

Submitter : Ms. Elizabeth Mueller
Organization : Valley Oncology Associates
Category : Individual

Date: 03/10/2005

Issue Areas/Comments

GENERAL

GENERAL

The program for MVI presents a myriad of problems for the community based private oncology practice. This year we are still reeling from the reduction in drug reimbursement which has in some cases made the drug more expensive than the reimbursement from Medicare. In some instances we can't and don't use certain drugs anymore.

While we don't expect Medicare to supplement the 20% payment for those patients who can not afford their copayment, we can not supplement the expense for drug when a patient can not afford their copayment. We can not forgive their deficit. Some patients may choose to simply forgo treatment.

Today a patient in our practice presented for shots of growth factor. She had previously bounced several copayment checks to our group. We could do nothing for her today but offer to send her to the hospital.

Enter MVI.

There are several problems with this system.

When drug is received, it is received for a particular patient. Our practice would have to keep multiple inventories for each patient. Since up to 40% of our practice is Medicare this would be a nightmare of labeling, storing, ordering, etc. If our patient doesn't make the copayment to the MV will they still send the drug? If the treatment changes or the patient needs another drug what will happen to the drug already shipped? What will happen if the patient dies and we have drug? Do we send it back? I would most likely have to hire another person to do nothing but handle the paperwork associated with this project.

CMS has complicated the issue of access to care for cancer patients. The Oncology community needs to be appropriately paid for the services it renders to our most ill population. CMS is failing at this presently. By all accounts we are not reimbursed adequately to support the costs of our staff, building, our supplies, etc.

Every viable business in the US and abroad survives by operating on a profit margin. CMS will block access to care by simply making it impossible for outpatient cancer centers to survive. We request that Congress take a very hard look at the numbers that COA, ASCO, US Oncology and others have presented in support of review of reimbursement for administration of cancer services in the out patient setting and the reimbursement for drug making an equitable adjustment to allow us to continue our work in the community.

Thank you,

Elizabeth Mueller, Administrator, Valley Oncology Associates

Submitter :

Date: 03/10/2005

Organization :

Category : Physician

Issue Areas/Comments

1-15

Claims Processing Overview

To state that the extra burden of maintaining a separate inventory for CAP drugs would place little, if any, additional burden on physician practices and therefore, there would be no additional payment for this burden since it would be considered as included in the drug administration reimbursement is an oversight of this proposal. I believe the proposal is ignoring the extra burden and costs associated with maintaining a separate inventory driven by prescription numbers for CAP drugs. Faxing an order (with all the proposed required information) for each drug administration on each patient would certainly require more staff time for physician practices who now do not keep patient-specific inventories due to the extra expense and time involved. The handling of the deliveries and returns of such prescriptions would particularly take up more staff time as well.

On paper, it certainly appears plausible that a prescription delivery could be kept at the physician's office and matched up to each patient upon administration. However, in the real world, when patients are being rushed through their visits due to volume, time constraints, storage limitations, patient demands, staff turnover, and staff shortages, it would be very difficult to maintain a CAP inventory with absolutely no allowance for human error. Bear in mind, too, that physician practices would also need to maintain a separate inventory for emergency stock and non-CAP drugs billed to non-Medicare payers. There would be multiple inventories in the mix.

There are three ways to resolve this: 1) raise the administration reimbursement to physicians for the increased practice expense component of RBRVS 2) create a new billing code for the physician handling of CAP drugs or 3) create a defined allowance credit in anticipation of inevitable human error.

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. Donna Hurt
Organization : Cahaba GBA
Category : Nurse Practitioner

Date: 03/14/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Dr. Mark Moskowitz
Organization : Florida Cancer Specialists
Category : Physician

Date: 03/14/2005

Issue Areas/Comments

GENERAL

GENERAL

This program has the potential of creating an enormous, expensive bureaucracy that will be almost impossible to contain. Why on earth would CMS want to meddle with a system that works? At this point the physicians administer treatment at the point of service, there are no questions of adulteration (remember Kansas City)and if accidents happen one knows where to fix both problem and blame. This system will lead to incredible waste, since as many as 1/3rd of patients like to have chemotherapy hold because of low counts or concurrent illness. It will lead to inevitable communications problems between vendor, physician and patient. This will be a disaster!!!

Submitter : Dr. Alfred Denio
Organization : Virginia Society of Rheumatologists
Category : Physician

Date: 03/15/2005

Issue Areas/Comments

GENERAL

GENERAL

I am a practicing rheumatologist in Virginia and I hope you will Beta test this before launch. I foresee a number of practical problems with having to obtain drugs for infusion to patients with rheumatic disease when I have to obtain the drug through acquisition programs. Will I be able to adjust the dose at the last second? Do I get allowances for storage, handling, taxes (my city taxes me on the cost of the drug infused to my patient), insurance for spoilage? Do I bill it or does the acquisition plan? Does it get billed when delivered to the provider, or when infused in the patient? Rheumatologists have never done business in this fashion and will need considerable education to understand and implement it. Would someone from CMS be able to come to our Virginia Beach state meeting in October to "teach" Virginia rheumatologists? Please respond if CMS can send someone. Or we could be part of your "beta test".

Al Denio, MD

Director, Division of Rheumatology

Eastern Virginia School of Medicine

Secretary/Treasurer

Virginia Society of Rheumatologists

CMS-1325-P-6

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. James Welsh

Date & Time: 03/15/2005

Organization : Carolina Blood and Cancer Care

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

A couple of comments from a practicing Oncologist:

1) Payment must be changed!

CMS is not proposing to make any payment to physicians for administrative work. CMS believes that the clerical and inventory expenses related to use of the CAP are no greater than for ASP-based reimbursement and that the payment for such work is bundled into the payment for the drug administration codes.

It is my opinion that the added administrative work can not be considered as bundled into the old drug administration codes as the new work could not have been factored into any calculations made 1-2 years ago. If the calculations were included, please show me the data.

2) The following are identified as additional administrative work areas required of physician offices

- * Share information with the vendor to facilitate the collection of the deductible and coinsurance.
- * Promptly file claims.
- * Pursue claims that are denied for lack of medical necessity.
- * Notify the vendor when a drug is not administered.
- * Maintain an inventory record for each CAP drug.
- * Comply with the rules on emergency drug replacement and on seeking ASP-based reimbursement for medically required formulations different from those offered by the vendor.

I am certain that as this program evolves, more and more administrative work will be added as compliance

testing and quality assurance becomes recognized as a

necessity.

For these reasons, in order to participate in such a program, Physician offices will face increased costs and decreased reimbursements. This plan needs major reworking. An explanation from CMS is demanded regarding the bundling question raised above.

James D. Welsh MD
1583 Health Care Dr.
Rock Hill, SC 29732

CMS-1325-P-7

**Medicare Part B - Competitive Acquisition of Outpatient Drugs and
Biologicals**

Submitter : Mr. Brian Rokusek

Date & Time: 03/15/2005

Organization : McCook Clinic, P.C.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

CMS-1325-P-8

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. Corinne Phillips-Ward

Date & Time: 03/15/2005

Organization : McCook Clinic, P.C.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-8-Attach-1.DOC

McCOOK CLINIC, P.C.

1401 East H Street, Suite B, P.O. Box 1207 • McCook, NE 69001 • 308-345-4110

Mark W. Serbousek, M.D.
Richard F. Klug, M.D.
Corinne Phillips-Ward, M.D.
John W. West, M.D.
Lori L. Reece, M.D.

Toby D. Free, M.D.
Kathleen Farrell, M.D.
Brett Schmitz, PA-C
Charles Krysl, PA-C
JoAnn Sueper, PA-C

March 15, 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: Our comment concerns the proposed rules for resupplying drugs that require immediate administration.

Proposal (1) The drugs were required immediately.

Proposal (2) The physician could not have anticipated the need for the drug.

Proposal (3) The vendor could not have delivered the drugs in a timely manner.

Proposal (4) The drugs were administered in an emergency situation.

There is concern with proposal (4) due to the fact that all of these criteria assume that a medication would only be immediately necessary in an emergency situation that directly relates back to the definition of emergency. Is the immediate administration of an intramuscular antibiotic an emergency situation? We contend that the answer would be NO but for the sake of appropriate treatment of the patient and delivery of quality healthcare is it required immediately. We say YES! Would a patient with acute joint pain requiring administration of an analgesic injection say that the situation is an emergency, POSSIBLY? Would we contend that it was an emergency situation, NO but we would like to treat the patient immediately to alleviate their pain without waiting for a vendor to deliver the product.

We therefore propose that proposal (4) be eliminated or the that the definition of emergency be expanded to include all products that require immediate administration, could not have been anticipated, and for which the vendor is unable to provide in the appropriate time frame for the standard of care required based on the diagnosis of the patient's conditions.

Sincerely,

Corinne Phillips-Ward, M.D.
McCook Clinic, P.C.

CMS-1325-P-9

**Medicare Part B - Competitive Acquisition of Outpatient Drugs and
Biologicals**

Submitter : Ms. Brian Rokusek

Date & Time: 03/15/2005

Organization : McCook Clinic, P.C.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-9-Attach-1.DOC

McCOOK CLINIC, P.C.

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March 15, 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: Statutory Requirements Concerning Claims Processing

We are concerned that the dispense as written (DAW) provision of this program unfairly increases costs to small and rural providers of healthcare services since it utilizes the current ASP methodology of reimbursement. The ASP pricing system assumes that all providers have equal access to pricing but in reality small and rural healthcare providers seldom receive the pricing that larger entities obtain for the products they dispense. This results in the reimbursement levels being set far below the actual product costs for small and rural healthcare providers. We would propose that a provision be added to allow federally designated healthcare professional shortage areas to be reimbursed at invoice cost for products that are required to be administered (DAW).

Brian Rokusek
Practice Administrator
McCook Clinic, P.C.

CMS-1325-P-10

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. Jeffrey Shinoda

Date & Time: 03/17/2005

Organization : California Oncology

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1325-P-10-Attach-1.DOC

March 15, 2005

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

Re: CMS-1325-P

Ladies and Gentlemen,

In regard to the section "**Overview of the CAP**" page 17, 18, stated that Research Triangle Institute (RTI) was awarded the contract to obtain information and develop alternatives regarding the implementation of the competitive bidding program. As stated RTI consulted with groups representing beneficiaries, physicians and suppliers, drug suppliers, and drug manufacturers. An electronic mailbox MMA303DDrugBid@cms.hhs.gov was established, as well as a Request for Information (RFI). According to your document only 15 responses were received.

As you are aware, this is a very low number. One can only conclude that the research numbers are very inaccurate. Furthermore, if this is any indication of how the proposed ruling of the Competitive Acquisition of Outpatient Drugs and Biologicals Part B was developed, it constitutes further investigation of the true nature of the embodiment, intent, and integrity of this proposed rule.

One may further question who was informed of such research in the interest of good patient care. As of 2003, the current amount of Medicare Beneficiaries were over 40 million¹, The number of members currently enrolled in the American Society of Clinical Oncology (ASCO) is over 16,000², as well as every state has a state board of pharmacy, and state board of medicine. Furthermore, on a national level there is the existence of the American Pharmacists Association with a membership of over 50,000, and the American Society of Health Systems Pharmacist with a membership of over 35,000. Clearly, with the combined numbers of these few mentioned entities listed would have resulted in more than 15 responses in regards to the development of this proposed rule. Moreover, the use of the term "vendor" would not have been placed in this document if such organizations had been involved. The proper term would have been "Pharmacy" and "Pharmacists".

¹ **Sources:** CMS Statistics: Medicare State Enrollment, Centers for Medicare and Medicaid Services, website at <http://cms.hhs.gov/statistics/enrollment/default.asp> .

² Sources: ASCO annual report 2000-2001

In regard to the section entitled "**Claims Processing Overview**" pages 45-64, the proposed arrangement is that the "vendor" would supply pharmaceuticals to a physician's office for a beneficiary (patient). The "vendor" would then submit a claim with a prescription number for the pharmaceutical agent to a designated carrier that would match the date of service submitted for administration by the physician. Despite what you would like to call the pharmaceutical agent, an order, or prescription, the information described throughout the entire process is the filling of a "prescription" for a patient. According to federal as well as state law only a pharmacist may take an order for a prescription. The supplying of the pharmaceutical agent, order, or prescription for a beneficiary (patient) is filling a prescription which must be done by a licensed pharmacist in a licensed pharmacy. Once again the language utilized throughout this entire proposed rule must be in accordance with federal and state law. Therefore the word "vendor" should be changed to licensed Pharmacy and Pharmacists.

In regard to the section entitled "**Competitive Acquisition Areas**" the proposed rule seems to view the pharmaceutical component as a "mail order" pharmacy. The fact that if the "vendor" was limited to a regional setting, or a national setting the "vendor" would only supply the pharmaceutical agents. As a healthcare practitioner it is vital that the "vendor" have an in depth knowledge of providing such pharmaceutical agents. The pharmaceutical drug complexity associated with these medications from drug -drug interactions, to proper dosing, to side effect management, must be available to the physician at the local level in order to continue to provide quality patient care. The fact is that the "Regional" set up on healthcare pharmaceuticals with high drug complexities as well as high cost association is not in the best interest of patient care as well as not cost effective for our healthcare system.

I would like to remind everyone that during the mid 80's when Home infusion pharmacies were dispensing high dollar therapies (prescriptions), several well known pharmaceutical companies produced their own division of home infusion pharmacy and tried to compete against the local home infusion pharmacies. These "Mail Order" pharmacies were awarded certain third party exclusive contracts. They were a regional set up that would Fed-Ex the pharmaceutical product to the patient. Ultimately, because of drug wastage, and poor patient care as well as poor patient service these "mail order vendors" ended up costing the third party insurance carriers more money. Today, these divisions do not even exist.³ In contrast, the local Home infusion pharmacies continue to provide quality care to patients within the local area. Individualized patient care must continue at the local area level to continue to provide the quality healthcare that our patients expect and deserve.

In regard to the section "**Contracting Process-Quality and Product Integrity Aspects**" page 73 clearly states that the propose rule wants to utilize wholesaler, distributors, or distribution centers as the vendors for this contract. This is a violation of Federal and State laws, since even a licensed wholesaler, distributor, or distribution center, cannot

³ The Wall Street Journal Europe May 15, 1996 **MedPartners Proposed Buy of Caremark Would Be the Latest in a Series of Acquisitions**

supply pharmaceutical agents to a physician's office for specific beneficiaries (patients). This is a function of a licensed pharmacist and a licensed pharmacy. Once again I must conclude that full research was not done with all interested parties and must question the intent, integrity and embodiment of this proposed rule. Clearly, the best interest to our beneficiaries (patients) and quality healthcare delivery was not top priority for these oversights to occur throughout this proposed rule.

As I continue to read through out the entire proposal it has become very evident and apparent that the "vendors" are viewed as Wholesalers, distributors, and distribution centers. The entire proposed rule is not in the best interest of patient care, and clearly was written without the input of healthcare professionals associated with providing quality care to our patients. This is not the intent of this proposal nor does it coincide with the mission or vision of CMS. The CMS mission and vision is very simple "We assure health care security for beneficiaries." "In serving beneficiaries, we will open our programs to full partnership with the **entire health community** to improve quality and efficiency in an evolving health care system."⁴ This proposed rule does not reflect the mission, vision and values of CMS as well as the healthcare community.

Thank you very much in regards to these matters. If you should have any questions or concerns, or if I may be of any service to your organization, please do not hesitate to contact me (559) 435-2425 or you can e-mail me at DrShinoda@aol.com.

Partners in Excellence,

Jeffrey K. Shinoda, Pharm. D.
Clinical Pharmacist / Oncology Specialist

⁴ **Sources:** CMS Mission, Vision, Goals and Objectives, Centers for Medicare and Medicaid Services, website at <http://www.cms.hhs.gov/about/mission.asp>

CMS-1325-P-11

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. Jeffrey Shinoda

Date & Time: 03/18/2005

Organization : Jeffrey K. Shinoda, Pharm. D., Inc.

Category : Pharmacist

Issue Areas/Comments

1-15

Bidding Entity Qualifications

In regard to the section entitled "Bidding Entity Qualifications" Clearly, this is slanted for the use of a wholesaler, distributor, or distribution center. This is a dis-service for any pharmacy, or pharmacist that is currently gearing their practice to provide this service to a local physician. The fact that CMS would require a "vendor" to have been in the business of furnishing Part B injectable drugs for at least 3 years has no benefit to medicare beneficiaries (patients). Pharmacies have not been able to bill Medicare for Part B medications, nor are Pharmacists recognized as a medicare healthcare provider. If a physician just graduates, from college, and passes his boards, he can obtain a medicare provider number. This same right must be given to all pharmacists that would like to participate in this CAP program. A new physician does not have to jump through the financial records of audited financial records, nor do they have to substantiate their "drug volume managed" (dollars and units). etc. This section must be redone to include all pharmacists and pharmacies that would like to provide such services to medicare beneficiaries.

Categories of Drugs to be Included under the CAP

In regard to the section "Drugs to be included under the CAP" Clearly, phasing this model will take more thought. First of all, the overall design is incorrect. The fact that the CAP model is utilizing limited "vendors" to do move a pharmaceutical agent as a "commodity" is clearly a dis-service to our patients. A licensed pharmacy, and a licensed pharmacist who is trained in the disease state managements, as well as pharmaceutical managements should be allowed to participate in the CAP program. Any pharmacy, and a licensed pharmacist, can obtain all of the pharmaceutical agents at any given time. So as long as any pharmacist and Pharmacy is allowed to participate in this CAP program, I can see a better service to the physicians, and beneficiaries (patients). Many pharmacies are within any local area, the outreach to supplying the physicians would result in better service.

Claims Processing Overview

In regard to the section entitled 'Claims Processing Overview' pages 45-64, the proposed arrangement is that the 'vendor' would supply pharmaceuticals to a physician's office for a beneficiary (patient). The 'vendor' would then submit a claim with a prescription number for the pharmaceutical agent to a designated carrier that would match the date of service submitted for administration by the physician. Despite what you would like to call the pharmaceutical agent, an order, or prescription, the information described throughout the entire process is the filling of a 'prescription' for a patient. According to federal as well as state law only a pharmacist may take an order for a prescription. The supplying of the pharmaceutical agent, order, or prescription for a beneficiary (patient) is filling a prescription which must be done by a licensed pharmacist in a licensed pharmacy. Once again the language utilized throughout this entire proposed rule must be in accordance with federal and state law. Therefore the word 'vendor' should be changed to licensed Pharmacy and Pharmacists.

Competitive Acquisitions Areas

In regard to the section entitled 'Competitive Acquisition Areas' the proposed rule seems to view the pharmaceutical component as a 'mail order' pharmacy. The fact that if the 'vendor' was limited to a regional setting, or a national setting the 'vendor' would only supply the pharmaceutical agents. As a healthcare practitioner it is vital that the 'vendor' have an in depth knowledge of providing such pharmaceutical agents. The pharmaceutical drug complexity associated with these medications from drug -drug interactions, to proper dosing, to side effect management, must be available to the physician at the local level in order to continue to provide quality patient care. The fact is that the 'Regional' set up on healthcare pharmaceuticals with high drug complexities as well as high cost association is not in the best interest of patient care as well as not cost effective for our healthcare system.

I would like to remind everyone that during the mid 80's when Home infusion pharmacies were dispensing high dollar therapies (prescriptions), several well known pharmaceutical companies produced their own division of home infusion pharmacy and tried to compete against the local home infusion pharmacies. These 'Mail Order' pharmacies were awarded certain third party exclusive contracts. They were a regional set up that would Fed-Ex the pharmaceutical product to the patient. Ultimately, because of drug wastage, and poor patient care as well as poor patient service these 'mail order vendors' ended up costing the third party insurance carriers more money. Today, these divisions do not even exist. In contrast, the local Home infusion pharmacies continue to provide quality care to patients within the local area. Individualized patient care must continue at the local area level to continue to provide the quality healthcare that our patients expect and deserve.

Overview of the CAP

In regard to the section 'Overview of the CAP' page 17, 18, stated that Research Triangle Institute (RTI) was awarded the contract to obtain information and develop alternatives regarding the implementation of the competitive bidding program. As stated RTI consulted with groups representing beneficiaries, physicians and suppliers, drug suppliers, and drug manufacturers. An electronic mailbox MMA303DDrugBid@cms.hhs.gov was established, as well as a Request for Information (RFI). According to your document only 15 responses were received.

As you are aware, this is a very low number. One can only conclude that the research numbers are very inaccurate. Furthermore, if this is any indication of how the proposed ruling of the Competitive Acquisition of Outpatient Drugs and Biologicals Part B was developed, it constitutes further investigation of the true nature of the embodiment, intent, and integrity of this proposed rule.

One may further question who was informed of such research in the interest of good patient care. As of 2003, the current amount of Medicare Beneficiaries were over 40 million, The number of members currently enrolled in the American Society of Clinical Oncology (ASCO) is over 16,000, as well as every state has a state board of pharmacy, and state board of medicine. Furthermore, on a national level there is the existence of the American Pharmacists Association with a membership of over 50,000, and the American Society of Health Systems Pharmacist with a membership of over 35,000. Clearly, with the combined numbers of these few mentioned entities listed would have resulted in more than 15 responses in regards to the development of this proposed rule. Moreover, the use of the term 'vendor' would not have been placed in this document if such organizations had been involved. The proper term would have been 'Pharmacy' and 'Pharmacists'.

Statutory Requirements Concerning Claims Processing

In regard to the section entitled "Statutory Requirements Concerning Claims Processing" Several real case scenarios can be seen where a physician may order a drug, that is not an FDA labeled indication, the agent is not compendia listed for the disease state, and limited information in regards to "peer" review articles are unavailable. Current statutory requirements must address such issues. In such an event, will the "vendor" still be paid for the pharmaceutical agent even if it is for the wrong diagnosis? Since the "vendor" in this model is not a licensed pharmacist or licensed pharmacy, they cannot be held accountable for inappropriate usage of the pharmaceutical agent.

CMS-1325-P-12

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. Gerard Ventura

Date & Time: 03/18/2005

Organization : Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

also here:

Subject: CAP brief comments

> 1) Without price controls on the drugs from the true source - the manufacturer - any talk of "competition" in the acquisition process to bring down CMS costs is an illusion. Case in point: We already have a fair number of drug wholesalers with huge economies of scale competing with each other for our business (Florida infusion, Schein, etc) - and that didn't lower prices. Why would the same system, only extending it directly into the arena of patient care, be expected to? The exorbitant prices and their increases remain unregulated at the source.

Congress needs to face the political reality and fix the problem at the source. Medicare has limiting charges on doctor visits, hospital stays, durable med equipment, etc - it needs to have it for drugs as well.

> 2) The extra layers of administration, book-keeping, tracking shipments, etc etc will add further costs to the program in the doctor's office/clinic way beyond the present costs. I believe most offices will either continue buying the drugs themselves, or give up administration entirely, forcing it into the hospital outpatient setting (paradoxically further driving up CMS costs).

3) Taking drug delivery out of the oncologists office will not stop the (hopefully) few doctors who give too many drugs too often out of abuse, as they will continue to bill for administration, visits, etc. Ironically again, those very few bad apples will probably increase their pattern of abuse in such a system.

4) This proposed system is disturbing, in that it has a whole 'Rube Goldberg' feel to it that is divorced from the reality of cancer care. The biggest stumbling block, once again, is the true source of the problem -

an FDA which approves drugs without consideration of cost, and the prohibition against negotiating cost from the manufacturer. That will destroy any house of cards no matter how elegant on paper.

- > Gerard Ventura MD
- > Nacogdoches, Texas

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

CMS-1325-P-13

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. Eric White

Date & Time: 03/18/2005

Organization : Integrated Care Systems

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

After careful review of the proposed CAP rule (CMS-1325-P) it has become evident that the use of the word vendor is being viewed as a Wholesaler, Distributor, or Distribution Center. As you are aware these pharmaceutical agents, are more than just a commodity. They are pharmaceutical agents utilized to treat a specific disease state. More importantly, what is described is a pharmaceutical agent for a specific patient. This is a prescription. In light of this, the only qualified and legal person allowed by federal and state law to dispense such an order for a patient is a licensed pharmacist in a licensed pharmacy.

I have reviewed the letter submitted by Dr. Jeffrey K. Shinoda, in Fresno, CA. I must agree with his points entirely. The ultimate goal of any healthcare provider is to provide quality patient care including the Medicare beneficiary. What has been described in this proposed rule is an injustice to patients and the healthcare community.
Eric White, Pharm.D. 03/18/05

Submitter :

Date: 03/18/2005

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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CMS-1325-P-15

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Mrs. Kristen Whiteley

Date & Time: 03/19/2005

Organization : Mrs. Kristen Whiteley

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

After careful review of the proposed CAP rule (CMS-1325-P) it has become evident that the use of the word vendor is being viewed as a Wholesaler, Distributor, or Distribution Center. As you are aware these pharmaceutical agents, are more than just a commodity. They are pharmaceutical agents utilized to treat a specific disease state. More importantly, what is described is a pharmaceutical agent for a specific patient. This is a prescription. In light of this, the only qualified and legal person allowed by federal and state law to dispense such an order for a patient is a licensed pharmacist in a licensed pharmacy.

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"see Attachment"

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

March 15, 2005

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

Re: CMS-1325-P

Ladies and Gentlemen,

In regard to the section "**Overview of the CAP**" page 17, 18, stated that Research Triangle Institute (RTI) was awarded the contract to obtain information and develop alternatives regarding the implementation of the competitive bidding program. As stated RTI consulted with groups representing beneficiaries, physicians and suppliers, drug suppliers, and drug manufacturers. An electronic mailbox MMA303DDrugBid@cms.hhs.gov was established, as well as a Request for Information (RFI). According to your document only 15 responses were received.

As you are aware, this is a very low number. One can only conclude that the research numbers are very inaccurate. Furthermore, if this is any indication of how the proposed ruling of the Competitive Acquisition of Outpatient Drugs and Biologicals Part B was developed, it constitutes further investigation of the true nature of the embodiment, intent, and integrity of this proposed rule.

One may further question who was informed of such research in the interest of good patient care. As of 2003, the current amount of Medicare Beneficiaries were over 40 million¹, The number of members currently enrolled in the American Society of Clinical Oncology (ASCO) is over 16,000², as well as every state has a state board of pharmacy, and state board of medicine. Furthermore, on a national level there is the existence of the American Pharmacists Association with a membership of over 50,000, and the American Society of Health Systems Pharmacist with a membership of over 35,000. Clearly, with the combined numbers of these few mentioned entities listed would have resulted in more than 15 responses in regards to the development of this proposed rule. Moreover, the use of the term "vendor" would not have been placed in this document if such organizations had been involved. The proper term would have been "Pharmacy" and "Pharmacists".

¹ Sources: CMS Statistics: Medicare State Enrollment, Centers for Medicare and Medicaid Services, website at <http://cms.hhs.gov/statistics/enrollment/default.asp> .

² Sources: ASCO annual report 2000-2001

In regard to the section entitled "**Claims Processing Overview**" pages 45-64, the proposed arrangement is that the "vendor" would supply pharmaceuticals to a physician's office for a beneficiary (patient). The "vendor" would then submit a claim with a prescription number for the pharmaceutical agent to a designated carrier that would match the date of service submitted for administration by the physician. Despite what you would like to call the pharmaceutical agent, an order, or prescription, the information described throughout the entire process is the filling of a "prescription" for a patient. According to federal as well as state law only a pharmacist may take an order for a prescription. The supplying of the pharmaceutical agent, order, or prescription for a beneficiary (patient) is filling a prescription which must be done by a licensed pharmacist in a licensed pharmacy. Once again the language utilized throughout this entire proposed rule must be in accordance with federal and state law. Therefore the word "vendor" should be changed to licensed Pharmacy and Pharmacists.

In regard to the section entitled "**Competitive Acquisition Areas**" the proposed rule seems to view the pharmaceutical component as a "mail order" pharmacy. The fact that if the "vendor" was limited to a regional setting, or a national setting the "vendor" would only supply the pharmaceutical agents. As a healthcare practitioner it is vital that the "vendor" have an in depth knowledge of providing such pharmaceutical agents. The pharmaceutical drug complexity associated with these medications from drug -drug interactions, to proper dosing, to side effect management, must be available to the physician at the local level in order to continue to provide quality patient care. The fact is that the "Regional" set up on healthcare pharmaceuticals with high drug complexities as well as high cost association is not in the best interest of patient care as well as not cost effective for our healthcare system.

I would like to remind everyone that during the mid 80's when Home infusion pharmacies were dispensing high dollar therapies (prescriptions), several well known pharmaceutical companies produced their own division of home infusion pharmacy and tried to compete against the local home infusion pharmacies. These "Mail Order" pharmacies were awarded certain third party exclusive contracts. They were a regional set up that would Fed-Ex the pharmaceutical product to the patient. Ultimately, because of drug wastage, and poor patient care as well as poor patient service these "mail order vendors" ended up costing the third party insurance carriers more money. Today, these divisions do not even exist.³ In contrast, the local Home infusion pharmacies continue to provide quality care to patients within the local area. Individualized patient care must continue at the local area level to continue to provide the quality healthcare that our patients expect and deserve.

In regard to the section "**Contracting Process-Quality and Product Integrity Aspects**" page 73 clearly states that the propose rule wants to utilize wholesaler, distributors, or distribution centers as the vendors for this contract. This is a violation of Federal and State laws, since even a licensed wholesaler, distributor, or distribution center, cannot

³ The Wall Street Journal Europe May 15, 1996 **MedPartners Proposed Buy of Caremark Would Be the Latest in a Series of Acquisitions**

supply pharmaceutical agents to a physician's office for specific beneficiaries (patients). This is a function of a licensed pharmacist and a licensed pharmacy. Once again I must conclude that full research was not done with all interested parties and must question the intent, integrity and embodiment of this proposed rule. Clearly, the best interest to our beneficiaries (patients) and quality healthcare delivery was not top priority for these oversights to occur throughout this proposed rule.

As I continue to read through out the entire proposal it has become very evident and apparent that the "vendors" are viewed as Wholesalers, distributors, and distribution centers. The entire proposed rule is not in the best interest of patient care, and clearly was written without the input of healthcare professionals associated with providing quality care to our patients. This is not the intent of this proposal nor does it coincide with the mission or vision of CMS. The CMS mission and vision is very simple "We assure health care security for beneficiaries." "In serving beneficiaries, we will open our programs to full partnership with the **entire health community** to improve quality and efficiency in an evolving health care system."⁴ This proposed rule does not reflect the mission, vision and values of CMS as well as the healthcare community.

Thank you very much in regards to these matters. If you should have any questions or concerns, or if I may be of any service to your organization, please do not hesitate to contact me (559) 435-2425 or you can e-mail me at DrShinoda@aol.com.

Partners in Excellence,

Jeffrey K. Shinoda, Pharm. D.
Clinical Pharmacist / Oncology Specialist

⁴ **Sources:** CMS Mission, Vision, Goals and Objectives, Centers for Medicare and Medicaid Services, website at <http://www.cms.hhs.gov/about/mission.asp>

CMS-1325-P-16

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Mrs. Mary Jo Ferro

Date & Time: 03/19/2005

Organization : Mrs. Mary Jo Ferro

Category : Individual

Issue Areas/Comments**GENERAL**

GENERAL

After careful review of the proposed CAP rule (CMS-1325-P) it has become evident that the use of the word 'vendor' is being viewed as a Wholesaler, Distributor, or Distribution Center. As you are aware these pharmaceutical agents, are more than just a commodity. They are pharmaceutical agents utilized to treat a specific disease state. More importantly, what is described is a pharmaceutical agent for a specific patient. This is a prescription. In light of this, the only qualified and legal person allowed by federal and state law to dispense such an order for a patient is a licensed pharmacist in a licensed pharmacy.

I have reviewed the letter submitted by Dr. Jeffrey K. Shinoda, in Fresno, CA. I must agree with his points entirely. The ultimate goal of any healthcare provider is to provide quality patient care including the Medicare beneficiary. What has been described in this proposed rule is an injustice to patients and the healthcare community.

CMS-1325-P-17

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Mrs. Bettina Vernon

Date & Time: 03/21/2005

Organization : Mrs. Bettina Vernon

Category : Individual

Issue Areas/Comments**GENERAL**

GENERAL

After careful review of the proposed CAP rule (CMS-1325-P) it has become evident that the use of the word "vendor" is being viewed as a Wholesaler, Distributor, or Distribution Center. As you are aware these pharmaceutical agents, are more than just a commodity. They are pharmaceutical agents utilized to treat a specific disease state. More importantly, what is described is a pharmaceutical agent for a specific patient. This is a prescription. In light of this, the only qualified and legal person allowed by federal and state law to dispense such an order for a patient is a licensed pharmacist in a licensed pharmacy.

I have reviewed the letter submitted by Dr. Jeffrey K. Shinoda, in Fresno, CA. I must agree with his points entirely. The ultimate goal of any healthcare provider is to provide quality patient care including the Medicare beneficiary. What has been described in this proposed rule is an injustice to patients and the healthcare community.

CMS-1325-P-18

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals**Submitter :****Date & Time:** 03/21/2005**Organization :****Category :** Individual**Issue Areas/Comments**

GENERAL

GENERAL

After careful review of the proposed CAP rule (CMS-1325-P) it has become evident that the use of the word "vendor" is being viewed as a Wholesaler, Distributor, or Distribution Center. As you are aware these pharmaceutical agents, are more than just a commodity. They are pharmaceutical agents utilized to treat a specific disease state. More importantly, what is described is a pharmaceutical agent for a specific patient. This is a prescription. In light of this, the only qualified and legal person allowed by federal and state law to dispense such an order for a patient is a licensed pharmacist in a licensed pharmacy.

I have reviewed the letter submitted by Dr. Jeffrey K. Shinoda, in Fresno, CA. I must agree with his points entirely. The ultimate goal of any healthcare provider is to provide quality patient care including the Medicare beneficiary. What has been described in this proposed rule is an injustice to patients and the healthcare community.

CMS-1325-P-19

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. ERIC WESTERMAN

Date & Time: 03/22/2005

Organization : COLORADO ARTHRITIS CENTER

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

DEAR SIRs:

I HAVE BEEN INFUSING REMICADE IN MY OFFICE FOR A FEW YEARS AND HAVE BEEN VERY CONCERNED ABOUT COST CONTAINMENT FOR THIS VERY IMPORTANT YET EXPENSIVE DRUG. WE TYPICALLY DO NOT ACCEPT ASSIGNMENT ON MEDICARE AND JUST FOUND OUT, AS A RESULT, THAT WE MUST NOW SEND ALL OF OUR PATIENT'S TO THE HOSPITAL AS THE REIMBURSEMENT FOR REMICADE IS LOWER FOR THESE PEOPLE THAN THE COST OF THE DRUG. THIS REALLY IS CREATING MORE EXPENSES (HOSPITAL 3 TIMES AS EXPENSIVE THAN MY OFFICE) AND DIFFICULTY FOR THE PATIENT'S. WE PLAN ON TAKING ASSIGNMENT IN THE FUTURE BUT CANNOT DO SO UNTIL NEXT YEAR. I AM HOPING THAT THIS SITUATION CAN BE REMEDIED SOONER FOR THE SAKE OF MY PATIENTS AND FROM A COST SAVINGS PERSPECTIVE

DR ERIC M. WESTERMAN

CMS-1325-P-20

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals**Submitter :** Mr. Brett Sutton**Date & Time:** 03/25/2005**Organization :** Sutton Hatmaker Law Corporation**Category :** Individual**Issue Areas/Comments****GENERAL**

GENERAL

After careful review of the proposed CAP rule (CMS-1325-P) it has become evident that the use of the word vendor is being viewed as a Wholesaler, Distributor, or Distribution Center. As you are aware these pharmaceutical agents, are more than just a commodity. They are pharmaceutical agents utilized to treat a specific disease state. More importantly, what is described is a pharmaceutical agent for a specific patient. This is a prescription. In light of this, the only qualified and legal person allowed by federal and state law to dispense such an order for a patient is a licensed pharmacist in a licensed pharmacy.

I have reviewed the letter submitted by Dr. Jeffrey K. Shinoda, in Fresno, CA. I must agree with his points entirely. The ultimate goal of any healthcare provider is to provide quality patient care including the Medicare beneficiary. What has been described in this proposed rule is an injustice to patients and the healthcare community.

CMS-1325-P-21

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals**Submitter :** Mr. Thomas Harris**Date & Time:** 03/27/2005**Organization :** Mr. Thomas Harris**Category :** State Government**Issue Areas/Comments****GENERAL**

GENERAL

After careful review of the proposed CAP rule (CMS-1325-P) it has become evident that the use of the word vendor is being viewed as a Wholesaler, Distributor, or Distribution Center. As you are aware these pharmaceutical agents, are more than just a commodity. They are pharmaceutical agents utilized to treat a specific disease state. More importantly, what is described is a pharmaceutical agent for a specific patient. This is a prescription. In light of this, the only qualified and legal person allowed by federal and state law to dispense such an order for a patient is a licensed pharmacist in a licensed pharmacy.

I have reviewed the letter submitted by Dr. Jeffrey K. Shinoda, in Fresno, CA. I must agree with his points entirely. The ultimate goal of any healthcare provider is to provide quality patient care including the Medicare beneficiary. What has been described in this proposed rule is an injustice to patients and the healthcare community.

CMS-1325-P-22

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter :

Date & Time: 03/28/2005

Organization :

Category : Pharmacist

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

mental health drugs

Submitter : Mrs. Laura Welch

Date: 03/28/2005

Organization : Andrews Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

We would like to have the CAP(Competitive Acquisition Program) to provide the accessibility of Risperdal Consta just like an oral medication for dually eligible patients.

Submitter : Ms. Linda Bennis

Date: 03/28/2005

Organization : Hematology Oncology Associates of W. Suffolk, P.C.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Our practice would like to highlight questions of procedure as you prepare CAP rules and regulations for January, 2006.

1. Would Physicians be required to order ALL medications for a patient's treatment, including promeds and dilution solutions with the 'vendor of choice'?
2. Would Physicians have to store each patient's medications separately from other patients which would require large storage areas and refrigeration capacities? Would received drugs be able to be placed into general inventory?
3. Would each patient's medications be held exclusively for them, and treatments begun only when ALL medications were received?
4. Would the physician be held harmless for any incurred delays due to medication delivery?
5. Would changes in therapy require the patient to be rescheduled while waiting for the new order to be made and received?
6. Would the physician be held harmless for any incurred delay due to medication changes?
7. When changes in therapy occur and the medication on hand is no longer needed, will the physician be able to return it and credit be given to Medicare? Would the physician be able to use it for another Medicare patient (not bill Medicare for the medication)and thereby reduce costs to Medicare?
8. What recourse will be available to practices if service issues develop with the chosen vendor effecting prompt shipment or quality of the medication?
9. Will practices be able to code for drug disposal and waste expenses?

The physician currently holds all responsibility, including financial, when too much medication or the incorrect medication is ordered or treatment is delayed. If 'vendors of choice' become the intermediary, there will be medication wasted and Medicare will shoulder the financial liability. The big question is who will be held accountable if this slower method of delivery compromises care?

Linda Bennis, CMM
Office Manager
Hematology Oncology Associates of W. Suffolk
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Bay Shore, NY 11706
631-666-3555,x137
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CMS-1325-P-25

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. William Stein, III

Date & Time: 03/28/2005

Organization : HOS, L.L.C.

Category : Physician

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

Drugs provided by the CAP provider should be sent to the physicians in UNOPENED and timely dated original packaging. CAP providers must be licensed in the States within which they operate and subject to the laws of the States in which they operate. This should include the payment of all applicable sales and business taxes.

Competitive Acquisitions Areas

Will CAP providers be governed by ASP+6% and since they are a different class of trade than physicians and will pay a higher price, this will mean less of a spread for them. Will there be an adjustment just for the CAP providers in favor of their business but detrimental to physicians and patients?

Contracting Process-Quality and Product Integrity Aspects

It is imperative that the CAP providers be required to carry Insurance for Omissions and Commissions. Undoubtedly, they will make mistakes that will be harmful to patients and it is imperative that patients are protected.

Overview of the CAP

As a practicing oncologist, I have several concerns about the proposed rule.

1. I do not have the personnel nor the facilities to collect demographic information to provide to the CAP provider to assist in their billing.
2. I do not have the space or facilities to allow the CAP provider to come to my office to collect this information.
3. If the CAP provider is unable to collect coinsurance from the patient, does that mean that the patient will not be able to get their chemotherapy?
4. I can not be responsible for storing or caring for any unused medication in the event that a patient either does not show up for treatment or is unable to take it once the drugs are delivered.
5. Since I have closed my infusion center and released my nurse

and staff, I no longer have the ability to mix chemotherapy that has a very short stability time. How am I supposed to take care of these patients?

6. Since local private hospitals are no longer accepting Medicaid patients for chemotherapy and I can no longer see them, does this mean that they will now be able to receive chemotherapy? What happens if Medicaid does not pay the coinsurance?

7. Since Medicaid does not reimburse for administration in my State, who will give these patients chemotherapy?

8. Since there is a sales tax on drugs in my State of 5%, who is responsible for collecting this tax from patients and paying the State? If the patients do not pay the sales tax, who is liable and can they still be treated?

9. As I no longer have an infusion center and can no longer afford to open my office for administration of chemotherapy, where am I to send patients for this service on weekends and will the CAP provider be available to deliver drugs 24 hours a day, seven days a week? If not who will set the hours for patients who do not want to miss work? What will happen on holidays?

10. If a CAP provider goes out of business, as we have done, who will provide the chemotherapy in our region since these facilities are costly and time consuming to establish? Will the PRO allow these patients to be admitted to local hospitals?

11. Who will be responsible for resolving payment disagreements with the CAP? If Medicare is late paying, as is frequently the case, and the CAP provider delays delivery, what are the patients to do?

12. How will administration documentation be provided to the CAP provider so that they can submit a bill to the carrier and who will be responsible for insuring that this happens? Who will decide what a reasonable time period is and what will the penalties be for poor compliance? What agency will arbitrate this on behalf of the patients?

13. Who will be responsible for establishing a formulary and what happens if the physician feels a drug not on the CAP provider's formulary is best for his or her patient? How will formulary issues be resolved?

14. Will the CAP provider have the ability to exclude drugs from their formulary based solely upon financial impact on them? What happens if such a decision on the part of the CAP adversely effects patients or physicians medically or economically?

15. In anticipation of these changes, Medicaid patients are no longer being treated, infusion centers are being closed and nurses are being let go. What happens to the rest of our patients if this experiment doesn't work?

Thanks,

William Stein, III, M.D.

4228 Houma Blvd. #130

Metairie, La. 70006

504 883 2960

CMS-1325-P-26 Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. Robert Jeppson

Date & Time: 03/29/2005

Organization : Dr. Robert Jeppson

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-26-Attach-1.TXT

CMS-1325-P-27 Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Michael Stevens

Date & Time: 03/30/2005

Organization : Valley Mental Health

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment Michael C Stevens, M.D.

CMS-1325-P-27-Attach-1.DOC

I am writing in regards to the competitive acquisition of outpatient drugs and biologicals under CMS-1325-P; Medicare Part B. This is an area of great concern to me particularly as to the effects of decisions on the accessibility and use patterns of anti-psychotic medications. My research has included serving as a Principal Investigator in the Clinical Trials of Intervention Effectiveness (CATIE), a large Comparative study of anti-psychotics in conditions of usual clinical care,, funded by the NIMH.

I believe several fundamental areas of knowledge need to be delineated . The are, unfortunately, receiving little attention, yet are part of the critical knowledge base for making the decisions under consideration.

1. Second-generation anti-psychotic drugs are not “me-too” drugs. They each have distinct effects on both dopaminergic systems, and serotonergic systems. These affects, with other factors, result in enormous variability across individuals in response to these agents., both in regards to efficacy, and tolerability. We have no markers to predict differential response and tolerability across Individuals. It would be a serious error to limit access to these medications. Where this has been done by state Medicaid agencies, the effects have generally Been remarkably bad. In Kentucky, the total antipsychotic cost went up when one was eliminated from access. In New Hampshire, the pharmacy budget dropped when one was eliminated, but the disease management costs per Individual rose – in other words, eliminating access to one drug had a Significantly negative effect on clinical outcomes.
2. I mentioned disease management costs. Schizophrenia, Bipolar Disorder and Psychiatric disorders are biological brain disorders that most often begin in early adulthood, and persist through a persons life. The critical questions to be asked About any treatment are:
 - a. how effective is it compared to other treatments.?
 - b. Is the medicine cost-effective (or does it have cost-utility” ?These questions are enormously important to Medicaid and Medicare decisions On spending – the treatments that are most cost-effective should be utilized, not The treatments that have the lowest acquisition costs.
3. The first question has been answered in numerous studies showing more robust treatment effects, and greatly improved tolerability, especially in regards to neurological side effects.
4. The second question, the pharmacoeconomics of these agents, has been subject to many studies, virtually all showing at least equal, and often superior cost-effectiveness to 1st generation anti-psychotics. It is terribly misguided, and without scientific merit, to use acquisition costs as the “measure” of a drugs value.

4. I am particularly concerned about access to a very important improvement in these agents. In brief, since anti-psychotics were discovered, there have only been 2 major developments in this drug class. The first is the development of atypical anti-psychotics, and the second is the use of long-acting non-self-administered injectible forms of anti-psychotics.

We now have one 2nd generation agent in a long acting injectible form, and we should be assessing its value very carefully. Adherence to anti-psychotics, including 2nd generation anti-psychotics, is only about 50% when taken orally. Long-acting injectible non-self-administered forms of these medicines give us the opportunity to dramatically improve adherence to anti-psychotic medication. Non-adherence to oral anti-psychotic agents can rightfully be thought of as the "elephant in the living room" of our efforts to improve outcomes. It's a huge problem, and we have been ineffective in eliminating its enormous negative effects, yet we do not address it nearly as prominently and substantially as we should. This problem has sabotaged our efforts to take full advantage of the superior new anti-psychotics that have been developed. We need to make these medications accessible to clinicians and their patients as easily as other treatments.

To do so will, in the real world of community mental health systems, require that they be included in the pharmacy benefit of this program. CMHCs simply do not have the infrastructure to deal with complex billing and reimbursement systems. The only way to see what these long-acting injectible anti-psychotic agents are capable of, in improving adherence, and outcomes of anti-psychotic treatment is to roll them into the same funding structure – the pharmacy benefit, as other medicines, and as was the case with 1st generation long-acting injectible agents. This is the only way we will take advantage of the remarkable scientific advances in both medicines, and medicine-delivery technology, that are occurring. For anti-psychotic medications, they represent the capacity, for the first time, to utilize the two major advances in anti-psychotic treatment in a single entity, and every effort should be made to make clinicians aware that these are available choices. In the real world, making them part of the pharmacy benefit is the only practical way to do so.

Michael C Stevens, M.D.
Director, Psychopharmacology Research
Unit
Valley Mental Health
Salt Lake City, Utah.

CMS-1325-P-28

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. Michael Stumpf

Date & Time: 03/31/2005

Organization : Pinal Gila Behavioral Health Association

Category : Physician

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

Michael H. Stumpf, MD, DFAPA
Certified in Psychiatry, American Board of Psychiatry and Neurology
Pinal Gila Behavioral Health Association
2066 West Apache Trail Ste 116
Apache Junction, Arizona 85220
Phone (480) 982 1317
Fax (480) 982 7320

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS ? 1325 ? P

March 31, 2005

To Whom It May Concern:

I am the Chief Medical Officer for Pinal Gila Behavioral Health Association, which is the Regional Behavioral Health Authority contracted with Arizona Department of Health Services Division of Behavioral Health Services to plan, develop, and oversee a system of behavioral health services in Pinal and Gila Counties in Arizona. In addition, I serve as Public Affairs Chair for the Arizona Psychiatric Society (the state branch of the American Psychiatric Association) and am an Associate Professor for Midwestern University Arizona College of Osteopathic Medicine.

Long-acting injectable preparations of antipsychotics are highly desirable in treatment of chronic mental disorders such as Schizophrenia, in which poor patient adherence to treatment can result in expensive exacerbation of disorder. Multiple studies have shown that treatment costs go up when barriers exist to effective treatment for individuals with severe and chronic mental disorders. It is to the patients' advantage, society's advantage, and the taxpayers' advantage to ensure availability without barrier of all long-acting injectable antipsychotic medications.

Currently, a barrier exists in prescription of long-acting injectable anti-psychotic medications for the dual eligible population, in that long-acting injectable anti-psychotic medications cannot be billed under the individual patient unless pre-purchased by the facility, thus often preventing patients from receiving medications which may save money in the long term.

Please consider having all long-acting injectable antipsychotic medications available as a Medicare Outpatient Pharmacy benefit.

Sincerely,

Michael H. Stumpf, MD, DFAPA
Certified in Psychiatry, American Board of Psychiatry and Neurology

CMS-1325-P-28-Attach-1.WPD

PINAL GILA BEHAVIORAL HEALTH ASSOCIATION

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www.pgbha.org



Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS – 1325 – P

March 31, 2005

To Whom It May Concern:

I am the Chief Medical Officer for Pinal Gila Behavioral Health Association, which is the Regional Behavioral Health Authority contracted with Arizona Department of Health Services Division of Behavioral Health Services to plan, develop, and oversee a system of behavioral health services in Pinal and Gila Counties in Arizona. In addition, I serve as Public Affairs Chair for the Arizona Psychiatric Society (the state branch of the American Psychiatric Association) and am an Associate Professor for Midwestern University Arizona College of Osteopathic Medicine.

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Currently, a barrier exists in prescription of long-acting injectable anti-psychotic medications for the dual eligible population, in that long-acting injectable anti-psychotic medications cannot be billed under the individual patient unless pre-purchased by the facility, thus often preventing patients from receiving medications which may save money in the long term.

Please consider having all long-acting injectable antipsychotic medications available as a Medicare Outpatient Pharmacy benefit.

Sincerely,

Michael H. Stumpf, MD, DFAPA
Certified in Psychiatry, American Board of Psychiatry and Neurology

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CMS-1325-P-29

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. Daniel Luchins

Date & Time: 03/31/2005

Organization : University of Chicago

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

With the use of long acting injectable antipsychotic medications by persons with serious and persistent mental illnesses it would be important that this program include antipsychotic agents. The newer are expensive and most of the patients receiving these agents are cared for in the public mental health system which cannot "front" the cost of these medications.

CMS-1325-P-30

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Ms. Sharon Van Marter

Date & Time: 04/01/2005

Organization : Syracuse Hematology/Oncology PC

Category : Health Care Professional or Association

Issue Areas/Comments**GENERAL**

GENERAL

The CAP program will be a huge burden on practices. The CAP program will NOT save money and decrease administrative burdens, but rather will increase costs for practices who have to inventory drugs differently, individually by patient name and who will require additional space necessary for individual drug inventory. Record keeping will double, as well as man hours for data entries and management. Also, the distributors chosen by medicare will not be as efficient in the management of patient drugs, billing and collection of co-pays and deductibles. We are very concerned about the bad debt patients will ultimately rack up, as they have in our community practices for decades, and how the distributors will handle drug shipments when the patients do not pay the appropriate dollars. Medicare has chosen to ignore bad debt associated with our practices, but now must be able to deal with it on another level and still maintain drug shipments.

In addition, the "temporary" G codes for administration and the new 15 minute rule for infusions vs IVP is a fraud and abuse issue, as this ruling is in direct opposition to the Correct Coding Initiative, which is a LAW. The work and preparation for an infusion is clearly more labor intensive and time consuming, before the drugs are even administered, from an IVP, and CMS and the AMA have absolutely no right to inappropriately say otherwise.

The CAP program will delay treatments for patients, as ordering will not occur until after treatment plans are in place. As there is liability in delaying treatment to seriously ill patients, how do we get by the liability lawyers circling the wagons while CMS plays games with a well established and effective means of delivering care to cancer patients? Since the federal government cannot be sued, that leaves the providers hanging out there on a very shaky limb....

In addition, the delays in ordering the drugs will necessitate our bringing patients back into the office more than once, utilizing more E/M services and costing CMS more in the long run.

It makes no sense to purposely disrupt and force major changes in a well established delivery system. This is obviously intended by CMS and the present administration, to save money by foul and unethical means. Forcing providers to ration cancer care to medicare and medicaid patients is a devastating blow to the providers and patients alike. Perhaps some honesty from the government about saving money and being up front about CMS's true issue, ie. "do the ends justify the means" in the elderly and indigent cancer patient population would help everyone in the country understand what HHS/CMS is really trying to accomplish. Backing the providers of cancer care into corners to protect budgets and save money is dishonest, obscene, unethical and would be illegal in the private sector.

There is a way for cost cutting measures to work, but the government has no right to proceed without the community oncologists involved. You have neither the education, experience or mindset to properly change the cancer care delivery system.

This entire ASP plus the grossly underpaid 6%, and the CAP program for 2006 will also give the private insurance payers free reign to do their dirty

deeds, which have already started, thus causing the rationing, withholding and denying of cancer care to all patient age populations. Somewhere along the line, the American citizenry will stand up and fight back, but unfortunately not in time to save the elderly and indigent from being forced into rationing programs that keep them pain free but allow them to die much sooner. Would your grandparents' lives be worth more than mine? Should they all be allowed to die 18 months to 48 months sooner to save money for the federal government? How about the congressmen and senators all decreasing their income and benefits and place those dollars into a fund to help pay for cancer care to their medicare constituents?

Submitter : Dr. Michael Measom
Organization : Valley Mental Health
Category : Health Care Professional or Association

Date: 04/01/2005

Issue Areas/Comments

GENERAL

GENERAL

Hello, my name is Michael Measom and I am an addiction psychiatrist that works in a community mental health center (CMHC) in Salt Lake City, Utah. I am writing to you express my concern as I foresee issues that will arise pertaining to access to care issues.

First, I am concerned about a CMHC needing to do ?buy and bill? in order to get medication for a patient. This raises a few concerns for me.

First, it asks the CHMC to assume the financial responsibility and risk. CMHC?s are often strapped financially, not to mention that they would assume a credit risk.

Second, CMHCs often lack the infrastructure to do this medical benefit. Moreover, there will be an increased need for resources and staff regarding billing, inventory, and patient tracking.

Third, and most importantly to me, I am concerned that there will be less than optimal care. By this I mean that there will be are instances where the most appropriate medicine is chosen by ease of access not efficacy or what is in the patients best interest

Thank you for your time,

Michael Measom, MD

Submitter : Ms. M Chang

Date: 04/04/2005

Organization : Ms. M Chang

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

After careful review of the proposed CAP rule (CMS-1325-P) it has become evident that the use of the word vendor is being viewed as a Wholesaler, Distributor, or Distribution Center. As you are aware these pharmaceutical agents, are more than just a commodity. They are pharmaceutical agents utilized to treat a specific disease state. More importantly, what is described is a pharmaceutical agent for a specific patient. This is a prescription. In light of this, the only qualified and legal person allowed by federal and state law to dispense such an order for a patient is a licensed pharmacist in a licensed pharmacy.

I have reviewed the letter submitted by Dr. Jeffrey K. Shinoda, in Fresno, CA. I must agree with his points entirely. The ultimate goal of any healthcare provider is to provide quality patient care including the Medicare beneficiary. What has been described in this proposed rule is an injustice to patients and the healthcare community.

CMS-1325-P-32-Attach-1.PDF

March 15, 2005

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

Re: CMS-1325-P

Ladies and Gentlemen,

In regard to the section "**Overview of the CAP**" page 17, 18, stated that Research Triangle Institute (RTI) was awarded the contract to obtain information and develop alternatives regarding the implementation of the competitive bidding program. As stated RTI consulted with groups representing beneficiaries, physicians and suppliers, drug suppliers, and drug manufacturers. An electronic mailbox MMA303DDrugBid@cms.hhs.gov was established, as well as a Request for Information (RFI). According to your document only 15 responses were received.

As you are aware, this is a very low number. One can only conclude that the research numbers are very inaccurate. Furthermore, if this is any indication of how the proposed ruling of the Competitive Acquisition of Outpatient Drugs and Biologicals Part B was developed, it constitutes further investigation of the true nature of the embodiment, intent, and integrity of this proposed rule.

One may further question who was informed of such research in the interest of good patient care. As of 2003, the current amount of Medicare Beneficiaries were over 40 million¹, The number of members currently enrolled in the American Society of Clinical Oncology (ASCO) is over 16,000², as well as every state has a state board of pharmacy, and state board of medicine. Furthermore, on a national level there is the existence of the American Pharmacists Association with a membership of over 50,000, and the American Society of Health Systems Pharmacist with a membership of over 35,000. Clearly, with the combined numbers of these few mentioned entities listed would have resulted in more than 15 responses in regards to the development of this proposed rule. Moreover, the use of the term "vendor" would not have been placed in this document if such organizations had been involved. The proper term would have been "Pharmacy" and "Pharmacists".

¹ Sources: CMS Statistics: Medicare State Enrollment, Centers for Medicare and Medicaid Services, website at <http://cms.hhs.gov/statistics/enrollment/default.asp> .

² Sources: ASCO annual report 2000-2001

In regard to the section entitled "**Claims Processing Overview**" pages 45-64, the proposed arrangement is that the "vendor" would supply pharmaceuticals to a physician's office for a beneficiary (patient). The "vendor" would then submit a claim with a prescription number for the pharmaceutical agent to a designated carrier that would match the date of service submitted for administration by the physician. Despite what you would like to call the pharmaceutical agent, an order, or prescription, the information described throughout the entire process is the filling of a "prescription" for a patient. According to federal as well as state law only a pharmacist may take an order for a prescription. The supplying of the pharmaceutical agent, order, or prescription for a beneficiary (patient) is filling a prescription which must be done by a licensed pharmacist in a licensed pharmacy. Once again the language utilized throughout this entire proposed rule must be in accordance with federal and state law. Therefore the word "vendor" should be changed to licensed Pharmacy and Pharmacists.

In regard to the section entitled "**Competitive Acquisition Areas**" the proposed rule seems to view the pharmaceutical component as a "mail order" pharmacy. The fact that if the "vendor" was limited to a regional setting, or a national setting the "vendor" would only supply the pharmaceutical agents. As a healthcare practitioner it is vital that the "vendor" have an in depth knowledge of providing such pharmaceutical agents. The pharmaceutical drug complexity associated with these medications from drug -drug interactions, to proper dosing, to side effect management, must be available to the physician at the local level in order to continue to provide quality patient care. The fact is that the "Regional" set up on healthcare pharmaceuticals with high drug complexities as well as high cost association is not in the best interest of patient care as well as not cost effective for our healthcare system.

I would like to remind everyone that during the mid 80's when Home infusion pharmacies were dispensing high dollar therapies (prescriptions), several well known pharmaceutical companies produced their own division of home infusion pharmacy and tried to compete against the local home infusion pharmacies. These "Mail Order" pharmacies were awarded certain third party exclusive contracts. They were a regional set up that would Fed-Ex the pharmaceutical product to the patient. Ultimately, because of drug wastage, and poor patient care as well as poor patient service these "mail order vendors" ended up costing the third party insurance carriers more money. Today, these divisions do not even exist.³ In contrast, the local Home infusion pharmacies continue to provide quality care to patients within the local area. Individualized patient care must continue at the local area level to continue to provide the quality healthcare that our patients expect and deserve.

In regard to the section "**Contracting Process-Quality and Product Integrity Aspects**" page 73 clearly states that the propose rule wants to utilize wholesaler, distributors, or distribution centers as the vendors for this contract. This is a violation of Federal and State laws, since even a licensed wholesaler, distributor, or distribution center, cannot

³ The Wall Street Journal Europe May 15, 1996 **MedPartners Proposed Buy of Caremark Would Be the Latest in a Series of Acquisitions**

supply pharmaceutical agents to a physician's office for specific beneficiaries (patients). This is a function of a licensed pharmacist and a licensed pharmacy. Once again I must conclude that full research was not done with all interested parties and must question the intent, integrity and embodiment of this proposed rule. Clearly, the best interest to our beneficiaries (patients) and quality healthcare delivery was not top priority for these oversights to occur throughout this proposed rule.

As I continue to read through out the entire proposal it has become very evident and apparent that the "vendors" are viewed as Wholesalers, distributors, and distribution centers. The entire proposed rule is not in the best interest of patient care, and clearly was written without the input of healthcare professionals associated with providing quality care to our patients. This is not the intent of this proposal nor does it coincide with the mission or vision of CMS. The CMS mission and vision is very simple "We assure health care security for beneficiaries." "In serving beneficiaries, we will open our programs to full partnership with the **entire health community** to improve quality and efficiency in an evolving health care system."⁴ This proposed rule does not reflect the mission, vision and values of CMS as well as the healthcare community.

Thank you very much in regards to these matters. If you should have any questions or concerns, or if I may be of any service to your organization, please do not hesitate to contact me (559) 435-2425 or you can e-mail me at DrShinoda@aol.com.

Partners in Excellence,

Jeffrey K. Shinoda, Pharm. D.
Clinical Pharmacist / Oncology Specialist

⁴ **Sources:** CMS Mission, Vision, Goals and Objectives, Centers for Medicare and Medicaid Services, website at <http://www.cms.hhs.gov/about/mission.asp>

CMS-1325-P-33

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Ms. Mitzy Stewart

Date & Time: 04/04/2005

Organization : Valley Mental Health

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

April 4, 2005

I am writing to express concerns about the proposed changes that would affect access to care pertaining to our clients that we serve in our Community Mental Health Center. Valley Mental Health serves the chronically mentally ill and due to the high numbers of people we serve who carry a diagnosis of Schizophrenia and Bipolar Disorder I would like to see the proposed changes that would medications such as Haldol, Prolixin and Risperdal Consta which are the only means we have of treating and improving adherence to medications.

Due to shrinking funding of federal and state programs we do not have the resources it would take to provide the increased processes related to billing for these medications.

We have an ethical directive to serve our clients using the best medications possible, and using less than appropriate medications does not serve this ethical responsibility.

Thanks you for your time,

Mitzy Stewart APRN

CMS-1325-P-34

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. William Mac Laughlin

Date & Time: 04/04/2005

Organization : Cancer Specialists of Tidewater

Category : Physician

Issue Areas/Comments**GENERAL**

GENERAL

I am a practicing oncologist/hematologist in south Hampton Roads, Virginia, with 21 years experience in cancer medicine and active patient care, writing in comment concerning the Competitive Acquisition Program(CAP) to be implemented under the Medicare Modernization Act(MMA).

I have a number of concerns about the CAP, as proposed, and feel it will negatively impact patient care, overall outpatient cancer care, patient finances, without producing any true improvement in cancer care efficiency or productivity.

It appears quite evident that the current proposal was designed by individuals not actively involved in medical oncology care of patients, since many features will result in a weakening of the quality of out patient cancer care currently in use. The decision to design the system without input from community oncologists who have hands on knowledge of today's system and patient needs was a serious mistake by CMS.

Apparently the CAP system will be introduced without any formal testing or analysis in the real world. This is extremely risky to patient care/people with cancer, since it is a dramatic potential change to the current system, which is the result of over 30 years of refinement, improvements, adaptation in real world situations. I recommend much more study, and a limited trial period of some sort, to confirm the quality of the CAP before it is thrust upon the cancer care system.

Once an oncology practice signs up with a CAP drug vendor, they are to be locked in with that vendor for an entire year, with no provision to exit, even if the vendor provides a service of inferior quality, timeliness, accuracy, delivery, insurance coordination, or patient interaction. There is no way to change to another vendor, or ensure the CAP vendor provides a pharmacy service equal to that the oncology practice and their patients had previously come to expect/receive. This is a flaw that needs to be fixed, before implementation.

Under the CAP system, when chemotherapy drugs are changed, based upon changes in clinical status, patients will be inconvenienced by having to wait till the new drug or dose is ordered, and arrives from the CAP vendor. Currently, oncology practices already have a general active inventory on hand of the most frequently prescribed chemotherapeutics. This aspect of the CAP will not improve the quality of the chemotherapy experience for the Medicare population.

The proposed system appears to allow for a real likelihood that cancer drugs will be supplied by multiple vendors into the cancer care system. This is likely to provide a logistical complexity of significant proportion, difficult for oncology practices, the national cancer care system, and even Medicare itself to keep track of, without any evidence that the resulting complexity will improve the quality of care(it is more likely to have a negative effect on quality).

Most oncology practices currently maintain one comprehensive drug inventory for all of their practice and patients. The CAP system is almost certain to create a need for multiple inventory tracking, perhaps even a separate inventory for every patient receiving chemotherapy. This reduces overall efficiency, and thus, increases the true costs of chemotherapy administration. Even if Medicare refuses to pay for these costs, any program which reduces economic productivity can not be considered an improvement or cost effective.

The CAP system needs to be in compliance with Federal pharmacy laws and guidelines, as well as those of each of the 50 states and their varying laws and regulations. There are aspects of the proposed CAP program which appear to violate current pharmacy laws.

CMS has still not addressed the issue of 'bad debt' with chemotherapy(non-payment related to lack of or inadequate co-insurance). It is unlikely that CAP vendors will enjoy absorbing these debts, resulting in a greater likelihood of seniors, ill with cancer, being harassed by a CAP vendor they don't know, for money.

CMS-1325-P-35

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Mrs. Miriam Hermanson

Date & Time: 04/04/2005

Organization : Valley Mental Health

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

April 4, 2005

CMS

I am very concerned about the proposed changes with Medicare B, which would require Community Mental Health Centers to purchase and bill clients for non-self administered medications. I work for Valley Mental Health Storefront/ Safe Haven where we serve homeless mentally ill clients. If this new change is put into place it will highly effect the medications our clients will have access to. Medications, which work best for clients to reduce symptoms of their mental illness, should be at the heart of our treatment, not which medications we can afford to give them. If that becomes the case, what credibility can we give to our doctors who are forced to only prescribe certain medications? I urge you to stop these possible changes and help us to serve our clients to the best of our ability.

Thank you for your time and efforts,

Miriam Hermanson, SSW

CMS-1325-P-36

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Ms. Joan Magill

Date & Time: 04/05/2005

Organization : Weber Human Services

Category : Nurse Practitioner

Issue Areas/Comments**GENERAL**

GENERAL

CAP and Psychiatry: Rehabilitation Leads to Cost Savings.

In reviewing the Competitive Acquisition Program (CAP) I have several concerns. I am a nurse practitioner in psychiatry who treats the severely and persistently mentally ill in Community Mental Health Clinics (CMHC) and Long Term Care (LTC). One of the current philosophical approaches in CMHC is recovery and achieving the highest level of possible functioning for our clients. This is not possible without access to the latest technology including long acting atypical antipsychotics. In reviewing the current CAP document this will be Rheumatology and Oncology are approved to bill Medicare for long acting injectables. Psychiatry is missing.

Currently Community Mental Health Centers (CMHC) lack the financial infrastructure to participate in the buy and bill process. The Utah State Hospital will not utilize long acting atypical antipsychotics on patients going to nursing homes because they are not covered on Long Term Care.

Access long acting atypical antipsychotics in the State of Utah in LTC is limited; even when requesting injections for LTC providing compelling fiscal, rehabilitative, and quality of life arguments, access is restricted. In one instance, I was able to maintain a patient on an injectable alone, versus four psychotropics; she was ready to move to assisted living, and the injectable was discontinued by the State for cost reasons. The patient remains in LTC, refusing medications and with continued unstable psychosis, preventing her placement in lesser expensive community settings, such as assisted living. Another patient who has a history of polypharmacy (secondary to noncompliance) numerous comorbid medical problems, as well as several state hospitalizations, is ready for care in assisted living after several years of being institutionalized, secondary to access to a long acting atypical antipsychotic.

A number of these patients, while they are carefully observed in LTC, are non compliant with there medications, causing increased psychosis, lack of compliance with medical regimens, and rehospitalization. Hospitalization in the Utah State Hospital costs \$180,000 per year; my understanding is these are 100% state dollars.

Lack of compliance with psychiatric regimens is associated with a number of medical comorbidities in chronically and persistently mentally ill patients including diabetes, hypertension, obesity, lung disease, and liver problems, likely resulting in premature placement in a nursing home setting. Nursing home placement in Utah costs approximately 100-130 per day; 70% of these are federal dollars, 2100-2720 per month or

Moving a patient from LTC to assisted living saves approximately 14,000 per year in the State of Utah, this includes the cost of the associated rehabilitation program. The CAP (piloting psychiatry and long acting atypical injectables) in conjunction with a rehabilitation program, could determine noncompliant psychiatric patients capable of rehabilitation, and move them to less costly environments such as assisted living or their own apartment. In Utah, we have the appropriate psychosocial resources such as Flex Care and Weber MACS, to assist with psychosocial rehabilitation.

Providing a pilot program for psychiatry for long term injectables (with the appropriate psychosocial support) would substantiate costs savings to the Federal as well as State governments for mentally ill patients in Long Term Care; and more than pay for the cost of the injectable. The cost for an atypical antipsychotic long term agent ranges from (480 to 950 dollars per month) is comparable to polypharmacy of oral psychiatric medications, or high doses of oral medications.

In summary, other methods of reimbursement besides buy and bill, and other specialties, including psychiatry, should be including in CAP.

CMS-1325-P-37

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. robert bank

Date & Time: 04/05/2005

Organization : columbia area mental health

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

i strongly support the inclusion of mental health drugs in the first phase of competitive aquisition program. i believe that this will enhance access for patients and be a cost savings. most specifically patients with chronic mental illness would benefit from the inclusion of long acting injectables. access problems have been most problematic for risperdal consta which is the injectable with the least problematic side effects such as tardive dyskinesia. i hope this category will be considered for the earliest inclusion.

CMS-1325-P-38

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Mrs. Cindy Ostrowski

Date & Time: 04/06/2005

Organization : St. Luke's House

Category : Nurse Practitioner

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

It is critical that all mental health therapies, including non self-administered injectables (Part B) be covered for the financially needy, seriously and persistently mentally ill consumers whom we serve.
Competitive Acquisitions Areas

CAP would at least provide an alternative to buy and bill arrangements for consumers and providers, by simplifying the reimbursement process.

Overview of the CAP

The current buy and bill reimbursement system has created undue barriers to access for mental health consumers and financial constraints for small, nonprofit providers, such as ourselves. Of the many consumers who would benefit from use of such non self-administered injectables, we are only able to serve approximately 10%

CMS-1325-P-39

**Medicare Part B - Competitive Acquisition of Outpatient Drugs and
Biologicals**

Submitter : Jac queline Shipp

Date & Time: 04/06/2005

Organization : St. Luke's House, Inc.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

CMS Mail: CMS

DHHS

Attention: CMS-1325-P

PO Box 8010

Baltimore, MD 21244-8010

CMS-1325-P-39-Attach-2.DOC

CMS-1325-P-39-Attach-1.DOC

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

I am writing to you regarding Medicare Part B-Competitive Acquisition of Outpatient Drugs and Biologicals. I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

Outpatient Mental Health Clinics that serve those consumers who struggle with serious and persistent mentally illnesses such as schizophrenia have found that often the most clinically effective symptom management strategy is long-acting, non self-administered, injectable medications (e.g. Risperdal Consta). Currently, the only option for approximately 50 % of the consumers served, those under Medicare Part B, have for obtaining such drugs is the Buy and Bill process, one which is very expensive, administratively burdensome, and financially risky for both non profit providers and needy consumers alike.

I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

Thank you for your consideration of this most serious matter.

Sincerely,

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

I am writing to you regarding Medicare Part B-Competitive Acquisition of Outpatient Drugs and Biologicals. I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

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Thank you for your consideration of this most serious matter.

Sincerely,

CMS-1325-P-40

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Melanie Burgess

Date & Time: 04/06/2005

Organization : St. Luke's House, Inc.

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

GENERAL

GENERAL

I am writing to you regarding Medicare Part B-Competitive Acquisition of Outpatient Drugs and Biologicals. I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

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I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

Thank you for your consideration of this most serious matter.

Sincerely,

Melanie P. Burgess
Supported Employment Specialist
St. Luke's House, Inc.
burgess@stlukeshouse.com

CMS-1325-P-41

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Ms. Mary Ann Bergeron

Date & Time: 04/06/2005

Organization : Virginia Association of Community Services

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

The Virginia Association of Community Services Boards would strongly urge CMS to include categories of psychiatric medications in its CAP project. This would be a great benefit to consumers with serious mental illness and their treating physician. Currently, the process is convoluted and costly. Allowing psychiatric medications, including long-acting injectables, to be part of CAP will streamline the process, reduce administrative and billing overhead, and promote longevity of use by the consumer. This will greatly reduce episodes that require the most expensive care-hospitalization.

Should more information be required, please contact me at mabergeron@vacsb.org

Thank you,

Mary Ann Bergeron

CMS-1325-P-42

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. Howard Houghton MD

Date & Time: 04/06/2005

Organization : University of Missouri

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

currently there is a significant barrier with Part B medications to the use of new methods of medication delivery. While more urban areas have been able to gain better access (through their own internal processes) the rural areas of missouri don't have the resources to accomplish this. I have observed obvious impact on patient access to care as a result of this. While we are able to gain access the effort is often unreasonable. Please include mental health in the category of the competitive acquisition program as it would improve these frail consumers access to care.

CMS-1325-P-43

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Ms. Elizabeth Christenson

Date & Time: 04/07/2005

Organization : St. Luke's House

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

I am writing to you regarding Medicare Part B-Competitive Acquisition of Outpatient Drugs and Biologicals. I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

Outpatient Mental Health Clinics that serve those consumers who struggle with serious and persistent mentally illnesses such as schizophrenia have found that often the most clinically effective symptom management strategy is long-acting, non self-administered, injectable medications (e.g. Risperdal Consta). Currently, the only option for approximately 50 % of the consumers served, those under Medicare Part B, have for obtaining such drugs is the Buy and Bill process, one which is very expensive, administratively burdensome, and financially risky for both non profit providers and needy consumers alike.

I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

Thank you for your consideration of this most serious matter.

Sincerely,

Elizabeth Christenson

CMS-1325-P-44

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. John Lindstrom

Date & Time: 04/07/2005

Organization : Richmond Behavioral Health Authority

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

As the provider of public mental health, mental retardation and substance abuse services in Richmond, Virginia, the Richmond Behavioral Health Authority strongly encourages the following in Medicare Part B:

- 1)The inclusion of all psychiatric drugs, including long-acting injectables, in Phase I of the new Medicare Part B drug benefit.
- 2)It is recommended that long-acting injectables be considered a pharmacy benefit, not a medical benefit. The reason for this is our experience with Medicaid coverage/reimbursement. When managed care Medicaid determined that long-acting injectables were a medical service benefit as opposed to a prescription benefit, significant barriers to acquisition and reimbursement followed. The same is true under current Medicare rules in this state.
- 3)It is further recommended that CMS require any vendors awarded the contracts to provide this prescription benefit with the a co-pay structure no higher than Medicaid.

If incorporated in the the new rule for Medicare Part B, the result would be greater access to needed treatment and reduced reliance on more expensive treatments such as in-patient hospitalization.

CMS-1325-P-45

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Ms. Rebecca Dodge-Katz

Date & Time: 04/07/2005

Organization : St. Luke's House

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am writing to you regarding Medicare Part B-Competitive Acquisition of Outpatient Drugs and Biologicals. I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

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I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

Thank you for your consideration of this most serious matter.

Sincerely,

Rebecca Dodge-Katz
St. Luke's House, Inc.
6040 Southport Dr
Bethesda, MD 20912
301-493-0047 x295

CMS-1325-P-46

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Miss. Lottena Wolters

Date & Time: 04/07/2005

Organization : St. Luke's House, Inc.

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

GENERAL

GENERAL

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

I am writing to you regarding Medicare Part B-Competitive Acquisition of Outpatient Drugs and Biologicals. I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

Outpatient Mental Health Clinics that serve those consumers who struggle with serious and persistent mentally illnesses such as schizophrenia have found that often the most clinically effective symptom management strategy is long-acting, non self-administered, injectable medications (e.g. Risperdal Consta). Currently, the only option for approximately 50 % of the consumers served, those under Medicare Part B, have for obtaining such drugs is the Buy and Bill process, one which is very expensive, administratively burdensome, and financially risky for both non profit providers and needy consumers alike.

I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected.

Sincerely,

Lottena Wolters
Supported Employment Specialist

CMS-1325-P-47

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Mrs. Sharon Daniels

Date & Time: 04/07/2005

Organization : Valley Community Services Board

Category : Nurse

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

As a Registered Nurse working with consumers with Long Term Mental Disabilities, I am advocating that ALL psychotropic medications, including long-acting injectables be included in the first phase of the new Medicare Drug Plan. It is imperative that our nations citizen with mental illness have access to appropriate and safe treatment that allows these citizens to function within the freedom of our communities instead of on the wards of state run hospitals. Including these drugs in the first phase will streamline the acquisition and allow providers to focus our resources on positive consumer outcomes instead of spending valuable time seeking prior authorizations and struggling with billing issues.

GENERAL

GENERAL

CMS-1325-P-48

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Ms. Anne Sweeney

Date & Time: 04/07/2005

Organization : St. Luke's House

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

GENERAL

GENERAL

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

I am writing to you regarding Medicare Part B-Competitive Acquisition of Outpatient Drugs and Biologicals. I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

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I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

Thank you for your consideration of this most serious matter.

Sincerely,
Anne Sweeney

CMS-1325-P-49

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Mr. Kirk Morton

Date & Time: 04/07/2005

Organization : VACPN

Category : Nurse

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

All psychiatric medications, including long-acting injectable medications, should be included.

Claims Processing Overview

Specialized pharmacies should be able to provide the medications and bill Medicare. The provider should not have to be in this loop other than to write the prescription.

Contract Requirements

Vendors should be required to make all new generation antipsychotics available without prior authorization, including injectable formulations because they are substantially different from one another, unlike SSRIs. Furthermore, if co-pays are required, they should be based on the "straight" Medicaid rate.

Dispute Resolution

If there are disputes over a particular drug, that drug should be authorized on a temporary basis while under review to give the practitioner time to re-evaluate and come up with another plan. Sometimes consumers are prescribed certain meds while in the hospital, stabilized and then get out into the community where they find out their drug plan doesn't cover that particular medication and they go without and relapse.

CMS-1325-P-50

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Mrs. Christine Luchie

Date & Time: 04/07/2005

Organization : Hanover Community Services

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Please include all Psychiatric medications including long acting injectables in this program. Many persons with mental illness rely on psychiatric medications to live in the community, inability to obtain these medications could substantially impair not only mental health but physical health as well. Thank you for your consideration to this e-mail.
Christine Luchie MSRN, Nurse Supervisor HCCS

CMS-1325-P-51

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Mrs. Robin Dix

Date & Time: 04/07/2005

Organization : none

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Please include a category for mental health drugs including long-lasting injectable antipsychotics. Thank you for your attention to this matter.

CMS-1325-P-52

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Anne Coughlin

Date & Time: 04/07/2005

Organization : NAMI Colorado Springs

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

NAMI CS (National Alliance for the Mentally Ill of Colorado Springs) urges you to include mental health drugs, including longer lasting injectable drugs (note that these are NOT self-injectable) in the proposed 2006 CAP. These are important resources for persons impacted by severe and chronic mental illness and anything that can expedite timely access to these vital medications is urgently needed. Thank you, Anne Coughlin, President Emeritus, NAMI CS

CMS-1325-P-53

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Mrs. Deborah Volz

Date & Time: 04/08/2005

Organization : Northwest Center for Community Mental Health

Category : Nurse

Issue Areas/Comments**GENERAL**

GENERAL

I want to advocate for the chronically mentally ill clients in Virginia. I work with one of the most vulnerable of populations in our society. They often cannot work due to the severity of their mental illnesses and are reliant on the entitlement programs to survive. That is a very difficult task in Northern Virginia. These people need to be able to get their medications at a nominal fee or else they cannot afford them. Please put psychiatric medications, including long acting injectables in the first phase of this program. It is far more humane and cost effective to help these people with medications which keep them functioning in the community and out of the hospitals. It is especially crucial now that hospital beds are becoming very scarce. Please find a way to support the local mental health centers keep these very vulnerable people safe and medicated in our local communities.

CMS-1325-P-54

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Mr. Irvin W. Simpson

Date & Time: 04/08/2005

Organization : NAMI Rv

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please make sure that there is a category that includes mental health drugs, including the long lasting injectable antipsychotics.

CMS-1325-P-55

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. mitchell martin

Date & Time: 04/08/2005

Organization : Tennessee Cancer Specialists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am a practicing medical oncologist. The vendor system is dangerous for patients and will lead to medical errors. We deal with very sensitive, toxic drugs and have a system in place to insure no errors are made in delivering these drugs properly to cancer patients. A medical oncology practice will not be able to keep multiple inventories in place to accomodate the medicare population. I am convinced errors will occur, either with mixing of chemotherapy, improper lableing or mishandling of these toxic drugs. I am very disappointed that medical oncologists were not involved in formulating this process. These are not hypertension or diabetes drugs. These are infusions of drugs that can cause cause death if not respected. Can you imagine requiring a hospital to order a separate drug inventory for each patient? Of course not. But this is exactly what we are being asked to do. I urge CMS to abandon this system, for many reasons but mainly for patient safety.

CMS-1325-P-56

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Ms. Shannon Kay

Date & Time: 04/08/2005

Organization : Comprehensive Cancer Center of Nevada

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

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.

CMS-1325-P-57

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Mrs. Donna Grossman

Date & Time: 04/08/2005

Organization : Mrs. Donna Grossman

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I believe it is a foolish idea to give physicians access to more drugs than they already have unless it were a speciality practice that closely monitors all drugs a patient is taking, i.e. cancer care. In the case of Family physicians, too many rely on the knowledge of a drug rep to recommend a drug for a patient and too often these drugs may be contraindicative for interaction with other drugs. I have found with drugs that I have taken, my pharmacist will tell me if a drug is not compatible with something else I am taking. Physicians don't have all the chemical education to determine this.

Another thing, why open the door to physicians receiving more drug company perks for using a particular product. Granted that already happens. However, if there were abuse of a drug dispensation for the sake of perks, who would that physician be accountable to? A deceased patient's family?

CMS-1325-P-58**Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals****Submitter :** Mrs. Shonna Allen**Date & Time:** 04/08/2005**Organization :** NAMI Roanoke Valley**Category :** Individual**Issue Areas/Comments****GENERAL**

GENERAL

As a private citizen I am concerned about Medicare Part D. My son is dual eligible and currently gets his ANTIPSYCHOTIC medications through Medicaid in our home state. What I have heard is that only certain antipsychotic medications will be covered under the new program. Those of us who have mentally ill relatives want the range of acceptable antipsychotic medications to be as wide as possible. The different medications are NOT equal to one another and do different things for different people. In particular I have heard that injectable antipsychotic medications will be excluded from the new program. If this happens it will be a serious mistake and will send a number of mentally ill people into the hospitals or into jail. Please create a category that includes mental health drugs including long-lasting injectables.

CMS-1325-P-59 Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. Cary Present

Date & Time: 04/08/2005

Organization : Medical Oncology Association of Southern Californi

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

CMS-1325-P-60**Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals****Submitter : Dr. Gary Kay****Date & Time: 04/08/2005****Organization : Northwest Oncology****Category : Physician****Issue Areas/Comments****1-15****Bidding Entity Qualifications**

CMS is justifiably concerned about the need to ensure that CAP vendors are qualified to provide the services called for under Social Security Act ?1847B. I disagree, however, with two of the approaches that CMS has proposed for qualifying potential candidates.

CAP vendors must be licensed as a pharmacy in each state in their assigned service area. Although they may need to be licensed as a wholesaler as well, that credential alone is not sufficient because wholesalers are not permitted to ship patient-specific drug orders dispensed pursuant to a prescription. By focusing so extensively on distribution experience and the wholesaler credential, CMS is emphasizing the commodity aspect of the services that CAP vendors must provide, not the high-value aspects of those services.

Instead, CMS should focus on the dispensing aspects of a CAP vendor?s duties and pharmacy credentials. Just as important, CMS should place great emphasis on vendors? competence in patient-centric drug management services, in billing, claims processing, coordination of benefits and collections, and in their responsiveness to local market needs. Licensed pharmacies are more likely to have experience dealing with patient and physician complaints and are more likely to have, and be used to operating under, a code of conduct and a robust compliance program like that envisioned under 42 CFR ?414.914(c). It is these credentials that seem more relevant than CMS?s current focus on distribution capabilities.

I also disagree with the proposal to require all acceptable applicants to have 3 years of experience in ?the business of furnishing Part B injectable drugs.? Years of experience as a distributor are a poor proxy for the skill sets and capacity measures that will characterize efficient and effective CAP vendors. Moreover, the 3-year requirement will restrict competition and prevent new and higher quality entities from entering the market. A better approach would be to require that a bidder hold current pharmacy and wholesaler licenses in each state in the service area for which it is bidding and be enrolled as a Medicare supplier. CMS should then evaluate each applicant?s financial performance and solvency against pre-established criteria to identify organizations that are sufficiently capitalized to take on the challenge.

Similarly, CMS should collect information on personnel statistics, warehouse and dispensing capacities, distribution center locations, inventory sourcing relationships and the like and compare that information to pre-established criteria designed to ensure that the applicant has the wherewithal to handle the dispensing load CAP vendors can expected to face. It will be particularly important for vendors to have a broad geographic presence, either directly or through subcontract arrangements, with a wide network of pharmacies. Otherwise the vendor will be unable to make routine and emergency deliveries in time frames that meet patient needs.

CMS also should gather data about each applicant?s experience in critical functions such as pharmacy services management, billing and collection, and compliance to evaluate the applicant?s ability to provide the level of service and quality necessary to support physicians who furnish Part B drugs in their offices and the Medicare beneficiaries who depend on them for care. As part of this process, CMS should consider checking references to assess how satisfied customers of a size commensurate with that of most oncology practices have been with past service.

In each of these areas, the bidder's qualifications can be assessed not merely on the basis of their experience in the commodity service of distribution but in crucial service functions that will determine the difference between vendors who can safely and reliably serve CAP physicians needs, and those that cannot.

Cap Bidding Process-Evaluation and Selection

CMS intends to contract only with qualified CAP bidders that submit composite bids with a weighted average price per HCPCS unit that is no greater than 106% of the weighted ASP for the drugs in the category. US Oncology has consistently taken the position that reimbursement at 106% of ASP is inadequate to cover physicians' costs for chemotherapy drugs and for pharmacy management services and other associated expenses, including bad debt, that are currently not considered in the practice expense component of the drug administration G codes.

Just as I believe this level of reimbursement is inadequate for physicians under the buy-and-bill model, so too do I view reimbursement at 106% of ASP to be inadequate under the CAP model. Competition will not cause manufacturers of most single-source drugs to discount their products to CAP vendors or to any other class of buyer that must be considered when Best Price is calculated. And, like physician practices nationwide, bad debt will pose a major financial challenge to CAP vendors.

In addition, CAP vendors will incur significant middleman costs, including administrative, dispensing, shipping, product disposal, and bad debt costs. These costs are borne by physicians practices everyday, but CAP vendors will likely face even greater difficulty collecting due to the time delay between the dates of treatment and payment, as well as their lack of a direct relationship with patients. Beneficiaries who are already contending with deductibles and coinsurance payments not covered by secondary insurance, travel expenses, custodial care expenses, costs associated with changed dietary needs, etc., may place a relatively low priority on paying their CAP vendors.

Just as the absence of personal relationships between beneficiaries and CAP vendors is likely to exacerbate the vendors' bad debt collection problems, I fear it will also exacerbate some vendors' use of overly aggressive collection efforts, including decisions to stop providing drugs for patients who are too far in arrears. The Practicing Physicians Advisory Council has also raised this concern and proposed that CMS address it in the final CAP rule by mandating that vendors advance credit to patients unable to afford their coinsurance payments. CMS should go a step further and ask that the vendors also be required to have in place procedures for assessing indigence and waiving coinsurance when a non-Medicaid-eligible beneficiary's income, assets, and medical expenses meet certain pre-established criteria. Ideally, these procedures should incorporate the assistance of social workers trained to explore all payment options and assistance programs available to the individual.

Unlike the situation with physicians where reimbursement for Part B drugs supplied under the buy-and-bill model is set by statute at 106% of ASP, CMS may have the discretionary authority under Social Security Act §1847B to permit payments to CAP vendors at any level necessary to compensate them fairly and appropriately for their services. It appears that Congress only expected competition under the CAP model to save money on multi-source drug products, not single-source drugs and biologicals.

Pre-defining an unrealistically low reimbursement cap could under-capitalize vendors, resulting in too few qualified bidders, the provision of improper services, and patient harm. Therefore, CMS should either abandon the notion that CAP will save money in the aggregate for Medicare Part B or phase in the program slowly by starting with a small group of drugs or with a specialty that does not use "incident to" drugs intensively to test the impact of an potentially under-reimbursed CAP model on beneficiary access to care and on the robustness and financial viability of the CAP vendor market.

In either case, one conclusion should be recognized: just as 106% of ASP is too low in the buy-and-bill model, so too is it unsustainable in CAP.

Categories of Drugs to be Included under the CAP

The design and implementation of a competitive acquisition program for Part B drugs is an enormous undertaking. It is also an undertaking that

will move Medicare into largely uncharted waters. That fact alone argues for a cautious approach.

Although CMS has managed two competitive acquisition demonstration projects for certain types of durable medical equipment, prosthetics and supplies (DMEPOS) in limited geographic markets, it has never organized and run a competitive acquisition program on a national or even a regional scale. The Part B drug CAP differs significantly from the DMEPOS demonstrations because of complicated state licensing and regulatory schemes, the criticality of most of the products involved from a beneficiary perspective, the single-source nature of many of the drugs to be furnished, and the necessity for substantial changes in Medicare claims processing systems that go beyond anything required to implement the DMEPOS demonstrations.

With DME, there were numerous established suppliers operating in a largely unregulated state licensure environment. Because participation in the demonstration by Medicare beneficiaries living in the test areas was mandatory, the bidders knew the size of the potential market. The bidders also ran established businesses and clearly understood the cost structures of those businesses. Unlike the situation with single-source drugs that are the standard of care for many cancer patients today, each product category subject to DMEPOS competitive bidding included numerous items under most HCPCS codes subject to the demonstration. Also unlike the situation that will face manufacturers of Part B drugs in 2006, the discounts extended to DMEPOS competitive bidders did not impact Medicare reimbursement for the manufacturer's product in locations outside the demonstration area. In other words, with DMEPOS, CMS could count on an adequate supply of qualified bidders positioned to put forth bids consistent with required quality and service standards without sacrificing reasonable profitability and jeopardizing solvency. Furthermore, the product categories included in the DMEPOS demonstrations are not generally seen as carrying the same level concern about product integrity or medical errors as do Part B drugs. Therefore, if DMEPOS CAP vendors stunted on quality or service, the likely outcome for beneficiaries was not as potentially significant as if problems develop with the Part B drug CAP.

The GAO issued a final report to Congress assessing the DMEPOS demonstrations in September 2004. In that report, the GAO suggested that CMS consider conducting more competitive bidding demonstrations for items and services not in the original demonstrations prior to the beginning of the MMA-mandated implementation of CAP for DMEPOS.

This suggestion argues for taking a slow approach to the Part B drug CAP. In fact, it appears that CMS may already agree. In its final report on the DMEPOS CAP demonstration projects, CMS observed "one of the benefits of conducting demonstrations projects is the ability to learn from the demonstration and apply the lessons if the demonstration is adopted on a wider scale."

Instead of diving into a national CAP involving all Part B drugs used in "incident to" services, CMS should begin with a regional or national test involving a limited set of drugs that are typically administered by a physician specialty that uses drugs less intensely than oncology. This would allow CMS to refine its application and vendor selection procedures and its quality and service requirements, correct glitches in CAP upgrades to its claims processing systems, work out handling issues stemming from state regulations, assess and adjust for changes in practice expenses attributable to CAP, and complete the work needed to better match the reimbursement rates for drug administration services to actual costs for the various specialties before CAP is implemented more universal

Claims Processing Overview

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

If chemotherapy sessions must be rescheduled to wait for the delivery of the drug(s) that patients need, they will face additional coinsurance obligations for the repeat physician services. In addition, patients will face other financial

burdens in the form of higher transportation costs and additional missed time from work. This situation may also mean missed work time and reduced productivity for family members and other caregivers who must bring beneficiaries to the rescheduled treatment sessions.

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

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

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

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

Competitive Acquisitions Areas

A key issue relating to Competitive Acquisition Areas is the requirement that CAP vendors have arrangements in place sufficient to permit shipment "at least 5 days each week for competitively biddable drugs and biologicals . . . and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract." (See also 42 CFR 141.914(f)(2)). We appreciate CMS's request for comments both on "how to define timely delivery for routine and emergency drug shipments" and on the "feasibility of providing same day deliveries for orders received for emergency situations" (70 Fed. Reg. 10745,10760 (March 4, 2005)).

I believe that the proposed timelines for routine and emergency delivery are inadequate and that vendors must be required to make routine deliveries anywhere in their service area within 24-hours of a practice's submission of a new prescription 7 days a week. I base this recommendation on three principle considerations. First, it is not unusual for oncology practices to operate 6 and 7 days a week to meet their patients' needs. Second, it is estimated that approximately one-third of treatment plans must be modified on the day of treatment due to changes in a patient's health status. Third, the unavailability of drugs needed on the day of treatment would pose a significant burden on patients who would have to return another day for treatment. This burden can be particularly severe in rural areas where patients may have to travel long distances to receive cancer care.

CMS has the authority to require that CAP vendors be able to deliver drugs within 24 hours 7 days a week under the

statutory language in Social Security Act ?1847B(b)(2)(A)(i)(II). That provision imposes two standards on CAP vendors: the ability to make timely deliveries and the ability to ship at least 5 days each week. I believe that CMS should use its authority to define ?timely delivery? as a 24-hour turn around and 7-day-a-week delivery services. I fear that anything less could jeopardize the ability of cancer care specialists to meet their patients? clinical needs.

I believe CMS should not rely on an expectation that oncologists who choose CAP will continue to maintain an adequate inventory of drugs that can be used to treat Medicare patients in emergencies under the inventory replacement provisions of the CAP rule. CAP is expected to spur growth in

commercial payers? mandatory vendor imposition (MVI) programs. As a result, some physicians who elect CAP and continue offering in-office drug administration services may cease to maintain any on-site drug inventories. Even those practices that maintain inventories may limit them for a variety of reasons, including differences in the clinical needs of their Medicare and non-Medicare patient bases.

Finally, I note that neither the changes to 42 CFR 414.902 set forth in the proposed rule nor the text of the existing regulation define the term ?emergency.? It is essential for the definition of emergency to be clearly set forth in the final rule and not left to the discretion of each CAP vendor or to the discretion of local carriers tasked with adjudicating practices? claims for drug administration services. Moreover, the definition should turn on the treating physician?s clinical judgment that patient health would suffer from delay in treatment, not on the CAP vendor?s or the local carrier?s remote assessment of the situation.

In closing, I respectfully urge CMS to implement the ?timely delivery? requirement established by MMA as requiring CAP vendors to be able to deliver ordered drugs within 24 hours, 7 days a week.

Contract Requirements

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

Product integrity is about more than blocking the distribution of counterfeit goods, however. That is why I am concerned that the Proposed Rule?s provisions could jeopardize product integrity and violate state licensing laws. I suspect that CMS may not have thought through licensing and product integrity issues because it seems to have concluded that CAP vendors should be licensed as wholesalers but not as pharmacies. Indeed, many provisions in the Proposed Rule and the entire discussion of product integrity in the preamble focuses on wholesale distributors. I am convinced that CAP vendors must be licensed as pharmacies, however. The statute does not expressly define the class of trade of a CAP vendor and ?1847B(b)(4)(C) could suggest that Congress viewed CAP vendors as wholesalers. And yet, Social Security Act ?1847B(b)(6) seems to take a different position, stating that nothing in Social Security Act ?1847B ?shall be construed as waiving applicable State requirements relating to licensing of pharmacies.? CAP vendors must be licensed as pharmacies because they will accept patient-specific written orders for prescription drugs from physicians, assign prescription numbers to those orders, interpret the orders, presumably making generic substitutions as appropriate and permissible under applicable State law, and then transfer dispensed drugs to the prescribing physician for administration to the patient. This patient-specific transfer amounts to ?dispensing? a drug under state pharmacy practice acts and because CAP vendors dispense, they are practicing pharmacy and must be licensed accordingly.

Since CAP vendors must operate as licensed pharmacies, some of the operational aspects of CAP seem unworkable or in need of retooling. For example, state pharmacies laws do not permit a pharmacist to assign different prescription numbers to successive fills of a single prescription. Rather, prescription refills are always dispensed under the prescription number assigned to the original written order. A new prescription number is assigned only when a new written order is received. These practices are inconsistent with the prescription numbering system described in the preamble to the Proposed Rule.

Another critical problem is posed by CMS?s proposal for dealing with CAP drugs that cannot be administered to the

beneficiary for whom they were prescribed. Most state pharmacy laws prohibit the restocking of unused drugs after they have been dispensed. By establishing a process for the restocking and use of previously-dispensed drugs, however, the proposed rule appears to put the physician in the position of aiding and abetting the violation of these state pharmacy laws. In fact, none of the laws of which I am aware allow dispensed product to be redirected to another patient without going back to the dispensing pharmacy first.

Redirecting unused drugs dispensed by a CAP vendor from the intended recipient to another patient could expose physician practices to tort liability. Physicians participating in CAP will therefore need indemnification from CAP vendors when reuse decisions about drugs belonging to the vendor,

not the physician, are made based on discussions with the CAP pharmacist. CMS should build requirements for appropriate indemnities into the final rule.

Contracting Process-Quality and Product Integrity Aspects

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

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

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

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

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

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

Dispute Resolution

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

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

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

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

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

Fourth, CAP physicians will face much higher claims administration costs. CAP requires Medicare claims for drug administration services to be filed within 14 days of the drug administration service. This represents an increased burden since the Proposed Rule acknowledges that only about 75% of claims currently are filed within this timeframe and since claims processing software will need to be upgraded. Further, CAP physicians will be unable to make a cost-benefit decision about the value of appealing a claim denial for drug administration services. Instead, physicians could be forced to appeal all denials in a process that requires all the evidence needed to support the appeal to be collected and submitted.

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

Overview of the CAP

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

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

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

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

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

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

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

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

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

CMS-1325-P-61

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. Lin Soe

Date & Time: 04/08/2005

Organization : El dorado Hematology and Medical oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

As a physician in semirural area with limited patient number and not part of large group, we are not competitive at all with ASP program and We will be forced to participate in CAP program and worried very much on timely delivery of medications, being responsible for the waste of medications if patient cancel appointments, being responsible for damage of medications if required for storage, time wasted in communicating with distributor on dosage and frequency of treatment, delay of therapy when rapid switch in treatments are required when patient not responding to treatment, and refusal of delivery of expensive medication with low reimbursement from distributor

Submitter : Mr. Matt Brow

Date: 04/08/2005

Organization : US Oncology

Category : Physician

Issue Areas/Comments

1-15

Overview of the CAP

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

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Claims Processing Overview

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

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

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

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

implementation of CAP for DMEPOS.

This suggestion argues for taking a slow approach to the Part B drug CAP. In fact, it appears that CMS may already agree. In its final report on the DMEPOS CAP demonstration projects, CMS observed "one of the benefits of conducting demonstrations projects is the ability to learn from the demonstration and apply the lessons if the demonstration is adopted on a wider scale."

Instead of diving into a national CAP involving all Part B drugs used in "incident to" services, CMS should begin with a regional or national test involving a limited set of drugs that are typically administered by a physician specialty that uses drugs less intensely than oncology. This would allow CMS to refine its application and vendor selection procedures and its quality and service requirements, correct glitches in CAP upgrades to its claims processing systems, work out handling issues stemming from state regulations, assess and adjust for changes in practice expenses attributable to CAP, and complete the work needed to better match the reimbursement rates for drug administration services to actual costs for the various specialties before CAP is implemented more universally.

Competitive Acquisitions Areas

A key issue relating to Competitive Acquisition Areas is the requirement that CAP vendors have arrangements in place sufficient to permit shipment "at least 5 days each week for competitively biddable drugs and biologicals . . . and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract." (See also 42 CFR 141.914(f)(2)). We appreciate CMS's request for comments both on "how to define timely delivery for routine and emergency drug shipments" and on the "feasibility of providing same day deliveries for orders received for emergency situations" (70 Fed. Reg. 10745, 10760 (March 4, 2005)).

I believe that the proposed timelines for routine and emergency delivery are inadequate and that vendors must be required to make routine deliveries anywhere in their service area within 24-hours of a practice's submission of a new prescription 7 days a week. I base this recommendation on three principle considerations. First, it is not unusual for oncology practices to operate 6 and 7 days a week to meet their patients' needs. Second, it is estimated that approximately one-third of treatment plans must be modified on the day of treatment due to changes in a patient's health status. Third, the unavailability of drugs needed on the day of treatment would pose a significant burden on patients who would have to return another day for treatment. This burden can be particularly severe in rural areas where patients may have to travel long distances to receive cancer care.

CMS has the authority to require that CAP vendors be able to delivery drugs within 24 hours 7 days a week under the statutory language in Social Security Act §1847B(b)(2)(A)(i)(II). That provision imposes two standards on CAP vendors: the ability to make timely deliveries and the ability to ship at least 5 days each week. I believe that CMS should use its authority to define "timely delivery" as a 24-hour turn around and 7-day-a-week delivery services. I fear that anything less could jeopardize the ability of cancer care specialists to meet their patients' clinical needs.

I believe CMS should not rely on an expectation that oncologists who choose CAP will continue to maintain an adequate inventory of drugs that can be used to treat Medicare patients in emergencies under the inventory replacement provisions of the CAP rule. CAP is expected to spur growth in commercial payers' mandatory vendor imposition (MVI) programs. As a result, some physicians who elect CAP and continue offering in-office drug administration services may cease to maintain any on-site drug inventories. Even those practices that maintain inventories may limit them for a variety of reasons, including differences in the clinical needs of their Medicare and non-Medicare patient bases.

Finally, I note that neither the changes to 42 CFR 414.902 set forth in the proposed rule nor the text of the existing regulation define the term "emergency." It is essential for the definition of emergency to be clearly set forth in the final rule and not left to the discretion of each CAP vendor or to the discretion of local carriers tasked with adjudicating practices' claims for drug administration services. Moreover, the definition should turn on the treating physician's clinical judgment that patient health would suffer from delay in treatment, not on the CAP vendor's or the local carrier's remote assessment of the situation.

In closing, I respectfully urge CMS to implement the "timely delivery" requirement established by MMA as requiring CAP vendors to be able to deliver ordered drugs within 24 hours, 7 days a week.

Dispute Resolution

According to the preamble to the Proposed Rule, CMS believes that CAP will not significantly increase the administrative burden on physicians. As a result, CMS has concluded that the payment for clerical and inventory management services that is bundled into the drug administration codes should be adequate to cover the practice expenses which physicians will occur under CAP. This is unrealistic for a number of reasons, including the following: First, CAP practices will have to implement and operate a second, separate ordering process for CAP drugs to transmit patient-specific drug orders that include demographic and clinical information. The ordering system under the buy-and-bill model is much simpler because aggregate orders based on practice usage are placed with wholesalers. Buy-and-bill ordering does not involve the review of individual patient charts nor does it require input of substantial amounts of data for each vial of drug requested from the wholesaler. Second, CAP will increase the demands on oncology practices for pharmacy management services. Changes in individual treatment plans will have to be closely monitored so that new prescriptions can be sent to the vendor in timely fashion. The job of ensuring that drugs are given to the right patient and that patient-specific drug supplies provided in multi-dose vials have not expired or passed stability deadlines before the entire vial is used will be more complicated because the time that any particular multi-dose vial must be maintained and monitored will increase. The increases in complexity of required pharmacy management services will also increase the risk of medication errors. A study of oncology pharmacy costs by the University of Utah on behalf of the Global Access Project suggests that the average cost of these services per dose of chemotherapy preparation is already \$36.03. Since the current level of pharmacy services costs is not captured in the practice expense component of payments for drug administration services, the new costs imposed by CAP will be both additive and uncompensated. Third, CAP will likely increase hazardous waste disposal costs substantially due to complications regarding the redirection, in the physician's office, of unused drug dispensed for one patient to another patient. Waste handling costs will also be higher under CAP due to the increased likelihood that a drug designated for a particular patient will pass its expiration or stability deadline before all of the vial can be finished. As a result, total waste quantities could quickly exceed levels allowable for routine disposal, thereby adding even greater costs. Fourth, CAP physicians will face much higher claims administration costs. CAP requires Medicare claims for drug administration services to be filed within 14 days of the drug administration service. This represents an increased burden since the Proposed Rule acknowledges that only about 75% of claims currently are filed within this timeframe and since claims processing software will need to be upgraded. Further, CAP physicians will be unable to make a cost-benefit decision about the value of appealing a claim denial for drug administration services. Instead, physicians could be forced to appeal all denials in a process that requires all the evidence needed to support the appeal to be collected and submitted. Given the management, inventory control, drug preparation, paperwork, integrity assurance, and other necessary new or enhanced functions that will face physicians selecting CAP, CMS should establish a new HCPCS code for pharmacy management services to compensate physicians. To address the hazardous waste disposal problem, CMS should also require each CAP vendor to subcontract with properly licensed and permitted hazardous waste haulers and disposers to pick up from

physicians discarded drugs dispensed by the vendor and to destroy those drugs in accordance with applicable federal, state, and local laws

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Cap Bidding Process-Evaluation and Selection

CMS intends to contract only with qualified CAP bidders that submit composite bids with a weighted average price per HCPCS unit that is no greater than 106% of the weighted ASP for the drugs in the category. US Oncology has consistently taken the position that reimbursement at 106% of ASP is inadequate to cover physicians' costs for chemotherapy drugs and for pharmacy management services and other associated expenses, including bad debt, that are currently not considered in the practice expense component of the drug administration G codes.

Just as I believe this level of reimbursement is inadequate for physicians under the buy-and-bill model, so too do I view reimbursement at 106% of ASP to be inadequate under the CAP model. Competition will not cause manufacturers of most single-source drugs to discount their products to CAP vendors or to any other class of buyer that must be considered when Best Price is calculated. And, like physician practices nationwide, bad debt will pose a major financial challenge to CAP vendors.

In addition, CAP vendors will incur significant middleman costs, including administrative, dispensing, shipping, product disposal, and bad debt costs. These costs are borne by physicians practices everyday, but CAP vendors will likely face even greater difficulty collecting due to the time delay between the dates of treatment and payment, as well as their lack of a direct relationship with patients. Beneficiaries who are already contending with deductibles and coinsurance payments not covered by secondary insurance, travel expenses, custodial care expenses, costs associated with changed dietary needs, etc., may place a relatively low priority on paying their CAP vendors.

Just as the absence of personal relationships between beneficiaries and CAP vendors is likely to exacerbate the vendors' bad debt collection problems, I fear it will also exacerbate some vendors' use of overly aggressive collection efforts, including decisions to stop providing drugs for patients who are too far in arrears. The Practicing Physicians Advisory Council has also raised this concern and proposed that CMS address it in the final CAP rule by mandating that vendors advance credit to patients unable to afford their coinsurance payments. CMS should go a step further and ask that the vendors also be required to have in place procedures for assessing indigence and waiving coinsurance when a non-Medicaid-eligible beneficiary's income, assets, and medical expenses meet certain pre-established criteria. Ideally, these procedures should incorporate the assistance of social workers trained to explore all payment options and assistance programs available to the individual.

Unlike the situation with physicians where reimbursement for Part B drugs supplied under the buy-and-bill model is set by statute at 106% of ASP, CMS may have the discretionary authority under Social Security Act §1847B to permit payments to CAP vendors at any level necessary to compensate them fairly and appropriately for their services. It appears that Congress only expected competition under the CAP model to save money on multi-source drug products, not single-source drugs and biologicals.

Pre-defining an unrealistically low reimbursement cap could under-capitalize vendors, resulting in too few qualified bidders, the provision of improper services, and patient harm. Therefore, CMS should either abandon the notion that CAP will save money in the aggregate for Medicare Part B or phase in the program slowly by starting with a small group of drugs or with a specialty that does not use incident-to drugs intensively to test the impact of an potentially under-reimbursed CAP model on beneficiary access to care and on the robustness and financial viability of the CAP vendor market.

In either case, one conclusion should be recognized: just as 106% of ASP is too low in the buy-and-bill model, so too is it unsustainable in CAP.

Contract Requirements

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

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

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

I am convinced that CAP vendors must be licensed as pharmacies, however. The statute does not expressly define the class of trade of a CAP vendor and §1847B(b)(4)(C) could suggest that Congress viewed CAP vendors as wholesalers. And yet, Social Security Act §1847B(b)(6) seems to take a different position, stating that nothing in Social Security Act §1847B shall be construed as waiving applicable State requirements relating to licensing of pharmacies.

CAP vendors must be licensed as pharmacies because they will accept patient-specific written orders for prescription drugs from physicians, assign prescription numbers to those orders, interpret the orders, presumably making generic substitutions as appropriate and permissible under applicable State law, and then transfer dispensed drugs to the prescribing physician for administration to the patient. This patient-specific transfer amounts to dispensing a drug under state pharmacy practice acts and because CAP vendors dispense, they are practicing pharmacy and must be licensed accordingly.

Since CAP vendors must operate as licensed pharmacies, some of the operational aspects of CAP seem unworkable or in need of retooling. For example, state pharmacy laws do not permit a pharmacist to assign different prescription numbers to successive fills of a single prescription. Rather, prescription refills are always dispensed under the prescription number assigned to the original written order. A new prescription number is assigned only when a new written order is received. These practices are inconsistent with the prescription numbering system described in the preamble to the Proposed Rule.

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

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

CMS-1325-P-63

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals**Submitter :** Dr. Carl Atkins**Date & Time:** 04/09/2005**Organization :** S. Shore Hematology-Oncology Associates**Category :** Physician**Issue Areas/Comments**

1-15

Claims Processing Overview

CMS is grievously mistaken to think that this process requires no more administrative burden than billing under ASP+6. The logging of all drugs received and attributing them both to individual patients and individual order numbers will be extremely time consuming. The requirement to submit unique prescription numbers with each drug billed will vastly increase staff time to send claims, with tremendous risk of error, since each drug at each encounter will require a unique number that can only be checked manually. The physician's office will also need to maintain records of the prescription number submitted in case of dispute with the vendor. This would likely require extensive software modification (if it is at all possible). Submitting orders for drugs with all the required information, will be much more time consuming than the simple process we currently use for informing our nurses what chemotherapy is to be administered. It also seems unnecessary to provide the clinical information you suggest (allergies, height, weight) since the vendor is functioning as a drug distributor, not a pharmacy, and the physician is ultimately responsible for addressing clinical issues related to these. On the other hand, it would seem appropriate to include an ICD-9 code, to allow the vendor to verify that the order meets local carrier determination criteria.

The administrative burden proposed in this rule is unrealistic. I could not imagine electing to participate in the CAP program without hiring at least 1 or 2 additional full time employees with an expected cost of at least \$100,000 for my 5-physician practice. I do not see how a solo practitioner could manage at all. Unfortunately, the statutory requirements leave little room for an alternative, other than providing additional payment for drug administration services under the CAP program. The only other solution I can imagine, would be the development of a comprehensive electronic system by CMS that could allow for and link electronic drug orders, drug shipments (using bar codes), drug receipts (using bar codes), drug administration (automatically linked electronically), and CMS payments. This could obviously not be implemented by Jan. 1, 2006, but delaying implementation for an effective electronic solution would be well worthwhile.

Submitter : Dr. Thomas Reynolds
Organization : Thomas F. Reynolds, MD
Category : Physician

Date: 04/09/2005

Issue Areas/Comments

1-15

Overview of the CAP

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

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

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

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

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

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

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

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

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

Bidding Entity Qualifications

CMS is justifiably concerned about the need to ensure that CAP vendors are qualified to provide the services called for under Social Security Act §1847B. I disagree, however, with two of the approaches that CMS has proposed for qualifying potential candidates.

CAP vendors must be licensed as a pharmacy in each state in their assigned service area. Although they may need to be licensed as a wholesaler as well, that credential alone is not sufficient because wholesalers are not permitted to ship patient-specific drug orders dispensed pursuant to a prescription. By focusing so extensively on distribution experience and the wholesaler credential, CMS is emphasizing the commodity aspect of the services that CAP vendors must provide, not the high-value aspects of those services.

Instead, CMS should focus on the dispensing aspects of a CAP vendor's duties and pharmacy credentials. Just as important, CMS should place great emphasis on vendors' competence in patient-centric drug management services, in billing, claims processing, coordination of benefits and collections, and in their responsiveness to local market needs. Licensed pharmacies are more likely to have experience dealing with patient and physician complaints and are more likely to have, and be used to operating under, a code of conduct and a robust compliance program like that envisioned under 42 CFR §414.914(c). It is these credentials that seem more relevant than CMS's current focus on distribution capabilities.

I also disagree with the proposal to require all acceptable applicants to have 3 years of experience in "the business of furnishing Part B injectable drugs." Years of experience as a distributor are a poor proxy for the skill sets and capacity measures that will characterize efficient and effective CAP vendors. Moreover, the 3-year requirement will restrict competition and prevent new and higher quality entities from entering the market. A better approach would be to require that a bidder hold current pharmacy and wholesaler licenses in each state in the service area for which it is bidding and be enrolled as a Medicare supplier. CMS should then evaluate each applicant's financial performance and solvency against pre-established criteria to identify organizations that are sufficiently capitalized to take on the challenge.

Similarly, CMS should collect information on personnel statistics, warehouse and dispensing capacities, distribution center locations, inventory sourcing

relationships and the like and compare that information to pre-established criteria designed to ensure that the applicant has the wherewithal to handle the dispensing load CAP vendors can expect to face. It will be particularly important for vendors to have a broad geographic presence, either directly or through subcontract arrangements, with a wide network of pharmacies. Otherwise the vendor will be unable to make routine and emergency deliveries in time frames that meet patient needs.

CMS also should gather data about each applicant's experience in critical functions such as pharmacy services management, billing and collection, and compliance to evaluate the applicant's ability to provide the level of service and quality necessary to support physicians who furnish Part B drugs in their offices and the Medicare beneficiaries who depend on them for care. As part of this process, CMS should consider checking references to assess how satisfied customers of a size commensurate with that of most oncology practices have been with past service.

In each of these areas, the bidder's qualifications can be assessed not merely on the basis of their experience in the commodity service of distribution but in crucial service functions that will determine the difference between vendors who can safely and reliably serve CAP physicians needs, and those that cannot.

Claims Processing Overview

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

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

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

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

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

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

Categories of Drugs to be Included under the CAP

The design and implementation of a competitive acquisition program for Part B drugs is an enormous undertaking. It is also an undertaking that will move Medicare into largely uncharted waters. That fact alone argues for a cautious approach.

Although CMS has managed two competitive acquisition demonstration projects for certain types of durable medical equipment, prosthetics and supplies (DMEPOS) in limited geographic markets, it has never organized and run a competitive acquisition program on a national or even a regional scale. The Part B drug CAP differs significantly from the DMEPOS demonstrations because of complicated state licensing and regulatory schemes, the criticality of most of the products involved from a beneficiary perspective, the single-source nature of many of the drugs to be furnished, and the necessity for substantial changes in Medicare claims processing systems that go beyond anything required to implement the DMEPOS demonstrations.

With DME, there were numerous established suppliers operating in a largely unregulated state licensure environment. Because participation in the demonstration by Medicare beneficiaries living in the test areas was mandatory, the bidders knew the size of the potential market. The bidders also ran established businesses and clearly understood the cost structures of those businesses. Unlike the situation with single-source drugs that are the standard of care for many cancer patients today, each product category subject to DMEPOS competitive bidding included numerous items under most HCPCS codes subject to the demonstration. Also unlike the situation that will face manufacturers of Part B drugs in 2006, the discounts extended to DMEPOS competitive bidders did not impact Medicare reimbursement for the manufacturer's product in locations outside the demonstration area. In other words, with DMEPOS, CMS could count on an adequate supply of qualified bidders positioned to put forth bids consistent with required quality and service standards without sacrificing reasonable profitability and jeopardizing solvency. Furthermore, the product categories included in the DMEPOS demonstrations are not generally seen as carrying the same level concern about product integrity or medical errors as do Part B drugs. Therefore, if DMEPOS CAP vendors stunted on quality or service, the likely outcome for beneficiaries was not as potentially significant as if problems develop with the Part B drug CAP.

The GAO issued a final report to Congress assessing the DMEPOS demonstrations in September 2004. In that report, the GAO suggested that CMS consider

conducting more competitive bidding demonstrations for items and services not in the original demonstrations prior to the beginning of the MMA-mandated implementation of CAP for DMEPOS.

This suggestion argues for taking a slow approach to the Part B drug CAP. In fact, it appears that CMS may already agree. In its final report on the DMEPOS CAP demonstration projects, CMS observed "one of the benefits of conducting demonstrations projects is the ability to learn from the demonstration and apply the lessons if the demonstration is adopted on a wider scale."

Instead of diving into a national CAP involving all Part B drugs used in "incident to" services, CMS should begin with a regional or national test involving a limited set of drugs that are typically administered by a physician specialty that uses drugs less intensely than oncology. This would allow CMS to refine its application and vendor selection procedures and its quality and service requirements, correct glitches in CAP upgrades to its claims processing systems, work out handling issues stemming from state regulations, assess and adjust for changes in practice expenses attributable to CAP, and complete the work needed to better match the reimbursement rates for drug administration services to actual costs for the various specialties before CAP is implemented

Dispute Resolution

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

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

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

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

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

Fourth, CAP physicians will face much higher claims administration costs. CAP requires Medicare claims for drug administration services to be filed within 14 days of the drug administration service. This represents an increased burden since the Proposed Rule acknowledges that only about 75% of claims currently are filed within this timeframe and since claims processing software will need to be upgraded. Further, CAP physicians will be unable to make a cost-benefit decision about the value of appealing a claim denial for drug administration services. Instead, physicians could be forced to appeal all denials in a process that requires all the evidence needed to support the appeal to be collected and submitted.

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

Competitive Acquisitions Areas

A key issue relating to Competitive Acquisition Areas is the requirement that CAP vendors have arrangements in place sufficient to permit shipment "at least 5 days each week for competitively biddable drugs and biologicals . . . and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract." (See also 42 CFR 141.914(f)(2)). We appreciate CMS's request for comments both on "how to define timely delivery for routine and emergency drug shipments" and on the "feasibility of providing same day deliveries for orders received for emergency situations" (70 Fed. Reg. 10745,10760 (March 4, 2005)).

I believe that the proposed timelines for routine and emergency delivery are inadequate and that vendors must be required to make routine deliveries anywhere in their service area within 24-hours of a practice's submission of a new prescription 7 days a week. I base this recommendation on three principle considerations. First, it is not unusual for oncology practices to operate 6 and 7 days a week to meet their patients' needs. Second, it is estimated that approximately one-third of treatment plans must be modified on the day of treatment due to changes in a patient's health status. Third, the unavailability of drugs needed on the day of treatment would pose a significant burden on patients who would have to return another day for treatment. This burden can be particularly severe in rural areas where patients may have to travel long distances to receive cancer care.

CMS has the authority to require that CAP vendors be able to delivery drugs within 24 hours 7 days a week under the statutory language in Social Security Act ?1847B(b)(2)(A)(i)(II). That provision imposes two standards on CAP vendors: the ability to make timely deliveries and the ability to ship at least 5 days each week. I believe that CMS should use its authority to define "timely delivery" as a 24-hour turn around and 7-day-a-week delivery services. I fear that anything less could jeopardize the ability of cancer care specialists to meet their patients' clinical needs.

I believe CMS should not rely on an expectation that oncologists who choose CAP will continue to maintain an adequate inventory of drugs that can be used to treat Medicare patients in emergencies under the inventory replacement provisions of the CAP rule. CAP is expected to spur growth in commercial payers?

mandatory vendor imposition (MVI) programs. As a result, some physicians who elect CAP and continue offering in-office drug administration services may cease to maintain any on-site drug inventories. Even those practices that maintain inventories may limit them for a variety of reasons, including differences in the clinical needs of their Medicare and non-Medicare patient bases.

Finally, I note that neither the changes to 42 CFR 414.902 set forth in the proposed rule nor the text of the existing regulation define the term "emergency." It is essential for the definition of emergency to be clearly set forth in the final rule and not left to the discretion of each CAP vendor or to the discretion of local carriers tasked with adjudicating practices' claims for drug administration services. Moreover, the definition should turn on the treating physician's clinical judgment that patient health would suffer from delay in treatment, not on the CAP vendor's or the local carrier's remote assessment of the situation.

In closing, I respectfully urge CMS to implement the "timely delivery" requirement established by MMA as requiring CAP vendors to be able to deliver ordered drugs within 24 hours, 7 days a week.

Contracting Process-Quality and Product Integrity Aspects

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

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

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

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

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

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

Contract Requirements

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

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

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

I am convinced that CAP vendors must be licensed as pharmacies, however. The statute does not expressly define the class of trade of a CAP vendor and §1847B(b)(4)(C) could suggest that Congress viewed CAP vendors as wholesalers. And yet, Social Security Act §1847B(b)(6) seems to take a different position, stating that nothing in Social Security Act §1847B shall be construed as waiving applicable State requirements relating to licensing of pharmacies. CAP vendors must be licensed as pharmacies because they will accept patient-specific written orders for prescription drugs from physicians, assign prescription numbers to those orders, interpret the orders, presumably making generic substitutions as appropriate and permissible under applicable State law, and then transfer dispensed drugs to the prescribing physician for administration to the patient. This patient-specific transfer amounts to "dispensing" a drug under state pharmacy practice acts and because CAP vendors dispense, they are practicing pharmacy and must be licensed accordingly. Since CAP vendors must operate as licensed pharmacies, some of the operational aspects of CAP seem unworkable or in need of retooling. For example, state pharmacies laws do not permit a pharmacist to assign different prescription numbers to successive fills of a single prescription. Rather, prescription refills are always dispensed under the prescription number assigned to the original written order. A new prescription number is assigned only when a new written order is received. These practices are inconsistent with the prescription numbering system described in the preamble to the Proposed Rule.

Another critical problem is posed by CMS's proposal for dealing with CAP drugs that cannot be administered to the beneficiary for whom they were prescribed.

Most state pharmacy laws prohibit the restocking of unused drugs after they have been dispensed. By establishing a process for the restocking and use of previously-dispensed drugs, however, the proposed rule appears to put the physician in the position of aiding and abetting the violation of these state pharmacy laws. In fact, none of the laws of which I am aware allow dispensed product to be redirected to another patient without going back to the dispensing pharmacy first.

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

Cap Bidding Process-Evaluation and Selection

CMS intends to contract only with qualified CAP bidders that submit composite bids with a weighted average price per HCPCS unit that is no greater than 106% of the weighted ASP for the drugs in the category. US Oncology has consistently taken the position that reimbursement at 106% of ASP is inadequate to cover physicians' costs for chemotherapy drugs and for pharmacy management services and other associated expenses, including bad debt, that are currently not considered in the practice expense component of the drug administration G codes.

Just as I believe this level of reimbursement is inadequate for physicians under the buy-and-bill model, so too do I view reimbursement at 106% of ASP to be inadequate under the CAP model. Competition will not cause manufacturers of most single-source drugs to discount their products to CAP vendors or to any other class of buyer that must be considered when Best Price is calculated. And, like physician practices nationwide, bad debt will pose a major financial challenge to CAP vendors.

In addition, CAP vendors will incur significant middleman costs, including administrative, dispensing, shipping, product disposal, and bad debt costs. These costs are borne by physicians practices everyday, but CAP vendors will likely face even greater difficulty collecting due to the time delay between the dates of treatment and payment, as well as their lack of a direct relationship with patients. Beneficiaries who are already contending with deductibles and coinsurance payments not covered by secondary insurance, travel expenses, custodial care expenses, costs associated with changed dietary needs, etc., may place a relatively low priority on paying their CAP vendors.

Just as the absence of personal relationships between beneficiaries and CAP vendors is likely to exacerbate the vendors' bad debt collection problems, I fear it will also exacerbate some vendors' use of overly aggressive collection efforts, including decisions to stop providing drugs for patients who are too far in arrears. The Practicing Physicians Advisory Council has also raised this concern and proposed that CMS address it in the final CAP rule by mandating that vendors advance credit to patients unable to afford their coinsurance payments. CMS should go a step further and ask that the vendors also be required to have in place procedures for assessing indigence and waiving coinsurance when a non-Medicaid-eligible beneficiary's income, assets, and medical expenses meet certain pre-established criteria. Ideally, these procedures should incorporate the assistance of social workers trained to explore all payment options and assistance programs available to the individual.

Unlike the situation with physicians where reimbursement for Part B drugs supplied under the buy-and-bill model is set by statute at 106% of ASP, CMS may have the discretionary authority under Social Security Act ?1847B to permit payments to CAP vendors at any level necessary to compensate them fairly and appropriately for their services. It appears that Congress only expected competition under the CAP model to save money on multi-source drug products, not single-source drugs and biologicals.

Pre-defining an unrealistically low reimbursement cap could under-capitalize vendors, resulting in too few qualified bidders, the provision of improper services, and patient harm. Therefore, CMS should either abandon the notion that CAP will save money in the aggregate for Medicare Part B or phase in the program slowly by starting with a small group of drugs or with a specialty that does not use ?incident to? drugs intensively to test the impact of an potentially under-reimbursed CAP model on beneficiary access to care and on the robustness and financial viability of the CAP vendor market.

In either case, one conclusion should be recognized: just as 106% of ASP is too low in the buy-and-bill model, so too is it unsustainable in CAP.

Submitter : Dr. Peter Byeff
Organization : Offices of Drs. Peter Byeff and Kenneth Smith
Category : Physician

Date: 04/09/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

Unless the Medicare demonstration project is continued, our offices in Connecticut will no longer be able to treat Medicare patients. We have already seen a decline in revenue with the Medicare Modernization Act and the Competitive Acquisition of Outpatient Drugs and Biologicals would only make matters worse. We feel that we would simply go out of the practice of treating Medicare patients under this scenario, since we would simply be unable to afford to continue our current practice. Medicare must continue the demonstration project to allow us to continue to treat our Medicare patients. Peter D. Byeff, MD and Kenneth J. Smith, MD

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Product integrity is about more than blocking the distribution of counterfeit goods, however. That is why I am concerned that the Proposed Rule's provisions could jeopardize product integrity and violate state licensing laws. I suspect that CMS may not have thought through licensing and product integrity issues because it seems to have concluded that CAP vendors should be licensed as wholesalers but not as pharmacies. Indeed, many provisions in the Proposed Rule and the entire discussion of product integrity in the preamble focuses on wholesale distributors.

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load CAP vendors can expected to face. It will be particularly important for vendors to have a broad geographic presence, either directly or through subcontract arrangements, with a wide network of pharmacies. Otherwise the vendor will be unable to make routine and emergency deliveries in time frames that meet patient needs.

CMS also should gather data about each applicant's experience in critical functions such as pharmacy services management, billing and collection, and compliance to evaluate the applicant's ability to provide the level of service and quality necessary to support physicians who furnish Part B drugs in their offices and the Medicare beneficiaries who depend on them for care. As part of this process, CMS should consider checking references to assess how satisfied customers of a size commensurate with that of most oncology practices have been with past service.

In each of these areas, the bidder's qualifications can be assessed not merely on the basis of their experience in the commodity service of distribution but in crucial service functions that will determine the difference between vendors who can safely and reliably serve CAP physicians needs, and those that cannot.

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camp's ability to qualify as a group practice under the Stark Law. Although the provision of "incident to" drugs furnished by a CAP vendor presumably will not trigger the Stark Law since a practice will have no financial stake in the outpatient prescription drugs, many group practices rely on the in-office ancillary service exception for purposes beyond drug treatment and would have legitimate concerns about the implications of a partial break-away of group members under the "substantially all test" used to define group practices.

I recognize that CMS's claims processing systems are set up based on group numbers and that carriers may need to implement system changes to deal with individual choice. And yet, I also recognize that the statute, the Conference Report, and even statements made by the CMS Administrator all share one crucial theme: participation in CAP will be a physician's completely voluntary choice. Denying the right of individual choice simply to avoid system upgrades is unfounded and unacceptable.

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Submitter : Dr. Murtaza N Bhuriwala
Organization : JPS centre for Cancer care
Category : Physician

Date: 04/09/2005

Issue Areas/Comments

GENERAL

GENERAL

Its difficult for patients to fight against an immortal cancer & to make life more difficult for treating physician about drugs being dispensed is medically covered by medicare or not its going to make fight against cancer difficult at best.....Does some 1 care about patients outcome ? we need more help rather than restrictions to fight this WAR AGAINST CANCER , it will be lost before it begins if these legislations are fixed.

CMS-1325-P-67

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals**Submitter :** Dr. Dane Dickson**Date & Time:** 04/10/2005**Organization :** Teton Oncology**Category :** Physician**Issue Areas/Comments**

1-15

Overview of the CAP

CAP will place extreme administrative burden on offices without providing recourse for the added burden. Managing drug inventories is complex enough without having to manage drug inventory for each and every individual patient that is coming into the office at a given day. In addition, it is common to switch a treatment during an office visit due to toxicity or to progression of disease. If patients have to wait for new drugs to be acquired before being able to receive treatment then this will place an extreme burden on them, especially when some travel 200+ miles to receive treatment. In addition, needing to send back drug to the centralized clearing organization will be problematic given expense and time needed to manage this transaction.

Also, I believe that the money that would be saved by enforcing CAP will be lost in lost co-pays, and non-covered drug. Whereas a private office keeps close eye on both of these issues, by taking the control and placing it centrally it opens up huge problems for the chosen pharmacy.

In short, I feel that the administrative burden of CAP in oncology offices is extreme, that the delay in obtaining even by one day will cause profound issues with access and adversely affect cancer care, in addition, I feel it will cause huge losses for the chosen agency and thus will lead to a non-supportable methodology and eventually lead to profound access issues by termination of the program.

Submitter : Dr. richard berchou
Organization : Wayne State University
Category : Pharmacist

Date: 04/11/2005

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

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

To whom it may concern:

As a healthcare provider, I have concerns that Psychiatric Medications may not be incorporated under the Medicare Competitive Acquisition Program for Part B Drugs. I currently provide Psychopharmacology Consultation for the Community Mental Health Organizations in Southeastern Michigan; Wayne, Oakland, and Macomb Counties. These counties treat the majority of the severe and persistently mentally ill population in the State of Michigan. Many of these individuals are receiving Medicare and Medicaid Services. Because these medications have been considered as a "Medical Benefit", access to these medications has been severely restricted. Some primary care physicians providing injections for these individuals have refused to participate in the practice of "buy and bill". The physicians have numerous concerns regarding specialized billing, cost of medication, poor patient appointment compliance, and un-resolved storage issues. Similarly, community mental health agencies have found the structure of the billing process time consuming and cumbersome. There is also the need to designate secure storage space with the ability to refrigerate medications (e.g. Risperdal Consta). The "buy and bill" process also requires the allocation of funds to be set aside which decreases already limited resources for patient care. A more reasonable suggestion and one that I am recommending is to consider including the Psychiatric Injectables under the Competitive Acquisition Program. Creating additional and unnecessary barriers for those individuals with severe mental illness serves to further impair their access to needed medications.

Thank you for your concern in this matter.

Richard C. Berchou, Pharm. D.
Wayne State University
Department of Psychiatry and Behavioral Neurosciences

CMS-1325-P-69

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. kumud Tripathy

Date & Time: 04/11/2005

Organization : Cancer Clinic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

CAP is going to be a complicated process making Oncology practice a lot more difficult and practically unprofitable. As of now, the cost and potential for monetary loss (of money that I have already paid to buy the drug) becomes a very important consideration when I am deciding what agent I am going to treat a patient with. Patient gets treated in a setting that is less likely to cause a loss of money to me irrespective of his convenience and preference. This has been brought about by the recent changes in Medicare program and things like CAP are going to make every thing worse. For now I will be sending a lot more patients to hospital where the care is more costly and less efficient and takes more time out of patients' short remaining lifespan. But I am seriously considering retirement because I feel I am not putting patient interest as the only consideration when deciding on the treatment.

CMS-1325-P-70

Medicare Part B - Competitive Acquisition of Outpatient Drugs and Biologicals

Submitter : Dr. Leonard Horwitz

Date & Time: 04/11/2005

Organization : Leonard J. Horwitz, M.D., FACP

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS:

Having dealt with some MVI programs, if CAP will be anything like this, I am concerned about delivery times and errors, even under the best intentions. Also, any changes in dosing (or cancellations) lead to delays or wastage problems. Please keep these serious problems under consideration. Thank you.

Sincerely, Leonard J. Horwitz, M.D.

Submitter : Dr. Gerard Ventura

Date: 04/06/2005

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

file code CMS-1325-P

1) Without price controls on the drugs from the true source - the manufacturer - any talk of "competition" in the acquisition process to bring down CMS costs is an illusion. Case in point: We already have a fair number of drug wholesalers with huge economies of scale competing with each other for our business (Florida infusion, Schein, etc) - and that didn't lower prices. Why would the same system, only extending it directly into the arena of patient care, be expected to? The exorbitant prices and their increases remain unregulated at the source. Congress needs to face the political reality and fix the problem at the source. Medicare has limiting charges on doctor visits, hospital stays, durable med equipment, etc - it needs to have it for drugs as well.

2)
The extra layers of administration, book-keeping, tracking shipments, etc etc will add further costs to the program in the doctor's office/clinic way beyond the present costs. I believe most offices will either continue buying the drugs themselves, or give up administration entirely, forcing it into the hospital outpatient setting (paradoxically further driving up CMS costs).

3) Taking drug delivery out of the oncologists office will not stop the (hopefully) few doctors who give too many drugs too often out of abuse, as they will continue to bill for administration, visits, etc. Ironically again, those very few bad apples will probably increase their pattern of abuse in such a system.

4) This proposed system is disturbing, in that it has a whole 'Rube Goldberg' feel to it that is divorced from the reality of cancer care. The biggest stumbling block, once again, is the true source of the problem - an FDA that approves drugs without consideration of cost, and the prohibition against negotiating cost from the manufacturer. That will destroy any house of cards no matter how elegant on paper.

Gerard Ventura MD
Nacogdoches, Texas

Submitter : Dr. BRIAN ULRICH
Organization : CLINICS OF NORTH TEXAS
Category : Physician

Date: 04/06/2005

Issue Areas/Comments

GENERAL

GENERAL

THE PROVISION OF THE MVI STIPULATING THE DURATION OF VENDOR FOR A ONE YEAR PERIOD IS NOT IN THE BEST INTEREST OF THE MEDICARE PATIENTS. IF I ENCOUNTER POOR SERVICE ETC I AM UNABLE TO SEEK OTHER ARRANGEMENTS FOR A YEAR. I WOULD RECOMMEND A SHORTER PERIOD OF TIME SUCH AS 4-6 MONTHS AND LET THE VENDOR-DR ARRANGEMENTS BE MORE IN KEEPING WITH MARKET FORCES.

Submitter : Dr. Patrick Cobb
Organization : Hematology-Oncology Centers of the Northern Rockies
Category : Physician

Date: 04/06/2005

Issue Areas/Comments

GENERAL

GENERAL

Sirs:
My partners and I have several concerns after reviewing the CAP proposal by CMS. We believe this program has many flaws as it is currently structured. We also believe that implementing a program that will affect the main function of an oncology practice without a pilot program is very unwise. Here are some of our concerns:

- " How would the drugs be ordered? Online? Paper form to be faxed? This would create a significant paperwork increase. How would the drugs be shipped?
- " What happens to the drugs if a patient doesn't need them anymore? It's not clear from the summary how the drugs would be returned or credited. Who pays for the shipping and handling of sending the drug back? I would feel very uncomfortable using drugs that have been sent to a practice, returned to the vendor, and then sent to my practice. The opportunity for fraud and spoilage are simply too great.
- " Although the CAP drugs would not have to be stored separately, the requirement to maintain a separate inventory demands separate storage by default. What if a practice makes a mistake on your drug inventory? Would the practice be subject to prosecution for fraud and abuse?
- " What happens if a claim is denied by Medicare? Would this cause a problem for the practice?
- " What happens if a patient doesn't have co-insurance? Would the vendor have to right to deny services to patients who cannot pay? Would a physician be counseled if he orders chemotherapy on a patient who doesn't have co-insurance?
- " Who decides if an emergency situation exists that requires immediate treatment? Would this decision by the oncologist be subject to review by Medicare or by the vendor?
- " It is apparent that CMS will not give any payments for the administrative hassle of the CAP program. It's obvious that the program would require a significant amount of paperwork that will go unpaid by Medicare.
- " I am not aware of any vendors in Montana that could handle this type of business. Our current chemotherapy supplier, Oncology Therapeutics Network, has told us the CAP program doesn't make sense for their business and they don't intend to make a proposal.
- " Why would any vendor be interested in this business model? The margins on the drugs are so narrow that there shouldn't be much interest, especially given the administrative nightmare of collecting copayments from patients around the country, unless CMS is willing to give the vendors financial incentives to participate. Those financial incentives could be given to the private practices in the current system, with much more efficiency and less waste.
- " If a practice chooses to participate in CAP, it would be locked into the drug vendor for an entire year. What happens if there are problems with vendor adherence to quality, delivery, etc.? Would there be a mechanism to switch vendors in case of problems?

My partners and I feel that the CAP program will not work for our practice in Montana unless these concerns are addressed. We would urge the committee to call for further study and suggest a pilot program to make sure this radical change will not adversely affect access to cancer treatment for Medicare recipients.

Patrick Cobb, M.D.
Billings, Montana

CMS-1325-P-E3-Attach-1.doc

Sirs:

My partners and I have several concerns after reviewing the CAP proposal by CMS. We believe this program has many flaws as it is currently structured. We also believe that implementing a program that will affect the main function of an oncology practice without a pilot program is very unwise. Here are some of our concerns:

- How would the drugs be ordered? Online? Paper form to be faxed? This would create a significant paperwork increase. How would the drugs be shipped?
- What happens to the drugs if a patient doesn't need them anymore? It's not clear from the summary how the drugs would be returned or credited. Who pays for the shipping and handling of sending the drug back? I would feel very uncomfortable using drugs that have been sent to a practice, returned to the vendor, and then sent to my practice. The opportunity for fraud and spoilage are simply too great.
- Although the CAP drugs would not have to be stored separately, the requirement to maintain a separate inventory demands separate storage by default. What if a practice makes a mistake on your drug inventory? Would the practice be subject to prosecution for fraud and abuse?
- What happens if a claim is denied by Medicare? Would this cause a problem for the practice?
- What happens if a patient doesn't have co-insurance? Would the vendor have the right to deny services to patients who cannot pay? Would a physician be "counseled" if he orders chemotherapy on a patient who doesn't have co-insurance?
- Who decides if an "emergency situation" exists that requires immediate treatment? Would this decision by the oncologist be subject to review by Medicare or by the vendor?
- It is apparent that CMS will not give any payments for the administrative hassle of the CAP program. It's obvious that the program would require a significant amount of paperwork that will go unpaid by Medicare.
- I am not aware of any vendors in Montana that could handle this type of business. Our current chemotherapy supplier, Oncology Therapeutics Network, has told us the CAP program doesn't make sense for their business and they don't intend to make a proposal.
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- If a practice chooses to participate in CAP, it would be locked into the drug vendor for an entire year. What happens if there are problems with vendor adherence to quality, delivery, etc.? Would there be a mechanism to switch vendors in case of problems?

My partners and I feel that the CAP program will not work for our practice in Montana unless these concerns are addressed. We would urge the committee to call for further study and suggest a pilot program to make sure this radical change will not adversely affect access to cancer treatment for Medicare recipients.

Patrick Cobb, M.D.

Billings, Montana

Submitter : Dr. William McGarry

Date: 04/06/2005

Organization :

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

This is in regard to CMS-1325-P, mandating outpatient infusion centers to utilize a "mandatory vendor" on Jan 1 ,2006. Various private insurance companies have tried similar schemes to reduce costs in the past, all of which has resulted in minimal cost savings fo the health plan but more administrative overhead and inconvenience for the patient.

By limiting purchasing to one or two vendors, CMS will be effectively creating monopolies on the provision of cancer care in communities across the United States. This will inevitably result in less competition and higher prices to deliver care to cancer patients.

Under the current proposed rules, physicians must choose their mandatory vendor by Jan1, 2006. They are not allowed to change after this date for at least one year. If the vendor is later determined to be incompetent at providing the proper medications for the patients, a distinct possibility as this system has never been done before by any company on a national scale, there would be no recourse or correction that could be made by the treating physician to ensure quality care for the patient.

In effect, if this system is implemented despite its failures in the past, there should not be a "lockout". Oncologists should be able to choose from a variety of vendors or even resume purchasing the drugs directly on a case by case basis. This would prevent the "mandatory vendor" from establishing themselves as a monopolywith whom CMS and Congress will have a much more difficult time negotiating with in the future.

Submitter : Dr. David Mintzer
Organization : Pa. Oncology Hematology Assocs Inc
Category : Physician

Date: 04/06/2005

Issue Areas/Comments

GENERAL

GENERAL

Supplying chemotherapy to physicians' offices, and thus to patients, from an outside vendor will be inefficient, unsafe, impractical and wasteful. It will require many patients to double the number of visits to their physicians office--an unfair and undue burden on people who are already ill. This is because we will not have the treatment in stock for the patient so they will often need to return a second time once the medication has been shipped. Further, at least 30% of visits for chemotherapy result in the need to modify the treatment on the day of the visit depending on the patient's clinical status and blood work (patients symptoms, lab work change on a day to day basis often when they are ill). Thus, chemotherapy ordered several days ahead will be incorrect and wasted. Further as physicians who are responsible for the well being of the patients, we are being asked to administer toxic medications that have been prepared elsewhere, not under our supervision, and transported thru the mail under various conditions (impacting stability and sterility). In addition, ordering and keeping track of these medications from vendors will be a laborious task that wil consume significant office time that we do not have and for which you are not planning to reimburse. I cannot emphasize enough how ridiculous, unsafe, inefficient, impractical and unfair a proposal this is--for both patients and physicians. I strongly suggest you reconsider this proposal and instead work to fairly reimburse physicians for their handling of chemotherapy including the financial risk (incomplete collections), wastage, overhead, and expertise in the supply and administration of chemotherapy-- for our patients' sakes.