP (e.g., savings) thus would be contingent on including such drugs in the program. One option being contemplated by the agency involves limiting the scope of the CAP initially to drugs typically administered by oncologists. Drugs furnished by other specialties would be phased into the program in the future.

While we understand CMS' interest in initially restricting the CAP only to drugs commonly administered by oncologists, we have concerns about the implications of this option for cancer patients and their physicians. The CAP is an entirely new program advancing a different approach for procuring Part B drugs. CHA anticipates that operational issues would emerge in the beginning phases of the CAP's implementation, compelling CMS to make both minor and major changes to the program once it was already underway. If the CAP initially included only drugs typically furnished by oncologists, this means that oncologists would bear the brunt of any early operational problems interfering with drug delivery and access. Their patients would end up being at risk for delayed treatment, a frightening prospect for individuals who are in an

extremely fragile state of health. Given the absolute necessity for cancer patients to receive timely drug therapy, we recommend that CMS puts in place a contingency plan for cases in which the CAP confronts ongoing operational challenges that impede drug delivery to oncologists and jeopardize access to drugs for cancer patients. Such a contingency plan might include permitting oncologists to revert temporarily to the existing system in which they directly purchase drugs and are paid under the average sales price methodology until problems with the CAP were resolved.

We are very supportive of CMS' proposal for "furnish as written" cases in which medical necessity calls for specific National Drug Codes (NDC) or Healthcare Common Procedure Coding System (HCPCS) brands that are not supplied by the selected vendors of CAP physicians. Although the proposed rule requires vendors to supply all of the HCPCS codes contained in the drug categories for which they have CAP contracts, they are not required to supply every NDC associated with a HCPCS code. Vendors, in effect, would be allowed to establish drug formularies for CAP physicians that may not contain certain NDCs or HCPCS brands.

This has the potential to be very detrimental to patient care by denying access to critical drugs. The NDCs or HCPCS brands available through a vendor may not necessarily be the most clinically effective or appropriate drugs for patients. Even though CMS proposes that vendors be required to inform potential CAP physician participants about the specific NDCs that they would be able to supply, different patient drug needs may emerge over time following a physician's election into the CAP. There is the strong possibility that patients would need drugs in the future different than what the vendor could supply. CAP physicians could be forced into the difficult position of substituting less effective drugs from the vendor formularies for better performing drugs, thereby compromising the quality of care delivered as well as patient health. Patients either would need to accept the vendor formulary restrictions or leave their physicians since the proposed rule binds CAP physicians to the program for a minimum of one year. Neither option would be in the best interests of patient health or well-being. Cancer patients especially would suffer additional health risks if their oncologists did not have the ability to provide them with the best chemotherapy regimens. These patients often have longstanding relationships with their oncologists through which the oncologists have gained detailed knowledge about their medical needs and history. Our patients, and others like them, have developed a trust in their oncologists to provide them with the best care in a consistent and reliable way. Consequently, many cancer patients probably would be compelled to remain with their physicians even if they could not receive the drugs optimally suited for their treatment. The lack of access to the most clinically effective drugs could undermine their chances for full remission and recovery.

CMS takes a major step in preventing these potential problems by permitting CAP physicians, in cases of medical necessity, to procure from non-CAP sources those NDCs or HCPCS brands not available from CAP vendors, bill Medicare for them with a "furnish as written" modifier, and subsequently receive reimbursement for the drugs according to the average sales price methodology in place for non-CAP physicians. We urge CMS to retain this option in the final rule implementing the CAP. It is vital for ensuring that patients have access to the drugs they need. Furthermore, we encourage CMS to consider putting in place a requirement and process for a CAP vendor to supply any NDC or HCPCS brand not included in the vendor's original

formulary if the physician deems that the specific formulation is medically necessary. While the "furnish as written" option helps to alleviate the possible lack of access to certain drugs under the CAP, physicians would need to expend time and resources to execute this option without any guarantee that they would be able to acquire the necessary drugs for their patients in a timely manner. Physicians participating in the CAP should be able to rely on the program to satisfy most of their drug needs. Otherwise, CHA's physicians and others would have little reason to participate in the CAP.

Statutory Requirements Concerning Claims Processing

The statute requires a CAP physician to submit a written order to the vendor in order to receive the requested drug(s). It further specifies that physicians participating in the CAP would not be required to submit a written order for individual treatments of a drug. Instead, the statute and the proposed rule preserve physician discretion to submit an order for a single treatment or an order for a course of treatments. CHA is very supportive of this approach. To be able to provide the most appropriate and timeliest care, physicians under the CAP need the flexibility of having ready access to multiple treatments of a drug based on the medical needs of their patients. Moreover, giving physicians the opportunity to submit one order for an entire course of treatments would reduce the administrative burden of CAP participation as well as eliminate needless redundancy in ordering. This is particularly true for cancer treatments in which a course of chemotherapy often involves the same drug being administered to a patient in the same dose over an extended period of time. Not only would the submission of identical orders for individual treatments of a drug be administratively redundant, the time and resources spent on this would divert valuable staff attention away from direct patient care. From the vendor perspective, allowing a single order to be placed for an entire course of treatments likewise would be less burdensome for them while promoting more efficiency in the drug ordering process. This is because vendors would have fewer orders to review and fulfill. Therefore, physicians, their patients, and vendors all benefit from physicians having the flexibility to order an entire course of drug treatments.

Claims Processing Overview

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Allowing a telephone or fax order to trigger the drug ordering process would be important for enabling vendors to fulfill drug orders with the greatest possible speed. CMS proposes a number of information elements that must be included in a written order. Physician offices may require some time to collect and write this information, potentially resulting in a delay in submitting the written order to the vendor. If a vendor were required to have a written order in hand before it could begin the process of fulfilling the drug request, then even a minor delay in the physician's

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CHA also encourages the agency to consider establishing a comprehensive electronic drug ordering system in the future for CAP physicians and vendors. The system should allow physicians to access a secure website, submit electronic orders, and track shipments. Such a system would facilitate even greater efficiency and speediness in the delivery of drugs.

We are extremely concerned about a provision in the proposed rule that would allow a vendor to split a single drug order placed for a patient's entire course of treatments into multiple shipments. An entire course of treatments may take place within a very limited period of time. This is frequently the case with chemotherapy in which a chemotherapy regimen usually is administered over five to ten days. Therefore, it is often essential for a physician to have ready access to an entire course of treatments in order to provide the necessary uninterrupted patient care. The separation of a course of drug treatments into different shipments creates the opportunity for some of the drug treatments to be delayed in their delivery. This could cause harmful disruptions in patient therapy. CHA recommends that CMS prohibits vendors from splitting drug orders for entire courses of treatments into multiple shipments. Instead, the agency should require every vendor to ship an entire course of treatments in a single shipment so as to safeguard the continuity of patient care.

Bidding Entity Qualifications

CHA supports CMS' proposed requirement for potential vendors to be licensed in each State in which they would operate under the CAP. State licensure provides further assurance that CAP vendors are complying with important safety, quality, financial, and operational standards. We agree that potential vendors should supply state licensure information to CMS at the time they apply for CAP contracts so that only licensed vendors are considered for contract awards. We encourage the agency to undertake the appropriate measures to verify that vendors are licensed and remain licensed throughout their contract terms. Physicians participating in the CAP would have neither the ability nor the resources to confirm that vendors were licensed. The responsibility for verifying state licensure should lie with CMS due to the fact that the agency has full authority over the evaluation and selection of CAP vendors.

CAP Bidding Process—Evaluation and Selection

Because the proposed rule specifies that potential CAP vendors would need to include all drug shipping and handling costs in their bid prices submitted to CMS, this suggests that the agency would assume all of these costs and that physicians participating in the CAP would not be held responsible for them. CHA strongly supports CMS bearing the shipping and handling costs for

drugs delivered under the CAP. It would not make sense for CAP physicians to pay such costs since the vendors, not the physicians, would be under contract with CMS and receive Medicare reimbursement for all aspects of drug procurement and delivery.

Beneficiary Education

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Regulatory Impact Analysis

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Although physicians electing to participate in the CAP might enjoy a decrease in some of their overhead costs, it is equally feasible that their participation would lead to an increase in their acquisition costs for any drugs not included in the CAP. Physician groups probably would not be able to rely on the CAP to obtain all of the drugs they require. It is clear from the proposed rule that the CAP would only include drugs furnished incident to a physician's service. Even then, not every drug meeting this criterion would necessarily be included in the CAP. The drugs available under the CAP would depend on the vendors selected by CMS and how the agency ultimately decides to phase-in the program. As a result, physician practices participating in the program likely would find it necessary to continue to procure some drugs directly from their own suppliers. In the absence of the CAP, each physician group usually has attempted to procure all of its drugs from one or two suppliers. This purchasing strategy enables our group as well as others to leverage volume price discounts. However, with the advent of the CAP, physician groups would only be purchasing drugs not included in the CAP, a substantially smaller volume of drugs. There is a good chance that they subsequently would lose part of their ability to obtain volume price discounts. CAP physicians thus would end up incurring higher acquisition costs for their non-CAP drugs. This would hold especially true for small practices, medium-sized physician groups, and individual practitioners, all of whom have experienced difficulty in the past in securing the price discounts typically available to larger physician groups. As a mid-sized oncology group, CHA intends to consider this issue in its deliberations about participating in the CAP. We expect that potentially higher prices for non-CAP drugs would affect the CAP

election decisions of other physician groups too. We ask that CMS keeps this issue in mind as it examines the impact of the CAP on physicians and finalizes the program.

On a related note, CHA believes that the CAP could also negatively affect Medicare beneficiaries. If physician practices were unable to absorb higher costs for non-CAP drugs, there is a possibility that these costs would be passed directly on to their patients. Alternatively, physician groups may take the undesirable step of no longer making those particular drugs available as treatment options. Patient access to care, in either case, would be severely compromised. We urge CMS to evaluate this issue as well before final implementation of the CAP.

CHA thanks CMS for the opportunity to share our views of its proposed competitive acquisition program. We appreciate your consideration of our comments and recommendations as you proceed with implementing the CAP. We strongly believe that our recommendations would enhance the CAP's operations and protect patient care. Our cancer patients, as with patients everywhere, deserve nothing less than unimpeded access to the treatment and quality care they need.

Sincerely,

Karen K. Fields, M.D.
President, Cancer Healthcare Associates

Submitter : Dr. Joel Lamon
Organization : Southwest Cancer Care Medical Group
Category : Physician

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

Competitive Acquisition Process and Overview:

- 1) Competition may lower costs to the payer, in this case Medicare/CMS, but costs to the providers (medical oncologists) will go up: ordering, storage, verifying diagnosis and justification (a duplication to the E/M documentation...and with no compensation for those costs, as drug related income/expense will be with the elected vendor.
 - 2) We are locked into the vendor we choose for one year...we currently order from the vendor that offers the best price AND service on an order by order process. The competitive aspect of the system has nothing to do with service which includes: timely delivery of the right drug, on time and without disruption of the office function.
 - 3) There must be full disclosure of what the drug vendors are paid. I have never seen a system that inserts another layer of administration lower overall costs, improve service to providers and patients, or improve productivity. I assume that the vendors will be paid ASP + 6%. If they are paid more than that, then you are acknowledging that providing that one rather narrow service at current provider reimbursement is not feasible.
 - 3) Providers of care should be given the option to purchase drugs and be reimbursed at the same rate as vendors assigned by competitive bidding.
 - 4) The office efficiency process is a significant with decreasing reimbursement, this system ties our hands from attempts to improve the drug administration process. The tail will be wagging the dog! We will have to delay patients or reschedule or cancel patients on the basis of vendor service.
 - 5) If drugs are delivered for a course of therapy; how do we store the array of drugs on numerous individual patients?; what is the potential waste of drug if a patient dies during therapy or the treatment is stopped for proper cause?
- I am very concerned that administrative costs (communication, documentation, staff, proper storage and sufficient storage) will overwhelm our practice.

Joel Lamon

Submitter : Miss. Nat Webb
Organization : Urology Associates, LTD
Category : Health Care Professional or Association

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

Why would we only have 14 days to bill charges unde this CAP program. medicare usually allows 18 months to submit claims. The same should apply to this proposed program
Thank You

Submitter : Dr. Carl Clark
Organization : Colorado Behavioral Healthcare Council
Category : Health Care Provider/Association

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

I am writing in strong support of the proposed rule recently issued by the Centers for Medicare and Medicaid Services (CMS) that addresses implementation of the Competitive Acquisition Program

CMS-1325-P-171-Attach-1.DOC

April 21, 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:

It was a pleasure to meet you prior to the Senate Special Committee on Aging in March. I am sending this letter on behalf of all of the mental health centers in Colorado and especially on behalf of our consumers. All of the mental health center directors in the state support what I outline below.

I am writing in strong support of the proposed rule recently issued by the Centers for Medicare and Medicaid Services (CMS) that addresses implementation of the Competitive Acquisition Program (CAP). This program 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.

The use of injectable antipsychotics has been recognized as an important, evidence-based practice that addresses the noncompliance issue of many with schizophrenia. In addition, a new type of psychotropic medications show tremendous promise in addressing the issue of partial compliance among people with mental illnesses. These new medications are injectable, but do not have the side effect profile of older injectable depot psychotropics that consumers found objectionable, including lingering pain after the injection, sedation, and other effects. While a number of the new injectable medications are currently in development (including an antidepressant), one antipsychotic, an injectable form of risperidone, has been

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

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 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 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,

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.

Carl Clark, M.D.

CEO

Mental Health Center of Denver

And on behalf of the Colorado Behavioral Healthcare Council which represents all of the mental health centers in Colorado.

Submitter : Dr. Joseph DeFelice
Organization : Joseph M. DeFelice, M.D., P.A.
Category : Physician

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

There are multiple issues associated with the CAP as proposed by the new laws. I am a community oncologist and this change will burden my practice with paperwork, tracking drugs for individual patient at the risk of being found criminal and fined. In addition, I will no longer be able to profit even marginally on the drugs that my practice buys. This loss is not balanced by any other compensated reimbursement scheme devised by the new Medicare regulations ie observation projects.

I will not be able to have vendors compete to provide medications at lower rates and halting the concept of free trade in it's tracks. This no longer feels like provate practice but some state regulated health care system that would be restrictively cumbersome.

I fear that I would be faced with discontinuing to accept Medicare assignment. Please reconsider this change and it's impact on both patient care and the practice of oncology in the community.

Sincerely,
Joseph DeFelice, M.D.
Clearwater, FL

Submitter : Dr. Gary Gross
Organization : Blood and Cancer Center of East Texas
Category : Physician

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

I am an oncologist in private practice and I will not be able to afford to provide chemotherapy to my patients in our clinic if the changes recommended in the "CAP" are implemented for the following reasons:

1. Even though the cost of chemotherapy drugs is unquestionably high, the profit margin on our chemotherapy drugs is what has funded the entire operation of labor-intensive and technologically-intensive practice. Without that margin, unless we are paid appropriately for our cognitive services and the administration of chemotherapy (which is not happening) we cannot afford to provide the high quality, intimate care which our patients need and expect. The CAP program would force us to do all the clerical work and preparation of chemotherapy drugs for no remuneration.

2. CAP does not take into account the amount of wastage which is inherent in drug delivery. Every day we mix up chemo which patients are unable to take, either because they are too ill or have unanticipated reaction. Bottles of chemotherapy are occasionally broken. In the CAP system, as I understand it, all of this inevitable wastage would be at our expense.

3. I have major reservations about "brown bagging" of chemotherapy drugs into our office in terms of the safety of our patients. How can we know that meds have been mixed under sterile conditions, in appropriate doses (either too much or too little medicine is a potential disaster.)

4. All of the above issues put oncologists at huge liability. Although we would have no input as to the selection and mixing of chemo drugs, we oncologists would be the only ones with our fingerprints on the gun if there were a problem.

Please do not implement the CAP system. This would be another example of a piecemeal attempt to fix the problem of lowering the cost of chemotherapy delivery.

I encourage you to find a comprehensive restructuring of the system.....and, bring the drug companies to the table. Chemotherapy costs are going up because of the skyrocketing cost of drugs. All other issues are of secondary importance.

Thank you, Gary Gross, MD

Submitter : Dr. Marc Avery

Date: 04/21/2005

Organization : Valley Cities Counseling and Consultation

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-174-Attach-1.DOC



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Marilyn LaCelle
Chief Executive Officer

*A United Way
Agency since 1967*



April 14, 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:

I am writing you in behalf of my role as medical director of Valley Cities – a community mental health center in Washington State. I am writing to support of the proposed rule recently issued by the Centers for Medicare and Medicaid Services (CMS) that addresses implementation of the Competitive Acquisition Program (CAP). This program 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. **I urge that injectable antipsychotic medications be included in the initial phase of CAP implementation.**

I would be happy to provide additional information to you regarding the advantages of injectable psychiatric medications. In brief, these medications are a valuable tool for patients to improve adherence to their psychiatric medication regimen. Due to the details of how this medication is purchased and administered, there are significant obstacles to obtaining this medication for patient benefit. When injectable antipsychotics are included in the Medicare CAP program, this 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. I urge you to include coverage of antipsychotic injectable medications in the drug categories that compose the initial phase of CAP implementation.

Sincerely,

Marc Avery, MD

Chief Medical Officer

Valley Cities Counseling and Consultation

Submitter : Dr. Robert Siegel
Organization : Oncology Associates, PC
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

I am a practicing hematologist and medical oncologist serving both the urban and suburban regions of Hartford Connecticut. We have a moderately large practice of 8 physicians serving populations through four separate offices. Like other practices, we have weathered a variety of changes over the past year but are significantly concerned about the potential implications of CAP on our efficiency and our ability to function in a world of diminished reimbursement. I for one have welcomed the shift of reimbursement from commodity sales (drugs) to attempts at appropriate compensation for our services. Taken to its extreme, I would be happy to get out of the drug business all together if we were paid fairly for what we provided in service, and the system enacted would not impair our efficiency. CAP ostensibly is a step in that direction. However in its current configuration it leaves much to be desired and quite frankly is unworkable. Specifically, my partners and I have the following concerns: The first series of concerns reflects the inherent inefficiency of trying to keep track of delivered inventory patient by patient for those on Medicare, and somehow keep that inventory separate from our other inventory for non-Medicare patients. Similarly the ordering process will be much more complicated thereby increasing our overhead and space needs in an era of declining reimbursement. We will also still incur a cost for preparing these drugs which will be unreimbursed. Many patients have acute problems requiring immediate treatment. As best we can tell there is no such provision for this in the legislation. Currently if a patient's medical needs change they will be forced to reschedule his/her appointment until we can be resupplied with new medications. What happens to the drugs received that the patient no longer needs? Do we pay to send them back? Are they wasted? Currently we would simply use them on the next patient who needs them. The current situation is far more sensible, less wasteful and certainly more patient friendly. We are also concerned that we are locked into a CAP vendor for an entire year regardless of how it performs, their timeliness of response, etc. This seems like an awfully long time and ultimately it is the patient who suffers, and we often take the brunt of their frustrations. I am also a bit concerned about the CAP vendor's ability to create a formulary. Oncology is an ever changing discipline in which drugs are frequently used "off-label" legitimately. These vendors will not be as familiar with such changes and undoubtedly efforts to get meds off formulary will be tedious if not impossible.

Submitter : Ms. sharlene bence
Organization : Andrews & Patel Associates, P.C.
Category : Nurse

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

i have a multitude of concerns about CAP. It is untested. we do not know who the vendors are yet. we do not have facility space to store drugs for individual patients. we do not have enough staff,(nurses) to do the proposed paperwork to obtain drugs thru the CAP program. our doctors do not have the time to write each RX again, they do it once in the electronic record. that is enough. these drugs require special handling, refigeration, non refrigeration, protect from light. storage will be an issue if each of teh 600 medicare patients require individual storage areas so their drugs can be correctly stored and inventoried. who will care for patients who have no ability to pay the 20% copay, currently they go to the local hospital and are put on a payment plan or recieve charity care. also will they still be able to obtain free drug from patient assistance programs?
who will assume bad debt for chemotherapy? it is real, bad debt, we deal with it each and every day!!!! the individual rx number that must be placed on each claim is just another level of paper trail that will delay payment and cause difficulty. our HGSA provider told us they get 180,000 claims per day, if we have a delay, like we do now because of the new g codes, we will have to close our office becuase half of our patients have medicare and we can not afford a delay in payment and still be solvent!

Submitter : Mr. Irv Miller
Organization : Coastal Cancer Center
Category : Other Health Care Professional

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-177-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:

"Implementation of the CAP"

We the people of the United States, in order to form a more perfect union, establish justice, insure domestic tranquility, provide for the common defense, *promote the general welfare*, and secure the blessings of liberty to ourselves and our posterity, do ordain and establish this Constitution for the United States of America.

When I read the proposed new rules, CMS-1325-P, I have to wonder if CMS will be in compliance with the U.S. Constitution if this is put into effect. Under this rule, the highly trained physician becomes a pawn in a financial game that ultimately will not be in the patient's best interest. Furthermore, it definitely will not promote a U.S. citizen's general welfare. Under this proposal, the patient will have access to quality care compromised. In addition, CMS states that it believes the clerical and inventory expenses related to use of the CAP will be no greater than for ASP-based reimbursement.

**"Impact of Establishment of a Competitive Acquisition Program:
Impact on Beneficiaries:"**

We have the best-trained Oncologists in the world with six years post-medical school training. However, we are going to take away the ability of these highly skilled physicians to provide proper care by using general statistics and pre-set protocols. There is one hard and fast rule in medicine – the patient's condition is ever changing. CAP puts restraints on the ability of the physician to make adjustments in the patient care plan as required. Presently, adjustments can be made as a matter of routine care. The ability to individualize treatment and make appropriate and timely adjustments will be curtailed. Patients are not computer driven like robots with pre-set programs. They miss appointments, travel to different areas of the country for extended periods, require hospitalization and sometime succumb to their illness in an untimely manner. It is not uncommon to see providers of care change regularly which can result in different vendors.

One question that really concerns me pertains to the vendors. Since they will be responsible for collecting coinsurance and deductibles, what will happen if the patient cannot meet this financial obligation in a timely manner? I feel confident in stating that the drug will not be provided. Most physicians make allowances and/or arrangements for these patients and treatment continues. Under the CAP plan access to proper chemotherapy will be compromised. The vendor will make decisions based on business practices without benefit of patient association. How does this "promote the general welfare"?

I realize CMS has a financial responsibility to all citizens of the United States, not just those Medicare recipients receiving chemotherapy. However, I strongly believe if CMS would work with Oncology, an acceptable compromise could be established - one that would benefit the patient as well as maintain the viability of the practice of Oncology. The only one benefiting from this CAP proposal is the pharmaceutical industry.

Irv Miller,
Lab Supervisor
CCC

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

CMS-1325-P-178

Submitter : Mrs. Kimberley Belcastro-Fritz
Organization : Coastal Cancer Center
Category : Other Health Care Professional

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-178-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:

“Competitive Acquisition Program:”
“Over view of CAP”

After reviewing “CAP”, I would like to share my point of view with you on this matter. I find it disturbing that the Government sees this as a way to help our offices or as an answer to current problems with drug reimbursement in our practices. This program, in my opinion, is about pharmaceutical companies and certainly *not about the patients*.

Physicians have the same right to earn a decent living just as a football player or a government employee. A physician is a special person, one who has spent numerous years on an education and still continues to be educated even after medical school, who takes care of patients. A football player providing sports entertainment earns far more than a physician and does not provide the care and concern for people that physicians do

Oncology is constantly changing. Medicare is constantly changing. An Oncology practice requires a well trained staff, from clerical to clinical, to be able to provide quality care to save lives of patients and to give them comfort.

“Impact of the Establishment of CAP:”

I understand there needs to be change, but a mandatory vendor is not the answer. As purchasers of the drugs, we are responsible for recalls and the temperature sensitivity of these expensive medications. The practice will have no control over the drugs and as such I am very concerned about recalls and brown bagging. If the patient’s blood count is too low and they can’t receive the drugs, this will require more paperwork to complete for our staff. We can’t keep separate

inventories for every patient, nor can we combine it with our other inventory due to limited storage space. Some practices can only keep a certain amount of drugs to keep their insurance liability costs under control. Collecting all of the demographic/insurance information, etc., to provide to the vendor, we will require an increased workload and staff while we are getting reimbursed less and less.

ASP is not the answer, either. We should not be penalized for paying bills early. ASP discriminates against small practices that do not have the same opportunity as a larger entity to purchase drugs at a lesser price. Some patients may not receive treatment if we cannot afford to give them the drugs when we are reimbursed less than cost. Or, some patients may drive miles (even though they are tired and ill) to receive treatment elsewhere.

This is not good patient care! There must be another way to resolve this problem. I ask that you stop the CAP Rule until numerous inevitable problems can be further examined and a more sound solution can be found.

Respectfully submitted,

Kimberley Belcastro-Fritz
AR Director
Coastal Cancer Center

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Ms. Sandra Saltzer
Organization : Finger Lakes Hematology & Oncology
Category : Nurse

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comment.

CMS-1325-P-179-Attach-1.PDF

Ten Specific Problems with the Competitive Acquisition Program (CAP)

Problem #1: You are locked into a CAP vendor for one year

An oncologist who elects to participate in CAP will be "locked-in" for one year. The oncologist will not be able to leave CAP unless the approved vendor ceases to participate in the program, the oncologist relocates to another area that is not served by the CAP vendor, or other criteria is met as established by the Secretary of Health and Human Services.

Problem #2: CAP vendors can establish formularies

CAP vendors will have authority to establish formularies and these formularies will be driven by price, not clinical effectiveness. Participating oncologists have a choice: accept the CAP supplied drug (which may not be the most effective or appropriate) or purchase drugs outside CAP under the Medicare ASP-based reimbursement system.

Problem #3: Individual patient inventories

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.

Problem #4: Patient inconvenience and inventory resupply

Under CMS' proposed rules, CAP participating oncologists are prohibited from using CAP-acquired drugs and biologicals to resupply their inventories unless all four of the following conditions are met: (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; and (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."

Problem #5: No emergency provisions

No provision is made for emergency delivery of drugs. Under proposed rules, CAP vendors only would be required to furnish routine shipments of drugs within one or two business days and to furnish emergency drug orders on the next day for orders received by the vendor before 3 p.m.

Problem #6: Burdensome claims processing

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; and 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.

Problem #7: Vendors may have oncologists investigated and excluded

While no provision is made to compensate oncologists for administrative tasks associated with CAP, if a vendor experiences losses because an oncologist has failed to timely file claims or pursue appeals, the vendor may appeal to the designated carrier and request that the oncologist be investigated. The investigation may lead to exclusion, a notice of which is published in the Federal Register.

Problem #8: Treatment splitting

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. When an order is split, the CAP vendor must create a separate prescription number for each shipment and the oncologist must track each shipment separately.

Problem #9: Quality control and lack of vendor responsibility

If a CAP participating oncologist has concerns about a vendor's performance, the proposed rule states that oncologist's recourse is to file a grievance with the vendor. If the grievance isn't resolved, the oncologist can escalate the matter to the designated carrier. Concerns about quality and service, however, are not grounds for terminating the oncologist's election to acquire drugs from the vendor — the oncologist is still locked-in to the one-year CAP election.

Problem #10: Pharmacy costs are un-reimbursed

Although a primary goal of CAP is to reduce the financial burden of drug acquisition on community cancer clinics, clinics will still incur costs associated with drug handling and inventory management. Add these to the additional "uncompensated" costs of ordering, tracking, and filing CAP claims, pursuing appeals and sharing information with vendors to help them collect co-payments and it is clear that community cancer clinics, who are already facing a reimbursement shortfall, will experience further reimbursement erosion as a result of CAP.

Submitter : Dr. Vijay Paudel
Organization : Coastal Cancer Center
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-180-Attach-1.DOC

April 20, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

Dear CMS,

My name is Dr. Vijay Paudel and I am a practicing community medical oncologist in the greater Myrtle Beach, South Carolina area. I appreciate the opportunity to comment on the Competitive Acquisition Program (CAP). 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.

It appears that the billing system is cumbersome, as well as the ordering process. Furthermore, 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 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. For example, if the patient has Medicare coverage without a secondary co-insurance, would the vendor ship the drug to our office realizing they will only receive 80% of the cost of the drug? There is no coverage for indigent care, i.e. patients who do not have secondary co-pay insurance with the proposed CAP rule.

The rule does have a proposal for emergency situations, however it states that "emergency orders received by 3:00 p.m. would need to be delivered the next day". Again, 3:00 p.m. western time or

eastern time is obviously conflicting due to the three hour time differential from the east coast and west coast. The majority of vendor suppliers may be on the east coast or potentially on the west coast. This would be a serious problem to patient care, especially those requiring emergent therapy.

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. Here in the Myrtle Beach area of South Carolina we have created an excellent community cancer care program to allow life saving treatment for patients debilitated with malignant diseases.

I thank you for the opportunity to comment on the proposed program. 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,

Vijay Paudel, M.D.
Coastal Cancer Center
8121 Rourk St
Myrtle Beach, SC 29572
843-692-5000
www.coastalcancercenter.com
VP/cjc

Submitter : Dr. G. Lance Miller
Organization : Oklahoma Oncology
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-181-Attach-1.DOC



OKLAHOMA
ONCOLOGY

specialists in the treatment of cancer

G. Lance Miller, M.D.
Joseph P. Moore, M.D.
Vicki C. Baker, M.D.
Joseph P. Lynch, M.D.
Ravikumar Vasireddy, M.D.
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Claremore Clinic
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Tahlequah Cancer Center
Clinic in the Woods
1325 E. Boone St., #102
Tahlequah, OK 74464
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FAX (918) 431-0443

April 19, 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

Dear Dr. McClellan:

Pursuant to the instructions posted in the Federal Register, what follows are comments regarding CMS-1325-P, Competitive Acquisition Program (CAP). This letter is written on behalf of the physicians of Oklahoma Oncology in Tulsa Oklahoma.

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OKLAHOMA
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specialists in the treatment of cancer

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Sincerely,
The Physicians of Oklahoma Oncology

G. Lance Miller, MD
Medical Director

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

CMS-1325-P-182

Submitter : Dr. Vicki Baker
Organization : Oklahoma Oncology
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-182-Attach-1.DOC



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April 19, 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

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Sincerely,

Vicki C. Baker

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

Submitter : Dr. Donald Gravenor
Organization : Family Cancer Center
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

We are not sure of the agenda all of these changes are planned to bring about, but we believe that the ongoing underfunding will ultimately have a negative impact on our ability to provide the quality service that we provide today.

The other worry we have is that squeezing out profits which go to the pharmaceutical companies will ultimately dry up funding for innovative new drug research in this country. I believe that a more targeted attack on the marketing practices of big pharma might have been a more useful exercise.

Submitter : Mrs. Alison Williams
Organization : Peachtree Hematology & Oncology Consultants
Category : Health Care Professional or Association

Date: 04/22/2005

Issue Areas/Comments

GENERAL

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CAP will impose a burden on the patient financially. Those who are unable to pay the co-insurance could potentially be sent to a collections agency by the vendors. The burden of helping the patient deal with the vendors' billing processes will become the clinic's problem. Community oncologists will be forced into dealing with multiple vendors without knowing if the vendors are compliant with pharmacy laws. On top of that, it is unknown whether the vendors adhere to the standards of quality community oncologists are accustomed to with their current vendors.

Submitter : Dr. Joseph Moore
Organization : Oklahoma Oncology
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

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See attachment

CMS-1325-P-185-Attach-1.DOC



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April 19, 2005

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Submitter : Dr. Joseph Lynch
Organization : Oklahoma Oncology
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-186-Attach-1.DOC



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Sincerely,

Joseph P. Lynch, MD

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

CMS-1325-P-187

Submitter : Dr. Ravikumar Vasireddy
Organization : Oklahoma Oncology
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

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See attachment

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OKLAHOMA
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specialists in the treatment of cancer

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April 19, 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

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Sincerely,

Ravikumar Vasireddy, MD

Cc: Representative John Sullivan
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Representative Frank Lucas
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President George W. Bush

Submitter : Dr. Jihad Khattab
Organization : Oklahoma Oncology
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

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Sincerely,

Jihad Khattab, MD

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

Submitter : Dr. Jennifer Trotman
Organization : Oklahoma Oncology
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

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see attachment

CMS-1325-P-189-Attach-1.DOC



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Submitter : Dr. Renae Mayer
Organization : Oklahoma Oncology
Category : Physician

Date: 04/22/2005

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We urge CMS to take a long, hard look at the issues facing community oncology clinics and postpone the implementation of the CAP program until further analysis and testing can be completed on this system. This will insure that the quality of patient care will not be compromised because of an untested program. We appreciate your consideration of this very vital issue in providing quality cancer care to all Medicare patients.

Sincerely,

Jennifer Trotman, MD

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

CMS-1325-P-191

Submitter : Mr. Kent Butcher
Organization : Oklahoma Oncology
Category : Individual

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1325-P-191-Attach-1.DOC



OKLAHOMA
ONCOLOGY

specialists in the treatment of cancer

G. Lance Miller, M.D.
Joseph P. Moore, M.D.
Vicki C. Baker, M.D.
Joseph P. Lynch, M.D.
Ravikumar Vasireddy, M.D.
Jihad Khattab, M.D.
Jennifer E. Trotman, M.D.
Renae Mayer, M.D.

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Tulsa, OK 74104
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FAX (918) 744-3225

William Medical Building
6585 South Yale, Suite 701
Tulsa, OK 74136
(918) 494-8275
FAX (918) 494-8207

Muskogee Hospital Cancer Center
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Muskogee, OK 74401
(918) 682-1122
FAX (918) 687-5883

Bartlesville Clinic
224 Southeast DeBell Avenue
Bartlesville, OK 74006
(918) 333-5308
FAX (918) 333-6008

Claremore Clinic
1220 North Florence Ave. #7
Claremore, OK 74017
(918) 342-5103
FAX (918) 342-2953

Tahlequah Cancer Center
Clinic in the Woods
1325 E. Boone St., #102
Tahlequah, OK 74464
(918) 431-0441
FAX (918) 431-0443

April 19, 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

Dear Dr. McClellan:

Pursuant to the instructions posted in the Federal Register, what follows are comments regarding CMS-1325-P, Competitive Acquisition Program (CAP). This letter is written on behalf of the physicians of Oklahoma Oncology in Tulsa Oklahoma.

The Medicare Modernization Act has mandated the implementation of a competitive acquisition program (CAP) for cancer drugs that, although structured to allow community cancer clinics to participate in the program or continue purchasing drugs, mandates the selection of a specific vendor, which can not be switched during a given year, regardless of vendor adherence to quality, delivery timetables or flexibility of providing necessary changes to drug protocols. Our oncology practice will not be allowed to leave the CAP vendor unless the vendor ceases to participate in the program or the oncologists relocate to another area that is not served by the CAP vendor. Oncologists who have concerns with a CAP vendor have only one recourse, which is to file a grievance with the vendor. If the grievance is not resolved, the oncologists can escalate the matter to the designated carrier. Concerns about quality and service are NOT reason enough to terminate the agreement prior to fulfilling the one-year requirement.

We are extremely concerned that this program introduces a middleman between the sacred patient/physician relationships, because it will be the vendor dealing with the patient for the Medicare co-insurance drug payment. 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 collected. No commercial vendor is going to float these payments as community cancer clinics are forced to do on behalf of their patients, thus denying the patient access to care.

We are extremely concerned that CMS has developed this CAP program without any input from actual practicing community oncologists. Not one oncologist was involved in the design and development of this program. It becomes very obvious from the many problems with the design of this program. We are very concerned that CAP will be implemented without any testing or analysis of the radical change in the cancer care drug delivery system. The current drug delivery system developed by community cancer clinics is a time-tested, proven system. It is very 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 and could dramatically affect a patient's access to quality cancer care.

We have many concerns about the new CAP program. We have identified some additional issues that we view as the most crucial in the providing of quality cancer care. They are as follows:

- Community Cancer Clinics are locked into a vendor for an entire year regardless of the quality of service they are providing to community cancer centers.



OKLAHOMA
ONCOLOGY

specialists in the treatment of cancer

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- 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 the potential for millions of dollars of "waste" from unused and unusable medications. Patients will be inconvenienced and will have to return for treatment because drugs will have to be ordered. This will occur when it is a new patients or a patient that has had their treatment plan altered by the physician. For patients that live in rural Oklahoma this will result in long travel times and costly trips to the physician's office.
- Multiple vendors may be supplying drugs that go into a treatment regimen, thus creating a logistical nightmare. It will be impossible to coordinate the delivery of drugs from multiple sources.
- Under CMS' proposed rules, CAP participating oncologists are prohibited from using CAP acquired drugs and biologicals to re-supply their inventories unless all four of the following conditions are met: (1) the drugs are required immediately; (2) the oncologists 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. In situations where a scheduled treatment for a patient does not happen as planned because the patient's needs have changed, the patients' appointment will have to be rescheduled pending shipment and delivery of the CAP order.
- There has been NO provision for the emergency delivery of drugs. Under the proposed rules, CAP vendors only would be required to furnish routine shipments of drugs within one or two business days and to furnish emergency drug orders on the next day for orders received by the vendor before 3:00p.m. Many patients can NOT wait to receive a life saving drug.
- Although a primary goal of CAP is to reduce the financial burden of drug acquisition on community cancer clinics, clinics will still incur costs associated with drug handling and inventory management. Add these to the additional "uncompensated" costs of ordering, tracking, and filing CAP claims, pursuing appeals and sharing information with vendors to help them collect co-payments it is clear that community cancer clinics who are already facing a reimbursement shortfall, will experience further reimbursement erosion as a result of CAP. .

We urge CMS to take a long, hard look at the issues facing community oncology clinics and postpone the implementation of the CAP program until further analysis and testing can be completed on this system. This will insure that the quality of patient care will not be compromised because of an untested program. We appreciate your consideration of this very vital issue in providing quality cancer care to all Medicare patients.

Sincerely,

J. Kent Butcher
CEO

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

CMS-1325-P-192

Submitter : Dr. Peter Paul Yu
Organization : Association of Northern California Oncologists
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-192-Attach-1.DOC

ASSOCIATION OF
NORTHERN CALIFORNIA ONCOLOGISTS

State/Regional Affiliate, American Society of Clinical Oncology o Member,
Association of Community Cancer Centers

Member, National Coalition for Cancer Survivorship

Partner, California Oncology Consortium o Member, Hematology Oncology Leadership

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Network

Peter Paul Yu, M.D.
Sunnyvale

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April 26, 2005

Centers for Medicare & Medicaid Services

Attn: CMS-1325-P
Post Office Box 8010
Baltimore MD 21244-8010
(via USPS & e-mail)

Ladies & Gentlemen:

Below (attached if read via e-mail) are the
*Association of Northern California
Oncologists* (ANCO) comments on **CMS-1325-P,
the proposed Competitive Acquisition Program
(or CAP) for Medicare Part B drugs.**

By way of information, the *Association of
Northern California Oncologists* (ANCO) was
organized in 1990 to be an advocate for,
educate, and inform the practicing medical
oncologist and hematologist and currently
represents approximately 260 medical
oncologists and hematologists throughout
Northern California. While the majority of
our members are community-based physicians,
ANCO also represents the medical oncologists
of the regional academic cancer centers—
*Stanford University, UC Davis, and UC San
Francisco*. We serve the needs of our
physician members, their nurse and practice
managers, and their patients.

ANCO is a member of the *Association of
Community Cancer Centers* (ACCC), a
state/regional affiliate of the *American
Society of Clinical Oncology* (ASCO), a
partner with the *Medical Oncology
Association of Southern California* (MOASC)

in the *California Oncology Consortium* (COC), a member with several other state oncology and oncology practice manager societies of the *Hematology Oncology Leadership Network* (HOLN), and a member of the *National Coalition for Cancer Survivorship* (NCCS).

ANCO is dedicated to assisting oncologists and their staffs deliver the highest quality patient care by providing a forum for the exchange of ideas, data, and knowledge and by representing the interests of oncologists and their patients before state and federal government agencies, regional and national oncology and medical societies, and insurance and pharmaceutical companies.

ANCO's comments represent the opinions expressed by its physician *Board of Directors* as well as their practice pharmacists, nurses, and administrators.

In general, ANCO favors a system where medical oncologists are not dependent on the purchase and sale of drugs in order to survive. Running a medical oncology practice that is always hundreds of thousands of dollars in debt is inefficient and stressful. Rather, medical oncologists want and need to be reimbursed for their professional services as highly trained specialists and for the services they, their pharmacists, and their nurses provide to people with cancer.

Unfortunately, while Medicare's new drug reimbursement system makes it advisable for medical oncologists to remove themselves from drug purchasing and sale on behalf of their patients, Medicare's proposed *Competitive Acquisition Program* (CAP) is not a viable alternative for many reasons. Specifically:

- o CAP's unique logistical and tracking requirements make it untenable and unworkable, especially given that medical oncologists would need to maintain their current buy-and-bill systems for private payers in parallel. Adding a new drug acquisition system to medical oncology practices is an unacceptable administrative, logistical, and coding/billing burden. For example, ANCO member practice experience with the provision of drugs through outside vendors in the

private/commercial market finds that drug delivery is haphazard and often delayed.

- o the proposed CAP rule does not specify how drugs are to be delivered to practices, who will take responsibility when the inevitable snafus occur, and how physicians will be reimbursed when physicians are forced to use drugs for Medicare beneficiaries from their own inventories.

- o CAP vendor contracts are to be let for three years. This would allow incompetent CAP vendors to remain in business far too long. On the other hand, letting CAP contracts annually and potentially changing CAP vendors annually is equally unacceptable. Most medical oncology practices establish long-term relationships with their drug distributors in order to maximize economies and efficiencies.

- o CAP vendors (i.e., drug wholesalers, drug distribution centers, and drug distributors) would dispense drugs and be reimbursed for patient services unlawfully as only a pharmacist or a licensed pharmacy may dispense a prescription to a specific patient.

However, if CAP is to be initiated in 2006 and if it is intended to impact medical oncology, then the following must occur:

- o CAP must be national, not regional or geographical.

- o CAP must cover all drugs used in medical oncology including antineoplastics and supportive care drugs (i.e., antiemetics, growth factors, and antibiotics). New drugs must be included as soon as they are available.

- o CAP vendors must fill all physician orders for all drugs regardless of the CAP vendor's past experience with a patient regarding payment or their concern about coverage for off-label use. In addition, CAP vendors must not be allowed to require patients to sign *Advance Beneficiary*

Notifications (ABNs) before they release drugs to the physician for a specific patient.

- o CAP prescriptions must not require the patient's age, height, weight, or other irrelevant information.

- o CAP vendors must not act as pharmacists or prescription benefit managers. Despite the fact that CAP vendors may employ pharmacists, their responsibility must be limited to sending ordered drugs to the ordering physician. In addition, CAP vendors must be prohibited from exercising the responsibilities of a physician or pharmacist with regard to drug interactions, appropriate dosing, or other issues that impinge on physician responsibilities. Finally, CAP vendors must be prohibited from providing therapeutic substitutions for ordered drugs to the ordering physician. In summary, CAP vendors must not be allowed to dictate what physicians can or cannot do for their patients. They must not be allowed to behave any differently than other drug wholesalers, drug distribution centers, and drug distributors with which physicians have existing relationships.

- o CAP vendors must carry substantial liability insurance and indemnify physicians for any losses they incur on the basis of the CAP vendor's negligence, errors, or omissions in filling physician drug orders.

- o CAP vendors, not participating physicians, must track the ultimate use and/or disposition of unused drugs.

- o physicians will incur additional administrative costs if they participate in CAP given its novelty and the fact that it must be done in parallel with existing buy-and-bill drug acquisition for commercial payers. Therefore, an additional administrative fee must be made to physicians to reimburse for these additional administrative costs.

o physicians must have the right to either chose another CAP vendor or opt out of CAP if their CAP vendor declares financial insolvency or proves incompetent during a the contracted year.

o any transfer of financial risk from the participating physician to the CAP vendor must be complete leaving absolutely no liability or penalty to the participating physician. For example, the risk of post-payment denial of claims for off-label use of drugs is a risk that medical oncologists have willingly borne in the best interest of their patients. Under CAP, this is a risk that must be accepted in full by the CAP vendor. They must not have the right to complain to CMS or local Medicare carriers about the drug ordering patterns of specific medical oncologists or to pressure physicians to alter their prescribing patterns. To do so would be an unacceptable intrusion on the independence of physician clinical decision making on behalf of his/her patient.

o Ambiguous terms/phrases in the proposed rule must be clarified. For example, *emergency situation* leaves the door open for an interpretation of a qualifying emergency that would be so restrictive as to negate the safeguard that is clearly intended.

Exceptions are to be allowed for situations where a *specific formulation* is needed that the vendor does not supply. This may be a good thing, but what exactly is a *specific formulation* and will this allow CAP vendors to not carry certain drugs if they find that CMS is not paying the vendor enough to cover their costs?

A physician must notify the CAP vendor if a drug is not administered *on the expected date of administration*. In reality, medical oncologists often delay administration by a week for low blood counts or failure to completely resolve the toxicities of a previous chemotherapy cycle. This notification requirement would be too burdensome if a medical oncologist had to add the CAP vendor

notification to an already long list of things to do.

Thank you for the opportunity to comment on CMS-1325-P, the *Competitive Acquisition Program*.

Sincerely,


Peter Paul Yu, M.D.
ANCO *President*

Submitter : Dr. Harry Neuwirth
Organization : Marin Urology Medical Group
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

Competitive Acquisition as currently conceived will inhibit access to care by medicare beneficiaries. Our practice cannot afford to spend uncompensated administrative time obtaining drugs for beneficiaries. We also cannot afford the risks entailed in the current ASP+6% plan, as we are then exposed to price increases by vendors. In any event, our costs for acquisition, storage, billing, loss, waste, etc, far exceeds 6%.

Since Congress has mandated that CMS beneficiaries be provided medications at a financial loss to providers, we suggest that beneficiaries be allowed to obtain these drugs by prescription at their pharmacies and bring the medication to us for administration.

Submitter : Dr. silwan chedid
Organization : MD Anderson Cancer Center
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

The cuts in reimbursement will dramatically curtail my ability to continue to provide quality care to my patients.

Most likely I will not be able to continue to provide chemotherapy to my patients in my clinic and will need to admit all patients to the hospital to receive chemotherapy. The hospital has already stated that they will not be able to handle the added burden of all these new patients.

Patient care will suffer, they will not be able to get the care they need. It will be a great disaster!

Submitter : Mr. Steve Nally
Organization : Atlanta Cancer Care
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

1-15

Overview of the CAP

This section is very vague and while asking for opinions about various alternatives is worthwhile, it concerns us that CMS will have difficulties meeting the various timelines such as physicians signing up for CAP with the details being so vague at this stage

Statutory Requirements Concerning Claims Processing

While the intent of CAP is to relieve physicians of the burden of drug management, it will actually have the opposite affect of increasing physicians' workload. In fact, CAP drugs will have to be separately managed, creating two inventories and still maintaining the mixing requirement and the additional information which must be provided to the CAP vendor. Order splitting without the ordering physician's approval is not workable given the changes that occur in the course of chemotherapy. By not mandating that CAP vendors stock all drugs within a class of drugs, the rule allows them to establish formularies and engage in therapeutic substitution. This is permitting the CAP vendor to dictate the treatments that Medicare patients will receive rather than the physician. This is obviously not quality care for the patients. In addition, this highlights the need for hold harmless clauses in the physician/vendor contract. This needs to be included even if the formulary and therapeutic substitution abilities are removed. There are just too many possibilities for errors on the part of vendors when handling drugs and as presently constructed the liability is shifted on to physicians. The rule states that "informal communication" will be used to solve service and payment problems between vendors and physicians. This will not work. As an example, what will happen when a patient fails to pay his drug co-payment? Will the vendor stop providing drug? Items of this nature need to be determined in advance so as not to compromise patient care.

Submitter : Dr. Beltran Pages
Organization : NC DOP
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachement

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 : Mrs. Cindy Stone
Organization : Ocala Oncology Center
Category : Individual

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

xxxx

Submitter : Shannon Rosenburg
Organization : Easter Seals
Category : Individual

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-198-Attach-1.RTF



Easter Seals – Michigan, Inc.

Providing services for children and adults with disabilities



Creating solutions, changing lives.

COMPANIES
TO WORK FOR

Headquarters

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Waterford, MI 48328

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Fax: (248) 338-0095

Toll Free: 1-800-75-SEALS

Easter Seals - Michigan offers other programs in locations throughout Michigan, including:

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- Mt. Clemens
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- Pontiac
- Saginaw
- Southfield
- Sterling Heights
- Warren
- Waterford

**Please call our main offices at:
(248) 451-2900 for program details, or visit us on the web at:**

www.mi.easterseals.com
or
www.essmichigan.org

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

April 22, 2005

To Whom It May Concern:

As a mental healthcare provider, it is important to express that the Competitive Acquisition Program includes the following issues:

Inclusion of Psychiatric Drugs- CMS proposes to not use exclusion authority in the proposed rule and this should be included in the final rule.

Inclusion of Psychiatric Drugs in Phase I- CMS should include psychiatric drugs in the initial stages of CAP to alleviate barriers to access inherent in the current system.

Inclusion of Mental Health Drug Category- CMS should create a category that includes mental health drugs, including long-acting injectable antipsychotics.

Ensure Rule Prevents Discontinuation of Therapy by Vendors- CMS should address how vendors can handle uncollectible co-pays and other reimbursement issues that would threaten therapy persistency.

As a mental healthcare provider, it would be beneficial to have psychiatric drugs included under the Competitive Acquisition Program. This would lift the financial burden related to the costs of serving clients with the necessary psychiatric medications.

Sincerely,

Shannon Rosenberg

Easter Seals is a member of



Easter Seals provides therapy and support services for children and adults with disabilities and their families.

MICS License #3847



Submitter : Ms. VICKI BOWMAN R.N.

Date: 04/22/2005

Organization : USONCOLOGY

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Cap Bidding Process-Evaluation and Selection
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 : Carolyn Davis CMA, CPC, CCP
Organization : Oncology Hematology West
Category : Other Health Care Professional

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

I am commenting on the policy as a whole. So many times the patient may fail standard treatment and we need to use a drug off label. When this happens who will be fighting to get it paid? Will the vendor request and send in the documentation to be sure payment is received? Will the responsibility be put upon the patient? And when the patient can't afford the co-insurance, will the vendor look for alternative funding or write off the balance based on hardship or will the patient be turned over for collection? What if the treatment changes? Will the patient need to be rescheduled because we won't have the drugs at our disposal? What if an interaction occurs? There will never be a time when oncologists won't need meds in the office. So to do this as an all or nothing choice for the practices penalizes both the patient and the practice. Why can't it be set up for the practices to order those drugs that lose money like IVIG and to continue to carry others in the practice. Why not get the manufacturers to more accurately price the drugs so that ASP truly covers the cost? IVIG is a good example as CMS assigns new Q codes, lowers the reimbursement and Baxter raises the price. Why should this be allowed by CMS or the any other branch of the government yet we won't have the opportunity to chose which drugs to order from your vendor and which ones to order from ours. The key issue for us is patient care. When patient's are being turned over to collections because they can't pay, or they aren't getting the help they need they will just stop taking their treatments. Is this what CMS wants? Please look at the bill from a patient point of view who has had a reaction to their treatment, needed additional meds due to nausea or fatigue, has no secondary insurance and doesn't qualify for Medicaid, or has to be on an off label use of a drug because all other treatments have failed. What do we do for them? They will stop their treatment as they won't be able to do anything else. If you really want this fixed then go to the drug companies. Get the rebates under control so that pricing is the same across the board and get them to get their prices in line with Medicare reimbursement. Thank you Carolyn Davis

Submitter : Mrs. Patricia Cosgrove
Organization : Oregon Hematology Oncology Associates
Category : Other Health Care Professional

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

I am very concerned about CAP and its planned 2006 implementation date. It is a program that has not yet been thoroughly researched or defined and is fraught with potential problems. I believe CAP will add another layer of administrative burden due to practices having to deal with another agency/organization (the mandatory vendor) in order to acquire drugs and will create communication barriers that will slow the process and increase the day to day unreimbursed workload for the physician practice. It will potentially create access to care issues for patients when drugs do not arrive on time, orders have not been received appropriately, or patient payment status/information is not adequate. It may negatively impact the quality of care provided in the oncologist's office setting and increase the liability of the physician and practice through loss of control of the management of the drug and potential unwillingness of the vendor to assume liability for the appropriate control of the drugs. It is my opinion that the cost savings that CMS is trying to achieve will not be achieved through CAP. I would encourage you to rethink this program and certainly not implement it before the issues associated with it can be worked out.

Submitter : Mr. Greg Fronizer
Organization : Easter Seals - Michigan Inc.
Category : Other Health Care Provider

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

As a Mental Health care provider, it is important to express that the Competitive Acquisition Program includes the following issues:

Inclusion of Psychiatric Drugs- CMS proposes to not use exclusion authority in the proposed rule and this should be included in the final rule.

Inclusion of Psychiatric Drugs in Phase 1- CMS should include psychiatric drugs in the initial stages of CAP to alleviate barriers to access inherent in the current system.

Inclusion of Mental Health Drug Category- CMS should create a category that includes mental health drugs, including long-acting injectable antipsychotics.

Ensure Rule Prevents Discontinuation of Therapy by Vendors- CMS should address how vendors can handle uncollectible co-pays and other reimbursement issues that would threaten therapy persistency.

As a mental healthcare provider, it would be beneficial to have psychiatric drugs included under the Competitive Acquisition Program. This would lift the financial burden related to the costs of serving clients with the necessary psychiatric medications.

Greg Fronizer
COO
EASTER SEALS - MICHIGAN INC.
(248) 451-2900

CMS-1325-P-202-Attach-1.DOC



Easter Seals – Michigan, Inc.

Providing services for children and adults with disabilities



AND



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April 22, 2005

Headquarters

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Waterford, MI 48328

Phone: (248) 451-2900

Fax: (248) 338-0095

Toll Free: 1-800-75-SEALS

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

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To Whom It May Concern:

As a Mental Health care provider, it is important to express that the Competitive Acquisition Program includes the following issues:

Inclusion of Psychiatric Drugs- CMS proposes to not use exclusion authority in the proposed rule and this should be included in the final rule.

Inclusion of Psychiatric Drugs in Phase 1- CMS should include psychiatric drugs in the initial stages of CAP to alleviate barriers to access inherent in the current system.

Inclusion of Mental Health Drug Category- CMS should create a category that includes mental health drugs, including long-acting injectable antipsychotics.

Ensure Rule Prevents Discontinuation of Therapy by Vendors- CMS should address how vendors can handle uncollectible co-pays and other reimbursement issues that would threaten therapy persistency.

As a mental healthcare provider, it would be beneficial to have psychiatric drugs included under the Competitive Acquisition Program. This would lift the financial burden related to the costs of serving clients with the necessary psychiatric medications.

Sincerely,

Gregory M. Fronizer
COO
Easter Seals – Michigan Inc.

**Please call our main offices at:
(248) 451-2900 for program details, or visit us on the web at:**

www.mi.easterseals.com
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www.essmichigan.org

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Submitter : Dr. Arthur Staddon
Organization : Pennsylvania Oncology Hematology Associates
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

I am an oncologist in a 7 physician, 3 nurse practioner group in Philadlephia PA, and am concerned about the effect of a CAP program on community oncology patient care and on the ability of the oncology practices to continue to give care. I am concerned about having patients need to come to our office and have the chemotherapy orders written, then have to come another day to get the drugs. I am concerned about the cost in personel to my office in having to provide the demographic information, and billing information to the CAP vendor. I am concerned that there will be further delay for patients with no co-pays, or with poor paying medigap policies. I am concerned about the integrity of the drugs provided. It is not clear whether the drugs would be provided already mixed, and if so how am I to be sure the mixing was dose appropriatly and in the correct amount. Who will be liable for mistakes? If the drug is not provided already mixed who will pay for the drug to be mixed by my pharm tech, and pharmacist? What is to be done for drug that can not be used(no show, weather, change in clinical status, change in labs)?. How is unused drug to be handled? Who is going to pay for the cost associated with obtaining drugs, and keeping drugs separated for each medicare patient? Will the drug usage of physicians data be sold by CAP vendors? All in al I think this will severcey affect oncology patient care in a negative way.

Submitter : Dr. Douglas Lee
Organization : Puget Sound Cancer Center
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

Gentlemen: I have been informed that if the present Medicare reform takes place unchanged, the oncology network nationally will lose almost 621 million dollars per annum. This will severely limit access to cancer care for our seniors.

Submitter : Dr. Keith logie
Organization : Central Indiana Cancer Centers
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

As a practicing oncologist, I have many concerns regarding the Competitive acquisition of outpatient drugs. I do not feel the process has been tried and proven to implement on a national scale. I suspect many flaws could develop to bring the system down and have severe impact on my ability to treat patients. I have reviewed both the ASCO and USON comments on CAP and strongly endorse their positions. The potential for increased administration costs to my practice is substantial (transmittal of demographics to the vendor, separate drug inventories, emergency replacement of drugs not available from vendor, disposal of toxic wastes of unused drugs etc are just a few examples which will increase my costs). The other real concern is that patients may be denied drugs by the vendor because of unpaid bills (especially if they do not have supplemental insurance). Will the vendors have the right to refuse to supply drugs to patients with large outstanding balance? What is the guarantee of patient access to treatment if vendor does not supply drugs in a timely fashion. My office cannot break even at ASP + 6%. Will the vendors be paid at a higher rate than my office currently is. How much effort does my office need to place on the patient to pay the vendor? PLEASE review the ASCO and USON comments in depth and address the problems they outline prior to implementation of CAP 1/06.. Thanks Keith Logie, MD

Submitter : Dr. Gregory Willis
Organization : WCCCP
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

If enforced, and mandatory vendor implementation is forced on community oncologists, I will be forced out of buisness and Medicare patients will die in droves. I will be forced to terminate 17 full time employees and leave Pennsylvania. All oncology practices in central pa will stop treating medicare patients in the outpatient setting.

Submitter : Mr. Roy Conley
Organization : Mountain Comprehensive Care Center
Category : Other Health Care Professional

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

It is important that CMS include psychiatric drugs in phase I in the initial stages of CAP, including long acting injectable antipsychotic. The uncollectable copays for these drugs are stressing the resources of providers and affect the decisions in using these drugs.

Submitter :

Date: 04/22/2005

Organization :

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

Please include Mental Health in the CAP when implemented in January 2006. We struggle with billing consumers who have Medicare and Medicaid QMB coverage.

Thanks you for your help.

Submitter : Dr. Dean Gesme, Jr.
Organization : American Society of Clinical Oncology
Category : Health Care Professional or Association

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-209-Attach-1.DOC

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April 21, 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: Comments on the Proposal for Competitive Acquisition of Outpatient
Drugs and Biologicals Under Medicare Part B

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the proposed rules governing the Competitive Acquisition Program (CAP) for drugs administered in physician offices, which were published in the Federal Register on March 4, 2005. ASCO is the national organization representing physicians who specialize in the treatment of cancer. Drugs used in cancer chemotherapy represent a substantial portion of the drugs covered by Medicare Part B, and ASCO's members therefore are very interested in the design and implementation of the CAP.

ASCO has a number of concerns with the proposed regulations. As requested in the Federal Register notice, our comments are organized by the subjects specified in the notice.

DRUGS TO BE INCLUDED IN THE CAP

The statute allows CMS to phase in the CAP, and CMS has asked for comments on various possibilities. In terms of the drugs covered by the CAP, one approach would be to start with the relatively large number of drugs typically used by oncologists, a second approach would be to start with a smaller number of drugs used by other specialties, and a third approach would be to include all drugs in the CAP. In terms of geography, the CAP could initially begin nationwide or, alternatively, only in certain regions.

Implementation of the CAP

As outlined in these comments, ASCO believes that there are a number of issues that require clarification to ensure that the CAP will operate appropriately. We are uncertain whether the CAP will be widely accepted by oncologists because of these uncertainties and the additional administrative burdens that the program will impose. Nevertheless, ASCO urges that the CAP be made available nationwide in 2006 for all drugs.

The current reimbursement system, which sets payment at 106% of a historical average sales price, results in some drugs being unavailable to some physicians at a price that is less than the Medicare payment amount. Physicians should have the opportunity to avoid these out-of-pocket losses, as well as other drug-associated losses such as bad debt, by electing to participate in the CAP. During the legislative consideration of the



Medicare Modernization Act, the CAP was portrayed as an option that would be available to physicians who would otherwise incur losses. This protection should be offered to physicians who want it without delay beyond 2006.

CLAIMS PROCESSING OVERVIEW

As described in the proposal, in response to orders from physicians with respect to specific patients, the vendor would send the drugs to the physician with an identifying prescription number. When the physician administers a drug, he would submit a claim to his local carrier showing the drug administration codes, the J-codes for the drugs administered, and the prescription number supplied by the vendor for the drugs administered.

The local carrier would adjudicate the claim as usual and would determine whether it was a Medicare-covered service, applying local coverage determinations as applicable. If the service was covered, the local carrier would notify the carrier that handles vendor drug claims of the prescription number involved, at which time the drug carrier would pay the vendor and the vendor would be permitted to bill the patient, or the patient's secondary insurer, for the coinsurance.

Requirement for vendor to fill all orders

It is implicit in the proposed regulations that a vendor must fill all physician orders, but this should be made explicit. Vendors may be tempted to refuse filling a particular order for various reasons – e.g., the patient involved has not paid coinsurance owed to the vendor for a previous order, the Medicare carrier has denied coverage of a similar previous order, the vendor thinks that the carrier might deny coverage, etc. The regulations should state unequivocally that the vendor may not refuse to fill a properly completed physician's order for any reason whatever. Similarly, the regulations should provide that the vendor cannot require the patient to sign an advance beneficiary notice, in which the patient agrees to pay for the drug in the event of a coverage denial.

Information to be submitted with the order

The proposal would require the physician, in ordering a drug, to specify the "frequency/instructions," the anticipated date of drug administration, information about the patient's secondary insurance, and "additional patient info: date of birth, allergies, Ht/Wt/ICD-9, etc." Information on secondary insurance is appropriate because the vendor will need that information in billing for the coinsurance, but much of the other information would not appear to be relevant to the vendor's duties, and there should not be a requirement for its submission.

Specifically, information on "frequency/instructions," date of birth, allergies, height, weight, and diagnosis code seems to contemplate that the vendor will perform a pharmacist-type review of the order and label the drugs with instructions for use. We do not see any basis in the law for such action. We believe that the statute intends that the vendor act like a drug wholesaler does now, simply filling orders.

Delivery of drugs to office

CMS is proposing that all drugs will be delivered to the physician's office and not the patient. ASCO agrees with this proposal. To ensure proper handling, drugs should be delivered only to physicians.

Practices with multiple locations

Many practices have more than one office location. CMS should require the vendors to deliver each order to the office specified by the practice and not permit vendors to require that practices designate a single address for shipments.

Time for submission of claims

CMS is proposing that the physician would be required to submit all claims for drug administration services with fourteen days of the date of service. While we understand the need for prompt submission of claims, since the vendor is not paid for the drug until the drug has been administered, that schedule is too rapid for many practices. ASCO recommends instead that drug administration claims be required to be submitted within 30 days after the date of service.

Disposition of unused drug

The proposal contemplates that the physician, in ordering drugs for a particular patient, will specify an expected date of administration. If the drug supplied by a vendor is not administered on that date, the physician would notify the vendor and "reach an agreement on how to handle the unused drug, consistent with applicable State and Federal Law." If the vendor and the physician agree that the drug could be used at a later time for another Medicare patient, the physician would generate a new order for that other patient but note on the form that the vendor need not ship the drug. We have several issues with this aspect of the proposal.

First, the proposal appears to contemplate that the physician can predict the exact date on which drugs will be administered to the patient. A patient's schedule for cancer chemotherapy is subject to change based on the patient's condition, and it should not be assumed, as the proposal does, that a failure to administer a particular drug on the date predicted in advance means that the drug will go unused.

Second, it would be much more practical for the vendor to track the use of drug than the physician. The proposal contemplates that physicians would develop a new system of inventory records for each drug. An additional requirement that each drug must be tracked against the expected administration date provided to the vendor would be another system that would need to be developed and would be quite burdensome. We suggest that the vendor track the expected administration dates against claims submission, and if there is a substantial discrepancy (e.g., no claim submission within a reasonable time after the expected administration date), the vendor would query the physician about the status of the drug.

Third, the process for disposing of unused drug should be clarified. The proposal implies that the disposition of unused drug is at the discretion of the vendor and that, if the vendor cannot develop a

solution that is consistent with the state and federal law, the vendor incurs the financial loss. While we understand that CMS cannot resolve all of the state law questions that may be involved, it would be useful if CMS clarified the principles involved. In particular:

- Is the vendor allowed to do anything with the unused drug that is permissible under state law or are there any restrictions under the CAP or other federal law that would apply?
- To what extent is the physician required to cooperate with the vendor with respect to unused drug? For example, if the vendor concludes that it can legally take the unused drug back from the physician, is the physician required to send the drug back? If so, the physician should be permitted to charge the vendor a fee for the service of returning the drug; is such a charge allowed?
- Is the physician required to mitigate the vendor's loss by offering to administer the drug to a different Medicare patient?
- If it is permissible under state law, can the physician negotiate with the vendor to purchase the drug from the vendor at an agreed-upon price?

Payment for administrative costs

CMS is proposing not to make any payment to physicians for the administrative costs associated with obtaining drugs through the CAP on the ground that the inventory and clerical costs do not exceed those that are incurred by physicians who buy drugs and seek reimbursement. ASCO disagrees with this conclusion and requests that a separate payment be established. As we will now outline, at each step in the process of procuring, using, and billing for drugs under the CAP, the administrative work is greater than under the reimbursement system.

The costs of ordering drugs under the CAP would be significantly greater than under the reimbursement system. Under the reimbursement system, physicians generally maintain an inventory for each type of drug and order additional units when the inventory falls below a certain level. Oncologists often use an automated storage and inventory control system that tracks the remaining amount of each drug. By contrast to this relatively simple method of ordering in bulk, the CAP requires orders to be submitted to the vendor for each patient, and those orders would need to provide significant patient-specific information instead of simply the number of units requested.

An additional significant new cost would be the creation of an inventory record for each drug, as the proposal would require. The identity of each drug received from the CAP vendor would need to be entered into a record together with the identifying number furnished by the CAP, and a further entry into the inventory record would be required when the drug was administered. Physicians currently do not maintain any similar inventory records, and the additional work involved would appear to be substantial.

The storage costs would be at least as large under the CAP as under the reimbursement method, and storage may be more difficult to manage. Although the proposal states that the CAP drug inventory would not need to be segregated from other inventory, there may need to be some form of segregation so that the office staff can ascertain the amount of inventory available for non-Medicare patients. For example, if a physician has ten vials of a particular drug on hand, it will not be clear from visual observation whether all of the vials have been received from the vendor for Medicare patients or whether part of the inventory is available for non-Medicare patients.

At the billing stage, there would be more work under the CAP than under the reimbursement method. The content of the claims would be identical in most respects under both systems, but the CAP claim would need to include a prescription number for each of the drug codes billed. Retrieving the prescription number for each drug and including it in the claim would be significant additional work beyond what is now required.

CMS has proposed that if the drug is not used on what was reported to the vendor as the expected date of administration, the physician would be required to notify the vendor. ASCO has recommended in these comments that physicians should be relieved of that duty, but as proposed, this would be a new reporting obligation that is not comparable to any work in the reimbursement system.

In sum, ASCO does not see the basis for CMS's conclusion that no extra administrative costs are incurred by physicians participating in the CAP. To the contrary, there would appear to be significant additional work involved. We recommend that a reasonable payment be established that would fully cover the extra costs involved. The payment amount could be paid with respect to each drug administered. That is, the claim submitted to Medicare for an encounter involving drug administration would include a code for the drug handling service with the units reported for the code equal to the number of drugs administered during the encounter.

Vendor-imposed technology costs

If a vendor imposes any requirements that physicians use particular hardware or software in submitting orders or otherwise participating in the CAP, CMS should require the vendor to clearly disclose those requirements prior to the election period. If physicians are responsible for the costs of such technology, that obligation should also be stated clearly in the information about the vendor.

DISPUTE RESOLUTION

Under the proposal, only the physician would have appeal rights in the case of claims that are denied for medical necessity or other reasons. If the vendor dispenses drugs and cannot obtain Medicare payment because the physician's claims are denied, CMS is proposing that the vendor should have the right to complain to its carrier if the losses with respect to an individual physician exceed an "acceptable threshold." If that occurs, the carrier will counsel the physician to submit clean claims and to pursue administrative appeal rights on denied claims. If problems persist, the carrier could recommend to CMS that the physician be suspended from the CAP, and CMS would decide whether to do so.

CAP vendors would also be required to have procedures to handle complaints about service from physicians and about billing issues from patients.

CMS should clarify physicians' responsibilities in the case of denied claims

ASCO agrees with CMS that, under the statute, only the physician has appeal rights with respect to denied claims. We request that CMS clarify the extent of the physician's responsibility to appeal denied claims. We believe that the physician's duty should be only to seek review by the carrier (or redetermination by the carrier under the new appeals regulations). Further appeals should be at the discretion of the physician, who should be permitted to weigh the chance of success against the expense and burden of the appeal.

The process for resolution of beneficiary disputes should be made clear to beneficiaries

The proposal indicates that beneficiary billing disputes would be handled by the beneficiary first using the vendor's grievance process and, if the beneficiary is dissatisfied with the result, requesting intervention by the vendor's carrier. The carrier would investigate the facts and then facilitate correction to the claim record and beneficiary file.

This process should be made very clear to beneficiaries. We suggest that CMS develop standard language that vendors would be required to include in every bill to beneficiaries explaining the grievance process and the method for subsequently appealing any issues to the designated carrier. The information should make clear that the beneficiary's physician is not involved in the billing and has no authority to resolve any disputes.

CMS and carrier involvement in unresolved disputes

The proposed rule does not set out a clear mechanism for resolution of disputes related to quality of service or beneficiary billing. The preamble states only that the Medicare carrier will attempt to resolve such disputes if the vendor and the physician or beneficiary cannot. We believe that the process should be more definitive. At a minimum, the carrier should be given a clear mandate to resolve disputes, the process for doing so should be clear and should offer the parties an opportunity to participate in a meaningful way, the carrier should have the legal authority to impose a solution, and there should be oversight of the carrier's actions by CMS.

CONTRACTING PROCESS – QUALITY AND PRODUCT INTEGRITY ASPECTS

The proposed regulations include a number of provisions intended to ensure that the vendors provide drugs that meet quality and product integrity standards.

Vendors should be prohibited from opening drug containers

The statute authorizes CMS to impose product integrity safeguards. An issue that the regulations should deal with expressly is the authority of vendors to open drug containers. ASCO is concerned, for example,

that if a vendor believes that a particular patient's order does not require a full container of drug, the vendor, acting as a pharmacy, may open a container and dispense only the portion that the vendor believes is necessary by transferring a portion of the drug to another container for shipment to the ordering physician.

Any compromise of package integrity in this manner would be unacceptable. The regulations should clearly require vendors to ship products to physicians in containers that are unopened and otherwise in the same condition as received from the drugs' manufacturers.

Return of damaged or suspicious drugs

The rules should permit physicians to return to the vendor without penalty any drug that arrives in damaged condition or whose integrity the physician reasonably believes may have been compromised. The vendor should not be permitted to require the physician to seek a remedy from the company that delivered the product.

Vendors should be required to carry substantial liability insurance

The proposed financial standards should include a requirement that vendors carry substantial liability insurance. In the event that vendor errors cause harm to patients, their liability for damages could be substantial, and the metrics in the proposed regulations for financial adequacy to conduct a drug distribution business may not be adequate to ensure their ability to pay damages. Thus, liability insurance in sufficient amount to cover potentially serious adverse events should be required.

Vendors should be required to indemnify physicians for any losses they cause

If actions by the vendors in handling the drugs result in injury to patients, it is possible that claims will be made against the physicians who administered the drugs. The regulations should require vendors to indemnify physicians for any losses, damages, and costs (including attorneys fees) incurred by the physician as a result of the vendor's negligence, errors, or omissions.

CMS should audit compliance with and enforce the standards

The only review and enforcement mechanism in the proposed regulations with respect to the quality and other standards appears to be the vendor's certifications that it is in compliance. We believe that CMS should take a more affirmative role in determining vendor compliance by, for example, inspecting vendor facilities, monitoring complaints, auditing vendor compliance with time schedules in the regulations, and so forth.

BIDDING ENTITY QUALIFICATIONS

The proposal notes that vendors would be considered covered entities under HIPAA, including the HIPAA Privacy Rule. ASCO would like to raise two HIPAA issues.

election would ordinarily take place in the period October 1 through November 15 of each year, but a CAP participating physician could select a replacement vendor mid-year if the selected vendor leaves the program.

Physicians should have the option to elect reimbursement if the selected CAP vendor leaves the program mid-year

CMS seeks comment on the options that should be available to a physician if the physician's selected CAP vendor leaves the program in the middle of the year. ASCO recommends that the physician have the choice of leaving the CAP program or selecting a different CAP vendor. A physician should not be compelled to select a different CAP vendor, since the vendor originally selected by the physician may have been the only vendor acceptable to that physician.

Physicians should have the option to elect reimbursement or change vendors based on problems with the vendor

The proposal allows vendors to exit the CAP midyear and, under certain circumstances, allows a physician to be expelled from the program. The proposal, however, does not include a parallel provision allowing physicians to change vendors or leave the program midyear if the physician's vendor is unsatisfactory. ASCO recommends that the regulations permit such action if the vendor has a record of unsatisfactory service, unresolved disputes, or similar negative acts. For example, the regulations could permit a physician to apply to CMS for permission to leave the program midyear because of dissatisfaction with the vendor, and CMS would grant the application unless the basis for the request was unreasonable.

BENEFICIARY EDUCATION

CMS is proposing to prepare a fact sheet on the CAP program that would be made available to beneficiaries and to physicians who could provide it to beneficiaries. CMS asks for comment on the burden involved in requiring physicians to furnish it to their patients.

CMS should not require physicians to furnish the fact sheet to patients

ASCO appreciates CMS's efforts to develop patient education materials related to the CAP program. We agree that patients who receive a coinsurance bill for drugs from the CAP vendor may be confused. These issues are best handled, however, on a patient-by-patient basis rather than requiring physicians to distribute a CMS fact sheet to every patient. Physicians have an incentive to clear up any confusion on the part of their patients and will take the steps they believe are necessary, which may vary from patient to patient.

CMS MONITORING OF PROGRAM



Finally, ASCO recommends that CMS establish a process for monitoring the effects of the CAP on patient access to drugs and on physician practices, particularly with respect to extra costs imposed on practices. Such a program would permit CMS to identify potential problems and rectify them.

Thank you for the opportunity to comment on the proposed regulations.

Sincerely,

A handwritten signature in black ink, appearing to read "Dean H. Gesme, Jr., MD". The signature is written in a cursive style.

Dean H. Gesme, Jr., MD
Chair, Clinical Practice Committee

Submitter :

Date: 04/22/2005

Organization :

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-210-Attach-1.DOC



<http://www.devx.com>

Printed from <http://www.devx.com/asp/Article/16414>

Our Top 10 Tips for Classic ASP

Tidy up your server-side programming techniques with these 10 great tricks for classic ASP.

by Rama Ramachandran

 Our focus has always been on assisting the new ASP programmer in mastering the techniques that the pros use all the time. Thus, to help you wade through the list of tips and tricks on our site, we present you with a "Top 10 List" of what we consider to be our best. (You can browse the entire list of tips and tricks [here](#)).

Remember that this list is current only as of today. As we add new tips and articles, the "best" will undoubtedly change. But, for now...drum roll, please...here they are:

Logging File Download

This is a very simple and elegant method to monitor how many people download a resource from your Web site. Former ASP Pro Ken Cox provides a brief solution to this often-asked question.



Question:

We need to keep track of users' file download activity on our site. When a user clicks on a hyperlink to download a file, it will run an ASP page on the server to log something into SQL Server and then download the file into the client. How can an ASP page download a file back to the client after the logging process?



Answer:

The trick is to use a hyperlink to launch a second "background" script that logs the filename and initiates the download. If the second script doesn't produce any HTML output, the first page stays on the user's browser screen.

Here's how the hyperlink looks in the first file:

[Download code.zip](#) (Don't click on this link, it is only for demonstration, it won't do anything)

The above link was created using the following code:

```
<A HREF="dnladd.asp?filename=code.zip">Download code.zip</A>
```

When the user clicks the hyperlink, we pass the requested filename to the second file, `dnladd.asp`. `Dnladd.asp` contains the script and SQL commands that write the filename and other information to the database. After that, `dnladd.asp` initiates the download with these lines:

```
Response.ContentType = "application/x-zip-compressed"  
Response.Redirect request("filename")
```

Remember: don't put any HTML code in `dnladd.asp`.

9 What's the Deal with DLL?

If you've been using Visual Basic COM components, you've probably repeatedly banged your head against the wall trying to deal with the "Unable to write (or copy) DLL, Permission Denied," error message that pops up when you try to update a new version of your COM component. This tip provides a nifty little batch file that you can use to automate the shut down and start up of the MTS process that is holding on to your DLL. This is a standard technique I use all the time in my work.



Question:

We have Internet Information Server (IIS) 4.0 running Active Server Pages (ASP) with a Visual Basic 6.0 DLL serving data content to the ASP pages. The problem lies when we try to update the DLL on the Web server with a new version, it appears to always be in use and therefore we are unable to upload and re-register a new version. We have shutdown the Web site and also IIS but the DLL is still in use. The only way to clear this is to shutdown the server. As you can imagine, when the site is live, shutting down the box is not really an option. Do you know of a solution to this problem? There is a useful 16-bit utility named WPS which allows DLLs to be closed, however, it doesn't appear to work with VB6 DLLs.



Answer:

The reason you are unable to update is because Microsoft Transaction Server (MTS) has the instance of the DLL open. You need to use the utility `mtxstop` to unload it. First, create a batch file called `FlushCache.bat`. In the batch file, create these lines:

```
net stop iisadmin /y  
mtxstop  
net start w3svc
```

Run the batch file. It will bring down your Web site and bring it back up instantly within about five seconds or so. In between bringing it down and back up, it will also clear the MTS cache. You should then be able to update your DLL.

When you run the batch file for the first time, notice what other services are also stopped (for example, FTP Publishing Service and so forth). Keep a list of them. Then go back to the batch file, and add new lines to start those services back again using:

```
net start <name of service>
```

Update 6/3/00: Bill Bassett suggested this alternative solution:

An easier way to get around the problem of trying to rewrite a DLL is to set up the application so that it runs in its own separate memory space. Using the IIS MMC, right click the virtual directory containing your application. Next, select Properties. In the Application Settings area in the middle of the properties page, then enter a name for the application and check the box to Run in a separate memory space.

Once the application is running, by bringing up the properties page again, the Unload button will be available. When you press the unload button, the application unloads, and you can rewrite the DLL. This won't de-register the DLL, so you may have to do that and the register of the DLL by hand, using *regsvr32*. It beats having to stop and restart IIS and other services each time.

8 To Be or Not to Be: Verifying Files in ASP

If you're using ASP pages to manage files, you'll need to know if a file exists before you nuke it with a new copy. Use this efficient little code to find out if a file exists.



Question:

I am trying to access some PDF files in a database. I give the address of the file in the browser as an IP address. I am trying to create links for these files in a page. Before painting the link, I want to verify whether the link is valid and that the file exists. How can I do this in ASP?



Answer:

Use the FileExists method of the FileSystemObject from ASP to check if the file exists.

```
Dim fs, strFileNameAndPath

strFileNameAndPath = Your file name
' -- Use file name and path
' -- from the database. Remember to map it
' -- to the Web Server's point of view.
' -- Use Server.MapPath for help.

Set fs = CreateObject("Scripting.FileSystemObject")
If fs.FileExists(strFileNameAndPath) Then
    ' -- file exists
else
    ' -- file does not exist
end if
```

7 Beating the Cookie Monster

So you've found that your user has disabled cookies? He may not trust you, but if he can be sneaky, so can you. Use this technique to find out if the user has disabled cookies, and to politely tell him to turn it back on if he wants to use all the functionality on your site.



Question:

How do I find out if a user has disabled cookies?



Answer:

To find out if a user has disabled cookies, follow these steps:

1. Set a cookie.
2. Redirect to your own page.
3. In the redirect, read the cookie.
4. If your cookie has a value, user has enabled cookies. If there is no value, then the user has disabled cookies.
5. Use the Querystring to determine if you are on step 1 or step 3.

To set the cookie, use the following code:

```
Dim strCookie, strTry
strCookie = Request.Cookies("MyCookie")
strTry = Request.QueryString("Try")

If strCookie = "" Then
    ' Check to see if this is a redirect
    ' after setting the cookie
    If strTry = "" Then
        Response.Cookies("MyCookie") = "Set"
        ' Redirect to this page and try again.
Response.Redirect(Request.ServerVariables("SCRIPT_NAME")
& "?Try=Yes")
    Else
        ' User/Browser didn't accept cookies
        ' Do something...
    End If
Else
    ' -- Hooray! User is accepting cookies
    ' -- Delete our cookie: by setting its
    ' -- expiry date to waaaay back
```

```
Response.Cookies("MyCookie").Expires = "January 1,  
1980"  
    ' Do something...  
End If
```

16 Quibbling with Quotes in SQL Queries

How many times have you fumbled with this issue: you try to create a valid SQL statement concatenating a field value that the user has entered on his HTML form. However, the presence of an apostrophe (as in the name O'Brian) or double quotes fouls up your SQL string in VB Script. Find out how to avoid this problem.



Question:

I have a problem with the add and update query in SQL. I am trying to update the database with a string which contains one or more apostrophes. SQL reads it like a syntax in query and gives an error message. What I can do? Are there other text delimiters? I have tried "", [], or {} or double apostrophe without success.



Answer:

Before sending data to your SQL Server, convert all your apostrophes (') in data to double apostrophes (").

So, if a user name is O'Brian then in your SQL Statement, the apostrophe will cause a problem:

```
Update Table Set NameField = 'O'Brian'
```

Instead, you need to convert it to double apostrophes:

```
Update Table Set NameField = 'O''Brian'
```

To convert single apostrophes to double, use the Replace function.

```
strName = Replace(strName, "'", "''" )
```

15 Stringing Dates Along to the Database

If passing strings that contain quotes causes problems, then passing dates to databases is even more confusing to our readers. This tip explains how to do it properly, depending on the kind of database you are using.



Question:

How can I pass a date to a database using ASP?



Answer:

The answer depends on what database you are using. Say you are using a variable called 'strDate' to hold your date value. If you are using Access, build a string:

```
strSQL = " valid sql string " & "#" & strDate & "#"
```

If you are using SQL Server, Sybase, or Oracle, build a string:

```
strSQL = " valid sql string " & "'" & strDate & "'"
```

Note the difference is in the delimiters used for sending the date variable. Access uses the pound sign (#), the others use the single quote (').

Formatting Numbers for Display

One unexpected feature of VBScript for VB programmers making the change to ASP is that the familiar Format function is missing. So how do you format numbers the way you want them instead of the way they are stored in the database—for example, as a percentage, as a currency, or even with decimal places? Use the code in this example which shows you how to use the new FormatXXXXX functions that replace the VB Format function.



Question:

On a particular page in the application I'm developing, I'd like to display some numbers, in ####.#### format. How do I go about doing that in ASP?



Answer:

Use the FormatNumber function in VBScript. This returns an expression formatted as a number.

Syntax:

```
FormatNumber(Expression [,NumDigitsAfterDecimal  
[,IncludeLeadingDigit  
[,UseParensForNegativeNumbers [,GroupDigits]]]])
```

For example, FormatNumber("123.45",4) would return 123.4500

Check the VBScript help at <http://msdn.microsoft.com/scripting> for more info.

3 Keying Into Smart Database Searches

Writing your own little search routine has never been easier. But consider the fact that your users would like to do partial text searches on data within your database and it gets worse. You can't retrieve records that match the text "ASP Pro" just by doing a search on the text "pro" and using an equal to sign. This tip explains how to use the LIKE SQL clause to do partial text searches.



Question:

When setting up a recordset, is it possible to get a record when the field contains more than the word that I'm looking for and where the words are in no particular order?

For example:

```
StrName = 'Direct'  
RSShops = Server.CreateObject("ADODB.Recordset")  
strSql = "SELECT * FROM Shops WHERE Name =  
        '" & StrName & "'"
```

Can I get the recordset to contain any shop/company with 'direct' in it's name?



Answer:

Instead of using the Equal to (=) operator, use the LIKE operator in your SQL Statement.

To hunt for Shops with names that have the word 'direct' in them, your SQL statement would look like this:

```
SELECT * FROM Shops WHERE Name LIKE '%direct%'
```

You can thus modify your code accordingly.

2 Keeping Up to Data with Recordsets

As you start using recordsets within your ASP page, you will frequently run into this problem. You want to access the data within your recordset, but you need to make sure it has data before you access it. Remember that, if the recordset has no data, you will get an ugly, run time error message. You can use the code in this tip to solve your problem.



Question:

I have several years of experience with VB but am brand new to ASP (VB Script). Right now, I'm trying to open an access database, count the number of records and display the information on the Web page. I know that my database contains a table (people) called 'sean.mdb' which has

three records. However, when I run the script it says that there are -1 records in the table.

Can you tell me what I'm doing wrong in my code:

```
<%  
  
Set objConn = Server.CreateObject("ADODB.Connection")  
Set objRst = Server.CreateObject("ADODB.Recordset")  
  
objConn.Open("DRIVER={Microsoft Access Driver (*.mdb)};  
DBQ=  
" & Server.MapPath("\seannewell\db\sean.mdb"))  
  
strSQL = "SELECT * FROM people"  
  
objRst.Open strSQL, objConn  
  
Response.write( "<P>" & strSQL & "</P>" )  
Response.write("<H2>There are " & objRst.RecordCount &  
" People in the database</H2>")  
  
If objRst.RecordCount > 0 Then  
    objRst.MoveFirst  
    Do While Not objRst.EOF  
        Response.write( "Name = " & objRst.fields(0) )  
        objRst.MoveNext  
    Loop  
else  
    Response.write( "It's EMPTY!" )  
End If  
  
objRst.Close  
Set objRst = Nothing  
objConn.Close  
Set objConn = Nothing  
%>
```



Answer:

The RecordCount property returns -1 in older versions of MDAC. Try to upgrade the MDAC files on your server to the latest ones, available at www.microsoft.com/data.

If you cannot do that because your Web server is hosted by your ISP and you do not have control over it, change your code.

Instead of using:

If objRst.RecordCount > 0 Then ...
to check if there are records in your Recordset, use the following:

```
If objRst.BOF and objRst.EOF Then
    ' Recordset is Empty
Else
    Do While not objRst.EOF
        'Process the recordset
        objRst.MoveNext
    Loop
End If
```

Update 6/30/00: Daryl Egarr from New Zealand made this observation:

The page implies that the code in question is okay but that "The RecordCount property returns -1 in older versions of MDAC." While this may be true, the author should not make that assumption based on the code in question, as there is nothing in the code that suggests an older version MDAC.

The author missed the whole point, which is that not all properties and/or methods are supported by all cursor types (regardless of database type). The real reason the code failed is that when using the default cursor location(which the code does):

```
Recordset.CursorLocation = adUseServer
```

the RecordCount property is only available if the Recordset uses CursorType 1 or 3 (adOpenKeyset or adOpenStatic). The code doesn't specify a CursorType, so therefore 0 (adOpenForwardOnly—the fastest cursortype) is used, and any RecordCount call will return -1.

The Solution is to simply change the line ...

```
objRst.Open strSQL, objConn
to ...
```

```
objRst.Open strSQL, objConn ,1
```

1 Dodging the Dinosaur of DSN

Still connecting to databases using an ODBC system or file DSNs? Get with it, man! Don't be a dinosaur—instead, use the much faster OLEDB Provider technique to connect to your database without using a DSN. No more pleading with your ISP (or your DBA/Webmaster) to create a System DSN for you. And no more configuration changes when you move Web files.



Question:

I see many examples of using a data source name (DSN) to connect to a database. I would like to access a database without using a DSN. Can I do this with ASP? Could you show some

sample connection code? I would like to pass the Driver, Server Name, UID, PWD, and Database in a connection string and not depend on a DSN on a machine.



Answer:

If you are using SQL Server 7, use this code as your connection string:

```
strConnString = "DSN='';DRIVER={SQL SERVER};" & _  
"UID=myuid;PWD=mypwd;" & _  
"DATABASE=MyDb;SERVER=MyServer;"
```

The most important parameter is the DRIVER= portion. If you want to bypass ODBC and use SQL Server using OLEDB (this is supposed to be faster), use this syntax:

```
strConnString = "Provider=SQLOLEDB.1;Password=mypassword;" &  
_  
"Persist Security Info=True;User ID=myuid;" & _  
"Initial Catalog=mydbname;" & _  
"Data Source=myserver;Connect Timeout=15"
```



Big Tip:

If you require a connection string but are unfamiliar with the syntax required by the OLE DB provider, use either the Data Environment designer or the ADO Data Control in Visual Basic to create one, and copy it for use with the ADO Connection object. In the Immediate window, type: ? dataenvironment1.connection1.ConnectionString to get the actual string.

Note: The syntax for Microsoft Access is different.

For more information on using the non-DSN connections with Access, check out the tip, [Syntax for DSN-Less Connection for MS Access](#)

Rama Ramachandran is the Vice President of Technology with Imperium Solutions and is a Microsoft Certified Solution Developer and Site Builder. He has extensive experience with building database systems and has co-authored several books including Professional Visual InterDev 6 Programming and Professional Data Access (Wrox). Rama Ramachandran teaches Visual Basic and Web development at Fairfield University and University of Connecticut.

Submitter : Dr. Frederick Zivnuska
Organization : The Center for Cancer Care and Research
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

US Oncology has estimated that (medical oncology) practice losses will be in excess of \$1000 per Medicare cancer patient beneficiary with the new allowable drug fees and physician fees. This sort of thing needs to be reconsidered. I'm sure US Oncology has submitted its data to you. I am not in medical oncology and do not administer these drugs but I am 65 now and I'm not sure I'd like to have \$ enter into the equation of my oncology care so prominently if I were in such a fix. Please rethink this course of action.

Thank you.

Submitter : Dr. Stuart Munro
Organization : Department of Psychiatry, UMKC School of Medicine
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

Stuart Munro, M.D.
Chair, Department of Psychiatry
School of Medicine
University of Missouri-Kansas City

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Kansas City, Missouri 64108
816 512-7417
FAX 816 512-7440
stuart.munro@dmh.mo.gov

April 26, 2005

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

To whom it may concern:

I am writing to express my support for the inclusion of psychiatric medications in Phase I of the Medicare Competitive Acquisition Program for Part B Drugs. I have reviewed the program as described in the Federal Register of March 4, 2005 and feel that inclusion of psychiatric medications as soon as possible will be of great benefit to the patients we serve through the Department of Psychiatry at the University of Missouri-Kansas City School of Medicine. Continuity of care and access to vital medications will be enhanced at our primary clinical sites, namely, Western Missouri Mental Health Center and Truman Medical Center Behavioral Health Network by inclusion of psychiatric medications at the earliest stage (January 1, 2006).

I also feel that it would be important that CMS create a category of Part B drugs that includes mental health drugs, including long-acting injectable antipsychotic medication.

I would like to thank-you for your kind attention to my comments.

Sincerely,

Stuart Munro, MD
Chair

Submitter : Dr. Richard Gillespie
Organization : US TOO Chapter, Westminster/Potomac Hospital
Category : Consumer Group

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

I, an Agent Orange Prostate Cancer Survivor who is the leader of an US TOO prostate cancer support group in Woodbridge VA, have reviewed the Medicare CAP program, and am deeply concerned that it will unduly restrict patient ability to choose the best hormone therapy drugs. I am about to go on hormone therapy and find that the effectiveness of hormone therapy drugs varies considerably between members of my chapter. Members I know are using a wide variety of drugs and prices. The drug Lupron works better than the much cheaper drug Zoladex for most men I know. While Zoladex works for some, I have seen others on which it has not worked, forcing them into a more effective, but more expensive drug. Survivors really must have access to the widest choice of these drugs. Piling Virginia's Least Cost Alternative legislation on top of the proposed CAP program will seriously restrict our access to the best therapy for us seniors.

Submitter : Ms. Guyla Stidmon
Organization : National Alliance for the Mentally Ill of KC
Category : Consumer Group

Date: 04/23/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-214-Attach-1.DOC

TO WHOM IT MAY CONCERN.

On behalf of the National Alliance for the Mentally Ill of Greater Kansas City (NAMI-KC), I am submitting this letter of concern for the proposed MMA system of obtaining drugs currently covered under Medicare Part B.

First, this program will keep innovative technology from being available to persons who suffer from one of the most devastating of illnesses. The program would provide inadequate coverage and force persons with mental illness to participate in an archaic system that would negatively affect their health and well-being. Individuals would be forced to use medication that could result in more hospitalizations at a greater cost to taxpayers. Persons with mental illness are often non compliant with drug treatment due to various side effects or their inability to comply with a regular treatment regime, therefore every option must be available to ensure they continue taking their medication.

Second, with many mental illnesses, Medicare is the primary payer, therefore providing partial payment is not an option for individuals who depend on their Medicare benefit. **THEY WILL STOP TAKING THEIR MEDICATION BECAUSE THEY CANNOT AFFORD THE MEDICATION** without the assistance of Medicare. Without medication, these individuals will be out on the streets, in jail or in some cases dead. Persons with mental illness who are not on their medication are a danger to themselves and to others, thus causing a public health care problems of great magnitude.

Third, is the concern that psychiatrists will not prescribe the appropriate medication because they will not be able to afford to participate in a system that will only provide partial payment with the bearer of responsibility falling on the psychiatrist, not the payer source. The payment process is already complicated, yet psychiatrists will be forced to go through many more steps before any payment would be received, a wait of possibly six months with increased chances of incorrect billing procedures. No one can continue to do business this way and provide good service. What will result is limited access to certain therapies based on payer source, rather than treatment efficacy. Newly identified consumers cannot receive therapy and successfully treated consumers are removed from therapy.

How do we solve these problems? It is NAMI-KC's hope that a competitive acquisition program be developed and that psychiatric medications be phased in as soon as possible. This will result in:

- Improves consumer access to care, resulting in more cost effective care and treatment of a vulnerable population,
- Allows drugs to be handled the same way regardless of route of administration,
- Eliminates coverage and process problems,
- Streamlines billing process,
- Reduces the financial risk to psychiatrists.

Sincerely,
Guyla Stidmon, Executive Director
National Alliance for the Mentally Ill
Of Greater Kansas City
406 W. 34th Street, Suite 506
Kansas City, MO 64111
(816) 931-0030

Submitter : Dr. Maryada Reddy
Organization : Dallas Oncology Consultants
Category : Physician

Date: 04/23/2005

Issue Areas/Comments

GENERAL

GENERAL

Cannot treat patients on the day of first visit. It adds second visit to the patient.

It adds additional paper work and phone calls to the already cumbersome process.

It is not clear what happens if the chemotherapeutic agent is not used either because, patient's blood counts are low, patient does not show, patient expires or regimen needs change.

I doubt this will in any way reduce costs, it only replaces existing system with a middleman.

What about the safety and integrity of the drugs? Who will be responsible for the safe delivery of drugs?

Let us say patient is all set to receive chemo and the drug is either not delivered on time or is damaged during shipment, who is going to do the explanation to the patient?

Submitter : Dr. joseph mcevoy
Organization : john umstead hospital
Category : Physician

Date: 04/23/2005

Issue Areas/Comments

GENERAL

GENERAL

It will be important to include drugs for mental illness. The NIMH-supported CATIE trials results will soon be published and available for guidance. It makes sense to include a long-acting injectable antipsychotic, because of frequent non-compliance among this population. CMS may want to fund a study of the cost-effectiveness of the new vs older long-acting injectables.

Submitter : Dr. vivek swaminathan

Date: 04/23/2005

Organization : FOUR RIVERS MENTAL HEALTH CENTER

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am a pharmacist at a large mental health center and we do a some buy and bill at this time for our medicare population. I am sorry that some of the oncologist have abused the system and taken advantage of the old system. It is very important that CMS consider psychiatric drugs be included in phase I. Most of these patients are mentally ill and we have to make sure they are on these meds to be some what functional in society. mental health centers dont have the ability to do buy and bill for all these drugs. As a large CMHC center we dont have the ability to do buy and bill as you know we are not a pharmacy we are a mental health center. Please consider this as you make this decision

Submitter : Dr. Leonard Kalman
Organization : Oncology Hematology Group of South Florida, PA
Category : Physician

Date: 04/23/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-218-Attach-1.DOC

CMS-1325-P-218-Attach-2.DOC

I am a practicing medical oncologist. The CAP system is simply unworkable from the patient access to care point of view, and will lead to excessive costs to Medicare.

When a patient is in the midst of a chemotherapy regimen they make frequent office visits to their oncologist, are evaluated by the doctor on a same day basis for their symptoms, overall performance status, and blood counts, and then a chemotherapy decision is made. Doses are frequently adjusted upwards or downwards on a same day basis, and regimens are changed if the patient has disease progression or unacceptable toxicities.

This prescription based system would lead to individual inventories from multiple CAP providers for each patient (a costly logistical burden on practices). There would be an increased frequency of office visits because the patient would need to be re-evaluated on the day all the drugs in their multi-drug regimen have finally arrived from the various CAP providers (increasing the number of office visits charged to Medicare, and increasing scheduling burdens on physician offices). Costly partial drug wastage will occur if doses are reduced, and complete drug wastage will occur if doses are increased, or a regimen changed, because ordered drug would not be able to be delivered on the scheduled day, and thus the "whole process" of evaluation and treatment would need to be re-scheduled again. Emergency usage of CAP drugs would be eliminated, requiring costly hospital admissions for drugs previously delivered more cost effectively in the outpatient setting.

Issues of co-insurance payment are worrisome. We have forgiven co-pays or worked with our patients to make sure they get their therapy on time. But an anonymous third party (or third parties for multiple drug regimens and therefore multiple providers) who does not collect on an increasing patient balance is unlikely to deliver drug to our practice to treat their "bad debtor."

The current delivery system of a community practice ordering, inventorying, and delivering chemotherapy drugs to their patients is time tested, and is working to afford access to cancer care in the cost effective outpatient setting. Please do not disrupt this system with a costly and burdensome unproven experiment.

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 : Ms. Kelly Gunning

Date: 04/23/2005

Organization : NAMI

Category : Health Care Professional or Association

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

We insist upon the inclusion of Psychiatric drugs in CAP. We implore you to include psychiatric drugs in the initial stages of CAP to alleviate barriers to access inherent in the current system. We include in this request, access to ALL psychiatric medications, including the long-acting injectable antipsychotics. These drugs like many for oncology and HIV/AIDS have very specific actions and must be made available to ALL patients suffering from these debilitating illnesses.

Submitter : Dr. Larry Corum
Organization : Olathe Cancer Care
Category : Physician

Date: 04/23/2005

Issue Areas/Comments

GENERAL

GENERAL

The proposed CAP is riddled with potential problems and pitfalls. These range from quality control in assuring what a patient receives to the timely delivery of drugs to last minute changes in drug regimens that are inevitable in the necessarily fluid world of oncology daily practice. In short, this is a bad plan conceived by people who apparently have little knowledge of the daily workings of an oncology practice.

Submitter : Mrs. Judith Morrison
Organization : Oncology Hematology of Lehigh Valley
Category : Health Care Provider/Association

Date: 04/23/2005

Issue Areas/Comments

GENERAL

GENERAL

This is going to negatively affect the way cancer care is currently being delivered. It will be an enormous inconvenience to patients who will have to have multiple visits to the physicians office for each treatment instead of all being done in one visit, i.e. doctor examination, blood count, chemo given. The amount of additional paper work is unfair, the room needed to store individual patient drugs is non-existent. The present system is not broke, may need some tweeking, but to drastically alter it will cause the greatest harm to the patient, the dedicated nurses and to the quality of exceptional cancer care that has been developed over many years. The whole idea should be carefully rethought and dropped.

Submitter : Ms. Lucinda Smith
Organization : Ms. Lucinda Smith
Category : Individual

Date: 04/24/2005

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1325-P-222-Attach-1.DOC

April 23, 2005

Center for Medicare and Medicaid Services (CMS)

Proposed Rule: Competitive Acquisition Program (CMS-1325-P)

As mother of a son with chronic paranoid schizophrenia I am concerned about the referenced proposed rule, and believe that the long-acting injectable anti-psychotics should be included in the list of medications under this Competitive Acquisition Program (CAP).

Finding an effective medication for the treatment of this illness is quite challenging. Thousands of persons with serious mental illness currently receive these injections as an option to the traditional pill form of the anti-psychotics. The reasons are numerous but in short it increases the likelihood of continued recovery from the mental illnesses since it eliminates the need for compliance with daily doses. With the implementation of the Medicare Prescription Benefit in January, 2006, these injectable medications will not be as accessible to the persons with serious mental illnesses since they would be required to purchase the medication and file for reimbursement. This is simply not possible economically nor realistic for these individuals.

The cost to the Medicare program will be more in terms of the adverse consequences of inpatient hospitalization than if this class of medications were included in the CAP program. As a result, these patients, especially those who have dual eligibility for Medicaid and Medicare, will not have continuous access to their medications.

I am requesting that a change to the proposed rule be made to include the long-acting injectable anti-psychotics under this Competitive Acquisition Program (CAP) as it would be more cost and access effective than the proposed rule.

Sincerely,

Lucinda Smith
433 Devon Drive
Birmingham, AL 35209

Submitter :

Date: 04/24/2005

Organization :

Category : Other Health Care Provider

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

Include psychiatric and mental health drugs and do it in Phase I. There would definitely be a significant savings and there would be a significant improvement in patient access. Most seniors are excluded from State programs because of their income levels and the barriers created by the State to avoid cost-shifting from federal to state programs. As a community mental health center in Pennsylvania we are often told by County, State, and Medicaid officials that it is okay for Medicare clients to go into the hospital even though it could be avoided if there was a payor source for their medications. They resent, and so aren't, subsidizing the gaps in Medicare coverage. We say, 'This person is going to end up in the hospital unless you pay for their meds.' Their response is, 'We don't care because the hospitalization doesn't come out of our budget.' That has to be costing the system more.

GENERAL

GENERAL

Please give consideration to vendors and providers regarding the reimbursement processes. Allow for kinder and gentler handling of uncollectible copays. Often, a behavioral patient is unlikely to connect their need to pay with the benefit to be derived by them from medication compliance and clinical success.

Submitter : Dr. Mark Thompson
Organization : Mid-Ohio Oncology/ Hematology, Inc.
Category : Physician
Issue Areas/Comments

Date: 04/24/2005

1-15

Overview of the CAP

I am the Managing Partner of Mid-Ohio Oncology/Hematology in Columbus, Ohio. We are a twelve person group providing about 25-30% of all oncology care in our area. I am commenting on behalf of our group. I have read the proposed rule in detail. Our stance is simple- we think the idea is bad medicine and that there is no way that this will save anyone money. This program is labor intensive. There are no provisions for vendors to provide electronic interfaces. We have spent 8 years developing a system to do away with paper and this is a step backwards-there are no provisions to mandate vendors to provide electronic ways of doing business with them. We would have to go back to paper. There are no software programs to interface with vendors on the market now. We keep a single inventory low by keeping the amount of drug we need on hand and automatically reorder electronically when inventory falls to low levels- a great and cost effective way of providing service and keeping costs down. This rule leaves our office trying to maintain 200-300 individual inventories, if one looks at just the numbers of our Medicare population of patients undergoing treatment at any time. Doesn't it seem likely that that will add costs to trying to maintain all this in the most cost ineffective way there is-paper? There is no reimbursement for maintaining new sets of records. Certainly Medicare and CMS are aware that maintaining the required records will cost physicians in number of employees, paperwork costs, postage, etc. We have layers of records we now are required to keep for CMS and HIPPA. This will add a whole new layer to already onerous regulations and rules to the mix. It may be that purchases of drugs in this way may save dollars for the Medicare program, but it is clear to those of us on the line that it simply will be cost shifting enormous costs and energies for each provider. We feel strongly that the time of our staff and of our physicians should be spent on patient care and not on layers of regulatory documentation.

There are still no provisions for financial burdens associated with ordering drugs through a CAP vendor, storing them in safe environments, handling these agents for large numbers of Medicare patients and distributing them to patients. This is not a minor set of duties for any clinic. Our burden is not lessened as providers using CAP, but increased. We no longer have the 6% over ASP to pay in some fashion for these duties, we have zero. Perhaps a facilities fee should be considered for the unreimbursed costs of these activities. AS a comment, recent studies have shown that the costs associated with drug handling and dispensing are mor like 20% of ASP rather than 6%.

Contracting Process-Quality and Product Integrity Aspects

No vendors are in the marketplace at present to demonstrate that this system can work. A middleman is added to an already complex process. We have great concerns that additional bureaucracy and added steps in the drug procurement process can make things less safe and much more inefficient than they are now. We currently work with vendors who have safety measures in place and proven track records for safety and ease of partnering with. Most chemotherapy drugs need to be handle in specific ways to insure their stability and efficacy. There are no provisions for what occurs if a provider receives drugs that were not handled appropriately. There are no provisions for breakage issues and how they will be handled. These are real life things that happen daily accross this country in every oncology clinic. Providers can not be held responsible for a CAP program that doesn't assure that the drugs we give to patients have been handled in the same rigorous way that we do now. The rules must put punitive measures and responsibility where it may rightfully belong using a CAP program- on the poorly performing vendors.

Claims Processing Overview

There are provisons for punitive measures agaist providers in this rule. There are none, that we can find, regarding vendors. There are no experienced CAP providers in the marketplace now. There needs to be some rules that allow providers and beneficiaries to have recourse for a poorer performing CAP vendor.

There are provisons for vendors to have providers investigated and excluded from CAP participation, but not for exclusion of poorly performing CAP vendors. Our bias is that we will see many of these in the first few years of this program.

Statutory Requirements Concerning Claims Processing

These rules add work for physician offices. There are no fewer documentation provisions than providers already have under ASP. Actually, given another middleman in the process, this adds to the providers burden. The cost of doing the documentations are further complicated by no having provisions for these to be electronically interfaced. No provisons to make vendors use interface technology is in this rule. There are no provisons for providers to change vendors if vendors are providing poor service, yet vendors can drop physicians. Poor claims problems for vendors don't necessarily equate to providers being the problem. No provisions are in this rule for providers to be gauranteed that each CAP vendor will do their best to minimize the requirements and ease of data capture form each provider.

It seems that little forethought on some of these basic business principles are included in this rule. We have carefully picked partners that have been easy to work with and for which a win-win has occurred for both businesses. The ability for us to change to a different partners puts competitive pressure on vendors to perform at their best. There is no provision in this rule for this. We are concerned that there will be many mediocre CAP vendors out there because of this and that we will be forced to work with vendors for a year even if they really don't meet the standard.

Categories of Drugs to be Included under the CAP

The wording of these provisions suggests to us a basic lack of understanding of the care of cancer patients. Although the drugs to be included and process of procuring them may satisfy drug delivery in most cases, there are no satisfactory provisions for drugs needed on an emergent basis. As an example, I had a Medicare patient present last week very ill secondary to rapid development of hypercalcemia. She needed a biphosphonate drug immediately as her levels were life threatening. Tomorrow would not have been soon enough. The provisions for emergency use of our inventory to help save this life would have been more difficult than should be expected of healthcare providers providers.

There are no provisions for an emergency "code" cart set of drugs in this rule. If there is an allergic reaction to the drugs being given, not an uncommon event with several mainstay chemotherapy agents, drugs need to be on hand at that time for dealing with this emergency-these reactions are life-threatening. Some amount of drug needs to be on hand at every facility to insure safe care.

There is a provision for the vendor to develop formularies. We are troubled that a vendor is not qualified to decide on which therapeutic options are most efficacious for cancer patients. Cheaper is not necessarily best in cancer care. This rule should have provisions for medical supervision of the formularies based on solid, evidence based medicine and not on a businessman's assessment of costs.

There is no benefit to patients in this rule that we can see. They will likely be unable to have changes made in their individualized care plans without adding visits. This will impact the patients, but also their sons and daughters and granddaughters and friends that have to take off work to bring them. This cost shifts to the community as a whole in decreased productivity. The societal costs of cancer care are not to be minimized. This rule lends itself to inefficiency and added burdens to those who are part of the care continuum like family. Any added visit adds to costs! The rule writers need to understand this part of the complexity of managing cancer care.

We are unassured that patients with no co-insurance will be provided drug by vendors. I find no rule requiring them to do so. We do this daily, because it is the right thing to do. What happens in the future? We are healthcare direct service providers. No CAP vendor can assume that role. Providers likely will be put in the middle of this issue. The rule should cover this problem in advance.

There are no provisions for anti-emetics on hand in case the one's ordered in advance don't work. This is common. Provisions for agents such as these are requirements of providing quality care. I doubt any of us feel we should let folks be nauseated and vomit simply because there are no provisions for these as needed drugs.

We feel that there are multiple reasons that CAP is bad medicine as written in this rule. Cancer care is very complex. It necessarily requires individualized therapies based on patient's co-morbidities and tolerances to therapies. This complexity cannot be distilled down to the simplest of terms like this rule intends to do without major risks for diminishing the quality of cancer care. This rule misses the mark on understanding some of the most basic and common difficulties cancer chemotherapy patients face day to day. This rule is simply not ready for implementation until those writing this rule have a better understanding of the complexities and have insured common contingencies are accounted for.

Submitter : Mrs. Mary Almaguer
Organization : Virginia Beach Community Services Board
Category : Local Government

Date: 04/24/2005

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

long - acting injectables

CMS-1325-P-225-Attach-1.DOC

Mary Almaguer
Virginia Beach Community Service Board Member
Member of the National Alliance of the Mentally Ill
Parent of Child with Schizophrenia
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April 24, 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:

I am writing in strong support of the proposed rule recently issued by the Centers for Medicare and Medicaid Services (CMS) that addresses implementation of the Competitive Acquisition Program (CAP). This program 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. I urge that injectable antipsychotic medications be included in the initial phase of CAP implementation.

I am writing as a member of the Virginia Beach Community Services Board, The Mental Health Committee, a member of the National Alliance of the Mentally Ill and a parent of a child with the diagnosis of Schizophrenia. My son is 28 years old. When he was first diagnosed, he had a very difficult time complying with his medication. This caused him to be hospitalized several times. He also was kicked out of his housing and day program because of inappropriate behaviors because he could not be compliant with his oral medications. Finally the doctor prescribed the injected long-acting Haldol. This eliminated the need for a daily compliance with oral medication. Haldol was at this time the only medication that was available in the injectable long-acting form. Haldol had many strong side effects, including making my son very sedated so he was not able to think clearly and not able to move to any form of social improvement. After my son had been on Haldol for several years we were able to try another medication. At this time in his life he was able to be compliant with an oral medication. I strongly believe that injectable long-acting medications for the Schizophrenia patient are an absolute must. Sometimes there is a time in the person's life that he is not able to use oral medications because of the illness. This is not a permanent condition, but a real necessity at that point in the illness. Many times there are no alternatives but using a long-acting injection. Haldol is an old

medication with many severe side effects. I strongly urge you to consider the desperate need for the use of the new injectable long-acting antipsychotics. In many cases access to the long-acting antipsychotic injection will save money by helping those with Schizophrenia stay out of the hospital. It will give a much better quality of life to the patient and his family. Compliance with medication is a major part of recovery for any individual with the diagnosis of Schizophrenia.

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.

The use of injectable antipsychotics has been recognized as an important, evidence-based practice that addresses the noncompliance of many with schizophrenia. In addition, a new type of psychotropic medications show tremendous promise in addressing the issue of partial compliance among people with mental illnesses. These new medications are injectable, but do not have the side effect profile of older injectable depot psychotropics that consumers found objectionable, including lingering pain after the injection, sedation, and other effects. While a number of the new injectable medications are currently in development (including an antidepressant), one 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

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

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 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 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.

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.

Sincerely,

Mary A. Almaguer
Virginia Beach Community Service Board Member
Member of the National Alliance of the Mentally Ill
Parent of a child with Schizophrenia