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August 26, 2011

Donald Berwick, MD

Administrator

Centers for Medicare & Medicaid Services Department of Health and Human Services

Room 445-G

Hubert H. Humphrey Building 200 Independence Ave. SW Washington, DC 20201

Re: CMS-1524-P (Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2012)

Dear Administrator Berwick:

On behalf of the Association of Community Cancer Centers (ACCC), we appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule regarding payment policies under the Medicare physician fee schedule (PFS) for calendar year (CY), published in the Federal Register on July 19, 2011 (the "Proposed Rule"). 1

ACCC represents more than 17,000 cancer care professionals from approximately 900 hospitals and more than 1,200 private practices nationwide. These include Cancer Program Members, Individual Members, and members from 25 state oncology societies. It is estimated that 60 percent of cancer patients nationwide are treated by a member of ACCC.

In our comments below, we recommend that CMS:

- Work with Congress to develop a fix to the Sustainable Growth Rate (SGR) formula and avert a 29.5 percent reduction to the conversation
- Halt the cuts to chemotherapy administration services;
- Exercise caution as it evaluates potentially misvalued services and ensure that the review of drug administration codes includes the substantial time and practice expenses searching for and making accommodations for drugs in short supply and for complying with rapidly increasing Risk Evaluation and Mitigation Strategy (REMS) requirements;

<sup>&</sup>lt;sup>1</sup> 76 Fed. Reg. 42772 (July 19, 2011).

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- Not expand the Multiple Procedure Payment Reduction (MPPR) policy to the professional component (PC) of advanced imaging services;
- Implement the provisions related to the Physician Quality Reporting System (PQRS), the Electronic Prescribing (eRx) Incentive Program, and the Electronic Health Records (EHR) Incentive Program;
- Work with ACCC and other specialty societies on the implementation of the Value-Based Payment Modifier;
- Consult the ACCC report on patient transitions from hospital to community setting in order to improve hospital discharge care coordination; and
- Implement reimbursement for patient education about cancer therapy by physicians and nurses.

We discuss these recommendations in depth below.

# I. CMS should continue to work with Congress to develop a long-term fix to the SGR formula

Many cancer patients turn to physician offices to receive their treatment and related care, and it is vitally important that physicians are reimbursed appropriately for these services. ACCC is concerned that once again, the SGR formula will produce a drastic cut to the conversion factor if Congress does not act to prevent this reduction from taking effect. The proposed cut of 29.5 percent would lower the conversion factor to \$23.9635 from the current rate of \$33.9764.<sup>2</sup> This reduction would present significant access issues for cancer patients, as many providers would no longer be able to see Medicare patients in their offices. Although Congress has acted several times in recent years to enact short-term measures to prevent payment cuts, there remains significant uncertainty about future payment rates. Without confidence that future reimbursement rates will be adequate, practices may not be able to plan for the future, make hiring decisions, and invest in new technology. We are encouraged that CMS has stated it will continue to work with Congress to permanently reform the SGR methodology,<sup>3</sup> and we urge CMS to develop a stable update formula for the future to ensure that physicians are adequately reimbursed for the quality cancer care that they deliver to their patients.

## II. CMS should halt the cuts to chemotherapy administration services.

CMS proposes to continue to phase-in revised practice expense relative value units (RVUs) calculated using the Physician Practice Expense Information Survey (PPIS) data, supplemented with additional data for oncology drug administration services. These changes will reduce payment for most chemotherapy administration codes from 2011 to 2012, and even greater reductions are predicted when the new RVUs are fully implemented in 2013. These reductions, combined with likely cuts or no increase in the conversion factor, will mean that physicians will be paid less for chemotherapy administration 2013 than they were in 2010. Our

<sup>4</sup> Id. at 42780.

<sup>&</sup>lt;sup>2</sup> <u>Id.</u> at 42929, 42780.

<sup>&</sup>lt;sup>3</sup> Id. at 42929.

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members are deeply concerned that if these cuts to Medicare payments are implemented as proposed, they will have to shift more patients to hospitals and likely will have to reduce staff.

Even if Congress acts to reverse the conversion factor reduction, the decreases in payment rates due to the revised RVUs could lead oncologists to consider reducing the number of Medicare patients they treat, forgo investments in new technologies, and find other costsaving measures that could limit beneficiaries' treatment options. ACCC is concerned that patient access to oncology services may suffer as a result of these cuts. In addition, many members are concerned that private payers will implement similar reductions as most base their reimbursement on the Medicare PFS RVUs.

ACCC urges CMS to halt these proposed reductions and provide stable, adequate reimbursement for cancer care.

III. CMS should exercise caution as it evaluates potentially misvalued services and ensure that the review of drug administration codes includes the substantial time and practice expenses searching for and making accommodations for drugs in short supply and for complying with rapidly increasing REMS requirements.

In the Proposed Rule, CMS identifies as potentially misvalued services for review by the American Medical Association (AMA) Relative (Value) Update Committee (RUC) all evaluation and management (E&M) codes as well as other codes that had more than \$10 million in allowed charges at the specialty level in 2010.<sup>5</sup> This list includes a number of drug administration and imaging services that are crucial to the delivery of high quality cancer care.<sup>6</sup>

ACCC urges CMS to exercise caution in evaluating the RVUs for services identified as potentially misvalued based solely on rapid growth or high total changes. High levels of utilization of chemotherapy administration reflect both the significant need for those services among the Medicare population and expanded treatment options for cancer patients. Many of the fastest growing codes or codes with the highest charges represent newer, more innovative therapies in the field of oncology care, and increasing utilization may indicate improved quality of care. A reduction in reimbursement may lead to a decrease in patient access to these therapies. Instead, we strongly believe the reimbursement rates for drug administration services should be increased substantially.

Toward this end, we ask CMS to ensure that the review of the drug administration codes takes into account the increased time and effort spent by physicians searching for and making accommodations for drugs in short supply as well as in complying with the rapidly increasing Risk Evaluation and Mitigation Strategy (REMS) requirements imposed by the Food and Drug Administration (FDA). Unfortunately, in 2010, there were 178 drug shortages reported to the FDA, and in 2011, this problem appears to be getting even worse as a "record number" of

<sup>&</sup>lt;sup>5</sup> <u>Id.</u> at 42793-42794.

<sup>&</sup>lt;sup>6</sup> Id. at 42794.

<sup>&</sup>lt;sup>7</sup> FDA, Frequently Asked Questions About Drug Shortages, available at: http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm.

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shortages have been reported.<sup>8</sup> Drug shortages can "adversely affect drug therapy, compromise or delay medical procedures, and result in medication errors" and must be actively managed by physicians, requiring substantial time and resources to ensure that beneficiaries can receive their treatments as prescribed and scheduled.

Similarly, REMS requirements also require physicians to expend significant time and resources that are not reflected in the RVUs for the drug administration service itself. For example, physicians may be required to review medical guides with patients, obtain special training, enter patients into registries, monitor patients periodically, or provide special documentation of "safe use." These requirements can be so onerous and time consuming that recognizing this additional work and physician time in the reimbursement for administration procedures is vital to maintaining patient access to the drugs. We ask CMS and the RUC to work closely with oncologists and other relevant specialists to better understand these issues and to ensure that the RUC includes appropriate and comprehensive physician work and practice expenses for drug administration services accordingly.

In addition, CMS asks the AMA RUC to review at least half of the list of E&M codes and half of the list of procedure codes by July 2012 so that CMS can include any revised valuations in the CY 2013 PFS final rule with comment period. The remaining codes would be reviewed by July 2013 for inclusion in the CY 2014 PFS final rule with comment period. Although stakeholders would be permitted to comment on the revised values after the final rule is released, the values likely would go into effect before our comments could be considered. To ensure that any reimbursement changes are developed with full, meaningful stakeholder input, we ask CMS to request that the AMA RUC complete its review earlier, so that any revised valuations can be included in the PFS proposed rule for the relevant year, rather than the final rule.

### IV. CMS should not expand the MPPR to the PC of advanced imaging services.

CMS proposes to expand application of the MPPR policy to the PC of advanced imaging services. <sup>12</sup> This reduction would add to a long list of cuts over the past five years that have lowered reimbursement for many imaging procedures. In 2007, CMS adopted an MPPR of 25 percent for the technical component (TC) of certain diagnostic imaging procedures, applied to the second and subsequent services when more than one service is furnished using the same imaging modality on a contiguous body area in a single session. In July 2010, section 3135 of the Patient Protection and Affordable Care Act (ACA) increased the imaging MPPR from 25 percent to 50 percent, further reducing the reimbursement rate for the lower-priced procedure

 $^{12}$   $\overline{\text{Id.}}$  at 42812.

<sup>&</sup>lt;sup>8</sup> G. Harris, "U.S. Scrambling to Ease Shortage of Vital Medicine," New York Times, Aug. 19, 2011; L. Szabo, "Drug Shortages to Reach Record Levels," USA Today, Aug. 15, 2011.

<sup>&</sup>lt;sup>9</sup> American Society of Health-System Pharmacists (ASHP), ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems, 66 Am J Health-System Pharm 1399 (August 1, 2009), available at: <a href="http://www.ashp.org/DocLibrary/Policy/DrugShortages/ASHP">http://www.ashp.org/DocLibrary/Policy/DrugShortages/ASHP</a> shortage guide09.pdf.

<sup>&</sup>lt;sup>10</sup> 76 Fed. Reg. at 42793-42794.

<sup>11 &</sup>lt;u>Id.</u>

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when more than one imaging service is provided on contiguous body parts in a single session. In addition to implementing this requirement, CMS also expanded the MPPR to combinations of advanced imaging services performed during the same session, regardless of the modality or body area, in the final rule for CY 2011.

In the Proposed Rule, CMS proposes to extend the MPPR policy even further to the PC of advanced imaging services. Under this proposal, the 50 percent payment reduction would apply to the PC of the second and subsequent advanced imaging services furnished in the same session, without regard to whether the services are of the same modality or are furnished for contiguous body parts. This proposal, when combined with other changes in the PE RVUs, would result in a decrease in Medicare payments to radiologists of 4 percent in 2012 and 6 percent in 2013. 14

We believe the proposed expansion of the MPPR is not justified and could harm access to appropriate cancer care. Imaging services are an essential part of diagnosing and treating cancer. At times, patients may need to have scans with different modalities performed during the same visit to best assess the state of their cancer. Although there may be small efficiencies associated with reviewing two or more scans at the same time, CMS presents no data verifying its assumption that a 50 percent payment reduction is justified. CMS's proposal appears to be based on three reviews of imaging services: a report by the Medicare Payment Advisory Commission (MedPAC), a report by the Government Accountability Office (GAO), and the AMA RUC's "recent methodology and rationale in valuing the work for a combined CT of the pelvis . . . and abdomen." None of these reviews supports CMS proposal, however.

First, CMS refers to the March 2010 MedPAC report's "recommendations regarding the expansion of MPPR policies under the PFS to account for additional efficiencies." Such a recommendation was not in the March 2010 report, and although MedPAC subsequently encouraged CMS to "explore" an expansion of the MPPR to the PC of imaging services, it has not supported a uniform reduction or a reduction of 50 percent. In its June 2011 report, MedPAC expressed support for Congressional action to "apply a multiple procedure payment reduction to the professional component of diagnostic imaging services provided by the same practitioner in the same session," but it also recognized that "efficiencies may vary by type of imaging." For this reason, MedPAC recommended that CMS "calculate the payment reduction for the second and subsequent professional component services performed in the same session by analyzing the efficiencies in physician work associated with multiple services." CMS has not performed this analysis and instead proposes a uniform reduction of 50 percent.

<sup>14</sup> <u>Id.</u> at 42930.

<sup>17</sup> Letter from G. Hackbarth to D. Berwick regarding the Medicare physician fee schedule proposed rule for CY 2011, August 23, 2011, http://medpac.gov/documents/CMS-1503-P.pdf.

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<sup>13</sup> Id

 $<sup>\</sup>overline{\text{Id.}}$  at 42812.

<sup>&</sup>lt;sup>10</sup> <u>Id.</u>

<sup>&</sup>lt;sup>18</sup> MedPAC, Report to the Congress: Medicare and the Health Delivery System, June 2011, at 41, http://www.medpac.gov/chapters/Jun11 Ch02.pdf.

<sup>&</sup>lt;sup>19</sup> Id. at 40.

<sup>&</sup>lt;sup>20</sup> <u>Id.</u>

Second, similar to MedPAC, GAO recommended that CMS conduct a thorough analysis before implementing any expansion of the MPPR to physician work. Specifically, GAO recommended that CMS "take further steps to ensure that fees for services paid under Medicare's physician fee schedule reflect efficiencies that occur when services are performed by the same physician to the same beneficiary on the same day." These steps could include "systematically reviewing services commonly furnished together and implementing an MPPR to capture efficiencies in both physician work and practice expenses, where appropriate, for these services." Most important, GAO recognized that the results of its limited analysis of 118 pairs of services "cannot be generalized" to all combinations of services. CMS's own analysis is far more limited – reviewing just the codes for CT of the abdomen and pelvis – and is even less appropriate to use as the basis for an across-the-board payment cut.

Third, combined CT of the abdomen and pelvis is not an appropriate example to justify expansion of the MPPR to the PC of all advanced imaging services. Of all the pairs of services that would be affected by the proposed policy, few, if any, would present the same opportunities for efficiency as are found for CT of the abdomen and pelvis. Unlike many of the services that would be subject to the expanded MPPR, CT of the abdomen and pelvis involve use of the same modality on contiguous body areas. Not only is the same equipment used for both scans, but the images taken during these scans may overlap. The GAO noted that this overlap permits radiologists to review fewer images in the combined service than when each service is performed separately.<sup>24</sup> This efficiency simply is not found during imaging services using different modalities or performed on noncontiguous body areas. CMS should not implement any expansion of the MPPR based on an small, unrepresentative sample of services.

For these reasons, ACCC urges CMS not to finalize this proposal. CMS should not expand the MPPR to the PC of advanced imaging services until it conducts the thorough, systematic review and analysis recommended by MedPAC and GAO.

# V. <u>CMS should implement the provisions related to the PQRS, the eRx Incentive Program, and the EHR Incentive Program.</u>

ACCC supported the creation of the Physician Quality Reporting Initiative (PQRI) (now the PQRS) by Congress in 2006. We believe that the implementation of pertinent quality reporting measures can lead to improved quality of care for patients. ACCC also supported the extension and expansion of the PQRS program as required by the ACA.<sup>25</sup> We believed that extending the bonus-based model through 2014, along with other improvements to the reporting and record keeping requirements, would promote increased participation in the program.

<sup>&</sup>lt;sup>21</sup> GAO, Medicare Physician Payments: Fees Could Better Reflect Efficiencies Achieved When Services Are Provided Together, GAO-09-647, July 2009, at 15, <a href="http://www.gao.gov/new.items/d09647.pdf">http://www.gao.gov/new.items/d09647.pdf</a>. <a href="http://www.gao.gov/new.items/d09647.pdf">http://www.gao.gov/new.items/d09647.p

 $<sup>\</sup>frac{10}{10}$  at 18.

 $<sup>\</sup>frac{10.}{10.}$  at 15.

<sup>&</sup>lt;sup>25</sup> ACA § 3002, Pub. L. No. 111-148 (2010).

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ACCC supports the proposed addition of several new codes related to oncology care and prevention, including the following measures: Immunohistochemical (IHC) Evaluation of HER2 for Breast Cancer Patients; Preoperative Diagnosis of Breast Cancer; Sentinel Lymph Node Biopsy for Invasive Breast Cancer; and Biopsy Follow-up. We recommend that CMS finalize these measures. We also recommend that CMS continue to work with providers and specialty societies both to develop new quality measures and to ensure the best and most administratively simple reporting methods are being used.

With regard to the eRx Incentive Program, the Proposed Rule would modify the electronic prescribing measure to allow eligible professionals to use either a qualified electronic prescribing system or certified EHR technology. For the 2013 and 2014 payment adjustments, CMS proposes to eliminate the requirement that the measure only be reported during specified instances. CMS also would provide significant hardship exemption categories for certain professionals who meet the required criteria. ACCC believes that these changes will allow more providers to adequately participate in the eRx program, and therefore, we support the proposal.

Finally, in regard to the EHR Incentive Program, ACCC supports the PQRS-Medicare EHR Incentive Pilot, which would allow eligible professionals to submit clinical quality measures electronically. ACCC urges CMS to continue to work on its ability to receive clinical quality measure information electronically to minimize the burdens on physicians and the agency.

# VI. CMS should work with ACCC and other specialty societies on the implementation of the Value-Based Payment Modifier

Under the ACA, CMS is required to implement a Value-Based Payment Modifier that would adjust payment based on quality of care compared to cost, no later than Jan. 1, 2015. The Act requires CMS to publish this year: the quality of care and cost measures established by the Secretary for purposes of the modifier; the dates for implementation of the value modifier; and the initial performance period for application of value modifier in 2015. CMS proposes to use total per capita cost measures and per capita cost measures for beneficiaries with four chronic conditions: chronic obstructive pulmonary disease; heart failure; coronary artery disease; and diabetes. ACCC supports this choice of conditions. We strongly support efforts to encourage improved quality of care for patients with cancer, but we believe that the variety of manifestations for cancer, the array of treatment options, and the rapidly evolving standard of care, combined with a lack of quality measures for many cancers, would make application of a Value-Based Payment Modifier inappropriate for cancer care. ACCC urges CMS to work with specialty societies in the development and implementation of the care and cost measures to be included in this provision.

 $^{28}$   $\overline{\text{Id.}}$  at 42896.

<sup>&</sup>lt;sup>26</sup> 76 Fed. Reg. at 42864.

<sup>&</sup>lt;sup>27</sup> <u>Id.</u> at 42889.

 $<sup>\</sup>frac{1}{10}$  at 42900.

 $<sup>\</sup>frac{10}{10}$  at 42913.

#### VII. CMS should consult the ACCC report on patient transitions from hospital to community setting in order to improve hospital discharge care coordination.

In the Proposed Rule, CMS is requesting comments on hospital discharge care coordination services in order to ensure that certain codes are properly valued.<sup>31</sup> In 2010 and 2011, ACCC conducted an educational program for its members that evaluated the best practices in patient transition programs from the hospital setting to the community setting.<sup>32</sup> ACCC recommends that CMS review this program and related report in order to determine what procedures are necessary in order to ensure a successful patient transition between care settings. To view the final report, please go to: http://www.accc-cancer.org/education/educationtransitions.asp.

## VIII. CMS should provide reimbursement for patient education about cancer therapy by physicians and nurses.

ACCC believes that CMS should provide reimbursement for the time and resources physicians and nurses spend educating patients and their caregivers about the symptoms and side effects associated with cancer treatment, including surgery, chemotherapy (both oral and injectable therapies), and radiation therapy. Patient education helps to optimize treatment outcomes, decreases adverse events, office visits, and hospitalizations, and substantially reduces costs in an already burdened health system.

Currently, there is no dedicated payment for a period of treatment education for people with cancer and their caregivers, prior to the onset of treatment. Medicare's payment for infused chemotherapy includes the costs of only 48 minutes, amortized over an average of six cycles, of patient education during the infusion, and recognizes some costs for post procedure education.<sup>33</sup> However, the time and payment allocated for this education does not cover its cost and is not sufficient to cover the requisite initial and ongoing teaching. In addition, the cost of education is factored into payment for administration of infusion therapies but not into payment for surgery, radiation therapy, or oral chemotherapy.

By providing distinct reimbursement under the PFS for a one-hour cancer patient treatment education session delivered by a physician or a registered nurse under the supervision of a physician, CMS can help address this disparity in access to care and ensure that all patients, irrespective of treatment modality or treatment setting, have access to the information they need to minimize adverse events and maximize their quality of life and outcomes. We urge CMS to reimburse physicians and nurses for these important patient education services accordingly.

<sup>&</sup>lt;sup>31</sup> <u>Id.</u> at 42917.

ACCC's Center for Provider Education, Transitions Between Care Settings, available at: <a href="http://www.accc-">http://www.accc-</a> <u>cancer.org/education/education-transitions.asp.</u>
 <sup>33</sup> Correspondence from the Oncology Nursing Society (ONS) to Amy Bassano, CMS, May 27, 2010.

## IX. 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 these very important matters.

Respectfully submitted,

Thomas Whittaker, MD, FACP

President

Association of Community Cancer Centers (ACCC)

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