Submitter : **Jennifer Rand** **Date: 09/05/2005**

Organization : **Jennifer Rand**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1372-IFC
PO Box 8013
Baltimore, MD 21244-8013

Dear Centers for Medicare and Medicaid Services:

I am a thyroid cancer patient, and I am writing to request that Thyrogen? (thyrotropin alfa for injection) be included in the list of drugs available through the Medicare competitive acquisition program (CAP) in 2006.

Thyrogen is crucial for the follow-up of my thyroid cancer treatment, in testing used to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment.

It would reduce the quality of care for the Center for Medicare and Medicaid Services to deny access to Thyrogen through the Medicare Competitive Acquisition Program.

I am concerned that your proposed guidelines will exclude Thyrogen from the CAP. Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,

Jennifer Rand

3631 E. Montecito Apt. #1
Phoenix, AZ 85018

Submitter : Dr. Maria Verso **Date:** 09/05/2005

Organization : Phoenix Endocrinology Clinic Ltd.

Category : Physician

Issue Areas/Comments

Background

Background

People who have had thyroid cancer are required to have a whole body scan yearly to search for metastases. This necessitates taking them off thyroid hormone for 3-4 weeks.After the scan and possible subsequent RadioIodine Therapy,the thyroid hormone is restarted. However, since many of these pts. are elderly, they must be restarted and continued for a long time on a token dose because of the stress on their hearts. When they are hypothyroid off medicine, there is a great increase in cholesterol, which may last for months. This makes them suspectible to heart attacks for several months. In addition, these people are greatly fatigued,with insufficient stamina to carry on the routine of daily living for many weeks. As you may be aware, a product called Thyrogen can be given that preserves the body's uptake of Radioactive Iodine without demanding that the pt. come off thyroid medicine. Thus, there is no change in lifestyle, no increase in cholesterol, no cardiac stress, while the patient can be successfully treated. There is no doubt that it is a pricey item since it sells for about $700. However, that should be balanced against the cost of a CCU if the patient sustains a heart attack. Since it has been shown that Thyrogen is as effective as thyroid withdrawal, one needs to remember that it is for treatment of the very group for whom withdrawal carries the most peril.
M.A. Verso, M..D., F.A.C.P, F.A.C.E.

Submitter : **Ms. Norma Muir** **Date: 09/05/2005**

Organization : **Ms. Norma Muir**

Category : **Individual**

Issue Areas/Comments

Background

Background

I am a very close friend of a thyroid cancer patient and I am requesting that Thyrogen be included in the list of drugs available through the Medicare competitive acquisition program (CAP) in 2006.

Submitter : **Ms. Charlotte Wunderlich** **Date: 09/06/2005**

Organization : **ThyCa: Thyroid Cancer Survivors' Association, Inc.**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

10113 Parkwood Terrace
Bethesda, Maryland 20814
September 5, 2005

Dear Centers for Medicare and Medicaid Services:

I am a thyroid cancer patient, diagnosed in 1999. I am also in my seventh year as a volunteer for ThyCa: Thyroid Cancer Survivors' Association, for which I'm the Outreach Coordinator.

Today I write to ask that the Medicare competitive acquisition program (CAP) include Thyrogen (thyrotropin alfa for injection) in the list of available drugs.

Thyrogen is part of my thyroid cancer care, because it's used in the testing that I require to determine whether or not I am free of disease or whether my thyroid cancer has recurred or spread and requires further treatment.

I am concerned that your proposed guidelines exclude Thyrogen from the CAP. It is unfair to exclude Medicare beneficiaries from this access to Thyrogen.

Please change your proposed guidelines. The CAP should include Thyrogen (thyrotropin alfa for injection) in CAP so that patients on Medicare beneficiaries have access to Thyrogen in the same way that other drugs are included.

Thank you.

Sincerely yours,
Charlotte F. Wunderlich

Submitter : **Janet Adams** **Date: 09/06/2005**

Organization : **patient**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dear Centers for Medicare and Medicaid Services,

As a thryoid cancer patient since 1983,I am writing to request that Thyrogen (thyropropin alfa for injection) be included in the list of drugs available through the Medicare competitive acquisition program in 2006.

This thyrogen drug is an important key in follow-up of thyroid cancer treatment. I have been thru the alternate method of withdrawing the thyroid replacement hormone 3 times already and now that an alternative has been developed, I feel that it should be included in the CAP to improve the quality of care for Medicare patients who need follow-up treatment to test for the presence of thryoid cancer.

By including thyrogen, you will alleviate paperwork and effort on the part of physicians, and and alleviate a possible financial burden on a Medicare patient.

Thank you for your consideration of this matter.

Sincerely,
Janet Adams

Janet Adams
Farmers Branch, Texas

Submitter :

Date: 09/06/2005

Organization :

Category : Individual

Issue Areas/Comments

Background

Background

I am the parent of a thyroid cancer survivor

GENERAL

GENERAL

Dear Centers for Medicare and Medicaid Services:

I am the parent of a thyroid cancer patient, and am writing to request that Thyrogen (thyrotropin alfa for injection) be included in the list of drugs available through the Medicare competitive acquisition program (CAP) in 2006.

Thyrogen is crucial for the follow-up of her thyroid cancer treatment, in testing used to determine whether or not she is free of disease or whether her thyroid cancer has recurred or spread and requires further treatment. Denying access to Thyrogen through the CAP will reduce the quality of care for the Center for Medicare and Medicaid Services as Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,
Colleen Schnur

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

na

Regulatory Impact Analysis

Regulatory Impact Analysis

na

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

na

Submitter : **Dr. Robert Provenzano** **Date: 09/06/2005**

Organization : **Renal Physicians Association**

Category : **Physician**

Issue Areas/Comments

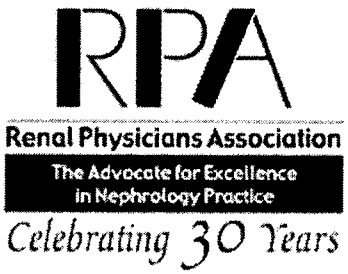
GENERAL

GENERAL

See attachment

CMS-1325-IFC-137-Attach-1.WPD

#137



September 6, 2005

Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Attn: CMS-1325-IFC
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B (CMS—1325—IFC) Interim Final Rule

Dear Dr. McClellan:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with renal disease. We are writing to provide comments on selected portions of the Interim Final Rule establishing the Competitive Acquisition Program (CAP) for Part B Covered Drugs and Biologicals in the Medicare program.

Overview of the CAP

RPA understands that CMS was fulfilling a legislative mandate with the issuance of the interim final rule, and we believe the Agency made a good faith effort to implement the underlying statute as written. However, it is RPA's opinion that the unresolved issues that remain, despite the Agency's best efforts to identify and resolve them through the comment and review process, make the CAP program virtually unworkable from the physician practice perspective. Primarily, the degree to which the physician's practice must carry out record keeping and information transmission functions without additional reimbursement for the practice expenses involved in performing these activities will, in our opinion, make the cost of participating in the CAP program prohibitively expensive for the vast majority of physician's offices. We therefore commend CMS for its recent decision to suspend the CAP vendor bidding process and take additional time to analyze

comments received on the interim final rule in an effort to improve the attractiveness and efficiency of the CAP. Accordingly, RPA urges CMS to refrain from implementation of the CAP program until the operational issues identified through the comment and review process have been resolved to the maximum extent practicable. The balance of RPA's comment will focus on specific points of concern raised by the interim final rule.

Vendor Implications

In the interim final rule, CMS finalizes its proposal to require vendors to submit bids on at least one drug for each HCPCS code within a category, but goes on to state its belief that that it is not "advisable or feasible to require vendors to provide all available FDA-approved drugs within a HCPCS code." RPA believes that this decision if left unchanged will have ramifications not only for physician prescribing autonomy but also for the quality of patient care. For example, kidney patients will often tolerate one intravenous iron preparation well but may have an adverse reaction to another, and thus problems may arise if the preferable drug or biologic is unavailable to patients and providers due to the structure of the CAP program. RPA urges CMS to revise the CAP program interim final rule so that physician practices are able to provide the best and most appropriate drug and biologic therapies to their patients. If left unaddressed, the limitation in this area may serve to be a deterrent to physician participation in the CAP program.

Content of CAP Drug Order/Submission of Beneficiary-Specific Information

CMS notes in the interim final rule that it is seeking to address the issue of compliance with HIPAA guidelines by noting that the HIPAA guidelines allow the sharing of beneficiary-specific information necessary for treatment purposes. However, the volume and content of patient-specific data that will be transmitted for CAP purposes seems to be not only fertile ground for scrutiny from federal oversight agencies but also potentially could have the adverse, unintended consequence of serving as the basis for inappropriate litigation in some situations. To address this concern prospectively, RPA strongly suggests that CMS make a more explicit and definitive statement in this area to assure practitioners that the data transfer necessary to participate in the CAP program will not inappropriately subject participating physician practices to undue oversight.

Content of CAP Drug Order/Anticipated Date of Administration

Among the comments addressed in the interim final rule is the concern that in ordering drugs from a vendor the physician may not be able to determine the anticipated date of administration with any accuracy, and in response CMS has specified that providing the vendor with a range of dates over a 7-day period will be sufficient. While RPA appreciates that CMS chose the 7-day timeframe with the understanding that many of the CAP drugs are used in a treatment regimen that is based on a weekly cycle, we do not believe that the 7-day range sufficiently accounts for potential complexities arising from patient scheduling and compliance issues. RPA thus recommends that CMS include in this provision language indicating that the physician's practice will be held harmless if the date of administration does not fall within the outlined 7-day period.

Drug Administration/Timely Filing

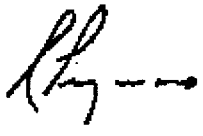
In the proposed rule on the CAP program, CMS outlined the use of a 14-day timely filing period for drug administration claims provided through the CAP program, and despite comments calling for an extension of that timeframe, the Agency upheld the timely filing period in the interim final rule. RPA urges CMS to revisit that decision. We concur with the commenter who offered that requiring CAP physicians to submit claims within 14 days is too drastic a change from the current 365 day current standard, and with the suggestion to change the requirement to 30 days. It is RPA's opinion that the 14-day requirement by itself is a significant and unnecessary initial disincentive to participate in the CAP program, and that extension of the deadline to 30 days would remove this disincentive.

Beneficiary Coinsurance

RPA continues to have profound concerns regarding the provision stating that CMS will not require approved CAP vendors to continue to provide CAP drugs for beneficiaries who do not pay their deductible or coinsurance under certain circumstances. Despite CMS' lengthy and logic-based discussion of the rationale for this decision and the methods through which beneficiaries unable to make these payments can seek assistance, we believe this provision will have a chilling effect on the continuity of care provided to low-income beneficiaries, a disproportionate percentage of whom are represented in the chronic kidney disease (CKD) and end stage renal disease (ESRD) patient sub-populations. RPA recognizes and supports CMS' charge to carry out its fiduciary responsibilities, and that collection of coinsurance by providers of services play a role in exercising that fiduciary responsibility. Further, we fully understand the necessity of CAP vendors to be as viable as possible. However, it is also our belief that CMS should be seeking methodologies to optimize and facilitate the delivery of care to the most marginalized Medicare patient populations, and that this provision does not achieve that standard.

As always, we welcome the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's ESRD patients, and we stand ready as a resource to CMS in its future endeavors.

Sincerely,



Robert Provenzano, M.D.
President

Submitter :

Date: 09/06/2005

Organization : **American Academy of Neurology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-IFC-138-Attach-1.DOC

AMERICAN ACADEMY OF
NEUROLOGY

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fax: 651.695.2791

www.aan.com

September 1, 2005

Mark McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services

Re: Competitive Acquisition of Outpatient Drugs and Biologicals under Part B of Medicare; CMS-1325-IFC

Dear Dr. McClellan:

The American Academy of Neurology ("the Academy") appreciates this opportunity to comment on the interim final rule on the Medicare Part B Competitive Acquisition Program (CAP) as published in the July 6, 2005 Federal Register.

We commend CMS for its efforts to include the concerns of the physician community in the interim final rule. In addition, we believe the decision to suspend the implementation of CAP pending further review is a prudent one. As you continue your review of how to best implement CAP, we urge you to consider the following concerns.

1. Alternative to Annual Enrollment: The current rule requires the physician to make a one year commitment to a CAP vendor with only very limited opportunity to opt out of that commitment. Since, at the outset, physicians will have no experience with CAP or with specific CAP vendors, we believe the rule should provide the physician with an opportunity to cease participation in the program if, for whatever reason, the physician determines that the program does not meet his or her needs or the needs of the patient. For example, a physician may find that the administrative and paperwork requirements burdens of participating in CAP are too burdensome or may find an alternative approach to obtaining drugs that works better for his or her practice. Some physician practices may find the requirement that drugs not be moved from one practice location to another to be unworkable. In addition, the physician may find that the CAP vendor is unable to comply with delivery times or shortages prevent the vendor from filling orders thereby putting patients at risk. Many of these problems may not manifest themselves until after the arrangement is entered into. As currently written, the physician could not opt out of the contract unless there are problems with vendor performance and then only by going through a dispute resolution process which could take several weeks or months.

We believe, at least during the first year of a contract with a new vendor, physicians should be given an opportunity to terminate the contract at any time and for any reason. Without this flexibility, we believe physicians will be reluctant to participate in

the program and may be precluded from taking action that is in the best interests of their patients.

2. Physician Opt Out/ Use of Alternative Sources: The rule would make participation in CAP an all or nothing proposition for all physicians in a group. We believe this approach is unnecessarily restrictive and will discourage participation.

For example, in a multi-specialty group with largely diversified subspecialties, participation in CAP may be advantageous for some subspecialties but totally unworkable for others depending on the types of drugs that group provides and the conditions under which they are provided. Where need for a drug is predictable and planned, such as botox infusions, obtaining drugs through a CAP vendor may provide certain efficiencies. However, for neurologists that, for example, offer emergency steroid infusions for patients with multiple sclerosis, obtaining drugs from a CAP vendor would not work since drugs would need to be ordered in advance. Even drugs ordered on an emergency basis would not be available until the next business day.

We believe the rule should provide more flexibility. The requirement that all physicians in a practice participate should be eliminated. Physicians should be permitted to make this decision on an individual basis. In addition, physicians who do participate should not have to agree to obtain all of their drugs from the CAP vendor but rather should be allowed to exclude drugs, such as those which are often provided on an emergency basis, from the CAP contract.

3. Shortage Drugs: The rule does not address the physician's options when there is a drug shortage or the drug is on allocation. If the CAP vendor cannot provide the drug, the physician should be permitted to obtain it elsewhere without it being a violation of the vendor contract.

4. Drug Wastage: The rule would not permit physicians to split vials of medication between different patients to avoid wastage. This will result in higher costs including higher charges to Medicare beneficiaries. For example, many neurology practices that administer botox infusions split vials of the medication between two patients in cases where a patient does not need the full vial. This reduces the patient's cost as well as that of the Medicare program. However, the CAP rule would not permit this. As a result, expensive drugs would have to be unnecessarily discarded and beneficiaries would be required to pay higher copayments for drugs they did not actually receive. We believe the final rule should provide a mechanism by which vials can be split between more than one patient.

5. Time period for submission of claims: The rule would require physicians to submit claims for drug administration within 14 days. This time frame is unrealistic given the complexities of billing and Medicare documentation requirements. Many practices have internal review and compliance procedures which may require full review of the chart prior to claims submission. The 14 day rule would require physician practices to short circuit this process and could result in claims submission errors. We understand that CMS does not wish to make payment to the vendor until the drug has been delivered, as evidenced by a claim for the drug administration. However, we urge the agency to consider other mechanisms for ensuring proper vendor payment. At the very least, the time frame should be considerably longer – at least 30 days with a longer period for problematic claims.

6. Restrictions on Moving Drugs: The rule would prohibit practices from moving drugs from one practice site to another. This restriction will negatively impact practices, particularly those in rural areas that have a number of satellite offices that are open on a less than full time schedule. Patients would be limited to receiving the drug at the location to which it had been shipped and on days that location was open rather than going to another location. This would make it difficult to address situations in which the patient, for medical reasons, needs to change the date of his or her treatment and the location at which they usually receive treatment is not open. While we understand CMS'

concern with proper storage and handling of drugs, we believe that physician practices should be permitted to transfer the drug to another location. It would be the responsibility of the practice to observe proper drug storage and handling procedures.

Currently, Medicare does not restrict physicians who order drugs directly from the manufacturer from moving those drugs to another location and we see no reason why a different policy should apply under CAP.

*****

We appreciate the opportunity to comment on this issue. If you have any questions regarding our comments, please contact Amanda Bettmann at the AAN at (651) 695-2718 or abettmann@aan.com.

Sincerely,

Laura B Powers MD

Laura Powers, MD
Chair, AAN Medical Economics and Management Subcommittee

Submitter : Mr. Michael LaBrecque **Date:** 09/06/2005

Organization : Priority Healthcare Corp.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-139-Attach-1.DOC

CMS-1325-IFC-139-Attach-2.DOC

Privileged and Confidential

August 29, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-1325-IFC (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B)

Dear Dr. McClellan:

Priority Healthcare Corporation (Priority), a specialty pharmaceutical distributor and specialty pharmacy services provider, is pleased to submit comments in response to the interim final rule for the competitive acquisition program (CAP) of outpatient drugs and biologicals. Priority supports the Centers for Medicare and Medicaid Services' (CMS) efforts to implement the CAP program and achieve the policy goals of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) in a manner that best serves the interests of beneficiaries, providers, taxpayers and the healthcare system as a whole.

Priority understands that optimal patient care and convenience are primary goals of Congress and CMS, a nd s trongly s upports t hat p osition. We f urther b elieve t hat t he f inal b usiness m odel should be sensitive to the needs of the physician community and be operationally efficient and economically sustainable for participating vendors. Furthermore, we support CMS in its position that the community physician office setting is the right place to provide most of the drugs covered under this rule with appropriate compensation for administration and delivery of high quality care.

In these comments, Priority seeks to ensure that the CAP program regulations promote convenience, optimal patient care, appropriate reimbursement for physician offices, as well as fair compensation and risk mitigation for CAP vendors. Additionally, we seek to ensure the

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Lake Mary, FL 32746
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www.priorityhealthcare.com

integrity and availability of products through a logistically sound and operationally efficient distribution model by appropriately allocating risk among all parties, based upon what each party can directly control.

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

Introduction to Priority Healthcare

As you may know, Priority Healthcare has been very active in collaborating with CMS on the impact of the Interim Final Rule. In all our interactions we have found CMS to be willing to listen and to incorporate our thoughts and comments to the extent practicable and allowed by law. We appreciate that very much and have written the comments below in the same thoughtful and deliberate manner in which we have approached the agency these many months.

As both a specialty distributor (distribution of specialty and biotech drugs to physician offices, clinics, etc. in their "bulk" form, non-patient specific), and a specialty pharmacy (provision of pharmacy services for specialty and biotech products on a patient specific basis, to the physician's office or directly to the patient's home), Priority is uniquely positioned to meet the requirements of the CAP program for CMS, participating physicians and beneficiaries. We also believe that we possess the required experience and knowledge to be able to consult with CMS in the development of the final rule and operation model.

Unlike most other pharmaceutical distributors, Priority has extensive capabilities and experience as a licensed medical services provider. Priority manages medical billing and payment for its services from health plans, and also counsels patients on health plan benefits. Priority provides a range of clinical services in conjunction with its pharmacy services, including 24/7/365 nursing and pharmacy support, that define a comprehensive program of specialty pharmacy care. To this end, Priority has developed our Caringpaths clinical programs based on core criteria and utilization management protocols specific to best practice standards that are both drug and disease specific. Our Caringpaths care management therapeutic programs help to ensure that patients and physicians are successfully managing these therapies and lead to successful outcomes. Additionally, Priority is an experienced provider of other related patient and physician office support services that include metric based compliance tracking, electronic medical record integration and disease treatment management programs, all of which are a testament to our experience working to build best in class specialty pharmacy programs.

Priority is also distinguished from other pharmacies as we have extensive expertise in logistics and cost effective distribution systems, augmented by our clear focus and expertise in the specialty channel. Therefore, Priority has significant insight into this market and is uniquely qualified to offer input to CMS on the CAP program, and to work with CMS to craft the type of solution that meets all of the aforementioned objectives.

Comments

Claim Adjudication Risk

Under the interim final rule as proposed, CAP vendors must wait until the proposed date of administration before they can submit a claim for reimbursement to the designated carrier. If the drug was not administered or the dose that was administered is different from that which was distributed to the physician, the physician by rule must contact the vendor and communicate this information in order to prevent an incorrect/invalid claim from being submitted to the designated carrier. This is problematic from many perspectives. Providers of pharmaceutical services are customarily entitled to payment after a drug has been delivered. Updated information from the physician regarding dose or date of administration is often unlikely to be communicated, even when warranted.

Billing delays that are incurred waiting for the administration date to pass will materially and adversely affect the provider's costs. Priority's experience in the commercial and current Medicare market dictates that it is unrealistic to expect that the physician's office will communicate this information to the vendor in a timely manner. Most offices do not possess the required staff to coordinate such activities. The vendor has limited knowledge and little way of knowing when and what to bill CMS. The only way the vendor can truly know is for them to place a follow-up call to the physician's office for each claim prior to billing the designated carrier. This follow-up activity adds costs and further lengthens the time in which the vendor will receive payment.

Regarding situations in which the drug is never administered, the interim final rule allows the drug to be used for another Medicare beneficiary. It indicates that the vendor and physician need to work out the required administration and paperwork to make that happen. It also refers to State Law having precedence over the distribution of product. CMS needs to understand that these two statements will often conflict with each other and not allow the necessary resolution to take place. This is only a pharmacy concern and does not apply if the drug is distributed to the physician under a distribution license.

It is our belief that if the vendor in good faith received a valid prescription order from the physician and shipped that order to the physician, they should be paid for the drug. In the case of the drug not being administered, the final rule should have allowances that are hassle-free and economically neutral to both the physician and vendor. The goal would be to eliminate unnecessary administrative activities and significantly cut down on returns. The details of this should be spelled out in the physicians' contract with both CMS and the Vendor.

In the final rule, CMS should develop an operational model that does not burden the physician's office with more administrative functions than they currently have the capacity to handle. Secondly, the CAP vendor should not be penalized for circumstances that are totally outside of their control. CMS should consider many of the commercial practices that are in use today, both from a "Buy and Bill" and "Pharmacy Administration/Adjudication" standpoint.

Credit Risk

Under the interim final rule, the CAP vendor's claim must be matched to the physician's claim before a bill for coinsurance or deductible can be generated. This situation turns the collection of beneficiary co-payments into a potential economic loss for the vendor. Our extensive experience shows that every day that transpires without collecting a co-payment significantly impairs the vendor's ability to realize the full price of the product, with the risk of non-collection being another cost factor that must be considered by CMS and CAP vendors. Placement of this credit risk on the CAP vendor places an undue burden upon them and therefore makes the program such a high risk that participation may be untenable.

Detailed (in Attachment A) is a timeline that hi-lites cash flow as it relates to the CAP interim final rule. As depicted, even when everything works correctly, the CAP vendor will not receive full payment for product until 90 days from the time the drug was distributed to the physician's office. The case worsens when the beneficiary is not meeting their co-payment obligation. What also must be considered is that the vendor most likely purchased the product from the manufacturer approximately 10 to14 days prior to shipping the drug, thereby further eroding cash flow.

Therefore credit risk is particularly high in light of CMS' unwillingness to allow vendors to reasonably confirm coverage and collect copayments at the time the product is dispensed. Priority believes that CMS does possess the ability to take further action on this issue under the Secretary's demonstration authority. "The Secretary has been given the authority under sections 402(a)(1)(B) and 402(a)(2) of the Social Security Act Amendments of 1967 (Pub. L. 90-248), as amended, to develop and engage in experiments and demonstration projects to provide incentives for economy, while maintaining or improving quality in provision of health services -(69 Fed. Reg. 66236,66308 – Nov. 15, 2004).

Specifically, we recommend that the vendor be able to exercise the right not to ship product in circumstances where it is clear that an ABN has not been provided or no means have been agreed upon to ensure the collection of copayments. These issues need to be addressed to reduce the financial risk of the current program design to acceptable levels.

Other than the obvious economic efficiencies that this model promotes, it also allows the vendor to work closer and sooner with the beneficiary in order to capitalize and take advantage of "Patient Assistance" programs and/or establish individual payment plans that will meet the needs of the beneficiary over the course of therapy.

Distribution Risk

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

Other significant risks that need to be addressed in this section are as follows:

a.) Excess Drug – (example: Physician orders dosing based on HCPCS code but the vendor has to supply the product in the manufacturers' packaging which is associated with the NDC number)

The interim final rule indicates that the vendor can only be reimbursed for the amount of drug that is administered as compared to the amount the vendor is forced to ship to the physician.

Unless CMS allows vendors to ship product in amounts different than the manufacturers' packaging (NDC number), we strongly believe that the vendor's reimbursement should be based on the manufacturer's packaging and not on the dose administered, similar to the way it is handled today in the "Buy and Bill" model.

However, Priority is pleased that CMS has recently issued guidance providing more clarity concerning the issue of billing for unused portions of drugs. That guidance indicates that "good faith" efforts to avoid wastage and utilize the appropriate amount of drug for a beneficiary will allow the CAP vendor to recoup the full cost of the drug product. Priority appreciates CMS' modification and believes it should affirm this policy in the final rule.

b.) Forced Distribution – (example: CAP vendor knows that a prescription order is inconsistent with a local coverage determination (LCD) but must still ship drug fully knowing or suspecting based on past clinical precedent that the product will not be reimbursed).

We know from experience that if a physician determines a patient in Texas needs Erbitux, for example, off-label for head and neck that the Trailblazer medical director will deny the claim if the head and neck indication is not in compendia. Three other carriers act in the same manner with no deviation. In this situation, the vendor should not have to assume the risk. CMS should amend its current stance to say that local coverage determinations are to be adhered to under the CAP program and allow the vendor to exercise the right not to ship product. If the physician decides to maintain the prescribed drug regimen then we believe the best way to handle this is for CMS to treat it as a "Furnish as Written" exception and let the physician buy the drug and bill CMS under the "Buy and Bill" protocol. This way the physician has full control over the situation and is able to execute their clinical expertise.

We also believe that with today's technology, and the fact that there are seventeen (17) local carriers with as many sets of rules on reimbursement, CMS should seriously consider implementing a real time system answer (similar to the way Pharmacy Benefit Managers (PBMs) handle p rior a uthorizations a nd m edical ne cessity r equests) t o t his c omplicated a nd c omplex area.

c.) Pharmacy versus Distribution

When implementing a national program such as CAP, there should be no confusion regarding the type of license(s) a CAP vendor must obtain and utilize in order to fully perform its' obligations. Secondly, all "gray areas" of confusion regarding national versus state requirements need to be defined.

We encourage CMS to take a position as to the specific program and licensure requirements a CAP vendor needs to exercise. However, before doing so, CMS needs to fully comprehend the differences between a "Pharmacy" and "Distribution" model and all of the associated costs (operational, returns, etc..) since they differ significantly between models.

An example of this is that many states do not permit pharmacies to accept returns from patients except under specific circumstances such as when the product is returned in a properly labeled and sealed manufacturer's package or if customized units are individually sealed and part of a closed-drug delivery system.[1] The Food and Drug Administration (FDA) also recommends that pharmacists not accept return of drug products once they have left his or her possession.[2]

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

Other Important and Pertinent Areas to Address:

1) Inclusion of CAP Prices in the ASP calculation

Since CMS has expressly forbidden the use of formularies in the CAP program, and seems to indicate it would frown on payor cost management tools such as step therapy or fail first policies, vendors have very little negotiating leverage with the manufacturers of proprietary products other than those situations in which the HCPCS code has multisource products associated with it. Whatever negotiating leverage they do have is further diminished by including negotiated CAP prices in the drug's ASP. This becomes a significant disincentive for many manufacturers and is very difficult, if not impossible for them to have a good business reason as to why they should offer CAP vendors discounted pricing.

In our analysis, we found that much of the initial CAP pricing offered by manufacturers exceeded that for which physicians could purchase the identical product today. In some cases, the CAP price was greater than ASP + 6%. However, we were certainly not at all surprised by these results.

Priority does believe that CMS possesses the regulatory discretion to exempt CAP from the computation o f Av erage S ales P rice ("ASP"). C ongress v ery s pecifically created t wo s eparate payment structures because it wanted to provide physicians with a meaningful choice of how they were reimbursed for drugs.

Our perspective regarding CMS' discretion on this issue is derived from several statutory provisions. First, as we have articulated previously, CMS' demonstration

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

[2] FDA Compliance Policy Guide § 460.300 (CPG 7132.09).

authority is broad and would permit the Agency to implement the CAP program without incorporating ASP prices. The Social Security Act permits CMS "to determine whether, and if so which, changes in methods of payment or reimbursement...including a change in negotiated rates, would have the effect of increasing the efficiency and economy of health services..."Social Security Act, 42 U.S.C. 1395b-1. As exempting CAP negotiated prices from ASP calculations would represent a change in negotiated rates and would arguably increase the efficiency of health services, CMS possesses the ability to effectuate this change.

In addition to this demonstration authority, CMS should also find support for its authority to exempt CAP bids from ASP prices from the plain language of the MMA. According to Section 1847(a)(1)(B), the "Secretary shall establish categories of competitively biddable drugs and biologicals. The Secretary shall phase in the program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate.

2) One Drug Category

Although we believe CMS initially created the One (1) Drug Category as a means to simplify the program, we believe CMS should consider revisiting the complete economic ramifications behind that decision. Implicit in CMS' decision to reduce the number of available drugs under CAP from 440 to 181 is that cost-efficiencies will not be realized by the Program for small volume or inexpensive drugs. In fact, a CAP vendor would lose money on every shipment of these less expensive drugs. We therefore recommend that the Agency exclude an even wider class of inexpensive and low-volume drugs from the bidding process. Inexpensive and low-volume drugs represent a fixed cost to the CAP vendor that make it considerably more difficult to comply with the Agency's aggregate bidding cap of ASP + 6%. CAP simply cannot save money for the Medicare Program if a vendor is required to undertake shipping costs for a product when it may cost more to send the product to the physician than the vendor will realize from Medicare.

We therefore ask CMS to consider including only the high dollar claim drug categories in the initial program launch. After a successful launch, CMS could consider excluding these other specialties for the duration of the program or establish a minimum payment amount per claim and include all currently proposed drugs and specialties. Another option for CMS is to establish multiple drug categories of which vendors can select those they are interested in bidding on. We do not have a problem, as was posited by the biotechnology companies, with inclusion of orphan products in the CAP program; so long as they fit into the high dollar claim categories previously discussed.

3) Supplemental Insurance

In the interim final rule, CMS states that approximately 80% of Medicare beneficiaries have some form of supplemental insurance (i.e. Medicaid, Medigap, etc.) that will reimburse the CAP vendor for the remaining 20% of the drug cost. What CMS may not recognize is that no one vendor is in network with 100% of these supplemental insurers. In fact, even in the best case scenario, vendors will be in-network 75% of the time. The situation worsens when you consider that distributors in general are not contracted with supplemental insurers.

Another classic example for CMS to recognize is the case of "dual-eligibles". Many states do not award a Medicaid license to a provider unless that business entity meets specific eligibility requirements. Therefore, this reality presents an additional risk to CAP vendors in many states.

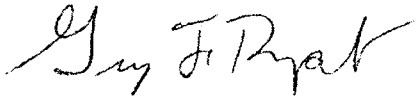
Some Medicaid agencies (such as the State of Texas) require a physical presence in the state (or a border state) before the provider may be enrolled. Many commercial plans limit contracting to specific providers. In each case, secondary reimbursement under the terms of coverage may not be available to the CAP vendor.

4) Addition of New NDCs

We believe that vendors should be allowed to add new NDCs as soon as they are available on the market or additional NDCs during the year for drugs already included in CAP. The interim final rule allows vendors to furnish more than one NDC for a HCPCS code, and, in limited circumstances, vendors may substitute a different NDC for the NDC currently offered. However, it does not clearly state whether vendors can add new or additional NDCs, not merely to substitute for NDCs offered, but also to expand choice under the CAP. We firmly believe that CAP vendors should be allowed to add NDCs throughout the year to improve beneficiary and physician choice of treatment options. We suggest that payment for these additional NDCs continue to be based upon the established price for the HCPCS code.

In closing, Priority Healthcare wishes to express again its interests in assisting CMS in a successful implementation of the CAP program and its commitment to CMS to give serious consideration to becoming a CAP vendor. We welcome the opportunity to come in and discuss any of this information at a face-to-face meeting. We hope our suggestions will help CMS address these important issues in the final rule. Please contact Mike LaBrecque R.Ph., MBA at 407-804-8179 if you have any questions regarding our comments. Thank you again for this continuing opportunity to work with CMS to improve the mechanics of this very important program for Medicare physicians and beneficiaries.

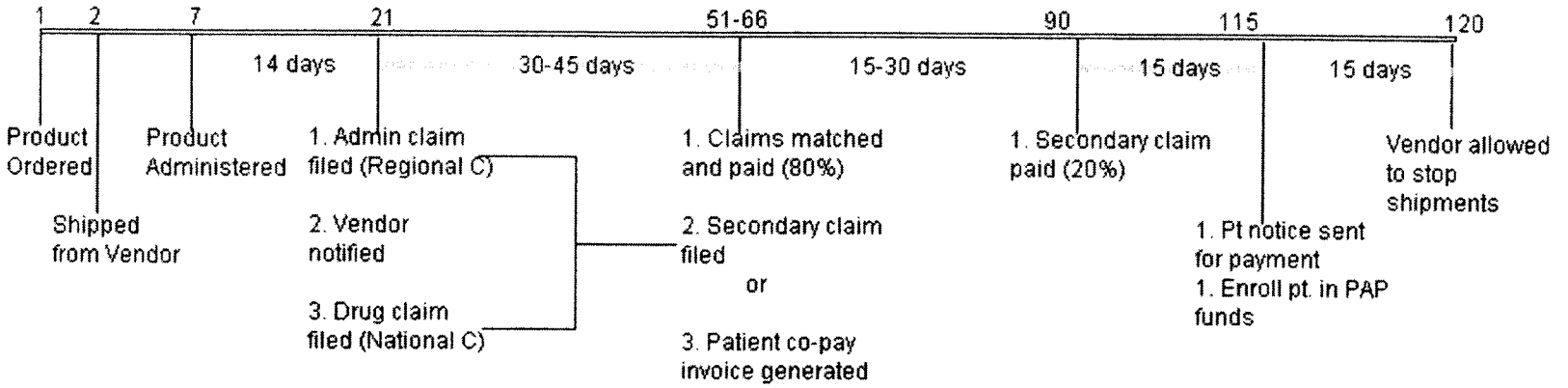
Respectfully submitted,



Guy Bryant
Executive Vice President & General Manager, Distribution Services

CAP Vendor Cash Flow
Time and Risk Analysis

Attachment A



Therapy On-therapy | Off-therapy | On-therapy | Off-therapy | On-therapy | Off-therapy | On-therapy

Risk Points:

1.Claim is not filed within 14 days
2. Claim filed improperly

1. Delay
2. Denial
3. Dependency on Dr. appeal

1. Secondary denial
2. PHC out of network of secondary insurance
3. Pt does not pay
4. Pt receives additional product

1.Pt does not pay
2.Pt received additional product

1.Pt does not pay
2.Pt received additional product

Submitter : **Dr. Michael Repka** **Date: 09/06/2005**

Organization : **American Academy of Ophthalmology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-140-Attach-1.PDF

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Federal Affairs Department

September 6, 2005

via Electronic Mail
Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-1325-IFC (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B)—Interim Final Rule

Dear Dr. McClellan:

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

The Academy has been and remains supportive of the development of a Competitive Acquisition Program (CAP) program for Part B drugs, as enabled by section 303(d) of the Medicare Modernization Act. The Academy continues to support CMS's efforts to implement this program which will provide physicians with an alternative to stabilize drug costs.

The Academy is encouraged by the interim final rule's adoption of several of the suggestions raised in our comments on the proposed rule including nationwide implementation, one category of drugs that are accessible to all physicians, and the inclusion of Visudyne among the list of approved drugs. However, the Academy continues to have concerns regarding implementation, administrative burdens, and the inclusion of drugs in the program. We would like to take this opportunity to highlight some of our outstanding concerns and praise of the interim final rule.

Phasing in CAP Drugs by Physician Specialty

The Academy is pleased with CMS's decision to open participation in the CAP to all physicians who are interested. We are also pleased with the decision to include a category of drugs that contains many of the administered drugs that present access problems to practicing physicians. The Academy would however like to raise a concern regarding the criteria used to determine which drugs are included on the CAP list.

Visudyne (verteporfin), a drug used by ophthalmologists in the treatment of Age Related Macular Degeneration (ARMD), is included on the list of CAP approved drugs. Visudyne is one of only two drugs that are currently approved to treat this disease. The other drug, Macugen (pegaptanib), was approved for use in treating this condition in December of 2004. Macugen is administered in the physician's office over 99% of the time. Volume for the drug is expected to exceed that of Visudyne in 2005.

Among the criteria used to determine coverage for drugs under the CAP is "more than $50,000 in office charges during 2004." Unfortunately, because Macugen was approved for treatment late in 2004 it does not meet the dollar thresholds for inclusion on the list of CAP approved drugs.

The Academy is concerned that the failure to add Macugen to the list of CAP approved drugs may result in an unfair market advantage for Visudyne and may result in limited patient access to all of the drugs available to treat ARMD. Ophthalmologists have found it very expensive to stock and store ARMD drugs in their offices. This became a huge issue with regards to Visudyne because of the high cost to procure the drug. This same problem will become an issue for Macugen unless physicians are allowed to procure it through the CAP program. Addition of Macugen to the list of CAP approved drugs will not only alleviate procurement issues, but will also ensure that physicians have access to all of the drugs that their patients need to treat this disease. This is an important factor to consider in light of the relative effectiveness of ARMD drugs in different patient populations and in relation to evolving ARMD therapies that involve the use of both Visudyne and Macugen in the same patient.

While the Academy understands the criteria used by CMS as well as the agency's concern that low volume drugs would otherwise be included in the CAP program we urge reconsideration of this criteria as it relates specifically to Macugen. The Academy urges CMS to add Macugen to the list of CAP approved drugs.

Ordering the CAP Drugs

The Academy is pleased with CMS's clarification of the standards for providing drugs to participating physicians in instances where the vendor questions whether the drug order is consistent with an LCD. We are pleased that CMS has decided to leave prescribing decisions to the discretion of the treating physician. In circumstances like the one described in the rule we believe that the physician, not the CAP vendor, is in the best position to determine whether a drug meets local or national coverage decision requirements. The Academy does however support the recommendation to have the vendor require the patient to execute an ABN in situations where there are questions regarding whether the prescription meets the requirements of an LCD and believes that this represents a reasonable compromise.

Content of the CAP Drug Order

CMS's decision to allow physicians to specify a range of expected administration dates will be useful in assuring patient access to the drugs they need during their scheduled appointment. This added flexibility should minimize patient inconvenience associated with drugs not being available during a visit.

Though CMS provides an explanation for their request that certain personal information regarding the patient be submitted with the drug order, the Academy maintains that some of this information in not relevant. However, if CMS insists that information regarding patient DOB, height, weight, allergies, and ICD-9 codes be recorded on the CAP drug order form the Academy would ask that a mechanism be created to transfer this data to the final claim form that will be filed with Medicare. This step would insure that the administrative time associated with gathering this data is not duplicated for each claim submission. We would urge CMS to give strong consideration to this request.

The Academy appreciates CMS's clarification of the circumstances under which a CAP participating physician may order drugs under the ASP system using the "furnish as written" exception. The Academy also appreciates further clarification of the emergency shipment timeframes. Though the rule now identifies the process for delivering drugs in one business day, the model falls short of achieving a workable solution for physicians' offices and staff. Additional delays created by the currently proposed one business day delivery system pose a risk to beneficiary safety.

An example included in the interim final rule states that an order received in writing at the CAP vendors office by 1 p.m. on a Wednesday must be received by the ordering physicians' office by 5 p.m. on Thursday. This is not one business day in the context of most office based physician practices. Many physicians' offices close prior to 5 p.m. or at a minimum stop seeing patients before this hour. Using the one business day example cited in the interim final rule, the patient for whom the drug was ordered using the emergency provision on Wednesday would probably not get access to the medication until Friday—two days after placement of the drug order. Because most express delivery services schedule deliveries for various times throughout the day it would be more reasonable to require that the drug arrive by 1 p.m. on Thursday. The Academy would recommend that CAP vendors supplying drugs under the one-business day emergency exception be required to deliver the drugs no later than 24 hours after receiving the written request.

Resupply Option for Emergency Situation

The Academy is pleased with CMS's decision to allow physicians to use their clinical judgment in determining whether a patient requires immediate treatment that necessitates the use of drugs that are in the physician's existing inventory.

Delivery of the CAP Drugs

The Academy supports CMS's decision to require that CAP order forms contain an area to identify the delivery location. This will be beneficial in allowing delivery of drugs to the appropriate location in the case of CAP participating physicians who practice out of more than one office. Further clarification of the policy requiring shipment of drugs directly to the location at which they will be administered is also helpful. These clarifications should help reduce instances of damage and waste that could arise if drugs were transported from the point of delivery to another location for administration.

Storing the CAP Drugs

The Academy appreciates the clarification that the interim final rule provides regarding the disposition of drugs that are not administered and the remaining portion of administered drugs. This issue is of particular concern to ophthalmology as wastage from Visudyne is commonly used to treat indigent patients with ARMD who cannot otherwise afford the medication. The practice of using the wastage from Visudyne in this manner has been commonly accepted by most carriers. We appreciate CMS's deference to State law on issues related to the disposal and use of un-administered drugs under the CAP program.

The Academy also appreciates CMS's clarification of the methods for dealing with dually eligible Medicare beneficiaries and those with gap coverage. We believe that providing CAP vendors with the ability to bill insurers as appropriate will expedite claims processing and payment and will alleviate burdens on the beneficiary.

Beneficiary Coinsurance

The Academy appreciates CMS's clarification of several issues related to vendor liability in the interim final rule. We are however concerned with the impact that some of the methods to limit liability will ultimately have on physicians who participate in the CAP. Of greatest concern is the proposed solution regarding beneficiaries who do not pay their coinsurance and deductibles.

The interim final rule suggests that after making several attempts to accommodate beneficiaries a vendor may refuse to provide drugs for the patient. While the Academy understands the rationale behind this we are concerned with the next steps announced in the interim final rule. In particular we are troubled by the recommendation that the CAP physician opt out of CAP for the drug category involving that particular beneficiary and procure drugs through the ASP. This is a less than desirable solution for the many ophthalmologists who have for years been saddled with the burden of paying up front costs associated with administered drugs that they must store in their offices. Under CMS's proposal a physician could very well be faced with the reality of reverting back to an unworkable drug procurement system based solely on one beneficiary's failure to satisfy their coinsurance obligations. Additionally, depending on the length of time that the beneficiary remains a patient of the physician this could mean an indefinite hold on the physicians' ability to participate in the CAP program potentially compromising long-term access to drugs by other patients.

One patient's payment problems should not be allowed to impact all of the other patients who might otherwise benefit from their physicians ability to procure drugs through the CAP program. The Academy views the current proposal as extreme and would instead suggest that a system be put in place that would allow a physician to procure drugs through the ASP system for a particular patient that has been refused drugs by a vendor due to non-payment issues. We believe that this solution is a more reasonable and feasible way of addressing the problem while absolving both the vendor and physician of liability issues related to drug access.

Dispute Resolution: b. Resolution of Physician's Drug Quality and Service Complaints

The Academy commends CMS's efforts to further clarify the dispute resolution process as it applies to CAP participating physicians. While the interim final rule does a good job explaining the mechanisms available to resolve disputes and encourages a collaborative approach to resolving problems between vendors and physicians it fails to clearly explain the options for physicians who have been unable to reach a satisfactory resolution with their existing CAP vendor.

The rule provides a very detailed explanation regarding how a CAP vendor may terminate a relationship with a physician. As this is a very important issue for both physicians and vendors we would encourage CMS to provide the same level of attention to the problems that may be faced by physicians participating in the CAP program. It is critical that CMS clarify the process for a physician to terminate a CAP contract.

The Academy appreciates inclusion of language in the interim final rule prohibiting a vendor from terminating a physician's CAP contract based on the inability of the vendor to collect co-payments from one or more of the physician's patients. However, we continue to urge CMS to incorporate a provision that prohibits CAP vendors from barring physicians who meet Medicare guidelines from participating in the CAP.

CAP Contracting Process: Quality Integrity

The Academy appreciates CMS's clarification of the standards that will apply to vendors related to the shipping and integrity of drugs. We believe that this clarification will go a long way towards eliminating confusion regarding the responsibility for return charges and shipment of new orders in instances where drugs shipped from vendors arrive in either an unusable or damaged condition. Assessing liability for drugs, until they are administered, to the vendors will hopefully lead to added steps on the part vendors to insure the integrity and safe transportation of drugs to the CAP physicians. Additionally, we support the decision to require the vendor to bear the cost of returning and disposing of excess drug product.

CAP Bidding Process—Evaluation and Selection- Determining the Single Price for Category of Drugs

The Academy is pleased that the interim final rule includes a method for modifying the vendor-approved drug list which would take into account new drugs developed during the course of a vendor contract. However, we are concerned that this method deprives physicians of any means for bringing new drugs to the attention of CMS for addition to the list. The method outlined in the interim final rule leaves too much discretion with the CAP vendors.

The rule as currently written would make the vendor solely responsible for urging CMS to add newly developed drugs or those that previously lacked sufficient sales data to the list of CAP approved drugs. Because the vendor has no vested interest (i.e. no patients) it is unlikely that they will be proactive in urging CMS to add additional drugs to the list. In

order to ensure that patients continue to have access to the newest and most efficacious drugs it is imperative that the rule adopt a method that allows physicians to have input regarding the proposed addition of drugs to the CAP list.

In response to comments on the proposed rule CMS has clarified that prices offered under the CAP must be included in ASP calculations. The Academy believes that this will result in grievous harm to the CAP program. The CAP was designed with the intent of functioning separate and apart from the ASP program. As currently structured the program is expected to alleviate the high costs of procuring drugs by physicians and to create Medicare cost savings.

While vendors will not be able to offer bids above 106% of ASP it is anticipated that they may very well offer prices below this threshold. Inclusion of prices offered by vendors to CAP participants in ASP calculations may spell the demise of the ASP program. At best, this requirement will force physicians who chose not to procure drugs through the CAP to do so. Another scenario would involve CAP vendors reducing the level of discounts to CAP physicians because of the feared impact on ASP data. The Academy does not support including CAP pricing data in the ASP calculation.

Beneficiary Education

The Academy is pleased that the interim final rule further clarifies the steps that CMS will take to educate Medicare beneficiaries about the CAP program. The methods of beneficiary education proposed in the interim final rule including a standardized fact sheet, additional language in the Medicare & You and Your Medicare Benefits booklets, a customer helpline, and FAQs should prove helpful in transitioning beneficiaries affected by the new program. The Academy further appreciates that CMS has taken on the task of creating these standardized materials-- alleviating much of the administrative time and costs that would otherwise have been borne by CAP participating physicians.

Provisions of the Interim Final Rule

The Academy applauds CMS's effort to provide further clarification of the proposed rule by adding and modifying the definitions of many of the terms contained therein including further explanation of the one business day requirement for emergency shipping and the definition of emergency situation. We further appreciate clarification of the shipping standards to include a clear statement that drugs shipped from CAP vendors must be in unopened vials or in the original container supplied by the distributor. This clarification will help to reduce disputes and to dispel concerns related to product integrity.

CAP Election Agreement

Lastly, the Academy would like to thank CMS for clarifying that all CAP physicians must be enrolled in the Medicare program even though they are not required to accept assignment of all Medicare services. We also appreciate clarification of the fact that non-participating physicians who join CAP will be required to accept assignment for CAP drug administration. This information will prove invaluable to many physicians as they deliberate their participation in the CAP program.

Conclusion

The Academy appreciates the consideration that was given to our prior comments as reflected in the interim final rule and urges CMS to give serious consideration to the additional recommendations contained in this comment letter. The Academy continues to look forward to implementation of the CAP program in 2006. Again, the Academy would like to thank you for providing us with the opportunity to comment and looks forward to CMS's response.

Sincerely,

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

Submitter : Dr. Joseph Corriere

Date: 09/06/2005

Organization : American Urological Associatio

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-IFC-141-Attach-1.DOC

American
Urological
Association

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September 6, 2005

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

Re: CMS-1325-IFC – Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B.

Dear Dr. McClellan:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, I am pleased to submit comments on the July 6, 2005 interim final rule on Medicare's competitive acquisition program (CAP) for outpatient drugs. We appreciate that CMS took the suggestion of the AUA and others and published the rule as an interim final rule in order to allow additional comment on certain provisions that weren't completely clear in the proposed rule.

However, while CMS did address a few of the suggestions that were pointed out by physician groups to improve the CAP, CMS did not or could not fix many aspects of the CAP that are likely to keep physicians from participating in the program. The AUA still believes that the CAP will be burdensome and confusing for physicians and beneficiaries and we are extremely concerned that CMS did not deal with two of the largest problems—unreimbursed administrative expenses for physicians who participate in the CAP and inclusion of the CAP vendor drug prices in ASP calculations.

The recent postponement of the CAP highlights the difficulty of implementing this new program in a way that is appealing to the diverse interests of both vendors and physicians. The postponement as well as many aspects of the interim final rule seem to reflect a tendency toward making concessions for potential CAP vendors. Unless similar concessions are made for physicians, the program is not likely to be a success.

Our comments below address these concerns as well as many of the issues that CMS solicited comments on in the rule, including the 2006 carve out from the CAP of Leuprolide acetate (J9217).

CATEGORIES OF DRUGS TO BE INCLUDED UNDER THE CAP

Initial category of drugs for 2006

In our proposed rule comments, we suggested that CMS implement the CAP for all part B drugs that are furnished incident to a physician's service at the onset of the program. Although CMS is not including all part B drugs in 2006, we agree that the method CMS used to develop the CAP drug list led to a relatively comprehensive and reasonable list of drugs that are administered in urology offices.

We are especially pleased that CMS's methodology led to the inclusion of many of the drugs that urologists are currently not able to buy at or less than 106 percent of ASP. Many commenters, including the AUA, urged CMS to incorporate into the CAP those drugs that have been identified as posing acquisition problems for physicians under the ASP system. CMS acknowledges that their methodology did not specifically account for these drugs, but that the list, by default, includes most of the drugs that have been reported to CMS as posing access problems for physicians under the ASP system.

However, we are confused by the fact that CMS lists only ten drugs as being reported to pose problems under the ASP system, and does not acknowledge the complete list of problem drugs that is being maintained by the CMS Physician Regulatory Issues Team (PRIT). It is extremely frustrating to the AUA that we have informed CMS numerous times about the problems urologists are having buying bladder cancer drugs, and we have reported them to the PRIT, yet they are not even included on the list of problem drugs in the rule. Although they did get included in the 2006 CAP drug category by default, we still have still concerns about the situation with bladder cancer drugs and the effects it will have on bladder cancer patients.

The AUA supports including the bladder cancer drugs in the CAP, but we have serious concerns about future problems, especially if CAP vendor drug prices are included in the ASP calculations. This will only drive down the ASP-based payment for these drugs even more, and it is already clear now that urologists can not buy bladder cancer drugs at or below 106 percent of ASP, as bladder cancer drug manufacturers do not sell drugs directly to physicians. Therefore, the ASP reflects prices that are paid by wholesale companies who sell the drugs to physicians at a marked-up price that is not reflected in the physician payment.

CMS has encouraged specialty societies to help their members identify alternate sources for buying drugs and also to educate their members about how to become better purchasers of drugs. **The AUA heeded this advice and investigated the possibility of becoming a national buying group for urologists. However, after reviewing the Medicare data on the volume of bladder cancer drugs, none of the groups that sell bladder cancer drugs were interested in working with us in this regard. The problem stems from the fact that bladder cancer drugs are not sold directly to physicians, but through wholesalers. Therefore, the prices reported by the manufacturers are those given to wholesalers, who then mark up the price to physicians.**

As a reminder, here is the list of bladder cancer drugs that are affected by this problem. While the CAP may offer some relief, there is still a great deal of uncertainty about the CAP. Therefore, we are still extremely interested in working with CMS to address this problem.

- J9031, BCG per instillation
- J9214, Interferon alfa-2b inj, 1 million units
- J9291, Mitomycin 40 mg inj 40 mg
- J9340, Thiotepa injection, 15 mg

Future categories of drugs
CMs also solicits comments on how to phase in additional drug categories in the future, saying that it expects to phase in multiple drug categories, probably defined around the drugs commonly used by physician specialties as the CAP is refined and developed.

It is evident by the design of the CAP that physicians are likely to favor narrow drug categories while CAP vendors are likely to favor broad drug categories. Therefore, CMS has the difficult job of striking a balance that will allow maximum benefit and encourage participation by both physicians and CAP vendors. For the urology practices that do choose to participate in the CAP, some of them will prefer to acquire all of their office-administered drugs through the CAP. However, some practices will prefer to acquire certain drug categories through the CAP while they continue to buy and bill certain other drug categories under the ASP payment methodology. **Therefore, to give the largest number of urology practices the option of using the CAP in the future if they so desire, we recommend placing urology drugs in categories that are as narrow as possible.**

However the drug categories are ultimately structured, to ensure that all Part B drugs are available to Medicare beneficiaries in the physician office setting, the CAP should provide a safety net for drugs for which physicians are suffering financial loss under the ASP payment system. CMS could address this by creating a separate category of problem drugs for each specialty or a large category of problem drugs that includes the problem drugs of all specialties, as vendors are likely to be able to negotiate lower prices than physicians can negotiate for these drugs because they will be buying in larger quantities.

Exclusion of leuprolide from the CAP in 2006
To date, Medicare carriers have implemented least costly alternative (LCA) policies for Leuprolide acetate (J9217) and Goserelin acetate (J9202) in most (but not all) states based on the belief that the two drugs are equally efficacious. This means that carriers will only pay for the cheaper drug, Goserelin Acetate, even when physicians bill for Leuprolide Acetate.

CMs acknowledges that the existence of LCA policies, and the fact that they will apply under the CAP just as they apply outside the CAP, have obvious implications for the provision of certain drugs under the CAP. Because Leuprolide is subject to LCA policies in all carrier jurisdictions (but not all states), its inclusion in the current CAP drug category would have the effect of requiring vendors to supply the drug at the cost of goserelin in each instance in which a participating CAP physician orders it, regardless of the price established for leuprolide under the bidding and single price determination processes and regardless of the geographic location of the

participating CAP physician. CMS solicits comments on how to deal with this issue in later stages of implementing the CAP program.

In light of the problem for the CAP that is posed by the fact that all carrier local coverage determinations will apply to CAP vendors, the AUA recommends that CMS advise its contractors to discontinue LCA policies. The AUA has suggested this to CMS previously based on the fact that the new drug payment system eliminates the need for LCA policies because it bases drug payments on market forces and it more accurately reflects the actual cost of drugs than the previous system.

The need for LCA policies will decrease even more as the ASP payment system matures, because the market will drive payments for similar drugs closer and closer. The AUA also believes that LCA policies should be discontinued because of carriers' proven inability to implement the policies correctly. There are numerous examples of problems that have occurred in multiple states (including Alabama, Rhode Island, Utah, Missouri, North Carolina and Oklahoma) due to carriers' inability to properly program the computer edits required for an LCA policy.

This issue will only get more complicated, as carriers are now beginning to apply LCA policies beyond J9202 and J9217 to the other drugs within the class of luteinizing hormone-releasing hormone or LH/RH drugs. For example, the California Medicare carrier, National Heritage Insurance Co., has an LCA policy for J9202, J9217 and J9219 (Leuprolide acetate implant), which is available at http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=9933&lcd_version=30&show=all. And, there are more LH/RH drugs in the pipeline. The current LH/RH drugs include:

	Drug	Name	Units
J3315	Triptorelin Pamoate	Trelstar	3.75 mg
J3490	Histrelin Implant	Vantas	5 mg
J9202	Goserelin acetate implant	Zoladex	3.6 mg
J9217	Leuprolide acetate suspension	Lupron and Eligard	7.5 mg
J9219	Leuprolide acetate implant	Viadur	65 mg

Under the previous Medicare Part B drug payment system that was based on average wholesale price, LCA policies were an attractive method for carriers to save money on Part B drug spending because they could be implemented without Congressional intervention. However, now that Congress has intervened and reformed the drug payment system and it is evident that LCA policies will only complicate the CAP, we sincerely urge CMS to reconsider eliminating LCA policies.

If CMS feels that it can not discontinue LCA policies across-the-board because of financial implications, the other alternative solution to this problem is to carve out of the CAP all drugs to which LCA policies apply. Otherwise, it will become an administrative burden for CMS, its carriers, the designated carrier, CAP vendors and CAP physicians. Also, carving out

only the more expensive drugs under LCA policies could be perceived as unfair by drug manufacturers that still have products in the CAP, as the ASP for their drugs will be driven down by CAP vendor prices while the ASP for the carved-out drugs will not.

CLAIMS PROCESSING

Restricting physicians to one vendor

CMS had solicited comments in the proposed rule on whether, in the future, when there are additional CAP drug categories, physicians should be allowed to obtain different categories of drugs from different CAP vendors. The AUA supported physicians being allowed to do so, and we applaud CMS for confirming in the interim final rule that physicians will be able to select a different vendor for each category of drugs if the physician decides that it best meets their needs.

ABNs

If the vendor believes a drug order is not consistent with an LCD, the vendor may call the physician to discuss the order and try to determine why the physician believes it will be covered under the local carrier's LCD. If the physician declines to change the order, but the vendor still believes the local carrier will not cover the drug, the vendor may ask the beneficiary to sign an advanced beneficiary notice (ABN), and a signed ABN would make the beneficiary liable to pay for the drug if the carrier denied the claim. The vendor will be required to provide the drug to the physician whether or not they are successful in collecting an ABN. If a drug-administration claim is denied, the physician is required to pursue an appeal of the denial with the local carrier. If the claim untimately remains unpaid, the vendor may ask the designated carrier for assistance under the dispute resolution process.

LCA and ABNs

CMS asks that when ordering drugs, physicians be mindful of the fact that the vendor's claim for drug payment will be dependent on the local carrier's coverage policies, including LCA. This is because the vendor will have to ship an ordered drug even if the vendor believes it will receive a reduced payment because of a carrier policy. Although the vendor may call the physician to discuss the order, if the physician confirms the order, the vendor must ship it. CMS states that the vendor would also have the right to collect an ABN from the benficiary in this situation.

This is yet another example of additional administrative burdens physicians will have to bear under the CAP, as the vendor will contact the physician to try and persuade the physician to order the cheaper drug, and if the physician does not agree, the vendor will then ask the physician to have the beneficiary sign an ABN. If the physician refuses to ask the beneficiary to sign an ABN, the vendor may then contact the beneficiary and ask them to sign one, which will add more confusion for the beneficiary as well.

Allowing vendors to collect an ABN will add even more confusion for beneficiaries, and additional burden on physicians, who will undoubtably have to answer questions from beneficiaries who do not understand why the CAP vendor is asking them to sign an ABN.

Emergency resupply process

In emergency situations drugs acquired under the CAP could be used to resupply inventories of drugs administered by physicians as long as the physician could demonstrate that:

1) The drugs were required immediately
2) The physician could not have anticipated the need for the drugs
3) The vendor could not have delivered the drugs in a timely manner
4) The drugs were administered in an emergency situation

In our proposed rule comments, we said, assuming that a physician has their own stock outside of what has been ordered from the CAP vendor, this process would be useful to physicians as long as CMS defines emergency situations broadly enough to incorporate unanticipated situations such as changing a patient's course of treatment during an office visit or patients who reschedule appointments for an earlier time. We appreciate that CMS defined emergency situation to be a situation that in the physician's clinical judgment is unforeseen and requires immediate treatment of the patient. However, we are still concerned that there will be problems with this process.

Administrative burden
According to CMS, "Although we agree that a physician may have to make some adjustments in his or her practice in order to comply with the requirements under the CAP, we believe that the relief of the financial burden of purchasing the drugs and billing Medicare for these drugs will be a substantial improvement and benefit for many physicians." Many provisions of the interim final rule will actually increase the administrative burden, including the addition of data elements that are required on the prescription order, maintaining the 14-day requirement for drug administration claims filing and requiring physicians to appeal claim denials. **Therefore, the AUA reiterates its concern that unless some mechanism is established to reimburse physicians for extra administrative costs associated with the CAP, physicians will have no incentive to participate.**

Content of the CAP drug order
In the interim final rule, CMS discusses the data elements that the physician would be required to submit to the CAP vendor on a prescription order. Although the AUA and many other commenters felt that many of the elements—especially the additional patient information elements (date of birth, allergies, height, weight and ICD-9 codes)—are unnecessary, CMS maintained all the proposed elements and even added additional elements. **The AUA continues to believe that many of the data elements required for the prescription order are unnecessary and that including them on a prescription order is burdensome, duplicative and unnecessary. The requirements should be limited to what is necessary for a regular prescription.**

Also, CMS did not clarify the ordering process for drugs that come in multi-use vials, which is an important issue for urology. For example, testosterone cypionate (J1080), which is frequently used by urologists, typically comes in a 10 cc vial, which equates to about 10 injections. It would be a logistical nightmare to order one vial from the vendor and then have to track all the different patients that are given injections from that vial so that you could properly bill Medicare. **A process must be developed to handle such drugs or CMS may want to consider these types of drugs as eligible for exclusion from the CAP.** Although testosterone

is not included in the CAP drug category for 2006, this will be an issue in the future and it should be addressed.

Payment to vendor
We appreciate that CMS will include in the CAP contract a requirement that the vendor ship the drug in most situations because CMS believes that under the CAP program as it is being implemented, it would be inappropriate for the CAP vendor to interfere in the participating CAP physician's clinical decision making. **However, there are still many steps the vendor is allowed to take that will place extra administrative burden on physicians, as the vendor is allowed to contact the physician and try to persuade them to change their order if the vendor believes the drug will not be covered for some reason.**

Billing beneficiaries for deductible and coinsurance
CMS notes in the interim final rule that many commenters were concerned about the effect the CAP could have on beneficiaries because vendors will not be as sympathetic as physicians are for beneficiaries who are not able to pay their coinsurance. CMS realizes that there will be instances where a beneficiary may have difficulty in meeting the deductible or coinsurance payment and that physicians currently often help the beneficiary find assistance to meet this obligation or might choose not to pursue collection of the cost sharing if the physician has made a good faith determination of financial need or reasonable collection efforts have failed.

To address these concerns, CMS is modifying the program requirements to include a provision requiring vendors to provide information on sources of cost-sharing assistance available to beneficiaries on request. Also, CMS will not require vendors to continue to provide CAP drugs for beneficiaries who do not pay their cost sharing, but will permit participating CAP physician to opt out of that CAP drug category in instances where a vendor refuses to ship for a specific beneficiary. Because there is only one drug category for 2006, a physician who exercised this option in 2006 would be opting out of the entire CAP program until the next election period. **However, for future years, when there is more than one drug category, we urge CMS to allow physicians in these circumstances to not only opt of the effected drug category, but to opt out of the CAP entirely if they so desire. Otherwise, it may be burdensome for the physician to keep track of the administrative and inventory requirements for the various categories.**

DISPUTE RESOLUTION

The AUA was concerned that the proposed rule was largely silent on resolution of physicians' drug quality and service complaints, and we appreciate that CMS added a new section that sets forth a process culminating in termination of the approved CAP vendor's contract for serious quality or service issues. We also appreciate that CMS changed some of the requirements for resolution of vendors' disputes against physicians, including removing the requirement that the names of physicians who are suspended from the CAP be published in the *Federal Register* and specifying that vendors disputes about claim denials will be reviewed on an individual basis rather than specifying an appropriate loss threshold that an approved CAP vendor would have to bear before requesting suspension of a participating CAP vendor.

BIDDING PROCESS

CAP Prices

The AUA strongly disagrees with CMS's decision to not exempt CAP prices from the calculation of ASP, which is based on the fact that CMS does not believe it has the statutory authority to exclude prices determined under the CAP from ASP computations. We strongly urge CMS to revisit this decision, especially based on comments from Representative Bill Thomas (R-CA) who was an author of the Medicare Modernization Act which established the CAP and the ASP payment reform. Including vendor prices is counter to the intent of the statute because it gives disproportionate weight to the drugs purchased at volume discounts only attainable by CAP vendors. This would punish physicians who wish to continue buying and billing Medicare for drugs under the ASP payment methodology. This would also undermine the voluntary nature of the CAP and the hybrid drug payment system, as it would eventually force all physicians to choose to participate in a costly and burdensome CAP or to stop administering drugs in the office.

CAP PHYSICIAN ELECTION PROCESS

The AUA still continues to believe that physicians should be able to choose to opt out of the CAP at any time during their annual election if there are egregious service-related issues, especially during the early years of the CAP while there is still a great deal of uncertainty. Nevertheless, we do appreciate that CMS has added certain safeguards for physicians who elect to participate in the CAP and has specified certain circumstances under which physicians can opt out of the CAP or choose a different CAP vendor more frequently than annually. These circumstances include termination of the previously selected CAP vendor's contract, a participating CAP physician leaving the group practice that had selected the given approved CAP vendor, or the participating CAP physician relocating to another CAA.

Thank you for considering our comments. If you have any questions or need additional information, please contact Robin Hudson, AUA Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

Joseph N. Corriere, Jr., M.D.
President

James B. Regan, M.D.
Chair, Health Policy Council

Submitter : Mr. James Greenwood

Date: 09/06/2005

Organization : Biotechnology Industry Organization

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

See Attached.

GENERAL

GENERAL

See Attached.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

See Attached.

Regulatory Impact Analysis

Regulatory Impact Analysis

See Attached.

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

See Attached.

CMS-1325-IFC-142-Attach-1.DOC

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

September 6, 2005

BY ELECTRONIC DELIVERY

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Re: CMS-1325-IFC (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B)

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) interim final rule with comment period regarding the competitive acquisition program (CAP) for outpatient drugs and biologicals under Part B, published in the Federal Register on July 6, 2005 (IFC).1 BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

1 70 Fed. Reg. 39021 (July 6, 2005).

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Representing an industry that is devoted to discovering new cures and ensuring patient access to them, BIO is pleased that the CAP will offer physicians a choice of methods of obtaining drugs and biologicals for their patients. We appreciate the improvements CMS has made to the program to protect patients' access to drug and biological therapies obtained through the CAP and are encouraged that the agency intends to make additional modifications in the final rule before implementing the program. BIO applauds CMS for its hard work to implement the CAP as soon as possible, ensuring that it is a viable program that will provide a true option for all physicians.

BIO supports CMS' decision to phase in the CAP with an initial nationwide region and a single, broad drug category that addresses many specialties' drug needs. We also agree with the exclusion of certain types of drugs and biologicals, such as contrast agents, blood and blood products, plasma-derived and recombinant analog therapies, and intravenous immune globulin (IVIG). We appreciate CMS' clear statement that vendors do not have the authority to create formularies by offering only certain Health Care Common Procedure Coding System (HCPCS) codes in the category.[2] It is imperative that this not be changed as the rule is finalized.

We also commend CMS' efforts to protect beneficiaries' access to appropriate therapies by including provisions that respect physicians' clinical judgment. In particular, we support the IFC's clarification that vendors cannot make determinations of medical necessity and generally must ship the therapy ordered by the physician. CMS' definition of "emergency situations" allows physicians to determine the best course of treatment for their patients and to order replacement inventory of necessary therapies through the CAP.

We also support the provisions of the IFC that address beneficiaries, physicians, and vendors' concerns about the costs of participating in the CAP. The requirement for vendors to provide beneficiaries with information on sources of cost-sharing assistance when requested by the beneficiary will facilitate continued access to drug and biological therapies, regardless of the beneficiary's ability to pay. CMS has eased physicians' burdens somewhat by allowing vendors to appeal denied claims. The clarification that vendors bear the cost of returned drugs and biologicals also lessens physicians' concerns about the cost of participating in the CAP. Finally, we support the decision to update the single prices for CAP drugs and biologicals to the mid-point of

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[2] Id. at 39034.

calendar year 2006 by the Producer Price Index for prescription preparations. Updating prices through this mechanism will encourage more potential vendors to participate in the CAP by helping to ensure that payment for CAP drugs reflects current market conditions.

To further improve the CAP, we ask CMS to make the following changes in the final rule:

- CAP vendors should be permitted to incorporate new or additional National Drug Codes (NDCs) during the year;
- Orphan drugs and biologicals should not be excluded categorically from the CAP. In fact, these tend to be the very therapies that should be included to ensure patient access to them. We ask CMS to individually evaluate each orphan drug or biological for inclusion in the single category in the final rule. However, Alpha 1-proteinase inhibitor should be excluded from the CAP;
- CMS should instruct carriers should not apply their least costly alternative (LCA) policies to the CAP;
- New drugs and biologicals should be added to the CAP as soon as possible after they are available on the market and should be paid at their average sales price (ASP) plus 6 percent or at their wholesale acquisition cost (WAC) plus 6 percent until an ASP-based rate can be implemented;
- Physicians should be permitted to request from the CAP vendor an advance supply of drugs likely to be used in emergency situations;
- CMS should state explicitly in the next CAP final rule that its longstanding discarded drug policy also applies to CAP, in the spirit of a recent response to a CAP vendor question;
- CMS should make partial payment to CAP vendors at the time a drug or biological is dispensed;
- CMS should clarify that the CAP does not impose any forced sale requirements on manufacturers; and
- When a patient is denied drug shipments by a CAP vendor, the physician should have the option of obtaining drugs and biologicals outside of the CAP program for that patient and be allowed reimbursement at ASP plus 6 percent, while continuing to participate in the CAP for other Medicare beneficiaries, in addition to the option of discontinuing CAP altogether.

We are pleased by CMS' progress toward addressing our concerns about the proposed rule and look forward to working with the agency as it moves toward implementing CAP. We hope that our comments will help CMS resolve our remaining concerns about the program.

A. Categories of Drugs to be Included Under the CAP

1. Choice of Drugs and Biologicals in the Single Category

BIO supports CMS' selection of a single category of 169 drugs and biologicals, plus 12 new therapies, for inclusion in the initial CAP category.[3] We believe this category, which represents approximately 85 percent of physicians' Part B drugs by billed charges, will make the CAP a workable option for many physicians. By including a broad range of products, the CAP category is likely to include therapies to serve most patients' needs and attract more physicians to the program. To make the CAP even more useful for beneficiaries and physicians, we urge CMS to expand the CAP to include additional therapies as soon as possible. As discussed in further depth below, we believe most orphan drugs and biologicals and new drugs should be added to the CAP's single category in the final rule.

CMS protected beneficiary access to biologicals and single-source drugs by explicitly stating CAP vendors must provide at least one National Drug Code (NDC) for each HCPCS in the category.[4] This requirement reflects the statute's clear instructions for vendors to provide "at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area."[5] To better address Medicare beneficiaries' drug and biological needs and provide greater choice and flexibility in clinical management under the CAP, we believe that CAP vendors should provide substantially more than one NDC per HCPCS. When a vendor offers more than one NDC per HCPCS, physicians should be permitted to specify which NDC they are ordering.

We also recommend that vendors be allowed to incorporate new NDCs as soon as they are available on the market or additional NDCs during the year for drugs already included in a CAP HCPCS. The IFC allows vendors to

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3 Id. at 39030.
4 Id. at 39034.
5 Social Security Act (SSA) § 1847B(b)(1).

furnish more than one NDC for a HCPCS code, and, in limited circumstances, vendors may substitute a different NDC for the NDC currently offered.6 The IFC does not clearly state whether vendors can incorporate new or additional NDCs, not merely to substitute for NDCs offered, but also to expand choice and flexibility under the CAP. We firmly believe that CAP vendors should be allowed to add NDCs throughout the year to improve beneficiary and physician choice of treatment options so the treatment regimen ordered can be the most appropriate regimen for the patient and to minimize discard of excess supplies. We suggest that payment for these additional NDCs continue to be based upon the established price for the HCPCS code.

2. Drugs and Biologicals Excluded from the Single Category

Additionally, we appreciate CMS' efforts to exclude drugs and biologicals that are likely to face access problems under the CAP. We agree with the agency's decision to exclude contrast agents and blood and blood products from the CAP.7 We thank CMS for deciding not to include IVIG in the CAP, but we remain concerned that the agency has not acknowledged Congress' clear intent to exclude this therapy from the program.8 Likewise, we believe that CMS should acknowledge Congressional intent to exclude radiopharmaceuticals from the CAP as well.9 Congress recognized that the unique characteristics of radiopharmaceuticals made these products highly unsuitable for the CAP structure, and these therapies are excluded by statute, not solely at CMS' discretion.

In response to several commenters' concerns about access problems, the agency decided to exclude CMS-designated single indication orphan drugs from the CAP.10 BIO urges CMS to reconsider this decision. In general, we believe that access to orphan drugs would be enhanced, not harmed, by inclusion in the CAP. The CAP is intended to improve access to drugs and biologicals by reducing physicians' costs of acquiring and billing for therapies. Because demand for orphan drugs is extremely low and variable, they are costly to

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6 42 C.F.R. § 414.906(f).
7 70 Fed. Reg. at 39029.
8 SSA § 1842(o)(1)(E) establishes payment for IVIG at 106 percent of ASP; See also H. Rep. No. 108-391, at 593.
9 MMA § 303(h) states that "nothing in the amendments made by this section [including the creation of the CAP in section 303(d)] shall be construed as changing the payment methodology under part B of title XVIII of the Social Security Act for radiopharmaceuticals;" See also H. Rep. No. 108-391, at 593.
10 70 Fed. Reg. at 39028.

manufacture and costly for physicians to keep in inventory. Orphan drugs are precisely the types of therapies for which physicians most want to be relieved of the financial burdens of acquisition and payment collection and for which patients most need to be assured of uninterrupted access. Many patients with rare diseases rely on orphan drugs to keep them alive. Including these therapies in the CAP would allow physicians to provide their patients with critical therapies without assuming the risk of not collecting beneficiary coinsurance or receiving adequate reimbursement.

Moreover, excluding only the designated single indication orphans and not other drugs and biologicals used to treat rare disorders leads to inconsistent results. It also may make electing the CAP less attractive for physicians who cannot get all the therapies they need through the program. For example, one of our members manufactures four orphan enzyme replacement therapies. Although the therapies are similar, two are designated single indication orphan drugs that have been excluded from the CAP – Cerezyme® and Ceredase®, and two – Fabrazyme® and Aldurazyme® – are included in the program. All four therapies are administered by the same physician specialty, typically hematologist/oncologists. Including all four therapies in the CAP would make the program more consistent and would increase its attractiveness to physicians.

For these reasons, we urge CMS not to exclude orphan drugs categorically from the CAP. Each orphan therapy should be eligible for inclusion under the CAP under criteria applicable to other drugs and biologicals unless a concern about patient access from inclusion under CAP is raised to CMS by interested stakeholders with respect to a specific orphan drug. Accordingly, we sincerely hope CMS will add most orphan drugs and biologicals to the CAP's single category in the final rule.

We recommend that one orphan therapy, alpha 1-proteinase inhibitor (J0256), continue to be excluded from the CAP. Alpha 1-proteinase inhibitor is a plasma-derived and recombinant analog therapy. Several brand name versions of this therapy are included in code J0256, but the individual brands are not therapeutically equivalent. Each brand has a unique effect on the patient, and response to each brand can vary from patient to patient, making it critical that each patient receives the specific brand that is best suited for his or her condition. As long as CAP vendors are required to offer only one NDC for this HCPCS code, it is highly unlikely that a CAP vendor would provide each patient's specific brand. We expect that physicians would have to use the

"furnish as written" option frequently for patients who need alpha 1-proteinase inhibitor. It makes more sense, therefore, to exclude alpha 1-proteinase inhibitor from the CAP than to require physicians to routinely use the "furnish as written" option. Each patient's access to alpha 1-proteinase inhibitor would be protected best by excluding these products from the CAP.

CMS also decided to exclude injectable forms of leuprolide from the CAP because carriers have applied LCA policies to this therapy that set its payment at the rate applicable to goserelin.[11] CMS explains that including leuprolide in the CAP "would have the effect of requiring vendors to supply the drug at the cost of goserelin in each instance in which a participating CAP physician orders it, regardless of the price established for leuprolide under the bidding and single price determination processes."[12] We agree that substituting one drug or biological's price for another's is inconsistent in a system where a vendor competitively bids to supply each HCPCS in a given category and the composite bids are capped at 106 percent of ASP. We believe that a better approach to this issue would be to instruct carriers not to apply their LCA policies to the CAP.

3. Inclusion of New Drugs and Biologicals in the CAP

BIO thanks CMS for requiring CAP vendors to bid on and provide the 12 new drugs and biologicals listed in Addendum B.[13] By including these drugs and biologicals, CMS allows physicians participating in the CAP to provide Medicare beneficiaries with the most advanced therapies available. We are concerned, however, that the agency does not require CAP vendors to include other new drugs and biologicals in the program once they are available on the market. We urge CMS to make this change in the final rule and reimburse vendors 106 percent of ASP (or 106 percent of WAC until an ASP-based payment rate can be established) for these therapies as soon as they become available.

The IFC places new drugs at a significant disadvantage among physicians opting for CAP, effectively denying access to the best available therapies to patients whose physicians have chosen to obtain products in this manner. Currently, the IFC excludes drugs from the CAP that have not yet been

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11 70 Fed. Reg. at 39029.
12 Id.
13 Id at 39072, 39102.

assigned a permanent HCPCS code. Unfortunately, it typically takes more than a year to obtain a permanent J-code, meaning new drugs will not be available in the CAP until they have been widely adopted in other Medicare treatment settings. For some drugs, CMS recognizes the need to assign product specific HCPCs codes such as Q-codes prior to the assignment of a permanent J-code for claims processing purposes. Some of these drugs retain Q-codes for years before being assigned a J-code, if ever.

Because vendor contracts are for a three-year period, the availability of new drugs could be delayed for this period of time – three years. Once a permanent code is assigned, the IFC states that CAP vendors have the *option* of offering the product through CAP, and if so, they will be reimbursed ASP plus 6 percent – the same amount physicians declining CAP participation will be reimbursed.

Although the IFC does allow CAP-participating physicians to purchase non-CAP products through the buy-and-bill method, such a requirement is inconsistent with the overall goal of CAP – to provide physicians with a choice of obtaining therapies through either method. Physicians opting to participate in CAP will do so due to the administrative advantages CAP offers and, therefore, should not be forced to go outside of the program to purchase and prescribe newer drugs. This is particularly the case for certain specialties that have little experience with "buy-and-bill." As written, this provision serves as a significant disincentive to prescribe new and innovative drugs, creating barriers for access to these therapies within the Medicare program. In addition, the provision creates perverse incentives for competing products in a therapeutic class. If this issue is not resolved, the CAP program will be the only venue within Part B of Medicare in which new products are not made available to Medicare beneficiaries immediately upon FDA approval.

To ensure access to new products by physicians and Medicare beneficiaries, we urge CMS to modify the final rule to allow for immediate adoption of new drugs within the CAP program. We ask that CMS:

1) Mandate that vendors make available to CAP-participating physicians new drugs upon FDA approval and reimburse vendors at 106 percent of ASP (WAC plus 6 percent until ASP data are gathered and reported). As written, the IFC specifies reimbursement of 106 percent of ASP for CAP vendors voluntarily offering new drugs to physicians. As such, this modification would

ensure vendors are held harmless on the costs of offering new drugs and would ensure consistency between the CAP and physician office settings within Part B.

2) Specify that vendors may bill for new products using product specific Q-codes. Currently the IFR includes three drugs which Q-codes are used to bill Medicare in its list of 169 drugs to be provided by CAP vendors. In the interest of consistency, BIO urges CMS to clarify in the final rule the definition of "permanent HCPCS codes" to mean any product-specific HCPCS code nationally recognized in the physician office setting by Medicare, including both J-codes and Q-codes.

3) Specify that vendors may bill for new products using the same miscellaneous J-codes available to physician offices under buy-and-bill (e.g., J9999 for oncology products). Although miscellaneous J-codes are used to bill multiple products, they can be (and are) annotated with specific NDCs to identify the specific therapy used. A similar mechanism is used to bill for new drugs in the hospital outpatient department prospective payment system.

These changes will ensure consistency between the physician office, hospital outpatient, and CAP settings and will help ensure patients and providers have equal access to new drugs upon FDA approval.

B. Claims Processing Overview

1. Emergency Re-supply Option

BIO commends CMS for the improvements it has made to the claims processing provisions of the CAP. We applaud the agency's efforts to "ensure that the physician's judgment about the appropriate treatment for the beneficiary is primary in the decision-making process."[14] First, we support CMS' definition of an "emergency situation" as "an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock."[15] This definition will allow physicians to provide critical treatments to their patients without concerns about obtaining replacement drugs through the CAP.

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14 70 Fed. Reg. at 39039.
15 42 C.F.R. § 414.902.

We recommend that now and as the CAP is expanded CMS further improve access to drugs and biologicals used in emergency situations, such as anti-emetics and therapies that dissolve blood clots, by allowing physicians to request an advanced supply of these therapies from the CAP vendor. Instead of having to maintain his or her own stock of these treatments, the physician should be allowed to request them from the CAP vendor and submit claims as they are used. Such a process would not disrupt claims processing or even require additional steps. The physician would order the drug or biological by giving the date of administration and other beneficiary information, the vendor would supply a doses-specific prescription number for the claim, and the vendor would re-supply the physician under provisions specifically agreed upon between the physician and the vendor under the sort of contractual arrangements CMS has endorsed in the IFR.

2. Determinations of Medical Necessity

BIO endorses CMS' clarification that CAP vendors cannot make determinations of medical necessity and must ship the therapy ordered by the physician.16 Thanks to this clarification, the CAP vendor will not be able to overrule a physician's judgment about the most appropriate therapy for his or her patient. If a physician determines that a drug or biological is appropriate for the patient and prescribes it consistently with any local coverage determinations, the beneficiary will be able to receive it through the CAP. This clarification will help protect beneficiaries' access to drugs prescribed for medically accepted off-label uses. It also simplifies physicians' participation in the CAP by reassuring them that the same coverage policies are in effect regardless of whether the drug is reimbursed under the ASP system or obtained through the CAP.17

3. Payment for Discarded Drugs

We also thank CMS for its response to CAP vendor questions regarding whether CAP vendors may file claims for unused portions of drug, and we ask CMS to include this response in the next CAP final rule. In response to this question, CMS explained that it "expect[s] that vendors will be able to bill the program for unused drugs under the CAP program in a similar fashion if

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16 70 Fed. Reg. at 39038-39.
17 Id. at 39039.

physicians and vendors act in good faith with respect to the ordering and use of the drugs."18 For the reasons discussed below, we believe the position articulated in this response is consistent with the statute, and best maintains uniform policies for Part B drugs furnished by physicians, whether electing CAP or not.

The statute does not prohibit CMS from applying its current discarded drug policy to CAP drugs. Without citing to a statutory provision, the IFC states that discarded drugs will not be eligible for payment because the CAP statute only authorizes CMS to pay upon the administration of a drug. Presumably, the agency is referencing SSA § 1847B(a)(3)(A)(ii), (iii)(II), conditioning payment and collection of deductible and coinsurance amounts on administration of a drug or biological. Paying a CAP vendor for discarded product would be consistent with these provisions, however, because, under CMS's discarded drug policy, there *is* an administration of a drug. That is all the statute requires. It does not address how much drug can be billed for; it only insists that a drug be administered.19 Accordingly, we believe that the agency's reading of the statute in the IFC was overly narrow and that the statute is susceptible to another reading. BIO submits that an alternate reading of the statute permitting the continued application of the discarded drug policy is a better one because it harmonizes the statute with the agency's preexisting policy and would apply like policies to Part B drugs regardless of whether a physician elects CAP or not.

CMS also could look to other provisions of the statute to authorize the continued application of the discarded drug policy in the CAP context. For instance, the statutory authority to provide a process for making payment adjustments when payment is made for drugs and biologicals which were dispensed but not actually administered20 could support the application of the policy to CAP. If the agency were to determine that CAP vendors only could bill for the amount of product administered, the process CMS is supposed to

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18 *See* "Response to CAP Vendor Questions", available at http://www.cms.hhs.gov/providers/drugs/compbid/capquestions081005.pdf.

19 One also can argue that these statutory provisions mainly govern the order of steps to be followed in submitting CAP claims. They require the vendor first to submit a claim for the drug or biological, but prohibit the vendor from collecting payment from Medicare or the patient until the drug has been administered, but do not address the quantity of the drug to be reimbursed. Because the discarded drug policy is about the quantity of drug Medicare will pay for, these statutory provisions should not be read to prohibit the continued application of the discarded drug policy.

20 SSA § 1847B(a)(3)(B).

provide could include a payment adjustment for a drug that is not administered consistent with its discarded drug policy.

Although not cited by CMS as prohibiting the application of the discard policy to CAP, BIO recognizes that the statute instructs that bid prices "shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage."[21] This applies only to the bid prices that are used to set the payment rates to CAP vendors, not to the billing policy that directs entities as to how to capture discarded drugs from single use vials. Just as wastage, spillage, or spoilage does not factor into setting ASP-based rates, yet physicians can follow the discarded drug policy, so too should the lack of inclusion in the bid prices not affect the ability of the CAP vendor to follow that policy.[22]

BIO urges CMS to state explicitly in the next CAP final rule that the discarded drug policy applies to CAP vendors just as it applies to physicians, as the agency recently has done in response to CAP vendor questions. For the above reasons, BIO believes that CMS has discretion under the statute to take such action and that doing so appropriately would continue to apply a longstanding Part B drug and biological policy uniformly in the physician office setting, regardless of whether the physician participates in CAP or is administering a CAP drug. Moreover, failing to pay for discarded drugs also could discourage vendors from bidding and ultimately could jeopardize the success of the program.

4. Beneficiary Coinsurance

BIO also supports CMS' efforts to address beneficiaries' concerns about payment of coinsurance for drugs obtained through the CAP. Currently, many physicians allow beneficiaries to continue their treatment, even if they cannot meet their coinsurance obligations. Physicians often work with beneficiaries to find assistance or ultimately do not to collect unpaid coinsurance.[23] Under the proposed rule, it was not clear that beneficiaries would be assured of access to

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21 SSA § 1847B(c)(6)(B).

22 Moreover, it is not clear that "wastage" must include discarded drugs. Because that term is not defined in the statute, CMS could interpret "wastage" to involve therapies that are prepared for administration, but no part of which is given to the patient due to changes in the patient's condition, cancellation of the appointment, or other reasons. That reading would mean that SSA § 1847B(c)(6)(B) has no bearing on the application of the discarded drug policy to CAP.

23 70 Fed. Reg. at 39053.

care or payment assistance if they could not pay their coinsurance debts to the CAP vendor. We support the IFC's requirement for vendors to provide beneficiaries with information on sources of cost-sharing assistance if requested by the beneficiary. This requirement, along with the procedures that must be followed before a CAP vendor may refuse to make further shipments for a beneficiary,[24] will help beneficiaries continue to receive care while they investigate sources of financial support.

5. Partial Payments to Vendors

BIO asks CMS to reconsider its decision to pay only when both the vendor claim and the physician's administration claim have been matched in the claims processing system.[25] BIO remains concerned that delayed cash flow could harm vendors' ability to continue to participate in the CAP and therefore could limit physicians' choice of drug acquisition methods. We recommend that the agency make a partial payment to a vendor when a drug administration claim is delayed by more than 28 days. CMS should consult with the specialty pharmacy industry to set an appropriate percentage for these payments.

C. Dispute Resolution

We support CMS' clarification that CAP vendors may file appeals of denied claims directly to the local carrier. The proposed rule would have assigned the physician full responsibility for appealing a denial of a drug or biological administration claim.[26] This could have placed a significant burden on physicians to pursue all appeals, regardless of the amount at issue for the physician, so the CAP vendor could have its claims reconsidered as well. The clarification somewhat relieves physicians of this considerable burden.

D. CAP Bidding Process – Evaluation and Selection

BIO supports the decision to update the single prices for CAP drugs and biologicals to the mid-point of calendar year 2006 by the Producer Price Index for prescription preparations. Updating prices through this mechanism will encourage more potential vendors to participate in the CAP by helping to ensure that payment for CAP drugs will keep up with inflation.

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24 42 C.F.R. § 414.914(h).
25 70 Fed. Reg. at 39052.
26 70 Fed. Reg. 10747, 10758 (March 4, 2005).

We request an additional clarification to the CAP bidding process. CMS should be clear that the CAP vendor's requirement to provide at least one NDC per biological in a HCPCS code does not impose any forced sale requirements on manufacturers. The statute requires vendors to acquire drugs and biological products "from the manufacturer or from a distributor that has acquired the products directly from the manufacturer."[27] BIO asks CMS to clarify that the statute does not interfere with a manufacturer's exclusive contract with a distributor. CAP vendors can acquire drugs and biologicals as required by the statute while respecting manufacturers' existing distribution agreements by seeking to obtain the drugs or biologicals from the distributor.

Likewise, CMS should confirm that CAP will not interfere or impose additional obligations or requirements with respect to manufacturer distribution models in which manufacturers ship products directly to physicians, which is how some products are delivered under the current buy-and-bill system. BIO believes that vendors should be permitted to allow a manufacturer to ship a CAP product that it makes directly to the ordering physician on the vendor's behalf without imposing additional obligations on manufacturers. In other words, a manufacturer should not have to be treated as a subcontractor that must meet all of CMS' CAP vendor requirements in these limited circumstances.[28] Those requirements are not appropriate for manufacturers that supply their own products directly to physicians. Therefore, BIO asks that CMS confirm that manufacturers are permitted to ship an ordered CAP product directly to a physician on the vendor's behalf without having to be treated as a subcontractor of the vendor.

E. Physician Election

Finally, the IFC allows a physician to opt out of the CAP for the remainder of the year if the CAP vendor refuses to ship drugs for one of his or her patients.[29] This provision allows the physician to continue to treat the patient by buying the necessary drugs and billing under the ASP system. It also requires the physician to forgo the benefits of participating in the CAP for all of his or her patients based on the needs of a *single* patient. We believe this remedy is unnecessarily harsh and might discourage many physicians from

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27 SSA § 1847B(b)(4)(C).

28 *See* 70 Fed. Reg. at 39060 (allowing vendors to subcontract with a drug distributor or pharmacy if the entity meets CAP vendor requirements).

29 42 C.F.R. § 414.908(a)(5).

choosing to participate in the CAP. We recommend instead that the physician be allowed to opt out of the CAP for that specific beneficiary, but continue to obtain drugs and biologicals for other beneficiaries through the CAP. CMS should work with physicians to develop an appropriate monitoring system to verify that physicians exercise this option only for a limited number of patients in their practice.

F. Conclusion

BIO appreciates this opportunity to comment on our concerns about the IFC, and we look forward to working with CMS to protect Medicare beneficiaries' access to life-improving drug therapies. We hope our suggestions will help CMS address these important issues in the final rule. Please contact Jayson Slotnik at 202-962-9200 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Jim Greenwood
President and CEO
Biotechnology Industry
Organization

Submitter : **Dr. William Jessee** **Date: 09/06/2005**

Organization : **Medical Group Management Association**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

On August 3, the Centers for Medicare & Medicaid Services (CMS) suspended the vendor bidding process for the competitive acquisition program (CAP), thus delaying implementation of the interim final rule. The notice clarified that the agency continues to seek comment on the rule, but that providers will be unable to acquire drugs through the program until July 2006. We applaud CMS for recognizing that the program will not be ready for implementation by January 1. MGMA looks forward to working with the agency as the vendor and medical communities evaluate how the CAP can be implemented in a responsible manner. For these reasons, the Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the interim final rule entitled the ?Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B,? as published in the July 6, 2005 Federal Register.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

MGMA is encouraged by a number of modifications to the interim final rule that address concerns raised by the provider community. In particular, MGMA supports CMS? adoption of broad phase-in, a large initial category definition, a national vendor acquisition area and the breadth of information made available to physicians as they choose whether or not to participate in the CAP. However, MGMA has several concerns and recommendations related to this rule, as outlined in the attached.

CMS-1325-IFC-143-Attach-1.PDF

MGMA

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

September 6, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-IFC
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

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

Dear Dr. McClellan:

On August 3, the Centers for Medicare & Medicaid Services (CMS) suspended the vendor bidding process for the competitive acquisition program (CAP), thus delaying implementation of the interim final rule. The notice clarified that the agency continues to seek comment on the rule, but that providers will be unable to acquire drugs through the program until July 2006. We applaud CMS for recognizing that the program will not be ready for implementation by January 1. MGMA looks forward to working with the agency as the vendor and medical communities evaluate how the CAP can be implemented in a responsible manner. For these reasons, the Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the interim final rule entitled the "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B," as published in the July 6, 2005 *Federal Register*.

MGMA is the nation's principal voice for medical group practice. MGMA's 19,500 members manage and lead more than 11,500 organizations in which more than 240,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

Policy for the CAP

MGMA is encouraged by a number of modifications to the interim final rule that address concerns raised by the provider community. In particular, MGMA supports CMS' adoption of broad phase-in, a large initial category definition, a national vendor acquisition area and the breadth of information made available to physicians as they choose whether or not to participate in the CAP. However, MGMA has several concerns and recommendations related to this rule, as outlined below.

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Phase-in implementation

MGMA is pleased by the phase-in adoption of a wide category of drugs. However, we continue to recommend that the drug list should include those drugs that many providers have been unable to obtain at rates close to or below the average sales price plus six percent. MGMA understands that the Physician Regulatory Issues Team (PRIT) and the Office of the Inspector General developed a brief list of drugs in this category. Since the list was not disclosed in the interim final rule, it is unclear how many drugs were included from this list. MGMA suggests that CMS identify specific drugs on the PRIT list in the final rule and explain why drugs were or were not included in the phase-in category.

Categories of drugs to be included under the CAP

MGMA continues to assert that the inclusion of CAP vendor prices in the calculation of the ASP is inappropriate and thus rejects CMS' position: "We do not believe that we have the statutory authority to exclude prices determined under the CAP from the computation of ASP under section 1847A of the Act. Section 1847A(c)(2) of the Act contains a specific list of sales that are exempt from the ASP calculation, and sales to vendors operating under CAP are not included on that list. Prices offered under the CAP must therefore be included in ASP calculations." 70 Fed. Reg. 39077. MGMA simply views the inclusion of the CAP rates in the calculation of ASP as duplicative and highly unfair to physicians electing to not participate in the CAP. MGMA recommends that CMS work with Chairman Bill Thomas of the House Ways and Means Committee to clarify how Congress intended the ASP and CAP systems to co-mingle, if at all.

Operational Aspects of the CAP

MGMA is pleased by the clarifications on CAP implementation issues, including several definitions and timelines. However, a number important concerns remain as described below.

Content of the CAP order

The data elements for the CAP order (70 Fed. Reg. 39041) are duplicative to those submitted on a service claim and do not reflect either a drug prescription or drug order. As currently required, MGMA strongly believes that the mandate is too burdensome and does not reflect current industry standards. Instead, the data elements reflect requirements for the Medicare billing system. As noted in the interim final rule, "It is not possible to link beneficiary-specific information from our claims processing system with the physician's order before the drug vendors compiling the information necessary to prepare the drug order and return it to the physician because it is not possible for a provider to query the system and obtain beneficiary billing information." 70 Fed. Reg. 39040. While MGMA appreciates the difficulty faced by the agency for the implementation of this program, the burden of the collection of claims data should not be placed on CAP participating physicians. MGMA continues to recommend that many of the data elements sought in the interim final rule be obtained through claims adjudication and not CAP orders.

While MGMA is encouraged by the inclusion of the health insurance number as we requested, we are also alarmed by a new aspect of the program. The interim final rule states that "the participating CAP physician will be required to provide the approved CAP vendor complete patient information only for the initial order, or when the information changes." 70 Fed. Reg. 39040. This limitation is helpful, although still too burdensome. However, the rule continues, "The approved CAP vendor will specify which information is necessary on a follow-up order." *Id.* This provision gives the CAP vendors too much deference and each vendor could mandate different levels of information required for follow-up orders. Furthermore, the necessary information could vary by drug. MGMA urges CMS to specify what

information is required for follow-up orders as a national standard and strongly suggests that the information be the minimum necessary and simplified as much as possible.

Drug vendor's prescription order process

The interim final rule states that "CAP vendor[s] will contact the designated carrier by telephone to verify that the beneficiary has current Part B coverage." 70 Fed. Reg. 39042. MGMA is frustrated by this statement due to the availability of the 270/271 electronic transaction under the Health Insurance Portability and Accountability Act that can easily facilitate this inquiry. MGMA recommends that CMS quickly adopt this transaction system-wide to enable cost-effective implementation of the CAP.

Administrative burden and dispensing fee

The proposed CAP rule stated, "We do not believe that the clerical and inventory resources associated with participation in the CAP exceed the clerical and inventory resources associated with buying and billing drugs under the ASP system." 70 Fed. Reg. 10755. This position is mirrored in the interim final rule, "Although we agree that a physician may have to make some adjustments in his or her practice in order to comply with the requirements under the CAP, we believe that the relief of the financial burden of purchasing the drugs and billing Medicare for these drugs will be a substantial improvement and benefit for many physicians." 70 Fed. Reg. 39049. MGMA flatly rejects this assertion. Under the CAP as defined in the interim final rule, medical group practices will be required to keep a tracking inventory of CAP drugs and file duplicative claims data to participate. Providers purchasing drugs through the average sales price model do not carry these burdens.

MGMA-collected data indicate that the cost of operating a group practice rose by an average 4.8 percent per year over the last 10 years. In fact, between 2001 and 2003, MGMA data show that operating costs increased more than 10.9 percent. Medicare reimbursement rates for physician services have fallen far short of the increased cost of delivering quality services to Medicare payments and do not capture new administrative burdens such as the keeping of a drug inventory or the filing of duplicative claims data in drug orders. As noted in our previous comments, MGMA strongly recommends that CMS reimburse providers for the cost associated with the additional administrative burdens mandated by CAP participation. Provider costs will vary by the sophistication of practice claims processing and supply/drug inventory systems. Nevertheless, there still remains an element of human interaction with the system since providers need to identify what drugs are received in the mail, which patients the drugs are intended for and the dispensing date.

Drug administration

According to MGMA surveys, multi-specialty and small group practices take longer periods to file claims than the average. Therefore, MGMA continues to assert that a longer timeline must be established to accommodate all practitioners.

As previously noted, the Medicare program currently permits providers to submit claims generally within one year from the date of service. 42 CFR 424.44(a). The interim final rule stipulates that CAP physicians agree to file claims within 14 days of service. The abrupt modification of claims submission deadline from 365 to 14 days is an incredible change that is not substantiated by the arguments and observations of CMS in the proposed rule. For these reasons, MGMA recommends that CMS define prompt claims filing for the CAP to be at a minimum 30 business days from the date of service.

Beneficiary coinsurance

In our comments on the proposed CAP rule, MGMA sought clarification as to whether vendors were aware of the need for financial assistance for the numerous Medicare beneficiaries who are financially unable to meet their coinsurance for physician-administered drugs. The comprehensive discussion of this issue is a step in the right direction, however, CMS has adopted a dangerous public policy position whereby the agency has failed to address the current problem in the fee-for-service drug reimbursement model and left patients to the assistance of CAP for-profit vendors. The agency noted that you "seek comment on additional provisions that we should use to define these processes to protect the vendor and the beneficiary." 70 Fed. Reg. 39053. MGMA submits the following observations.

MGMA believes that CMS itself does not have a clear picture of the extent of write-offs physician group practices make in relation to Part B drugs. We are encouraged by the customer-friendly requirements that the interim final rule adopts for vendor bids and this may offer CMS a glimpse into the "bad debt" world of Part B providers. However, CMS is jeopardizing patient care by allowing vendors to exclude patients based on their non-payment of coinsurance. "[I]n the case of a beneficiary who fails to satisfy his or her cost-sharing obligations for CAP drugs ordered by a particular participating CAP physician, we will allow the vendor to refuse to make further shipments to that physician for that beneficiary." 70 Fed. Reg. 39053.

MGMA strongly rejects this policy and asserts that no beneficiary should be excluded from the CAP program due to non-payment of coinsurance amounts. And while it is helpful to allow a physician to withdraw from the program if a vendor excludes a patient, this does not address the underlying issue of coinsurance "bad debt." MGMA urges CMS to begin to investigate and address this issue for Part B providers, and recommends that CMS revise 42 CFR 414.914(h) so that vendors may not exclude a patient based on their ability to pay and subsection (9) be withdrawn.

Implementation of the CAP

Participating CAP physician election process

The interim final rule would mandate that if one physician in a group practice enrolls in the CAP program, all physicians in the group must adhere to the participation decision of the individual. This highly discriminatory policy places solo practitioners in a much better position than group practices when it comes to evaluating CAP enrollment. MGMA believes that the participation decision should be determined on an individual physician level and should not be attributed to a whole group.

Also of significance, this is the only Medicare enrollment decision where the decision of an individual provider binds the entire group practice. Medicare participation is made on an individual basis and may be billed under a group number. Thus, MGMA strongly recommends CMS withdraw the group practice provision found in 42 CFR 414.908(a)(4).

Vendor and physician education

MGMA strongly urges CMS to publish timely articles and education materials for vendors and physicians. Also, CMS should work with vendors to test drug order processing system and issue guidance in advance of Jan. 1. MGMA looks forward to collaborating with CMS to educate carriers and medical group practices on the CAP.

Beneficiary education

MGMA welcomes the development of materials for distribution to patients and looks forward to partnering with CMS to aid in the education of physicians on their availability, but opposes any mandate to provide specific materials to beneficiaries receiving CAP drugs. This mandate continues to be an unfunded requirement of the CAP that discriminates against participating providers making it a less attractive option than the average sales price drug model. This burden should be the responsibility of the Medicare program and CAP vendors and not providers. MGMA urges CMS to withdraw the provisions of 42 CFR 414.908(a)(3)(xi).

Regulatory impact analysis

As noted above, the administrative burden to comply with the CAP program is excessive and can easily be decreased by following the recommendations made in this letter. However, additional administrative tasks still remain, all of which are not currently captured in Medicare reimbursement for physician-administered drugs. We urge CMS to revise the regulatory impact analysis and reimburse physicians for the additional burden imposed by participating in the CAP.

MGMA appreciates your consideration of these comments. If you should have any questions, please contact Jennifer Searfoss Miller in the Government Affairs Department at (202) 293-3450.

Sincerely,

William F. Jessee, MD, FACPME
President and Chief Executive Officer

Submitter : Dr. Jerry Ransom **Date:** 09/06/2005

Organization : OmniSYS, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1325-IFC-144-Attach-1.DOC

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September 6, 2005

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

Via Electronic Mail

Attention: CMS-1325-IFC

Re: Comments on Interim Final Rule: Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B CMS-1325-IFC (42 C.F.R. Part 414) (70 Fed. Reg., July 6, 2005)

Dear Dr. McClellan:

OmniSYS, Inc. submits the following comments regarding the Interim Final Rule (IFR) for Competitive Acquisition of Drugs and Biologicals dated July 6, 2005. OmniSYS has extensive Medicare Part B domain expertise as a provider of systems and services related to claims billing, documentation and receivables management for over 17,000 community pharmacies nationwide.

OmniSYS supports the Centers for Medicare and Medicaid Services (CMS) efforts to implement a Competitive Acquisition Program (CAP) that assures patient access and exceptional care. These comments address Claims Processing and Operational issues that affect all participants in the healthcare delivery chain.

In an efficient healthcare system, all parties must act responsibly including Beneficiaries, Payors and participating CAP Providers. For CAP, CMS should also be sensitive when establishing program policies and procedures to ensure they are fair and equitable in allocating financial risk. By way of example, all Medicare programs include annual deductible and coinsurance components to be paid by Beneficiaries – in fact, routinely waiving Beneficiary deductible and/or coinsurance payments is statutorily prohibited. As CAP is currently defined, we believe situations exist where it is likely Providers (Vendors and Physicians) will unfairly bear these costs.

CAP is a ground-breaking approach with the potential for long-term Medicare savings; however, concomitant policies and procedures should be equally innovative so as not to compromise participation in the program and, further, to insure participants do not bear undue financial risk. In summary, because the CAP Model differs significantly from other Medicare Part B programs, traditional Medicare Rules should not apply as discussed below:

a. Vendor reimbursement depends on Physician's complete and accurate reporting of Beneficiary Information (the "Drug Order") at the point-of-service; and, subsequently, Physician's timely and accurate filing of claims to Local Carriers. In most cases, drug costs will far outweigh Physician's "incident to services" fees creating "unbalanced" incentives, which compare to "a dollar waiting on a dime".

b. Vendor reimbursement depends on Beneficiary's timely payment of deductible and coinsurance long after the drug has been administered. As currently proposed, the payor hierarchy for each claim must be exhausted in its entirety before the Beneficiary is billed. Weeks, or even months, may be required to complete primary, secondary and tertiary billing and remittance posting following drug administration.

c. Under the CAP Model, Vendor has no opportunity to develop a face-to-face relationship with the Beneficiary and, further, following the initial Beneficiary encounter, the relationship is unlikely to improve when faced with uncomfortable discussions regarding cost-sharing assistance, Advance Beneficiary Notices; billing and collection of deductible/coinsurance, explanation of bills for services that occurred months after services were rendered, etc.

CAP savings should not be at Vendor expense. As currently defined, Vendors are unable to quantify financial risk associated with the certainty of supplemental insurance payments including deductibles and coinsurance; claims denials and appeals; and, billing and collection from Beneficiaries, etc. These issues must be incorporated into CAP distribution cost models because they significantly impact cash flow. The following comments are intended to address these issues and, further, to respectively persuade CMS to change proposed policies and procedures in the IFR to make some situations more equitable, to wit:

Advance Beneficiary Notice (ABN)

The IFR (Page 39,039) provides guidance regarding situations when a Vendor believes ordered drugs are not covered by the Local Carrier Determination (LCD). When the Physician declines to change the Order after discussing the Vendor's concerns, the Vendor may ask the Beneficiary to sign an Advance Beneficiary Notice (ABN) making the Beneficiary liable for payment if Medicare denies the claim. In either situation - whether the Beneficiary does or does not sign the ABN - the Vendor is still required to ship the drug. While this is intended to affirm the Physician's judgment in the decision-making process, these situations will often result in claims denials leading to costly and time-consuming appeals that increase Vendor financial risk and impact cash flow.

This policy should be reconsidered for the following reasons:

a. For typical "ABN Situations", Medicare Providers experience direct (face-to-face) contact with Beneficiaries at the "point-of-service" during which the Medicare Provider explains coverage gaps and the reasons an ABN is required. In the CAP Model, Vendors will not have direct contact with Beneficiaries – essentially, Vendors will have to arrange for Beneficiaries to execute the ABN "remotely" thereby increasing the risk that the ABN will go unsigned.

b. In typical Medicare service scenarios, the Beneficiary must execute an ABN prior to the rendering of services. Under CAP, the Vendor will be required to execute the ABN within the so-called "routine" or "emergency" shipment timeframe. This will be especially challenging for seniors without access to modern conveniences such as fax, email, etc.

c. For these situations, the Physicians are unlikely to request an ABN since in their judgment the drug and administration fees **are** covered by LCD, which will be confusing for Beneficiaries.

d. The Physician's appeal and Vendor payment will depend on the Physician's original belief that the drug **was** covered by LCD (i.e. Medical Policy). In addition, since drug costs will usually outweigh Physician's administration fees the incentives for aggressively pursuing payment through the Dispute Resolution process are not the same.

In summary, Vendors should not incur financial risk when disputing an LCD, drug shipment is mandatory and Vendor formally requests an ABN (regardless if is executed by Beneficiary). The policy should be changed to either: 1) require the Physician to process the claim through the traditional ASP system (Physician would assume financial risk for the claim); or, 2) require the Beneficiary to post a deposit or "proof-of-payment" (such as a pre-approved credit card) for the services in question.

Drug Order Information

The IFR (Page 39,041) includes a "required list" of Drug Order Information provided by the Physician to Vendor including "Supplementary Insurance (if applicable)" and "Medicaid Info (if applicable)". This information is required for orders and drug shipment; in addition; it represents the minimal data set required for claims billing. As stated in the IFR, it should be a mandatory for Physicians to provide complete and accurate information for each Drug Order. Vendors should not be responsible for "tracking down" Beneficiaries to clarify or correct this information. Participating Physicians should understand this is part and parcel of their responsibilities as a CAP Provider.

In summary, Vendors should only be responsible for exhausting the payor hierarchy provided by the Physician through the Drug Order. In the CAP Model, it is clearly the responsibility of the Beneficiary to inform the Physician of Supplemental Insurance. If the Beneficiary fails to notify the Physician of Supplemental Insurance at the "point-of-service", the Vendor should not be responsible for acquiring this information from the Beneficiary.

Beneficiary Cost Sharing Obligations

The IFR (Page 39,053) references the 2003 Medicare Current Beneficiary Survey which indicates that approximately eighty percent (80%) of Beneficiaries have some form of Supplemental Insurance. We believe this percentage (as evidenced from actual claims) is extremely high and reflects Beneficiary uncertainty regarding Supplemental Insurance coverage as subsequently stated in the same paragraph of the IFR. This will increase the incidence of scenarios where Beneficiaries will seek cost-sharing assistance. As currently proposed, Vendors are required to accommodate Beneficiaries experiencing financial hardship through referrals to charitable organizations, implementation of payment plans; or, full or partial waiver of cost-sharing amounts.

In summary, cost-sharing assistance is a necessary component of CAP because of anticipated drug costs; however, because these services are not typical to most Medicare settings, Vendors should be given consideration for rendering these cost-sharing services in the form of a "one-time" administrative fee – particularly, for remote Beneficiaries with whom they have no opportunity for face-to-face contact.

Dispute Resolution

As currently defined in the IFR (Page 39,054), Vendors are dependent on the Physician's assistance to appeal disputed claims. **The Dispute Resolution process should be better defined as to the specific conditions and circumstances including medical necessity under which Vendors can unilaterally file administrative appeals for denied drug claims with Local Carriers.**

Please contact Ms. Heather Benzi or me directly at 800.448.6891 if you have questions regarding these comments, which are respectively submitted in the spirit of ensuring a cost-efficient and successful CAP program.

Sincerely,

Jerry J. Ransom, Ph.D.
President - CEO
OmniSYS, Inc.

Submitter : Ms. Sajini Thomas **Date:** 09/06/2005

Organization : wright medical technology

Category : Device Industry

Issue Areas/Comments

Background

Background

Re: Interim Final Rule, Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B, (CMS-1325-IFC)

On behalf of Wright Medical Technology, Inc., we are pleased to submit comments on the above-captioned Interim Final Rule (IFR) on the Competitive Acquisition Program for Part B drugs and biologicals (the CAP). Wright Medical Technology develops and manufactures orthopedic tissue biologics as well as medical devices. Our GRAFTJACKET line tissue biologics are covered as incident-to drugs and biologics under the Part B Medicare Program. These products include GRAFTJACKET Regenerative Tissue Matrix Ulcer Repair and GRAFTJACKET XPRESS Flowable Soft Tissue Scaffold, which are used in the treatment of complex wounds.
SEE ATTACHMENT FOR DETAILED COMMENTS

GENERAL

GENERAL

See Attachment FOR DETAILED COMMENTS

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Wright Medical recommends:

Human tissue biologics, such as GRAFTJACKET Ulcer Repair Matrix and XPRESS Soft Tissue Matrix should not be categorically excluded from the CAP program. These are covered as incident-to biologics under Part B like other drugs and biologicals eligible for the CAP program.

Human dermal tissue biologics without metabolically active elements (HCPCS J7344) should be included in the CAP program. These products meet the claims volume and charge thresholds identified by CMS for eligibility for the CAP program in the IFR.

Regulatory Impact Analysis

Regulatory Impact Analysis

SEE ATTACHMENT FOR DETAILED COMMENTS

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

SEE ATTACHMENT FOR DETAILED COMMENTS

CMS-1325-IFC-145-Attach-1.PDF

Mark McClellan, M.D. Ph. D
Administrator, Centers for Medicare and Medicaid Services
7500 Security Boulevard,
Baltimore,
MD 21244 - 1850

Re: Interim Final Rule, Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B, (CMS-1325-IFC)

Dear Dr. McClellan

On behalf of Wright Medical Technology, Inc., we are pleased to submit comments on the above-captioned Interim Final Rule (IFR) on the Competitive Acquisition Program for Part B drugs and biologicals (the CAP). Wright Medical Technology develops and manufactures orthopedic tissue biologics as well as medical devices. Our GRAFTJACKET® line tissue biologics are covered as incident-to drugs and biologics under the Part B Medicare Program. These products include GRAFTJACKET® Regenerative Tissue Matrix—Ulcer Repair and GRAFTJACKET® XPRESS Flowable Soft Tissue Scaffold, which are used in the treatment of complex wounds.

We appreciate the Centers for Medicare and Medicaid Services's (CMS's) efforts to implement this new program consistent with congressional intent to offer physicians an alternative to current Part B drug acquisition and billing as well as potentially offering savings to the Medicare program. We agree with CMS's determination that implementation of this new program should not be hurried, and we were pleased to learn that the Agency decided to delay implementation so you could consider fully comments from interested stakeholders in response to the IFR.

As explained more fully below, Wright Medical recommends:

- Human tissue biologics, such as GRAFTJACKET® Ulcer Repair Matrix and XPRESS Soft Tissue Matrix should not be categorically excluded from the CAP program. These are covered as incident-to biologics under Part B like other drugs and biologicals eligible for the CAP program.

- Human dermal tissue biologics without metabolically active elements (HCPCS J7344)[1] should be included in the CAP program. These products meet the claims volume and charge thresholds identified by CMS for eligibility for the CAP program in the IFR.

1. Human tissue biologics should be eligible for the CAP program.

In the IFR, CMS stated: "Tissues (for example, dermal, metabolically active, etc.). (Tissues are not considered drug products, and do not appropriately belong under the category of physician administered drugs that we have devised in response to the comments.)"[2] We were perplexed by this statement. Human tissue biologics, including dermal or dermal plus epidermal tissues with or without metabolically active elements (HCPCS codes J7340, J7342, J7344, and J7350) have been covered as incident-to drugs and biologicals under Medicare Part B. These biologics currently are paid under the average sales price methodology (ASP+6%) under Part

[1] J7344 "Dermal tissue, of human origin, with or without other bioengineered or processed elements, without metabolically active elements, per square centimeter."
[2] 70 Fed. Reg. 39022, 39031 (July 6, 2005)

B when provided in a physician's office setting. These products also are paid as pass - through drugs and biologicals under the Outpatient Prospective Payment System. As with other drugs and biologicals paid under the ASP methodology in the physician office setting, human dermal tissue biologics should be eligible for inclusion under CAP.

There are important policy reasons for including human tissue biologics under the CAP program:

Human dermal tissue biologics, such as GRAFTJACKET® Ulcer Repair Matrix are used in the treatment of patients with complex, chronic wounds. Inclusion of these products in the CAP program will provide physicians a choice between--(1) obtaining these biologics from vendors selected through a competitive bidding process; or (2) directly purchasing these biologics and being paid under the ASP methodology. These products are relatively high cost products that may represent a financial burden for some physicians. Including these high cost tissue biologics in the CAP program will increase their availability of these products for the treatment of a vulnerable, patient population.

In addition, these products have a long history of being handled by specialty pharmacies that are familiar with the handling and storage of these products. For all the reasons listed above, we request the inclusion of the human dermal tissue biologics, including the GRAFTJACKET® Ulcer Repair Matrix billed under HCPCS J7344 among the drugs and biologicals included in the CAP program.

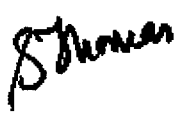
2. Human dermal tissue biologics should be included in the CAP program as these meet claims volume and charge threshold criteria.

HCPCS code J7344 was released effective January 1, 2005. This replaced a temporary code, which was in effect earlier. We do not have access to allowed charge information from 2004. However, based upon the volume of sales of our GRAFTJACKET® brand of human dermal tissue biologics reported under code J7344 for 2005 year-to-date and the proportion of Medicare patients among those who are candidates for these products, we believe these products would meet the claims volume and charge thresholds identified by CMS in the IFR. We would be pleased to share these sales data with the Agency on a confidential basis, if you would like to review these to confirm eligibility for the CAP program.

* * * *

We appreciate the opportunity to submit comments on the above-captioned rule. If you have any questions or would like additional information, please contact Sajini Thomas at 901.606.6224.

Sincerely yours,



Sajini Thomas
Director of Reimbursement Services

headquarters
Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002 **901.867.9971** phone **www.wmt.com**
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011.39.0250.678.227 Italy **011.81.3.3538.0474** Japan **011.44.1483.721.404** UK

Submitter : Ms. Linda Rosenberg

Date: 09/06/2005

Organization : National Council for Community Behavioral Healthca

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-146-Attach-1.DOC

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National Council for Community Behavioral Healthcare

September 6, 2005

Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Attn: CMS-1325-P
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

RE: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B (CMS-1325-IFC)

Dear Administrator McClellan:

On behalf of the National Council for Community Behavioral Healthcare (NCCBH), I am writing to thank you for including long acting injectable atypical antipsychotic medications in the Interim Final Rule (IFR) issued by the Centers for Medicare and Medicaid Services (CMS) regarding implementation of the Competitive Acquisition Program (CAP) for Part B drugs and biologics published in the Federal Register on July 6, 2005.

The National Council's response to the IFR will focus on CAP implementation issues, and our overall goal is to speed the availability of this new innovative medical technology to the patients who need it the most.

NCCBH represents over 1,200 Community Mental Health Centers (CMHCs) and other community-based behavioral health entities across the United States. These safety net providers are the backbone of the public mental health system serving over 4.5 million adults per year; fully one half of these individuals have serious mental illnesses including schizophrenia and bipolar disorder. At least 75% of this service population receives health insurance coverage through Medicaid. Significantly, up to 40% of a typical CMHC's caseload is composed of persons who are eligible for both the Medicare and Medicaid program (hereinafter referred to as dual eligibles).

Some preliminary observations are in order before we begin our detailed response to the IFR. The interim rule mandates that only individual physicians employed by CMHCs – rather than CMHCs themselves – can elect to participate in CAP for the provision of Part B drugs. This is one of many issues relative to CMHCs and Medicare – stretching from discrimination against CMHCs in telehealth policies to the mental health payment limitation to appropriate fees for the administration of Part B covered medications – that we would like to discuss with you and your staff at the appropriate time.

In addition, NCCBH was disappointed to learn that CMS has planned a six month delay in implementation of the program from January 1 to July 1, 2006. We strongly believe that the delay should not be used as an opportunity to either reduce the number of medical therapies included in CAP or to scale back the planned national roll out of the program in 2006.

I. Categories of Drugs To Be Included Under CAP

A.) Number of National Drug Codes – The Practice of Community Psychiatry

The agency's decision in the IFR to not require CAP vendors to provide every National Drug Code (NDC) associated with a Healthcare Common Procedure Coding System (NCPCS) code may have unintended consequences on the practice of psychiatry in CMHCs.[1]

NCCBH Recommendation: At a minimum, an exception to the above referenced policy should be promulgated requiring CAP vendors to bid on all NDCs within an HCPCS code if they are unit doses of the same single source medication. Here's why.

Atypical antipsychotic medications often come with a recommended target dosage designed to achieve the maximum clinical effect. But a physician will prescribe above or below the target dosage depending upon such factors as the patient's medical history, family medical history, the side effect profile of the antipsychotic medicine being contemplated, and medical interactions with medications in the patient's overall drug regimen. Prescribing decisions in CMHCs are further complicated by the fact that patients have a high prevalence of co-occurring substance abuse disorders and medical/surgical conditions.

However, the IFR appears to authorize vendors to bid on and provide only one dosage level to physicians participating in CAP. Specifically, a CAP vendor could choose to bid on a NDC representing only the target dosage, or only the lowest dosage strength of a given product. This outcome could have a significant impact on everyday clinical practice by requiring CMHC psychiatrists to inject the same product multiple times in order to properly treat persons with severe mental illnesses. While the interim rule includes a "furnish as written" provision, surely the drafters of the IFR did not intend for physicians to use this exceptional administrative procedure in order to implement standard medical practices as part of a treatment plan.

Similarly, a CAP vendor should be required to bid on at least one NDC for each single-source drug and biological in a category to ensure that beneficiaries have access to the brand that works best for them. In our view, these two common sense exceptions will create few administrative burdens for CAP vendors while, at the same time, protecting the clinical discretion front of line physicians.

B.) New Drugs – Future Drug Categories

In contrast to existing Medicaid law, the IFR does not require CAP vendors to bid on and provide new Part B drug therapies that are likely to be approved by the Food and Drug Administration (FDA) over the initial three year CAP implementation period.[2]

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[1] 70 Fed. Reg. 39034

NCCBH Recommendation: CMS should require vendors to bid on and provide new Part B medications no later than four months following FDA approval, and a broad structure should be maintained for new categories.

Title XIX of the Social Security Act requires states to add new medications to their prescription drug programs once these innovative therapies have been approved by the FDA as safe and effective. In order to ensure that patients participating in Part B have access to the latest medicines, there is a compelling policy rationale for applying the same approach to the CAP bidding process. Similarly, the National Council urges CMS to maintain a broad category structure so that multiple Part B products are included in the psychiatry category.[3]

II. Claims Processing Review

C.) Coinsurance Requirements: Dual Eligible Exception Is Needed

As we indicated at the beginning of this correspondence, CMHCs provide mental health care for a very large number of low-income dual eligible persons. According to Medpac, almost 40% of the 7 million dual eligibles in the United States have cognitive impairments or mental illnesses. Private estimates indicate that fully 50% of all public sector patients with schizophrenia are dual eligible. Many of these individuals obtained their initial Medicaid entitlement because they were eligible for the Supplemental Security Income (SSI) program whose average monthly income payments might be as low as $600.

Consequently, this section of the IFR makes for alarming reading indeed. The interim rule appears to authorize CAP vendors to suspend shipments to physicians when beneficiaries cannot pay their deductible or coinsurance. At least for dually eligible persons, this policy is unacceptable.

NCCBH Recommendation: CMS must use its clear administrative discretion to create an exception whereby CAP vendors are prohibited from suspending CAP drug shipments on behalf of dual eligible beneficiaries when a State Medicaid program has upheld its statutory obligation relating to coinsurance payments.

Differing pharmacy and provider fee schedules at the State level produce varying results under Medicaid Upper Payment Limit (UPL) requirements. However, in many States, UPL provisions require State Medicaid agencies to limit coinsurance payments to the extent that any such payment, when combined with Medicare Part B payments, equals the amount of upper payment limits under the State Medicaid program.[4] As a result, a State Medicaid agency may deem a CAP vendor to be paid in full even if it has received either no coinsurance payment or a reduced payment for from the State. Clearly, an amendment to the IFR is needed stipulating that once a State has made coinsurance payments on behalf of dually eligible persons, CAP vendors are

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[2] Id. At 39075
[3] Id. At 39030
[4] Social Security Act, Section 1902(n)(2)

prohibited either from suspending future shipments to physicians or pursuing the beneficiary for the remaining balance.

D.) Extension of Coinsurance Waiting Period

Under the IFR, "[I]f the beneficiary requests cost-sharing assistance and the vendor refers the beneficiary to a bona fide independent charitable organization for assistance or offers a payment plan, the vendor must wait **an additional 15 days** from the postmark date of the approved CAP vendor's response to the beneficiary's request for cost-sharing assistance."[5] The CAP vendor is authorized to suspend shipment of Part B drugs to the physician on behalf of that patient if the cost-sharing requirements are not met. To put it as plainly as possible, this regulatory requirement is simply inappropriate as applied to persons with serious mental illnesses.

NCCBH Recommendation: For beneficiaries with mental illnesses and other cognitive impairments, CMS should establish a minimum waiting period of 75 days or more before CAP vendors are authorized to discontinue shipments of Part B drugs after the patient has requested third party financial assistance.

As the National Council noted in our April 26, 2005 correspondence responding to the proposed CAP rule, mental illnesses like schizophrenia and bipolar disorder are typically associated with cognitive impairments effecting speech, memory and executive decision making. Moreover, the IFR notwithstanding, over worked case managers employed by CMHCs and family members – not CAP vendors -- will actually be responsible for locating bona fide independent charitable organizations capable of making the required copayments. Given the clinical symptoms of serious mental illnesses and the crisis-driven nature of service delivery in many CMHCs across the nation, we strongly believe that a more compassionate waiting period is manifestly in order.

E.) Physician Opt Out

Similar to the waiting period discussion above, the IFR's physician opt out rule fails to reflect the realities of clinical practice in public sector settings. As we read the interim rule, in instances where a beneficiary has failed to meet his or her obligations to pay coinsurance or deductible for a drug and the vendor has refused to continue providing the medication, CAP physicians have the option of opting out of **that entire drug category** for CAP. Again, this rule seems inflexible given the patient population at issue.[6]

NCCBH Recommendation: A better physician opt out rule would permit front line doctors to "buy and bill" for specific beneficiaries struggling with cost sharing requirements, while continuing to serve patients who are successfully fulfilling their co-payment obligations under CAP.

Many CMHCs operate in behavioral and mental health professional shortage areas throughout the United States. It is easy to foresee that standard operation of the IFR's existing physician opt

[5] Id. at 39053
[6] Id at 39053

out rule – without a common sense modification -- would impose serious administrative burdens on CMHCs and lead to substantial operational challenges.

F.) Physician Management Fee Needed

The National Council is compelled to point out that CMHCs are safety net providers often operating in resource poor environments serving low-income people with serious disabilities. In other words, many CMHCs may not have the personnel, automated payment systems, information technology and other operational advantages enjoyed by private physician practices and group practices.

NCCBH Recommendation: For physicians employed by CMHCs, CMS should authorize a management fee to compensate for some of added costs associated with participating in the CAP program.

While there is no question that CAP will offer substantial improvements over the existing buy and bill system, there will be costs **accruing to CMHCs** for the individual decisions of physicians they employ to participate in CAP. These administrative expenses involve actual administration of the therapy, billing for the drug administration and collecting the required co-insurance.

Closely associated costs include patient education by case managers and line clinical staff, training CMHC psychiatric nurses to administer long acting injectable antipsychotic medications, and establishing individualized purchasing mechanisms to assist the CAP physician with acquiring the product from the vendor. A parallel procurement system will be needed just for CAP implementation as well as modifications to existing systems. Unlike physicians operating in private practice, these costs will be borne by publicly supported CMHCs, not the doctors themselves. Because of these unique circumstances, a management fee paid to CMHCs seems appropriate to offset these costs.

Let me conclude by stating that the National Council is firmly committed to successful implementation of the CAP program. We believe that promulgation of the final rule and the issuance of clarifying directives during the six month delay can effectively address virtually all of the concerns addressed in this correspondence.

Thank you for your attention to these important matters.

Sincerely,

Linda Rosenberg

Linda Rosenberg
Executive Director

Submitter : Mrs. Laura Davis
Organization : Snat Rosa Memorial Hospital
Category : Individual
Date: 09/06/2005

Issue Areas/Comments

Background

Background

This would be of great benefit of our community.

Submitter : Kirsten Beronio

Date: 09/06/2005

Organization : National Mental Health Association

Category : Consumer Group

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

See Attachment

CMS-1325-IFC-148-Attach-1.DOC

National Mental Health Association

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Government Affairs Office: 413 East Capitol St, SE, Washington, DC 20003-9997 • Fax (202) 675-8389 • www.nmha.org
Cynthia Wainscott, **Chair of the Board** • Michael M. Faenza, **President and CEO**

September 6, 2005

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

Dear Dr. McClellan:

On behalf of the National Mental Health Association, I am writing regarding the Center for Medicare and Medicaid Services' (CMS') interim final rule [CMS-1325-IFC] to establish a Competitive Acquisition Program (CAP) for medications covered by Medicare Part B. We are particularly interested in the impact this regulation will have on mental health consumers.

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

Thus, we were pleased to see that CMS responded to our comments on the proposed CAP regulation by including injectible mental health medications in the CAP. Overly complex and confusing reimbursement policies for this type of medication have caused physicians to discontinue use of injectible mental health medications for financial reasons instead of therapeutic concerns. Moreover, the heightened risk of non-reimbursement associated with this type of medication also discourages physicians from even offering this type of treatment to consumers who may benefit from it. Mental health disorders require highly individualized care, and thus in order to receive effective treatment, consumers need access to the full array of treatment options including non-self-administered, injectible medications.

However, we are very concerned that under the CAP interim final rule, vulnerable consumers, particularly those with serious mental illnesses for whom injectible medications may be the most effective form of treatment, will still be denied access to these medications because of their inability to pay a co-payment. This barrier to care will be impossible for most to overcome, particularly if the 50 percent co-payment requirement for outpatient mental health services under

Part B is inappropriately applied to the cost of these medications. Even a 20 percent co-payment will be insurmountable for people with serious mental illnesses that often significantly impair a person's ability to work. Those with extremely low incomes may qualify for Medicaid, but the coverage provided through their state's Medicaid program may not be sufficient to cover the co-payment for injectible mental health medications either.

Previously, physicians were able to help their low-income patients who could not afford the co-payments for these injectible medications, but under the CAP, Medicare beneficiaries will instead be billed for cost-sharing for injectible drugs by the specialized vendors supplying these medications. We are concerned that, unlike treating physicians who have a personal and on-going relationship with their patients, these vendors have no incentive to assist beneficiaries unable to pay their co-payments and that the provisions included in the IFR directing CAP vendors to establish payment plans for consumers in financial need or refer them to charities are too vague to provide adequate protections for vulnerable beneficiaries struggling with mental illness. Moreover, these vendors are simply required to *refer* needy beneficiaries to charities and may still refuse shipment to those beneficiaries regardless of whether those charities are able to assist them.

We greatly appreciate the actions that CMS has taken to address the special needs of individuals with mental illness in the Medicare Part D prescription drug benefit. Similar accommodations must be made in the CAP to ensure that unreasonable co-payments do not prevent mental health consumers from accessing needed medications. Protections must be included in the CAP for beneficiaries with mental illness because they are more likely to experience very low-incomes since mental illness is one of the primary causes of disability in the country. In particular, we urge CMS to require CAP vendors to ship mental health medications even if these vulnerable consumers are unable to pay the co-payments. In the alternative, we urge you to allow physicians to "buy and bill" for mental health consumers for whom a CAP vendor has denied shipment for lack of payment without requiring that physician to opt out of the CAP altogether. Finally, we encourage CMS to maintain the requirement in the IFR that physicians provide fact sheets to their patients regarding the changes in reimbursement resulting from the CAP.

Thank you very much for your consideration of our views.

Sincerely,

Michael M. Faenza, MSSW
President and CEO

Submitter : Ms. Abbey Meyers **Date:** 09/06/2005

Organization : National Organization for Rare Disorders

Category : Consumer Group

Issue Areas/Comments

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Please see attached document.

CMS-1325-IFC-149-Attach-1.PDF

September 6, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Center for Medicare and Medicaid Services (CMS)
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Interim Rule
CMS-1325-IFC
"Provisions of the Interim Final Rule"

Dear Dr. McClellan:

On behalf of the National Organization for Rare Disorders (NORD), we request that CMS revise its position—stated in the CAP final rule—that some orphan drugs (ones defined by CMS as "single indication") should be excluded from the CAP program. We appreciate CMS' concern for rare disease patients and, in hindsight, recognize that there was some ambiguity in the position stated in our comments of May 23, 2005.

At this time, there is no evidence, nor plausible reason, to exclude orphan drugs—as a class—from the CAP program. Indeed, we can imagine situations where inclusion in the CAP program will result in increased access for rare disease patients (e.g. physicians may be more likely to order and administer an orphan drug that is available through the CAP program). We believe that the best policy would be to include all orphan drugs in the CAP program, while allowing consideration of specific drugs/treated populations where exclusion may be warranted.

We know there will be a problem where multiple drug products share a HCPCS code and are not interchangeable for all patients. There was sufficient concern about this for Congress to exclude intravenous immune globulin (IVIG) products from the CAP process. The same situation applies to antihemophilia clotting factors and alpha-1-proteinase inhibitor and they are appropriately excluded by the final CAP rule.

In sum, (1) all orphan drugs should be eligible for inclusion under CAP, (2) alpha-1-proteinase inhibitor, antihemophilia clotting factors and intravenous immune globulin should be excluded from CAP as requested by those knowledgeable about the use of those products and (3) a review mechanism should be established where relatively rapid decisions can be made by CMS to evaluate access problems and exclude a drug that would otherwise be included.

Dr. McClellan, this also seems an appropriate place to comment on CMS's decision to treat "single indication orphans" as a class under the CAP regulations. CMS originally developed this definition as part

of the HOPPS regulatory process in 2002 in order to distinguish certain products that would be paid under methods expected to provide a higher percentage reimbursement under that program. At the time, NORD offered several alternative approaches to address the concerns about inadequate payment rates for all orphan drugs and biologicals under HOPPS.

We believe strongly that CMS should not have (indeed, has no need for) a definition of "orphan drugs" that is different than the statutory definition in the Food, Drug and Cosmetic Act. We expressed our concern in our comments on the proposed HOPPS rules in 2002, 2003, and 2004, as well as in several other meetings and communications with CMS. Shortly, we will be reiterating our opposition to treating "single indication orphan drugs" as a class in our comments on the proposed 2005 HOPPS rule. Simply put, "single indication orphan drugs" is not a meaningful way to distinguish among orphan drugs and rare disease patients. It is bad policy and inconsistent with actions taken by other government agencies.

While we disagree vehemently with the use of the CMS orphan drug definition in HOPPS and we have proposed alternatives, we at least understood the goals that CMS was trying to achieve when it developed the definition. No such rationale applies with regard to CAP. We fear that CMS has taken a definition created to meet a very specific (HOPPS) program goal and decided that those are the only orphan drugs/rare disease patients to whom CMS has legal and moral obligations. That may not be CMS' intent, but it is the consequence of your actions in the final CAP regulation.

We look forward to seeing revisions to the CAP final rule and would be happy to work with CMS officials to develop a process that will be timely, fair and not burdensome to CMS or to those asking for exclusions. Further, we would like an opportunity in the next few weeks to discuss the importance of CMS bringing its orphan drug definition into line with the statutory definition used by the rest of government.

We are grateful for your consideration of these requests. If you would like this assistance or need further information, please contact Diane Dorman at NORD's Washington, DC office: 202.496.1296 or ddorman@rarediseases.org.

Sincerely,

Abbey S. Meyers
President

cc: Diane E. Dorman, Vice President, Public Policy

Submitter : Dr. Gregory Schimizzi **Date: 09/06/2005**

Organization : Coalition of State Rheumatology Associations

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS
1710 South 17th Street
Wilmington, North Carolina
Telephone: (910) 762-1182 Fax: (910) 332-1111

Gregory F. Schimizzi, M.D.
President

September 6, 2005

Via Electronic Submission
Mark D. McClellan, M.D.
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1325-P
Room 445-G, Hubert Humphrey Building
200 Independence Ave., SW
Washington, D.C. 20201

Re: Medicare Competitive Acquisition of Outpatient Drugs and Biologicals under part B (CMS-1325-P)

Dear Dr. McClellan:

On Behalf of the Coalition of State Rheumatology Organizations (CSRO) representing 1500 clinical practicing Rheumatologists in 22 states and regions, we would like to provide comments on certain aspects of the proposed rule regarding implementation of a Competitive Acquisition Program (CAP) for Part B drugs and biologicals published in March 2005 (70 Federal Register 10746) as they affect Rheumatology practices.

One of the CSRO?s missions continues to focus on improving patient access to high quality Rheumatologic care through fair reimbursement for professional services and adequate reimbursement for required pharmaceuticals. This applies equally to all patients with or without insurance. Without fair and adequate reimbursement, practicing medical professionals will be unable to provide necessary care. A CAP program, while offering an alternative to the current conventional system, will need to be developed with considerations for additional medical practice costs created by single source pharmaceuticals acquisition.

Our recommendations and comments regarding the proposed rule on CAP are listed here.

GENERAL

GENERAL

Example #1 There are physicians with one office / satellite in North Carolina and one office / satellite in South Carolina who already face significant differences in taxes and acquisition for the same medication provided to similar patients with identical diseases.

Example # 2: If a Medicare patient with chronic rheumatoid arthritis develops a flair of disease activity with multiple painful and inflamed joints and one painful swollen knee effusion, a rheumatologists usual response would be to perform an aspiration and injection procedure on the inflamed knee effusion with intra-articular steroid injection, administer a systemic dose of intravenous, intramuscular or oral tapering dose of corticosteroids to globally suppress the disease and increase or alter the patients disease modifying medications. Under the CAP program, it will be impossible to do all of this on the same day as the emergency encounter. This patient may have to go home untreated while medications are ordered or may need to be hospitalized for treatment. If the patient was sent home, the patient and perhaps their family member would likely need to assist the patient at home with activities of daily living. The patient and possibly a family member may have to return in 1, 2 or 3 days after the orders were placed, the patient information sheets completed, the demographics entered and the transmission to the CAP vendor confirmed. If there was a problem with any of the information (out of date insurance card, clerical error in demographics, etc.) further delays could be expected. This would not qualify as a good example of the efficient delivery of high quality medical care.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Categories of Drugs The CSRO believes that all medical specialties be given the freedom to choose the categories of drugs and biologicals that they would like to obtain from the CAP vendors required to manage the patient mix within their practices. Restricting categories of choices within categories will limit a physician?s ability to develop a treatment program that best suits each individual patient. Such a restriction would reduce the quality of care to specific individuals who have special needs. This will be especially true in the case of complex patients with complicated chronic diseases who have comorbid conditions and multiple medical therapies such as patients treated for complex Rheumatology diseases. We strongly recommend that all complex biologics, intravenous immunoglobulin and all

office administered disease modifying agents for the treatment of autoimmune diseases be included in the CAP program.

We believe that the list of drugs for all specialties should be developed with broad availability of medications that will allow for the treatment of all patients in need of care. We request that CMS address each category of medications and specialty disease treatment with equally comprehensive choices for quality care purposes. From a Rheumatology perspective, complex infused biologics, immunoglobulin and chemotherapy agents used for the treatment of autoimmune diseases need to be given particular attention. The array of new therapies for serious, chronic, deforming and deadly diseases requires attention to prevent the loss of availability of these therapies for stricken patients. A provision for the efficient addition of new therapies needs to be addressed in a clear and concise manner in the final rule.

Competitive Acquisition Areas for Vendors It will be important to foster competition between vendors while at the same time preventing drug selection among vendors. Large national vendors may not be inclined to provide all available medications in sufficient quantities for all diseases. Large national vendors may also limit low volume medications in favor of the most commonly prescribed agents. A state area vendor may be better able to respond to the needs of the practicing physicians and patients in that state but may have a lower capacity to respond in an emergency need for any particular disease such as might be needed after catastrophic or cataclysmic disasters. For these reasons, a regional based system of vendors or a state based system with regional cooperation may be the best available option.

We would also recommend no phase in of the CAP areas and a nation-wide implementation on the start date. It is also important for physicians to have the availability to utilize vendors with uniform policies, medication lists and supply channels.

Claims Processing Emergency medication supplies are readily available under the current prevailing methods of medication acquisition without the need for documentation of need, extra vendor communications or added inventory manipulation / management. The Proposed Rule while `allowing? for emergency medication dosage changes and usage creates additional administrative burdens, management costs (inventory adjustments), additional clerical costs (vendor communications) and could potentially cause delayed treatment adversely affecting patient care in the event that medications were not available when a patient presents with an emergency need for earlier-than- planned treatment. Additionally, there is always the possibility of a dispute between the physician acting on behalf of his/her patient?s need and the vendor / health agency on agreement with the term `emergency use?. This could pose additional problems for physician offices in re-supplying medications used under those circumstances.

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

Other issues under the proposed rule are also of great concern to Rheumatologists. CAP will create additional costs, challenges and paperwork for physician offices. The costs of additional paperwork to communicate individual patient identification, individual patient demographics and individual patient insurance information with vendors will not be reimbursed yet will pose a significant increase over the current simple system of volume purchases from the lowest cost source, simple distribution to each patient form total inventory and billing for provided services and administered medication quantities. The CAP program inherently assigns additional complexity to the storage and management of inventory with individual patient identification. Each new prescription with new dosing will require a repeat performance of this `Red Tape Tap Dance?. There will be inconveniences and increased expense for patients, delay in the care of emergency patients and an increase in practice expenses under the proposed CAP program. (See example 2 below)

There is the additional problem of treating patients who are not Medicare beneficiaries. These patients? inventoried medications will need to be separately accounted, sorted, stored and managed. It can be assumed that a second entire method of inventory management will be required in order for physicians to participate in the CAP program. A CAP program needs to take into account the myriad of problems that are outlined here as not only affecting health care costs but affecting the ability of physicians to administer the medications at all. Adding additional work, costs and complexity to any system will affect the ability of patients in need to maintain access to the care that they require in a timely and efficient manner.

The CSRO appreciates the opportunity to submit the above comments to CMS on the proposed rule regarding the Part B CAP program. If you have any questions or require additional information, please feel free to contact me at 910-762-1182 ext.1411.

Gregory F. Schimizzi, M.D.
President

Submitter : Dr. Michael Maves **Date:** 09/06/2005

Organization : American Medical Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-151-Attach-1.PDF

AMA
AMERICAN
MEDICAL
ASSOCIATION

Michael D. Maves, MD, MBA, Executive Vice President, CEO

September 6, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B; Interim Final Rule with Comment Period; 70 Fed. Reg. 39021 (July 6, 2005); File Code CMS-1325-IFC

Dear Dr. McClellan:

The American Medical Association (AMA) appreciates the opportunity to submit our comments concerning the Centers for Medicare and Medicaid Services' (CMS) interim final rule (IFR) to implement a competitive acquisition program (CAP) in the Medicare Program, *Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; 70 Fed. Reg. 39021* (July 6, 2005). We are pleased that CMS honored our request, and that of many other stakeholders, to issue an interim final rule with comment period rather than moving immediately to a final rule.

Overview of the CAP

We appreciate CMS' favorable response to several other physician recommendations, including making the program national in scope rather than phasing it in by region or specialty, and including most of the drugs that physicians administer to Medicare patients, particularly those that frequently cannot be purchased at the average sales price. However, the AMA still has several major concerns about the CAP. For example, we continue to believe that CMS should not include CAP prices in its calculation of future ASPs, creating a downward spiral and prices that are well below the purchase price for most physicians. We remain concerned about the extent of information CMS is requiring to be included in physicians' drug orders. We are worried some physicians may not be able to file drug administration claims within 14 days and we also believe that the administrative burden associated with participating in the CAP still needs to be reduced.

American Medical Association 515 North State Street Chicago Illinois 60610
phone: 312 464 5000 fax: 312 464 4184 www.ama-assn.org

Finally, although we are pleased that CMS is requiring vendors to create a process for helping beneficiaries who cannot meet their co-payment obligations, we are very concerned that vendors ultimately will be allowed to refuse to dispense additional drugs through the end of the calendar year to patients who have not paid their coinsurance within certain time limits. Although the interim final rule allows physicians to opt out of the particular drug category involved if this situation arises, we are concerned that this will have negative consequences for patients' health, and discourage physicians from participating in CAP at all. These concerns are discussed in more detail below.

Categories of Drugs to be Included under CAP and Competitive Acquisition Areas

In its IFR, CMS indicates that the CAP will be limited in scope, at least initially, to drugs administered in physician offices that are incident to a physician's service, even though the statute provides a broader definition of "competitively biddable drugs and biologicals." As we indicated in our comment letter on CMS' proposed CAP rule, dated April 26, 2005, the AMA agrees with this approach.

Likewise, we agree with CMS' decision to implement the CAP with a single broad category of drugs. In the IFR, CMS identifies a set of 169 drugs that are most commonly administered incident to a physician's service – 85% of physicians' Part B drugs by billed charges – for inclusion in the initial stage of the CAP. According to CMS, included on its 169-drug list are most of the drugs identified by the Physicians Regulatory Issues Team (PRIT) as "problem" drugs – e.g., Part B drugs that physicians have reported as unavailable at ASP. However, since the PRIT list has never been made publicly available, and the IFR lists only some of the drugs on the PRIT list, we urge CMS to identify any drug on the PRIT list that will not be offered in the CAP, explain why it is not being included in the CAP, and indicate how CMS is planning to address the issue of making these drugs available to physicians. Furthermore, if CMS has not already done so, CMS should forward the PRIT list to the Office of the Inspector General (OIG), so that this information can be considered as the OIG prepares its statutorily-mandated report to Congress on the ability of hematologists and oncologists to obtain drugs at 106% of the ASP.

Finally, we also agree with CMS' decision to implement the CAP on a nationwide basis, using a single nationwide competitive acquisition area.

Operational Aspects of the CAP

We appreciate CMS' willingness to modify the proposed rule with respect to several operational issues under the CAP in response to concerns expressed by the AMA and other physician organizations. First, in the preamble to the IFR, CMS has clarified the types of HIPAA-compliant formats that physicians may use in ordering drugs from a vendor. Second, CMS has clarified the vendor's obligation to fill valid (e.g., properly completed) orders received from physicians (except in certain limited circumstances). We strongly agree with CMS about the need to ensure that "the physician's judgment about the appropriate treatment for the beneficiary

is primary in the decision-making process," and would not want to see that scaled back in any way as the CAP is implemented. Third, CMS has agreed to allow physicians to provide a range of dates over a 7-day period rather than a specific date for administering a drug to a patient.

However, we still have concerns about several issues that we expressed in our April 26th letter that CMS did not adequately address, including the following:

- The extent of "additional patient information" CMS is requiring to be included in physicians' drug orders, which we still do not think is necessary and which will create additional costs for physicians;
- The requirement that physicians must file all claims for drug administration services within 14 days of the date of service, a timeframe that we believe is too tight, will be difficult for many practices to meet and will discourage physicians from participating in the CAP;
- The refusal by CMS to recognize the need to provide reimbursement for any administrative costs;
- The definition of "timely deliveries" and "emergencies" – although CMS has moved in the right direction in relying upon a physician's judgment as to what constitutes an emergency, this raises the risk that physicians may be subjected to unwarranted audits after the fact; and
- The impact on beneficiaries, especially the new provision in the IFR allowing vendors to refuse to dispense additional drugs for patients who have not paid their coinsurance (see discussion below).

Impact on Beneficiaries

Although we are pleased that CMS will require vendors to create a process for helping beneficiaries who cannot meet their co-insurance obligations, we are extremely concerned that CMS will allow vendors who follow this process to refuse to dispense additional drugs to physicians for patients who have not been able to pay their coinsurance within certain time limits. As we have previously noted, co-payments for most of the drugs that will be involved in the CAP are significant. For patients who lack any supplemental coverage, the costs are prohibitive; in fact, even those patients who do have some supplemental insurance could face substantial difficulties due to possible differences between the drugs covered under these policies and those provided by the vendor. It is the current practice of many physicians to waive the co-payments for many of these patients.

We strongly believe that allowing vendors to refuse to dispense drugs to patients who are unable to pay their copayments will have negative consequences for the health of some of our most vulnerable Medicare patients, and do not understand how CMS can claim otherwise, as it does in the preamble at page 39092: "We do not believe that beneficiaries would experience drug access issues as a result of the implementation of the CAP." CMS notes that physicians will be allowed to opt out of the particular drug category involved until the end of the calendar year. In the initial implementation phase, however, since there is only one broad drug category, the result will be that physicians will not be able to participate at all in the CAP for such patients. This could discourage physicians from electing to participate in the CAP at all, thus defeating the main purpose of providing an alternative to "buy and bill" for physicians.

We appreciate the opportunity to provide our views on this Interim Final Rule, and look forward to continuing to work with CMS in resolving these important issues.

Sincerely,

Michael D. Maves, MD, MBA

Submitter : Dr. Nick Poulios

Date: 09/06/2005

Organization : Elan Pharmaceuticals

Category : Drug Industry

Issue Areas/Comments

Background

Background

See attachment.

GENERAL

GENERAL

See attachment. Note: Elan submitted comments via certified mail on August 22, 2006 however as of today, Sept 6, 2006 we have not received confirmation that the comments were received. We apologize for the duplicate submission.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

See attachment.

Regulatory Impact Analysis

Regulatory Impact Analysis

See attachment.

Waiver of Delayed Effective Date

Waiver of Delayed Effective Date

See attachment.

CMS-1325-IFC-152-Attach-1.DOC

August 22, 2005

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

Re: CMS-1325-IFC (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B)

Dear Administrator McClellan:

Elan is a neuroscience-based biotechnology company that is focused on discovering, developing, manufacturing and marketing advanced therapies in neurology, autoimmune diseases, and severe pain. On December 28, 2004, we received FDA approval for our newest product, PRIALT® (ziconotide **intrathecal infusion**), which is indicated for management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or IT morphine. PRIALT® is neither an opioid nor a controlled substance.

PRIALT® is intended for intrathecal delivery using a programmable implanted variable-rate microinfusion device or an external microinfusion device and catheter. Depending on the site of service and the drug's method of delivery, PRIALT® may be billed through the Medicare intermediaries as a hospital outpatient service, through the Medicare carriers as an "incident to" physician service, and through the DMERCs under the DME benefit.

We would like to take this opportunity to comment on certain aspects of Interim Final Rule CMS-1325-IFC, "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B" (the "Interim Final Rule") published in the *Federal Register* on July 6, 2005.[1] The Interim Final Rule describes an alternative distribution model for Part B drugs designed to give physicians a choice between buying and billing for the drugs and biologicals (henceforth "drugs" for simplicity) they administer to their patients or having those drugs dispensed and billed to the program by a Medicare contractor selected through a competitive acquisition program ("CAP"). Authority for the CAP can be found

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[1] 70 *Fed. Reg.* 39022 (July 6, 2005).

in Social Security Act § 1847B, as added by Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") §303(d).

Elan is strongly supportive of the goals of the CAP. We want to commend CMS for its efforts toward developing the program. We believe that many physicians who use our products will welcome the opportunity to obtain the drugs they need to treat patients in their offices without having to assume the inventory and collection risks associated with buying and billing for drugs furnished as an "incident to" physician service so long as the administrative changes necessitated by the CAP are manageable.

We applaud CMS' decisions to make the CAP available to all physician specialties and to include an expansive list of drugs in the initial phase of the program. We are appreciative of the clarity that the Interim Final Rule brings to questions about vendor formularies and the applicability of local coverage rules. The positions CMS has taken on these issues are conducive to broader acceptance of the CAP in the physician community. At the same time, the new provisions on Advanced Beneficiary Notices and CAP vendor appeal rights in the Interim Final Rule should improve the attractiveness of the program to potential vendors.

We are disappointed that CMS has decided to suspend bidding on the CAP program,[2] but we appreciate the complexity of the CAP development task. Ensuring a program design that is workable from the perspectives of vendors and physicians is paramount. We remain hopeful that CMS will be able to move forward with the CAP in accordance with the timeline set forth in its suspension notice. We encourage CMS to use the delay to reconsider the comments submitted by Elan and many others in response to the Proposed Rule about the implications of placing an ASP + 6% aggregate reimbursement limit on the CAP. We also believe the CAP would benefit from further refinements designed to address physician concerns. Certainly, reports about the CAP in the trade press shortly after the Interim Final Rule was published suggested that a significant proportion of physicians would reject the program as overly burdensome and disruptive to current office practices. Significantly shortening the drug delivery times detailed in the Interim Final Rule would be a welcome step in the right direction.[3] We remain convinced that enhanced physician reimbursement for pharmacy handling costs and/or the added administrative expenses associated with drug ordering, vendor coordination, rapid claims filing, and increased claims appeal activities under the CAP also may be appropriate.

To assist the agency fine-tune its plans for CAP and thereby better ensure continued patient access to needed Part B therapies in the face of the reimbursement cuts physicians face under ASP+6%, we offer the following recommendations for making the CAP more attractive to potential bidders and more accommodating to the needs of physicians and the patients they treat. We have also provided additional information about PRIALT® to clear up any misconceptions about the appropriateness of the product for inclusion in the

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2 http://www.cms.hhs.gov/providers/drugs/compbid/cap_08032005.pdf

3 In an informal survey conducted by Part B News between July 5-11, 47% of physician practices said that waiting for delivery of CAP drugs would affect the operation of their practices in a "major way" and an additional 38% foresaw a "moderate-to-medium effect" on practice operations.

CAP. In the interest of efficiency, we have not repeated comments we offered in response to the Proposed Rule even though we encourage CMS to reconsider our recommendations that it chose not to incorporate in the Interim Final Rule in light of its decision to rework and enhance the design of the CAP over the next six to twelve months.

I. "Incident To" Drugs Administered by Intrathecal Pump

Elan is extremely pleased that CMS has concluded "in principle that opioid medications administered intrathecally through implanted variable-rate infusion devices could be included under the CAP, when they are administered by physicians in their offices incident to their services."[4] We assume the "in principle" limitation was included only because controlled substances have been deemed inappropriate for the initial phase of the CAP. Similarly, we assume the "opioid" limitation merely reflects the reality that the majority of such pain medications are scheduled drugs, not an intention on CMS' part to exclude non-scheduled intrathecally administered pain medications from the CAP. We recognize that at least one non-opioid medication approved for intrathecal treatment of spasticity – Baclofen (J0475) – has been included in the list of CAP drugs in Addendum A. Though Baclofen is indicated for the management of severe spasticity, according to the USPDI, Baclofen is also useful in relieving flexor spasms and concomitant pain. Another non-opioid medication commonly used intrathecally to treat severe chronic pain, Clonidine Hydrochloride, was also included in the list of CAP drugs. That said, to eliminate any potential for confusion on the part of physicians offering intrathecal therapy who are considering a CAP election or on the part of CAP vendors who are choosing new products for addition to their approved drug lists, Elan urges CMS to state expressly in the Final Rule that non-scheduled pain medications designed for intrathecal administration are suitable for inclusion in the initial phase of CAP.

Elan also would appreciate it if CMS would correct the mischaracterization of PRIALT® in the Interim Final Rule as an opioid medication.[5] PRIALT® is neither an opioid nor a controlled substance. In fact, the drug is indicated for individuals who are intolerant of intrathecal morphine. A careful reading of CMS's response to the comment that contains the mischaracterization suggests the agency understands the true nature of PRIALT®. However, we are afraid that, absent an explicit clarification in the Final Rule, some physicians and CAP vendors might not realize that PRIALT® is not a controlled substance and that, because it is not, it can be provided by CAP vendors. But for the fact that PRIALT® has not yet been assigned a HCPCS code, the product would have qualified for the Addendum B list under a threshold requirement that Medicare allowable charges in an office setting must be at least $50,000 a year. In fact, PRIALT® exceeded that target during the first quarter of 2005. Moreover, we expect PRIALT® to be assigned a HCPCS code this fall. Because a CAP program that is as expansive as possible will benefit physicians and improve patient access to important therapies, we strongly urge CMS to expand the list of drugs in Addendum B when it publishes the Final

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4 70 *Fed. Reg.* 39028.

5 70 *Fed.Reg.* 39028 ("One commenter asked about the status of opioid medications administered intrathecally through implanted variable-rate infusion devices (for example, PRIALT®.")

Rule to include suitable new products like PRIALT® that will be assigned HCPCS codes during the bidding suspension.

II. Procedures for Adding Newly Introduced Products

We appreciate the rationale for excluding drugs from the CAP that must be billed using one of the miscellaneous HCPCS codes.[6] We recognize that one implication of this decision is that drugs introduced too late to have an assigned HCPCS code at the time of CAP bidding cannot be included in the single drug category list of products subject to the composite bid methodology (e.g., drugs listed in Addendum A). Similarly, drugs without an assigned HCPCS cannot be accommodated in a listing of newer products for which too little utilization data exists to permit the weighting required for drugs in the composite bid pool (e.g., for 2006, those drugs listed in Addendum B).

Because we suspect that some physicians who have elected the CAP may be reluctant to return to the buy-and-bill model to obtain newly introduced products for their patients, we applaud CMS for including a process in the Interim Final Rule for vendors to add products with newly assigned HCPCS codes to the list of drugs they will ship to physicians. We hope the agency is correct in its assumption that market forces will push vendors to make newly introduced products available promptly. We suspect, however, that beneficiary access would be better served – or at least served with more certitude – if CMS would make new product additions mandatory beginning the quarter after claims data establish that allowable charges for a new product that otherwise meets the criteria for inclusion in the CAP have reached the $50,000 minimum annual threshold.[7] We strongly encourage CMS to codify such a provision when it promulgates the Final Rule.

We also urge CMS to give CAP vendors the flexibility to add otherwise suitable new products to their approved products lists on a voluntary basis before utilization levels reach the $50,000 threshold. Providing this flexibility would allow CAP vendors to anticipate the needs of their physician customers and could, thereby, foster improved beneficiary access. For example, it is not hard to imagine that some physicians in specialties that historically have not billed for substantial quantities of "incident to" drugs might choose CAP because the launch of a potentially breakthrough product targeting their patient base seems imminent. In this situation, the very pressures that motivated the CAP selection might deter these physicians from using the buy-and-bill model until they could get the new product from their CAP vendor, thus impeding early beneficiary access to the new therapy.

Regardless of whether CMS is willing to accept our recommendation to make certain new drug additions to CAP mandatory, the agency should spell out the criteria that it intends to apply before it approves vendors' proposals for voluntary additions to their approved drug lists and provides for payment for the newly added drugs at the next quarterly update. Neither the regulations nor the preamble to the Interim Final Rule

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6 70 *Fed. Reg.* 39030.

7 70 *Fed. Reg.* 39032.

clearly define how CMS will "determine that the new drug is appropriate for inclusion on the approved CAP vendor's approved list." At a minimum, the Final Rule should declare expressly that CMS would apply the same criteria that it used to identify the select list of drugs introduced in 2004 or after and in including in CAP through Addendum B. Ideally, CMS should add a step to the approval process to weigh more subtle access issues as well and, if necessary, to waive the $50,000 minimum threshold for vendors who have affirmatively asked to take on a still low-volume product that holds great promise for Medicare beneficiaries. Since the rationale for the threshold was to "lessen the inventory burden for vendors,"[8] granting such waivers pursuant to a vendor's request would not be inconsistent with the decision tree established to identify the drugs designated for inclusion in the CAP in the Interim Final Rule.

III. Updates to Include Products Recently Assigned HCPCS Codes

Inevitably, a number of new products will be assigned HCPCS codes between now and the time when the provisions of the Final Rule will be drafted. CMS should update the list of drugs in Addendum B to the Final Rule to include those new drugs deemed suitable for CAP that meet the criteria established in the Interim Final Rule for integrating relatively new products with assigned HCPCS into the program. We recognize that it is not common for CMS to add new products to fee schedule rules between the proposed and final rule stage, but the unexpected suspension in the implementation of CAP and the market-based nature of this new, never-before-tried drug delivery system favor a break from traditional patterns in this instance. Not to do so would be inconsistent with beneficiary access and with CMS's stated intent of designing a CAP program that is workable and attractive to both physicians and vendors.

IV. Reimbursement for Discarded Drugs from Single-Use Vials

We are concerned that an overly aggressive interpretation of the requirement under MMA §303(d) prohibiting payments to CAP vendors for "wastage, spillage, or spoilage" could make the CAP too unattractive to prospective bidders. Based on CMS's responses to questions posed at the Special Open Door Forum for prospective vendors held July 8, 2005, we understood the agency intended to limit reimbursement for drugs dispensed from the smallest available single-use vial to the amount actually administered to a patient, rounded up to the closest full HCPCS code unit of measure, even if product remaining in the vial after treatment must be discarded for safety reasons. Elan disagreed with that approach.

We are pleased that CMS has already rethought its position and posted an FAQ on its website aligning single-use vial wastage policies under CAP with those applicable to physicians operating under the buy-and-bill model. We urge CMS to affirmatively state in the Final Rule that Medicare Claims Processing Manual, Chapter 17 "Drugs and Biologicals" § 40 applies to CAP. That manual provision states:

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8 70 *Fed. Reg.* 39032.

> The CMS encourages physicians to schedule patients in such a way that they can use drugs most efficiently. If a physician must discard the remainder of a vial or other package after administering it to a Medicare patient, the program covers the amount of drug discarded along with the amount administered. NOTE: The coverage of discarded drugs applies only to single-use vials. Multi-use vials are not subject to payment for discarded amounts of drug.

We are encouraged by CMS' commitment in the FAQ to provide more guidance on ways physicians and CAP vendors can work cooperatively to control waste. We hope the Final Rule will contain significantly more detail about approaches to waste minimization under CAP. It is clear that concerns about the financial implications of the MMA prohibition against reimbursing vendors for waste must be resolved to make CAP a viable option.

V. Provisions to Address Concerns Unique to Compounded Drugs

The current structure of the CAP may disincentivize physicians who offer pain management therapy from selecting the program simply because of the carve-out of controlled substances from the list of drugs deemed appropriate for the initial round. For those physicians offering pain management services who may still see benefit in the CAP, the program, as structured, may impose an additional hurdle that could prove insurmountable. That hurdle relates to the prescribing of compounded drugs that include one or more drugs from the list of products included in the initial phase of the CAP. Since a physician participating in the CAP cannot be reimbursed under the buy-and-bill payment system for a drug on his or her CAP vendor's approved list of products, it appears that physicians selecting the CAP could be left without a way to obtain full payment for compounded drugs that include one or more of the CAP products unless CMS takes corrective action.

CMS could begin to rectify the situation by including a provision in the Final Rule that would permit CAP physicians to be paid for any compounded drug under the buy-and-bill model,[9] regardless of whether the compound contains a component on the list of drugs included in the CAP or even components exclusively from the CAP list, unless the physician's vendor could provide the required compounding services. Absent additional reimbursement for compounding services, we suspect that few, if any, CAP vendors would be willing to admix compounded drugs from their approved drug list given the ASP + 6% composite payment limitation of the CAP, the unreimbursed pharmacy costs that would be associated with preparing and dispensing compounded drugs, and, to the extent that state law permits CAP vendors to operate with only a wholesaler license, the legal barriers to engaging in compounding.

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[9] We are not endorsing the current poorly developed, often inconsistent local reimbursement policies for compounded drugs under the buy-and-bill model (or under the DME benefit). We fully intend to submit comments on the 2006 Physician Fee Schedule Proposed Rule articulating our concerns and making recommendations for the development of a more appropriate national payment methodology for compounded drugs.

In addition, CMS must add provisions in the Final Rule loosening the restrictions on transporting CAP drugs[10] and – since the majority of physicians do not have the safety equipment necessary to compound highly toxic products in their offices – providing for adequate physician payment for subcontracted compounding pharmacy services. Such a provision will be essential when CAP physicians prescribe a compounded product that contains both controlled substances and one or more non-scheduled drugs from the CAP vendor's approved list. We know of no statutory or regulatory impediment to including provisions in the Final Rule that would permit CAP vendors to ship drugs to a compounding pharmacy for subsequent delivery to a CAP physician. The preamble to the Interim Final Rule acknowledges this fact, saying "[a]lthough the statute allows us to provide for the shipment of drugs to other settings under certain conditions, we did not propose to implement the CAP in alternative settings at this time."

We recognize that the 2006 Physician Fee Schedule would likely be the proper regulatory vehicle for accomplishing the payment reforms needed to permit separate physician reimbursement for compounding pharmacy services under the CAP. We plan to address this issue in our comments on that rule along with our concerns about (1) confusion surrounding buy-and-bill reimbursement amounts for infusion drugs carved out of the ASP + 6% methodology under the MMA and (2) the inadequacy of current payment levels for procedures associated with drug administration by intrathecal pump. In the meanwhile, we urge CMS to work with the DEA to resolve the concerns that caused it to deem controlled substances inappropriate for the initial phase of the CAP. We feel strongly that making adequate pain management therapy options available to beneficiaries will require making compounded drugs – including those containing controlled substances – available through the CAP because, in our experience, many pain management physicians are unwilling to take on the administrative burden and financial risk of purchasing compounded products for their Medicare patients under the current poorly defined and ill-structured buy-and-bill system applicable to such products.

* * * *

We appreciate the opportunity to comment on the Interim Final Rule and we hope our suggestions will help CMS structure the Final Rule in ways that will make the CAP attractive to a sufficient number of bidders and a workable option for all physicians who furnish Part B drugs to their patients as an incident to service. We again urge you to reconsider our comments on the Proposed Rule as you work to refine and improve the attractiveness of the CAP to potential vendors and potential physician participants. In addition, as we have explained above, CMS should take steps to facilitate further the timely addition of new products to the CAP and, consistent with this goal, should update the list of Addendum B drugs before it promulgates the Final Rule to include suitable new products assigned HCPCS codes since the Interim Final Rule was drafted. CMS should provide guidance to physicians and vendors about practical, effective waste minimization strategies under CAP. CMS also must address concerns unique to

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[10] 70 *Fed. Reg.*39047 ("[W]e will require that physicians must have CAP drugs shipped directly to the location at which they plan to administer them. The physician may not transport CAP drugs from one location to another."); 42 C.F.R. §414908((a)(3)(x).

compounded drugs in the Final Rule; otherwise, physicians offering pain management therapies will be effectively precluded from availing themselves of the advantages of CAP for those non-scheduled drugs included in the initial phase of the program. Finally, we urge you to appropriately characterize PRIALT® in the Final Rule, ideally by including it as an addition to Addendum B.

If you have any questions about our comments or would like to discuss issues we have raised further, please do not hesitate to contact me.

Sincerely,

Nick Poulios
Vice President
Pricing & Reimbursement
Elan Pharmaceuticals

Submitter : Mrs. Laura Cline
Organization : TAP Pharmaceuticals
Category : Drug Industry
Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-153-Attach-1.DOC

PHARMACEUTICALS INC.

September 6, 2005

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

Re: Comments on CMS-1325-IFC (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B)

Dear Administrator McClellan:

TAP Pharmaceuticals Products Inc. ("TAP" or the "company") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") interim final rule ("IFC") regarding the Competitive Acquisition Program ("CAP"), published in the Federal Register on July 6, 2005. TAP is one of the nation's leading pharmaceutical companies and is committed to delivering high quality pharmaceutical products for patients. The company provides innovative and effective products in diversified treatment areas, including oncology, gastroenterology, and gynecology.

TAP also submitted comments to the proposed rule published in the Federal Register on March 4, 2005. Although some of our comments were addressed in the IFC, we remain deeply concerned about the application of the Least Costly Alternative ("LCA") policy to the CAP and believe it will compromise the attractiveness of the CAP to both vendors and physicians.

"Ordering the CAP Drugs"

In the interest of seeing this program succeed, improving both its efficiency and its appeal to vendors and physicians, TAP urges CMS to reconsider the application of LCA to the CAP. The IFC states, "We are implementing the CAP initially through a single, broad drug category and a single,

national competitive acquisition area; therefore, because leuprolide is subject to LCA policies in all carrier jurisdictions, its inclusion in the current CAP drug category would have the effect of requiring vendors to supply the drug at the cost of goserelin in each instance in which a participating CAP physician orders it, regardless of the price established for leuprolide under the bidding and single price determination processes ... and regardless of the geographic location (and local carrier jurisdiction) of the participating CAP physician." It appears that CMS excluded Lupron in an effort to protect the vendors against the application of the LCA policy within the CAP. However, the current solution disregards a number of factors which remain problematic for vendors, and lessens the desirability for physician participation by excluding the preferred and most widely used prostate cancer therapy from the CAP.

First, the IFC states that, "every carrier has applied an LCA policy to injectable forms of leuprolide." However, at this time, not all Medicare carriers have adopted the LCA policy, nor do those that adhere to it uniformly apply the policy. For example, the product that each carrier determines to be the least costly agent varies by carrier, and a number of carriers include a grandfather clause in their policies, while others do not. Furthermore, as the ASPs for these products change on a quarterly basis, it is not unlikely that prostate cancer therapies other than goserelin could become the least costly agent. In fact, over the course of the last three quarters of ASP reporting, three different prostate cancer products served as the least costly agent. The expectation that vendors will be able to manage the accounting of all of the individual carriers' application of this policy in addition to their quarterly allowables, and do what is necessary to recoup their own costs means that physicians and patients may suffer the unintended consequence of limited access to therapy.

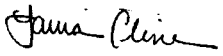
More importantly, the LCA policy goes well beyond the scope of simply leuprolide and goserelin alone. CMS included a number of prostate cancer therapies in the CAP, specifically triptorelin pamoate, leuprolide acetate implant, and abarelix injection, each of which is also included in a number of local carriers' LCA policies. . For example, the local Medicare carriers Noridian, Palmetto of SC, NHIC of New England, HGSA, Cahaba, BC/BS of Arkansas, and the three carriers of NY state, covering a total of twenty-seven states have either already included triptorelin pamoate in their LCA policies or have effective dates for its inclusion before the year's end. This means that this product and others are also subject to payment at the level of the least costly agent in the class. Additionally, by the time CMS implements the CAP in July of 2006, it is likely that those carriers with LCA policies will have rolled in most of the products in the LHRH class. Therefore, vendors will not have relief from managing their costs and administration as they relate to the LCA policy. The best way to alleviate the problem would be to remove the LCA policy from the CAP.

Conclusion

In summary, TAP continues to be concerned that the application of LCA to the CAP will greatly interfere with the success of this program. The inconsistencies inherent in the application of the policy by the local carriers, and the policy's dependence on changing quarterly ASPs to determine the least costly agent will complicate CAP operations. Furthermore, the fact that many local carriers have extended their LCA policies to a number of the prostate cancer products included in the CAP means that vendors must bid on this drug class without knowing how much they will be reimbursed. In order to make the CAP most attractive to vendors and physicians, and to ensure patient access to appropriate prostate cancer treatment, TAP strongly recommends that CMS prevent the LCA policy from applying to the CAP and consider including in the program the most widely used therapy to treat this disease.

TAP appreciates the opportunity to comment on this significant issue and looks forward to working with CMS to ensure that beneficiaries have continued access to much needed pharmaceutical products. We sincerely hope that the agency will give thoughtful consideration to our comments and will incorporate our suggestions in the final rule. Please contact Laura Cline at 410-280-9726 if you have any questions regarding our comments or need any additional information.

Respectfully Submitted,



Laura Cline
National Manager
Government Affairs

Submitter : Mrs. Terese Ghio **Date:** 09/06/2005

Organization : Ligand Pharmaceuticals Incorporated

Category : Drug Industry

Issue Areas/Comments

Background

Background

Ligand Pharmaceuticals Incorporated welcomes the opportunity to comment the Centers for Medicare and Medicaid Services interim final rule regarding the Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B, published in the Federal Register on July 6, 2005. Ligand is a San Diego based emerging specialty pharmaceutical company that discovers, develops and markets innovative small molecule drugs and one biological to address critical, unmet medical needs with four Orphan-designated products for oncology and dermatology: ONTAK (denileukin diftitox), TARGRETIN capsules (bexarotene), TARGRETIN gel and PANRETIN gel (alitretinoin), and AVINZA in the area of chronic pain management (morphine sulfate extended-release capsules)

One of Ligand's products, ONTAK, is a recombinant DNA-derived cytotoxic fusion protein that is a covered by Medicare under Part B in both the hospital outpatient setting and in the physician office. ONTAK received orphan designation from the FDA and is used to treat the limited population of patients with advanced stages of Cutaneous T-Cell Lymphoma (CTCL). Approximately 850 patients were treated with ONTAK in the past year and we estimate less than 35% were covered by Medicare under Part B. This product and the patient population it services truly meet the intent of the legislature?s definition of Orphan Product. CTCL is a rare cancer and while the prognosis for early stage patients is quite good with median survival of 12 years, later stage patients for whom ONTAK is an approved therapy and principally utilized have a median survival of 2.5-5 years. (Siegel R. JCO, Vol 18, No. 15, 2000 pp 2908-2925). Patients most often succumb to opportunistic infection and so selecting therapies that are less immuno/myelosuppressive is an important consideration. ONTAK is one of the very few therapies FDA approved for late stage CTCL. In addition, because it is less immuno/myelosuppressive than available chemotherapies it is often the patient's only hope of a response to this aggressive disease.
Ligand respectfully submits the following comments to CMS for purposes of ensuring adequate reimbursement and access to ONTAK for the limited Medicare population in need of this important therapy.

GENERAL

GENERAL

Ligand is very supportive of the program and believes it will result in improved access to many therapies as intended in the MMA by reducing physicians costs of acquiring and billing for therapies. We greatly appreciate all CMS has done in a very short time to put this interim final rule in place. Ligand supports in full the comments submitted by both the Biotechnology Industry Organization (BIO) and the National Organization for Rare Disorders (NORD). Ligand sincerely appreciates the opportunity to comment on these rules and the open and interactive approach CMS has taken with stakeholders across the medical and health care communities. Please contact us for questions or to request additional information related to our products or ideas and positions on Medicare policy.

Provisions of the Interim Final Rule With Comment Period

Provisions of the Interim Final Rule With Comment Period

Categorical Exclusion of Single Indication Orphan Products:
CMS specifically requested comments on their decision to exclude single indication orphan drugs from the CAP. The interim final rule stated that several commenters on the proposed rule expressed concerns that the CAP might result in access problems.

We believe that orphan drugs and biologicals should not be excluded categorically from the CAP, but that they should be categorically included. Orphan products tend to be the very therapies that should be included to ensure patient access to them. Therefore, all orphan drugs which are provided in the physician's office under Medicare Part B should be in the CAP program and then, if necessary, CMS should individually evaluate those orphan drugs or biologicals for which there is a specific rational for exclusion from the program.

To this end, Ligand Pharmaceuticals specifically requests that CMS add Ontak (denileukin diftitox - J9160) to the category of products to be made available via the CAP at the inception of the program which is currently planned for July 2006. Because demand for orphan drugs, like ONTAK, is extremely low and variable, they are costly to manufacture and costly for physicians to keep in inventory. The CAP will therefore, we believe, improve access to this important therapy.

Submitter : Mr. Don Lynam **Date:** 09/06/2005

Organization : Us TOO International

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. James H. Scully, Jr.

Date: 09/06/2005

Organization : The American Psychiatric Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment--comments to interim final rule.

CMS-1325-IFC-156-Attach-1.DOC

CMS-1325-IFC-156-Attach-2.DOC

CMS-1325-IFC-156-Attach-3.DOC

September 6, 2005

Mark B. McLellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS–1325–IFC
P.O. Box 8013
Baltimore, MD 21244–8013

RE: Interim Final Rule: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B [CMS–1325–IFC]

Dear Administrator McLellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 36,000 psychiatric physicians, nationwide, appreciates the opportunity to submit these comments concerning the interim final rule for acquisition of drugs and biologicals, under 42 C.F.R. Part 414, published in the Federal Register on July 6, 2005, with the title, "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B"[1]

While APA appreciates that CMS has acknowledged much of the substance of APA's comments of April 26, 2005, to the proposed rule and has made certain alterations in that rule in response to these comments, the interim final rule is still of concern to APA in a number of respects. APA will articulate those concerns in the following comments, while incorporating by reference the relevant substance and recommendations of its prior comments.

APA appreciates the burdens attendant to the drug and biologicals acquisition process that psychiatrists and other physicians have used thus far and generally supports CMS' stated goal of relieving some of those burdens. However, there are specific aspects of this competitive acquisition process that will substantially impact APA members in an adverse manner. One primary problem resides in the numerous, burdensome, time-consuming administrative requirements imposed upon physicians who elect to participate in CAP.

It operates to the substantial disadvantage of physicians, to shift the initial administrative discovery and adjudication process from a neutral federal adjudicative body, which ordinarily handles such matters, to the vendor's designated carrier and the CMS-appointed hearing officer, who can be an agent of that carrier. This allows a biased, private insurance carrier with a fiduciary duty to the vendor and business interests contrary to those of the physicians to make legal decisions that impact the physician. The process is ostensibly set up for vendors to resolve disputes, but it does not even require an

[1] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-IFC [Federal Register: July 6, 2005 (Volume 70, No. 42)].

actual dispute to be initiated. It essentially moves physicians, for some purposes, out of the Medicare Part B adjudicative process, which is the physicians' avenue of redress. It does so by placing first-level administrative adjudicative authority, as to issues of physicians' compliance with legal obligations under CAP, into the hands of the vendor's private carrier, which whom CMS contracts to process vendors' claims. The vendor can initiate this process at will and in absence of any criteria, other than some unspecified percentage, number or amount of unreimbursed vendor's claims. Moreover, CMS continues to propose that the vendor's carrier, at the request of the vendor, should have the authority to recommend to CMS that a physician be suspended from CAP. Details regarding these issues and other concerns are outlined in the comments, below.

It is essential that this CAP process be implemented in line with CMS' stated goal of making it easier for physicians to handle drug acquisitions and treat their patients, rather than imposing complexities that have the opposite effects. As proposed, the CAP system contains substantial deterrents to adoption by the physician community. However, many of these problems are subject to simple corrective measures, as APA will recommend within these comments. Following CMS' lead, use of the word "drugs" herein will comprise both drugs and biologicals under CAP.

I. CAP Effective Date and Trial or Phase-in Approaches

APA and other commenters to the proposed rule have expressed serious reservations about CMS's choice of January 1, 2006, as the effective date for the CAP program. Now, it is two months later, merely four months away from the intended effective date and CMS' final rule on CAP has yet to be published. The original concerns are now condensed into a more truncated time period, in which CMS has still to re-open the currently suspended vendor bidding process and determine how a number of operational issues for this program will be resolved and implemented. CMS' sole reason for adhering to this short timeframe is that, "the regulatory framework established through this rulemaking supportive of the proposal for the CAP, provides a firm basis for implementing the CAP program in January 2006."[2] That reasoning is elliptical and does not resolve the issue of how to make the transition from the ASP to the CAP program smooth for both physicians and their patients.

APA strongly urges CMS to reconsider the many solid reasons for revisiting this effective date to ensure that patient care is not compromised through systemic glitches that interfere with the timely delivery of therapeutic agents to physicians for their patients. Until CAP is instituted, it will not be possible to evaluate whether vendors' intended delivery systems will be able to ensure smooth pathways for timely drug deliveries.

In addition to prolonging the effective date, for overall operational efficiency, APA agrees with other comments advocating for a trial period or phase-in for CAP that would provide a sensible, smaller-scale mode for identifying and correcting systemic issues. This trial or phase-in would be most practically accomplished on a geographic

[2] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128], at 39025.

scale smaller than a national one, as CMS favors, for the reason of easier assessment and correction of small-scale activities than larger ones.[3] While it would be ideal to provide an alternative to the ASP program expediently, the concern is that doing so within such a short timeframe on a wide, national scale may magnify unforeseen systemic problems. In turn, remedying systemic glitches on a large scale is more difficult and can cause a tremendous time input that will preclude effective implementation of CAP and maintenance of high-quality care for patients.

APA disagrees with CMS' conclusion that phasing in the CAP program with a limited number of nationwide vendors is the best approach.[4] Doing so will restrict the market substantially and create more monopolization of the market share, than would be true if more vendors were involved. Decreased competition tends to diminish choice and increase prices, since there is less incentive to bid lower against only a few known competitors. In addition, unless CMS clearly restricts vendor bidding to companies that are not subsidiaries or other affiliates of the same company, there is an enhanced opportunity for monopolization of the process. Once the chosen few vendors are supplying nationwide CAP drug orders, it could be highly difficult, if not impossible, to introduce more vendor competitors into the process later.

Recommendation- CAP Effective Date and Trial or Phase-in Approaches: The CAP effective date of January 1, 2006, should be extended to allow for complete resolution of operational issues, including the vendor bidding and delivery process and sufficient time for physicians to evaluate CAP vendors fully, enroll, and rework their administrative systems to accommodate CAP procedures. Further, a CAP trial period and/or phase-in approach will allow for small-scale operational evaluation and implementation of corrective measures, to ensure that patient care will not be inadvertently compromised.

II. Statutorily Permissible Categories of CAP Drugs

In its prior CAP comments, APA urged CMS to either create a category of CAP drugs that encompassed psychotherapeutic agents or include drugs used in psychiatry within other CAP categories. The point was to have psychotherapeutic agents included in the CAP program early in the process, in order to facilitate their availability to patients as soon as possible. APA commends CMS for including injectable Risperidone in its initial category of CAP drug offerings.[5]

In addition, it would seem prudent to resolve the question addressed by CMS and commenters as to how broadly to interpret the statutory language of "competitively biddable drugs," prior to determining whether or not to restrict CAP drugs to those administered "incident to" a physician's service. While CMS plans to analyze the

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[3] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128], at 39035.

[4] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128], at 39035-6.

[5] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128]; 42 C.F.R. Sec. 414.916(b) at 39102.

statutory language at some future date, there is no convincing reason why this should not be done at present, before the CAP effective date. To the extent that a broader inclusion of drugs within CAP would facilitate CMS's stated goals of physicians' adoption of CAP and provision of its benefits to more patients, it would seem that a broader statutory interpretation would yield positive results. If it is possible to include in CAP Part B drugs administered through durable medical equipment (DME) or dispensed by pharmacies, those drugs should be included.

CMS's reason for restricting CAP at present to physician-administered drugs because the statute requires a physician to elect CAP participation[6] does not seem to take into account the fact that provision of any prescribed drugs is physician-driven, since it is physicians who write the prescriptions. If the barrier is that the underlying election process needs to be expanded to include pharmacists, then that should be accomplished, to meet the broader statutory intent for provision of CAP drugs to patients.

Recommendation-Statutorily Permissible Categories of CAP Drugs: APA strongly urges CMS to determine, prior to the CAP effective date, how broadly encompassing the statutory language is with regard to "competitively biddable drugs." This analysis should be finalized prior to CMS' determination as to whether CAP drugs must be restricted to those administered "incident to" a physician's service.

III. Inclusion of CAP Drugs within Categories

APA commends CMS for responding favorably to its advocacy for inclusion drugs commonly billed incident to the services of psychiatrists in the initial CAP offerings, including the long-acting injectable anti-psychotic Risperidone.[7][8] Improved access to this injectable anti-psychotic will undoubtedly benefit many patients with schizophrenia, particularly those who face heightened challenges to maintaining a regimen on short-acting anti-psychotic drugs. APA strongly urges CMS to include more psychotherapeutic agents in the initial CAP offerings, in order to benefit a broader spectrum of patients.

APA disagrees with CMS's exclusion of Schedule II, III and IV controlled substances from CAP on the grounds that they require special record-keeping. This approach unnecessarily prohibits access to such drugs for physicians, including psychiatrists, and for their patients, who require a number of these drugs routinely.[9]

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[6] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128], at 39026-7.

[7] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128], at 39030.

[8] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128], at 39102: long-acting Risperidone J2794 on "Addendum B.--New Drugs for CAP Bidding for 2006."

[9] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128], at 39028.

Commonly used psychotherapeutics that fall within these Schedules, include Schedule II drugs used for treatment of pain (i.e., morphine) and opioid dependence (i.e., Methadone). Another essential Schedule II drugs used by psychiatrists, especially for children and adolescents, is methylphenidate (Ritalin), prescribed for attention deficit and hyperactivity disorders (ADHD). Commonly used Schedule IV drugs include diazepam (Valium) and Phenobarbital, which are calming agents.[10]

Computerized records will facilitate whatever compliance is necessary for records on such drugs and minimize the opportunity for diversion and abuse, which is of concern to DEA. Far more cumbersome manual or partially computerized record-keeping systems for these drugs have been used for years, so this should not pose a barrier sufficient to exclude such drugs from physicians who require them to treat patients.

Recommendation- Inclusion of CAP Drugs within Categories: APA strongly urges CMS include more psychotherapeutic drugs in its initial CAP offerings and to refrain from excluding Schedule II, III and IV controlled substances from CAP, especially on the grounds that they require special record-keeping. Record-keeping issues can be resolved through computer technology and otherwise. Many drugs within these Schedules are used routinely by psychiatrists and need to be available for patients under CAP.

IV. Vendor Bidding under HCPCS Codes

It is essential that CMS require vendors to bid on more than one drug per HCPCS Code, since various drugs from different manufacturers can fall under a single per HCPCS Code.[11] This approach makes it more likely that vendors will be bidding on different drugs under a given such code, making cross-comparisons with vendor formularies more difficult. In addition, it is important for psychiatric patients to have access to a full spectrum of drugs, since psychotherapeutic drugs are highly idiosyncratic in their effects, even within the same drug class, for instance SSRIs.

Recommendation- Vendor Bidding under HCPCS Codes: CMS should require vendors to submit bids on more than one drug under each HCPCS code, to ensure wide availability of drugs to patients, especially psychiatric patients who often require specific non-generic drugs to maintain their level of function.

V. Vendor Collection of Beneficiaries' Deductibles and Co-insurance and Termination of Drug Delivery

CMS is certainly on the right track in recognizing the various problems for physicians and beneficiary-patients attendant to the vendor's mandate to collect Medicare deductibles and co-insurance from beneficiaries. This mandate places the physician in an unfortunate position. The physician receives pressure to find the patient financial

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[10] Drug Enforcement Agency (DEA) Schedules for controlled substances: website http://www.usdoj.gov/dea/pubs/scheduling.html; retrieved September 3, 2005.

[11] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128], at 39033-4.

assistance to pay the vendor, in order to forestall the vendor's termination of drug supplies for the patient. This is an unduly burdensome position for the physician, as well as a situation that is likely to severely compromise patient care if CAP drugs are terminated. In addition, there are liability considerations for the physician. At what point will the physician have done enough to ensure that the patient can pay the vendor and continue receiving needed drugs? If the CAP drugs are terminated for a patient, what effect will that have on continuity of care? CMS should structure the situation to avoid placing the physician and patient in such an untenable position, practically and legally.

While CMS has drafted some language about vendors assisting beneficiaries financially, the revised regulation does not go far enough, since its minimal requirement is that the vendor refer the beneficiary to a charity, which may or may not be positioned to provide financial assistance to the beneficiary.[12] The regulation does not even require that the charity has ever provided such assistance to anyone in the past, or that it intends to do so in future. The other forms of assistance listed in this regulation would actually help the beneficiary. Those are either providing a payment plan or a waiver, partial or full, of the money the beneficiary owes the vendor for deductibles or co-insurance.[13]

In addition, the regulatory language should be consistent in what the vendor is required to do. Sec. 414.914(g) uses the words: "(u)nder the terms of the contract, the approved CAP vendor must provide assistance to beneficiaries experiencing financial difficulty in paying their costsharing amounts . . ."[14] Yet, another part of this provision states that the vendor "may inform the beneficiary of any types of cost-sharing assistance that may be available . . ." [15] If CMS requires the vendor to provide assistance, then it is logical that it should require the vendor to inform the beneficiary about that assistance. This logical inconsistency should be resolved by making the language "must" instead of "may," to make it a requirement, rather than a discretionary act.

Another problematic aspect is the ability of the CAP vendor to refuse to ship a beneficiary's drugs if the beneficiary's billed balance is not paid within 15 days of the postmarked date of the vendor's written referral of the beneficiary to a charity. Given three mailing days, that leaves 12 calendar days for the beneficiary to make an appointment with the charity, for the charity to process financial assistance to the beneficiary and for that financial help to reach the vendor. Shaving off three days more

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[12] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128]; 42 C.F.R. 414.914 (g), at 39096-7.

[13] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128]; 42 C.F.R. 414.914 (g), at 39096-7.

[14] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128]; 42 C.F.R. 414.914 (g), at 39096.

[15] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128]; 42 C.F.R. 414.914 (g), at 39097.

for mailing a check from the charity to the vendor, that leaves the beneficiary with 9 calendar days to complete this process. This is an exceedingly short timeframe, especially when the stakes are so high for the beneficiary in having a drug supply cut off. This also provides an inadequate timeframe for the physician to cope with the possibility of having to obtain a drug from another source other than CAP for the patient, when the physician is essentially locked into CAP and into caring for the patient. That is an untenable position for both patient and physician. This timeframe must be elongated, to allow for the practical aspects of the situation to be fulfilled.

Recommendation- Vendor Collection of Beneficiaries' Deductibles and Co-insurance and Termination of Drug Delivery: APA strongly urges CMS to require that vendors provide meaningful assistance to beneficiaries, such as a payment plan or waiver of monies owed, and revise the regulatory language to reflect this. APA further urges CMS to revise its timeframes for beneficiary completion of financial assistance efforts, in order to prevent patient-care compromises that would result from vendors terminating drug supplies to patients while their applications for financial assistance to pay deductibles or co-insurance are in process.

VI. Dispute Resolution Process-"Provisions of the Interim Final Rule"

APA notes that CMS has made some revisions in the regulatory language for the dispute resolution process for vendors. However, the designated vendor's carrier still has the role of being a first-line investigatory authority to gathering information from several sources, then making a recommendation to CMS as to a physician's compliance with CAP requirements for claims filing.[16] It is more appropriate that CMS, instead of the designated carrier's internal CMS-appointed hearing officer, will have responsibility for making a determination as to a physician's suspension from CAP, upon the vendor's recommendation.

However, APA's original concern that the trigger point for this vendor dispute resolution process had not been defined still exists. The vagueness of the regulatory language does not clearly require the existence of specific criteria: "(w)hen an approved CAP vendor is not paid on claims submitted to the designated carrier . . ."[17] There exists a choice of methods by which to arrive at a reasonable, practical definition for a trigger point that is more specific. This does not specified a time period or a number or monetary amount of claims. Instead, it inappropriately leaves it to the subjectivity of a vendor to launch this complex process that implicates the physician in what becomes a legal process that develops a legal evidentiary record for compliance with a federal program. With such great implications for the physician, it would seem fair and prudent to develop more objective criteria to be met, prior to the vendor availing itself of this

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[16] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128], at 39087; 42 C.F.R. Sec. 414.916 at 39097.

[17] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128]; 42 C.F.R. Sec. 414.916(b) at 39097.

process. There are still too few due process protections for the physician in this dispute resolution process.

Another area of concern is allowing a CMS-appointed hearing officer conduct a discretionary informal hearing, in response to a request for reconsideration of a CMS decision to suspend a physician from the CAP program for non-compliance.[18] APA's position is that no part of this legal process should be performed by CMS' appointees, especially if they can be agents or employees of the vendor's carrier, whose interests are contrary to those of the physician. CMS's current concept that the hearing upon reconsideration request is informal, rather than formal, deprives the physician of due process protections. In addition, if the appointed hearing officer is an agent of the vendor's designated carrier, it is highly inappropriate and a conflict of interest for that person to write a report containing "findings of fact" and "legal conclusions," per the provisions of Sec. 414.916.[19] This establishes a legal evidentiary record on the physician's CAP compliance, which should only be done by a party entirely without a conflict of interest, which a designated carrier's agent, who is appointed as a hearing officer, cannot have. The entirety of this process should remain within the purview of CMS directly, in order to ensure that due process is followed, to avoid conflicts of interest, and to enhance uniformity of the process.

APA also notes that, while CMS made some improvement in the due process aspect of this dispute resolution process and balances it by physician access to the process, there still is no requirement in the revised regulation, 42 C.F.R., Sec. 414.916, for the vendor's carrier to take affirmative action to find the source of non-payment of the claims at issue. CMS just vaguely requires the designated carrier to gather information without any clearly defined methodology for doing this or to requirement to determine where the problem with non-payment lies, such as with the vendor's own records, its designated carrier, the local carrier, or otherwise, prior to instigating this process.[20]

It would greatly improve the chance to locate and remedy a systemic problem, if CMS were to require that the vendor and its carrier follow some sort of trouble-shooting process at the start. The current resolution process still misses that opportunity for improvement but, instead, jumps from the vendor's initiation of a legal process to the physician's implication of fault in the process, while missing all that may lie in between.

Recommendation- Dispute Resolution Process: APA continues to strongly urge CMS to make further revisions in this dispute resolution process. Specifically, one revision should be to ensure minimal involvement by the designated carrier, which should not

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[18] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128]; 42 C.F.R. Sec. 414.916(b) at 39097-8.

[19] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128]; 42 C.F.R. Sec. 414.916(b) at 39098.

[20] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128]; 42 C.F.R. Sec. 414.916(b) at 39097.

have any of its employees, contractors or other agents involved in the dispute resolution process, including as hearing officers of any type. Another revision should be for CMS to maximize the potential of the dispute resolution process as a problem-solving tool by making affirmative requirements for vendors to resolve problems prior to invoking this process. CMS should balance the due process and practical needs of the parties involved. This requires ensuring that physicians are implicated only where there is substantial reason to believe that the reason for non-payment of vendor claims is more likely the physician's non-compliance with CAP requirements than other causes.

VII. 14-Day Limit for Physician's Claims

While it may be ideal, it is unrealistic to expect physicians to be able to submit claims within 14 days. CMS' own Medicare claims filing data shows that 25% of physicians do not file claims within 14 days.[21] It is fair to assume that this is for reasons outside the control of the physician, considering the advantage obtained by filing sooner to be paid sooner.

Recommendation- 14-Day Limit for Physician's Claims: APA maintains that a more reasonable time frame should be adopted that would provide flexibility to the physician's administrative needs, while prompting payment to both the physician and, by extension, the vendor, as fast as possible.

CONCLUSION AND RECOMMENDATIONS

APA finds that CMS' proposals for CAP contain substantial conceptual flaws and omissions that impede an efficient system of drug acquisition. These place an undue administrative burden upon physicians to comply with CAP requirements. Many physicians will not find that the advantages of the program sufficiently offset these burdens. In addition, CMS' proposed dispute resolution system does not provide a forum for resolution of disputes, does not even require an actual dispute to exist and is at odds with traditional judicial methods of handling citizen's rights under federal programs through federal administrative adjudicatory bodies. CMS's proposal instead diverts this authority into the hands of a private insurance company affiliated with the vendor's interests. Under CMS's proposal, non-attorneys in a biased, private insurance company would be making the initial legal record and selectively gathering documentation, then making legal or quasi-legal determinations about physicians' compliance with federal contractual obligations under CAP. CMS could also appoint such persons in the company as "hearing officers." The insurance companies would also have the power to recommend the physician's suspension from CAP, which can be finalized by an internal hearing officer through an informal hearing. While CMS has revised the regulatory language somewhat, this process still requires insufficient direct participation from CMS and does not reflect adequate due process protections for the physician. In sum, it is highly inappropriate, misplaces authority and significantly impedes upon physicians' rights and interests.

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[21] CMS Interim Final Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS–1325–IFC [Federal Register: July 6, 2005 [Vol. 70, No. 128]; 42 C.F.R. Sec. 414.916(b) at 39050.

The following are APA's recommendations, including reiterations of those initially set forth in APA's comments to CMS's proposed rule,[22] meant to address these issues and offer corrective solutions:

Recommendation- CAP Effective Date and Trial or Phase-in Approaches: The CAP effective date of January 1, 2006, should be extended to allow for complete resolution of operational issues, including the vendor bidding and delivery process and sufficient time for physicians to evaluate CAP vendors fully, enroll, and rework their administrative systems to accommodate CAP procedures. Further, a CAP trial period and/or phase-in approach will allow for small-scale operational evaluation and implementation of corrective measures, to ensure that patient care will not be inadvertently compromised.

Recommendation- Statutorily Permissible Categories of CAP Drugs: APA strongly urges CMS to determine, prior to the CAP effective date, how broadly encompassing the statutory language is with regard to "competitively biddable drugs." This analysis should be finalized prior to CMS' determination as to whether CAP drugs must be restricted to those administered "incident to" a physician's service.

Recommendation- Inclusion of CAP Drugs within Categories: APA strongly urges CMS include more psychotherapeutic drugs in its initial CAP offerings and to refrain from excluding Schedule II, III and IV controlled substances from CAP, especially on the grounds that they require special record-keeping. Record- keeping issues can be resolved through computer technology. Many drugs within these Schedules are used routinely by psychiatrists and need to be available for patients under CAP.

Recommendation- Vendor Bidding under HCPCS Codes: CMS should require vendors to submit bids on more than one drug under each HCPCS code, to ensure wide availability of drugs to patients, especially psychiatric patients who often require specific non-generic drugs to maintain their level of function.

Recommendation- Vendor Collection of Beneficiaries' Deductibles and Co-insurance and Termination of Drug Delivery: APA strongly urges CMS to require that vendors provide meaningful assistance to beneficiaries, such as a payment plan or waiver of monies owed, and revise the regulatory language to reflect this. APA further urges CMS to revise its timeframes for beneficiary completion of financial assistance efforts, in order to prevent patient-care compromises that would result from vendors terminating drug supplies to patients while their applications for financial assistance to pay deductibles or co-insurance are in process.

Recommendation- Dispute Resolution Process: APA continues to strongly urge CMS to make further revisions in this dispute resolution process. Specifically, one revision should be to ensure minimal involvement by the designated carrier, which should not have any of its employees, contractors or other agents involved in the dispute resolution process, including as hearing officers of any type. Another revision should be for CMS

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[22] Asterisked recommendations are from APA's comments of April 26, 2005, to CMS' Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)].

to maximize the potential of the dispute resolution process as a problem-solving tool by making affirmative requirements for vendors to resolve problems prior to invoking this process. CMS should balance the due process and practical needs of the parties involved. This requires ensuring that physicians are implicated only where there is substantial reason to believe that the reason for non-payment of vendor claims is more likely the physician's non-compliance with CAP requirements than other causes.

Recommendation- 14-Day Limit for Physician's Claims: APA maintains that a more reasonable time frame should be adopted that would provide flexibility to the physician's administrative needs, while prompting payment to both the physician and, by extension, the vendor, as fast as possible.

****Recommendation- Physicians' Choice of Categories:*** APA urges CMS to allow physicians to select specific drug categories from more than one vendor. This will allow them more flexibility in obtaining drugs to meet their practice needs and an incentive to elect CAP. This will also create more bidding competition within each drug category, to maximize cost-savings for Part B drugs.

****Recommendation- Competitive Acquisition Areas:*** APA continues to urge CMS to establish competitive acquisition areas based on single states, to maximize bidding competition and local oversight of vendors.

****Recommendation- Drug Categories, Vendors and Precluding Monopoly:*** CMS should require full disclosure of a vendor's corporate relationships during the bidding process and take concrete steps to prevent monopolization by any one company within the bidding or contract award stages of the CAP program. This includes adopting regulatory language within Sec. 42 C.F.R. Part 414 that requires corporate-structure disclosure and specifically prohibits vendor subsidiaries from bidding against their parent company or other subsidiaries with the same parent company. CMS should revise the language of Sec. 414.908(e) "*Multiple contracts for a category,*" Sec. 414.910(a) on the bidding process, and elsewhere, to reflect this bidding and contract award restriction.

****Recommendation- Vendors and Patient Privacy:*** CMS should explicitly prohibit vendors under CAP from using, sharing or selling patient information for any purpose other than that which is strictly related to fulfilling CAP orders.

****Recommendation- Extra Costs and Burden upon Physicians:*** CMS must adopt clear regulatory language to prevent vendors from charging physicians fees that physicians cannot recoup, such as for product returns or for damaged products. Physicians cannot be in the position of underwriting losses for damaged goods and return costs attendant to handling CAP drugs. This has still not been worked out within the interim final rule.

****Recommendation- Physicians' Choice of Categories:*** APA urges CMS in its final rule to allow physicians to select multiple drug categories, to be added in future, from more than one vendor. This will allow them more flexibility in obtaining drugs to meet their practice needs and an incentive to elect CAP. This will also create more bidding competition within each drug category, to maximize cost-savings for Part B drugs.

Recommendation- Emergency Drug Administration and Replacement: CMS' four conditions for physicians to prove that drugs were administered in an emergency should not be applied in the manner CMS intends. Even more leeway should be afforded to the physician in determining when using this mechanism is necessary. The requirements are burdensome and serve as barriers to reimbursement. The physician can verify emergency administration of the drug by simply checking a box captioned "Emergency Administration" on the claims form. Alleviating the need for a carrier to conduct post-payment reviews of emergency drug replacement claims, to determine physicians' compliance, will result in cost-savings for the program.

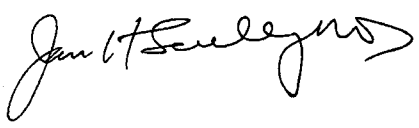
Recommendation- Medical Necessity and CAP Exception: APA continues to strongly urge CMS to change the language of the proposed rule for CAP exceptions, Sec. 414.906(2)(ii), to read, as follows *(additional language in italics)*:

"(ii) When medical necessity, *as determined by the treating physician*, requires a certain brand, *formulation (including but not limited to form, i.e., orally, injection-administered), dosage strength, or delivery system)* that the approved vendor, *elected by that physician*, has not been contracted to furnish under CAP."[23]

Alternatively, the physician's determination of "medical necessity" should be afforded the weight of a legal presumption, which would have to be rebutted by the local carrier to deny a physician's claim. CMS should furnish guidance to physicians, as to what carriers consider to be acceptable factors for determining "medical necessity" so that physicians' orders can more consistently fall within the expected parameters for CAP claims purposes.

Recommendation- Unused Drugs: CMS should allow a physician the freedom to either return unused drugs to the vendor or retain the drug in inventory without taking other steps. The drug is under the physician's legal custody, unless it is returned to the vendor or administered to a patient. The vendor will be reimbursed for the drug when the vendor's carrier matches prescription numbers from the vendor and physician during the claims process. CMS should delete the requirement that a physician notify the vendor when a drug is not administered, under Sec. 414.908(3)(vi), as it is especially onerous to psychiatrists, especially those in community mental health clinics, who may have many patients who do not keep appointments for drug administration.

Thank you for your consideration of these comments.



James H. Scully Jr., M.D.
Medical Director, American Psychiatric Association

[23] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10770.

Submitter : **Dr. Gregory Brent** **Date: 09/06/2005**

Organization : **American Thyroid Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-IFC-157-Attach-1.DOC

AMERICAN
THYROID
ASSOCIATION
FOUNDED 1923

September 1, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1325-IFC
PO Box 8013
Baltimore, MD 21244-8013

Dear Sir/Madam:

We are writing on behalf of the members of the American Thyroid Association, the leading organization of physicians and scientists dedicated to better understanding and treatment of thyroid diseases. Thyroid cancer is the most common endocrine cancer in the United States and the most rapidly increasing cancer in incidence among women. Our members are at the forefront of innovations in the diagnosis and treatment of thyroid cancer.

Human recombinant thyrotropin (Thyrotropin alfa, thyrotropin alfa for injection) is a unique drug used in the management of thyroid cancer patients and no other drug can be substituted. The availability of thyrotropin alfa has had a major impact on the approach to diagnosis, treatment, and surveillance of thyroid cancer. The major advantage of thyrotropin alfa, compared to the previous approach of thyroxine withdrawal for whole body radioiodine scanning, is that patients do not need to suffer weeks of hypothyroidism with symptoms that are often disabling. This is a special problem in the elderly, in whom thyroid cancer occurs more commonly and is more often an aggressive malignancy compared to its presentation in younger individuals. Consequently, older thyroid cancer patients typically require more intensive disease surveillance. Without thyrotropin alfa, this would mean more cycles of thyroid hormone withdrawal in these individuals.

We request that thyrotropin alfa be included in the list of drugs available through the Medicare competitive acquisition program (CAP). Our members practice in a range of clinical settings, but for those in private practice, the financial risk and administrative efforts to obtain thyrotropin alfa without Medicare coverage are a significant barrier to its clinical use. Permitting physicians the option of using a CAP vendor to obtain thyrotropin alfa is important to assure thyroid cancer patients the widest possible access to the drug.

We urge you to reconsider and include thyrotropin alfa in the vendor bid process. Thyrotropin alfa is a key element in the diagnosis and treatment of thyroid cancer. Allowing physicians to obtain Thyrotropin alfa through CAP will ensure that Medicare beneficiaries will have access to this major advance in thyroid cancer care.

Sincerely,

David S. Cooper, MD
Chair, Clinical Affairs Committee

Gregory A. Brent, MD
ATA Secretary

Charles Emerson, MD
ATA Treasurer