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September 6, 2005

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

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

Dear Dr. McClellan:

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

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

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



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

CATEGORIES OF DRUGS TO BE INCLUDED UNDER THE CAP

Initial category of drugs for 2006

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

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

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

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

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

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

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

Future categories of drugs

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

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

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

Exclusion of leuprolide from the CAP in 2006

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

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

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

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

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

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

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

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

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

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

CLAIMS PROCESSING

Restricting physicians to one vendor

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

ABNs

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

LCA and ABNs

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

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

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

Emergency resupply process

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

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

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

Administrative burden

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

Content of the CAP drug order

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

Also, CMS did not clarify the ordering process for drugs that come in multi-use vials, which is an important issue for urology. For example, testosterone cypionate (J1080), which is frequently used by urologists, typically comes in a 10 cc vial, which equates to about 10 injections. It would be a logistical nightmare to order one vial from the vendor and then have to track all the different patients that are given injections from that vial so that you could properly

bill Medicare. **A process must be developed to handle such drugs or CMS may want to consider these types of drugs as eligible for exclusion from the CAP.** Although testosterone is not included in the CAP drug category for 2006, this will be an issue in the future and it should be addressed.

Payment to vendor

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

Billing beneficiaries for deductible and coinsurance

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

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

DISPUTE RESOLUTION

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

rather than specifying an appropriate loss threshold that an approved CAP vendor would have to bear before requesting suspension of a participating CAP vendor.

BIDDING PROCESS

CAP Prices

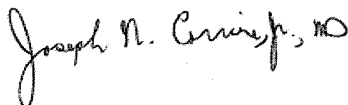
The AUA strongly disagrees with CMS's decision to not exempt CAP prices from the calculation of ASP, which is based on the fact that CMS does not believe it has the statutory authority to exclude prices determined under the CAP from ASP computations. We strongly urge CMS to revisit this decision, especially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

CAP PHYSICIAN ELECTION PROCESS

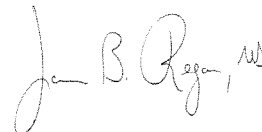
The AUA still continues to believe that physicians should be able to choose to opt out of the CAP at any time during their annual election if there are egregious service-related issues, especially during the early years of the CAP while there is still a great deal of uncertainty. Nevertheless, we do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

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

Sincerely,



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



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