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October 9, 2006

*BY ELECTRONIC FILING*

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-1321-P (Medicare Program; Revisions to Payment  
Policies Under the Physician Fee Schedule for Calendar  
Year 2007 and Other Changes to Payment Under Part B)**

Dear Administrator McClellan:

On behalf of the Association of Community Cancer Centers ("ACCC"), we appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") proposed rule regarding revisions to payment policies under the Medicare physician fee schedule,

published in the Federal Register on August 22, 2006 (the “Proposed Rule”).<sup>1</sup> 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 percent of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60 percent of all U.S. cancer patients.

Medicare beneficiaries depend upon advanced drugs<sup>2</sup> to fight cancer, but their physicians only can provide these drugs if Medicare’s payment rates adequately cover physicians’ expenses for providing them. Since CMS began implementing the payment reforms required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), ACCC has been deeply concerned that reimbursement for cancer therapies, drug administration, and other necessary support services, might not be sufficient to cover physicians’ costs. We have been pleased with the steps CMS has taken so far to protect access to care, including introducing new codes for drug administration services, implementing the supplying fees for oral anticancer and anti-emetic drugs, and creating the demonstration projects in 2005 and 2006 to improve the quality of care provided patients undergoing chemotherapy, but we remain concerned.

In 2007, we anticipate that physician offices will be under greater pressure than ever to provide care to a growing number of beneficiaries, yet also face greater uncertainty about Medicare reimbursement for these services. CMS predicts that changes in the fee schedule, including the predicted 5.1 percent reduction in payments for all physician fee schedule services, implementation of certain provisions of the Deficit Reduction Act of 2005 (DRA), and other changes will reduce Medicare payments for hematology and oncology services by 5.6 percent.<sup>3</sup> Physicians cannot sustain their current levels of services under these payment cuts. We urge CMS to take whatever steps are necessary to ensure that physicians are adequately reimbursed for providing advanced cancer care and to protect Medicare beneficiaries’ access to life-saving and life-extending treatments.

With these general concerns in mind, we recommend that CMS make the following specific revisions under the physician fee schedule for 2007:

- Work with Congress and all interested parties to make changes to the Sustainable Growth Rate (SGR) or take other action to permanently stabilize

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<sup>1</sup> 71 Fed. Reg. 48982 (Aug. 22, 2006).

<sup>2</sup> Throughout our comments, we use “drugs” to refer to both drugs and biologicals.

<sup>3</sup> 71 Fed. Reg. at 49070.

physician payments at levels adequate to protect beneficiary access to care and work with the physician community to develop appropriate quality measures linked to payment incentives.

- Not implement the significant reductions in payment for drug administration services, as would occur under the proposed changes to the practice expense methodology, at least until the effect of these changes can be considered in conjunction with the expected reduction in the conversion factor and other changes mandated under the MMA and DRA and a determination can be made that beneficiary access to cancer care won't be compromised.
- Ensure continued beneficiary access to essential IVIG services by continuing to pay physicians for preadministration-related services for standard and specialty IVIG. If CMS believes there is a basis for discontinuing payment for these services, the reasons must be articulated and interested parties must have an opportunity to comment.
- Not impose any further reduction in payment for second and subsequent imaging services in the same session and continue to study the resources used in combinations of imaging services and assess the interaction of the existing multiple imaging procedure policy with the imaging payment reductions also required by the DRA;
- In order to ensure the accuracy and validity of the data used, and to protect beneficiary access to care, assure that adequate procedural and substantive safeguards are in place before using the widely available market price (WAMP) or average manufacturer price (AMP) for drugs instead of payment based on average sales price (ASP);
- Ensure that when compounded drugs are prescribed and provided, the costs associated with such compounding are included in the pricing, and instruct contractors accordingly in order to promote standardization in policies and pricing related to compounded drugs.

We discuss these recommendations below.

## **I. Background**

### **A. Sustainable Growth Rate**

Under the existing formula for calculating the physician fee schedule updates, physicians have been threatened with payment reductions for several years. Only through "eleventh hour" congressional action have the payment rates

instead been frozen. Once again, CMS anticipates a 5.1 reduction in the conversion factor for 2007 and further negative updates in later years. ACCC is very concerned about the effects of these cuts, and continued freezes, in payment rates on beneficiary access to cancer care and supportive services. A payment system that does not reflect the reality of health economics cannot be sustained, and physicians cannot continue to be held hostage each year under the specter of significant reductions in reimbursement. We urge CMS to work with physician groups and Congress to identify actions the agency can take to stabilize physician payments at appropriate levels permanently to protect beneficiary access to care. We strongly recommend that CMS implement any changes necessary to prevent the expected payment cuts.

CMS repeatedly has expressed its intention to promote improved quality of care while also ensuring adequate physician payments. ACCC continues to share CMS' interest in developing incentives to promote improved quality of care, and we urge CMS to continue to work with the physician community on developing quality measures and incentives. By linking consensus-based quality measures to payment incentives, Medicare could ensure that reimbursement remains adequate to protect beneficiary access to care while also encouraging physicians to improve the quality of care they provide.

## **B. Practice Expense Issues and Drug Administration**

As set forth in more detail in ACCC's comments on CMS' proposed changes regarding the work relative value units ("RVUs") under the physician fee schedule and proposed changes to the practice expense ("PE") methodology, published in the Federal Register on June 29<sup>th</sup>, 2006, we have serious concerns about these proposed changes and their effect on beneficiary access to cancer care, particularly when they are considered in conjunction with other payment reductions set forth in this Proposed Rule.<sup>4</sup> As proposed, these PE RVU changes would result in 0.5 to 8.4 percent cuts in many drug administration codes in the first year, and once fully phased in, the payments for these codes would be reduced by 0.5 to 25 percent, before any changes in the conversion factor are applied.

ACCC urges CMS to carefully consider our previously submitted comments on the proposed changes to the PE RVUs and not to implement these reductions in drug administration payments before complete claims data for 2006 are available, and CMS has the opportunity to study the effect of these and other

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<sup>4</sup> Letter from Christian Downs, Executive Director of ACCC, to Mark McClellan, Administrator, CMS (August 21, 2006), available at [http://www.accc-cancer.org/PUBPOL/pubpol\\_physissues.asp](http://www.accc-cancer.org/PUBPOL/pubpol_physissues.asp)

payment changes required by the MMA and DRA and assure that beneficiary access to care won't be adversely affected.

### **C. Preadministration-Related Services for Standard and Specialty IVIG**

ACCC was pleased that in last year's physician fee schedule final rule CMS established a code (G0332) to allow billing for preadministration-related services for IVIG, and we are very concerned that this code is now listed in the Proposed Rule for 2007 as "deleted" even though there is no discussion of it in the preamble to the rule. As CMS noted in establishing the code last year, physicians incur additional costs related to obtaining standard and specialty IVIG, scheduling administration for specific patients, and ensuring that patients receive the most appropriate IVIG available at the time, taking into consideration the patient's condition and medical history. The circumstances that led CMS to establish this code have not changed, and CMS has not articulated any basis for changing the policy established last year. Therefore, the cost of these preadministration services must be continued.

If CMS intends to discontinue payment for preadministration related services for standard and specialty IVIG, the basis for this significant policy changes must be articulated and interested parties should have an opportunity to have their comments heard by CMS. Unless this dialogue occurs before implementation of the 2007 fee schedule, CMS should continue to pay physician for preadministration-related services for standard and specialty IVIG, to ensure patient access and patient safety.

### **D. Radiation Oncology**

As also noted in our previous comments, we urge CMS to finalize the work RVUs for the nine radiation oncology codes submitted by ACCC to the AMA/Specialty Society Relative Value Scale Committee (RUC) for review.<sup>5</sup> We also want to reiterate our concern that CMS' proposed practice RVUs for medical physics services are too low. Payment for these services that are essential to the provision of safe and effective radiation therapy would be reduced dramatically, even as demand for trained medical physicists has increased significantly. We urge CMS to review the direct practice expense inputs for these codes and ensure that accurate salary and time data are developed for the codes for 2008.

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<sup>5</sup> Id. The codes at issue are 77263, 77280, 77290, 77300, 77315, 77331, 77334, and 77470.

ACCC also encourages CMS to continue the ongoing oncology demonstration project with any necessary adjustments. This demonstration provides data on quality issues and is an important additional source of reimbursement for physicians providing care to cancer patients.

**II. Miscellaneous Coding Issues – Global Period for Remote After-loading High Intensity Brachytherapy Procedures**

We are pleased to see that CMS is proposing to eliminate the global period for remote after-loading high intensity brachytherapy procedures and permit separate payment each time the services are provided. This is consistent with the way care is actually provided to patients and is a more rationale payment approach. We would be interested in working with the AMA's Relative Value Update Committee (RUC) in considering any necessary revaluation of the work and practice expense values.

**III. DRA Proposals – Payment for Imaging Services**

ACCC continues to be concerned about the effect of the current 25 percent reduction in payment for certain multiple imaging procedures performed on contiguous body parts, but we appreciate that CMS is proposing to maintain the cut at 25 percent rather than phasing in a 50 percent reduction, as originally proposed. We particularly urge CMS to make no further reductions until actual use of resources associated with multiple imaging procedures can be assessed in more detail, and the effects of the imaging provisions of the DRA can be considered. As we have noted previously, many of the costs associated with imaging procedures, such as equipment and supply costs, are the same for each scan, no matter how many scans are performed in a single session, and the technician often must readjust the patient's body position for each scan, even if the subsequent scan is of a contiguous body part. Therefore, we urge CMS to continue to seek the input of the American College of Radiology and other interested groups to assess the resources actually required to perform various combinations of imaging services and to determine the appropriate adjustment for multiple procedures.

In addition to the reduction in payment for multiple imaging procedures, CMS is proposing, pursuant to section 5102(b)(1) of the DRA, to reduce the payment for the technical component of imaging services under the physician fee schedule if the payment for the service under the outpatient prospective payment system (OPPS) is lower. Under such circumstances, payment under the physician fee schedule will be capped at the hospital outpatient department payment amount. We urge CMS to carefully assess the effect this payment cap has on the provision of the limited number of procedures for which physician fee

schedule rates are higher than the corresponding outpatient department rates and also to ensure that the cap is applied only to imaging services and not to codes that are integral to the provision of therapy, even if an imaging technology is a necessary component of the therapeutic procedure.

#### IV. ASP Issues

##### A. Substitution of WAMP or AMP for ASP

As set forth in previous comments, ACCC has serious concerns about the substitution of WAMP or AMP for ASP and the effect this lowering of reimbursement would have on the ability of physicians to continue to provide advanced cancer therapies to Medicare beneficiaries.<sup>6</sup> We are pleased CMS appreciates that there are complex issues involved in substituting a lower payment amount for a drug if the OIG finds that the ASP exceeds the WAMP or AMP by more than the established threshold and urge CMS to move cautiously, if at all. CMS' authority in this area is discretionary, and we ask that any consideration to substitute WAMP or AMP for ASP be accompanied by procedural and substantive safeguards, such as notice and comment rulemaking, identification of the specific sources of information used to make such determinations, and explanations of the methodology and criteria for selecting such sources, as Congress intended.<sup>7</sup> It is vital that stakeholders have an opportunity to provide input and participate in this decision to ensure that cuts in reimbursement rates do not adversely affect beneficiary access to cancer care.

##### B. Payment for Compounding of Drugs

ACCC is concerned about the lack of guidance from CMS to its contractors regarding pricing for compounded drugs and the resulting variation in policies around the country, including one contractor who has discontinued payment of a compounding fee.<sup>8</sup> This is particularly important with respect to pain drugs that often are administered intrathecally.

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<sup>6</sup> Letter from E. Strode Weaver, President, ACCC, to Mark McClellan, Administrator, CMS (September 30, 2005), available at: [http://www.accc-cancer.org/PUBPOL/pubpol\\_physissues.asp](http://www.accc-cancer.org/PUBPOL/pubpol_physissues.asp)

<sup>7</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, H. Rep. No. 108-391, at 592.

<sup>8</sup> [https://www.noridianmedicare.com/p-medb/news/bulletins/docs/Medicare\\_B\\_News\\_Issue\\_227\\_April\\_4,\\_20061.pdf](https://www.noridianmedicare.com/p-medb/news/bulletins/docs/Medicare_B_News_Issue_227_April_4,_20061.pdf) (Noridian discontinues payment of compounding fee effective May 1, 2006).

When a drug or biological requiring compounding is ordered, time and effort are required to safely and accurately mix the products according to specification and in compliance with extensive state and federal regulations. In particular, intrathecally administered products for pain management usually are purchased from the manufacturer and must be compounded by specially trained pharmacists. Special equipment, including a laminar flow hood, is required. Physicians then typically purchase the product from the pharmacy and bill Part B. Sterile compounding is expensive and time consuming, but it is an essential service to provide quality patient care and should be reimbursed. These costs should be taken into account, and contractors should not have complete discretion on pricing for compounded drugs.

CMS has acknowledged the costs associated with compounded drugs in the Part D arena, stating that “labor costs associated with mixing a compounded drug product that contains at least one FDA approved prescription drug component can be included in dispensing fees.”<sup>9</sup> We ask CMS to direct its contractors to include the costs associated with compounding when pricing drugs and to encourage more standardization in contractor policies regarding compounded drugs.

## V. Conclusion

In summary, ACCC continues to be concerned that the expected substantial reduction in the conversion factor, combined with other cuts in reimbursement pursuant to the MMA and DRA, will have a serious negative effect on patients battling cancer. Physicians simply cannot continue to absorb the significant cuts in payment rates for cancer services without substantial ramifications for patient care. In order to ensure that Medicare patients continue to have access to essential cancer services, we respectfully request that CMS adopt the following recommendations:

1. Take any action possible to prevent the expected 5.1 percent cut in the conversion factor and work with Congress to address the ongoing problems with physician payment updates permanently pursuant to the SGR methodology in order to maintain beneficiary access to essential cancer care while also improving the quality of care provided;
2. Prior to implementation, carefully assess the effects of the proposed significant cuts in payment for drug administration, in conjunction with the reduction in the conversion factor and other payment changes

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<sup>9</sup> 70 Fed. Reg. 4194, 4232 (Jan. 28, 2005).

- pursuant to the MMA and DRA, to ensure that beneficiary access to cancer care won't be adversely affected;
3. Continue to pay physicians for preadministration-related services for standard and specialty IVIG to ensure these services are available to beneficiaries and that these essential drugs are provided as safely as possible;
  4. Continue to study the resources involved in performing multiple imaging services before imposing any further payment adjustments and take into consideration the added effect of expected reductions in the conversion factor and other changes in payment policies affecting imaging;
  5. Implement adequate safeguards and allow stakeholder input prior to any decision to substitute WAMP or AMP for ASP-based payment and provide us with the information we need to ensure the accuracy and validity of the data used and to protect against harm to beneficiary access to care;
  6. Continue the oncology demonstration project and work with ACCC and other oncology specialty groups to identify appropriate quality measures and payment incentives to improve access to quality cancer care;
  7. Ensure continued beneficiary access to the best and most appropriate pain medications by providing guidance to CMS contractors to include the costs associated with compounding when pricing compounded drugs.

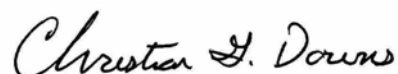
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ACCC appreciates the opportunity for offer these comments, and we look forward to continuing to work with CMS to address these vital issues. Please contact me at 301-984-9496, if you have any questions or if ACCC can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,



Christian G. Downs  
Executive Director