The premier education and advocacy organization for the oncology team

Association of Community Cancer Centers

August 29, 2008

Kerry Weems, Acting 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-1403-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009)

Dear Acting Administrator Weems:

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 7, 2008 (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. We are relieved

[1] 73 Fed. Reg. 38502 (July 7, 2008).

that the Medicare Improvements for Patients and Physicians Act of 2008 (MIPPA) will prevent the payment reductions that CMS predicted for 2009 and will extend the Physician Quality Reporting Initiative (PQRI).

In the coming years, the number of Medicare beneficiaries 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 in 2010 and beyond that would make it more difficult to respond to the growing need for their services. We are thankful that Congress acted in July and eliminated the scheduled cuts caused by the Sustainable Growth Rate (SGR) formula, sparing hematologists and oncologists a nearly 15 percent decrease in Medicare reimbursement for the next 18 months. These cuts have been untenable and would have posed serious threats to patient access to care. Unfortunately, physicians will face similar cuts in 2010 of Congress and CMS do not act again. We encourage CMS to take the necessary steps to ensure physicians are adequately reimbursed for the quality cancer care that they deliver to their patients by developing a permanent and stable update formula for the future.

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

- Continue to work with Congress to develop a permanent and stable update formula;
- Continue to make payments for pre-administration-related services for intravenous infusion of immune globulin (IVIG);
- Expand the PQRI and revise the oncology measures to reflect appropriate use of oral and injectable chemotherapy.
- Exercise caution as it evaluates potentially misvalued services;
- Not implement the proposed expansion of the Independent Diagnostic Testing Facility (IDTF) regulations; and
- Implement the changes it proposed to the Competitive Acquisition Program (CAP).

We discuss these recommendations in depth below.

I. CMS should continue to work with Congress to develop a permanent and stable update formula. (Background, Impact)

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. This happened again this year, where physicians once again faced a 10.6 decrease for the remainder of 2008 and another cut for 2009. In

MIPPA, Congress prevented these cuts and implemented a slight increase for 2009. There will be more cuts in years to come if the SGR problem is not addressed, however. Even if Congress acts again to freeze reimbursement in the future, 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 in other settings. When Congress delayed in acting for the first two weeks of July, some ACCC members did not accept new Medicare patients during that time period, knowing that their reimbursement would be inadequate. ACCC urges CMS to work with Congress and other stakeholders to develop a more stable and appropriate payment update formula for the future.

II. CMS should continue to make payments for pre-administration-related services for IVIG. (Coding Issues)

ACCC disagrees with CMS's proposal to discontinue payment using code G0332 for pre-administration-related services for IVIG.[2] 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. Contrary to CMS's assertions, we believe that continued separate payment for pre-administration services is necessary.

CMS states that a recent OIG report, finding that just over half of the IVIG sales to hospitals and physicians were are prices below Medicare payment amounts, suggests that the stability of the IVIG market has improved.[3] We believe the fact that almost half of all sales were are prices above Medicare's payment rates indicates that providers still encounter significant difficulty obtaining IVIG for their patients. We also have heard from our members that they continue to have difficulty obtaining liquid IVIG, which they prefer over the powder forms because it produces fewer adverse reactions and requires less time to prepare. CMS also claims that increased utilization of the pre-administration services code indicates that pricing and access may be improving. To the contrary, we believe that modest increases in the use of this code and claims for IVIG reflects providers' growing awareness of the code and continued demand for IVIG, but does not indicate that

[2] Id. at 38518.
[3] Id. at 38519.

access to IVIG has improved. We ask CMS to continue to make payment for G0332 in 2009.

ACCC also supports the development of a permanent additional payment for acquisition of IVIG, similar to the payment for clotting factor, to help ensure access to this important therapy.

III. CMS should expand the PQRI and revise the oncology measures to reflect appropriate use of oral and injectable chemotherapy. (PQRI)

ACCC supported the creation of the Physician Quality Reporting Initiative (PQRI) by Congress in 2006. We hope that the implementation of pertinent quality reporting measures will lead to improved quality of care for patients. ACCC also supports the extension and expansion of the PQRI program for 2009.[4] To ensure that the program encourages quality improvement, we recommend that the agency use data from the initial PQRI reporting period in 2007 and 2008 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.

In particular, we recommend that CMS work closely with physician specialties to develop and seek the endorsement of consensus organizations, such as the National Quality Forum (NQF) or AQA Alliance, for quality measures and specifications that reflect the use of oral therapies as well as injectables in oncology care. Currently, the instructions for measure 73, plan for chemotheraoy documented before chemotherapy administered, state that it is anticipated that clinicians who treat patients with breast, colon, or rectal cancer who are receiving intravenous chemotherapy administration will submit this measure. This measure uses all patients with breast, colon, or rectal cancer who receive chemotherapy as the denominator. If a physician prescribes an oral chemotherapeutic agent instead of an injectable, however, the patient will not be included. ACCC believes that CMS should revise this measure and its instructions to include appropriate use of both oral and injectable chemotherapy.

IV. CMS should exercise caution as it evaluates potentially misvalued services. (Potentially Misvalued Services under the PFS)

In the Proposed Rule, CMS identifies services that may be misvalued under the physician fee schedule and proposes steps to ensure that the correct relative

[4] Id. at 38559.

value units (RVUs) are assigned to these services.[5] ACCC agrees with CMS's proposal to ask the RUC to review approximately 2,900 codes that were valued almost 20 years ago using data that has not been evaluated by the RUC. We are concerned, however, by CMS's proposal to review the fastest growing procedure codes. This list includes services that have experienced three consecutive years of 10 percent annual growth, have more than $1 million in allowed charges in 2007, and are still in use in 2008. ACCC is concerned that CMS is targeting services based on growth and spending, not inappropriate use. Many of these codes represent newer, more innovative therapies in the field of oncology care, and increasing utilization rates may indicate improved quality of care. We urge CMS to exercise care in evaluating the RVUs for these services. A reduction in their reimbursement may lead to a decrease in patient access to these therapies. ACCC recommends that CMS work closely with oncology specialty societies in determining the proper value of these procedures.

V. CMS should not implement the proposed expansion of the IDTF regulations. (Independent Diagnostic Testing Facilities)

CMS proposes to require all physician and non-physician practitioner entities that provide diagnostic testing services to enroll in the Medicare program as IDTFs.[6] CMS explains that it believes this requirement is necessary to ensure the quality of care provided to beneficiaries. We agree that all Medicare beneficiaries should receive the highest quality care, but we do not believe that expanding the application of the IDTF regulations to physician practices is needed to accomplish this goal.

First, MIPPA includes a new accreditation requirement for providers of advanced imaging services, such as CT, PET, and MRI. This requirement will address any concerns CMS has about the quality of these services provided to beneficiaries by establishing requirements for physicians, non-physician personnel, and equipment that meet or exceed the requirements under the IDTF regulations. Similar to the IDTF standards, MIPPA will require supervising physicians to demonstrate proficiency in the performance and interpretation of diagnostic imaging services.

Many carriers determine which physicians are proficient under the IDTF standards based solely on their certification in a particular specialty. MIPPA's accreditation standards better reflect the training programs and clinical expertise of the physicians who provide imaging services by requiring the supervising physician to receive training in advanced diagnostic imaging services in a residency program

[5] Id. at 38582.
[6] Id. at 38534.

for their particular specialty; attain, through experience, the necessary expertise to be a supervising physician; or complete continuing education courses related to the advanced imaging services they provide. This is consistent with MedPAC's recommendation that permission to bill for imaging procedures be based on training, experience, and continuing education requirements instead of the physician's specialty.[7]

MIPPA and the IDTF regulations establish similar standards for non-physician practitioners who furnish the technical component of advanced diagnostic imaging services. MIPPA also requires imaging equipment to meet performance standards and requires providers to furnish services safely to patients, similar to the IDTF regulations. Unlike the IDTF regulations, MIPPA also requires providers to have in place a quality assurance program to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images. MIPPA's standards also exceed those under the IDTF regulations by including requirements regarding site visits, timely consideration of applications, updating standards to reflect new technology, and consideration of the capacities of rural providers. MIPPA's provisions will be sufficient to protect the quality of imaging services provided to Medicare beneficiaries, and we urge CMS to dedicate its resources to implementing the new law rather than expanding the application of the IDTF regulations.

Second, we also believe that enrollment as an IDTF is not necessary to ensure the quality of other diagnostic testing services, such as ultrasound imaging. Physicians receive training in these services during their residencies and through continuing medical education. Physicians often perform these services themselves, and when they use non-physician personnel, CMS acknowledges that most practices use qualified non-physician personnel.[8] Therefore, CMS has not demonstrated a need to implement new regulations at this time.

In addition, we are concerned that implementation of the proposal actually could harm access to care by qualified professionals. Carriers' current IDTF policies often designate certain specialties as being qualified to provide imaging services, but omit many physicians who have received appropriate training. For example, in Medicare Administrative Contractor Jurisdiction 5, breast surgeons are not automatically deemed to be proficient to supervise breast ultrasound.[9] Denying access to imaging services by these physicians could delay and further complicate beneficiaries' treatment for breast cancer. If CMS required all physicians who provide diagnostic testing and imaging services to enroll as IDTFs, many qualified

[7] MedPAC Recommendations on Imaging Services, Statement of Mark E. Miller, Ph.D. to the Subcommittee on Health, Committee on Ways and Means, March 17, 2005, at 6.
[8] Id.
[9] Wisconsin Physicians Service Insurance Corporation, LCD for Independent Diagnostic Testing Facilities, L26687, for MAC Jurisdiction 5.

physicians would not be able to provide care to Medicare beneficiaries. This could create access problems, particularly for patients in rural and underserved areas.

Finally, we are concerned that a substantial expansion of the IDTF program will be extremely difficult for CMS and its contractors to implement. Under the IDTF regulations, all sites must be inspected before enrollment. Currently, contractors do not have sufficient resources to provide timely visits to all of the entities that seek to enroll as IDTFs. Bringing the providers of ultrasound or X-ray – at least 100,000 practices – under the IDTF regulations would place an impossible burden on CMS's contractors. We believe Medicare's resources would be used more effectively if they are dedicated to implementing MIPPA and maintaining the IDTF program as is. In light of CMS's limited resources and recent legislation, we urge the agency to not implement this proposal.

VI. CMS should implement the revisions it proposed to the CAP. (CAP Issues)

Finally, we appreciate CMS's proposals to revise the CAP to make participation in the CAP less burdensome for physicians. CMS proposes to change the definition of a CAP physician, alter the restriction on physician transportation of CAP drugs, and also to change the dispute resolution process.[10] We believe that these changes may make the CAP program more appealing to oncologists. As we have stated in the past, allowing physicians greater flexibility may make the CAP a viable option for physicians. We ask CMS to revise the CAP as stated above.

VII. Conclusion

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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[10] Id. at 38591.