

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

Date: 04/26/2005

Issue Areas/Comments

1-15

Overview of the CAP

The current CAP model will have a negative impact on the patient's in my two-physician community cancer practice here in northern Michigan. It is an inflexible system that does not deal with the realities of cancer care. If chemotherapy sessions must be rescheduled to wait for the delivery of the drug(s) that patients need, they will face additional coinsurance obligations for the repeat physician services. In addition, patients will face other financial burdens in the form of higher transportation costs and additional missed time from work. This situation may also mean missed work time and reduced productivity for family members and other caregivers who must bring beneficiaries to the rescheduled treatment sessions.

Claims Processing Overview

Neither the changes to 42 CFR 414.902 set forth in the proposed rule nor the text of the existing regulation define the term "emergency." It is essential for the definition of emergency to be clearly set forth in the final rule and not left to the discretion of each CAP vendor or to the discretion of local carriers tasked with adjudicating practices' claims for drug administration services. Moreover, the definition should turn on the treating physician's clinical judgment that patient health would suffer from delay in treatment, not on the CAP vendor's or the local carrier's remote assessment of the situation. In addition to the huge burden of documenting all four reasons why the drug replacement was necessary, option also raises the question about whether commercial insurers are being asked to subsidize a portion of the drug costs for Medicare beneficiaries in CAP, since Medicare would not be paying a physician for the ordering, financing, inventorying and handling costs associated with drugs borrowed from the practice's inventory.

Competitive Acquisitions Areas

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

Categories of Drugs to be Included under the CAP

The implementation of a CAP for Part B drugs should be undertaken with a cautious approach. Although CMS has managed two CAP for limited types of DME and POS in limited geographic markets, it has never organized and run a CAP on a national or even regional scale. Before diving into a national CAP involving all Part B drugs used "incident to" services, CMS should begin with a regional or national test involving a limited set of drugs administered by a specialty less intense than oncology. Experimenting with a terminally ill patient population whose care requires urgent treatment does not make sense. This would allow CMS to refine its application and vendor selection procedures and its quality and service requirements, correct glitches in CAP upgrades to its claims processing systems, work out handling issues stemming from state regulations, assess and adjust for changes in practice expenses attributable to CAP, and complete the work needed to better match the reimbursement rates for drug administration services to actual costs for the various specialties before CAP is implemented more universally.

Dispute Resolution

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

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

Contract Requirements

The World Health Organization estimates that 6% of all drugs distributed in the world are counterfeit and some observers believe it to be as high as 12%. While Congress' decision to require CAP vendors to acquire all of their drugs directly from the manufacturer or from a wholesaler that buys direct is a good step toward product integrity, it falls short of the mark. Product integrity is about more than blocking the distribution of counterfeit goods. That is why I am concerned that the Proposed Rule's provisions could jeopardize product integrity and violate state licensing laws. I believe CAP vendors must be licensed as pharmacies because they will accept patient-specific written orders for prescription drugs from physicians, assign prescription numbers to those orders, interpret the orders, presumably making generic substitutions as appropriate and permissible under applicable State law, and then transfer dispensed drugs to the prescribing physician for administration to the patient. This patient-specific transfer amounts to "dispensing" a drug under state pharmacy practice acts and because CAP vendors dispense, they are practicing pharmacy and must be licensed accordingly.

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

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

Contracting Process-Quality and Product Integrity Aspects

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

Submitter : Mr. E. Strode Weaver
Organization : Association of Community Cancer Centers
Category : Health Care Professional or Association

Date: 04/26/2005

Issue Areas/Comments

GENERAL

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Please see attachment.

CMS-1325-P-362-Attach-1.PDF

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organization for the oncology team



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April 26, 2005

VIA ELECTRONIC SUBMISSION

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-P (Medicare Program;
Competitive Acquisition of Outpatient Drugs
and Biologicals Under Part B)**

Dear Administrator McClellan:

On behalf of the Association of Community Cancer Centers (ACCC), I appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding the competitive acquisition program (CAP) for outpatient drugs and biologicals under Part B, published in the Federal Register on March 4, 2005 (the Proposed Rule).¹

ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 member institutions and organizations treat 45% of all U.S. cancer patients. Combined with our physician membership, ACCC represent the facilities and providers responsible for treating over 60% of all U.S. cancer patients.

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to the most appropriate cancer therapies. Recent advances in medicine, including the development of new drugs and biologicals and new uses for these therapies, have expanded our options in the fight against cancer. Patients can benefit from these options, however, only if they have access to the right combination of therapies at the right stage of treatment. As we have explained in prior comments to CMS, reimbursement changes for outpatient drugs,¹ mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), have raised concerns about physicians' ability to continue to offer their Medicare patients life-saving drugs.² Physicians have been especially nervous about their ability to purchase and provide drugs cost-effectively under Medicare's new average sales price (ASP) reimbursement method. Unless physicians are adequately compensated for the costs of providing drug and biological therapies to their patients, they may be compelled to reduce the amount of services they provide in their offices. Their patients would suffer disruptions in their care and they could be obliged to seek treatment in less convenient and more costly inpatient settings.

We are hopeful that the CAP will facilitate Medicare beneficiaries' access to cancer drugs by relieving physicians of many of the burdens associated with purchasing and billing for these therapies. Congress intended for the CAP to provide physicians with an alternate method of obtaining Medicare-covered drugs for their patients. Indeed, according to results of an on-line survey [See Appendix 1] conducted by ACCC on physician member level of interest in participating in the CAP, and their perceptions of potential advantages and disadvantages of the program, practices in smaller urban or rural areas may be potentially receptive to learning more about or participating in the CAP.

While we appreciate CMS' efforts in developing the Proposed Rule, it includes several issues that are vague and subject to interpretation, creating confusion among a vast majority of physicians on how (or whether) the CAP can be practically implemented. In particular, we remain concerned about the

¹ Throughout these comments, we use "drugs" to mean "drugs and biologicals."

² See, e.g., Letter from Patti A. Jamieson-Baker, President, ACCC, to Mark McClellan, Administrator, CMS (Sept. 24, 2004) (ACCC's comments on the 2005 Medicare physician fee schedule).

agency's failure to recognize the extensive administrative resources³ that physicians electing the CAP will incur. In fact, according to ACCC's survey, respondents identified this as the principal issue affecting physicians' decision *not* to participate in the CAP. This failure could discourage participation in the CAP and thus undercut the enhanced access to cancer drugs that otherwise might be obtainable through the CAP. We hope that CMS will acknowledge that the potentially extensive negative aspects of the program's requirements may far outweigh the program's benefits, and will work to resolve these barriers to physician participation.

We offer the following comments to help CMS address the remaining gaps in the Proposed Rule and encourage CMS to review survey responses provided by ACCC physician members on the complex implementation issues imposed by the program.

- Because the CAP could promote patient access to important therapies, we support the inclusion of oncology drugs in the initial phase-in of the CAP, if CMS also establishes a strong mechanism to compensate physicians for the added costs of participating in the CAP.
- To ensure that the CAP offers physicians a real choice of drugs, the final rule must clearly state that CAP vendors must offer at least one formulation of a drug or biological in each billing and payment code within a CAP category.
- As proposed, the CAP will impose substantial costs on participating physicians. These burdens must be reduced, when possible, and offset by additional compensation to physicians.
- Physicians must be able to use the "furnish as written" option with minimal administrative inconvenience to provide drugs that are not available through the CAP vendor.
- Physicians must be allowed to use the resupply option to provide timely, uninterrupted care to their patients. Physicians also should be allowed to request from the CAP vendor an advance supply of drugs used to treat acute conditions.
- CMS' current coverage policies, including the requirements for coverage of medically accepted off-label uses of cancer drugs, must apply to the CAP, and vendors must be required to supply drugs regardless of whether they are ordered for off-label uses.

³ This includes requiring separate drug inventories, imposing administratively burdensome program requirements, having to use additional staff resources to operate under the CAP, and imposing unrealistic emergency drug requirements.

- As required by the Medicare statute, physicians must be allowed to select vendors on a category-by-category basis.
- Beneficiary access to drugs under the CAP must not be denied if the beneficiary's coinsurance or deductible is unpaid.
- The dispute resolution process must be revised to reduce the burdens on physicians, resolve unanswered questions, and provide a mechanism to ensure that vendors comply with delivery timeframes.
- In addition to the proposed requirements for product integrity, vendors should be instructed to deliver drugs unmixed to lessen physicians' uncertainty about the quality of the drugs.
- CMS should finalize its proposed delivery timeframes.
- Vendors should be allowed to add new drugs to their lists when a drug they offer is no longer available, and should be allowed to remove drugs from their lists only when required to address safety concerns or when the drug has been removed from the market.
- Physicians must be allowed to select a new vendor outside the annual election process when their vendor fails to provide drugs in a timely manner.

I. Categories of Drugs to be Included Under the CAP

A. Phase-In of the CAP

In the Proposed Rule, CMS does not set forth a specific proposal for a category or multiple categories of products to be included under CAP. Instead, the agency identifies a few approaches it is considering. One of these approaches is implementing the CAP initially for drugs administered by oncologists or for drugs administered by other specialties. Given our belief that the CAP could promote patient access to oncology drugs, ACCC could support the inclusion of oncology drugs in the CAP. Our support, however, is accompanied by a strong recommendation, as discussed below in Section II(A), that the agency establish a mechanism to compensate physicians for the added administrative costs they will incur should they elect the CAP.

B. Physician Choice of Drugs

Since our support for the CAP is based on an expectation that the program will enhance patient access to oncology drugs, it is vital that the CAP allows physicians to provide their patients with the most appropriate drugs for their conditions. The CAP must protect patient access to critical therapies by offering physicians a real choice of drugs. At a minimum, the CAP must include a broad range of drugs, covering all of the Healthcare Common Procedure

Coding System (HCPCS) codes within a category. CMS proposes to require vendors to submit bids on all of the HCPCS codes in a category.⁴ We strongly support this proposal, and we urge CMS to reject any suggestions that it allow vendors to exclude certain HCPCS codes from their bids. Congress clearly intended that CAP vendors would provide “at least one competitively biddable drug or biological within each billing and payment code within each category for each competitive acquisition area,”⁵ including both multiple source and single source drugs. This requirement is particularly important in oncology because many of the drugs our members use have their own HCPCS codes. If vendors are allowed to exclude these therapies from their CAP bids, the CAP would fail to provide our members with an alternative means of fulfilling their patients’ needs for drugs. Contrary to Congress’ intent, our members would have no choice but to purchase and bill for drugs provided to Medicare beneficiaries, and patient access would continue to depend on physicians’ ability to purchase drugs at or below 106% of ASP. ACCC recommends that CMS clearly state in the final rule that a vendor must offer at least one formulation of a drug or biological in each HCPCS code within a CAP category.

II. Claims Processing Overview

A. Clerical and Inventory Burdens of Participating in the CAP

In addition to providing a real choice of drugs, the CAP must allow physicians to obtain therapies with minimal administrative burden. Our members report that increased administrative requirements would strongly discourage them from participating in the CAP. We disagree with CMS’ conclusion that the clerical and inventory resources associated with participation in the CAP will not exceed the resources associated with buying and billing drugs under the ASP system.⁶ The CAP would create many new obligations for physicians and their staffs, including:

- notifying vendors when a drug is not used, arranging to return unused drugs or submitting additional orders to allow the drugs to be used for other patients, and making appropriate notations in drug orders and inventory records;⁷

⁴ 70 Fed. Reg. at 10751.

⁵ Social Security Act (SSA) § 1847B(b)(1). The legislative history confirms this and makes clear that the statutory reference to “billing and payment code” means HCPCS code. H.R. Conf. Rep. No. 108-3091, at 594 (2003).

⁶ 70 Fed. Reg. at 10755.

⁷ 70 Fed. Reg. at 10756.

- maintaining a separate paper or electronic inventory for each drug obtained through the CAP,⁸ and creating separate physical storage spaces for drugs;
- submitting claims within 14 days of administering the drug;⁹
- providing new data on claims for drugs, such as prescription numbers and the patient's height and weight,¹⁰ and updating billing software to accept these items; and
- responding to beneficiaries' questions about the CAP.

None of these obligations exist under the ASP-based reimbursement system, and they are likely to impose substantial costs on participating physicians. For example, in addition to maintaining separate inventory records, the proposed program requirements would necessitate participating physicians to dedicate separate storage space for drugs obtained through the CAP to ensure that these drugs are not mixed in with their supply for non-Medicare patients (even though CMS may not require this). This issue was the top ranking concern identified by respondents in the ACCC survey. ACCC members have also suggested that maintaining a separate inventory would require a full time person. While it is not uncommon for physicians to create separate physical inventories for drugs provided to them at no charge to ensure that they are not used for patients for whom they will bill the drug, the notable difference is that physicians are compensated. For example, when clinical trials require physicians to store drugs separately, the trial sponsors provide payment for these costs. Likewise, for National Cancer Institute trials, part of the grant monies reimburse physicians for the costs of maintaining separate inventories. Yet, in the Proposed Rule, CMS does not propose any financial assistance for inventory management. The additional administrative costs will be even more significant if CAP vendors' limited selection of drugs forces physicians to continue to purchase and bill for many drugs. If this happens, physicians' burdens could increase exponentially because they would have to comply with two different sets of Medicare billing requirements and procedures, as well as the procedures used for their non-Medicare patients.

CMS does not propose an additional payment to defray these costs because "payment for clerical and inventory resources associated with buying and billing for drugs under the ASP system is bundled into the drug administration payment under the physician fee schedule."¹¹ This statement ignores the additional costs that physicians will incur, which are set forth above.

⁸ 70 Fed. Reg. at 10756.

⁹ 70 Fed. Reg. at 10755. While CMS indicates that about 75% of claims are submitted within 14 days, for the 25% of physicians that do not, this requirement may impose additional burdens, particularly among small revenue practices.

¹⁰ 70 Fed. Reg. at 10756.

¹¹ 70 Fed. Reg. at 10755.

Medicare's reimbursement for drug administration services will not be adequate to address these costs because these are additional resource burdens that are not factored into the payment rates established under the physician fee schedule. CMS' view also fails to account for the steep declines in drug administration reimbursement that will occur when Medicare's projected payment cuts for drug administration services go into effect, the MMA's transition adjustment expires, and the cancer care demonstration project ends. Our members are already concerned that Medicare's drug administration will not be adequate next year. Adding new administrative costs without adjusting the payment rate to account for them only increases our members' apprehension about their ability to provide care to Medicare beneficiaries.

ACCC urges CMS to carefully review the proposed administrative requirements for participating physicians to ensure that they comply with the CAP's goal of reducing physicians' costs of providing drugs to their patients. We recommend that CMS minimize physicians' administrative burdens as much as possible and eliminate unnecessary requirements, such as providing both the patients' height and weight and the dose administered on claims forms. As recommended by the Practicing Physicians Advisory Council (PPAC), physicians should not be responsible for the costs of returning drugs to the vendor.¹² While minimizing physician burden is important, ACCC believes it will remain necessary for CMS to compensate physicians for their extra costs incurred should they elect to participate in the CAP.

B. The "Furnish as Written" Option

We thank CMS for proposing the "furnish as written" option to allow physicians to obtain and bill for the specific formulations their patients need, and we urge the agency to implement this option with minimal administrative burdens for physicians. As we explained above, ACCC strongly recommends that CMS require CAP vendors to offer at least one drug per HCPCS code. We understand, however, that it may not be possible for a CAP vendor to provide every formulation of the drugs in a category, and the "furnish as written" provision will be crucial for ensuring that participating physicians can use the CAP for most drugs, but still have the flexibility to obtain the precise therapies their patients need.

CMS proposes to require physicians to use a modifier to identify claims for drugs provided through the "furnish as written" option, and the agency anticipates that local carriers will, at times, subject these claims to post-

¹² "Competitive Acquisition Vendors Should Pay Drug Returns – CMS Doctor Panel," The Pink Sheet, Mar. 14, 2005, at 25.

payment review.¹³ These requirements do not apply to claims for drugs normally reimbursed at 106% of ASP when provided by a physician who does not choose the CAP, and they should not apply to drugs reimbursed at the same rate when the drugs are not available through the CAP. We encourage CMS to minimize the administrative inconvenience of obtaining drugs that are not available through the CAP vendor.

C. The Resupply Option and Access to Drugs for Acute Conditions

Cancer care often involves the use of several drugs, provided on precise schedules, with periodic readjustments to respond to changes in the patient's condition. Under ASP-based reimbursement, when an oncologist determines that a patient's dosage or choice of drug should be changed, he or she can administer the new therapy immediately. Under the CAP, in such circumstances, the patient may be required to return for treatment on another day, after the CAP vendor has delivered the new therapy. At best, this delay would inconvenience the patient and increase costs to the patient, physician, and Medicare, including the costs of additional office visits, travel, and re-ordering drugs from the CAP vendor. At worst, making the patient wait for treatment could cause increased suffering for the patient and could destabilize the patient's health status.

If our members choose to participate in the CAP, they will need to be able to administer drugs when their patients need them, not just when the CAP vendor can deliver them. If the physician cannot obtain a drug from the CAP when the patient needs it, the physician must be allowed to provide a drug from his or her inventory and order a replacement through the CAP. As required by the Medicare statute,¹⁴ CMS proposes to allow physicians to order drugs from the CAP to resupply drugs from the physicians' own inventories provided to Medicare beneficiaries.¹⁵ The resupply option would be available if the physician could demonstrate all of the following to the local carrier: (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; and (4) the drugs were administered in an emergency situation. CMS does not define "emergency situation," but seeks comments on how to do so.

¹³ 70 Fed. Reg. at 10756. We note that when the vendor supplies the drug, any payments for the drug that may be recovered after a post-payment audit can only be recovered from the CAP vendor, not the physician, since it was the vendor that received the Medicare payment. The final rule should make this point explicitly.

¹⁴ SSA § 1847B(b)(5).

¹⁵ 70 Fed. Reg. at 10755.

We believe the resupply option will be very important to our members and their patients, and we urge CMS to define "emergency situation" broadly to allow physicians to provide timely, uninterrupted cancer care. According to ACCC's survey, this concern was much more prevalent among small urban and rural providers. We urge CMS to allow physicians to use the CAP's resupply option when: (1) the patient has come to the office for a drug administration service, but the drug has not been delivered timely by the CAP vendor or is unusable; (2) the physician first decides during an appointment to give a drug to a patient and thus could not have ordered the drug in advance; or (3) a change in the patient's condition, including the development of an adverse reaction, requires prompt administration of a different drug. We also recommend that CMS use the same timeframes for delivery of resupply orders as are proposed for regular orders (discussed below in Section V).

ACCC believes CMS also should recognize that some drugs are frequently used for acute conditions that are used to treat cancer patients but that cannot be predicted but do require immediate treatment if an adverse event occurs. Adverse events would include patients receiving cancer therapies who might require drugs such as streptokinase and urokinase to treat blood clots, diphenhydramine (Benadryl) and dexamethasone to treat allergic reactions, and intravenous antibiotics. Although physicians can not predict at the time of placing a CAP order that these drugs will be needed, they should have them on hand to respond to immediate changes in the patient's condition. Physicians who maintain their own supplies of these drugs could use the resupply option to obtain replacements from the CAP. However, a physician who chooses to use the CAP to obtain all drugs may not be able to use the resupply option. We recommend that CMS allow these physicians to request an initial supply of these drugs from the CAP vendor so the physician can be adequately prepared to address the patient's needs.

D. Application of Current Coverage Policies to Drugs Provided Through the CAP

Whether physicians obtain drugs through the CAP or purchase them on their own, Medicare beneficiaries must be assured that they will be able to receive an appropriate course of treatment. ACCC strongly supports Medicare's existing coverage rules, which require coverage for medically accepted off-label uses of drugs,¹⁶ and we believe they should apply to the CAP as well as to claims made under ASP-based reimbursement. In the Proposed Rule, CMS explains that physicians and local carriers would be responsible for verifying that a drug or biological is used consistent with these and other coverage

¹⁶ Medicare Benefit Policy Manual (CMS Pub. 100-02), ch. 15, § 50.4.5.

rules,¹⁷ but the proposal does not suggest that CAP vendors or the designated CAP carrier would perform a similar review.

Indeed, these entities should not perform such a review. The vendor's role is to be a pharmacy and fill orders from physicians, who must be able to decide which therapy to administer to a patient. The designated carrier should not conduct such a review because that would be redundant of the local carriers' function and inefficient in that the designated carrier would have to apply each individual carrier's policies. Adding new layers of review would only obstruct patient access to critical drugs. We urge CMS to clearly state in the final rule that the existing coverage process remains unchanged by the CAP and that CAP vendors must deliver the drugs requested, whether or not they are ordered for off-label use. CMS recently made these statements to the PPAC,¹⁸ and we ask that they be repeated in the final rule.

E. Physicians' Choice of Categories of Drugs to Obtain through the CAP

CMS asks for public comment on whether physicians must order all categories of drugs from one vendor, or whether they should be allowed to obtain different categories from different vendors.¹⁹ We believe the statute is clear: physicians may select the "contractor through which drugs within a category of drugs will be acquired and delivered to the physician."²⁰ In other words, physicians may select vendors on a category-by-category basis. The statute does not permit CMS to require physicians to obtain all categories of drugs from a single vendor, and we urge CMS to clarify this requirement in the final rule.

F. Beneficiary Access to Drugs and Payment of Coinsurance

Finally, we have heard concerns that vendors will stop providing drugs to physicians for a beneficiary if that beneficiary does not pay his or her coinsurance or deductible. CMS should clarify in the final rule that the vendors' agreement with CMS does not permit them to withhold shipments if the beneficiary's coinsurance or deductible is unpaid. In addition, CMS needs to bolster the available dispute resolution processes for physicians to address these situations, as discussed in the next section.

¹⁷ 70 Fed. Reg. at 10755.

¹⁸ "Competitive Acquisition Vendors Should Pay Drug Returns – CMS Doctor Panel," The Pink Sheet, Mar. 14, 2005, at 25; "CAP Vendors Given Leverage Over Generics, Little Power for Single-Source Drug Prices," Inside Washington Publisher's Inside CMS, Vol. 8, No. 5 (March 10, 2005).

¹⁹ 70 Fed. Reg. at 10755.

²⁰ SSA § 1847B(a)(1)(A)(iii).

III. Dispute Resolution

We are greatly concerned that the proposed dispute resolution process will impose enormous burdens on physicians to address CAP vendors' concerns, but offers little to help physicians resolve their own concerns about the vendors. First, CMS proposes to hold physicians fully responsible for appealing denials of claims for drug administration, which are linked to claims for drugs provided under the CAP.²¹ The physician's CAP participation agreement will require the physician to "submit an appeal accompanied by all required documentation (such as medical records or a certification) necessary to support payment" if the drug administration claim is denied.²² If the physician fails to fulfill this obligation, the CAP vendor can request that the physician's participation agreement be suspended. We believe physicians will take these obligations seriously in deciding whether to participate in the CAP. Unfortunately, the Proposed Rule does not provide enough information about how the appeals process will work to help physicians understand whether the potential benefits of the CAP outweigh the burdens of these requirements. For example, the Proposed Rule does not specify how far through the appeals process a physician would have to pursue his claim. Physicians understandably will be reluctant to pursue appeals for drug administration claims that could be as little as \$20, when their costs to do so would be more than the amount they would recoup if they prevailed. It also is unclear whether the cost of the drug will be counted toward the amount in controversy. If it is not, then the physician would not be allowed to pursue an appeal before an Administrative Law Judge if the drug administration claim is less than \$100. We urge CMS to clarify physicians' obligations and opportunities to pursue appeals, and to consider allowing vendors pursue appeals as the real party in interest.

Second, in contrast to the clear sanctions that apply to physicians who fail to fulfill their obligations, the Proposed Rule offers no penalties to encourage vendors to improve their performance. If the physician has a concern about the vendor's performance, CMS proposes to require the physician to use the vendor's grievance process first, and then request intervention from the designated carrier if the problem is not resolved.²³ We are concerned that critical issues, such as a vendor's failure to provide timely deliveries of drugs, will not be resolved through the proposed grievance process. We urge CMS to create an adequate mechanism to ensure that vendors comply with the delivery timeframes, such as a process that could include review by a CMS hearing officer (to whom CAP vendors can take their complaints about physicians).

²¹ 70 Fed. Reg. at 10758.

²² Proposed 42 C.F.R. § 414.908(a)(3)(ix).

²³ 70 Fed. Reg. at 10758.

Third, CMS proposes to terminate a physician's participation in the CAP for the rest of the CAP election cycle if he or she does not fulfill the obligation to file clean claims and pursue administrative appeals. The Proposed Rule is unclear about how the physician would obtain drugs after his or her CAP participation is suspended or terminated. We ask that CMS clarify that the physician could purchase drugs and would be reimbursed at 106% of ASP.

IV. Contracting Process – Quality and Product Integrity Aspects

ACCC agrees with CMS' assessment that "physicians would be reluctant to participate in the CAP if they have little confidence that CAP vendors would be reliable and provide quality CAP products."²⁴ CMS proposes to use the CAP contracting process to assess prospective vendors' ability to provide quality service and ensure product integrity. One element of this process is an assessment of prospective CAP vendors' ability to assure that products are not adulterated, misbranded, spoiled, contaminated, expired, or counterfeit. These assurances are fundamental to earning physicians' trust, and we support the proposal to require them. Physicians also cannot vouch for the quality of a drug if it has been mixed or repackaged before they receive it. We urge CMS to require that CAP vendors deliver drugs in the form in which they are received from the manufacturer or wholesaler, without mixing or repackaging, as physicians have numerous concerns about their own liability related to the products provided by vendors and what occurs during the shipping process.

V. Bidding Entity Qualifications

As we said above, many cancer treatment regimens must be provided on precise schedules. Physicians must be able to depend upon their CAP vendors to reliably deliver drugs on time, in perfect condition. CMS proposes to require vendors to furnish routine shipments of drugs within one to two business days, and the duration of the delivery time period must not exceed the drug's stability in appropriate shipping containers and packaging. Vendors would be required to provide emergency orders the next day if the order is received by 3:00 p.m.²⁵ ACCC supports these timeframes and requests that CMS implement them in the final rule.

CMS also proposes to allow physicians to place an order for an entire course a treatment and to allow the CAP vendor to split the order into "appropriately spaced shipments."²⁶ CMS does not describe how those shipments should be timed, but seems to vest discretion solely in the vendor to

²⁴ 70 Fed. Reg. at 10759.

²⁵ 70 Fed. Reg. at 10760.

²⁶ 70 Fed. Reg. at 10754.

determine the spacing of the shipments. Physicians must have input into this decision to ensure that they have enough of the drug on hand in case the patient needs a larger dose, which has the potential to reduce the need for emergency orders of additional drugs.

VI. CAP Bidding Process – Evaluation and Selection

In the Proposed Rule's discussion of the bidding process, CMS describes its plans to adjust prices when new drugs are introduced, a drug patent expires, or a material shortage results in a significant price increase for a drug.²⁷ The agency does not describe what a vendor's obligations will be when a drug it offers is no longer available, such as when the drug is recalled. We recommend that the vendor be allowed to add a new drug to its list in these circumstances to replace or complement the drug that is not available. Vendors also should be allowed to remove drugs from the list only when required to address safety concerns or when the drug has been removed from the market.

As required by the statute, CMS proposes to pay for new drugs under the CAP using the ASP methodology.²⁸ We believe this will help to ensure timely access to new drugs under the CAP, and we recommend that CMS implement the proposal in the final rule.

VII. Physician Election

CMS proposes to allow physicians to make an election outside the annual process in exigent circumstances. For example, a physician could select a new vendor when their previously selected vendor ceases participation in the CAP, if the physician leaves the practice that had selected the vendor, or if the physician relocates to another competitive area.²⁹ We recommend that physicians also be allowed to select a new vendor outside the annual election process if their vendor does not provide drugs timely. A vendor's repeated failure to deliver drugs on time could cause serious disruptions in patient care and additional expense for patients, physicians, and Medicare. This should be considered an exigent circumstance and physicians must be allowed to select a new vendor who will provide reliable service.

VIII. Conclusion

ACCC appreciates the opportunity to offer these comments on CMS' proposals to implement the CAP. We hope that our comments will help CMS to

²⁷ 70 Fed. Reg. at 10765.

²⁸ 70 Fed. Reg. at 10764.

²⁹ 70 Fed. Reg. at 10766.

develop the program as a viable option for physicians. To summarize our recommendations, we urge CMS to:

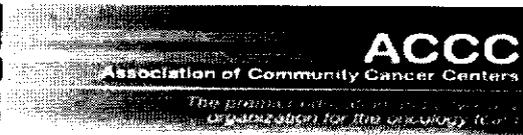
- include oncology drugs in the initial phase-in of the CAP, along with a strong mechanism to compensate physicians for the added costs of participating in the CAP;
- clearly state in the final rule that CAP vendors must offer at least one formulation of a drug or biological in each HCPCS code within a CAP category;
- reduce physicians' administrative burdens under the CAP and provide additional compensation to offset the added administrative costs physicians will incur if they elect the CAP;
- allow physicians to use the "furnish as written" option with minimal administrative inconvenience to provide drugs that are not available through the CAP vendor;
- allow physicians to use the resupply option liberally to provide timely, uninterrupted care to their patients, and allow physicians to request from the CAP vendor an advance supply of drugs used to treat acute conditions;
- apply CMS' current coverage policies, including the requirements for coverage of medically accepted off-label uses of cancer drugs, to the CAP, and require vendors to supply drugs regardless of whether they are ordered for off-label uses;
- allow physicians to select vendors on a category-by-category basis, as required by the statute;
- ensure that beneficiary access to drugs under the CAP is not denied if the beneficiary's coinsurance or deductible is unpaid;
- revise the dispute resolution process to reduce the burdens on physicians, resolve unanswered questions, and provide a mechanism to ensure that vendors comply with delivery timeframes;
- instruct vendors to deliver drugs unmixed to lessen physicians' uncertainty about the quality of the drugs;
- finalize the proposed delivery timeframes;
- allow vendors to add new drugs to their lists when a drug it offers is no longer available, and allow the removal of drugs from the list only when required to address safety concerns or when the drug has been removed from the market; and
- allow physicians to select a new vendor outside the annual election process when their vendor fails to provide drugs in a timely manner.

We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact our staff person, Deborah Walter, at (301) 984-5067, if you have any questions or if ACCC can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "E. Strobe Weaver". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

E.Strobe Weaver, FACHE, MBA, MHSA
President
Association of Community Cancer Centers
Executive Director, Oncology Services
University of Colorado Hospital
Anschutz Cancer Pavilion



APPENDIX 1: ONLINE SURVEY REVEALS MOST PHYSICIANS UNLIKELY TO PARTICIPATE IN THE CAP

INTRODUCTION. Beginning on January 1, 2006, Medicare will offer physicians the choice of directly purchasing drugs and being paid based on the average sales price (ASP) methodology or electing to obtain drugs through a Competitive Acquisition Program (CAP) vendor instead.

ACCC surveyed physician practice members on their level of interest in participating in the CAP, and their perceptions of potential advantages and disadvantages of the program. Responses to an online CAP survey were received from 227 physician practice members. Information on specific practice demographics included three categories: location (large urban vs. rural practice), total annual revenue (\$400,000-\$999,999 or \geq \$1 million), and patient mix (population <50% Medicare-only vs. \geq 50% Medicare-only).

Attachment 1 provides an overview of the study methodology and response data to each question, in aggregate and by practice category (i.e., location, total annual revenue, and patient mix).

OVERVIEW OF SURVEY FINDINGS. Generally, the majority of respondents appear unwilling to participate in the CAP. Not surprising, respondents are more likely to consider obtaining drugs through a CAP vendor if favorable pricing could not be obtained outside the CAP. Overwhelmingly, respondents—regardless of specific practice demographics—tend to view CAP as administratively burdensome and resource intensive. Also problematic is the perception of the need to maintain separate inventories—which most practices do not find feasible given space limitations. These shortcomings seem to outweigh any benefits that the program offers. Finally, responses suggest that most billing systems are able to process claims on a 14-day vs. the typical 30-day cycle, but many small-revenue generating practices' systems cannot accommodate claims submitted on a 14 day cycle. Survey findings are presented below—in aggregate and by each of the three physician practice categories.

AGGREGATE FINDINGS

CAP PARTICIPATION. *High level of disinterest among respondents in participating in the CAP.*

- 52% of respondents indicated that they were “definitely not” likely to participate in the CAP.
- 3% indicated that the likelihood of their participation was a “definite yes.”
- Approximately one-quarter were either “undecided” or “needed more information” before they could estimate the likelihood of their participation in the program (26% and 20%, respectively).

POSSIBLE FACTORS INFLUENCING PROVIDER DECISION TO PARTICIPATE IN THE CAP.

Potentially negative aspects of the program's requirements far outweigh any of its perceived benefits.

Issues that could potentially affect respondents' decision not to participate in the CAP include:

- requiring separate drug inventories (76%)
- imposing administratively burdensome program requirements (75%)
- having to use additional staff resources to operate under CAP (74%)
- imposing unrealistic emergency drug requirements (63%).

Issues that could potentially affect respondents' decision to participate in the CAP include:

- reducing or eliminating bad debt on co pays or need to collect co-pays (26%)
- reducing or eliminating patient billing (24%)
- reducing or eliminating potential losses on drugs (23%)
- reducing or eliminating need for large drug inventories (21%).

PHYSICIAN'S ABILITY TO NEGOTIATE FAVORABLE DRUG PRICES. *A large portion of respondents are generally disinterested in participating in the CAP, regardless of their ability to obtain favorable pricing.*

- More than one in three would not consider obtaining drugs through a CAP vendor regardless of the level of ASP+ 6% (38%).
- More than half would consider obtaining drugs through a CAP vendor only if ASP + 6% is lower than or at the price that their practice is able to acquire drugs (43% and 12%, respectively).
- Approximately one out of six would consider CAP if ASP+ 6% is higher than their practice could acquire drugs (16%).

EXISTING BILLING SYSTEMS. *For most respondents, the existing billing system is not an obstacle in accommodating more frequent claims processing.*

- 55% indicated that their current billing systems can accommodate claims submitted on a 14-day cycle rather than the 'typical' 30-day cycle.
- 13% indicated that the 14-day requirement would force them to modify their billing system.

PHYSICIAN PRACTICE LOCATION: LARGE URBAN VS. RURAL

Practices were grouped according to geographic location of the practice. Large urban is defined as 1 million+ and the rural/other category combines other urban/suburban practices and 37 rural respondents.

- *Respondents in rural practices are more "undecided" than those in large urban practices about whether to participate in the CAP (38% vs. 27%, respectively), and express a comparatively greater need for more information (27% vs. 16%, respectively).*
 - Respondents in rural practices are less opposed to "definitely not" participating in the CAP than those in large urban areas (35% vs. 57%, respectively).
- *Respondents in rural practices' willingness to consider participating in the CAP is more price sensitive than those in large urban areas.*
 - Respondents in rural practices are more willing to participate in the CAP based on their ability to obtain favorable pricing outside the CAP, i.e., ASP+ 6% would have to be lower than or at the price that their practice is able to acquire drugs. (65% vs. 52%, respectively).
- *Respondents in rural and large practices identify similar issues that could be influential in their decision to participate in the CAP, with two notable exceptions.*
 - While respondents in rural practices appear much more concerned than those in large urban practices about the unrealistic emergency drug requirements that may be imposed under CAP (78% vs. 57%, respectively), respondents in rural practices are more likely to believe CAP could reduce losses on drugs (38% vs. 27%, respectively).
- *Rural practice billing systems are comparable to those in large urban practices.*
 - Rural practices and large urban practices are equally likely to accommodate claims submitted on a 14-day cycle (59% vs. 58%, respectively).

TOTAL ANNUAL PHYSICIAN REVENUE: LARGE VS. SMALL-REVENUE GENERATING PRACTICES

Practices were grouped according to the revenue produced annually—large revenue practices are defined as \$1 million+ and small revenue practices are defined as \$400,000-\$999,999.

- *Respondents in small revenue practices are less interested than large revenue practices in participating or even learning more about CAP.*
 - Respondents in small revenue practices are more likely to indicate they will definitely not participate in the CAP (60% vs. 50%, respectively), or even need any additional information about the program (7% vs. 24%, respectively).

- Respondents in small and large revenue practices generally identify similar issues that could be influential in their decision to participate in the CAP, with several notable differences:
 - Respondents in small revenue practices are notably more concerned than those in large revenue practices that modifications to existing billing systems will be required (74% vs. 55%, respectively) and that unrealistic emergency drug requirements may be imposed (74% vs. 61%, respectively).
 - Respondents in small revenue practices are notably less concerned than those in large revenue practices with three issues that could potentially affect the respondents' decision to participate in the CAP:
 - reducing or eliminating bad debt on co-pays (19% vs. 27%, respectively)
 - reducing or eliminating need for large drug inventories (12% vs. 25%, respectively)
 - reducing wasted drugs (5% vs. 13%, respectively).
- Respondents in small revenue practices suggest billing systems may be less sophisticated than those in large revenue practices.
 - Respondents in small revenue practices are less likely than those in larger revenue practices to submit claims on a 14-day cycle (43% vs. 62%, respectively).

PATIENT MIX: <50% MEDICARE-ONLY PATIENTS VS. ≥50% MEDICARE-ONLY PATIENTS

Practices were grouped according to proportion of Medicare patient population that they treat—defined as practices with <50% Medicare-only patients vs. ≥50% Medicare-only patients.

- Respondents in practices with ≥50% Medicare-only patients indicate less likelihood of participating in the CAP than those practices with <50% Medicare-only patients (48% vs. 54%, respectively).
- Respondents in practices with ≥50% Medicare-only patients may be more willing than those practices with <50% Medicare-only patients to consider participating in the CAP, regardless of their ability to obtain favorable pricing.
 - Respondents in practices with ≥50% Medicare-only patients are more likely than those practices with <50% Medicare-only patients to participate in the CAP if they are able to obtain favorable pricing outside the CAP, i.e., ASP+ 6% lower than or at the price that their practice is able to acquire drugs. (62% vs. 51%, respectively).
 - Respondents in practices with ≥50% Medicare-only patients are more willing than those practices with <50% Medicare-only patients to participate in the CAP if ASP+ 6% is higher than the price that their practice is able to acquire drugs (21% vs. 13%, respectively).
- Respondents in practices with ≥50% Medicare-only patients and those with <50% Medicare-only patients identify similar issues that could be influential in respondents' decision to participate in the CAP, with one notable exception:
 - Respondents in practices with ≥50% Medicare-only patients indicate a greater likelihood than those practices with <50% Medicare-only patients to participate if the need to collect co-pays is eliminated (32% vs. 23%, respectively).
- Respondents in practices with ≥50% Medicare-only patients may have less sophisticated billing systems than those practices with <50% Medicare-only patients.
 - Respondents in practices with ≥50% Medicare-only patient billing systems are much less able than those practices with <50% Medicare-only patients to accommodate claims submitted on a 14-day cycle (49% vs. 62%, respectively).



ATTACHMENT 1: ACCC CAP SURVEY RESULTS

METHODOLOGY

ACCC conducted an online survey regarding the Competitive Acquisition Program (CAP). The four-question survey was sent out on March 23, 2005, with two follow-up reminders sent on April 7th and 13th. Two of the four questions allowed for multiple responses, and, thus, total percentages may not necessarily equal 100%.

RESPONDENTS

A total of 227 responses were received from ACCC physician practice members. Responses were also analyzed by key demographic information including: location (large urban vs. rural practice)¹; total annual revenue (practices with \$1,000,000+ vs. \$400,000-\$999,999)²; and patient mix (practices with a patient population mix of ≥50% Medicare-only patients vs. <50% Medicare-only patients)³.

RESPONDENT DEMOGRAPHICS	RESPONDENTS (N=227)
Location	
Large urban practices	83
Rural/other practices	144
Annual Practice Revenue	
\$1,000,000+	146
\$400,000-\$999,999	58
Other	23
Patient mix	
≥50%	90
<50%	137

1. How likely would you be to participate in the competitive acquisition program (CAP)? [Check only one]

Likely to participate in the CAP	Total% N = 227	Physician Area N = 227		Annual Revenue N = 204		Patient Mix N = 227	
		Large Urban %	Rural %	\$1 Million %	\$400,000-\$999,999 %	≥50% Medicare%	<50% Medicare%
Definitely no	51.98	56.63	35.14	50.00	59.52	47.78	54.33
Undecided	26.43	26.51	37.84	25.34	26.19	31.11	22.05
Need more info	20.26	15.66	27.03	23.97	7.14	18.89	22.05
Definitely yes	3.08	1.20	0.00	2.05	7.14	4.44	1.57
Other	1.32	2.41	0.00	1.37	2.38	1.11	1.57

2. Under which circumstance would you consider obtaining drugs through a CAP vendor? [Check as many as apply]

Would consider if ASP+6% reimbursement rate is-

ASP + 6% in relation to acquisition price	Total % N = 227	Physician Area N = 227		Annual Revenue N = 204		Patient Mix N = 227	
		Large Urban %	Rural %	\$1 Million %	\$400,000-\$999,999 %	≥50% Medicare%	<50% Medicare%
Never	38.33	43.37	24.32	39.04	38.10	32.22	42.52
Lower than	43.17	42.17	48.65	43.84	45.24	45.56	41.73
Equal to	11.89	9.64	16.22	13.70	9.52	16.67	9.45
Higher than	16.30	14.46	16.22	15.07	16.67	21.11	12.60
Other	2.64	2.41	2.70	3.42	0.00	1.11	3.94

¹ Large urban is defined as 1 million+ and rural/other category includes other urban/suburban practices with 37 rural respondents.

² Other category includes <\$400,000 and undefined

³ Medicare only refers to Medicare only coverage with no supplemental, private insurance, or Medicaid

3. What issues are you contemplating that could potentially affect your decision to obtain drugs through a CAP vendor? [Check as many as apply]

Issues affecting decision to participate in the CAP	Total % N = 227	Physician Area N = 227		Annual Revenue N = 204		Patient Mix N = 227	
		Large Urban %	Rural %	\$1 Million %	\$400,000-\$999,999 %	≥50% Medicare %	<50% Medicare %
May require separate inventories	76.21	71.08	78.38	76.03	85.71	74.44	77.95
Administratively burdensome	74.89	72.29	78.38	75.34	80.95	77.78	72.44
Additional staff resources	74.45	72.29	81.08	71.92	80.95	75.56	73.23
Unrealistic emergency requirements	63.44	56.63	78.38	60.96	73.81	63.33	62.99
Requires substantial modifications to billing system	60.79	54.22	67.57	55.48	73.81	65.56	57.48
All or nothing proposition	59.03	53.01	62.16	59.59	57.14	60.00	59.06
Unrealistic compliance for dispute resolution	40.53	42.17	48.65	42.47	33.33	36.67	40.94
Eliminates bad debt on co-pays	26.43	18.07	24.32	27.40	19.05	30.00	23.62
Eliminates need to collect co-pays	26.43	24.10	27.03	26.71	33.33	32.22	22.83
Eliminates patient billing	24.23	22.89	27.03	25.34	23.81	25.56	22.83
May reduce losses on drugs	23.35	26.51	37.84	21.23	23.81	26.67	22.05
Eliminates need for large drug inventories	21.15	19.28	21.62	25.34	11.90	20.00	21.26
Reduces/eliminates wasted drugs	12.78	15.66	21.62	13.01	4.76	12.22	11.81
Reduces visits from drug representatives	3.08	3.61	2.70	3.42	2.38	3.33	1.57
Other	9.69	10.84	8.11	10.27	4.76	6.67	12.60

4. Can your current billing system accommodate claims submitted on a 14-day vs. the "typical" 30-day cycle? [Check only one]

Billing system can accommodate 14 day cycle	Total % N = 227	Physician Area N = 227		Annual Revenue N = 204		Patient Mix N = 227	
		Large Urban %	Rural %	\$1,000,000 %	\$400,000-\$999,999 %	≥50% Medicare %	<50% Medicare %
Yes	54.63	57.83	59.46	61.64	42.86	48.89	62.20
No	13.22	12.05	8.11	10.96	21.43	15.56	9.45
Don't know	29.96	28.92	29.73	26.03	33.33	32.22	27.56

Submitter : Mr. Wilson Washington
Organization : Community Health of South Dade, Inc.
Category : Health Care Professional or Association

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

We are in support of the Medicare Competitive Acquisition Program for Part B Drugs. In the South Miami Dade area, the Behavioral Health Care Center, Community Health of South Dade, Inc. (CHI) service over 7000 clients with over 40,000 mental health visits annually. Our mission is to 'deliver readily accessible quality health service to the people in the South Dade area in the quality required, and in a way that assures the dignity and respect to the individual consumer and provider of health services by planning, organizing, developing and operating a coordinated health care delivery system.' A majority of our clients are uninsured or underinsured. More specifically, over 93% of our clients are either Medicaid, Medicare or uninsured. In a few words, CHI services the 'working poor'. Therefore, any changes in our client medicaid or medicare benefits will tremendously impact our ability to meet our mission. We believe that CMS should include Psychiatric Drugs in the final rule for CAP under the Medicare Modernization Act (MMA). It is also important that CMS include Psychiatric drugs in the initial stages of CAP to alleviate barriers to access inherent in the current system. Further, it is important that CMS create a category that includes mental health drugs, including long-acting injectable antipsychotics. And, finally, it is crucially important that CMS address how vendors should handle uncollectible copays and other reimbursement issues that would threaten therapy persistency. This would prevent arbitrary discontinuation of therapy by vendors.

Submitter :

Date: 04/26/2005

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

CAP and MVI sound good on paper but when you are receiving treatment to save your life, you don't want to be told that you have to wait while the new process is followed. Why are we introducing a middleman into the picture, isn't that going to increase costs. Seems that in your zeal to cut costs you have forgotten about the people who need these drugs and their physician's office to administer. Heaven forbid we have to go to the hospital for chemo.

Submitter : Jacqueline Burke
Organization : DeKalb CSB
Category : Other Health Care Provider

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

please include mental health injectables in the CAP beginning 01/01/06 as a way to improve access to care for this consumer population.

Submitter : greg Paffhouse
Organization : northern lakes cmh and NAMI of Northwest Michigan
Category : Health Care Professional or Association

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

April 25, 2005

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

Dear CMS Personnel:

Together we are writing to express our support for the CMS February 25, 2005 proposed rule that would implement the Competitive Acquisition Program (CAP). We see this as a preferred alternative to the current "buy and bill" system for obtaining Part B covered medication, as it will promote access to appropriate medications.

At the same time we share concerns on several issues regarding its implementation:

1. Inclusion of Psychiatric Drugs ? our understanding is that CMS has the authority to exclude from CAP any drugs for which the application of CAP is unlikely to result in significant savings or likely to cause patient access problems. We appreciate that CMS has proposed not to exclude and we hope this will be included in the final rule. It is absolutely critical that mental health consumers (inclusive of the dual eligible Medicare and Medicaid population) have access to the full range of medications. This concern applies to both Part D (prescription drug benefit oral medication) and Part B (physician services non-self administered therapies).
2. Inclusion of Psychiatric Drugs in Phase I ? our understanding is that CMS may be planning to phase in psychiatric drugs. We strongly urge that CMS include such medications in the initial stages to eliminate current barriers and avoid future complications.
3. Inclusion of Mental Health Drug Category ? our understanding is that CMS has yet to define the categories of Part B drugs that vendors will bid to provide to physicians. It is essential that CMS create a category that includes mental health drugs, including long-acting injectable antipsychotics.
4. Ensure Rule Prevents Discontinuation of Therapy by Vendors ? our understanding is that CMS has explored the vendor reimbursement process. We hope this will be done in a way that will avoid uncollectible copay and other reimbursement issues threatening ongoing therapy.

We are encouraged that CMS has actively sought comment and appreciate our opportunity to comment. We remain hopeful that the final rules will promote consumer and provider friendly guidelines and that such rules will promote consumer recovery.

Sincerely,

Maxine Rideout Greg Paffhouse
President Chief Executive Officer
NAMI of Northwest Michigan Northern Lakes CMH

Submitter : Mr. David Golding
Organization : Caremark Rx, Inc.
Category : Health Care Industry

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-367-Attach-1.DOC



April 26, 2005

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Comments on Proposed Rule for the Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B, CMS-1325-P (published at 70 *Federal Register* 10746, March 4, 2005)

Dear Administrator McClellan:

Caremark appreciates the opportunity to provide comments on the proposed rule to implement the Competitive Acquisition Program (CAP) pursuant to Section 303(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA or, the Act).

Caremark Rx, Inc. (Caremark) is a leading pharmacy benefit management (PBM) company, providing through its affiliates comprehensive drug benefit services to over 2,000 health plan sponsors and their plan participants throughout the U.S. Caremark's clients include employers, health plans, managed care organizations, insurance companies, unions, government agencies, the Federal Employees Health Benefits Program (FEHBP), CalPERS, and other funded benefit plans. Caremark operates a national retail pharmacy network with over 59,000 participating pharmacies, seven mail-service pharmacies, the industry's only FDA-regulated repackaging plant, and 21JCAHO-accredited specialty pharmacies for the delivery of advanced medications to individuals with chronic or genetic diseases and disorders. Caremark processes over 550 million prescriptions annually.

Caremark is one of the nation's largest providers of specialty pharmacy products, offering clinically appropriate services to the community for more than 26 years. Based on our extensive experience in specialty pharmacy, we are pleased to provide our comments regarding the proposed CAP rules.

SPECIFIC COMMENTS

Categories Of Drugs To Be Included Under The CAP

1. **The CAP should be limited to drugs administered incident to a physician's service.** Caremark supports CMS' reading of section 1847B of the Act as applying only to drugs administered incident to a physician's service. This is clear from the fact that only physicians are given the opportunity to elect to participate in the CAP, and the mechanism and condition for initiating payment under the CAP is the administration of the drug by the physician. It is also consistent with Congressional intent in enacting section 1847B, which was not only to achieve savings over the AWP payment system, which reimbursed physicians based on AWP, but also to reduce the financial and administration burden for physicians. Indeed, extending the CAP to drugs beyond those administered incident to a physician's services would not only be unworkable, given that the CAP is built around physician drug administration, but also unnecessary. The inefficiencies and lack of competitive forces inherent in the existing approach to reimbursement of physicians for Part B drugs do not apply to self-administered drugs, which can be obtained from a wide variety of specialty pharmacies that compete on price and service and, unlike physicians, are in the drug distribution business.

Consistent with above, while the MMA defines "competitively biddable drugs and biologicals" for purposes of the CAP as including "a drug or biological described in section 1842(o) (1)(C) of the Act", this should be viewed as the potential universe of drugs covered, but limited to those drugs that meet this threshold that are also administered in a physician's office. Thus, for example, clotting factor and IVIG, while included under section 1842(o) (1)(C), are includable in CAP only to the extent they are administered by a physician. To the extent these drugs are generally self-administered, they should be excluded from the CAP. In our experience, physicians do not routinely administer clotting factor and therefore, we do not provide stock of these drugs in the physician office setting. These products are typically administered through hemophilia treatment centers or, more often, self-administered in the home, rather than in a physician office. Thus, these products should be excluded from the CAP.

2. **CAP should be phased in, starting with (i) specialties that use fewer Part B drugs, and (ii) only one region at a time.** Given the radical change that the CAP represents from the current reimbursement system, CMS should proceed cautiously with a more limited program. Starting with drugs commonly prescribed by one of the specialties other than oncology (for example, neurology, ophthalmology, or rheumatology) will provide CMS with the opportunity to test all aspects of the program, and to identify and address any operational or other issues before implementing the CAP on a full-scale basis. While this does potentially delay the anticipated benefits of the CAP, these benefits assume a properly working program, which is what the more limited phase-in will assure. A more limited phase-in will also encourage more entities to consider bidding as a CAP vendor, since their risks

with an untested program will be limited. We believe, given our experience with specialty pharmacy distribution, that it would be administratively difficult for a vendor to enter this market without an implementation phase-in.

As discussed below, Caremark supports the concept of four regional competitive acquisition areas and, consistent with its belief that the CAP should be phased-in, believes that CMS should consider choosing just one region for the first phase of the program. This would also encourage more potential CAP vendors at the regional level to bid, especially if a central region that would be serviced by most CAP vendors were chosen for the first phase of the program.

3. **Drug categories should be defined broadly to include all drugs typically administered by a given medical specialty (but excluding limited distribution drugs).** Drug categories should be defined broadly, to include all drugs typically administered by a given medical specialty, but excluding those drugs that a manufacturer has chosen to distribute through exclusive or limited distribution relationships. Manufacturers may choose to limit distribution channels for certain drugs when, for example, the drug requires special handling or monitoring.

Broadly defining drug categories will simplify the program for vendors, physicians and CMS, since most physicians will then generally be able to choose only one CAP vendor to meet their Part B drug needs. It will also ensure adequate coverage and competition for less used and less financially advantageous drugs, and will limit the opportunities for abuse and misuse of the system by either CAP vendors or physicians. For example, by having the CAP apply to broad categories of drugs, physicians will generally have fewer opportunities to choose to use the CAP system for less financial advantageous drugs, while purchasing more financially advantageous drugs outside the CAP. Manufacturers will be encouraged to broaden their distribution channels if they wish their drugs to be included in the CAP.

II. Competitive Acquisition Areas

1. **Caremark supports the establishment of four large regional competitive acquisition areas for the CAP.** Larger areas will allow for greater economies of scale, and will be administratively less complicated and burdensome for physicians, vendors and CMS alike. These smaller regional areas will be large enough to encourage larger vendors to participate and seek to gain market share, but not so large as to limit participation by smaller vendors. Four large regions will also make the program more attractive to national vendors, which will not be required to submit multiple bids. Finally, it will allow phase-in one region at a time, since a single region will be large enough to test all aspects of the program, while containing the risk for potential vendors.

III. Claims Processing Overview

The following comments focus on the vendor relationship with the physician in the CAP program. As CMS recognizes, CAP vendors and the CAP program will be entirely dependent on physicians' filing of their drug administration claims in a timely manner. It is imperative that CMS provide effective incentives to ensure that physicians comply with their CAP obligations. In the case where a physician does not comply with those standards, the vendor must have appropriate recourse. The following provides several recommendations to that end.

While CMS may choose not to explicitly regulate the relationship between vendors and physicians in CAP, we believe it is important for CMS to include language in the final rule that at least allows vendors wide discretion when establishing contractual relationships with physicians. This includes allowing vendors to negotiate with physicians to limit total financial and administrative liability in the program.

1. **Physicians should be deemed to have purchased the drugs at the CAP price if the drug administration claim is not filed within 14 days of the anticipated date of service.** As stated previously, CMS recognizes, the proper functioning of the CAP, will be entirely dependent on physicians' filing their drug administration claims in a timely manner. As long as this occurs, claims can be matched, coverage determined and payments made, allowing CAP vendors to replenish inventory and take new orders. However, if physicians fail to file their claims in a timely manner – for whatever reason – the CAP fails to function. An effective incentive for physicians to file, and appropriate recourse for CAP vendors if they do not, is to deem the physician to have purchased the drug from the vendor at the CAP price. CAP vendors cannot and should not be expected to operate differently from every other provider or distributor of a product, by allowing the recipient to take possession of the product without any financial responsibility to pay for it or – the equivalent in the CAP – to file the drug administration claim for it. Since the physician ordered the product and already holds the product, it makes sense that the physician should either administer the drug as ordered and file the claim, or otherwise takes ownership of it and uses it as he or she wishes.

To enable vendors to bill physicians after the 14 day filing period has expired, we suggest that a process be established by CMS that will notify CAP vendors when claims have not been filed by physicians within the specified time period, so that the CAP vendor may take appropriate steps to bill the physician accordingly.

2. **For “furnished as written” situations, the CAP vendor should be given the first opportunity to fill the order.** Caremark understands that there may be situations where, for medical reasons, a physician needs to administer a drug that is not part of the CAP vendor's inventory. However, rather than immediately allowing the physician to obtain the drug through the ASP system, we believe that the physician should be required to at least give the CAP vendor the first opportunity to fill the order (a type of “right of first refusal”) through the CAP

system or otherwise at the ASP price. If the CAP vendor declines, the physician should then be able to obtain the drug under the ASP methodology. By requiring physicians to give the CAP vendor this right of first refusal, CMS will reduce the likelihood of physicians attempting to use the "furnished as written" option to obtain drugs outside the CAP when it is financially advantageous for them to do so. It will also make CMS less dependent on the post payment review by the carrier of use of "furnished as written" option, which is insufficient, on its own, to limit or detect abuses. In any event, such reviews are particularly difficult to conduct effectively in the case of medical necessity determinations, which are largely subjective and within the physician's professional judgment.

3. **When a physician selects a CAP vendor, that selection should apply to all drug categories provided by that CAP vendor.** Consistent with its position that drug categories should be defined broadly, Caremark believes that each physician should select a single CAP vendor, and obtain all his or her CAP drugs through that vendor. This will make most sense if the drug categories are broadly defined (e.g. including all drugs typically prescribed by a particular specialty), since it will be administratively simpler for physicians and CAP vendors to deal with one CAP vendor relationship per physician. However, irrespective of how broadly or narrowly drug categories are defined, each potential CAP vendor should be required to bid on, and offer, all the drugs categories in the CAP, with the only exception being drugs where the manufacturer has chosen to have an exclusive distributor relationship (since most CAP vendors will not have access to them).

By requiring CAP vendors to offer a full menu of drugs, CMS will lessen the opportunities for CAP vendors and physicians to pick and choose between more and less financially advantageous drugs, thereby undermining the integrity and efficiency that the CAP potentially offers. Physicians will not need to select and deal with more than one CAP vendor, and each CAP vendor will similarly establish a relationship with, and support the needs of its physicians. To the extent that a particular drug is not offered by a CAP vendor because of an exclusive manufacturer arrangement, this drug would be obtainable by the physician outside the CAP through the ASP methodology. It is anticipated that this would be a narrow exception for a very limited number of products. It would be unfair to include such a drug under the CAP when most CAP vendors would not have the means to offer it. Moreover, it would provide an incentive for the manufacturer to reconsider the exclusive distribution relationship if it would like the drug to be available through the CAP.

4. **CAP vendors must be given the same rights regarding collection of cost sharing obligations from beneficiaries, and the same rights in the event beneficiaries do not meet these obligations, as Medicare Part B providers have currently.** Given that CAP vendors, instead of the physician, will now be collecting deductibles and coinsurance from beneficiaries, it is appropriate that any rights that providers have under Part B to collect such amounts and potentially seek recourse in the event such amounts are uncollectible, now accrue

to the CAP vendor. In addition, we believe that as long as the CAP vendor has put forth "reasonable" collection efforts as specified in 42 CFR 413.80, that vendor may count bad debt as an allowable cost, to be reimbursed by CMS. Without these basic protections, CAP vendors will have no means of containing bad debts, managing their receivables or, ultimately, staying in business.

5. **CAP vendors should be allowed to decline the selection by a particular physician or terminate an existing relationship with a physician for good cause.** Since CAP vendors will be entirely dependent on physicians' actions in filing their drug administration claims and otherwise meeting their CAP obligations, CAP vendors must be allowed the right to decline to work with a physician who (i) has previously failed to pay for drugs on a timely basis, or (ii) materially breaches his/her contractual obligations to the CAP vendor or his/her CAP participation agreement with CMS, or (iii) acts in a manner that obstructs the purpose or intent of the CAP or otherwise hinders its effectiveness, or (iv) otherwise acts in bad faith. This is necessary because the CAP vendor will be totally dependent on the actions of the physician in fulfilling his/her CAP obligations to receive reimbursement from CMS. It is also especially important for the CAP vendor to have some recourse when it will potentially be selling drug products to the physician, and thus, potentially be owed significant amounts by a physician in certain situations contemplated in these comments.
6. **If a physician decides for any reason not to administer an ordered drug, the physician should be deemed to have purchased the drug for his/her own inventory and should not be permitted to return it.** Once a CAP vendor has delivered a drug product to the physician, the CAP vendor has no control over storage or safekeeping of that product. Therefore, for product integrity and safety reasons, a CAP vendor cannot accept back into inventory a drug where possession of that drug has left the control of the CAP vendor. Such drugs would simply have to be discarded, resulting in significant loss and wastage. Since the ordering of the drug is the physician's decision, and once delivered, the drug is in the control and safekeeping of the physician, the physician should take responsibility for the drug. The physician may either administer the drug as anticipated and submit the claim within 14 days of the anticipated date of service, or if the physician chooses not to administer the drug within this timeframe for any reason, he/she will be deemed to have purchased the drug into his/her inventory at the CAP price.
7. **To protect the vendor from coverage denials, physicians should be required to obtain a signed advance beneficiary notice (ABN) from the beneficiary** in any case where (i) the physician obtains an ABN for his/her own services in administering the drug in question, and (ii) the CAP vendor requests an ABN based on the CAP vendor's determination that Medicare coverage is uncertain. Since CAP vendors will not have any control over what drug the physician orders, or for what medical conditions and circumstances, they will be relying on physicians to make these determinations appropriately. In addition, the CAP vendor will have no direct contact with the beneficiary, and so no opportunity to

obtain an ABN when necessary. Therefore, in those cases where a physician decides it is appropriate to obtain an ABN for his/her own services in administering the drug in question, the physician should be required to have a copy on file for the CAP vendor.

In addition, since CAP vendors and physicians may not always have the same views on coverage issues, or different issues may arise regarding coverage of the product vs. coverage of the physician's services, physicians should be required to obtain an ABN for the CAP vendor whenever requested by the CAP vendor to do so. . This is a basic protection that is afforded all Medicare providers, and CAP vendors should be situated no differently simply because they do not interact directly with the beneficiary. If the physician refuses or fails to obtain the ABN in either of these circumstances, the CAP vendor should be allowed to deny service. Alternately, if the drug has already been delivered before the CAP vendor learns that the physician did not obtain the ABN, the physician should be deemed to have purchased the drug from the CAP vendor if the claim is subsequently denied by CMS.

IV. Dispute Resolution

1. **CMS must institute a dispute resolution process that has meaningful penalties for non-compliance by physicians.** Caremark recognizes that the existing Medicare Part B appeals process, as currently framed, may not be appropriate for resolving CAP vendor disputes. However, it believes that CMS can and should implement a process –beyond counseling and/or informal alternate dispute resolution – to address the issue of nonpayment of CAP vendor claims. While counseling a party to meet its obligations should always be an option, it is seldom sufficient. CMS acknowledges that the physician has full and exclusive control of the claim filed for the administration of the drug, and further acknowledges that the CAP vendor has no means of bringing any appeal against a physician directly. In these circumstances, if the CAP is to be effective at all, it is incumbent upon CMS to put in place significant and effective deterrents against a party failing to fulfill its CAP obligations.

In the case of physicians, exclusion from the CAP for the next CAP cycle is not such a deterrent, as long as the physician has the option of obtaining Part B drugs under the ASP methodology. It simply limits the physician's choices, but in no way imposes an appropriate financial penalty, or operates to discourage noncompliance. A more effective deterrent would be, for example, exclusion from the Medicare program. In addition, as stated previously, it is imperative that CAP vendors have some direct recourse to protect themselves against physicians that are noncompliant, or otherwise act in bad faith or without regard for their CAP obligations. In these circumstances, the CAP vendor must have the option of no longer providing services to such a physician.

V. Contracting Process – Quality and Product Integrity Aspects

1. **CAP vendors should be required to meet certain minimum quality, service and financial integrity standards.** Critical to the success of the CAP is the assurance to physicians that drug products obtained from a CAP vendor are genuine, unadulterated, unspoiled and meet all applicable product quality standards. This can be accomplished by requiring that CAP vendors put in place appropriate processes and systems to ensure that products are not adulterated, misbranded, spoiled, contaminated, expired or counterfeit. Among other things, CAP vendors must be required to: (i) obtain their products either directly from the manufacturer or from a primary distributor, (ii) comply with industry best practices, including appropriate industry guidelines for pharmaceutical distribution system integrity, (iii) have in place adequate recall capabilities, (iv) have well-trained personnel, including appropriately qualified clinical staff; (v) have in place mechanisms to obtain timely information about suspected counterfeits in the marketplace, and to educate their employees about them, (vi) have physical facilities that meet certain security requirements, including access controls, (vii) meet financial solvency standards, and (viii) implement internal and, as appropriate, external, integrity controls, including a compliance program with a fraud and abuse component.

2. **CAP vendors should be capable of accepting and submitting e-prescribing transactions in accordance with final e-prescribing standards.** While only Part D plan sponsors are required to support and comply with the foundation e-prescribing standards by January 1, 2006 (and with the final e-prescribing standards when effective, but no later than January 1, 2009), beginning January 1, 2009, any provider using e-prescribing under the Part D program must do so according to the final e-prescribing standards. Given the benefits of e-prescribing including increased patient safety and improved efficiencies, we encourage CMS to consider regulations that would require CAP vendors to comply with the foundation and final e-prescribing standards as issued under the Medicare Part D program. This may encourage physicians who are considering adoption of e-prescribing under Part D to do so, since this would enable them to leverage e-prescribing in the context of Part B. The use of e-prescribing and compliance with e-prescribing standards under the CAP also help to increase the efficiency of the program, and will help promote broader adoption and expansion of e-prescribing generally. Finally, because most CAP vendors will be required to comply with certain technical requirements and thus will likely have a fairly rigorous technical infrastructure in place, it is unlikely that compliance with these e-prescribing standards will impose an undue hardship on them.

VI. Bidding Entity Qualifications

1. **At a minimum, CAP vendors should be required to be licensed pharmacies in good standing in each state in which they seek to operate.** While many, if not most, states will already require a pharmacy license, it should be an explicit qualification for a bidding entity under the CAP. CAP vendors should comply with OBRA' 90 requirements for pharmacies, including drug safety screening, and patient counseling by a pharmacist. This is important in that the role of the CAP vendor extends well beyond that of a traditional wholesaler or distributor, and more closely resembles that of a specialty pharmacy provider. Appropriate clinical expertise and clinical safety edits by CAP vendors will contribute significantly to the success and effectiveness of the CAP, by improving patient care and clinical outcomes and should be required. Additional specific clinical services that should be minimal CAP offerings include:
 - Providing access to a qualified pharmacist on a 24/7/365 basis to respond to patient and physician inquiries or emergencies.
 - Ability to track and recall specific drug products by NDC code and by lot number, to ensure timely and effective identification of patients who have received a particular lot of a drug that has been subject to a drug recall.

2. **CAP vendors should be required to meet minimum service requirements.** Minimum service standards include:
 - Performance standards, at least consistent with industry best practices, for delivery of routine and emergency drug shipments. For routine drug shipments, delivery should be within one to two business days, and for emergency shipments, by the next day, assuming in each case a clean order (i.e. that no patient safety or financial barriers that must be resolved prior to shipment).
 - A minimum of five years industry experience in furnishing Part B injectable drugs.
 - Performance standards, consistent with industry best practices, for customer service. At the least, each CAP vendor should offer 24/7 toll-free call center assistance, Spanish language capability, and the ability to assist the disabled and hearing-impaired.
 - A formal complaint resolution process.

3. **Potential CAP vendor must bid on, and offer, all drugs categories offered under the CAP.** In order to ensure the integrity of the CAP, it is important that each CAP vendor bid on and offer all drugs under the CAP. This will prevent vendors from selectively offering certain drug categories, and will simplify the selection process for physicians, CMS and CAP vendors alike. It will ensure vigorous competition for all drugs, and reduce the likelihood of physicians needing to obtain drugs outside the CAP.

VII. CAP Bidding Process – Evaluation and Selection

1. **Cost information provided by CAP vendors should be kept strictly confidential, and protected from public disclosure.** Potential vendors will not be willing to participate in the CAP unless they have the assurance that their data will be kept confidential and not used for any purpose other than the CAP bid process. CMS should therefore adopt protections from disclosure similar to those in place for Part D sponsor applicants.
2. **Quarterly drug price adjustments should not be limited to unusual situations or minimum price fluctuation thresholds.** It is important that CMS recognize that, while CAP vendors will engage in vigorous drug price negotiations with manufacturers, ultimately they may not be able to secure fixed drug prices for an entire year. To the extent that CAP vendors are required to accept price changes from manufacturers, they should be permitted to pass through these price changes to CMS without the imposition of minimum thresholds or meeting special conditions. Otherwise CAP vendors are essentially put at risk for an aspect of the CAP, namely drug acquisition costs, which are determined by many factors largely outside the control of the CAP vendor. Given the high cost of many Part D drugs, and the fact that even a small percentage change in cost can have a significant impact for CAP vendors, CAP vendors should be allowed to seek (and CMS may similarly require) price adjustments on a quarterly basis, irrespective of the amount or cause of the change.

VIII. Physician Election Process

1. **Protections need to be established to prevent physicians groups from gaming the system by combining or channeling their drug acquisitions through different CAP vendors.** As CMS recognizes, the CAP is entirely dependent for its proper operation on physicians acting responsibly and complying with their CAP obligations. However, even if physicians technically meet their CAP obligations, there are potentially several ways in which the CAP could be used to create financial advantage. This is particularly the case because the CAP is structured on an individual physician basis, and is entirely voluntary. Since many physicians do not practice on an individual basis, but as part of a single or multi-specialty group practice, this raises the possibility that a group practice may channel different purchases through different physicians, thereby allowing the group to choose on a per drug basis whether to use the CAP process or the ASP methodology. To avoid this type of gaming, group practices (including any entities controlled by a group practice) should be required to choose as a group to participate in the CAP. As such, physicians that are part of the group practice should not be permitted to bill separately for drugs covered under the CAP, even though claims are billed by physicians on an individual basis.

Conclusion

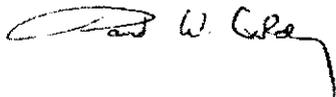
Caremark is committed to working with CMS to ensure the success of the CAP and to its continued provision of high quality clinical patient care and physician support services. In order to maximize the opportunity for the success of the CAP, Caremark believes that CMS should:

- Limit the program to products that are strictly administered in physicians' offices.
- Implement the program prudently, in consideration of the operational challenges that program participants will face.
- Seek to establish a balanced business relationship between the CAP vendor and physicians that recognizes the interdependence of the parties and the unique economic reliance of the CAP vendor on the physician's actions.
- Ensure the clinical integrity of the drug delivery system by requiring that CAP vendors be appropriately qualified as pharmacies providing critical clinical patient care and physician support services.

Finally, Caremark believes that it is important to recognize that, in order to be successful, the CAP must evolve. Clinical and financial management of complex products administered by physicians presents a unique challenge. The experience and insights gained during initial implementation will be very valuable, and should be considered together with experience in related health care areas, such as the management of pharmacy drug benefits, to see how the program could be enhanced to further align participant incentives to improve clinical and financial outcomes. Pricing strategies, such as Maximum Allowable Cost (MAC) pricing, may have an application in the CAP.

Caremark appreciates this opportunity to provide comments on the Proposed Rule for the Competitive Acquisition of Part B Drugs and Biologics in the Medicare program. We look forward to working collaboratively with CMS in the future on this and other programs. If you have any questions, or would like discuss our comments please do not hesitate to contact Wendy Parker, Vice President Federal Relations for Caremark, at 202-772-3500.

Sincerely,



David W. Golding
Senior Vice President
Specialty Pharmacy Services

Submitter : Mr. Paul Nowacki
Organization : Louisiana Hematology Oncology Associates
Category : Other Health Care Professional

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

As a business manager of Louisiana Hematology Oncology Associates, a community cancer clinic in Baton Rouge, I am in total opposition of this rule. CAP is a regulatory burden without any benefit to cancer clinics and it is not the answer to the drug payment problem. Pharmaceuticals will have zero incentive to bid drugs and this rule will only increase costs to Medicare. This rule will cause a great administrative burden to community cancer clinics and a terrible inconvenience to the patients of those clinics. Instead of this rule we need to fix the ASP drug reimbursement system and extend the time of the demonstration project so proper data can be collected.

Submitter : Ms. Karen Bacher
Organization : Us TOO International Prostate Cancer Education & S
Category : Consumer Group

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1325-P-369-Attach-1.DOC

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April 26, 2005

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

Comments on the Proposal for Competitive Acquisition of Outpatient Drugs and Biologicals under Medicare Part B

These comments are submitted by Us TOO International Prostate Cancer Education & Support Network (Us TOO) in response to the proposed rules governing the Competitive Acquisition Program (CAP) for drugs administered in physician offices, which were published in the Federal Register on March 4, 2005. Us TOO is a 501 (c) (3) not for profit charitable organization (with more than 325 chapters throughout the U.S. and abroad) dedicated to helping men and their families learn more about prostate cancer in order to make better decisions on treatment options and better cope with quality of life issues following treatment. Every year over 232,000 men are diagnosed with prostate cancer and about 30,000 die. Drugs used to treat prostate cancer are represented in the drugs covered by Medicare Part B, therefore Us TOO is very interested in the design and implementation of the CAP.

Us TOO's major concern about the proposed CAP is that decisions about prostate cancer therapy should be based on the best interests of the patients and not on cost. Any adverse impact on the patient's health and well being resulting from the proposed rules is unacceptable to Us TOO and our constituents.

We believe patient choice is essential, as we are dealing with a major disease where there are a large number of variables such as grade, stage, side effects, age, level of fitness, etc.

Men and their families, in conjunction with their physicians, need the ability to choose the best medications, dosages of medications, and treatments to meet their individual needs and issues. **The choice should be based on the best possible outcome for the patient and not cost.**

We urge CMS to consider our concerns about impacts on beneficiaries. The rule states the impact on beneficiaries will be neutral. However, we have concerns as noted above on adverse impacts.

Overview of CAP

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs.

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

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

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who choose to give up the

traditional buy-and-bill model and select the CAP model instead. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

Unless significant changes are made, many urologists and oncologists will face a loss under the buy-and-bill model, a loss that will be even greater should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services – which will fall well below the cost of providing drug administration services.

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

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

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. We urge CMS to extend the quality demonstration while it works to match drug administration cost and payments.

Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare prostate cancer patients likely will be forced back to hospitals for treatment.

Categories of Drugs to be Included under the CAP

The current statute allows CMS phase in the CAP and CMS has requested comments on potential possibilities. Instead of moving to a national CAP involving all Part B drugs used in “incident to” services (specifically by urologists and oncologists), CMS should consider a regional or national pilot program involving a limited set of drugs that are typically administered by a physician specialty – not singling out oncology.

This would allow CMS to refine its application and vendor selection procedures and its quality and service requirements, correct glitches in CAP upgrades to its claims processing systems, work out handling issues stemming from state regulations, assess and adjust for changes in practice expenses attributable to CAP, and complete the work needed to better match the reimbursement rates for drug administration services to actual costs for the various specialties before CAP is implemented more universally.

Us TOO does not recommend making the oncology community the test market for a program that is not proven to work.

Us TOO is concerned about limitations on the numbers and dosages of therapy drugs. We are concerned the proposed rule will limit the options patients have for medication decisions and treatments. Patients should not be forced to switch therapies and treatment options.

In addition, the proposed rule is not clear on **Least Costly Alternative (LCA)**. If LCA is enforced, providers may not have access to all drugs available under the CAP. Providers may be forced to change their patients’ therapy and/or consider other treatment options.

We have been advised that some prostate cancer patients have been told by their physicians that under LCA they would be forced to use a less costly medication that may not be appropriate for them. This type of scare-tactic only decreases the patient’s confidence in their overall treatment and whether or not they are receiving the type of quality care they deserve.

Men and their families need to be able to have choices not based solely on the cost. The proposed CAP rule is not clear on LCA but it appears physicians who do not elect to participate in CAP would be bound by LCA—and there is a potential for LCA to be applied to CAP. We strongly oppose the LCA approach and urge CMS to clarify whether or not it will be used.

Us TOO believes there are a number of issues that need to be clarified to ensure CAP will operate smoothly and not prohibit access to necessary therapies for patients. Currently, we are not convinced that CAP will be widely accepted by physicians because of the uncertainties in the program and additional administrative burdens the programs will impose on physicians and their patients.

CAP Bidding Process

One of our major concerns is the possibility for a reduction in the patient/physician relationship and the impact this will have on the beneficiaries. Patients will now have to deal with large vendors instead of physicians' offices for coinsurance and payments. The absence of personal relationships between beneficiaries and CAP vendors is likely to exacerbate the vendors' bad debt collection problems. In addition, it will also exacerbate some vendors' use of overly aggressive collection efforts, including decisions to stop providing drugs for patients who are too far in arrears – potentially resulting in financial ruin of the patient. Thus the physician who may have forgiven payments can no longer do so.

This will adversely affect the most vulnerable populations (minorities and under-served individuals) which are at greatest risk of prostate cancer.

The Practicing Physicians Advisory Council has also raised this concern and proposed that CMS address it in the final CAP rule by mandating that vendors advance credit to patients unable to afford their coinsurance payments.

CMS should go a step further and ask that the vendors also be required to have in place procedures for assessing indigence and waiving coinsurance when a non-Medicaid-eligible beneficiary's income, assets, and medical expenses meet certain pre-established criteria. Ideally, these procedures should incorporate the assistance of social workers trained to explore all payment options and assistance programs available to the individual.

These measures will help ensure that all patients have access to therapies regardless of their income or ability to pay for treatment.

New drugs should be available from the CAP immediately. The proposed rule indicates that adjustments to vendors' schedule will generally be made once a year. There will be exceptions (including introduction of a new drug), but not more than quarterly. This implies that CAP vendors would not have to provide newly approved drugs to physicians—for what could be a period of several months.

It is imperative that all new products covered under Medicare be made available immediately to Medicare beneficiaries. This is especially important in the case of newly approved treatments for prostate cancer—which could extend or save lives.

Also, CMS should clarify in the regulation that physicians who participate in CAP are able to purchase and seek reimbursement for new drugs until they are available from their CAP vendor.

Beneficiary Education

CMS is proposing the preparation of a fact sheet on the CAP program for physicians to distribute to beneficiaries. CMS is interested in whether or not this would be a burden to the physicians.

CMS should require physicians to furnish fact sheets to patients and their caregivers.

We strongly support CMS' proposal to develop patient education materials to explain the CAP and its impacts. We believe that some patients may be confused when they receive a coinsurance bill for a prescription from the CAP vendor and not from their physician and/or someone they recognize. Therefore, information explaining the CAP is essential.

The materials need to be easy to understand and in laymen terms. Our organization would be very willing to help in the development and distribution of materials to beneficiaries.

Thank you for the opportunity to present our comments and concerns.

Sincerely,

Jim Kiefert

Don Lynam

Thomas Kirk

Jim Kiefert
Chair, Board of Directors

Don Lynam
Chair, Legislative Awareness
& Advocacy Committee

Thomas Kirk
President/CEO

Submitter : Dr. Nick Poulos
Organization : Elan Pharmaceuticals
Category : Drug Industry

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-370-Attach-1.DOC



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26 April 2005

**FILED ELECTRONICALLY TO
[HTTP://WWW.CMS.HHS.GOV/REGULATIONS/ECOMMENTS](http://www.cms.hhs.gov/regulations/ecomments)**

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-P (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. We received FDA approval at the end of December 2004 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 treatments, such as systemic analgesics or adjunctive therapies of intravenous morphine.

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 the provisions in Proposed Rule CMS-1325-P, "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B" (the "Proposed Rule") published in the *Federal Register* on March 4, 2005¹. The Proposed Rule describes an alternative distribution model for Part B drugs designed to give physicians a choice

¹ 70 *Fed. Reg.* 10745 (Mar. 4, 2005).



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

Elan commends CMS for its initial efforts toward developing the CAP. To assist the agency fine-tune its implementation plans for CAP and thereby ensure patient access to needed therapies, we offer the following recommendations for minimizing the administrative burdens of CAP and for guaranteeing that physicians are truly free to elect CAP when they believe it will be best for their patients and their practices. We have also included one recommendation specific to Prialt® and other pain medications administered intrathecally through implanted pumps because the Proposed Rule does not expressly address a key question about the applicability of the CAP to such drugs.

I. **Prialt® and Other Drugs Administered Intrathecally Through Implanted Pumps Should Be Eligible for the CAP**

Issue Identifier: Categories of Drugs to be Included under the CAP

Because the option to select participation in the CAP lies with the physician, CMS only intends to implement CAP for “drugs administered as incident to a physician’s service” at this point in time.² CMS has invited comments on the adoption of a potentially broader definition of competitively biddable drugs and biologicals that would allow an expansion of the CAP to drugs, other than infusion drugs, administered through DME (e.g., inhalation drugs), and to some drugs usually dispensed by pharmacies (e.g., oral immunosuppressive drugs). CMS notes, however, that, under MMA, “vaccines, drugs infused through a covered item of DME, and blood and blood products . . . are not included in the CAP because they are expressly excluded from section 1842(0)(1)(C) of the Act.”³

This discussion creates confusion about the status of Prialt® and of opioid pain medications administered intrathecally through implanted variable-rate infusion devices. Historically, opioid pain medications furnished by physicians in their offices have been covered as incident to drugs that are billed through the local carrier, not as drugs infused through covered DME billed under

² 70 Fed. Reg. 10749.

³ *Id.*



the DME benefit through the DMERCs. According to the Medicare Claims Processing Manual, Part B carriers, not DMERCs, are responsible for processing claims for drugs used in conjunction with an implantable infusion pump when the drug is administered by a physician.⁴ In all other instances, however, claims for infused pain medications are to be submitted to the DMERCs and paid under the DME benefit.⁵ A review of current Local Medical Review Policies for implantable infusion pumps also indicates that pain medications furnished by physicians to refill such pumps are to be treated, for payment purposes, as incident to physician services.⁶ Similarly, articles on local carrier websites discussing the coverage on implantable infusion pumps for treatment of chronic intractable pain take the same view.⁷

Given that pain medications like Prialt® can be billed both as incident to services and under the DME benefit depending on where and how they are administered and that infused drugs billed under the DME benefit are, by statute carved out of the CAP, Elan urges CMS to state expressly in the Final Rule that Prialt® and other pain medications administered by physicians intrathecally through implanted pumps to treat intractable pain will be eligible for the CAP once the CAP is available to specialties that administer such pain medications to their patients in-office.

II. The ASP +6% Limitation on Acceptable CAP Bids Is Inappropriate

Issue Identifier: CAP Bidding Process – Evaluation and Selection

Elan has significant concerns about CMS's decision to require potential CAP vendors to submit bids at or below 106% of the weighted composite manufacturers' Average Sales Price ("ASP") for the drugs in the CAP category. Many physician groups, patient advocacy groups, and manufacturers continue to question whether reimbursement at 106% of ASP will prove adequate to permit physicians to afford the costs of Part B drugs (some of which reportedly are not

⁴ CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 127 (Mar. 26, 2004).

⁵ Jurisdiction List, Region B DMERC Newsletters, Supplier Bulletin (June 2003); Local Carrier Jurisdiction, Region C DMERC Newsletters, Medicare Advisory Issue 27, p 129 (Winter 1998).

⁶ See, e.g., LMRP for Implantable Infusion Pump (L4630) for HGS Administrators dated Jan. 1, 2004 (listing physician services under the benefit category); LMRP for Implantable Infusion Pump (L14745) for Blue Cross and Blue Shield of Arkansas dated Dec. 15, 2003 (listing physician services under the benefit category); LMRP for Implantable Infusion Pump (L14744) for Blue Cross and Blue Shield of Arkansas dated Dec. 15, 2003 (listing physician services under the benefit category).

⁷ Implantable Infusion Pump for Treatment of Chronic Intractable Pain (A25893) and Implantable Infusion Pump for Treatment of Chronic Intractable Pain (A25828), both published by National Heritage Insurance Company (Jan. 1, 2004).



available to most physicians at less than ASP + 6%) and the cost of pharmacy management services and other associated expenses, including bad debt, that are currently not considered in the practice expense component of drug administration codes. Because the ASP-based reimbursement model is still new, it remains to be seen whether the traditional buy-and-bill model for furnishing Part B drugs will be sustainable at these payment levels.

By structuring the CAP alternative to the traditional buy-and-bill model using the ASP amount as a ceiling, CMS may be artificially limiting vendors' abilities to offer bid prices that are truly reflective of their costs for drugs and the other costs involved with this new drug delivery model. We appreciate CMS' desire to carrying out the CAP as mandated by the MMA and, at the same time, to reduce the costs of Part B drugs to the Medicare program. We know, however, that the successful implementation of the CAP requires the participation of quality vendors. We are concerned about the impact the proposed ceiling on bid amounts could have on the ability of prospective vendors to participate in CAP and provide the quality, services and financial stability that will be necessary to allow the model to succeed as a viable alternative for physicians who no longer want to buy and bill for drugs furnished to their Part B patients.

It seems unreasonable to assume that competition will cause manufacturers of most single-source drugs to discount their products to CAP vendors or, for that matter, to other classes of buyer that must be considered when Best Price and ASP are calculated. After all, MMA sets reimbursement rates for providers of Part B drugs. It does not regulate how manufacturers must price those products. Similarly, MMA does not provide CMS with authority to interfere in the relationships between manufacturers and their customers. Despite MMA, manufacturers remain free to distribute products under exclusive arrangements with a wholesaler or specialty distributor even though such arrangements will force CAP vendors to buy through these distributors. Manufacturers also can elect to sell more broadly to multiple wholesalers, but still require CAP vendors to acquire products through the normal distribution channel. Simply put, the implementation of CAP does not obligate manufacturers to sell direct to CAP vendors, nor does it require manufacturers to offer these vendors discounts. CMS should expressly acknowledge this reality in the CAP Final Rule.

CAP vendors will incur middleman costs that do not accrue to physicians that operate under the buy-and-bill model. These costs include administrative costs as well as dispensing costs, shipping costs, and costs that result when dispensed product must be destroyed either because it was damaged in shipment or it could not be administered to the beneficiary for whom it was originally dispensed. Bad debt undoubtedly will add to these costs.



Even though physician practices have personal relationships with the patients they treat, many report having substantial difficulty collecting coinsurance on expensive Part B drugs. In all likelihood, CAP vendors will have more difficulty collecting. They will not have the ability to seek payment on the day a drug is administered. Rather, under the claims processing procedure in the Proposed Rule, they will have to wait until they have been paid the 80% due them for drugs by the Medicare CAP carrier – an event unlikely to occur until a month or more after the drug was administered – before they can initiate the coinsurance collection effort through bills sent by mail. To make matters worse, CAP vendors will not have face-to-face relationships with the beneficiaries they are billing. They will be only an impersonal, invisible distant company that the patient does not know or even necessarily associate with the care received. This reality argues strongly for focused CMS outreach to educate beneficiaries about the operation of the CAP and their responsibility to pay coinsurance amounts to the vendor regardless of the time interval between drug administration and the arrival of the bill

Unlike the situation with physicians where reimbursement for Part B drugs supplied under the buy-and-bill model is set by statute at 106% of ASP, CMS has the discretionary authority under Social Security Act §1847B to set payments to CAP vendors at any level necessary to compensate them fairly and appropriately for their services. Congress only expected competition under the CAP model to save money on multi-source drug products.⁸ It did not expect the same result for single-source drugs nor did it presume to conclude whether the savings on multi-source drugs would be sufficient to drive down overall Part B drug prices to the ASP + 6% level. Rather, it simply directed CMS to “base selection [of CAP vendors] on bid prices for competitively biddable products, bid prices for distribution of those products, ability to ensure product integrity, customer service, past experience with drug and biologic distribution, and other factors.”⁹

Elan does not want the CAP to fail – much as Medicare + Choice did – because of reimbursement inadequacies. Accordingly, we urge CMS to reconsider its decision to pre-define a reimbursement cap for the program. Competition will drive prices under CAP below 106% of ASP if the costs involved in administering the program so warrant. We fear, however, that setting a cap on payments under the new delivery model without giving the market an

⁸ H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 594 (2003) (“The competition within a HCPCS code for multiple source drug products is intended to produce competitive forces that will lower bid prices for drugs.”). See also Social Security Act §1847B(b)(1).

⁹ *Id.* at 595.



opportunity to work could result in too few bidders to meet the statutory requirement that at least two vendors be awarded CAP contracts in each category and area opened to the program.¹⁰

III. **CAP as a Voluntary Program: Adequate Reimbursement for Drug Administration Services Is Key**

Issue Identifier: Overview of the CAP

Elan recognizes that the CAP will alleviate some of the financial pressures that physicians face when they provide drugs to their Medicare patients under the buy-and-bill model. Specifically, under CAP, physicians will no longer bear the administrative and financial burdens of purchasing and inventorying drugs. Nor will they be a financial risk for the collection of coinsurance amounts of "incident to" drugs. Nonetheless, even if intrathecally administered pain medications delivered through implanted variable-rate pumps are included in the CAP, CMS should not assume that patient access to such products in the physician office setting will be improved. The simple reality is that the CAP is not a more viable option for physicians than is the buy-and-bill model if payments for the professional services associated with the administration of drugs do not adequately reflect the physician work and practice expenses involved under either model.

In accordance with the mandate in Social Security Act §§1848(c)(2)(H)(iv) and 1848(c)(2)(J) (as added by MMA §303(a)), CMS substantially increased reimbursement for chemotherapy-related drug administration services in 2004 and further refined those payment rates in 2005. Because MMA was focused almost exclusively on oncology services, there was no statutory mandate to revise payments for other drug administration services such as those associated with the intrathecal administration of pain medications like Prialt®. As a result, even though physicians typically view the refilling and maintenance of variable-rate pumps used to administer intrathecal pain medications as more demanding than the refilling and maintenance of pumps used to administer chemotherapeutics, the payment rates for maintaining implanted intrathecal pumps do not reflect the complexity of the work involved. The 2005 Physician Fee Schedule¹¹ assigns non-facility resource based relative value units ("RBRVUs") to the practice expense component of CPT codes 95990 and 95991 of only 1.50 and 1.46, respectively, compared with practice expense RBRVUs of 3.76 and 2.64 for chemotherapy-related CPT codes 96520 and 96530, respectively. There is no clinical or resource utilization rationale to support this level of differential between the administration of the pain medications and the administration of the

¹⁰ Social Security Act §1847B(b)(3).

¹¹ 69 Fed. Reg. 66235 (Nov. 15, 2004).



chemotherapy. In fact, if any differential in RVUs is supportable, the values assigned to drug administration services associated with the administration of pain medications should be higher than those for chemotherapy.

Regardless of how it structures CAP, Elan encourages CMS to ask the Resource-Based Relative Value Update Committee ("RUC") to review CPT codes 95900 and 95911 before the 2006 Physician Fee Schedule proposed rule is published this summer so that the physician community and other interested parties will have the opportunity to review and comment of the RUC's recommendations before the rule is finalized. If timing does not permit RUC review on this timeline, CMS should, nonetheless, proceed with the review as expeditiously as possible so that more appropriate payment rates for CPT codes 95990 and 95991 can be included in the 2006 Physician Fee Schedule. Otherwise, inadequate reimbursement for professional services may force physicians to refer patient to hospitals for pain management services requiring intrathecal pump refills and maintenance.

IV. The CAP Should Be Open to All Physicians

Issue Identifier: Categories of Drugs to be Included under the CAP
Competitive Acquisition Areas

CMS presents two options for phasing-in the CAP: beginning the program with drugs administered by oncologists or with drugs administered by other specialties. In Elan's view, CMS should not limit physician participation in CAP to only oncologists as this phase-in approach restricts the benefits of the CAP to a physician pool that typically has the practice infrastructure to support the buy-and-bill model for drugs. One of the purposes of the CAP is to provide another choice for physicians who are uncomfortable with this model under the new ASP-based reimbursement methodology currently applicable to incident to drugs.

The buy-and-bill model is unduly cost prohibitive for many non-oncologists, such as neurologists, anesthesiologists and pain management physicians. They simply do not have the inventory and pharmacy management, infusion administration staffing and infrastructure, or the lines of credit needed to effectively and efficiently support the delivery of drugs under a buy-and-bill model. As a result, many of these physicians are unwilling to take on the responsibility for administering drugs to their patients in their offices and choose instead to refer their patients to outpatient hospital departments for treatment. It is these physicians and their patients who could most benefit from the CAP program.



There is no programmatic justification to favor one specialty over another specialty and limit accessibility to the CAP to a particular group of physicians. Elan recommends that CMS provide all specialties the choice to use the CAP as a means of protecting patient access to appropriate drug therapies in the physician office setting where care is often more comfortable for the patient and more affordable for the Medicare program. As long as CMS can ensure that vendors will be able to provide timely access to high quality, properly stored drug products, the initial implementation of the CAP should also include a broad range of drug categories to allow all specialties to participate.

We also favor national implementation so that all physicians will have an opportunity to participate in the CAP. Although CMS cites Social Security Act §§ 1847B(a)(1)(B) and 1847B(a)(2)(C), read together, as authority for the proposition that it has the authority to implement CAP in one or more states, we disagree. Social Security Act §1847B(a)(1)(B) permits CMS to phase in the CAP with respect to “categories” of competitively biddable drugs, not on a basis of geographic regions.

V. **CAP Vendors Should Be Expressly Prohibited from Establishing Formularies**

Issue Identifier: Categories of Drugs to be Included under the CAP

Patient access to critical therapies under the CAP depends largely on physicians having an adequate choice of drugs. Although Congress clearly expected CAP vendors to force generic substitution whenever possible,¹² Congress did not envision the CAP involving the use of formularies that require physicians to (1) select a specific single-source drug over another single-source product that could be considered a therapeutic alternative¹³ or (2) rely upon the Proposed Rule’s “furnish as written” authority, which comes as a welcome addition to the proposal but which forces physicians to reassume the very administrative and financial burdens that the CAP is intended to relieve.¹⁴ Rather, Congress expected CAP vendors to offer at least one drug in each HCPCS code within the category the vendor was selected to furnish. Elan recognizes that the implementation of formularies by CAP vendors would likely save the Medicare program

¹² Social Security Act §1847B(b)(1).

¹³ H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 594 (2003) (“The Secretary will conduct a competition among entities for the acquisition of at least one competitively biddable drug or biological that is a multiple source or a single source drug or biological within each billing and payment code within each category for each area.”).

¹⁴ Elan hope that CMS will include the furnish as written provision in the Final Rule, but we urge CMS to minimize the discretion given to the local carrier to overrule the physician’s decision to use the option through post-payment review.



money, but it opposes such formularies both because they run counter to the dictates of the MMA and Congressional intent and because they have the potential to skew clinical judgment and adversely affect beneficiary access to the most appropriate therapy for the beneficiary's situation.

Elan urges CMS to affirmatively state in the Final Rule that CAP vendors do not have the authority to construct formularies and that they must supply at least one competitively biddable drug within each HCPCS code within each category for each competitive acquisition area. In other words, CMS must not permit vendors to exclude a single HCPCS code that is within a CMS-defined biddable category. When there is only one product in a HCPCS code, as is true with many single-source drugs and most biologicals, and that therapy falls within a CAP category, then each vendor submitting a bid for the category must offer at least one formulation of that product.

As we indicated earlier in these comments, CMS should also clarify that the CAP vendor's obligation to furnish at least one NDC per HCPCS code does not impose any forced sale requirements on manufacturers. Although Congress mandated that CAP vendors offer one drug per HCPCS code in a category, the Social Security Act does not provide CMS with the authority to force manufacturers to contract directly with CAP vendors or offer them discounted prices. CAP vendors are free to attempt to negotiate favorable direct purchase contracts with manufacturers but, if they cannot, they must meet their obligation to offer one NDC per HCPCS code by purchasing those products through established distribution channels from wholesalers that are authorized distributors of the manufacturer and take delivery of all product sold to CAP vendors directly from the manufacturer.¹⁵

Social Security Act §1847B(a)(1)(A)(iii) clearly specifies that physicians should be allowed to choose the "contractor through which drugs and biologicals *within a category* of drugs and biologicals will be acquired and delivered to the physician" (emphasis added). Since Congress mandated that each physician be allowed to select a different vendor for each CAP category defined by CMS, rather than be limited to one CAP vendor for all categories of drugs, Elan urges CMS to clarify in the Final Rule that a physician who selects CAP will not be required to obtain all products from a single vendor. Rather the physician will be permitted to select a different vendor for each CAP category that CMS defines.

¹⁵ Social Security Act §1847(b)(b)(C)(i).



VI. **The CAP Processes Should Be Fine-Tuned to Minimize Burdens on Physicians and Vendors**

Issue Identifier: Claims Processing Overview

Timely Delivery and the Resupply Option. – Many drugs need to be administered on a precise schedule. For patients receiving such therapies, it is imperative for their physicians to be able to administer the right drug at the right time. This can be challenging when changes in a patient’s condition or an adverse drug reaction require immediate adjustments to the patient’s course of therapy. Consequently, CMS should modify the timely deliver requirements and the limitation on the resupply option under the Proposed Rule to provide additional assurances that patients will have timely access to the drugs they need. Elan has three recommendations in this regard.

First, when evaluating prospective CAP vendors, CMS should collect information on each vendor’s personnel statistics, warehouse and dispensing capacities, distribution center locations, and inventory sourcing relationships and compare that data to pre-established criteria that ensure the vendor can handle the dispensing load and time pressures it will be expected to manage. In Elan's view, quality patient care may well demand that CAP vendors have arrangements with a broad network of local pharmacies. Otherwise, the CAP vendors may be unable to make routine and emergency deliveries in time frames adequate to meet patient needs. We note that the Department of Defense and CMS have developed criteria for assessing the adequacy of retail pharmacy networks under Tricare and the Part D rule¹⁶ that will be implemented in 2006. We see no reason why CMS cannot take the same approach to establishing acceptable criteria for CAP vendor delivery networks.

Second, CMS must move beyond the minimum delivery standard set forth in the Proposed Rule. It simply is not sufficient to permit CAP vendors to ship only 5 days a week in a manner that insures routine deliveries in 1-2 business days and emergency deliveries the next business day for orders submitted before 3 pm. Rather, to ensure adequate patient access, CAP vendors must be required to ship 7 days a week and provide routine next-day drug deliveries, with same day or even twice daily “emergency” deliveries.

Third, CMS also should liberalize the emergency replacement and resupply procedures available to physicians who select CAP. The Proposed Rule would allow a physician to use drugs and biologicals from the physician’s own inventory and then resupply the inventory with products

¹⁶ 70 Fed. Reg. 4193 (Jan. 28, 2005).



acquired under the CAP only if the physician demonstrates 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; and (4) the drugs were administered in an emergency situation.¹⁷ CMS does not propose a definition of an “emergency” for purposes of accessing applicable delivery standards or for determining when the resupply option would be available, but asks for comment on how it should be defined.

To avoid interruptions in patient care, CMS must make the CAP more nimble. Although physicians often will be able to plan a patient’s course of treatment far enough in advance to order drugs through the CAP vendor, physicians cannot always anticipate a patient’s response to a particular therapy regime or need. Physicians also cannot predict adverse reactions to a drug. Nor do they know when a scheduled delivery from their CAP vendor will be delayed. The delivery standards and resupply procedures in the Proposed Rule could force a patient who is in the physician’s office needing treatment to go home and wait one or more days for a CAP order to arrive. Not only could this unacceptably delay care, in many instances, it would be burdensome for the patient and perhaps also for a family member or other caregiver assisting the patient, who, by having to return to the physician’s office on another day, would endure additional hardship as a result of the difficulty in traveling to and from the provider’s office and, perhaps, the need to take additional time off from work. The patient also would incur additional coinsurance expenses for an extra physician visit.

To address the timing problem under CAP, a physician should, in most instances, be able to revise a patient’s treatment plan in the morning and still take delivery of needed drugs on the day the patient presents so that patients have the option of waiting a few hours rather than returning another day. We recognize that implementing this option could require a CAP vendor to have an extensive network of relationships with local pharmacies throughout its geographic service area. Such an approach would, however, cut down on the need for physicians to rely upon their own inventories and the Proposed Rule’s resupply option. Elan views this as an important consideration since practices that treat primarily Medicare patients may not maintain sufficient inventories after selecting CAP to satisfy all patient care needs. That said, Elan also believes that patients and physicians should have the choice of immediate access if the physician is able to furnish the needed therapy from his or her own stock without concern about after-the-fact denials of the drug replacement obtained from the CAP vendor under an inappropriate, rigid definition of

¹⁷ Proposed 42 C.F.R. § 414.906(e), *see also* 70 *Fed. Reg.* at 10755.



“emergency.” Otherwise, CAP vendors, not physicians, will be dictating medical decisions for patients. This is simply unacceptable.

Alternatively, if state pharmacy laws permit, CMS could allow physicians to request that a CAP vendor provide, at the vendor’s expense, an advance supply of certain drugs that have not been dispensed by the vendor for a specific patient, but rather that are available to the physician to use only in response to immediate patient needs. The vendor also would be responsible for managing the inventory and seeing that it is rotated as necessary to ensure the availability of fresh product. The physician would notify the vendor when a drug was used from the consigned inventory and provide the vendor with a patient specific order so that the vendor could then bill the Medicare program for the product.

Clerical and Administrative Burdens. – Although CMS states that it does not believe the clerical and inventory resources associated with participation in the CAP will exceed the costs of purchasing and billing for drugs under the ASP system,¹⁸ we remain concerned that this may not be the case.

We are uncertain that applicable state pharmacy laws will allow physicians to use paper or electronic inventories in lieu of holding separate patient-specific inventories of dispensed products. We also believe that state pharmacy laws impose limitations on the use of automated dispensing systems in physician offices. We urge CMS to explore this issue in more detail and to explain in the Final Rule exactly how physicians are to handle drugs sent to them by the CAP vendor.

We suspect the requirement that physicians bill for CAP drugs within 14 days will impose a burden on many practices since CMS admits that only 75% of claims are currently billed this quickly. We also recognize that participation in CAP will eliminate a physician’s ability to make a cost-benefit decision about whether to file an appeal in the face of a claim denial for drug administration services under a new claims appeal process that will require more upfront work on the part of the physician beginning in 2006¹⁹ when CAP also is scheduled to start.

The claims processing system for the CAP also envisions physicians monitoring patient treatment plans and placing orders with vendors in time to have stock on hand for anticipated patient visits.

¹⁸ 70 Fed.Reg. 10755.

¹⁹ 70 Fed. Reg. 11419 (Mar.8, 2005).



CMS should eliminate the requirement that these orders include the patient's height and weight since it is not information that the vendor needs to process an order and file a claim. Physicians also will have to coordinate with CAP vendors when dispensed drugs cannot be used and need to be redirected to another patient. All of these things take time and, as CMS well knows, time is money.

We encourage CMS to review its proposed claims processing requirements and consider input from physicians to ensure that the administrative burden of CAP is, in reality, no greater than the cost of the inventory management and debt collection duties that physician's will avoid by selecting CAP. If CAP costs will be higher, either the process will need to be modified or CMS will need to consider how to pay physicians who select CAP for their increased costs. Since it likely would be difficult to do this through adjustments to the practice expense component of drug administration codes that are used by buy-and-bill physicians as well as CAP physicians, perhaps the creation of a new CPT for CAP management services would be a better approach.

Responsibility for Coverage Determinations -- Although the Proposed Rule indicates that physicians and their local carriers will be responsible for determining whether the use of a drug is consistent with local coverage determination policies, it does not expressly prohibit a CAP vendor from conducting its own coverage review before it ships a drug to the requesting physician. In its statements to the Practicing Physician Advisory Council (PPAC) CMS has said, "nothing in the CAP program in any way modifies the existing coverage process."²⁰ The Proposed Rule provides that no payments will be made to the CAP vendor until after the local carrier has made its coverage determination on the drug administration claim, which suggests that it is CMS' intention that physicians initially should make this determination. However, to ensure that coverage decisions fully reside with the treating physician, subject to review only by the local carrier, and that the CAP vendor cannot refuse to fill an order from a physician who has the CAP, Elan urges CMS to clarify that CAP vendors are not responsible for making any coverage determinations, including decisions relating to the coverage of off-label indications, nor are they permitted to delay or stop a shipment of a drug to a requesting physician based on coverage concerns. In all cases, physicians, not CAP vendors, must decide what therapy a patient will receive.

Application of Least Costly Alternative – The Final Rule should expressly state that local carriers' least costly alternative policies should not apply under the CAP. Substituting one drug's price for

²⁰ "Competitive Acquisition Vendors Should Pay Drug Returns – CMS Doctor Panel," The Pink Sheet, Mar. 14, 2005, at 25.



another's is inconsistent with a system where a vendor competitively bids to supply each HCPCS in a given category at a specific price determined by the bidding process. To impose additional limitations or reductions in reimbursement rates would be unfair to the vendors holding CAP contracts since the rule should require them to ship whatever drug a physician orders.

In addition, administrative hurdles make the application of the least costly alternative ("LCA") approach inappropriate and impracticable under the CAP. Carriers that apply LCA allow physicians wanting to provide the higher cost drug to collect an amount in excess of the Medicare payment from the patient so long as the patient signs an Advance Beneficiary Notice ("ABN"). CAP vendors would not routinely be able to obtain ABNs from patients because they have no patient contact and likely could not rely upon ordering physicians to get ABNs for them.

Partial Payments – Under the Proposed Rule, payments to the CAP vendor are dependent on the filing and approval for payment of the physician's drug administration claims. CMS has asked for comments on whether it should make a partial payment to the vendor when a drug administration claim has not been received within 28 days of the anticipated date of administration.²¹ Elan encourages CMS to adopt a partial payment approach to alleviate potential cash flow problems.

As the Proposed Rule now stands, vendors would be required to wait for the physician's claim to be filed and processed before they could submit a claim to Medicare and then wait for Medicare to process that claim before beginning the coinsurance collection process. Given the delays inherent in the complex claims processing system that CMS envisions for the CAP, it is unreasonable to expect CAP vendors to pay for Part B drugs – many of which can be quite expensive – without receiving some payment upfront. We note too that there is precedent under Medicare for partial payments when lengthy timelines like those potentially facing CAP vendors are involved. Specifically, home health agencies receive a portion of the episodic payment for home care services at the time of patient admission and the remainder at the close of each 60-day episode of care. We suggest the CMS consult with the specialty pharmacy industry to set an appropriate percentage for partial payments under the CAP.

²¹ 70 Fed. Reg. 10755.



VII. **CAP Vendors Need To Have More of a Role in the Appeal of Denied Claims**

Issue Identifier: Dispute Resolution

If the local carrier denies payment for a physician's claim for drug administration services, the Proposed Rule assigns the physician full responsibility for appealing the denial even though the CAP vendor's claim will be automatically denied as well.²² Although the regulation and the physician's CAP election agreement will obligate the physician to appeal all denied drug administration claims, the Proposed Rule fails to include any provisions designed to ensure that the physician puts forth a solid effort when he or she formulates the appeal, assembles all the evidence and argues the case.

The problem that CAP vendors face because of their forced reliance upon physicians to prosecute appeals is significant for a number of reasons. First, the physician's drug administration claim could be for as little as \$20, which is far less than the cost of taking an appeal under current procedures. Furthermore, under the new claims appeal process that becomes effective for Part B providers in January 2006, no new evidence may be introduced after the initial level of the appeal (the re-determination level) so no documentation or legal arguments can be added to the case thereafter. Finally, according to the CAP election agreement posted on the CMS website, physicians will not be required to take claims appeals beyond the reconsideration level (the second level of the new claims appeal process). As a result, we suspect that physicians will rarely take denied drug administration claims to the ALJ level (third level) where, historically, providers have had the greatest degree of success.

Certainly, CMS should specify in the Final Rule that the allowable amount for the drug as well as that for the drug administration should be considered when the amount in controversy is determined for appeal purposes. CMS also should consider appropriate ways for allowing CAP vendors to be parties to appeals, to contribute to the development of appeals at the initial level where the case will have to be framed in full, and to take over moving the appeal through successive levels beyond the reconsideration level if the vendors deems it

VIII. **Ambiguities About the CAP Bidding Process and CAP Payment Rates Must Be Clarified**

²² 70 Fed. Reg. 10758.



Issue Identifier: CAP Bidding Process – Evaluation and Selection

Need for a Bidders' Conference – Elan suggests that CMS conduct a bidders' conference for potential CAP vendors. The conference should involve an open forum much like those held for vendors interested in offering Medicare-endorsed discount cards, freestanding Part D Prescription Drug Plans, and Medicare Advantage plans. CMS should provide more details about the mechanics of the CAP program and answer questions from potential vendors. It should make information available to potential vendors about the structure of the categories and geographic areas that will be open for bid and provide 2004 utilization data for the drugs in each category in each geographic area. Estimates of the number of physicians likely to participate in each category and region as well as the number of beneficiaries likely to be serviced in each category and region, organized by zip code if possible, should be provided.

Weighting for New Drugs -- The Proposed Rule provides no information on how drugs introduced after 2004 should be weighted for purposes of determining weighted CAP bid amounts. Nor does it address how weighting should be adjusted to anticipate the ramp up in sales of newly introduced products brought to market at the end of 2004. These issues must be addressed with particularity in the Final Rule.

Handling of "Not Otherwise Classified" Drugs – CAP vendors must be required to furnish all drugs classified under the miscellaneous J Codes to ensure that Medicare beneficiaries have access to improved treatment options, as they become available. As a practical matter, new drugs may have missed the window for applying for a HCPCS code, or not otherwise have been assigned a HCPCS code, and must, therefore be billed under the miscellaneous J Code. The essential purpose of the miscellaneous J Codes is to provide a reimbursement mechanism for new drug therapies until they can be assigned a specific HCPCS code. The Proposed Rule provides no information on how vendors should account for "not otherwise classified" drugs when they submit their bids. Accounting for them as a group under the miscellaneous codes seems unworkable since prices and utilization can vary widely within this group of products. CMS should clarify in the Final Rule how bids for these products should be structured and how they will be assessed. Further guidance on how not otherwise classified products will be reimbursed under CAP is also essential.

Defining the ASP Values To Be Used in Assessing the 106% Ceiling on CAP Bids – CMS does not say which ASP it plans to use to determine if CAP bids are under the 106% of ASP ceiling it has proposed. Elan urges CMS to use the most current ASP data available and to make



projections for future changes in ASP payment rates. For example, if CMS uses 3Q ASP rates to assess composite bids from CAP vendors for 2006, it should update the ASP rates so the comparison is to amounts during the same time period. The agency made a similar adjustment when it constructed the 2005 payment rates for separately billable drugs furnished by end-stage renal dialysis facilities pursuant to the requirements of MMA §623. In that instance, the agency used the Producer Price Index to update prices from 2003 to 2005.²³

Reporting of Net Acquisition Cost Data and Adjusting Payments to CAP Vendors Over Time — CMS proposes adjusting drugs prices annually based on net acquisition cost data reported by CAP vendors. Prices will be adjusted either up or down based on the cost data. CMS suggests that it plans to establish a threshold level that must be reached before price changes would be implemented and proposes 5% for comment²⁴. Given that payments are to be capped at ASP + 6% when the initial contract is let and that physicians selecting buy-and-bill routinely will receive a 6% mark up on ASP values that are only two quarters old, the 5% threshold seems completely out of line. If contract prices were to be adjusted annually, it would be preferable to make the adjustment based on cost data without any threshold.

Elan would prefer to see CMS exercise the authority given it under MMA to require quarterly reporting of net acquisition costs by CAP vendors²⁵ so that it could implement routine quarterly adjustments to CAP prices. This approach would put CAP vendors on a more level playing field with physicians who continue to operate under the buy-and-bill model. It seems unreasonable to expect CAP vendors to live with a 15-month lag in pricing when physician who do not elect CAP will only face a 6-month lag.

Elan also urges CMS to stipulate in the Final Rule that all data provide by CAP vendors on their reasonable, net acquisition costs is proprietary and confidential trade secret information that will be afforded the same protections as AMP and Best Price data reported for Medicaid drug rebate purposes and ASP data reported to support Part B reimbursement under the buy-and-bill model.

CMS proposes making CAP pricing changes more frequently than annually but no more frequently than quarterly in three cases: (1) introduction of a new drug, (2) expiration of a drug patent, or (3) a material shortage that results in a significant price increase.²⁶ We agree with the

²³ 69 *Fed. Reg.* 66236, 66321 (Nov. 15, 2004).

²⁴ 70 *Fed. Reg.* 10764.

²⁵ Social Security Act §1857B(c)(7).

²⁶ 70 *Fed. Reg.* 10765.



first and the last of these exceptions. However, in our view, it is inappropriate to tie a price change to the expiration of a patent, particularly for biologicals for which follow-on generics are not yet lawful. The relevant question is not whether a drug is under patent, but rather, whether generic competition for the drug has actually entered the market. CMS should clear up this point in the Final Rule.

Compounded Drugs under the CAP – The Proposed Rule is silent on how compounded drugs will be handled under the CAP. Potential vendors are given no information about how to include the provision of such drugs in their bids nor are they told how prices for compounded products will be set. We are not surprised by this omission given the essentially infinite variety of compounded orders that could be placed with a vendor. Furthermore, we recognize that CMS has not yet developed a consistent national reimbursement policy for compounded drugs under the buy-and-bill model or under the DME benefit. Instead, it has elected to give local carriers the discretion to set the reimbursement methodologies used to pay for compounded products. As a result, a variety of methodologies have proliferated, some of which appear to underpay physicians for pain management drugs and likely contribute to underutilization of appropriate pain management among the Medicare population.

Elan urges CMS not to let the CAP follow in the footsteps of buy-and-billing in this regard. Rather, we encourage CMS to develop a rational payment methodology for compounded drugs and include compounded drugs in the CAP. Chronic intractable pain is reportedly undertreated in this country despite the fact that unrelieved pain has many negative health consequences including, but not limited to: increased stress, metabolic rate, blood clotting and water retention; delayed healing; hormonal imbalances; impaired immune system and gastrointestinal functioning; decreased mobility; problems with appetite and sleep, and needless suffering.²⁷ Chronic nonmalignant pain also causes many psychological problems, such as feelings of low self-esteem, powerlessness, hopelessness, and depression. Undertreatment can result in suicide. In a recent survey, 50% of chronic pain patients had inadequate pain relief and had considered suicide to escape the unrelenting agony.

To address this problem, CMS should take steps to maximize patient access to the full range of therapies for the management of intractable pain, including compounded drugs. In Elan's view, the single most important step the agency could take would be to establish clear, consistent payment rules for compounded drugs under both the CAP and the buy-and-bill model. Elan favors a payment methodology based on acquisition cost (invoice) plus an adequate percentage

²⁷ "Chronic Pain Fact Sheet" by Marcia E. Bedard, PhD, at http://www.cssa-inc.org/Articles/Chronic_Pain.htm



markup to reflect incurred costs because we believe that level of reimbursement is necessary to ensure that physicians can afford to treat Medicare beneficiaries faced with intractable pain. We also feel strongly that making compounded drugs available through the CAP will improve patient access because, in our experience, many pain management physicians are unwilling to take on the administrative burden and the financial risk of purchasing compounded products for their Medicare patients

Liability for Returned Product – The Proposed Rule recognizes that drugs will not always be administered to beneficiaries on the expected date. Even though CMS wants to ensure that unused drugs will be redirected to other patients to the extent possible, considering not only the needs of other patients of a physician practice but also applicable state pharmacy laws, it is inevitable that in some circumstances, drugs will need to be returned to the CAP vendor or destroyed as hazardous waste. Because the statute requires the CAP vendor’s bid price to include shipping and delivery costs, Elan endorses the position taken by the Practice Physician’s Advisory Committee that the cost of shipping product back to the vendor, when appropriate, also should be borne by the vendor. So too should the cost of any necessary hazardous waste disposal required when it is not feasible to return unused drugs to the CAP vendor. Elan also encourages CMS to explore further the potential for substantial increases in drug wastage under CAP if state pharmacy laws limit the ability of physicians to redirect dispensed product to other patients.

IX. CAP Must Be a Physician-Specific program, Not a Practice-Specific Program

Issue Identifier: Physician Election Process

Social Security Act §1847B(a)(1)(A)(ii) states that *each physician* may select between the buy-and-bill model and the CAP model on an annual basis. Further, §1847B(a)(1)(A)(iii) required that *each physician* selecting the CAP option be given the opportunity to pick the CAP vendor of his or her choice. CMS’s decision to make the choice between the buy-and-bill model and the CAP model a group practice decision²⁸ rather than a physician-specific decision is contrary to the plain language of the statute. It is also inconsistent with Congress’ stated intent that the choice of CAP should “be completely voluntary on behalf of *the* physician.”²⁹

²⁸ 70 *Fed. Reg.* 10766 (“We propose that, consistent with the Medicare Participating Physician Process, if members of a group practice elect to participate in the CAP, the entire practice would participate. . . . We propose that when a physician bills as a member of a group using the group PIN, he or she must follow the group’s election to participate or not to participate in the CAP”).

²⁹ H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)



CMS has justified its decision to make the choice between buy-and-bill and CAP a group practice choice by saying that Social Security Act §1847B(a)(5)(A) “requires that we coordinate the physician’s election to participate in the CAP with the Medicare Participating Physician Process described in section 1842(h) of the Act.”³⁰ That is not quite right. What §1847B(a)(5)(A)(ii) actually requires is that “[t]he *selection of a [CAP] contractor . . . shall be coordinated with agreements entered into under section 1842(h) [which authorizes the Medicare Participating Physician Process]*” (emphasis added). Instead of reading the statutory requirement to “coordinate” the CAP vendor selection process with the Medicare Participating Physician Process simply as a directive to minimize paperwork by aligning the two selection processes in time and utilizing the same form for both, CMS has taken a completely different tact. It has separated the two selection processes in time but chosen otherwise to model the CAP selection process after the Medicare Participating Physician Process. In so doing, it has converted the CAP selection process into a group practice decision and effectively eliminated the option of individual physician decision-making about CAP required by the plain language of statute.

We anticipate that in some instances, physicians in group practices will be unable to come to agreement about the choice between the buy-and-bill model and the CAP model. On the one hand, some physicians feel strongly about the risks to product integrity under CAP because of problems with counterfeit drugs experienced under the MVI programs required by certain commercial insurers. Others are concerned about the potential impact on beneficiary access if CAP vendors are permitted to “cut off” patients who fail to make timely coinsurance payments. Still others simply do not see how they can afford the increased administrative burden and increased drug-handling costs expected under CAP. On the other hand, other physicians see CAP in the way CMS has characterized it: “an alternative to physicians who d[o] not want to be in the drug purchasing business and d[o] not want to have to collect coinsurance on drugs.”³¹ These types of concerns promise to be more difficult to resolve than are disagreements about participating physician status and we could envision situations where the CAP question could cause practices to dissolve. Accordingly, Elan urges CMS to follow the language of the statute and recognize in the Final Rule that the CAP election must be made physician by physician.

X. **The Importance of Beneficiary Education About The CAP**

Issue Identifier: Beneficiary Education

³⁰ 70 Fed. Reg. 10765.

³¹ 70 Fed. Reg. 10749.



Elan applauds CMS for recognizing that beneficiaries will need to be educated about the CAP and its effects on their treatment options and financial responsibilities.³² Providing physicians with a fact sheet, including information in the “Medicare & You” handbook, and making information about the CAP available on the www.Medicare.gov website and at 1-800-Medicare will help to ease physicians’ burden of explaining the program to their patients. CMS should also elicit help with beneficiary outreach from patient advocacy groups serving patient populations most likely to be affected by the CAP. Finally, CMS should require CAP vendors to have in place procedures for assessing indigence and referring patients in need of financial assistance beyond coinsurance waivers that the vendor is prepared to offer under its own indigence policy to pharmaceutical companies that offer free drugs to needy patients and to foundations and other patient advocacy groups that offer financial assistance with copayment and coinsurance to qualified individuals.

We appreciate the opportunity to comment on the Proposed Rule and we hope our suggestions will help CMS structure the Final Rule in ways that will make the CAP a workable option available to all physicians who furnish Part B drugs to their patients. As we said above, there is no programmatic justification for favoring one specialty over another specialty and limiting accessibility to the CAP to a particular group of physicians. Especially for non-oncology products, allowing all specialties the choice to use the CAP will protect, and quite probably improve, patient access to appropriate drug therapies in the physician office setting where care is often more comfortable for the patient and more affordable for the Medicare program. To achieve the full benefit of the CAP option for pain management therapy, CMS also must ensure that compounded drugs will be available through the CAP.

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.

Yours sincerely,

A handwritten signature in cursive script, appearing to read "Nick Poullos MD".

Nick Poullos, PhD
V.P., Pricing and Reimbursement

³² 70 Fed. Reg. 10767.

Submitter :

Date: 04/26/2005

Organization :

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-371-Attach-1.DOC



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April 20, 2005

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

Dear Dr. McClellan:

RE: Competitive Acquisition Program – CMS – 1325 – P

The American Academy of Neurology appreciates the opportunity to comment regarding 42 CFR Part 414 – Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed Rule.

Categories of Drugs to be included under the CAP

CMS could initially implement the CAP for a limited set of drugs that are typically administered by oncologists. Drugs administered by other specialties would be included over the next few years to the program. The largest portion of expenditures for incident-to drugs under Medicare is the oncologist. An advantage of this oncology option is that during the phase in, CMS can focus the implementation efforts on one specialist with a more uniform set of concerns and issues. With the required physician education process, it would be streamlined and potentially more effective. Also, because oncology is such a large part of Part B, the program would realize much of the benefit that is possible under the CAP.

Narrowing the scope would limit the ability for CMS to identify concerns for specialties not initially included and that the CAP would not initially provide an alternative for physicians in other specialties. Phasing-in the program with one or more specialties other than oncology would allow lessons and issues to be identified prior to phasing-in larger drug classes at a later date. By limiting the program to smaller specialties, this could restrict the benefits of the program. The smaller market could discourage potential vendors from making a bid.

Competitive Acquisitions Areas

The phase in will occur by geographic area. Proposals for phasing in areas of the country are: 1) by region, 2) by state, or 3) no phase-in (include the entire county). By phasing-in across the country in one or two specialties for all drugs would allow a better idea of the magnitude of problems that are encountered across the country and would provide a snapshot of what the benefits/limitations are for a group of physicians with similarly situated practices. Regional market players in the pharmacy industry would otherwise be able to exert too much control over the market, possibly influencing price.

The physician should be allowed to pick and choose which drugs she/he will obtain through the CAP. The physician should be allowed to opt out of the CAP on an as needed basis as well, for drugs he/she has elected to obtain through the CAP, if she/he can get these drugs at a lower cost. The physician should be able to shop around for CAP vendors, and should not be held accountable to only one CAP vendor. Requiring the doctor to purchase all drugs through one CAP vendor for the period of one year will not allow the flexibility required for the physician who administers the drugs. It will reduce competition on the market and may ultimately lead to higher prices. If there is a shortage of a drug in the market place the physician needs to be able to obtain drugs from other sources.

Statutory Requirements Concerning Claims Processing

- CMS is proposing an exception to allow physicians to purchase a drug and seek reimbursement under the ASP-based methodology if medical necessity requires a specific formulation to be administered to a patient and the vendor does not furnish that formulation. This will create additional administrative burden.
- As a control to assure that vendors are billing only for drugs prescribed by physicians, a prescription number will be placed on the physician claim for drug administration services and this number will also be on the drug vendor claim. Currently, most billing systems are not designed to accommodate this number. Physicians will have to incur the cost of purchasing new software or editing their existing program.
- Physicians can treat a beneficiary with a drug from his or her stock in emergency situations. Physicians will also be allowed to obtain a drug under the ASP methodology in “furnish as written” cases when medical necessity requires that a specific formulation of a drug be furnished to the patient and it is not on the vendor’s list. A special modifier would be required on the claim, which would be subject to post-payment review to determine whether the specific formulation was medically necessary. Physicians obtaining drugs through the CAP would be required to agree to submit claims within 14 days of the date of service, unless there were extenuating circumstances. The 14-day window is not flexible enough for claims filing. Even the most diligent physician sometimes will be unable to meet this timeline. Extenuating circumstances need to account for problems with documentation, internal pre-billing audits and quality assurance activities. Offices may have to change billing practices in order to accommodate this requirement.
- If drug supplied by a vendor is not administered “on the expected date of administration,” the physician would notify the vendor and “reach an agreement on how to handle the unused drug, consistent with applicable State and Federal law.” If the vendor and the physician agree that the drug could be used at a later time for another Medicare patient, the physician would generate a new order for that other patient but note on the form that the vendor need not ship the drug. More undue administrative burden will be placed on the physician.
- The CAP vendor, not the physician, will file the claim with Medicare and receive payment for the drug. Providers must send patient information to the approved vendor for coinsurance collection. This means physicians will lose control over the collection process and the vendor may aggressively pursue the patient for collection. The CAP program could also negatively affect the most vulnerable patients. The vendor will not have an incentive to screen indigent patients for referral to patient assistance programs, thus creating a possible interruption in care and an undue financial burden to the patient.

Dispute Resolution

- In the case of claims that are denied for medical necessity or other reasons, only the physician will have appeal rights thus the physician will have to do all the paperwork to appeal the claim for vendor payment.

- It remains unclear what will happen if the drug arrives in a damaged vial, or the patient's condition now requires a new drug. Who then pays for the return shipping, and for the vial of unusable drug? CAP vendors should absorb the cost of returning drugs, or unusable drugs, and that the CAPs must be willing to advance credit for drugs for patients with no ability to pay the co-pay.

We are troubled that that CAP will be implemented without any testing or analysis of what is a significant change in the drug delivery system. Some specific concerns we have about CAP as currently structured are as follows:

- Doctors must select one CAP vendor to obtain all of their Part B drugs. Vendors would be required to supply a drug for each of the HCPCS J-codes identified, but in the case of multiple-source drugs, they would only be required to supply one manufacturer's version. Physicians may be forced to change a patient's therapy based on drugs available. Vendors should be required to inform physicians during the election period as to which manufacturer's products they would be dispensing in the case of multiple-source drugs.
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We thank you for the opportunity to comment on these important issues. If you have any questions about our comments please contact Ms. Kristina Schaab at the AAN (651)695-2783 or kschaab@aan.com.

Respectfully yours,

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

kms



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Respectfully yours,

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

kms

Submitter : Ms. Sita Diehl
Organization : NAMI Tennessee
Category : Social Worker

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

Please include psychiatric drugs in phase 1 of the CAP process. Medications are critical to ability of people with SPMI to live and work in their communities. Please include all of the classes of psychiatric drugs as individual classes, e.g. 1. atypical antipsychotics, 2. neuroleptics, long acting injectibles, 4. SSRIs, 5. TCAs, 6. MAOIs and other 7. antidepressants, etc. Please require vendors to dispense psychiatric medications even if the consumer does not pay the co-payment.

Submitter : Dr. Gary Stein

Date: 04/26/2005

Organization : American Society of Health-System Pharmacists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-373-Attach-1.DOC

April 26, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
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P.O. Box 8010
Baltimore, MD 21244-1850



Re: CMS-1325-P, Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B

To Whom It May Concern:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS's) March 4, 2005, proposed rule that would implement a competitive acquisition program for certain Medicare Part B drugs not paid on a cost or prospective payment system basis, as required by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems.

As of January 1, 2006, physicians will be able to choose between obtaining these Part B drugs from vendors who are selected through a competitive bidding process or directly purchasing these drugs and being paid under the average sales price (ASP) system. CMS's proposed rule particularly seeks comments on which of the proposed approaches the agency should use to implement the competitive acquisition program as well as the criteria and standards that should be applied in the selection and enrollment of vendors.

Although CMS seems to have done a good job in developing this proposed rule given the framework of the law, ASHP members are concerned about whether, under either the competitive bidding process or the direct ASP purchase of these drugs, physician offices will be able to continue to afford to provide appropriate medication therapy to Medicare beneficiaries.

There are many reasons that the CAP program could result in physicians' decisions not to administer a drug prescribed for a Medicare beneficiary. The administrative burdens that will be associated with operating a physician's service, such as an oncology practice, could be detrimental to patient care because of added costs due to the need to maintain a dual ordering and inventory system and the need to match the physician's and the vendor's bills.

ASHP's members are particularly concerned that the CAP program has the potential of shifting oncology patients from treatment in physicians' offices to inpatient hospital

treatment. Assuring that the CAP program will sufficiently reimburse physicians for handling costs of drugs will be necessary to prevent this scenario.

Another concern is that the proposed rule states that a physician would transmit the information to a CAP drug vendor from whom the physician elects to receive drugs, formats, such as "frequency/instructions," a patient's date of birth, allergies, height, weight, and diagnosis code. This seems to contemplate that the vendor will perform a pharmacist-type review of the physician's order and label the drugs with instructions for use. There is no basis in MMA or in other CMS regulations for such action. ASHP believes that the statute intends that a CAP vendor act like a drug wholesaler, not a pharmacist, simply filling physician orders.

For more than 60 years, ASHP has helped pharmacists and pharmacy technicians who practice in hospitals and health systems improve medication use and enhance patient outcomes. We appreciate the opportunity to present comments on this important patient care issue. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at gstein@ashp.org

Sincerely,

A handwritten signature in black ink, appearing to read "Gary C. Stein". The signature is fluid and cursive, with a long horizontal stroke extending to the right at the end.

Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

Submitter : Dr. Vikki Canfield
Organization : Cancer Care Associates
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1325-P-374-Attach-1.DOC

April 25, 2005

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

RE: CMS 1325-P Comments on the Proposal for Competitive Acquisition of Outpatient Drugs and Biologics Under Medicare Part B

To Whom It May Concern:

This letter is in response to the CMS request for comments regarding the Competitive Acquisition Program (CAP) as proposed by CMS as part of the Medicare modernization act of 2003. We represent Cancer Care Associates, a 36 physician practice in the state of Oklahoma. We serve multiple sites of service with physicians specializing in hematology, medical oncology, gynecologic oncology and radiation oncology. We provide cancer care to over half the rural and urban oncology patients treated in Oklahoma. We have reviewed the proposed plan and have several comments.

The benefit of the proposed CAP to our oncology patients is dubious, at best. Patients will likely have to make more doctor visits to be treated, and will receive additional bills which will be confusing and require explanation. It will not make chemotherapy any less expensive for patients. More payments from patients in the form of co-pays may be necessary, since they will be paying two different entities for services which may not occur on the same day or in the same place. The program will increase the amount of paper work and record keeping required of physician practices and hamper the physician-patient relationship by taking up more practice resources and leaving less time to devote to patient care. Unfortunately, the CAP does not address the crucial problem with chemotherapy reimbursement, that complex cancer treatment services per se are still inadequately reimbursed.

CMS realistically admits in its discussion of the plan that it may not save money for the government. The CAP appears to be more costly than the current ASP reimbursement system. A point also mentioned in CMS discussion. Further, the program will require additional governmental employees just to manage and administer the CAP program. In light of these realities, one must question who or what the program is designed and intended to benefit if not the patient, the publicly funded governmental agencies, or the physicians providing patient care. It readily appears that the ones to truly benefit from the CAP system are the vendors and pharmaceutical companies. The program allows middlemen to capture a larger share of the profit from the sale and distribution of cancer chemotherapeutics with not even a trickle down benefit for the patient.

This program was first initiated at the time that Thomas A. Scully was Director of CMS. Mr. Scully has been widely criticized for his ethics waiver and the fact that he negotiated his future employment prior to leaving CMS. Mr. Scully is now an affiliated advocate of laboratories, pharmaceutical companies, management companies and other entities who will reap the benefit of the CAP to the detriment of the oncology community, the governmental agencies and the patient. A cursory review of internet reports on Mr. Scully's allegiances, which we encourage you to review, does not present a pretty picture. Many of the companies he is now affiliated with, or is an advocate for, are the apparent beneficiaries, as well as potential vendors, of this ill conceived preferential program. The knowledge and appearance of such conflicts of interest makes it all the more imperative that this program be more closely examined.

The proposed program does not force pharmaceutical companies to lower their prices to levels more in line with Asia, Europe, or elsewhere. The program does not protect against obvious conflicts of interest or abuses by those who would commercialize cancer care.

We strongly oppose institution of the CAP program, and believe it will wreck havoc on the delivery of cancer treatment in America. While participation is initially voluntary, we are concerned that it could become mandatory for the treatment of Medicare beneficiaries. If the program is implemented despite the strong objections of the oncology community, then we suggest the following issues be carefully and methodically addressed.

CATEGORIES OF DRUGS TO BE INCLUDED UNDER THE CAP

1. Consider only including drugs where there will be significant savings for the patient and CMS if the drug is obtained through a CAP program rather than by the physician. (the proposal implies that there probably will not be significant savings for the patient or Medicare for most drugs)
2. Limit the initial phase in to the district of Columbia and four surrounding states, and not expand to other states until the program is working well. Alternatively, start with a specialty such as rheumatology or urology that has a limited amount of drug use.
3. Include only drugs administered in a physician=s office, including chemotherapy, biological therapy, radiopharmaceuticals and supportive care drugs such as anti-emetics and growth factors. Newly approved drugs should be included as soon as commercially available.

COMPETITIVE ACQUISITION AREAS

1. The areas should correspond to the states or areas currently managed by a single Medicare carrier.
2. Each area should have at least five qualified vendors from which to choose.
3. Physicians/practices should be allowed to change vendors quarterly to encourage competition in a rapidly changing marketplace.
4. The plan should allow for the most competition and for participation of smaller vendors and those with local or regional ties.
5. A grievance policy should be defined for all parties.
6. The program should minimize the record keeping burdens which are already onerous, and should pay the practice for the added bureaucratic expense.

STATUTORY REQUIREMENTS CONCERNING CLAIMS PROCESSING

1. The ability for physicians to write prescriptions for courses of treatment rather than individual doses may save on paper work, but changes in doses due to toxicity, drug intolerance, tumor progression or patient mortality will increase the likelihood that drugs are distributed, but not administered, creating additional logistical problems. Even if the physician writes a script for a course of treatment, the vendor should bill for each dose separately.
2. Separate claims for drugs and drug administration services creates more paperwork for Medicare.
3. Vendor and Physician should both be required to submit claims within 30 days of the drug prescription. Medicare should be responsible for seeing that both claims have been submitted prior to reimbursing .If the vendor submits a claim that includes all the doses of drugs for a course of therapy, they should be paid for each dose when the corresponding administration claim is submitted.
4. The issue of what happens to a drug dispensed and not used is not addressed. Defective or contaminated drugs, broken vials, and outdated drugs must be addressed. Does the vendor get paid for the unused drug in

any circumstance? Can the physician return unused drug, and if so, in what time frame?

CAP CONTRACTING PROCESS

1. The time interval between ordering drug and being able to treat the patient should be less than 72 hours, and there should be a mechanism to obtain drugs on an emergency basis within 24 hours. Safeguards for avoidance of sunlight, heat, and dangers of transport are very concerning.
2. If a drug is dispensed and an administration claim is denied, will the vendor still be paid for the drug? This is not clear in the proposal.

CAP CONTRACTING PROCESS-QUALITY AND PRODUCT INTEGRITY ASPECTS

1. Does CMS seek to see if entities applying to be vendors are solvent for reasons of competition or quality control?
2. Bidders should address financial relationships already in place with physician practices as well as their financial relationships with manufacturers and others to rule out conflicts of interest or double dipping.
3. The drug vendor will have an unavoidable temptation for abuse, since their prime reason for existence will be for profit as an additional middleman in the practice of oncology.
4. The vendor should guarantee product integrity in shipping and handling. The physician should be able to return any suspicious drug or any broken vials.

CAP BIDDING PROCESS AND EVALUATION AND SELECTION

1. Please clarify that CMS would pay the vendor's delivery and dispensing costs including shipping and that the vendor CANNOT charge physicians for these expenses.

PHYSICIAN ELECTION PROCESS

1. Please clarify if physicians who do not elect to participate in the first year will be penalized in any way similar to previous government programs. There is no incentive for our practice to enroll when there are more administrative hassles for physicians including keeping patient-specific inventories. It is unlikely that physicians practice costs for administering chemotherapy will go down!
2. CMS intends to quantify the additional burden of the CAP program on physician practices, but there is no stated intent to reimburse for that additional work.
3. No vendor should be paid more than an individual physician would be paid at 106% of ASP, directly or indirectly, from being a vendor or in combination with any other middleman capacity they may simultaneously have.
4. CMS needs to clarify what the physicians responsibility is if a claim is denied or there is a dispute with a beneficiary.

If neither patients, nor the government as payor, will benefit from the proposed system, we question how this proposal will "improve" patient care or efficiency. Review of the proposal clearly shows that the physicians will certainly not benefit by increased administrative costs, inadequate reimbursement for their services, or increased paperwork. Our time is best dedicated to patient care and disease management. This

program leaves the only foreseeable beneficiaries of the program, as far as we can see, to be the manufacturers of chemotherapeutics and institutional middlemen. The idea of accelerating already steep costs of cancer treatment with no recognizable benefit to the public should be condemned.

Commercial exploitation of our most critical human needs will only aggravate the problem. The rising cost of American medical care, and particularly drug costs, is increasingly a major focus of the general public, the medical community, outside business interests and our elected representatives. Our joint focus is best directed toward programs that optimize and improve patient care, treatment and the delivery of patient services. CMS should be at the forefront of constructive change rather than commercial exploitation. Practice management firms and similar middlemen already exact a heavy financial toll on the medical profession struggling to deal with the maze of regulations and administrative requirements. To add yet another level of costly intermediaries does little to alleviate our legitimate concerns.

CMS is expending great effort on implementing a program that will not save money, will inconvenience patients, and will complicate physician practices. Ultimately, the viability of continuing to provide oncology care in our communities under either the ASP system or the CAP system is dependent on the adequacy of reimbursement for chemotherapy administration. Physicians must be able to acquire chemotherapeutic drugs at a reasonable price and be reasonably reimbursed for the services they perform.

Thank you for the opportunity to share our thoughts.

Sincerely,

Daron Street, M.D.
President of Cancer Care Associates

Vikki Canfield, M.D.
Immediate Past President of Cancer Care Associates

CC: Senator Tom Coburn
Senator James Inhofe
Representative John Sullivan
Representative Dan Boren
Representative Frank Lucas
Representative Tom Cole
Representative Ernest Istook

Submitter : Dr. darell smith
Organization : six county inc.
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-375-Attach-1.DOC

Attach#375

April 25, 2005

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

RE: Request to Include All Mental Health Therapies in Phase 1 of Competitive Acquisition Program (CAP)

To Whom It May Concern:

As a community psychiatrist for the past forty years and as medical director of a non-profit community mental health center serving children, adults and older adults in six rural southeastern Ohio Appalachian counties, I make the following strong requests to the Centers for Medicare and Medicaid Services.

The first strong request is to include **all** psychiatric medications in Phase 1 in the Competitive Acquisition Program (CAP) to alleviate barriers inherent in the current system and to enhance access to the new long-acting injectable antipsychotic medications, for Medicare eligible patients. It is very important also that the Centers for Medicare and Medicaid Services create a category of Part B drugs that includes psychiatric drugs including long acting injectable antipsychotic medications. These inclusions would simplify, streamline and make more efficient the access to these psychiatric medications to Medicare eligible patients as well as the billing and payment for these medications themselves, especially for the new injectable long-acting antipsychotic medications. I would also strongly urge the Centers for Medicare and Medicaid Services, in finalizing the reimbursement processes to the selected specialty pharmacy provider vendors, that the final reimbursement processes include how vendors are to address uncollectible co-pays and any other reimbursement issues that would threaten therapy consistency.

It is my belief that, if the above requested inclusions are made in the finalization of the CAP, this will improve and increase access to the new injectable long-acting antipsychotic medications and will shift the reimbursement process for the medication from the psychiatric service provider to the specialty pharmacy provider vendor, where it should be. For one new injectable long-acting antipsychotic medication, the current process is dramatically different than for all other psychiatric medications, injectable and oral, that me and my fellow physicians here at the community mental health center prescribe and a nurse administers the injectables.

For this one new injectable antipsychotic medication, the current process is the exception in comparison to all other psychiatric medications we prescribe and/or administer. The current

process for this one injectable medication is time consuming and burdensome for the professional nursing and support staff and the Medicare patient, and causes additional costs in

staff time as well as cash flow problems for our non-profit and budget strapped mental health service provider. This new injectable antipsychotic medication is very costly. The current process for this one new injectable antipsychotic long-acting medication involves several steps that make the process time consuming, cumbersome and costly for the Medicare patient and the service provider which increase the cost for Medicare. The current process involves completing patient benefits verification forms, submitting them to the benefits verification vendor; obtaining verification of the patient's payer source for the medication itself, then ordering the medication from its distributor, receiving a bill from and paying the distributor of the medication, and finally, administering the injectable medication to the Medicare patient and the billing, and awaiting payment from, Medicare for the medication itself.

This "buy and bill" system can cause cash flow problems for the budget tight service provider, the real potential for which exponentially increases as the number of patients on the new injectable antipsychotic medications increases. This process certainly adds precious and limited professional nursing and support staff time and thus increases costs, in my view, unnecessarily. Patients receive this new injectable antipsychotic medication on a bi-weekly basis, and this new injectable medication is proving very effective in managing the patient's psychotic symptoms, enabling the patients to have better daily functions in the community. These are patients whose symptoms were not successfully managed on older antipsychotic medications, either the oral or injectable ones.

In contrast to the above described process for this new injectable antipsychotic medication, for all other injectable psychiatric medications, I and my fellow physicians issue a prescription that the Medicare or Medicaid patient takes to their pharmacy which then dispenses the medication by vial to the patient. The patient brings the vial with them to their appointment with me. The injection is then given by one of our psychiatric nurses and we retain the medication as patients are usually on a bi-weekly schedule for their injection. We then bill Medicare or Medicaid for the injection only and have no involvement in the ordering, payment to a distributor, and then billing to and awaiting payment from Medicare and Medicaid for the medication itself. This system for all other injectable psychiatric medications that are obtained by the Medicare patient at his/her pharmacy is a superiorly more efficient and more reliable and simple, system for the patient and the service provider. This has been the long established system to obtain all psychiatric medications whether oral or injectable that has required no additional nursing and support staff time and no cash flow problems for the service provider and no delays in the Medicare patient receiving the medication when they need it.

It is my understanding that the above described process for this one new injectable long-acting antipsychotic medication will be the same process for other new injectable long-acting antipsychotic medications that come on the market in the future unless the above requested Inclusions are made into Phase 1 of the CAP.

I appreciate the Centers for Medicare and Medicaid Services consideration of my request for the above specified Inclusions in the Competitive Acquisition Program.

Sincerely,

Darell Smith, MD
Medical Director

Submitter : Thelma Gordon
Organization : Jackson Health Systems
Category : Nurse

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

IT is very important for the care of persons with chronic mental illness to be able to have access to medication which will help them improve or maintain their quality of life and ability to function. It is therefore imperative that CMS include psychiatric drugs in initial stages of CAP(scheduled to begin Jan. 1, 2006) as this will help to alleviate some of the barriers present in the current system.

It is also necessary that CMS creates a category for mental health drugs including the long acting injectable psychotics such as Risperdal Consta and any other long acting injectables that may be developed in the future. It is of utmost importance that CMS addresses how vendors will collect uncollectable copays and other reimbursement issues that will threaten continuity of care and ability to maintain optimal mental/psychiatric health.

Submitter : Mr. John Wardle
Organization : PharmaCare
Category : Health Care Industry

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-377-Attach-1.DOC

April 25, 2005

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

Via Electronic Mail

Attention: CMS-1325-P

Re: Comments on Proposed Rule: Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals under Part B. NPRM CMS-1325-P(42 C.F.R. Part 414)(70 Fed. Reg. 10746, March 4, 2005)

Dear Dr. McClellan:

PharmaCare appreciates the opportunity to comment on the Proposed Rule to adopt standards for the competitive acquisition of Outpatient Drugs and Biologicals under Part B of the Medicare Program.

PharmaCare Specialty Services performs a full range of therapy management services for patients with complex and expensive chronic diseases, their physicians, and their health plans. Specifically, through our primary specialty mail service pharmacy located in Pittsburgh, Pennsylvania, we deliver specialty medications to patients' homes or physicians' offices. In addition, we provide access to 39 specialty pharmacy locations, seven satellite mail facilities, and 31 retail stores nationwide.

Our specialty program was established to create an intimate partnership with our patients. Patients have access to our clinical pharmacists 24 hours a day, seven days week. Also, PharmaCare Specialty Services has implemented a comprehensive set of disease-specific care management programs under the name ProtoCall™. These programs incorporate the use of treatment guidelines, provider coordination, patient support, outcomes, and feedback to optimize quality and manage overall treatment costs.

Currently, we offer specialty services to more than 40 million members through our relationships with managed care organizations nationwide. We have extensive payor contracts with over 300 different payor plans, including Medicare, most state Medicaid plans, renal disease programs, ADAP programs, and drug card plans with 12,930

associated bill groups. In addition, PharmaCare has been both pleased and privileged to serve as an endorsed Medicare discount sponsor and thus, through this program, CMS staff have become familiar with PharmaCare's other pharmacy benefit management services during the past two years.

In addition, during the past year, PharmaCare has participated in the Transplant Pharmacy Coalition which has had an ongoing dialogue with CMS staff related to certain specialty pharmacies providing immunosuppressive medications and additional services to Medicare patients and their physicians in a post-transplant setting. CMS has recognized those services are substantially different than might otherwise be provided to patient receiving medications that are to be covered under the Part D benefit of the Medicare Prescription Drug, Improvement and Modernization Act of 2003(MMA). Such services help assure that transplant patients receive appropriate care following organ transplant and that administrative processes, more cumbersome than on-line claims processing, are compensated outside of the reimbursement for the medication.

Comments below are organized by the section of the Proposed Rule to which they apply using the specific "issue identifier" that precedes the section. The order of these comments follow the issues as presented in the NPRM. Page number references are to the NPRM as published in the Federal Register on March 4, 2005.

1. Background

C. Revised Drug Payment Methodology (Pages 10747-48)

Proposed Rule: The proposed rule discussed the move away from flaws in the AWP drug payment system to an Average Sales Price (ASP) model.

PharmaCare Comment and Recommendation: PharmaCare believes that CMS should give careful consideration to the impact that the continued move from ASP to Competitive Acquisition Program pricing (CAP) will have on the delivery and distribution businesses currently working with patients and physicians to secure delivery of the affected pharmaceutical products. Unlike the delivery of other outpatient drugs through traditional retail and mail service channels where pharmacy benefit claims are processed in an efficient, on-line environment and there is more limited patient contact, the delivery, distribution and administrative processes are often more involved given not only the nature but the specific use and administration of the products. PharmaCare recognizes the policy objectives CMS has articulated in not only achieving cost savings but also separating the procurement of the pharmaceutical product from the service and administration of the product. PharmaCare recommends that CMS give careful consideration to the valuable services performed by specialty pharmacies not only in delivering and distributing these products but in also providing specialized services to patient and physician and maintain payment levels to support these services.

PharmaCare supports CMS pronouncements made during the past year regarding their desire to delivery quality care to the patients and work with their contractors to help manage care and costs. PharmaCare believes that as CMS continues to move to the

alternative pricing model of the CAP program, that the impact on specialty pharmacies and distributors of these Part B products should be carefully considered so as to not inadvertently impact patient care. PharmaCare also recognizes that within the context of the part B drugs several drugs exist that may not require the services levels afforded by specialty pharmacies. The cost efficient distribution for these drugs may be best served by a distribution system currently provided by drug wholesale distributors. Further, PharmaCare wishes CMS to know that it is well aware of longer-term considerations being given to creating administrative efficiencies by potentially moving Part B pharmaceutical product reimbursement to Part D. PharmaCare believes such a move might bring substantial administrative efficiencies and would welcome the opportunity to comment further at an appropriate time.

2. II. Provisions of the Proposed Rule

A. Policy for the CAP (Page 10748)

Overview of the CAP

Proposed Rule. The proposed rule recognizes that there is statutory flexibility in the development of the CAP and allows for a “phase-in” of the program.

PharmaCare Comment and Recommendation. Without commenting on the merits of a “phase-in” approach, PharmaCare wishes to comment that CMS, if it is considering any phase in, should consider two factors. PharmaCare believes CMS should review the volume of each pharmaceutical product being administered in physician offices and the cost of each of the various pharmaceutical products giving priority to those that are administered most frequently and provide the greatest opportunity to achieve cost savings. Such an analysis may lead CMS to look at a single specialty as it recognizes elsewhere in the proposed rule. Looking at both of these parameters will also allow CMS to support one its objectives of reducing the financial burden of drug acquisition by physicians who must employ working capital and often bear financial risk in the event of non-payment for drugs. (Federal Register, Page 10748)

It will also provide the opportunity to efficiently analyze current distribution and communication processes and allow for timely refinements if required before expanding to additional therapeutic categories.

3. II. Provisions of the Proposed Rule

B. Operational Aspects of the CAP

2. Proposed Claims Processing Overview (Page 10753)

Claims Processing Overview

Proposed Rule. The proposed rule specifies a desire to establish a claims processing methodology that establishes a prescription number used to identify both drug administration on the physician claim and the drug vendor's claim for the drug. The proposed rule also proposes to require prompt claim filing on the part of the physician to facilitate matching between the physician claim and the drug vendor claim.

PharmaCare Comment and Recommendation. To the extent that CMS has gleaned experience from review of other systems and is considering the longer term possibility of moving coverage for Part B medications to the MMA's Part D program, PharmaCare would urge CMS to consider the use of identification fields, terminology, and practices that may prove to be consistent with private-sector on-line point of sale systems and therefore, useful at a later date. The efficiency, timing, and accuracy requirements associated with these systems has proven to serve the patient, the provider and the payor with information that maximizes optimal cost effective outcomes. With respect to immunosuppressives, CMS is aware that the expense for claims administration and processing as well as communication with third party insurance is one of the more administratively costly services provided by specialty pharmacy distributors. PharmaCare believes industry standards organizations such as the National Council for Prescription Drug Programs (NCPDP) may be in a position to provide CMS with further input as it explores options in this area. Recognizing that CMS may be establishing a variety of tools to aid and assist MMA Part D vendors with eligibility and third party insurance verification, PharmaCare believes it may be useful to CMS to consider the longer term impact of any claims processing methodology it adopts.

With respect to requiring prompt claim filing on the part of the physicians who elect to participate in the CAP, PharmaCare supports this provision. Consistent with its earlier comments, PharmaCare would note that prompt payment is particularly critical as CMS moves to the CAP methodology. While one policy goal of the new rule is to allow physicians an opportunity to limit their financial burdens and risk by not entering into the business of drug acquisition, PharmaCare urges CMS to also recognize that changes in pricing methodology do have a substantial impact on distributors and specialty pharmacies engaged in the business of fulfilling these prescriptions to both patients and physicians. Further, PharmaCare urges CMS to consider the substantial impact such changes may have on both distributors and specialty pharmacies should prompt claim filing not be required. Again, PharmaCare believes that CMS should also explore the degree to which pharmacies handling these specialty pharmaceutical products perform other valuable services for both the patient and the physician in promoting quality of care and undertaking other administrative tasks.

4. C. CAP Contracting Process

1. Quality and Product Integrity Aspects and 2. Bidding Entity Qualifications. (Page 10758-10761)

Contracting Process Quality and Product Integrity Aspects

Proposed Rule. The proposed rule discusses a number of policy objectives related to promoting the quality and integrity of the delivery and distribution process to both patient and physician. In similar fashion, the rule suggests that CMS will seek to make sure that entities desiring to be a CAP contractor demonstrate experience in the business and make certain certifications.

PharmaCare Comments and Recommendations.

PharmaCare both recognizes and concurs with the CMS proposed rules and policy objectives related to the quality and integrity of the delivery and distribution processes. PharmaCare would further submit that the current acquisition and distribution process utilized in specialty pharmacy is supported by systems and procedures that would meet the standards for product integrity and distribution as specified. Additionally these systems have the inherent capabilities to provide accurate efficient information in order to validate ongoing vendor performance pertaining to distribution requirements. Finally these systems and processes have been developed and refined to meet the increased demands and complexities associated with current and future requirements for these disease states.

We appreciate the opportunity to offer these comments, which we strongly believe, will help CMS formulate a set of program rules that strengthen the overall coverage and reimbursement process for these products under the Part B benefit. Likewise, we believe that CMS will continue to formulate policies that take into account a desire to play a key role in delivering a high quality of care to the nation's Medicare population while effectively achieving desired cost savings.

We look forward to continuing to work with you and your staff on this and all other issues related to pharmacy benefits for the Medicare population.

Sincerely,

John Wardle
Senior Vice President
PharmaCare

Submitter : Mr. Art Alanis
Organization : South Texas Oncology
Category : Pharmacist

Date: 04/26/2005

Issue Areas/Comments

1-15

Overview of the CAP

Problem with CAP, is that it has never considered what the real cost are for a physician to procure, stock, inventory, mix and administer chemotherapy. There are a lot of hidden cost that need to be considered. One example is all ancillary's such as syringes, IV bag/fluids needles, cost to maintain IV Hoods etc.

Contracting Process-Quality and Product Integrity Aspects

Now we truly have socialized medicine because the physician nor the patient nor pharmacist have any control on product selection...the government does..The vendor will send what ever is on their shelf..

Claims Processing Overview

So is CMS going to also make the vendors provide all the tubing sets, IV bags and other equipment??? Has CMS considered the time/labor/cost that is required to provide pharmacy services..How will these clinics handle drug disposal and wastage??? Will we store 10-different vials of herceptin for the various patients & if the dose changes & we do not have enough will we have to wait for more drug before we can start a patient on therapy.

Bidding Entity Qualifications

CMS needs to be aware that hands on clinical experience has more value than just a vendor stating that they have been shipping drugs for 3-years.

Competitive Acquisitions Areas

We are dealing with a CAP Vendor who has no experience in providing or understanding the real needs of a practicing oncology office. This process is going to require a lot more shipping and has anyone considered variables like manufacturer back orders, wrong orders sent & or received, etc...

Categories of Drugs to be Included under the CAP

The concern here, is that no beta testing/study has ever been conducted & now CMS is going forward on a national level...CMS has no experience nor does the vendors in that practical application of providing this type of service... It's like trying a new surgery without any practice..haste makes for a lot of waste...especially with very expensive drugs...Why hasn't the government conducted or hired any consultants to provide any expert feedback??

Statutory Requirements Concerning Claims Processing

By not considering nor doing your homework, a lot of mistakes are going to happen and can hurt lives. In trying to understand how CMS expects a doctor's office to manage all that is required from paper work, to stock, storing and managing this project is not realistic nor safe. EX. Wrong drug sent, who will have to call and fix this issue..2). not enough drug sent or change in physician order, to name a few potential problems..

Dispute Resolution

What experience does CMS have in quality assurance in providing patient drug therapies...This process needs to be tested first before full national implementation occurs...

Submitter : Ms. Sue Fitzpatrick
Organization : Ms. Sue Fitzpatrick
Category : Individual

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-379-Attach-1.DOC

April 25, 2005

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

Via Electronic Mail

Attention: CMS-1325-P

Re: Comments on Proposed Rule: Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals under Part B. NPRM CMS-1325-P(42 C.F.R. Part 414)(70 Fed. Reg. 10746, March 4, 2005)

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PharmaCare Specialty Services performs a full range of therapy management services for patients with complex and expensive chronic diseases, their physicians, and their health plans. Specifically, through our primary specialty mail service pharmacy located in Pittsburgh, Pennsylvania, we deliver specialty medications to patients' homes or physicians' offices. In addition, we provide access to 39 specialty pharmacy locations, seven satellite mail facilities, and 31 retail stores nationwide.

Our specialty program was established to create an intimate partnership with our patients. Patients have access to our clinical pharmacists 24 hours a day, seven days week. Also, PharmaCare Specialty Services has implemented a comprehensive set of disease-specific care management programs under the name ProtoCall™. These programs incorporate the use of treatment guidelines, provider coordination, patient support, outcomes, and feedback to optimize quality and manage overall treatment costs.

Currently, we offer specialty services to more than 40 million members through our relationships with managed care organizations nationwide. We have extensive payor contracts with over 300 different payor plans, including Medicare, most state Medicaid plans, renal disease programs, ADAP programs, and drug card plans with 12,930

associated bill groups. In addition, PharmaCare has been both pleased and privileged to serve as an endorsed Medicare discount sponsor and thus, through this program, CMS staff have become familiar with PharmaCare's other pharmacy benefit management services during the past two years.

In addition, during the past year, PharmaCare has participated in the Transplant Pharmacy Coalition which has had an ongoing dialogue with CMS staff related to certain specialty pharmacies providing immunosuppressive medications and additional services to Medicare patients and their physicians in a post-transplant setting. CMS has recognized those services are substantially different than might otherwise be provided to patient receiving medications that are to be covered under the Part D benefit of the Medicare Prescription Drug, Improvement and Modernization Act of 2003(MMA). Such services help assure that transplant patients receive appropriate care following organ transplant and that administrative processes, more cumbersome than on-line claims processing, are compensated outside of the reimbursement for the medication.

Comments below are organized by the section of the Proposed Rule to which they apply using the specific "issue identifier" that precedes the section. The order of these comments follow the issues as presented in the NPRM. Page number references are to the NPRM as published in the Federal Register on March 4, 2005.

1. Background

C. Revised Drug Payment Methodology (Pages 10747-48)

Proposed Rule: The proposed rule discussed the move away from flaws in the AWP drug payment system to an Average Sales Price (ASP) model.

PharmaCare Comment and Recommendation: PharmaCare believes that CMS should give careful consideration to the impact that the continued move from ASP to Competitive Acquisition Program pricing (CAP) will have on the delivery and distribution businesses currently working with patients and physicians to secure delivery of the affected pharmaceutical products. Unlike the delivery of other outpatient drugs through traditional retail and mail service channels where pharmacy benefit claims are processed in an efficient, on-line environment and there is more limited patient contact, the delivery, distribution and administrative processes are often more involved given not only the nature but the specific use and administration of the products. PharmaCare recognizes the policy objectives CMS has articulated in not only achieving cost savings but also separating the procurement of the pharmaceutical product from the service and administration of the product. PharmaCare recommends that CMS give careful consideration to the valuable services performed by specialty pharmacies not only in delivering and distributing these products but in also providing specialized services to patient and physician and maintain payment levels to support these services.

PharmaCare supports CMS pronouncements made during the past year regarding their desire to delivery quality care to the patients and work with their contractors to help manage care and costs. PharmaCare believes that as CMS continues to move to the

alternative pricing model of the CAP program, that the impact on specialty pharmacies and distributors of these Part B products should be carefully considered so as to not inadvertently impact patient care. PharmaCare also recognizes that within the context of the part B drugs several drugs exist that may not require the services levels afforded by specialty pharmacies. The cost efficient distribution for these drugs may be best served by a distribution system currently provided by drug wholesale distributors. Further, PharmaCare wishes CMS to know that it is well aware of longer-term considerations being given to creating administrative efficiencies by potentially moving Part B pharmaceutical product reimbursement to Part D. PharmaCare believes such a move might bring substantial administrative efficiencies and would welcome the opportunity to comment further at an appropriate time.

2. II. Provisions of the Proposed Rule

A. Policy for the CAP (Page 10748)

Overview of the CAP

Proposed Rule. The proposed rule recognizes that there is statutory flexibility in the development of the CAP and allows for a “phase-in” of the program.

PharmaCare Comment and Recommendation. Without commenting on the merits of a “phase-in” approach, PharmaCare wishes to comment that CMS, if it is considering any phase in, should consider two factors. PharmaCare believes CMS should review the volume of each pharmaceutical product being administered in physician offices and the cost of each of the various pharmaceutical products giving priority to those that are administered most frequently and provide the greatest opportunity to achieve cost savings. Such an analysis may lead CMS to look at a single specialty as it recognizes elsewhere in the proposed rule. Looking at both of these parameters will also allow CMS to support one its objectives of reducing the financial burden of drug acquisition by physicians who must employ working capital and often bear financial risk in the event of non-payment for drugs. (Federal Register, Page 10748)

It will also provide the opportunity to efficiently analyze current distribution and communication processes and allow for timely refinements if required before expanding to additional therapeutic categories.

3. II. Provisions of the Proposed Rule

B. Operational Aspects of the CAP

2. Proposed Claims Processing Overview (Page 10753)

Claims Processing Overview

Proposed Rule. The proposed rule specifies a desire to establish a claims processing methodology that establishes a prescription number used to identify both drug administration on the physician claim and the drug vendor's claim for the drug. The proposed rule also proposes to require prompt claim filing on the part of the physician to facilitate matching between the physician claim and the drug vendor claim.

PharmaCare Comment and Recommendation. To the extent that CMS has gleaned experience from review of other systems and is considering the longer term possibility of moving coverage for Part B medications to the MMA's Part D program, PharmaCare would urge CMS to consider the use of identification fields, terminology, and practices that may prove to be consistent with private-sector on-line point of sale systems and therefore, useful at a later date. The efficiency, timing, and accuracy requirements associated with these systems has proven to serve the patient, the provider and the payor with information that maximizes optimal cost effective outcomes. With respect to immunosuppressives, CMS is aware that the expense for claims administration and processing as well as communication with third party insurance is one of the more administratively costly services provided by specialty pharmacy distributors. PharmaCare believes industry standards organizations such as the National Council for Prescription Drug Programs (NCPDP) may be in a position to provide CMS with further input as it explores options in this area. Recognizing that CMS may be establishing a variety of tools to aid and assist MMA Part D vendors with eligibility and third party insurance verification, PharmaCare believes it may be useful to CMS to consider the longer term impact of any claims processing methodology it adopts.

With respect to requiring prompt claim filing on the part of the physicians who elect to participate in the CAP, PharmaCare supports this provision. Consistent with its earlier comments, PharmaCare would note that prompt payment is particularly critical as CMS moves to the CAP methodology. While one policy goal of the new rule is to allow physicians an opportunity to limit their financial burdens and risk by not entering into the business of drug acquisition, PharmaCare urges CMS to also recognize that changes in pricing methodology do have a substantial impact on distributors and specialty pharmacies engaged in the business of fulfilling these prescriptions to both patients and physicians. Further, PharmaCare urges CMS to consider the substantial impact such changes may have on both distributors and specialty pharmacies should prompt claim filing not be required. Again, PharmaCare believes that CMS should also explore the degree to which pharmacies handling these specialty pharmaceutical products perform other valuable services for both the patient and the physician in promoting quality of care and undertaking other administrative tasks.

4. C. CAP Contracting Process

1. Quality and Product Integrity Aspects and 2. Bidding Entity Qualifications. (Page 10758-10761)

Contracting Process Quality and Product Integrity Aspects

Proposed Rule. The proposed rule discusses a number of policy objectives related to promoting the quality and integrity of the delivery and distribution process to both patient and physician. In similar fashion, the rule suggests that CMS will seek to make sure that entities desiring to be a CAP contractor demonstrate experience in the business and make certain certifications.

PharmaCare Comments and Recommendations.

PharmaCare both recognizes and concurs with the CMS proposed rules and policy objectives related to the quality and integrity of the delivery and distribution processes. PharmaCare would further submit that the current acquisition and distribution process utilized in specialty pharmacy is supported by systems and procedures that would meet the standards for product integrity and distribution as specified. Additionally these systems have the inherent capabilities to provide accurate efficient information in order to validate ongoing vendor performance pertaining to distribution requirements. Finally these systems and processes have been developed and refined to meet the increased demands and complexities associated with current and future requirements for these disease states.

We appreciate the opportunity to offer these comments, which we strongly believe, will help CMS formulate a set of program rules that strengthen the overall coverage and reimbursement process for these products under the Part B benefit. Likewise, we believe that CMS will continue to formulate policies that take into account a desire to play a key role in delivering a high quality of care to the nation's Medicare population while effectively achieving desired cost savings.

We look forward to continuing to work with you and your staff on this and all other issues related to pharmacy benefits for the Medicare population.

Sincerely,

John Wardle
Senior Vice President
PharmaCare

April 22, 2005

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

Attention: CMS-1325-P

To Whom It May Concern:

I am writing this letter in response to the Proposed Competitive Acquisition Program (CAP) Rule. My concerns are from two perspectives.

1. Patient care and patient perspective
2. Doctor/Clinic perspective

You see, I personally have two family members that are taking Chemotherapy treatments for cancer. It is a blessing to me that there are clinics and doctors available for them to choose to go to for their care. It was extremely comforting to know their physicians were able to decide what type of chemotherapy each of them should be given based on their bodies and test results. The treatment of cancer can't be contained to the same regimen for each patient. Each person's body responds differently to treatment. What might work extremely well on one person may not work well on others. When you have a loved one extremely sick, their wishes come first. To know they are sick or only have a short period of time to live makes you realize as their caregiver you would move heaven and earth to give them whatever means to sustain a normal life until their end. With the CAP program, Medicare might cause the closing of clinics all over the United States as some physicians will not be able to financially maintain their practices at the level of care patients need. It should not be the responsibility of patients to monitor the pharmaceutical companies.

From a physician/clinical side, I currently work for an Oncology practice that puts patient care first. We take a great deal of time educating patients on different choices of treatment and also family members on the care of their loved ones. We must have all medications for treatment available to our patients at all times. The physician should not be the person to control the drug manufacturers nor should the drug manufacturers control the physicians.

Another concern I have is the fact that patients are all different and one medication may work better for some patients than others or the patient during a reevaluation may require a different medication. The delays under such situations could be life-threatening to the patient. When a patient lives in one state but resides in another state for a time period of the year, under CAP will their treatment be uninterrupted and the same regimen be maintained in both places of treatment?

Physician offices do not have the space available to house each different individual's medications. Currently medicines are stored in vials of single dose or multi-dose and are available to all patients, regardless of insurance or ability to pay. Our clinic never turns away a patient in need of care for financial reasons. Will the vendors be willing to ship that individual's medication when they cannot afford to pay for the drug or can only afford to pay a minimum monthly payment? What does a physician do when a patient comes in for treatment and his drugs have not yet arrived from the vendor? Under the proposal, CMS believes that the clerical and inventory expenses related to use of the CAP are no greater than for ASP based reimbursement and that the payment for such work is bundled into the payment for the drug administration codes. If CMS is willing to pay the vendors for this service, does this mean the administration reimbursement to physicians will go down even more in spite of the fact that a greater work load and larger staff will be necessary for the physicians to maintain their standard of care

In reading all 157 pages of this proposal, it appears as though the only individuals that are not being hurt from this proposal are the pharmaceutical companies. Nothing will have changed for them and they will continue to charge high amounts for the medications that the local community cancer center will have to pay.

Please take the time to review all the comments on this proposal and make the decision in the best interest of the patient. Thank you for allowing me the opportunity to express my concerns.

Sincerely,

Sue Fitzpatrick

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

April 22, 2005

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

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Sincerely,

Sue Fitzpatrick

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter :

Date: 04/26/2005

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1325-P-380-Attach-1.DOC

CMS-1325-P-380-Attach-2.DOC

April 24, 2005

Attach#380

Dear Dr. McClellan:

Pursuant to the instructions posted in the Federal Register Friday, February 25, 2005/Rules and Regulations, what follows are comments regarding CMS-1325-P, Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B. This letter is written on behalf of Northwest Georgia Oncology Centers P.C. (NGOC) which represents the interest of sixteen medical oncologists, our staff and our patients.

“Overview of CAP”

NGOC is concerned that with an effective date of January 1, 2006, that CMS does not have enough time to finalize key requirements of the program, or to fully understand the probable inefficiencies in creating such a system. A rush to implement CAP without a complete understanding of the complexities involved will likely result in an increase in cost to CMS vs. the proposed savings.

“Categories of Drugs to be included under the CAP”

NGOC is concerned that CAP vendors have the ability to develop a formulary by choosing and/or excluding drugs that will be available through CAP. CAP vendors should be prohibited from developing formularies, and must be required to supply physicians with any drug(s) that the physician deems to be medically necessary.

“Statutory Requirements Concerning Claims Processing”

NGOC is concerned that the CAP process will create additional operational burdens and increase our cost of treating our Medicare patients. In 2004 roughly 1,230 (48%) Medicare patients were treated in our six locations. Under the proposed rule NGOC would have to create a separate system for ordering, “prescription” tracking, and maintaining our inventory for almost one half of our patients. Additionally, NGOC would have to develop a new overly burdensome system for providing additional clinical and financial patient specific information to the CAP vendor. Issues regarding Order Splitting, Inventory Re-supply, how to handle Unused Drugs, and Furnish as Written, add another layer of complexity and cost that must be addressed.

NGOC is very concerned regarding the lack of clarification in the event that a CAP vendor is unable to collect co-payments from a Medicare beneficiary. Specific guidelines must address this issue in the final rule. If CAP vendors are allowed to stop shipments of drugs to patients that cannot afford to pay their co-insurance, physicians should be allowed to immediately opt-out of the CAP program.

NGOC would also incur additional expenses in dealing with a CAP vendor regarding disputes that may (and most likely will) arise from time to time.

“Contracting Process-Quality and Product Integrity Aspects”

NGOC is concerned that no clear standards currently exist for CAP vendor’s quality control. Specific guidelines should address quality and performance standards, along with language protecting physicians from liability in the event of negligence and/or lack of performance by a CAP vendor. Physicians must also have the ability to opt-out of CAP programs in the event of poor quality or quality related incidents.

“Bidding Entity Qualifications”

NGOC recommends that a CAP vendor should have a minimum of three years experience in the delivery of each category of drug that it submits a bid for.

“Physician Election Process”

NGOC recommends that physicians may opt-out of the CAP program at anytime.

NGOC supports a fair and balanced approach to Medicare reform that addresses reasonable payment for both drugs and all other services associated with the provision of Cancer care. We are however disappointed that an untested CAP program is being rushed into without additional consideration and input of practicing community oncologists.

We are concerned that this rush to implement will have the unintended consequences of increasing cost (both to us and CMS), lowering quality, delaying and/or decreasing access, and creating needless complexity and confusion.

Thank you for your consideration of these important matters.

Bruce Gould M.D.
President and Medical Director

Submitter : Mr. mark perry
Organization : river edge behavioral health
Category : Pharmacist

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

Please include behavioral health injectable drugs in this program starting Jan 2006. We do not have the time or staff to fill out required paperwork. This would be an advantage to all people involved, including our clients.

Submitter :

Date: 04/26/2005

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1325-P-382-Attach-1.DOC

April 24, 2005

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Thank you for your consideration of these important matters.

Bruce Gould M.D.
President and Medical Director

Submitter : Mr. Kevin Champagne
Organization : Cancer Care Specialists
Category : Health Care Professional or Association

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-383-Attach-1.DOC

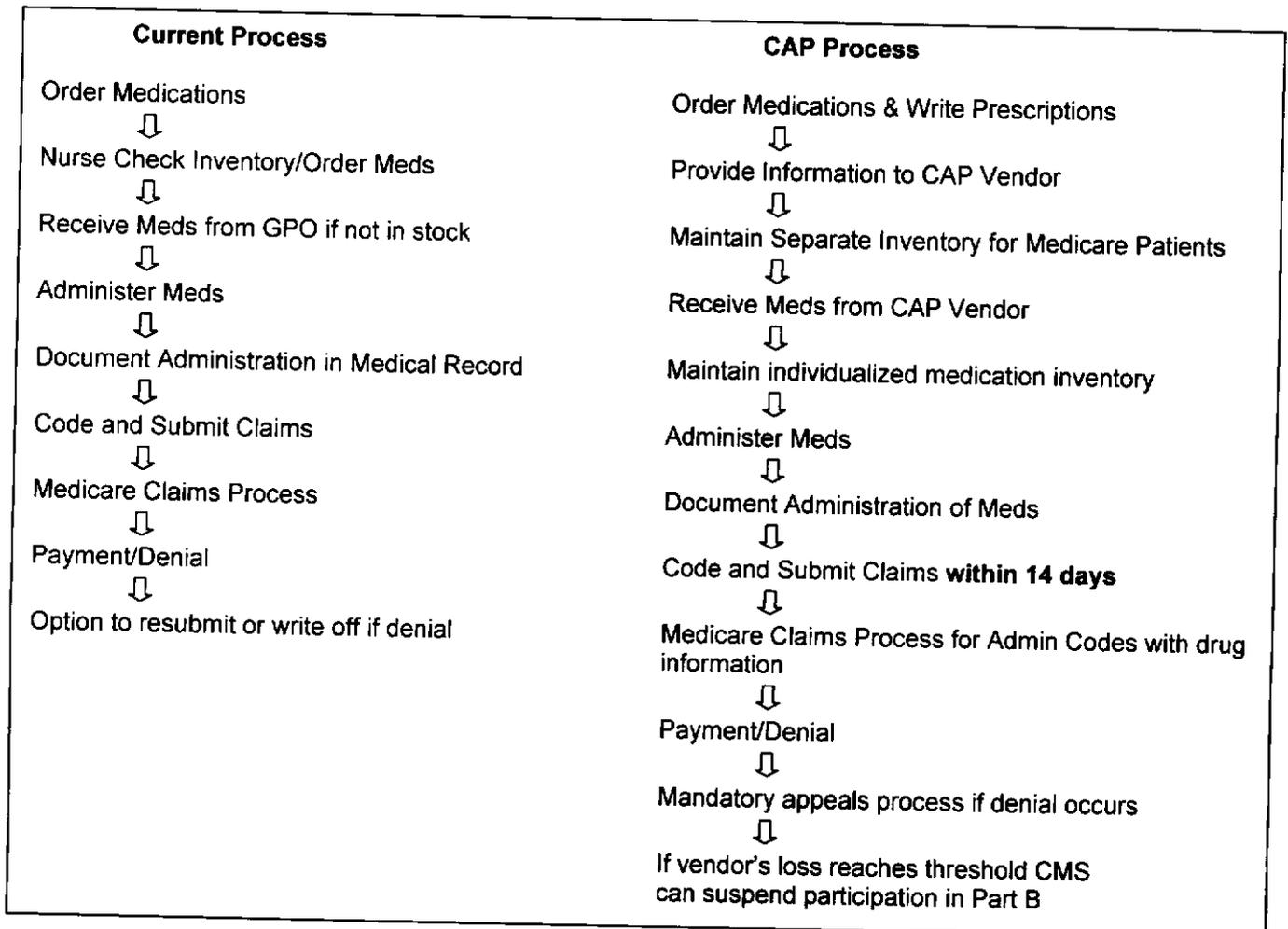
To: Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

From: Oncology/Hematology Center of the South
8120 Main Street, Suite 103
Houma, LA 70360

RE: Comments on CMS-1325-P

Statutory Requirements Concerning Claims Processing

The CAP proposed process for obtaining drugs will be much more burdensome to community oncology practices than the current process of acquiring drugs, maintaining a drug inventory, and seeking Medicare reimbursement. Additional steps will be required if an oncology practice decides to participate in CAP. These include providing vendors with written prescriptions, patient and payer information; submitting claims within 14 days of date of drug administration; maintaining patient specific inventory logs. Oncology practices also must notify the vendor when a drug is not administered and agree to submit an appeal accompanied by all required documentation necessary to support payment if the participating CAP oncologist drug administration claim is denied. In addition, there is no provision to compensate oncology practices for these additional steps.



Submitter : Dr. Carolyn Haynie
Organization : Bon Secours Baltimore Health System
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

i.e. "See Attachment"

CMS-1325-P-384-Attach-1.DOC

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

From: Oncology/Hematology Center of the South
8120 Main Street, Suite 103
Houma, LA 70360

RE: Comments on CMS-1325-P

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Current Process	CAP Process
Order Medications	Order Medications & Write Prescriptions
↓	↓
Nurse Check Inventory/Order Meds	Provide Information to CAP Vendor
↓	↓
Receive Meds from GPO if not in stock	Maintain Separate Inventory for Medicare Patients
↓	↓
Administer Meds	Receive Meds from CAP Vendor
↓	↓
Document Administration in Medical Record	Maintain individualized medication inventory
↓	↓
Code and Submit Claims	Administer Meds
↓	↓
Medicare Claims Process	Document Administration of Meds
↓	↓
Payment/Denial	Code and Submit Claims within 14 days
↓	↓
Option to resubmit or write off if denial	Medicare Claims Process for Admin Codes with drug information
	↓
	Payment/Denial
	↓
	Mandatory appeals process if denial occurs
	↓
	If vendor's loss reaches threshold CMS can suspend participation in Part B

April 14, 2005

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

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

Dear Dr. McClellan:

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

Advantages of Injectable Psychiatric Medications

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

Patient noncompliance with psychotropic medication regimens is similar to that for patients who take medications for somatic illnesses. A review of the literature has found that most patients probably only take 33 - 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a sizeable percentage are wholly noncompliant.¹ For people with schizophrenia and severe mood disorders, noncompliance with medications often results in the relapse of acute symptoms, frequently resulting in negative

outcomes such as rehospitalization, loss of employment/housing, and suicide. These negative consequences for the patient are compounded by a parallel negative impact on the service delivery system: costs escalate as outpatient treatment is stymied, the use of emergency facilities increases, and hospital stays are more frequent and longer.

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

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

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

Current Obstacles Faced by Providers Using Injectable Psychiatric Medications

Unfortunately, community mental health centers (CMHCs) and other multi-service community providers, which serve a large number of people with severe mental illnesses that are eligible for both Medicaid and Medicare, face serious obstacles in providing injectable medications. As safety-net providers, CMHCs are very often heavily burdened treatment settings that lack sophisticated information technology and a sufficient level of administrative staffing. For example, to provide the new injectable antipsychotic risperidone to patients, CMHCs must first purchase the medication, and then seek reimbursement from both Medicare (which makes only partial payment for mental health drugs) and Medicaid. Providers then bear the administrative burden of tracking the claims and the financial risk of receiving incomplete payment from one or both payers. This burden has become an impediment to expanding access to this medication to the full range of patients who could benefit from it. In some cases, CMHCs will only provide the medication to patients that are solely Medicaid beneficiaries. When injectable antipsychotics are included in the Medicare CAP program, this substantial impediment will be removed, as providers would have the option to obtain the medications from a drug vendor that will handle reimbursement from Medicare. Helping providers expand access to this medication will bring great benefit to our patients with schizophrenia.

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

Sincerely,

Carolyn R. Haynie, M.D.
Chairman
Behavioral Medicine

Submitter : Ms. Beth Levine
Organization : Pfizer Inc.
Category : Drug Industry

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

Pfizer Inc's comments to the Proposed CAP Rule are attached. The attached letter includes comments on most of the issues identified in the Proposed Rule. Each issue is identified in accordance with the subject headings suggested by CMS.

See Attachment.

CMS-1325-P-385-Attach-1.DOC

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Beth Levine
General Counsel, US Pharmaceuticals

April 26, 2005

Submitted Electronically

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

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

Dear Dr. McClellan:

Pfizer Inc. appreciates this opportunity to comment on the proposed rule to implement a competitive acquisition program for certain Medicare Part B drugs not paid on a cost or prospective payment system basis ("Proposed CAP Rule")¹. Pfizer is a research-based, global pharmaceutical company dedicated to the discovery and development of innovative medicines and treatments that improve the quality of life of people around the world. Pfizer markets a variety of Medicare Part B covered drugs including chemotherapeutic and ophthalmic agents as well as other physician administered therapies.

¹ Published at 70 Federal Register vol. 42, p. 10746 et seq. (March 4, 2005).

As a general matter, we believe a competitive acquisition program ("CAP") that is an efficient and reliable alternative distribution channel for physician administered drugs, that also permits physicians to avoid the burdens of acquiring and billing Medicare for those drugs, holds great promise for physicians, patients and the Medicare program. However, we also believe that *any* negative impact on patient access to appropriate therapies that may result from the implementation of the CAP would be highly inequitable and difficult to justify given that Medicare beneficiaries will have no choice in whether their medication is supplied through the CAP and individual patients are not ensured of getting any direct benefit from the program. Accordingly, as set forth in greater detail below, we strongly urge CMS to focus its resources and regulatory authority on facilitating the development of an efficient drug delivery and reimbursement system, through the CAP, which can capture any additional savings for the Medicare program but which strictly protects Medicare beneficiaries' access to the most appropriate Part B covered drugs.

Patient Access Must Not be Sacrificed to Implement CAP

We believe it is crucial to acknowledge explicitly that the CAP model is not primarily intended to benefit individual Medicare patients. The direct means of achieving cost savings for individual beneficiaries (through lowered beneficiary co-insurance payments) have already been put in place through the Part B payment reforms that went into effect, beginning in 2004, under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). So long as the payment system for Part B drugs based on average sales prices ("ASP") functions adequately, even an optimal CAP system offers no unique additional benefits for beneficiaries. The real potential beneficiaries of the CAP are (i) the Medicare program, which could capture some additional Federal savings through the bidding system; (ii) physicians who will now have the means to avoid the financial risks posed by potentially inadequate or anomalous drug payment rates and uncollectible co-insurance payments; and (iii) the vendors who can extend into and capture this new line of business.

Given that the impact of a successful CAP model is likely to be neutral for individual beneficiaries, it would be highly inequitable to build a CAP model that is premised on allowing vendors to capture additional savings or revenue by restricting beneficiary access to drugs, for example, by permitting the use of formularies or the implementation of other non-clinical incentives to prescribe one agent over another. That would result in a system that may incrementally benefit the Medicare program as a whole, or secure for physicians a means to avoid financial risks, but at the expense of Medicare beneficiaries whose access to therapies will be limited by CAP vendors that have no direct relationship with or obligation to the beneficiary.

Accordingly, in addition to the recommendations on specific program elements set forth below, in order to protect beneficiary access to the most appropriate therapies, at a minimum, CMS must:

- **Explicitly prohibit the use of formularies** or similar therapy management techniques that dictate or limit the prescriber's choice of agents.
- **When soliciting bids, explicitly identify each billing and payment code within each category of competitively biddable drug or biological for which a vendor must offer at least one covered drug.** If a CAP category includes HCPCS codes that contain only one drug or biological, the CAP vendor must be required to include that drug in its offer/bid. As noted in the comments to the Proposed CAP Rule submitted by the Biotechnology Industry Organization ("BIO"), this requirement would not require manufacturers with exclusive distribution arrangements to contract directly with CAP vendors; rather CAP vendors would acquire the drug or biological from the sole distributor.
- **Explicitly prohibit CAP vendors from instituting their own clinical or financial pre-screening processes** beyond verifying the beneficiary's enrollment in Medicare Part B. Permitting pre-screening of patients may result in additional barriers to care for those beneficiaries who cannot adequately demonstrate financial resources to meet co-insurance obligations or for beneficiaries receiving off-label therapies where Part B coverage may be uncertain.
- **Explicitly prohibit vendors from offering physicians financial incentives to stock preferred drugs specifically for "re-supply" under the CAP.** This will help prevent vendors from enforcing preferred status in the CAP by controlling which agents a physician keeps in-stock (for example, for their commercially insured patients).

Comments on Specific Program Elements

Set forth below are our comments on specific issues for which CMS solicited public input. Pfizer's comments are meant to complement, and should be read in conjunction with, the comments to the Proposed CAP Rule submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the comments submitted by the Biotechnology Industry Organization ("BIO"), both of which we broadly endorse.

A. Categories of Drugs to be Included

1. CAP should focus on physician administered drugs. We agree with CMS that it is appropriate and consistent with the statutory framework for the CAP to focus, in the first instance, on Part B drugs administered incident to physician services, rather than

all Part B covered drugs. As the program matures, CMS may choose to add other Part B drugs, as appropriate, to the list of biddable drugs.

2. CAP should include all categories of physician administered drugs. With regard to alternative phase-in options, we strongly urge CMS to seek bids for all categories of physician administered Part B drugs, rather than limiting the initial program to a specific specialty, but to consider phasing in the program geographically. We believe there is little advantage to limiting the CAP to a specialty, even a specialty such as oncology that comprises a large proportion of affected practitioners. Smaller specialties, including ophthalmology, which is not identified as a possible specialty for the phase-in period, should be offered the chance to participate in the benefits of a CAP. Also, the phase-in should be used as an opportunity to gain practical learnings from as wide a variety of situations as possible. From a vendor's perspective, the potential to serve more physicians across specialties should present a better opportunity than a more circumscribed pilot.

3. Each vendor should bid on all biddable categories. CMS should strongly encourage potential vendors to bid on all categories of biddable drugs in their competitive acquisition area by granting special preference to such vendors in the contractor selection process. By including all physician administered drugs from the outset and encouraging vendors to submit comprehensive bids, physicians selecting the CAP will be able to consolidate their Part B drug acquisition as much as possible. Also, CMS will be better able to ensure that the CAP attracts vendors that are interested foremost in building a reliable and efficient alternative distribution system for physician administered drugs generally, rather than vendors who are better poised, in the short run, to capitalize on established relationships with specific specialties. Because physicians are free to participate or not in the CAP, and because the CAP deals with medications for relatively serious conditions, the quality and reliability of the drug delivery system will be paramount to its success.

4. CMS should clarify that physicians are permitted to obtain all, or only some, categories of drugs from a CAP vendor. While vendors should be encouraged to offer all biddable categories in their CAP areas, CMS should clarify that physicians are permitted to select which categories of biddable drugs they wish to obtain under the CAP, and from which vendor(s). This freedom of choice is required under the MMA provisions authorizing the CAP. Section 303 of the MMA expressly describes physician selection under the CAP to mean selection of "the contractor through which drugs and biologicals *within a category of drugs and biologicals* will be acquired and delivered to the physician."²

5. CMS should specifically identify all payment and billing codes for which drugs must be offered within a biddable category. Finally, to ensure that CMS receives readily comparable bids for each category of drugs, and to further ensure *against* the use of formularies, CMS should explicitly identify, prior to seeking any bids, each

² Section 1847B(a)(1)(A)(iii) of the Social Security Act, as added by the MMA (emphasis added).

billing and payment code within each category of competitively biddable drug or biological for which a vendor must offer at least one covered drug. If a CAP category includes HCPCS codes that contain only one drug or biological, the CAP vendor must be required to include that drug in its offer/bid. Also, as noted in the comments to the Proposed CAP Rule submitted by BIO and PhRMA, if different single-source drugs that are not generic equivalents are grouped together in the same HCPCS code, the vendor should be required to offer each single-source drug or biological included in the enumerated HCPCS. This will ensure beneficiary access to the single-source drug the physician determines is most appropriate and minimize the need for physicians to resort to the "furnish as written" exceptions process, which may be more appropriate for multiple-source drugs.

B. Competitive Acquisition Areas

We strongly urge CMS to designate multi-state competitive acquisition areas ("CAA"). We believe national regions would unnecessarily limit the pool of potential vendors to entities that already have or can quickly attain national reach. On the other hand, we believe allowing each state to be a separate CAA may result in certain rural or less populous states, which may not be considered good commercial opportunities, to be carved out of the CAP entirely. Accordingly, to ensure that the CAP ultimately is available to physicians in all states, CMS should designate reasonable multi-state regions. Multi-state regions would allow the CAP to be phased in geographically. Multi-state regions also do not foreclose potential vendors with national reach from participating fully.

C. Statutory Requirements Concerning Claims Processing

1. In implementing the re-supply provisions, acknowledge that "emergency situations" may occur *routinely* for the patient population being served.

The MMA recognizes that there will be emergency situations that require a CAP-electing physician to treat a patient immediately and permits the physician to use the CAP ordering system to resupply the physician's inventory. CMS seeks comments on how "emergency" should be defined, including what delivery timeframes would be considered "timely" so as to obviate the need to resort to the resupply process.

As a general matter, we believe it is important, given the nature of Part B drugs and thus the patient population these provisions will effect, that CMS instruct its carriers that emergencies in this patient population may occur *routinely*, i.e., that the frequency of resupply claims should not by itself raise suspicions of their validity. For example, even for patients undergoing a course of therapy, a patient's condition on the day of a scheduled treatment may necessitate immediate adjustments to the treatment. Further, the standard of care with regard to specific conditions may call for treatment on the same day as diagnosis. The implementation of the emergency resupply provisions must accommodate such situations to ensure that established patterns of care are not disturbed solely because of the CAP.

In light of these considerations, with respect to the specific question of timeframes for timely delivery, we believe that unless the CAP vendor can arrange for the delivery of the needed drug on the same day, the physician must be deemed to have demonstrated that timely delivery was not possible.

Finally, while the resupply provisions must be implemented so as to allow physicians to feel secure about using their inventory to address a beneficiary's immediate treatment needs, CMS should monitor its potential misuse. Specifically, CMS should expressly prohibit vendors from offering physicians financial incentives to stock "preferred" drugs specifically for resupply under the CAP. This will help prevent vendors from indirectly enforcing formularies and preferred status under the CAP by controlling which agents a physician keeps in stock (for example, for their commercially insured patients).

2. Minimize the need to use the "furnish as written" exceptions process by requiring vendors to offer all single-source drugs within each HCPCS code.

The "furnish as written" process allows physicians to go outside the CAP process and obtain the most appropriate treatment for a given beneficiary, even if the needed drug is not offered by the physician's CAP vendor. This exceptions process is welcome; however, it involves additional administrative burdens for the physician. As stated above, to minimize the situations where the "furnish as written" process needs to be used, if different single-source drugs that are not generic equivalents are grouped together in the same HCPCS code, the CAP vendor should be required to offer each single-source drug or biological included in the enumerated HCPCS. This will ensure beneficiary access to the single-source drug the physician determines is most appropriate and minimize the need for physicians to resort to the "furnish as written" exceptions process, which may be more appropriate for multiple-source drugs.

3. Explicitly clarify that vendors may not require patient information to conduct financial or clinical pre-screenings.

The Proposed CAP Rule enumerates the patient-related information that participating physicians would be required to include in their orders to CAP vendors. We strongly believe that in the interest of patient privacy and to prevent CAP vendors from instituting any level of financial or clinical pre-screening, the patient information supplied to vendors must be limited to what is minimally necessary to ensure that (i) the vendor can verify Part B enrollment and (ii) the vendor can submit a clean claim for the drug supplied to its designated carrier and to any other insurer for the beneficiary. Accordingly, the "Additional Patient Info: date of birth, allergies, Ht/Wt/ICD-9, etc." should not be routinely required on drug orders. As noted above, permitting (or even facilitating) pre-screening of patients may result in additional barriers to care for those beneficiaries who may be deemed financially unable to meet co-insurance obligations or for beneficiaries receiving off-label therapies where Part B coverage may be more uncertain.

D. Contracting Process—Quality and Product Integrity Aspects

We commend CMS for the detailed proposals for assessing and verifying that vendors meet financial and quality of care requirements. We specifically endorse CMS' proposal to include in its vendor contracts the statutory requirement that a CAP vendor must "acquire all drugs and biologicals it distributes directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer." We also agree with CMS that all vendors must, at a minimum, be licensed as wholesalers under the laws of the state(s) they will operate in, as well as demonstrate full compliance with any other state or Federal requirements for wholesale distributors.

E. Bidding Entity Qualifications

1. Require vendors to demonstrate experience, financial stability and business integrity.

Ultimately, the success of the CAP—its ability to attract and keep physician customers—will depend largely on the quality, timeliness and reliability of the vendor's drug delivery system. Accordingly, we believe it will be crucial for CMS to communicate to potential vendors the minimum standards that bidders will be required to meet in order to qualify to even have their bids evaluated. Given the need to launch the CAP by 2006, proven experience in handling Part B injectible drugs should be an important consideration for the initial selection of vendors.

2. Ensure no conflict of interest that could result in interfering with physician's clinical judgment and beneficiary access to therapy.

Consistent with the need to avoid *de facto* formularies, CMS should ensure that CAP vendors do not have structural conflicts of interest that may inappropriately influence prescribing and result in restricting access to therapies for beneficiaries. For example, CMS should not permit a vendor to also be the entity that enforces a risk-sharing arrangement among the physicians it serves.

F. CAP Bidding Process—Evaluation and Selection

1. Threshold for successful bids should not be predetermined. CMS proposes to evaluate bid prices by computing a composite bid for each bidder for each category of biddable drugs. Only bidders with a composite bid of 106% or less of the weighted ASP for the drugs in the category may be chosen as vendors. For each biddable drug, CMS would use the median price actually bid for that drug by all qualifying bidders as the single payment rate for that CAA for the first year of the contract.

While we generally concur with the use of a composite bid to compare the bidders' submissions, we believe that imposing a bid ceiling of 106% of the weighted ASP as the predetermined threshold may result in too few vendors able or willing to

participate in the CAP. It remains uncertain whether 106% of ASP is an adequate reimbursement rate for Part B drugs. Indeed, a strong incentive for physicians to turn to the CAP may very well be the inadequacy of the ASP-based reimbursement. Also, inherent in the ASP system is the significant problem of the lag in reporting of price data, a flaw which would also impact the CAP system. Finally, because negotiated prices under CAP are not excluded from either the calculation of the manufacturer's ASP or its best price for Medicaid purposes, the level of achievable discounts remains uncertain. Under the circumstances, capping the qualifying bids at 106% of the weighted ASP may discourage otherwise reasonable bids. Accordingly, we strongly urge CMS not to announce a predetermined threshold for qualifying bids. CMS would still retain the authority to set the CAP payment rates for each biddable drug, which can be based on the drug's current ASP to ensure savings.

Although we strongly discourage CMS from setting a predetermined ceiling for qualifying bids, as stated above, we generally concur with the idea of comparing bids by constructing a composite bid for each category based on historic utilization. In order to help potential vendors and the public better understand this process, we, along with BIO, urge CMS to release promptly the utilization data it plans to use to assign weights to each biddable drug.

2. Post-award price adjustments should be based on net acquisition costs reported by vendors and existing price information, including ASP and survey data.

CMS suggests in the Proposed CAP Rule that vendors will be required to submit annually a wealth of documentation to support their "reasonable, net acquisition costs." Specifically, the Proposed Rule states that vendors will be required to submit

"full documentation reflecting these purchases, including contracts, invoices, and other agreements that reflect the actual purchase prices. This documentation would include all records reflecting discounts that result in a reduction of actual costs to the vendor."

Proposed CAP Rule, 70 Fed. Reg. at 10765. CMS gives no explanation of why, in this context, vendor *reported* price information would not be sufficient. CMS would always retain the right to audit price reports, as it does with manufacturer price reports, and to adjust payments prospectively if the vendor misreports its reasonable net acquisition costs. The Proposed CAP Rule also includes no provision for maintaining the confidentiality of vendor cost information.

To lessen the burden for all parties, and, importantly, to minimize the risk of inadvertently disclosing confidential business information, we strongly urge CMS to require periodic price/cost reports without supporting documentation, but with strong audit provisions that include a process for CMS to recover overpayments based on such audits. If CMS can support the need for disclosing the underlying documentation in specific cases, at a minimum, it should clarify that the same protections that apply to the information submitted for ASP purposes shall apply to the cost information provided by

CAP vendors—specifically, it should not be released in a form that discloses the identity of a specific manufacturer or wholesaler, or the prices charged by a manufacturer or wholesaler, except as necessary to carry out the CAP and ASP-based reimbursement.

CMS should also give serious consideration to adjusting payment rates to CAP vendors in years two and three of the contract based on available ASP information as well as cost survey information, which will be available in conjunction with the “widely available market price” surveys and surveys of Part B drug acquisition costs for hospitals.

3. New drugs should be made available promptly through CAP at 106% of the WAC for such new products. For the purposes of setting payment rates for new drugs under the ASP system, CMS has authorized temporary payment rates equal to 106% of the new product’s wholesale acquisition cost (“WAC”). Under the statutory framework of the CAP, CMS also must develop a payment rate methodology for new drugs under CAP. We believe that the WAC-based payment rate is an appropriate approach for setting payment amounts for new drugs before actual price data is available and reported. Because there is no compelling reason to set a different or lower add-on percentage for CAP versus the ASP system, we urge CMS also to adopt 106% of WAC as the payment rate for new CAP drugs and to explicitly incorporate the 106% of WAC methodology in the final CAP rule.

Additionally, to ensure that the CAP program is a convenient and up-to-date alternative to the current system, we urge CMS to take steps to ensure that new drugs are made available promptly by vendors. At a minimum, a provision requiring vendors to offer new drugs promptly should be included in the vendor contracts. This will minimize the need for physicians to resort to the furnish-as-written provisions and ensure that CAP functions as a one-stop resource to the extent possible.

G. CMS Should Monitor the Effect of CAP on Beneficiary Access

Finally, Pfizer continues to believe that the success of the Part B payment reforms must be measured in large part by their impact on beneficiary access to Part B drugs. In addition to the studies mandated by Congress to monitor various factors that may impact beneficiary access, Pfizer urges CMS to have in place comprehensive surveillance mechanisms monitoring the designated CAP carrier and local carrier coverage determinations to ensure that timely data is collected and that potential threats to beneficiary access to the most appropriate therapies at the most appropriate sites of service can be promptly identified and appropriately addressed as they arise.

* * * *

Mark McClellan, M.D.
April 26, 2005
Page 10

Again, we thank you for this opportunity to submit our recommendations on how to ensure the successful implementation of the CAP program. We look forward to working with CMS and other CAP stakeholders in the coming months to build an efficient alternative system that can enhance the delivery of appropriate care for beneficiaries and provide physicians with added flexibility with respect to their Part B services.

Respectfully submitted,

/s/

Beth Levine
General Counsel, US Pharmaceuticals
Pfizer Inc.

Submitter : Mr. Brian Abraham
Organization : MedImmune, Inc.
Category : Drug Industry

Date: 04/26/2005

Issue Areas/Comments

GENERAL

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See attachment

CMS-1325-P-386-Attach-1.PDF

April 26, 2005

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: CMS-1325-P, Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B

Dear Dr. McClellan:

MedImmune, Inc., is pleased to have the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule regarding the Competitive Acquisition Program (CAP) for outpatient drugs under Medicare Part B. MedImmune is a fully integrated biotechnology company that manufactures and markets drugs administered in the physician office setting to Medicare beneficiaries. Specifically, physicians provide our drugs Ethyof[®] (amifostine) as part of anti-cancer therapies and CytoGam[®] (cytomegalovirus intravenous immunoglobulin, human) for transplant patients.

As a company that strongly desires to preserve beneficiary access to breakthrough therapies, including new technologies, we welcome alternative programs for physicians who are looking for better ways to obtain and supply drugs to their patients. We are committed to helping you achieve that reform while ensuring that patients who need therapies are not limited by their own or their physicians' financial judgments ahead of sound medical decision making.

We also are committed to the principles set forth by the Biotechnology Industry Organization (BIO), of which we are a member. Although BIO will elaborate upon each of these principles in its comments, we reiterate the major concepts here for your review.

- CMS should state affirmatively that vendors do not have the authority to construct formularies for single source therapies.
- CMS should clarify that every CAP vendor must offer at least one drug or biological within every HCPCS code for each category and require vendors to bid on at least one NDC code for each single source drug and biological, even when the therapies are billed using the same HCPCS code.
- CMS should allow physicians wide latitude to use the resupply option to ensure timely access to drugs and biologicals and allow physicians to request an advance supply of certain therapies to treat patients whose needs cannot be predicted.
- CMS should implement the "furnish as written" option with minimal administrative burden on physicians.

- CMS should ensure that medical decisions are made by physicians, not CAP vendors, and convey to carriers that Least Costly Alternative policies are impractical and unnecessary in the CAP environment.
- CMS should allow flexibility for composite bids to exceed 106 percent of ASP if needed to encourage more bidders.
- CMS should protect the confidentiality of acquisition cost data provided by CAP vendors.

Our specific comments follow, laid out in the order of the Proposed Rule, as published in the *Federal Register* of March 4, 2005.

COMPETITIVE ACQUISITION AREAS

We believe that in order to promote competition, yet ensure the government achieves savings, that CMS should initiate CAP as a pilot program in one multi-state region. If CMS contends that the best drug category to begin the program is the entire medical specialty of oncology, we think that the region should be relatively small, such as CMS Region V (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin). If CMS chooses a smaller physician specialty area to initiate the program, though, the CAP region could be expanded, but only slightly and not to the whole nation. Because of our experience with this type of program for another of our products not generally dispensed to the Medicare population, we anticipate that CMS will experience a great deal of logistic and administrative complexity as the program begins. We are concerned that starting with a geographic area that is too large will lead to problems, including

- patients not receiving drug in a timely manner,
- physicians not being able to track orders for their patients,
- vendors not being able to trace shipments to physicians, and
- billing difficulties for beneficiaries.

Starting on a smaller scale will help CMS work out any systemic difficulties as well as help vendors and physicians understand the process.

That said, MedImmune believes that for Medicare beneficiaries to have the greatest opportunity to access a drug any of their physicians order, that the CAP should be open to all medical specialties. Our advice that the geography remain small is especially pertinent so that all of the bugs and difficulties can be resolved in a microcosm, instead of the entire country enduring a difficult experience, and dooming the program to failure before it even has a chance to demonstrate merit.

CLAIMS PROCESSING OVERVIEW

We agree that only drugs incident-to physician services should be included in the CAP. We do not think Prescription Drug Plans under Part D should be introduced into CAP at this time because the Part D program will just be launching. We strongly agree with

Health and Human Services Secretary Leavitt that Parts B and D integration should not be examined for two years.

In the Proposed Rule (70 FR 10755), you acknowledge CAP vendors are at financial risk for shipping drug prior to receiving notification that it was administered. You also ask for comments on partial payment to vendors who do not receive notification of a drug being administered. We suggest that instead of partial payment for these drugs, that CMS provide a guarantee to vendors that they will be compensated fully for drug shipped.

One guarantee would be to allow vendors and physicians to shift prescription numbers. This way, if a physician receives drug for a patient that ultimately is not treated with the drug, the vendor and physician can quickly shift the prescription number to a patient needing that drug, and can bill using the new prescription number.

Another guarantee would be to pay the vendor fully for the drug even if the physician office has not submitted its claim in a timely manner. A partial payment simply would not serve to encourage the vendor to supply a drug to all eligible beneficiaries. In the case that a vendor receives a claim denial for a drug, the financial onus then should be on both the vendor and physician to appeal the denial. If the physician orders the drug because he or she believes it is medically necessary (and in compliance with applicable Local Coverage Decisions (LCDs)), then the physician should be comfortable bearing financial responsibility in appealing a claim.

Instead of rescinding payment to the vendor when the physician's claim is not received in 90 days, CMS should impose some kind of instructive action or penalty to the physician for not complying with the CAP protocol. By CMS making sure that the physician is responsible for timely and complete submissions, vendors will be more likely to supply drug to them in the future, thus keeping beneficiary access to the drugs as open as possible.

Adding the drug to CAP stock at the physician office for emergency situations also is an alternative, and one we think should be applied with wide latitude. This way, the drug is not wasted and the vendor is not left with complete financial risk.

For "furnish as written" drugs, the physician would need to receive a drug with an NDC number outside of the stock of a CAP vendor. We suggest that Medicare allow for some type of modifier on the physician claim that signifies the drug was "furnished as written."

It seems that de facto, physicians would have to choose all drug categories because CMS does not intend to subdivide the categories deeper than by specialty. Oncologists, for example, would not be able to choose categories, if the only category available is oncology drugs. We envision greater participation in the program if CMS was willing to subdivide categories further so that oncologists, for example, could choose whether or not to have CAP vendors supply either anti-emetics, anti-neoplastics, growth factors, or all of them. We would support such sub-categorization because it would give physicians the

choice to opt in or out of the program incrementally while providing them with the chance to supply all the drugs to their patients they believe are necessary.

When a physician decides to order a drug from a CAP vendor after checking applicable LCDs, that should be enough to ensure that the drug is shipped. Therefore, we strongly agree with BIO that the vendor should not second-guess the doctor's medical decision making. If the vendor imposes additional restrictions, that would ultimately affect access for beneficiaries because physicians would choose not to use a particular drug, regardless of its effectiveness for a particular patient.

DISPUTE RESOLUTION

The designated carrier must have a mechanism in place to notify vendors about denials to physicians. Although this will need to be operationalized between the designated carrier and the vendor, we cannot discern how the vendor would be notified about physician claim denials. If payment does not materialize because the physician received a denial, then the vendor would not know whether it is a denied claim, a slow payment, or even if its claim was ever processed. We ask CMS to clarify this process so vendors can act accordingly when these disputes arise.

If the designated carrier denies the vendor's claim for a drug, we think the threshold, if allowed to be defined by the vendor (70 FR 10758), would be low enough to prevent additional drug from being shipped, thus limiting patient access. We have a grave concern that the vendor will refuse to ship drug for subsequent patients, thus effectively preventing the physician from obtaining any drug. We ask CMS to provide guidance to vendors that states each claim should have a threshold, not each physician account. Also, if the threshold is low, and the designated carrier is asked to counsel the physician, we think a major part of the unexpected duties of the designated carrier will be counseling physicians.

CONTRACTING PROCESS - Quality and Product Integrity Aspects

We agree that the requirements for contractors be stringent, and that CMS retain the authority to terminate or suspend a contract for non-performance. We implore CMS to choose vendors whose capacity is proven, and vendors that can ship on an immediate basis. Although Section 1847 (b)(2)(A) of the Act requires that vendors ship at least five days a week, we do not think this is sufficient. In an emergency situation, which should to some extent be defined by the treating physician, vendors should have mechanisms and contingencies in place to meet the needs of these irregular requests.

Related to the rapid shipping issue is product integrity. This discussion of integrity goes beyond product counterfeiting; if a product requires special handling (such as cold-chain storage and shipping) in order to maintain its viability, vendors need to be wholly responsible for that. We request that CMS require vendors to maintain records of product integrity from arrival at the vendor to the moment it arrives at the destination physician office. This documentation would cover storage and shipping requirements. In addition,

because the vendor is required to ensure arrival of the drug at the physician office, documentation should be maintained that indicated the drug's integrity until arrival at the physician office. If the vendor uses a third-party shipper, the vendor should still be responsible for the integrity of the product, and needs to maintain documentation stating so.

Although we agree with CMS that potential vendors should meet financial capability standards, as derived from the FAR, we hope no entity is unfairly excluded from consideration. By requiring prior year audited financial statements, CMS may inadvertently exclude some bidders who wish to grow from local distributors to regional ones; simply because capitalization is not present in one year does not mean that a potential vendor cannot acquire capital to embark on this project. If a potential vendor claims it has the financial capacity to participate in the CAP and meets the FAR requirements, we encourage CMS to request current financial statements (including letters of credit, etc.) in order to evaluate these companies. As much as we urge CMS to judge bidders on their capabilities, we ask that the Agency consider all bidders on their potential capacities.

BIDDING ENTITY QUALIFICATIONS

Timely delivery for routine and emergency shipments often depends on the product itself, as CMS alludes to in the Proposed Rule (70 FR 10760). As a manufacturer, we are concerned that the physicians who use our and others' products receive them on time for specific patients. It is essential that the drugs arrive when they are needed. Therefore, we recommend that a routine shipment occur within one business day, and an emergency shipment occur overnight, regardless if the arrival or shipping day is a business day or non-business day.

CAP BIDDING PROCESS – Evaluation and Selection

Although we understand CMS's desire that the most specific category of drug be by physician specialty, we certainly are open to specific categories within a specialty, as stated earlier. We reiterate that covered drugs in all specialties would provide the greatest savings to the Medicare program in the first year of operation. On that note, we caution CMS to be sure the system can handle such a large influx of claims. To limit possible backlogs, we ask again that CMS reconsider the categorization of drugs by examining optional subcategories within each medical specialty. We also emphasize our recommendation that the initial region be one multi-state pilot. By scaling down the geography, we believe CMS will achieve optimal operational efficiency as well as favorable cost savings on Part B drugs.

We would like to know how CMS will determine the drugs or HCPCS codes that should be included in each category. For the HCPCS codes in the oncologics J9xxx series, it is fairly obvious. But there are other drugs used for both curative and supportive care treatment in the oncology world. In the Proposed Rule, CMS did not mention how it would ensure that all of the drugs used in a specialty would be included. And when drugs

are used across specialties, but are included in CAP, we would encourage CMS not to require physicians, especially those in multi-specialty practices, to order through CAP.

The Proposed Rule states that the Act requires that the submitted bid price include all costs related to the delivery of the drug to the selecting physician, and the costs of the dispensing (including shipping) of the drug and management fees (70 FR 10762). We believe that in order to serve Medicare beneficiaries well, these bids may end up over 106 percent of Average Sales Price (ASP). Because it is likely that vendors will acquire drugs at or within a percentage point of ASP, the remaining 5 to 6 percent within the expected bid will be the only way for vendors to pay for receipt of goods, storage of goods, order taking, pharmacy counseling, compliance, special handling, and shipping. Even with economies of scale, we find it hard to perceive any potential vendor would be able to realize a profit on this venture if CMS expects no bid to exceed the reimbursement rate physicians now are allowed, particularly with single-source drugs that make up a substantial portion of the oncology specialty.

We recommend that instead of forcing CAP vendors to include all of these activities in the bid for the drug itself, that CMS compensate the vendors for the special handling in much the same way that they have compensated physicians who have expended additional resources when administering the drugs. Physicians now get paid for each administration of drugs, as well as the assessment of chemotherapy patients. Similarly, CMS should offer compensation to CAP vendors for necessary patient education, provider education, pharmacy counseling, compliance, and so forth.

Although we think that calculating composite bids based on volume is a sound method of evaluation, we are not sure that it provides CMS the desired outcome. While volume is important, and provides a gauge as to what CMS and vendors can expect, it does not indicate the amount of money the Medicare program can expect to spend to treat its population. If CMS calculated composite bids based on weighted averages of cost to the program, you would much more accurately be able to determine which bidders would save the Medicare program actual dollars expended. As you can see from our example at Attachment A, in which we pulled four drugs in oncology from 2003 data on the CMS web site, there is a big difference in which composite bids win the right to supply drugs to physicians, even though the dollar bids were the same. Regardless of the method CMS ends up requiring, we urge you to make public the drugs and the dollar amounts or volumes you expect bidders to benchmark from.

As stated earlier, we think it will be difficult for bidders to achieve a bid of less than 106 percent of ASP, much less five bidders per geography and category. In addition, at 70 FR 10763, you discuss not selecting any bid higher than 106 percent of the weighted ASP in a drug category. We urge CMS to publish what the weighted ASP is for an entire drug category, and how you arrived at that calculation. We also urge CMS caution here because you may be excluding a bidder that has attractive pricing for CMS, but the weighted average ends up disqualifying it. Although we agree that this limitation is consistent with the Congressional intent that CAP promote savings, we also believe

Congress did not intend to stem competition, especially with artificial criteria such as a weighted category ASP.

We encourage CMS not to pay CAP vendors on the median weighted ASP for a product. Rather, we ask you to pay a vendor the amount of their bid for a particular product. Although we understand the administrative burden to CMS increases when you adjust the price per HCPCS code on a more frequent than annual basis, we urge CMS to consider a quarterly adjustment to be consistent with the reimbursement methodology used in the physician office purchase and bill scenario. Because changes in the contracted cost of a drug may be less frequent for CAP vendors than for physician offices, we understand CMS's desire to have less frequent updates. However, by not tracking ASP on a quarterly basis, as CMS does for physician offices, you will effectively have two different ASP levels. If there are adjustments each quarter in ASP, then CMS will need to determine whether to use the ASP from two quarters earlier or the current quarter for the price adjustment in January. By making the ASP consistent between the two delivery channels, there will be no question from manufacturers or vendors about which quarter's ASP is the benchmark for reimbursement in either channel.

PHYSICIAN ELECTION PROCESS

We agree that CMS should notify physicians about the CAP on an ongoing basis throughout 2005, and that the election period be October 1 to November 15 of each calendar year. We urge CMS to provide communications at the following time intervals so that physicians can make informed decisions about participation and vendor choice:

- immediately following publication of the Final Rule
- immediately following selection of CAP vendors
- July 1 of each calendar year
- August 1 of each calendar year
- September 1 of each calendar year

Communication could be through CMS's regular conduits for physician communication, as well as MedLearn Matters bulletins.

We ask CMS to consider a couple of contingencies. First, if a vendor becomes insolvent or stops doing business in CAP prior to the three-year contract expiration, physicians will need a mechanism to choose a new CAP vendor quickly. Second, if a physician continually has disputes or quality problems with a vendor, the designated carrier will need authority to allow the physician to change vendors. We request that CMS implement a process for physicians to change CAP vendors when extenuating circumstances exist.

BENEFICIARY EDUCATION

We agree that beneficiaries may be confused if they receive coinsurance bills from an entity unknown to them. The CAP vendor as a supplier of physician-administered drugs

is different from either a retail pharmacy or an adjuvant physician such as an anesthesiologist or emergency department physician, and should thus be introduced as another entity to beneficiaries.

In that spirit, we encourage CMS to request that CAP vendors supply their own fact sheets or introductory letters to the physicians who contract with them. These letters should contain the name of the vendor (or the name of the company that will be sending a coinsurance notice), contact information, and the role of the vendor in the beneficiary's care.

REGULATORY IMPACT ANALYSIS

At 70 FR 10769 CMS states that it does not anticipate beneficiaries will experience drug access issues as a result of implementation of CAP. CMS further intends to monitor access issues closely to ensure that beneficiaries' access to drugs is not impacted. We urge CMS to continue this close monitoring on an ongoing basis. In addition, we are concerned that some physicians will not be aware they can prescribe the best drug available for a patient, thus not making a treatment decision in the best interest of the patient. We recommend that when physicians enroll in the CAP, they are made aware of the "furnish as written" provision so they can be confident that regardless of the CAP drugs generally available through a vendor, a drug needed for a specific patient will be available through the purchase and bill method.

We thank CMS again for the opportunity to provide comments. If you wish to discuss this program with us, please contact Brian Abraham, Associate Director of Reimbursement at (301) 398-4626 or abrahamb@medimmune.com.

Sincerely,

/s/

Caroline York
Vice President
Reimbursement and Government Affairs

Attachment

Drug	Total HCPCS Units	Relative Volume	Total HCPCS Dollars	Relative \$ Weight
J9310	1,184,899	0.0356	\$569,533,975	0.3721
J0880	22,365,638	0.6711	\$522,572,197	0.3414
J1260	8,905,614	0.2672	\$140,109,669	0.0915
J9170	871,900	0.0262	\$298,574,755	0.1950
	33,328,051	1	\$1,530,790,596	1

Source: Part B Physician/Supplier National Data CY 2003 (<http://www.cms.hhs.gov/statistics/feeforservice/top2002hcpcsbyservices03.asp>)

Drug	Avg Per Unit	Weight	Bidder 1	Bidder 2	Bidder 3	Bidder 4	Low Bidder
J9310	\$480.66	0.3721	\$475	\$480	\$485	\$479	4
J0880	\$23.36	0.3414	\$15	\$16	\$19	\$18	1
J1260	\$15.73	0.0915	\$11	\$12	\$15	\$18	1
J9170	\$342.44	0.195	\$330	\$342	\$345	\$300	4
Composite			\$247.23	\$251.86	\$255.60	\$244.53	4

WEIGHT	Weight	Bidder 1	Bidder 2	Bidder 3	Bidder 4	Low Bidder
Drug						
J9310	0.0356	\$475	\$480	\$485	\$479	4
J0880	0.6711	\$15	\$16	\$19	\$18	1
J1260	0.2672	\$11	\$12	\$15	\$18	1
J9170	0.0262	\$330	\$342	\$345	\$300	4
Composite		\$38.56	\$39.99	\$43.06	\$41.80	1

Submitter : Mr. Walter Moore
Organization : Genentech, Inc.
Category : Health Care Industry

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-387-Attach-1.PDF



April 26, 2005

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

Re: Comments to Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed Rule (CMS-1325-P)

Dear Dr. McClellan:

Genentech, Inc is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS') request for comments on the proposed rule entitled "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B (CMS-1325-P)," which was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Genentech is among the world's leading biotechnology companies with products available for serious and life-threatening medical conditions including cancer, asthma, and stroke. We are particularly interested in this proposed rule because the majority of our products are administered incident to a physician's service and are covered under Medicare Part B.

In establishing the Competitive Acquisition Program (CAP), Congress' primary policy objective was to offer physicians a choice—while maintaining patient access to needed therapies—in acquiring Part B drugs and biologicals ("drugs") for their patients without increasing the administrative burden associated with purchasing and administering drugs. We support these policy objectives to the extent they facilitate CMS' and Congress' overall goal that Medicare beneficiaries receive appropriate, high quality health care services and products, as prescribed by their physician.

Our remarks are designed to help CMS achieve the underlying policy objectives of the program, and focus on the following general issues: 1) Ensure patient access to appropriate therapies; 2) Maintain physician choice to appropriate therapies; 3) Limit administrative burden for physicians; 4) Ensure adequate education; and 5) Maintain confidentiality and integrity of vendor and manufacturer relationships.

Genentech further requests that CMS provide an additional comment period following the publication of any Final Rule implementing the CAP. Given that this proposed rule solicits input on a number of broad programmatic questions rather than proposes a specific program design, we are concerned that the Final Rule could outline a program that departs, both in substance and in policy, from that contemplated under the MMA. To ensure adequate opportunity for stakeholder input regarding actual program design, as mandated under the Administrative Procedures Act (APA), CMS should at a minimum publish a Final Rule with Comment and refrain from implementing CAP until the opportunity for full notice and comment is provided.

1. Ensure Patient Access to Appropriate Therapies

There are several provisions in the proposed rule that could affect patient access to appropriate therapies.

Offer At Least One Product per HCPCS Code

Section 1847B(b)(1) of the Social Security Act (SSA), as created by the MMA, requires CAP vendors to bid on "at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area."¹ This language requires CAP vendors to provide at least one drug for each HCPCS code within a CAP category, thereby protecting a physician's choice and patient access to the current standard of care and future innovations. To ensure patient access to products under Part B, the MMA, therefore, does not allow CAP vendors to impose a formulary within a CAP category, which would exclude some or all products identified by a HCPCS code.

Purchase of Drugs Not Offered by a CAP Vendor

Genentech agrees with the intent of the MMA that physicians and patients, not CAP vendors, should make medical decisions about drug treatment. As such, we strongly recommend that CMS implement their proposal to allow physicians to purchase drugs not offered by their vendor under CAP by writing a prescription for the non-CAP drug to be purchased via the ASP methodology and be "furnished as written." Such flexibility and physician discretion in appropriate treatment is required to provide optimal patient care and to ensure access to needed drugs and therapies.

Maintain Part B Coverage Policies

CMS proposes that existing coverage processes be followed, which require physicians to determine whether drugs they plan to administer are covered consistent with the local Part B contractor's coverage policies. Genentech agrees with CMS' proposal, understanding that it would prevent CAP vendors from refusing to deliver prescribed products for covered indications, including for uses outside the FDA-approved label.

¹ *Federal Register*, Volume 70, March 4, 2005, p 10751. "Billing and Payment Code" refers to Healthcare Common Procedure Coding System (HCPCS) code.

Genentech emphasizes that the intent of the MMA is to require vendors to deliver a CAP drug to a physician who has prescribed it in accordance with local coverage policies. CMS should explicitly state this policy in the Final Rule to ensure vendors cannot disrupt timely patient access to needed medications.

2. Maintain Physician Choice of Appropriate Therapies

Genentech urges CMS to finalize several provisions in the Proposed Rule, which would protect the ability of physicians to prescribe the drugs of their choice.

Inform Physicians Which NDCs Are Available by CAP Vendor

In addition to affirming the statutory requirement that CAP vendors include at least one product in each HCPCS code within a CAP category, Genentech urges CMS to finalize its proposal that CAP vendors provide participating physicians the National Drug Codes (NDCs) they will make available for each HCPCS code well in advance of the deadline for physicians to elect to participate in CAP. By requiring vendors to disclose the specific products they plan to provide as part of their bid, physicians will be able to select an appropriate CAP vendor based on the products most needed for their practice.

Obtaining Drugs Not Offered by CAP Vendor

As stated above, Genentech supports CMS' proposal to allow physicians to obtain a specific formulation of a drug—or a certain NDC for a multi-source drug—under the ASP methodology, when needed for treatment of a Medicare beneficiary, even if the specific drug is not available through the physician's CAP vendor.

Re-supplying Physician Inventories of CAP Drugs

Genentech encourages CMS to finalize its proposal to allow re-supplying of physician inventories for drugs administered under CAP if the physician demonstrates that 1) drugs are required immediately, 2) the physician could not have anticipated the need for the drugs, 3) the vendor could not have delivered the drugs in a timely manner, and 4) the drugs were administered in an emergency situation.² Genentech recommends that CMS define the terms "timely," and "emergency situation" as broadly as possible to allow physicians the maximum number of treatment options for their patients.

Individual versus Group Participation in CAP

Genentech recommends that CMS allow individual physicians within a group practice to decide whether to participate in CAP based on their specialty and according to their patients' needs. For example, if CMS creates a CAP category that encompasses Part B drugs typically administered by members of two or more physician specialties (e.g.,

² *Federal Register*, Volume 70, March 4, 2005, p 10755.

oncologists and rheumatologists), physicians of different specialties within a group practice should be able to decide separately whether to participate in CAP. This policy is consistent with CMS' proposal to allow physicians within a group practice who also have a solo practice to make a different determination regarding participation in CAP for each practice. If CMS does not allow individual physicians within a group to make their own decisions regarding CAP participation, then physicians may elect to provide care at other sites which are less convenient for patients and may decrease patient access to needed therapies.

Physician Choice in Selecting Different CAP Vendors for Different CAP Categories

CMS should clarify in the Final Rule that physicians have the ability to choose the category(ies) of drugs they wish to obtain from any given CAP vendor. If, for example, CMS implements CAP categories for oncology and rheumatology drugs, a physician who wishes to purchase oncology drugs from a CAP vendor should not be forced to purchase rheumatology drugs from the same vendor. A single CAP vendor may offer products appropriate for the physician's oncology patients but not for that physician's rheumatology patients.

3. Limit Administrative Burden for Physicians

The intent of the MMA was to make it simple and efficient for physicians to obtain drugs from a CAP vendor. In fact, Congress created the CAP specifically to decrease the financial and administrative burden associated with acquiring and billing drugs provided to Medicare beneficiaries.

Additional Payments for Administrative Requirements of CAP

CMS does not propose to make additional payments to physicians for the administrative work associated with participation in CAP because it believes the clerical and inventory requirements for CAP are no greater than when utilizing ASP-based reimbursement. However, our customers have indicated concerns about the likely administrative burdens of participating in CAP. Physicians' administrative burdens may be greater under CAP than the ASP payment methodology because under the CMS Proposed Rule:

- Physicians are required under CAP to maintain a separate electronic or paper inventory for each CAP drug obtained; and
- Physicians are *de facto* responsible for appealing denied drug administration claims on behalf of vendors.

For example, physicians might be required to appeal a denied drug administration claim in order for a CAP vendor to be reimbursed for the administered drug. Frequently, the cost of appealing a denied drug administration claim is greater than the payment for the claim itself. Furthermore, the amount of a drug administration claim might be

insufficient to meet the amount in controversy requirement for an administrative hearing. Although physicians will continue to receive practice expense payments under the CAP, the current codes and payments do not reflect the time, nor expense, involved with filing appeals.

Requirements for CAP Vendors to Meet High Quality, Service, and Financial Standards

Genentech encourages CMS to finalize its proposals requiring vendors to meet rigorous quality, financial, and service standards prior to participating in CAP in order to instill physician confidence in the system. CAP requires the participation of high-quality vendors who can deliver drugs in a timely and reliable manner because physicians who elect to use CAP will be concerned about product integrity, contractor reliability, additional staff time that may be needed to manage contractor relationships, and logistical issues such as maintaining adequate stock.

4. Create Sufficient Educational Materials

The feasibility of CAP requires significant outreach to all involved stakeholders to help foster the understanding of how the program is structured in comparison to the ASP methodology. CMS proposes numerous outreach and education activities targeted at physicians, vendors, and beneficiaries to help stakeholders better understand CAP. Genentech supports CMS' proposal to develop education procedures, services, and forums that use a variety of mass media and stakeholder partnerships to disseminate information and provide physicians and beneficiaries assistance regarding CAP.

5. Maintain Confidentiality and Integrity of Vendor and Manufacturer Relationships

The MMA requires CAP vendors to purchase products from a manufacturer or from a distributor who obtained the product directly from a manufacturer. The statute also does not give CMS authority to interfere in relationships between manufacturers and their authorized distributors. Furthermore, manufacturers are not required to enter into relationships and negotiate with CAP vendors.

CMS also should emphasize in its Final Rule that all vendor cost data remain confidential and not be identifiable by manufacturer or wholesaler. CMS has agreed to treat all ASP data submitted by manufacturers as proprietary trade secrets and we encourage the Agency to adopt this approach with CAP as well.

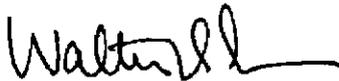
In its Final Rule, CMS should explicitly state that 1) manufacturers are not required to enter into relationships or negotiate with CAP vendors; and 2) vendor cost data will remain confidential.

Conclusion

Genentech thanks CMS for the opportunity to submit comments to the CAP Proposed Rule and urges the Agency to fulfill Congressional intent for CAP by ensuring that patients have access to the medical therapies chosen in consultation with their physician. Furthermore, we encourage CMS to work with all stakeholders such as physicians, potential vendors, manufacturers, and patients to ensure the program is implemented appropriately. Given the general nature of the proposed rule, an additional notice and comment period will be necessary to ensure necessary and appropriate stakeholder input.

Please do not hesitate to contact me directly at (202) 296-7272 if you have any questions about our comments or need additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Walter Moore", with a long horizontal flourish extending to the right.

Walter Moore
Vice President, Government Affairs
Genentech, Incorporated
1399 New York Avenue, NW, #300
Washington, DC 20005

Submitter : Dr. Jennifer Wootten
Organization : Grady Health System
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

Please include all mental health therapies in Phase 1. This would greatly improve the access to injectable therapies and thus improve patient compliance and outcomes.

Submitter : Mrs. Mary Highsmith
Organization : Richmond Behavioral Health Authority
Category : Nurse

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

As a Psychiatric Nurse, I am concerned about the cost of medication. Many of our clients require monthly injections in addition to the daily oral medications they are prescribed. Our clients must remain medication compliant in order to maintain their psychiatric stability and function in the community. Therefore, it is important that CMS include psychiatric drugs (including long-acting injectable antipsychotics) in the initial stages of CAP in an effort to alleviate barriers to access.

Thank you,
Mary Highsmith RN,BSN

CMS-1325-P-390

Submitter : Ms. Jill Drell
Organization : Walgreen Co
Category : Pharmacist

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1325-P-390-Attach-1.DOC

CMS-1325-P-390-Attach-2.DOC

April 26, 2005

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

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

Dear Sir or Madam:

This Company is a provider of Medicare Part B oral and inhalation drugs, specifically immunosuppressive, oral cancer and oral anti-emetic drugs, through our 4,750 local pharmacies operated in 45 states and Puerto Rico. Walgreen Co is responding to CMS' request for comments on whether the competitive acquisition program ("CAP") for outpatient drugs and biologicals, typically provided in a physician's office when incidental to services provided by the physician, should be expanded. The expansion being considered by CMS would be for the Medicare Part B drugs currently supplied by pharmacies. We are not commenting on the proposed rule as it would apply to the CAP for physicians offices.

We support the comments offered by the National Association of Chain Drug Stores and incorporate by reference the issues and concerns raised by that organization. Rather than repeat the details raised by NACDS in their comprehensive comments, we will only briefly address selected topics with which we have experience from operating retail, mail order and specialty pharmacies.

The CAP is intended to deliver necessary outpatient drugs and biologics to Medicare beneficiaries in an efficient and cost effective manner. Physicians can choose to avoid record keeping and purchasing functions including the collection of copayments from beneficiaries if they order from a CAP vendor. If CMS were to include Part B products currently supplied by a pharmacy as an additional group of drug products under the CAP, this would seem to be a step backwards in many ways..

Currently, a pharmacist dispenses Part B drugs and the patient takes the drug without the assistance of a physician to administer the prescription. Beneficiaries of Part B drugs have chronic conditions which would usually require a pharmacist to interact with a patient. Besides the counseling provided to a beneficiary, a pharmacist understands the complexities of these drugs and is able to suggest when adjustments are needed to the beneficiary's regimen during the early stages of use. Recently, CMS began to reimburse pharmacists with a higher supplier fee for immunosuppressive drugs in light of the value of the professional services provided.

A beneficiary's pharmacist usually their patients' prescription profiles and is able to identify and avoid possible drug interactions that might result from the drug prescribed by a physician. Physicians are not always aware of the other drugs the beneficiary is taking for other medical conditions. If oral Part B drugs are dispensed through the physician's office, there could be possible compromises in beneficiaries' quality of care.

Because of the convenience of the pharmacies, access is not a problem for beneficiaries in obtaining their prescriptions. To have to go to a physician's office to receive a drug, for which no medical expertise is required, would seem to impose an unnecessary burden on a sick individual.

If CMS would consider the use of a competitive vendor as a supplier to pharmacies for Part B products similar to the process contemplated for physicians, this would create an administrative burden. The pharmacy would dispense the Part B drug ordered by the physician and the CMS contractor would replace the pharmacy stock for the Part B drug dispensed. Pharmacies might be required to carry double inventories and any benefits from volume purchasing might be minimized if purchasing were not consolidated. If a pharmacy had to maintain Part B products separate from their existing stock, especially when the CAP contractor is not the retail pharmacy's contractor, this would be a burden. Even if a virtual inventory could be maintained this is also a challenge with possible cost implications.

The cost implication to pharmacies should not be minimized, especially when the possibility for savings if non-physician administered Part B drugs were made part of the CAP might be quite minimal. And, the possibility that some of the Part B oral and inhalation drugs will be part of the Medicare Part D program within the next few years should be a factor in CMS' deliberations. The change in the marketplace of having a physician's office involved in the dispensing of a drug where this professional's expertise is not required coupled with the possible inconveniences to either very sick or chronically ill beneficiaries should not be minimized. The new ASP based Medicare reimbursement formula has just been implemented. If there are any savings to be obtained to the Medicare program by including non-physician administered Part B drugs and biologicals, the evaluation should be done after the CAP has been established and the benefits from the ASP reimbursement model have been calculated. At that time, the possibility that Part B drugs would be rolled into the Part D program would be determined. If Part B drugs were to be included under Part D, the possible access and quality of care issues that might occur to beneficiaries if CAP were instituted would not be a factor.

Thank you very much for this opportunity to comments on the issue of whether Medicare Part B drugs traditionally obtained from pharmacies should be included in the CAP program.

Very truly yours,

Jill Leslie Drill
Director, WHS Governmental Affairs
Walgreens

April 26, 2005

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

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Thank you very much for this opportunity to comments on the issue of whether Medicare Part B drugs traditionally obtained from pharmacies should be included in the CAP program.

Very truly yours,

Jill Leslie Drill
Director, WHS Governmental Affairs
Walgreens

Submitter : Dr. William F. Jessee, MD, FACPME
Organization : Medical Group Management Association
Category : Health Care Provider/Association

Date: 04/26/2005

Issue Areas/Comments

1-15

Overview of the CAP

Inclusion of CAP in the calculation of ASP

Although not specifically addressed by the proposed rule, MGMA seeks clarification on how the CAP will influence ASP rates, if at all. We assert that the inclusion of CAP vendor prices in the calculation of the ASP is inappropriate. Only if a CAP vendor is a manufacturer, should the prices fall into the definition of ASP which includes the wholesale and sales price to distributors. Otherwise, the inclusion of the CAP rates in the calculation of ASP would be duplicative.

Definition of participating CAP physician

The definition proposed in the rule under the new 42 CFR 414.902 states that a 'participating CAP physician' is a 'Medicare physician.' We interpret 'Medicare physician' to mean a participating MD or DO who has enrolled in the Medicare program. If this is the appropriate reading of the definition, MGMA recommends that CMS revise the definition to clearly state that a 'participating CAP physician means a MD or DO who is enrolled in the Medicare program as a participating provider.'

However, MGMA cautions CMS that the availability of the CAP should not be limited to participating providers. As previously noted, the CAP can offer physicians treating Medicare patients a viable alternative to taking significant financial risks under the ASP reimbursement mechanism. Additionally, the definition of 'selecting physician' in §303(d)(5)(B) of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (42 USC 1395w-3b(d)(5)(B)) has no such limitation. Instead, the category of physicians eligible for participation is open to 'a physician who has elected this section to apply and has selected to apply under this section such contractor for such category and area.' Therefore, MGMA strongly recommends that CMS clarify that the program is open to all physicians who treat Medicare patients, regardless of their participation status, and that the agency modify the definition in such a way to reflect open enrollment.

Claims Processing Overview

Incident-to drug limitation

MGMA supports this limitation as part of the phase-in of the CAP program. However, once the program is fully implemented, the CAP should be made available for all categories of drugs, as described in 42 CFR 414.900.

Physician order for whole course of treatment

Many physicians currently order a drug supply sufficient to cover a typical course of treatment for a patient. MGMA appreciates that the CMS proposal permits this type of flexibility to occur. However, the course of treatment may take several months. Many patients do not schedule treatment dates more than a few weeks from the time when a physician orders the drugs. Thus, the flexibility of current drug administration scheduling may not be permitted by the required reporting of the anticipated date of administration at the time of order. Therefore, MGMA recommends that CMS relax the anticipated date of administration to permit doctors to give a 'ballpark' date, rather than a strict date of administration.

HIPAA compliance and billing instructions

MGMA appreciates CMS' clear intention to adhere to the transactions and code set mandate established by the Health Insurance Portability and Accountability Act (HIPAA). MGMA looks forward to the timely release of billing instructions which clarify which 837-compliant and CMS-1500 fields physicians should use to identify the prescription number and other required fields for billing CAP drugs and administration services.

Partial payment

In the proposed rule, CMS queries the public whether there is sufficient reason to offer vendors a provisional payment for drugs when a physician has not billed for the drug administration service within 28 days of the anticipated date of administration. As noted above, MGMA remains wary of a strict date of administration due to the nature of a course of treatment and patient schedules. Therefore, MGMA suggests that CMS use the timeline for provisional payment as currently used for Medicare secondary payer (MSP) claims.

The agency makes conditional payment for MSP claims where another insurance company is primary to Medicare when payment is not anticipated within 120 days of the date of service. MGMA believes that this timeline is consistent with Medicare policy and offers both the vendor and physician time to document services and file claims with regional carriers and the CAP designated carrier.

The proposed rule includes a brief explanation of a proposed methodology for partial payment to vendors for drugs supplied but not yet billed by a physician. The proposal notes that 'If a physician's claim was not received within 90 days, or the claim was not approved for payment, the initial partial payment made to the vendor would be recouped using CMS overpayment recovery process.' 70 Fed. Reg. 10757. The difficulty of the proposed processing system is that vendors will be held responsible for physician claims processing with a deadline of no longer than 90 days for partial payment. As noted above, MGMA does not support a 90-day period and alternatively recommends a 120-day partial payment waiting period.

Emergency situations and resupplying physician stock

CMS proposes that the emergency administration of drugs would be merited under the following scenario: (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; and (4) the drugs were administered in an emergency situation. These requirements were established in § 303(d)(1)(b)(5) of the MMA.

While this definition would generally permit doctors to administer drugs obtained outside the CAP program in a limited set of emergency situations. Yet, emergency scenarios falling outside of this definition would remain. These situations would arise when a drug is received by a provider to be administered in a timely fashion and the provider questions the integrity and quality.

Competitive Acquisitions Areas

MGMA supports the proposed national competitive acquisition area. This approach is consistent with the national ASP model used for Part B drugs. Additionally, supplies used in the calculation for geographic adjustments to the resource based relative value scale are also assessed on a national basis. Specifically, the geographic practice cost indices (GPCIs) assume that medical equipment, supplies and other miscellaneous expenses have a national market and input prices do not vary among geographic areas. For these reasons, MGMA believes that a national competitive acquisition area is consistent with Medicare policy and supports established national drug vendors and distributors.

Consistent with our recommendation, MGMA urges CMS to modify the proposed CFR 414.908(a)(2)(ii) to remove the example of 'physician relocates to another competitive area' as an exigent circumstance that would permit a physician to choose another vendor. It is not necessary for a nationally based acquisition area program.

Categories of Drugs to be Included under the CAP

Phase-in implementation

CMS proposed in the rule four different alternatives for phase-in implementation, invited comments on all options outlined in the notice and welcomed alternative suggestions. MGMA respectively rejects the proposals outlined, as the limitations imposed by them would restrict administrative and programmatic lessons learned to a small category of drugs and/or a single specialty. Alternatively, MGMA recommends that CMS initially make available a full-spectrum of categories of drugs under the program.

This list should include those drugs that many providers have been unable to obtain at rates close to or under ASP+6. MGMA understands that a brief list of approximately 40 codes is being worked on by the Physician Regulatory Issues Team as well as the Office of the Inspector General. This list should be the basis for which drugs would be first offered through the CAP. Specifically, MGMA urges CMS to offer bladder cancer drugs through the CAP, as we have received numerous member reports of difficulty in obtaining these drugs at or below ASP+6.

Category definitions

Specific drug categories were not identified in the proposed rule. Instead, CMS seeks comments on the structure of these categories.

MGMA first recommends that CMS propose a definition for these categories as an interim final rule with comment period. This will afford the public an opportunity to offer further advice and critique. It also addresses the phase-in and permits future comment as the program is incrementally implemented. Additionally, we suggest that the categories be narrowly defined, so that physicians may be able to choose vendors based upon the specific brands that they offer for multi-source drugs.

Off-label uses

The use of drugs purchased through the CAP program for covered off-label uses is not addressed in the proposed rule. MGMA seeks clarification as to whether physicians who intend to use drugs for experimental, clinical trial and other off-label uses covered by the Medicare program will be able to obtain drugs through the CAP system. Additionally, MGMA requests clarification on how code J9999 will be handled for the Medicare covered off-label use of certain drugs to match CAP drug orders and drug administration claims.

Provision of NCDs by vendors

MGMA applauds CMS' proposal that vendors be required to provide CAP prospective doctors with a list of specific National Drug Codes (NDCs) for multi-source drugs. However, the proposal notes that the 'information will be provided to physicians who request it no later than the beginning of the election period...' 70 Fed. Reg. 10751. MGMA asserts that it is imperative for a physician to have the list of NDCs that vendors will supply to make their selection of a vendor. Therefore, the list should not be made available upon request. Instead, it should be compulsory and posted to the CMS Website. This requirement should be incorporated into regulatory language of the physician selection of an approved vendor (proposed 42 CFR 414.908(a)), CAP program requirements (proposed 42 CFR 414.908(b)) and Terms of Contract (proposed 42 CFR 414.914).

Statutory Requirements Concerning Claims Processing

Although the preamble to the notice of proposed rulemaking noted that CMS uses the term 'prescription' and 'order' interchangeably and interprets it 'to include a written order submitted to the vendor,' no such definition is included in the proposed rule or current regulation. 70 Fed. Reg. 10753. MGMA recommends that CMS include a definition for 'prescription' and/or 'order' in the subsequent rule.

Dispute Resolution

Resolution of vendor's claim

The relationship created between vendors and physicians under the CAP rule is a unique situation where the vendor relies on the successful adjudication and payment of a physician claim. In many ways, this burdens the relationship between the vendor and physician by putting them at odds in the age old conflict over

CMS-1325-P-391

In the 2005 proposed Medicare physician fee schedule, CMS suggested that providers may solve any difficulty in finding drugs at the average sales price plus six percent (ASP+6) rate by joining a group purchasing organization. However, not all specialties have group purchasing organizations and they are not available in all regions where Medicare providers practice. Furthermore, it is an incorrect assumption that all group purchasing organizations can acquire drugs at or below ASP+6. MGMA practice managers report that group purchasing organizations, while helpful, do not all mirror the reimbursement rates set under ASP+6.

The competitive acquisition program (CAP) may offer a viable alternative for providers who are unable to obtain drugs at or below the ASP+6 rates. However, the program must be administered in such a way that it does not further complicate administrative aspects of physician administration of drugs, requires timely delivery of drugs and continues to be appealing to drug vendors. To assist the Centers for Medicare & Medicaid Services (CMS) in making this program a viable option for medical group practices, MGMA offers the following comments and recommendations.

CMS-1325-P-391-Attach-1.PDF

Submitter : LaNell Kommatas
Organization : Southeast Florida Hematology Oncology Group
Category : Other Health Care Professional

Date: 04/26/2005

Issue Areas/Comments

1-15

Overview of the CAP

Competitive Acquisition Program is flawed and is not the solution for independent oncologists.

1. Patient Access---Patients will have to be inconvenienced because the drugs will need to be ordered and shipped (for new or changed treatments).
2. Administrative burden placed on the physician---The administrative burden placed on the physicians (separate inventory, claims submission and claims appeal) is not reasonable and frankly unheard of. Our office would love to provide services today and have a third party be responsible for the inventory, documentation and billing of our services without charging the practice for these services. Where in America does this takes place! The vendor should be responsible for the submitting and appealing of their claims. Every requirement placed on the physician costs the practice money to perform without any mention of reimbursement.
3. Vendor Bidding Process--CAP vendors are allowed to submit bids to CMS based on all costs related to delivering and dispensing the drug. Why are physicians not reimbursed based on the costs of the drug as well as the costs to deliver and dispense? Why would the physician reimbursement rate be based on the acquisition price of a large vendor? Here again the small independent physician practice is being pushed out of business as there is no way that a small physician can buy the same as a large vendor.
4. Physician election--The physician is locked into one drug vendor for an entire year. What happens if the vendor is unable to deliver does not adhere to quality standards, etc.?

Submitter : Mr. John Akscin
Organization : Oncology Therapeutics Network
Category : Drug Industry

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

OTN appreciates this opportunity to submit comments on the CMS Proposed Rule "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Docket:CMS-1325-P

See attached

CMS-1325-P-393-Attach-1.PDF

Privileged and Confidential



395 Oyster Point Boulevard, Suite 500
South San Francisco, CA 94080

April 26, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: ~~CMS-1380-IFC~~ 1325P
P.O. Box 8010
Baltimore, MD 21244-1850

Dear Dr. McClellan:

Oncology Therapeutics Network (OTN), is a specialty distributor that manages the delivery of complex, breakthrough drugs and biologics to office based physicians, primarily in the specialties of hematology, oncology, rheumatology and urology. OTN submits these comments in response to the proposed rule for the competitive acquisition program (CAP) of outpatient drugs and biologics under Part B ("proposed rule").¹ OTN recognizes the great strides that CMS has made in preparing to implement CAP in the proposed rule. We do wish, however, to further refine it in a manner that increases efficiencies for the Program, generates cost savings and maintains product safety. As such, all of the comments offered in these reply comments are provided in the spirit of assisting CMS in its efforts to create a workable delivery system under Medicare Part B.

OTN in participation with the other members of the Specialty & Biotech Distributors Association ("SBDA") has submitted comments to the proposed rule, which OTN strongly reiterates. In addition to the views expressed in the SBDA's comment letter (which for brevity have not been restated in this letter) OTN seeks to provide CMS with additional comments, as follows:

- I. **Introduction to Oncology Therapeutics Network.**
- II. **Identification of oncology specific challenges and risks under CAP as currently drafted.**
 - a. CAP vs. Buy/Bill Model
 - b. Hidden costs of CAP
 - c. Administrative burden
 - d. Costs of "Day-of" treatment modifications

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

treatment changes). Many practices will incur a significant net loss and will be faced with the decision as to whether to discontinue offering services to Medicare beneficiaries, or worse yet, of closure. OTN does not believe that CMS intends to limit patient access to community cancer care, where over 80% of the most cost effective and highest quality treatment of cancer patients exists. Many Medicare cancer patients will be forced to hospitals to obtain their chemotherapy. This result seems to be the opposite of CMS's desired intent: to reduce costs and improve quality of and access to cancer care.

OTN's management feels that the ASP +6% methodology is an effective and sufficient way in which to achieve CMS's intent. In fact, we note that with the ASP +6% reimbursement methodology, CMS has already accomplished the following goals:

- Reduced the overall cost of care by decreasing the incidence of pharmaceutical price increases.
- Brought drug costs to the Medicare program more in line with prices paid for drugs in the marketplace.
- Preserved access to the high quality of patient care delivered by community oncology.

The benefits of ASP +6% continue to become apparent to CMS and its constituents. However, OTN is concerned that CAP will have significant unintended consequences that are counter to CMS' overall aims, and may in fact diminish some of the progress already made under ASP +6%. Unlike ASP +6%, CAP will not bring about significant efficiencies or additional cost savings for community oncology, but will substantially increase the administrative burden for these complicated disease states and adversely impact patient care.

b. Hidden Costs of CAP

OTN believes that CAP as currently drafted has the unintended effect of creating additional risks and costs in the delivery of oncology care. Some of these risks and costs are identified below.

- Costs for changes in therapy and wasted drug.
- Patient convenience and costs (multiple visits, increased travel to obtain drug).
- Lack of readily-available inventory of drugs (that are not designated for specific patients) for urgent needs potentially resulting in more referrals to hospital emergency rooms.
- Product integrity, Chain of control issues.
- Inventory inefficiencies (larger inventories required; no sharing of multi-

dose vials; no batch preparations; operations and workflow tailored to patient payor status rather than clinical efficiency; need to maintain multiple inventory systems).

- Larger volumes of hazardous waste (full vial wastage/higher disposal costs).
- Additional third party communication requirements and significant administrative burden.

c. Administrative Burden

The administrative burden of CAP on CMS, a CAP vendor and on a practice, must also be considered. The average practice will require additional staff for ordering from the CAP vendor, opening boxes from the vendor and checking the contents against the prescription, shelving and inventorying the contents, and making sure it is not used for anyone else. Additionally, if the patient does not arrive at the physician practice as scheduled, or cannot be treated for whatever reason, practice staff must take time away from treating patients to notify the CAP vendor and ship the product back. This will require that the practice has a tremendous amount of additional help. In fact, a clinic will need to develop a parallel claims processing capability for the CAP, which when coupled with the CAP vendor claims, is likely to substantially increase CMS' administrative costs of running the system and result in significant inefficiency.

OTN recommends that CMS evaluate the adequacy of the planned fee schedule under both the Buy/Bill Model and the CAP model, and institute additional administrative fees, such as a facility or pharmacy fees, to compensate physicians for these additional burdens.

d. Costs of "Day-of" treatment modifications

An open question, for example, is how the planned CAP system will deal with drugs that aren't administered as expected, a common occurrence unique to the oncology environment, as on average 30 % of patient treatment plans change when the patient presents for treatment due to factors such as low blood counts or clinical status change. This may raise both cost and patient convenience issues, as more office visits (and associated co-pays) may become necessary to complete a treatment regimen.

Returns and inventory control may also become larger concerns, as patient-specific drug supplies will need to be carefully segregated and controlled. It is unclear how the Medicare contracted CAP Vendors serving multi-state regions will deal with state law discrepancies related to returns. Some states in the region may allow returns and other may not. Either way, the issue of returning drugs to the CAP Vendor requires additional study and evaluation.

e. Hazardous Waste Costs

CAP as planned will likely increase hazardous waste disposal costs significantly as a result of higher quantities of unused drug from unanticipated treatment changes. Consequently, total waste quantities may significantly add to existing waste levels thus incurring additional disposal costs.

It is unclear which entity (the practice or the CAP vendor) will bear the burden of the hazardous waste disposal costs, including compliance with applicable federal, state and local laws regulating such disposal. Under the Proposed Rule there appears to be no financial consideration of this expense for either providers or CAP vendors. OTN recommends that the CAP vendor does not bear the responsibility for this, but that the physicians discard these drugs along with their other hazardous waste, since the product will already be at their practice. Regardless of which entity has responsibility for discarding hazardous waste, OTN believes that there should be appropriate consideration of this financial and operational burden in assessing reimbursement. OTN recommends a HCPCS code for "pharmacy services, including waste disposal."

III. Highlight differences Between Specialty Distribution and Specialty Pharmacy

Traditionally specialty distributors and specialty pharmacies have represented distinct elements of the supply chain. The CAP program appears to blend these roles as it contemplates contractors who will potentially inventory, distribute, and dispense drugs and biologicals based on patient specific orders. In the section on "Bidding Entity Qualifications," CMS notes that a CAP vendor "would be required to maintain an appropriate license in each State in which the drug vendor seeks to operate under the CAP." Because the CAP vendors will be accepting prescriptions for and dispensing Part B medicines, Medicare appears to be requiring each CAP vendor have state licensure as pharmacies in each state in which it operates as part of the CAP program. However, the CAP rule also indicates that vendors must also be licensed as distributors or wholesalers. Specialty distributors and pharmacies fall under entirely different aspects of state pharmacy laws, regulations and contractual arrangements.

OTN recommends that CMS clearly state whether it intends for vendors to operate under a specialty distribution model, a specialty pharmacy model, or an expanded specialty distribution/ "new hybrid" model. If CMS seeks to establish a new hybrid model, it will need to take these two disparate models and related compliance standards into account and consider establishing one straightforward set of rules for vendors to meet. Additionally, OTN recommends that CMS consider the added financial burdens for any vendor associated with a new hybrid model. Otherwise, the complexity in complying with multiple state licensing standards for both distributors and pharmacies will significantly discourage potential participation by vendors.

The chart below highlights some of the key differences between a specialty distributor and a specialty pharmacy that OTN recommends for consideration:

Specialty Distribution	Specialty Pharmacy
<ul style="list-style-type: none">• Licenses to distribute drug• Requires home state	<ul style="list-style-type: none">• Pharmacy Licenses allow dispensation and distribution of drug to patient

<p><u>wholesaler licensure to ship drug in-state, and out of state licensure in only certain jurisdictions to ship drugs from out of state</u></p> <ul style="list-style-type: none"> • No specific staffing requirements • Distributor does not own any prescription. Distributor owns inventory and sells inventory. Each sale of inventory is an <u>“Order number”</u> • Returns may be accepted under specific circumstances <u>as dictated by the manufacturer</u> • No prescription claims processing technology/ adjudication systems • HIPAA: Distributor is a “business associate” of a “covered entity”, but not actually a “covered entity” 	<ul style="list-style-type: none"> • In order to dispense product across state lines, must register with such state’s pharmacy board as a “non-resident” pharmacy • Requires a licensed pharmacist on staff at all times of dispensing • Pharmacy OWNS the prescription, which is assigned a <u>“prescription number”</u>. • Once medication is prescribed to a patient, if it is unused, it must be disposed of, UNLESS it is still in its original packaging. In that case it must be sent back to the original pharmacy. ONLY the dispensing pharmacy can re-dispense the drug to another patient. Each patient specific prescription must be checked against the product leaving the pharmacy. State laws prevent issuing a prescription number for drug already dispensed, without checking it against that prescription BY THE DISPENSING PHARMACY; • Claims processing, script adjudication capability (through PBM) required. • HIPAA: Pharmacy is a “covered entity,” collecting patient health information. <p>The above requirements are only for a pharmacy sending drugs “as is”, with no mixing, preparation, etc required. Generally single dose vials. If the pharmacy does any admixing, preparation, etc. additional standards apply</p>
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A. Returns

One clear example of the differences between distributors and pharmacies exists in the area of the returns of drug and biological products. Many states do not permit pharmacies to accept returns from patients except under specific circumstances such as when the product is returned in a properly labeled and sealed manufacturer’s package or if customized units are individually sealed and part of a closed-drug delivery system.² The Food and Drug Administration (FDA) also recommends that pharmacists not accept return of drug products once they have left his or her possession.³ In contrast, specialty distributors may generally accept

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

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

product returns under specific circumstances dictated by drug manufacturers. In some circumstances, distributors may be required to accept return of expired product.⁴

The proposed rule suggests that the issue of returns should be addressed between the physician and the distributor/pharmacy. However, while seemingly permissible under specialty distribution arrangements, this may not be feasible under various state pharmacy laws. Moreover, some organizations have suggested that vendors should bear the financial responsibility for all returns. OTN suggests mandated manufacturer acceptance so that the manufacturer bears some of this risk as well. Such a policy is inconsistent with today's practices and would render the CAP model untenable from a cost-management perspective.

There are other issues that CMS may wish to modify on its returns policy. Many of the products involved in CAP will require special storage and handling due to their sensitivity to temperature. Specialty distributors will, therefore, as a general matter, resist accepting some of the specialty products back into the supply channel, as product integrity cannot be verified. In addition, when you take into account that a significant amount of product may be "broken down" from original packaging by the CAP vendor in order to dispense a prescribed unit of dose, it is clear that product integrity would be jeopardized if specialty distributors were asked to accept these "broken down" returns – those that are not in the manufacturers' original, unopened packaging. At a minimum, CMS needs to be clear that broken down returns cannot be recycled back into the supply chain. To do otherwise, would actually violate the clear terms of the statute since the distributor would no longer be able to guarantee that it obtained product directly from the manufacturer.

B. Licensure Issues, Claims Processing and HIPAA

As CMS refines the CAP model in the final rule, it should also note the differences in licensure requirements between distributors and pharmacies. For example, pharmacies are often required to have licensed pharmacists on staff during hours of operation.⁵ In general, although distributors may be required to report extensive information about distributor ownership and management, they face far fewer specific staffing requirements.⁶ Additionally, a licensed pharmacy may generally interpret, evaluate, and dispense drug and biological products. Specialty distributors, however, manage inventory and ship product based on a drug order – not a prescription. Although specialty distributors may be registered or licensed by the state, they are not generally licensed to dispense drug product. If CMS is looking to establish a distribution model for CAP, it will need to consider how distributors will meet the additional standards required for specialty pharmacies. One federal licensing standard here should be appropriate.

Claims processing and adjudication represent other important distinctions between specialty distributors and pharmacies. Pharmacies must have the technical ability to process third-party payer claims, collect co-payments and adjudicate claims on a patient by

⁴ See, e.g., Ga. Code Ann. § 26-4-115(c) (instructing the Board of Pharmacy to promulgate rules for wholesale distributors that includes a requirement that distributors make adequate provisions for the return of outdated product); Ga. Comp. R. & Regs. r. 480-7-.07 (2004) (requiring wholesale distributors to make adequate provisions for the return of outdated prescription drug product for up to six months after the labeled expiration date).

⁵ E.g., Ga. Code Ann. § 26-4-110.

⁶ See, e.g., Fla. Stat. § 499.012 (enumerating requirements for applicants of wholesaler prescription drug permits).

patient basis. In contrast, distributors are not generally equipped to process such patient level claims and do not maintain systems or personnel who are trained to address these issues.

Treatment under HIPAA provisions is another distinguishing characteristic between specialty distributors and pharmacies. In the preamble to the proposed rule, CMS has indicated that vendors would be treated as “covered entities” under HIPAA provisions.⁷ This classification varies from that of specialty distributors, who are considered “business associates” under the HIPAA laws and regulations. Classification as a “covered entity” imposes significant administrative burdens that “business associates” do not necessarily face. If CMS is interested in “converting specialty distributors” into CAP vendors, it must take into account the added administrative and financial burdens associated with complying with a different set of HIPAA rules.

These differences are important for CMS to understand as it develops policies for CAP contractors who will interact with manufacturers, wholesalers, specialty distributors and physician offices. If CMS seeks to establish a new hybrid model, it will need to take these two disparate sets of compliance standards into account and consider establishing one straightforward set of rules for vendors to meet.

IV. Integrity of products distributed throughout the pharmaceutical and biotech supply Channel

In light of the structural changes within Part B reflected in this proposal, it will be particularly important for CMS to establish product integrity standards that reflect the “best practices” of the distribution industry in the CAP program, but that also do not impose significant new requirements which offer no improvement in product integrity for Medicare beneficiaries.

OTN commends CMS for the requirement that CAP vendors shall acquire the drugs and biological products that they distribute from the manufacturer or from a distributor who has acquired the drug directly from the manufacturer.⁸ This one requirement significantly protects product integrity under CAP by limiting purchases of potentially adulterated drugs from secondary markets. The proposed rule would also require CAP vendors to comport with applicable sections of the Federal Food, Drug, and Cosmetic Act, as well as to take appropriate measures “to assure that processing, handling, storage, and shipment of drugs and biologicals are adequate to maintain product integrity.”⁹ OTN supports these requirements and seeks to work with CMS to ensure compliance with federal law and manufacturer’s product specifications.

Compliance with these fundamental requirements alone will significantly protect the integrity of CAP drug and biological products. New requirements beyond these protections, will create an additional burden on CAP contractors, and may harm the efficiency and effectiveness of the CAP program while offering no improvement in product integrity for Medicare beneficiaries. Due to the adequacy of existing requirements, OTN does not consider new requirements necessary or advisable.

⁷ 70 Fed. Reg. 10,745, 10,760 (Mar. 4, 2005).

⁸ 70 Fed. Reg. at 10,759.

⁹ 70 Fed. Reg. at 10,759.

V. CAP Vendor qualifications and requirements

OTN commends CMS in its decision to require CAP bidders to have been in the business of furnishing Part B injectable drugs for at least three years to qualify as a vendor in the CAP program.¹⁰ This requirement ensures that CAP vendors have the requisite experience and stability to deliver timely service to physicians and Medicare beneficiaries. This experience also helps to ensure that CAP vendors are capable of furnishing product that meets all of the product integrity standards established in the proposed rule. OTN requests that CMS clarify that the term “furnishing” includes specialty distributor sales of products to providers under the buy and bill model, and also specialty pharmacy prescription model.

OTN also recommends that CMS consider the financial stability of the CAP contractor. Given the current risks of the program, it is entirely possible that a chosen contractor may become insolvent during the three year period of the contract. Establishing a threshold for potential bidders will help minimize the potential for bidders with a higher risk of insolvency being chosen for the program.

VI. Recommended items for exclusion from enumerated discounts determining “net acquisition costs” of Part B drugs under the CAP program

a. *Prompt Pay*

As part of the proposed rule, CMS will require CAP vendors to submit their “reasonable, net acquisition costs” for obtaining Part B medicines so that CMS may adjust the contract prices in year 2 and 3 of the contract.¹¹ These net acquisition costs represent “[a]ctual acquisition costs [that] are net of all discounts and rebates provided by the vendor’s own suppliers.”¹² Discounts enumerated by CMS include “volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, rebates, refunds, and other price concessions.” With respect to the calculation of vendors’ bid prices, OTN notes that CMS should not include bona fide prompt pay discounts into the contractor’s bid submission. Such credit practices, so long as they undertaken at fair market value and are not passed on to the provider, do not constitute price concessions and should not be treated in the same manner as a traditional price discount. In fact, OTN notes that it would be inconsistent for CMS to include the entirety of prompt pay discounts into bids, if the Agency were to remain consistent to its recent interpretations of the Part B Average Sales Price provisions. Given that the fair market value of bona fide services can be excluded from ASP – and prompt pay discounts currently reflect a large portion of the revenues used to reimburse entities for distribution services – then there is no logic for including most of the prompt pay terms in either the CAP vendor contract price or ASP. So long as the contract terms represent fair market value, arms length transactions and do not result in a reduction of the price actually realized by the manufacturer, CMS should not include them in the bid price.

b. *Time value of Money*

¹⁰ 70 Fed. Reg. at 10,760.

¹¹ 70 Fed. Reg. at 10,764.

¹² 70 Fed. Reg. at 10, 765.

OTN believes that the principle of the time value of money should be appropriately considered when determining when CAP contractors may receive payment for product shipped under the CAP program. The importance of the time value of money is evident in the CAP program. Under the proposed CAP rule, physicians are generally required to bill their claims within 14 calendar days of the date the drug was administered to the beneficiary.¹³ CAP vendors would not receive payment for the Part B product, nor be permitted to bill the beneficiary or the beneficiary's third-party insurance for the copayment, until both the vendor claim and physician claim had been reconciled.¹⁴ Even were the system to operate flawlessly, vendors would experience a greater than 28 day delay in payment between shipment of the drug, physician submission of the drug claim, and carrier reconciliation of the physician and CAP contractor claims. During this delay the CAP vendor would receive no payment for the lost interest that could have accumulated risk-free. Although the time period under this scenario may appear to be 28 days under optimal conditions, in reality delays of greater than 30 days will most likely be the norm. Any delays represent a significant amount of lost revenue for the CAP vendors.

VII. Recommended methods to provide Vendor compensation for assumption of risk

The present financial remuneration as outlined in the proposed rule places undue financial hardship on the CAP vendors. Financial risks such as claims rejection for drugs denied for lack of medical necessity, payments based upon the median of all bids from CAP vendors and not on a specific CAP vendor's bid, costs of wasted drug, and uncollectible co-payments from patients will most likely eliminate any potential for a CAP vendor to break even under CAP. We ask CMS to consider the following to help mitigate these risks:

a. Precertification:

OTN suggests CMS institute a pre-certification process to permit physicians and CAP vendors the opportunity to verify medical necessity before a drug order is filled. Under the proposed rule, physicians bear no risk for denial of drug claims and CAP vendors' ability to win appeal of such claims is highly dependent on the cooperation of the physicians whose financial incentive is limited solely to payment for the drug administration services.

b. Advanced payment

OTN notes that few mechanisms exist within the proposed rule to encourage physicians to submit their claims on a timely basis.¹⁵ Hopefully, the potential threat of suspension of a physician's CAP participation agreement should motivate physicians to submit their CAP claims in a timely manner.¹⁶ However, intermediate steps may also be required. Absent providing the contractors with some new mechanism or enforcement tool, it is quite likely that their ability to eventually realize all of the claims owed to them will be reduced. Other than the above listed threat (not necessarily considered meaningful for physicians), the physician has no real risk at stake by not filing the claim in a timely manner. However, the CAP vendor has a significant risk at stake. OTN believes that the vendor must be compensated for this risk, and

¹³ 70 Fed. Reg. at 10,755.

¹⁴ 70 Fed. Reg. at 10,756.

¹⁵ 70 Fed. Reg. at 10,758.

¹⁶ 70 Fed. Reg. at 10,758.

encourages CMS to adopt partial payment of the CAP vendor's claim upon shipment of the product and with the remaining payment due upon receipt of the drug administration claim by the carrier. This would lessen the financial harm experienced by the vendor from physician claim submission delays and at least attempts to account for the time value of the funds committed by the CAP vendors in the form of shipped product to physicians.

This provision appears especially equitable because the risk of non-payment when the physician fails to file a claim rests on the CAP vendor, who must expend time and resources to informally encourage the physician to file the appropriate claim or engage in the dispute resolution provisions proposed by CMS. We note that some type of enforcement is important in the event that informal processes fail to encourage timely filing of physician claims.

c. Co-pay collection

OTN notes that CMS should consider permitting a contracted relationship between the CAP vendor and the physician, incenting the physician to collect the co-pay at the time of care. Given the relationship between the physician and the patient, it is much more likely that the physician will be able to capture a co-pay than a vendor, with no perceived relationship to the patient. The physician could be incented to capture the co-pay on behalf of the vendor by obtaining a "collection fee" which would cover any associated administrative burden in doing so. Additionally, OTN believes that this method is not only preferable for the CAP vendor, but also for the patient and the physician, since it eliminates the possibility of overly aggressive collection efforts by the CAP vendor which could ultimately discourage patients from seeking treatment. Lastly, this recommendation also minimizes the potential to exacerbate a vendor's bad debt collection problems.

VIII. Phase-in of CAP recommended

Because of the complexities involved in the implementation of CAP, OTN strongly believes that this new system must be phased in slowly. Significant questions have arisen with respect to the leverage that contractors would actually possess under the proposed rule to manage prescription drug costs and the attendant level of risk that would be borne by the contractor during the three year contract period. Accordingly, OTN believes it most effective for the long term success of the program if CMS phased in CAP for one physician specialty, starting with a specialty with fewer complexities and risks to patients quality of and access to care than oncology, over a three-year period and limited the program to one geographic region for the first two years. OTN management believes that commencing the phase-in with Rheumatology is advisable, given that Rheumatoid Arthritis has fewer complexities and is much better suited to CAP. Working with appropriate stakeholders, CMS could utilize the multi-year phase in period to overcome the regulatory and statutory obstacles that may impede the establishment of a successful program.

OTN respectfully recommends that CMS should begin with a regional phase-in involving a limited set of drugs that are typically administered by a physician specialty with fewer complexities and risks to patient quality and access of care than oncology, thereby allowing time for refinement in the issues identified above. OTN appreciates your consideration of these positions and welcomes the opportunity to meaningfully contribute to the development of the the final rule.

XI. Summary of Recommendations

1. CMS needs to further clarify its intention and design of a CAP vendor as it relates to specialty distribution.
2. OTN asks CMS to reconsider the significant administrative burden to both CAP vendors and medicare providers associated with the CAP program
3. CMS needs to understand and address the significant financial risk borne by CAP vendors relating to the payment structure set forth in the Proposed Rule
4. OTN asks CMS to strongly consider phase in of the CAP program in both a single specialty, limited to certain drugs, and rolled out in one region.
5. OTN understands the statutory requirements placed upon CMS by MMA, however the potential waste, administrative burden to CAP vendors, providers and the CMS system, financial risks, and reductions in quality of care to cancer patients warrant continued evaluation and alternative solutions.

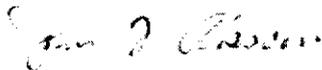
OTN thanks you for this opportunity to provide comments to the CAP program.



John Amos
President
Oncology Therapeutics Network



William Kushner
General Counsel
Oncology Therapeutics Network



John Akscin
Vice President of Government Relations
Oncology Therapeutics Network

Submitter : Dr. Ann Morrison
Organization : Dr. Ann Morrison
Category : Physician

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

I am a psychiatrist with many years of practice, administration and teaching in the public sector. My patients & those treated by others in the public mental health arena benefit from access to psychiatric medications. Patients are able to live in the community, maintain relationships with friends & family and experience relief from disabling & distressing symptoms. In many insurance plans psychiatric treatment, whether medications, psychotherapy or hospitalization is more restricted or limited than treatment for other medical conditions. I am requesting that with the Competitive Acquisition of Outpatient Drugs & Biologics effective treatments currently available be considered & covered. Placing psychiatric treatments on a second tier of coverage is not fair or equitable & will only hamper the struggles of patients & families in combatting these devastating illnesses. Thank you for your consideration. Ann K. Morrison, M.D.

Submitter : Ms. Carolyn Aldige
Organization : Cancer Research and Prevention Foundation
Category : Consumer Group

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

The Cancer Research and Prevention Foundation (CRPF) is a non-profit with the mission of cancer prevention through cutting-edge research and education.

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

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

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

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

Our Foundation is particularly concerned about of the Competitive Access Program and the shortfalls in cancer care reimbursement on the patient and on clinical research. Medicare patients may wind up in the hospital for their chemo and physician practices may be much less likely to spend the time to enroll them into trials. Also that the nursing shortage may drive nurses back to hospitals, further exacerbating the enrollment of older patients into clinical trials by community oncologists, since the research nurses are the ones who tend to spend the time explaining the informed consent process.

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

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

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

Sincerely,

Carolyn R. Aldige
President and Founder
Cancer Research and Prevention Foundation

Submitter : Mr. James Chambers
Organization : Bon Secours Baltimore Health System
Category : Psychiatric Hospital

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

i.e. "See Attachment"

CMS-1325-P-396-Attach-1.DOC

April 14, 2005

Attach#396

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

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

Dear Dr. McClellan:

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

Advantages of Injectable Psychiatric Medications

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

Patient noncompliance with psychotropic medication regimens is similar to that for patients who take medications for somatic illnesses. A review of the literature has found that most patients probably only take 33 - 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a sizeable percentage are wholly noncompliant.¹ For people with schizophrenia and severe mood disorders, noncompliance with medications often results in the relapse of acute symptoms, frequently resulting in negative

outcomes such as rehospitalization, loss of employment/housing, and suicide. These negative consequences for the patient are compounded by a parallel negative impact on the service delivery system: costs escalate as outpatient treatment is stymied, the use of emergency facilities increases, and hospital stays are more frequent and longer.

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

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

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

Current Obstacles Faced by Providers Using Injectable Psychiatric Medications

Unfortunately, community mental health centers (CMHCs) and other multi-service community providers, which serve a large number of people with severe mental illnesses that are eligible for both Medicaid and Medicare, face serious obstacles in providing injectable medications. As safety-net providers, CMHCs are very often heavily burdened treatment settings that lack sophisticated information technology and a sufficient level of administrative staffing. For example, to provide the new injectable antipsychotic risperidone to patients, CMHCs must first purchase the medication, and then seek reimbursement from both Medicare (which makes only partial payment for mental health drugs) and Medicaid. Providers then bear the administrative burden of tracking the claims and the financial risk of receiving incomplete payment from one or both payers. This burden has become an impediment to expanding access to this medication to the full range of patients who could benefit from it. In some cases, CMHCs will only provide the medication to patients that are solely Medicaid beneficiaries. When injectable antipsychotics are included in the Medicare CAP program, this substantial impediment will be removed, as providers would have the option to obtain the medications from a drug vendor that will handle reimbursement from Medicare. Helping providers expand access to this medication will bring great benefit to our patients with schizophrenia.

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

Sincerely,

James Chambers
Executive Director
Behavioral Medicine

Submitter : Ms. Lucinda Long
Organization : Wyeth Pharmaceuticals
Category : Drug Industry

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-397-Attach-1.DOC

Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426

Lucinda E. Long
Vice President
Global Public Policy and Professional Affairs
484-865-5133 - direct

Wyeth

April 26, 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 Ave., SW
Washington, DC 20201

Re: CMS-1325-P (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B) – Comments on Background and Provisions of the Proposed Rule

Dear Dr. McClellan:

Wyeth Pharmaceuticals welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule entitled "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed rule (CMS-1325-P)," which was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Wyeth Pharmaceuticals, a division of Wyeth, is one of the world's largest research driven pharmaceutical and health care companies with leading therapies in the areas of women's health, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology, and vaccines.

Wyeth supports the creation of new Medicare programs like the competitive acquisition program (CAP) that offer physicians a choice in acquiring Part B drugs and biologicals while maintaining patient access to medically necessary therapies. It is our hope that implementing CAP will continue to allow Medicare beneficiaries access to medical care in the most appropriate settings and fairly compensate physicians for their services without increasing their administrative burden. Our comments are framed in support of providing assurance to physicians and beneficiaries that CAP will facilitate appropriate patient care, including access to products and services patients have been accustomed to

Wyeth

Page 2
Mark McClellan, Administrator
April 22, 2005
CMS-1325-P

receiving from their providers. Based on those guiding principles, we offer the following specific comments.

Phase-In of CAP and Establishing Competitive Acquisition Areas

The proposed rule notes several options for limiting CAP's initial phase-in period, both by drug category and geographic area. Wyeth believes an initial roll-out that includes all physician-administered Part B drugs and biologicals distributed in a limited number of competitive acquisition areas (CAAs) would permit CMS to focus on a smaller geographical area and enable identification of broadly applicable issues that could be resolved more easily due to the smaller scale of the operation.

Wyeth also suggests that CMS create as many CAAs under CAP as possible in order to protect physician choice and patient access to Part B drugs and biologicals. In the proposed rule, CMS describes the creation of multi-state CAAs based on existing markets of regional drug distributors and specialty pharmacies. Wyeth agrees with this proposal and supports its implementation encouraging participation in CAP from a variety of small, large, regional and national distributors. In geographic areas where many vendors may not be present, it will be particularly important for multiple vendors to participate in CAP to ensure timely access to needed treatments. By creating multi-state CAAs, CMS will help ensure that enough vendors participate to provide all CAP categories in every CAA and give every physician who is interested in participating in CAP the opportunity to do so.

Page 3
Mark McClellan, Administrator
April 22, 2005
CMS-1325-P

Categories of Drugs to be Included in CAP

Physician Prescribing Choice and Access to Appropriate Therapies

Physicians are required under the MMA to decide each year whether to participate in CAP.¹ The proposed rule states that participating physicians may obtain drugs and biologicals for their patients outside of CAP, and be reimbursed at 106% of Average Sales Price (ASP). The MMA states that CAP vendors should provide at least one drug or biological for each Healthcare Common Procedure Coding System (HCPCS) code within each CAP category for each CAA.² The CAP proposed rule states that CMS will not require vendors to make available every National Drug Code (NDC) included within an individual HCPCS code. Wyeth believes this would severely restrict the choices physicians would have under CAP and in effect create a *de facto* formulary within a CAP category – something we believe was not the intent of Congress.

Wyeth urges CMS to issue a clarification in the final rule that CAP vendors be required to offer at least one formulation, (i.e., at least one NDC) for all single-source drugs that fall within the same HCPCS code. Because drugs or biologicals share the same HCPCS code does not mean the Food and Drug Administration (FDA) approved them as being therapeutically equivalent or bioequivalent. HCPCS codes are created for billing and payment purposes and do not represent medical determinations. Requiring that vendors supply at least one NDC for each single-source product within each category will assure physicians that their choice of products for their patients will be supported through CAP.

¹ SSA § 1847B(a)(1)(A)(ii).

² *Federal Register*, Volume 70, March 4, 2005, p 10751. "Billing and Payment Code: refers to a HCPCS code.



Page 4
Mark McClellan, Administrator
April 22, 2005
CMS-1325-P

Certain Products Should Be Excluded from CAP

Congress recognized when writing the MMA that certain products are not appropriate to be offered under CAP even though they may be covered under Medicare Part B.³ As described in Section 1847B(a)(1)(D) of the Social Security Act (SSA), CMS can exclude competitively biddable drugs and biologicals from CAP if “the application of competitive bidding to such drugs and biologicals: 1) is not likely to result in significant savings; or 2) is likely to have an adverse impact on access to such drugs and biologicals.”⁴ Clotting factors used to treat disorders like hemophilia and drugs or biologicals described with miscellaneous HCPCS codes are two examples of products that should be excluded from CAP.

Clotting Factors

In its proposed rule, CMS proposes to limit CAP to drugs and biologicals administered “incident to” a physician’s service. This proposal is based on several factors including statutory language that identifies physicians as the only Medicare providers who may elect to participate in CAP.⁵ Wyeth agrees that CMS should limit CAP to products administered incident to a physician’s service and encourages CMS to finalize its proposal.

To include in CAP clotting factors, which are not administered in the physician’s office, but are self-administered by the patient, is not only inconsistent with CMS’ own proposal but for the same reason, is also unlikely to result in financial savings to the Medicare program.

³ The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, p 155.

⁴ *Federal Register*, Volume 70, March 4, 2005, p 10749.

⁵ *Federal Register*, Volume 70, March 4, 2005, p 10749-10750.



Page 5
Mark McClellan, Administrator
April 22, 2005
CMS-1325-P

Clotting factors have been exempt from administration in a physician's office as "incident to physician's service" since 1974 when Congress enacted a special provision, Section 1861(s)(2)(I) of the SSA, allowing clotting factors to be covered and reimbursed under Part B as self administered. Since CAP applies to Part B covered drugs and biologicals that are covered "incident to" and as clotting factor, under previous law is not administered "incident to," we believe CMS would need a new authority to allow for coverage under CAP.

In addition, several HCPCS codes for clotting factors are used to describe more than one brand of clotting factor. For example, HCPCS code J7195, *Factor IX (antihemophilic factor, recombinant) per IU*, can be used to describe BeneFIX, Konyne®, and Proplex T. Different brands of clotting factors, though described by a single HCPCS code, are not interchangeable like therapeutically equivalent brand and generic drugs. Each brand of clotting factors has its own safety and efficacy profile and patients who are successfully using one brand of clotting factor may encounter severe clinical risks and a disruption in care if they are forced to switch products under CAP. As a practical matter, requiring a hemophilia patient to be infused in the physician's office each time the patient experiences a bleed may put the patient's life in jeopardy because immediate self-administration of clotting factor is vital to stop a bleed. Waiting until a physician infuses factor into the patient and removing the immediacy of treatment would push the quality of care and the technological advances of hemophilia treatment back more than three decades. Wyeth does not believe that CMS' intent in the implementation of CAP is to single out one group of Medicare beneficiaries to potentially suffer a set back in treatment for their disease. We therefore respectfully request that CMS use its statutory authority to exclude clotting factors from CAP and to clarify that exclusion in the final rule.

Wyeth

Page 6
Mark McClellan, Administrator
April 22, 2005
CMS-1325-P

Products Billed with Miscellaneous HCPCS Codes

Wyeth also believes that products described with a miscellaneous HCPCS code should not be included under CAP because a wide variety of unrelated products are billed using these codes.⁶ If CAP vendors are allowed to omit certain products described with a miscellaneous HCPCS code, patient access to those therapies will be jeopardized. CMS should clearly state in its final rule that any products that are described with a miscellaneous HCPCS code should only be available to physicians via the ASP methodology.

CAP Process Requirements

Many logistical and process details associated with CAP should be clarified in the final rule so that the program can be implemented in the most efficient and effective manner possible.

Re-supply of Physicians' CAP Inventories

Wyeth encourages CMS to finalize its proposal to allow re-supply of physician inventories for drugs administered under CAP if the physician demonstrates that:

1. the drugs are required immediately,
2. the physician could not have anticipated the need for the drug(s),
3. the vendor could not have delivered the drug(s) in a timely manner,
and
4. the drugs were administered in an emergency situation⁷

⁶ HCPCS J3490, *unclassified drugs*, and HCPCS J3590, *unclassified biologics*.

⁷ *Federal Register*, Volume 70, March 4, 2005, p 10755.

Wyeth

Page 7

Mark McClellan, Administrator

April 22, 2005

CMS-1325-P

Wyeth also recommends that CMS define the terms “timely,” and “emergency situation” broadly to allow physicians use of the most appropriate therapeutic options for their patients.

Maintaining Part B Coverage Policies

CMS proposes that under CAP, physicians and CAP vendors follow existing Medicare Part B coverage policies, which require that physicians determine whether the products they plan to administer are covered by their local Part B contractor. Wyeth agrees with CMS and suggests that CMS specifically state that CAP vendors cannot refuse delivery of prescribed products for covered uses. By emphasizing this policy in the final rule, CMS will help ensure that vendors not interfere with patient access to drugs and biologicals deemed medically necessary by physicians.

Proposed Claims Processing

In order to encourage physician participation in CAP, CMS should ensure that physicians maintain decision-making authority to manage their inventories and patient treatment decisions. CMS also should implement CAP in a manner that is not administratively burdensome for physicians who want to participate.

Individual Physicians versus Group Practice Participation

Wyeth suggests that CMS allow physicians within a group practice to individually decide whether to participate in CAP. Many group practices include physicians of different specialties who care for patients with a range of medical needs. A physician’s decision to participate in the program should be based upon their own specialty and patients’ needs; participation should not be dependent on the choice of other physicians in their practice. If CMS does not allow physicians participating in a group practice to make their own decisions regarding CAP, and

Page 8

Wyeth

Mark McClellan, Administrator
April 22, 2005
CMS-1325-P

the physician feels burdened by the ASP methodology, they may send patients to alternative sites of service (for example, the hospital outpatient department) to receive care. An abrupt change in care setting may not only be inconvenient for patients but may also result in a loss of continuity of care. Because physicians practicing in groups have both a group and individual personal identification number (PIN), we believe that identifying physicians (and their prescriptions under CAP) by their individual PIN for the purposes of CAP election makes this approach much more feasible.

Different Vendors for Different CAP Categories

CMS should clarify in its final rule that physicians have the ability to choose a different CAP vendor for each category of CAP drugs they wish to obtain. If, for example, CMS implements CAP categories for rheumatology and oncology products, a physician who wishes to purchase rheumatology drugs from a CAP vendor should not be forced to purchase oncology products from the same vendor.

CAP Administrative Requirements

When designing CAP, Congress intended to minimize physicians' administrative burdens when acquiring Part B drugs and biologicals. Specifically, Congress wanted to make it easier and more efficient for physicians to obtain drugs from a CAP vendor than under the ASP methodology.

Although CMS does not propose reimbursing physicians separately for the anticipated administrative work associated with CAP,⁸ physicians have voiced concern about the expected burdens. For example, physicians have indicated that the requirement under CAP to keep separate electronic or paper inventories for each CAP product will require more administrative work than is currently used to maintain ASP inventories. Physicians also are concerned that they will not be paid appropriately for the time and resources expended if CAP vendors pressure

Page 9

⁸ CMS states in the Proposed Rule that the clerical requirements for participation in CAP are no greater than participating in the ASP-based methodology. *Federal Register*, Volume 70, March 4, 2005, p 10755.

Wyeth

Mark McClellan, Administrator
April 22, 2005
CMS-1325-P

them to appeal a denied drug administration claim so they can receive payment for the administered product.

Also, because the amount of a drug administration claim might be insufficient to meet the amount required to qualify for an administrative law judicial hearing (i.e., the "amount in controversy" requirement), the effort exerted to pursue the appeal will be fruitless. If the amount of the administration claim is joined to the amount of the drug claim in order to meet the "amount in controversy" requirement, then it is only fair that the CAP vendor pay a pro-rated portion of the cost of pursuing an appeal by the physician.

Quality and Product Integrity Aspects

Under CAP, vendors are required to purchase drugs and biologicals from a manufacturer or distributor who obtains products directly from a manufacturer to facilitate assurance of the product quality.

Quality, Service, and Financial Standards for Vendors

For CAP to be successful, high-quality vendors must participate so products can be delivered in a reliable and timely manner and physicians can be convinced that they will be administering the same drugs and biologicals to all their Medicare patients. In order to ensure physicians are comfortable with administering drugs acquired under CAP, Wyeth encourages CMS to finalize its proposal that requires vendors to meet strict quality, financial, and service standards.

Confidentiality and Integrity of Vendor and Manufacturer Relationships

CMS also should emphasize in its final rule that all vendor cost data be confidential and unidentifiable by the manufacturer or wholesaler. CMS has agreed to treat all ASP data submitted to CMS by manufacturers as proprietary information and we encourage CMS to adopt this approach with CAP as well.

Wyeth

Mark McClellan, Administrator
April 22, 2005
CMS-1325-P

The section in the MMA describing CAP does not give CMS authority to intervene in the relationship between manufacturers and distributors. Furthermore, it does not require that manufacturers enter into relationships and negotiations with CAP vendors. CMS should explicitly clarify both of these points in its final rule.

Vendor, Physician and Beneficiary Education

The feasibility of CAP requires significant outreach to all involved stakeholders to help them understand how the program will operate compared to the ASP system. CMS proposes numerous outreach and educational activities targeted at physicians, vendors, and beneficiaries to help them better understand CAP. Wyeth supports the CMS proposal to develop education procedures, services, and forums that use a variety of means and stakeholder involvement to disseminate information and provide assistance regarding CAP. In order to ensure CAP is adopted with a minimum disruption to patient care, we encourage CMS to build relationships and work directly with various relevant groups such as physicians, potential vendors, manufacturers, and patient advocacy groups. Wyeth would be happy to assist in this outreach effort in any way possible.

Concluding Remarks

Wyeth thanks CMS for the opportunity to comment on the issues described in the CAP proposed rule. We strongly suggest that CMS ensure patient access be maintained to medically necessary therapies as prescribed by a patient's physician. We look forward to working with CMS to ensure that CAP is implemented in an appropriate and effective manner. We are happy to discuss these issues with you or your designees and provide additional information upon request. If you have any questions please do not hesitate to contact me at (484) 865-5133.

Sincerely,



Submitter : Mrs. Judie Thompson-Stokes
Organization : Bon Secours Baltimore Health System
Category : Psychiatric Hospital

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

i.e. "See Attachment"

CMS-1325-P-398-Attach-1.DOC

April 14, 2005

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

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

Dear Dr. McClellan:

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

Advantages of Injectable Psychiatric Medications

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

Patient noncompliance with psychotropic medication regimens is similar to that for patients who take medications for somatic illnesses. A review of the literature has found that most patients probably only take 33 - 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a sizeable percentage are wholly noncompliant.¹ For people with schizophrenia and severe mood disorders, noncompliance with medications often results in the relapse of acute symptoms, frequently resulting in negative

outcomes such as rehospitalization, loss of employment/housing, and suicide. These negative consequences for the patient are compounded by a parallel negative impact on the service delivery system: costs escalate as outpatient treatment is stymied, the use of emergency facilities increases, and hospital stays are more frequent and longer.

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

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

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

Current Obstacles Faced by Providers Using Injectable Psychiatric Medications

Unfortunately, community mental health centers (CMHCs) and other multi-service community providers, which serve a large number of people with severe mental illnesses that are eligible for both Medicaid and Medicare, face serious obstacles in providing injectable medications. As safety-net providers, CMHCs are very often heavily burdened treatment settings that lack sophisticated information technology and a sufficient level of administrative staffing. For example, to provide the new injectable antipsychotic risperidone to patients, CMHCs must first purchase the medication, and then seek reimbursement from both Medicare (which makes only partial payment for mental health drugs) and Medicaid. Providers then bear the administrative burden of tracking the claims and the financial risk of receiving incomplete payment from one or both payers. This burden has become an impediment to expanding access to this medication to the full range of patients who could benefit from it. In some cases, CMHCs will only provide the medication to patients that are solely Medicaid beneficiaries. When injectable antipsychotics are included in the Medicare CAP program, this substantial impediment will be removed, as providers would have the option to obtain the medications from a drug vendor that will handle reimbursement from Medicare. Helping providers expand access to this medication will bring great benefit to our patients with schizophrenia.

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

Sincerely,

Judie Thompson-Stokes, LCSW-C
Ambulatory Service-Line Director
Behavioral Medicine

Submitter : Mrs. Ardena Reddish
Organization : Bon Secours Baltimore Health System
Category : Psychiatric Hospital

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

i.e. "See Attachment"

CMS-1325-P-399-Attach-1.DOC

April 14, 2005

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

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

Dear Dr. McClellan:

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

Advantages of Injectable Psychiatric Medications

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

Patient noncompliance with psychotropic medication regimens is similar to that for patients who take medications for somatic illnesses. A review of the literature has found that most patients probably only take 33 - 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a sizeable percentage are wholly noncompliant.¹ For people with schizophrenia and severe mood disorders, noncompliance with medications often results in the relapse of acute symptoms, frequently resulting in negative

outcomes such as rehospitalization, loss of employment/housing, and suicide. These negative consequences for the patient are compounded by a parallel negative impact on the service delivery system: costs escalate as outpatient treatment is stymied, the use of emergency facilities increases, and hospital stays are more frequent and longer.

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

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

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

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Sincerely,

Ardena Reddish, LCSW-C
Acute Care Service-Line Director
Behavioral Medicine