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August 30, 2007

Herb B. Kuhn, Acting Deputy 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-1385-P (Medicare Program; Revisions to Payment
Policies under the Physician Fee Schedule for Calendar
Year 2008)**

Dear Deputy Administrator Kuhn:

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 July 12, 2007 (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 650 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.

Many cancer patients turn to physician offices to receive their treatment and related care, and it remains vitally important that physicians are properly reimbursed for these services. Since the implementation of the Medicare Modernization Act (MMA) of 2003,

¹ 72 Fed. Reg. 38121 (July 12, 2007).

ACCC has been concerned that reimbursement for cancer therapy, including drugs² and other services, may not be adequate to cover physicians' costs. In the past, we have been pleased to see CMS take steps to ensure access to quality care through measures such as implementing new codes for drug administration services, implementing supplying fees for oral anticancer and anti-emetic drugs, and creating the demonstration projects to improve the quality of care provided to patients undergoing chemotherapy in 2005 and 2006. This year, we also are pleased that CMS has proposed to continue to make add-on payments for the preadministration-related services associated with intravenous immunoglobulin (IVIG) and will implement the expanded Physician Quality Reporting Initiative (PQRI). However, we are concerned that if the fee schedule is implemented as proposed, medical and radiation oncologists will face major cuts to reimbursement that ultimately may affect patient access to quality care.

In 2008, the number of Medicare beneficiaries is will continue to grow, and the number of beneficiaries needing care for cancer also is likely to expand. As the demand for care increases, however, physicians once again face a proposed cut in Medicare reimbursement that would make it more difficult to respond to the growing need for their services. If Congress does not act, hematologists and oncologists are scheduled to have an 11 percent decrease in Medicare reimbursement. These cuts are due to the Sustainable Growth Rate (SGR) formula, calling for a 9.9 percent decrease in the conversion factor, in addition to an application of a budget neutrality adjustment to the work Relative Value Units (RVUs) and the continued phase-in of the new practice expense methodology. Even if Congress does act to eliminate the cut to the conversion factor, as they have in recent years, a one percent reduction still is predicted for hematology and oncology services.³ We encourage CMS to take the necessary steps to ensure physicians are reimbursed adequately for the quality cancer care that they deliver to their patients.

With these general concerns in mind, we recommend CMS make the following changes to the physician fee schedule for CY 2008:

- Work with Congress, the Medicare Payment Advisory Commission (MedPAC), and other parties to stabilize or replace the SGR formula so physicians do not face major cuts to reimbursement each year.
- Apply the budget neutrality adjustor to the conversion factor instead of to the work RVUs to distribute the impact of the reduction fairly among procedures.

² Throughout our comments, we use "drugs" to refer to both drugs and biologicals.

³ 72 Fed. Reg. at 38213.

- Continue to assume a 50 percent usage rate and 11 percent interest in determining the costs of medical equipment for calculating practice expense RVUs.
- Continue to make the add-on payment for preadministration-related services for IVIG and develop a permanent additional payment for the acquisition of this important therapy.
- Implement the PQRI program in a manner that promotes the best quality of care possible. CMS also should work with specialty groups to ensure that the measures currently in place accurately reflect quality of care in each specialty.
- Develop a clear and timely process for accepting and evaluating requests to revise the list of compendia used to determine covered uses of drugs and biologicals used in anticancer chemotherapeutic drug regimens.
- Provide more guidance in the implementation of reporting of hemoglobin or hematocrit levels when reporting the use of erythropoiesis stimulating agents (ESAs).
- Give manufacturers clear instructions for reporting average sales price (ASP) data to ensure that Medicare reimbursement reflects market prices.
- Exercise caution in implementing the payment limits for imaging procedures to protect patient access to these services.
- Revise the Competitive Acquisition Program (CAP) to make it a viable option for more physicians.

We discuss these recommendations below.

I. Sustainable Growth Rate (SGR) (Background, Impact, TRHCA – Section 101(d): PAQI)

Under the existing formula for calculating the physician fee schedule updates, physicians have been threatened with severe payment reductions in each of the past several years. Only through “eleventh hour” congressional action have the payment rates instead been frozen or increased minorly. This happened again last year, although Congress also created bonus payments for reporting quality data under the PQRI. For 2008, physicians once again face a 9.9 percent cut to the conversion factor and are likely to see more cuts in years to come as well. Even if Congress acts again to freeze reimbursement, Medicare payments effectively will be cut because they have not been adjusted for inflation. Physicians cannot plan for the future in an unpredictable reimbursement environment that fails to keep pace with the costs of labor and supplies. ACCC is deeply concerned about this situation because unstable reimbursement may force physicians to reduce the number of Medicare beneficiaries they treat, delay investments in new technologies, or ask

patients to seek care from other settings. ACCC urges CMS to work with Congress and other stakeholders to develop a more stable and appropriate payment formula for the future. We also ask CMS to take any steps necessary to minimize the effect of the cuts if Congress does not act, including using the Physician Assistance and Quality Initiative (PAQI) Fund to buy down the negative update to the conversion factor.

II. Budget Neutrality and Relative Value Units (RVUs) (Background, Impact)

If Congress does not step in to halt the 9.9 percent cut to the conversion factor, hematology and oncology services face a projected 11 percent decrease. About 10 percent of this can be attributed to the SGR update, leaving a one percent decrease caused in part by the implementation of a budget neutrality adjuster to all of the RVUs. The actual impact on physicians will be even greater when the effect of inflation is considered. Even if Congress does act to eliminate the nearly 10 percent cut in the conversion factor, the negative one percent update is still a major cause for concern for the membership of ACCC.

ACCC suggests that CMS apply the budget neutrality adjuster to the conversion factor instead to the work RVUs. If a reduction must be made to remain budget neutral, we believe the fairest method to do that is by applying the reduction to the conversion factor. This American Medical Association, the Relative Value Scale Update Committee (RUC), and numerous other specialty societies recommended this approach for the 2007 physician fee schedule,⁴ and we ask CMS to take this approach in 2008.

III. Equipment Usage and Interest Costs Included in Practice Expense RVUs (Resource-Based PE RVUs)

ACCC supports CMS's proposal to continue to apply an equipment usage assumption of 50 percent when determining amount of equipment costs to include in the practice expense RVUs.⁵ We share CMS's concern that increasing the assumed equipment usage percentage would produce insufficient allowances for equipment costs at the service level and could discourage the appropriate use of medical technologies. It is critical that Medicare's payments reflect the significant costs of equipment used in cancer care, such as radiation therapy equipment or imaging equipment. We also agree that the 50 percent rate may not be accurate for

⁴ 71 Fed. Reg. 69623, 69735 (Dec. 1, 2006).

⁵ 72 Fed. Reg. at 38132.

all equipment, but we recommend that CMS continue to apply the 50 percent usage assumption until sufficient empirical data are available to justify a change.

We also agree with the proposal to continue to assume that 11 percent interest is incurred in the purchase of medical equipment for purposes of calculating practice expense RVUs.⁶ CMS's analysis of the 2007 Small Business Administration data indicates that this rate continues to be appropriate. We concur with this conclusion, and we ask CMS to implement this proposal in the final rule.

IV. Preadministration-Related Services for IVIG (Coding – Payment for IVIG Add-On Code)

ACCC is pleased that CMS proposes to continue payment using code G0332 for preadministration-related services for IVIG.⁷ As CMS noted when it established the code, physicians incur additional costs related to obtaining IVIG and scheduling administration for specific patients. Physicians also must ensure that patients receive the most appropriate IVIG available at the time, taking into consideration the patient's condition and medical history. We thank CMS for recognizing the importance of IVIG and addressing concerns about access and availability. We ask CMS to finalize its proposal to continue payment for G0332 at the same level of PE RVUs as in 2007.

CMS also indicates that it might discontinue payment for preadministration-related services after 2008. Before implementing any change in payment, CMS should carefully consider the market conditions for IVIG and stakeholders' concerns about access and availability. ACCC also supports the development of a permanent payment additional for acquisition of IVIG, similar to the payment for clotting factor, to help ensure access to this important therapy.

⁶ Id.
⁷ Id. at 38146.

V. PQRI (TRHCA – Section 101(b): PQRI)

ACCC supported the creation of the PQRI by Congress in 2006. We hope that the implementation of pertinent quality reporting measures will lead to improved quality of care for patients. As CMS implements the program for 2008, we recommend that the agency use data from the initial PQRI reporting period in 2007 to determine if the current measures are appropriate and effective. We also recommend that CMS continually evaluate and revise the standards, if necessary, to ensure that they align with clinical practice and can be reported by physicians with minimal administrative burden.

ACCC recommends that CMS have an open dialogue with specialty societies to determine the best and most appropriate reporting measures. Oncologists have already seen that physicians are not able to report several of the current quality measures because the measures do not reflect accepted clinical practices. For example, several measures can be reported only when chemotherapy is provided on the same day as a physician evaluation and management (E&M) service, yet patients often receive chemotherapy without also receiving a physician E&M service. It also is possible that changes in treatments and procedures or regulations could render other reporting measures obsolete, and CMS should be ready to substitute those with more up-to-date measures. CMS can accomplish this by working closely with specialty societies to determine the best quality measures. In particular, we recommend that CMS replace several of the oncology measures with the more appropriate standards produced through the AMA-Physicians Consortium for Performance Improvement (AMA-PCPI). Specifically, measures 71, 72, 73, and 74 should be replaced with the new oncology measures developed by the AMA-PCPI.

Finally, we ask CMS to include the anemia quality indicators required by 110 of the Tax Relief and Health Care Act of 2006 (TRHCA) among the PQRI measures for oncology. As discussed in section VII below, section 110 requires physicians to report hemoglobin or hematocrit levels for patients receiving treatment for anemia in connection with treatment for cancer on or after January 1, 2008. CMS states that it will use these anemia quality indicators to measure the quality of care provided for this condition.⁸ We believe that the mandatory anemia measures, like the voluntary PQRI measures, will help to serve the goal of improving the quality of care provided and we ask CMS to acknowledge that they are of equal importance by including the anemia measures in the list of PQRI measures. Adding the anemia measures to the list of PQRI measures also might encourage more physicians to participate in the PQRI. CMS could implement this recommendation without changing the frequency requirements for each type of standard. Physicians would

⁸ Id. at 38204.

be required to report the anemia measures in all cases that meet the statutory requirements, and would be required to report other PQRI measures in at least 80 percent of the applicable cases.

VI. Compendia Process Changes (Drug Compendia)

ACCC appreciates CMS's goal of establishing a clear process for accepting and considering requests to revise the list of compendia used to determine medically-accepted indications for drugs used in an anti-cancer chemotherapeutic regimen. As CMS acknowledges, the Medicare statute identifies certain compendia that are used to determine the medically-accepted uses of a drug or biological used in an anti-cancer chemotherapeutic regimen.⁹ By statute, Medicare must cover off-label uses of cancer drugs that are supported by citations in the American Hospital Formulary Service-Drug Information (AHFS-DI), the United States Pharmacopoeia-Drug Information (USP-DI) or its successor publications, or the American Medical Association Drug Evaluations (AMA-DE) or by clinical evidence in peer-reviewed literature.¹⁰ This requirement protects beneficiary access to innovative therapies, used in conformity with evolving standards of care. At this time, however, the AMA-DE no longer is published, and USP-DI now is published by Thomson Micromedex® under the name DrugPoints®.

ACCC can not stress enough the importance of identifying several compendia for use in making coverage decisions so patients can have access to the most appropriate treatment option for their type of cancer. Because each compendium has a different review and publication schedule, CMS will best protect beneficiary access to care, provide physicians and carriers with more data regarding current treatment options, and increase the likelihood that at least one compendium will recognize a new development in a timely manner if it includes at least two compendia on the list for use by Medicare carriers.

ACCC agrees with CMS that all compendia used for Medicare coverage decisions should review research using the highest quality of standards and should abide by as many of the criteria identified by the Medicare Coverage Advisory Committee (MedCAC).¹¹ We recognize that any single publication might not meet all of the criteria, however. CMS should not refuse to recognize a compendium if it does not meet all of criteria, but instead should weigh the importance of the criteria and recognize publications that meet several of the factors.

⁹ Id. at 38177.

¹⁰ Social Security Act (SSA) § 1861(t)(2), as amended by the Deficit Reduction Act, Pub. L. No. 109-171 § 6001(f).

¹¹ 72 Fed. Reg. at 38178.

We also appreciate CMS's desire to engage the public and stakeholders on this matter. The addition or subtraction of compendia from the approved listings is not a process that should be taken without consultation from the public to determine the validity of the claims about each publication. We are concerned that CMS's proposed timeline for revising the list of compendia is too drawn-out and would prevent timely changes to the list. As described in the Proposed Rule, the process would take, at a minimum, 225 days, including a 45-day period before requests are accepted after CMS publishes a notice in the Federal Register, a 30-day period to accept requests, a 30-day comment period on those requests, and a 120-day period to consider requests and publish a decision.¹² We appreciate CMS's efforts to provide adequate notice and opportunity for comment, but we believe the process could be accelerated by eliminating the first 45 day period. We also ask CMS to minimize the delay between its acceptance of completed requests and the announcement of the comment period on those requests.

VII. Reporting of Hemoglobin or Hematocrit Levels with ESA Usage (TRHCA – Section 110: Anemia Quality Indicators)

ACCC supports the broad goal of gathering information to improve the quality of care, as evidenced by our support of the PQRI program. Similarly, ACCC supports the reporting of hemoglobin or hematocrit levels with the usage of ESAs in cancer patients, as required by section 110 of the TRHCA. We urge CMS to implement this requirement in a manner that produces useful quality data and imposes minimal burdens on physicians.

In the Proposed Rule, CMS acknowledges that section 110 requires the agency to use rulemaking to address implementation of the hemoglobin or hematocrit reporting requirement.¹³ CMS does not describe how it plans to implement this requirement, however. ACCC requests that CMS publish detailed guidance well in advance of the January 1, 2008 implementation date as to how exactly physicians should report these levels. A detailed set of instructions should be included in any final rule on this subject, similar to the instructions for reporting measures under the PQRI. The limited information released thus far regarding this proposal, including the new coding modifiers, has been limited and has caused confusion among our membership. CMS should provide clear instructions regarding the use of these modifiers. Alternatively, CMS could model the reporting process after the "hematocrit level in ESRD patients" measure that is currently in use in the PQRI.¹⁴

¹² Id. at 38178-79.

¹³ Id. at 38204.

¹⁴ Our support for this requirement should be viewed in conjunction with comments recently submitted to CMS regarding the reimbursement for ESAs in chemotherapy-induced anemia patients

VIII. More Accurate Reporting of ASP (ASP Issues)

ACCC is supportive of the basic idea of a more accurate ASP reporting methodology. We believe that CMS should provide clear instructions that will help manufacturers submit accurate and consistent data and ensure that the ASPs CMS uses to reimburse physicians reflect market prices.

IX. Payment for Imaging Procedures (Coding – Reduction in TC for Imaging Services)

ACCC remains concerned about the limit on payment for imaging services required by section 5102(b)(1) of the Deficit Reduction Act of 2005. We appreciate CMS's efforts to limit application of this requirement to certain procedures, and we ask the agency to continue to exercise great care in determining which procedures are subject to this limit. ACCC believes that this policy goes against the new CMS mission, which "...is changing from indemnity insurer-simply paying the bills-to trying to help people stay well, prevent complications, and avoid unnecessary healthcare costs."¹⁵ Imaging services such as MRIs, CTs, PET and PET/CT scans help to reduce treatment costs by allowing identification of tumors at their earlier, more treatable stages, facilitating appropriate diagnoses, and measuring tumors' response to treatment. By cutting the reimbursement on these exams, CMS is making it more difficult for physicians to provide appropriate cancer care in a cost-effective manner.

X. Revisions to the Competitive Acquisition Program (CAP Issues)

Finally, we appreciate CMS's proposals to revise the CAP to make participation less burdensome for physicians. CMS proposes to define a new exigent circumstance for opting out of the CAP.¹⁶ This exception would allow a physician to opt out of the CAP if, for example, participation poses a financial hardship, the practice is unable to update its billing system despite good faith efforts, or the practice relied on misleading information about the program from outside sources when it decided to enroll. In cases such as these, a physician could ask to withdraw from the program by submitting a written request within 30 days of the effective date of his or her participation election agreement. We support this proposal, but we ask CMS not to set a deadline for submitting requests. Thirty

and in patients with Myelodysplastic Syndrome (MDS). Comments from Dr. Richard Reiling, President, ACCC to Steve Phurrough MD, MPA, CMS June 4, 2007. Comments can be viewed at: http://www.accc-cancer.org/PUBPOL/pdf/ESA_comments_may07.pdf.

¹⁵ H. Kuhn; speech at ACCC President's Council Reception, Jan. 26, 2007.

¹⁶ 72 Fed. Reg. at 38157.

days may not be sufficient time for a physician to fully identify the hardship of participating in the CAP or make good faith efforts to upgrade his or her billing system. In addition, these hardships could emerge after the 30-day deadline. Instead of setting a time limit for requests to withdraw from the CAP, CMS should consider the timing of the request as one of several factors when processing it.

We also thank CMS for reconsidering the restriction on transporting CAP drugs between a physician's offices or other care settings.¹⁷ As other stakeholders have noted, allowing physicians to transport drugs between settings would allow greater flexibility in scheduling patients and may make the CAP a viable option for physicians who practice in several locations. We ask CMS to revise the CAP to allow physicians to transport drugs between locations.

XI. 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 DRA and budget neutrality, 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:


- Work with Congress, MedPAC, and other parties to stabilize or replace the SGR formula so physicians do not face major cuts to reimbursement each year.
- Apply the budget neutrality adjustor to the conversion factor instead of to the work RVUs to distribute the impact of the reduction fairly among procedures.
- Continue to assume a 50 percent usage rate and 11 percent interest in determining the costs of medical equipment for calculating practice expense RVUs.
- Continue to make the add-on payment for preadministration-related services for IVIG and develop a permanent additional payment for the acquisition of this important therapy.
- Implement the PQRI program in a manner that promotes the best quality of care possible. CMS should also work with specialty groups to ensure that the measures currently in place accurately reflect quality of care in each specialty.

¹⁷ Id. at 38158.

- Develop a clear and timely process for accepting and evaluating requests to revise the list of compendia used to determine covered uses of drugs and biologicals used in anticancer chemotherapeutic drug regimens.
- Provide more guidance in the implementation of reporting of hemoglobin or hematocrit levels when reporting the use of ESAs.
- Give manufacturers clear instructions for reporting ASP data to ensure that Medicare reimbursement reflects market prices.
- Exercise caution in implementing the payment limits for imaging procedures to protect patient access to these services.
- Revise CAP to make it a viable option for more physicians.

ACCC appreciates the opportunity to offer these comments, and we look forward to continuing to work with CMS to address these vital issues. Please contact Matthew Farber at 301-984-9496, ext. 221, 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,



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