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September 6, 2016

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### BY ELECTRONIC DELIVERY

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017 Proposed Rule (CMS-1654-P)

Dear Administrator Slavitt:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Physician Fee Schedule (PFS) proposed rule (the "Proposed Rule"). 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 represents more than 23,000 cancer care professionals from approximately 2,000 hospitals and private practices nationwide. These include Cancer Program Members, Individual Members, and members from 32 state oncology societies. It is estimated that 65 percent of cancer patients nationwide are treated by a member of ACCC.

ACCC is pleased to respond to this request for comments by the Centers for Medicare & Medicare Services (CMS). In our comments below, we recommend that CMS:

 Finalize its proposal to add the professional Picture Archiving and Communication System (PACS) workstation as a direct practice expense (PE) input for digital diagnostic imaging services;

<sup>&</sup>lt;sup>1</sup> 81 Fed. Reg. 46162 (July 15, 2016).

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- Not finalize proposals to reduce reimbursement for radiation treatment services and instead maintain payment for these essential services, including interstitial radiation treatment and radiation treatment devices, at levels adequate to reimburse physicians for the cost of providing such services;
- Finalize its cautious approach to setting Medicare payment for mammography and delay implementation of new inputs until stakeholders have an opportunity to submit a full record regarding the costs of providing mammography services;
- Finalize its proposal to make the requirement to consult appropriate use criteria for advanced diagnostic imaging services effective no earlier than January 1, 2018;
- Finalize its proposal to add advance care planning services to the telehealth list, with appropriate payment for such services, work with ACCC and other stakeholders to establish broader coverage for telehealth services under the PFS, and improve payment for advance care planning services;
- Finalize its proposal to establish payment for new care management and collaborative care services; and
- Assign a separate Healthcare Common Procedure Coding System (HCPCS) code for each biosimilar product.

We discuss these recommendations in depth below.

# I. CMS should finalize its proposal to add the professional PACS workstation as a direct PE input for digital diagnostic imaging services.

In the Proposed Rule, CMS proposes to add a professional PACS workstation as a direct PE input for certain digital diagnostic imaging services.<sup>2</sup> The workstation would be priced at \$14,616.93, based on invoices submitted by stakeholders. CMS developed the list of Current Procedural Terminology (CPT®<sup>3</sup>) codes for which the workstation would be added by looking at the codes that use the technical PACS workstation as a direct input, but excluding add-on codes, codes for non-diagnostic services, and image guidance codes where the dominant provider is not a radiologist.

ACCC strongly supports this proposal. The professional PACS workstation is an essential component of diagnostic imaging procedures now that physicians performing these procedures have largely transitioned from film technology to digital technology, and the professional workstation is appropriately included among the direct PE inputs for these codes.

<sup>&</sup>lt;sup>2</sup> Id. at 46171-74.

<sup>&</sup>lt;sup>3</sup> CPT is a registered trademark of the American Medical Association (AMA).

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II. CMS should not finalize proposals to reduce reimbursement for radiation treatment services and instead should maintain payment for these essential services, including interstitial radiation treatment and radiation treatment devices, at levels adequate to reimburse physicians for the cost of providing such services.

In the Proposed Rule, CMS proposes several significant changes to payment for radiation oncology procedures, which would collectively result in significant cuts in reimbursement for radiation oncology providers. These cuts would result in reimbursement rates for radiation treatment that do not reflect the cost of providing such services and would risk limiting Medicare beneficiaries' access to these life-saving cancer treatments. We urge CMS not to finalize these damaging and unjustified reductions in reimbursement.

First, CMS proposes to continue in CY 2017 the reduced reimbursement for interstitial radiation services, as described by CPT codes 77778 and 77790. In the interim final rule for CY 2016, 4 CMS noted that the American Medical Association (AMA) Relative Value Unit (RVU) Update Committee (RUC) had identified CPT code 77778 (interstitial radiation source application, complex, includes supervision, handling, loading of radiation source) and CPT code 77790 (supervision, handling, loading of radiation source) as potentially misvalued because the two codes were reported together more than 75 percent of the time, and consequently revised CPT code 77778 to include the supervision and handling of radiation sources previously reported with CPT code 77790. Because of this change, CMS finalized for CY 2016 a work RVU of zero for CPT code 77790. CMS also noted in that rulemaking that the specialty society's survey of service time indicated an average of 220 minutes and a median work RVU of 8.78, while the RUC recommended a total work time of 145 minutes and the same work RVU of 8.78. CMS identified the specialty society survey as an overestimate of the service time and stated its belief that the 25th percentile survey result was more likely to represent the overall work in a survey in which time is overestimated. Therefore CMS finalized for CY 2016 a work RVU of 8.00 for CPT code 77778. Following the same rationale, CMS proposes the same work RVUs for CPT codes 77778 and 77790 for CY 2017.<sup>5</sup> In so doing, CMS acknowledges but ultimately disregards comments explaining that the RUC's estimate of service time was lower because the RUC used pre-service packages in developing recommended work times, and that the lower work RVUs failed to account for the additional work that had been associated with CPT code 77790 but that was bundled into CPT code 77778. CMS also declines the alternative suggestion of referring CPT code 77778 to the multispecialty refinement panel.

We urge CMS to fully consider the arguments brought to CMS's attention in support of the RUC-recommended work RVU of 8.78 for CPT code 77778, particularly the comments submitted by the AMA RUC itself. These comments fully explain the discrepancy in estimated

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<sup>&</sup>lt;sup>4</sup> 80 Fed. Reg. 70886, 71057 (Nov. 16, 2015).

<sup>&</sup>lt;sup>5</sup> 81 Fed. Reg. at 46237.

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work times between the RUC estimate and the specialty society estimate, which was the entire basis for CMS's original decision to reduce the RVUs for CPT code 77778 for CY 2016. As the RUC explains, it "determined that the survey respondents accurately estimated the work RVU based on magnitude estimation while overestimating the relatively low intensity pre-service time involved in performing this service." In light of this explanation for the discrepancy, CMS's justification for the reduction in RVUs disappears. We urge CMS to finalize a work RVU of 8.78 for CPT code 77778, as recommended by the RUC.

Second, CMS proposes to reduce work RVUs for design and construction of radiation treatment devices (CPT codes 77332, 77333, and 77334), despite the RUC's recommendation of no change in the work RVUs for these codes. CMS acknowledges the RUC's recommendation, but proposes to reduce RVUs for each of the three codes because the RUC also recommended a decrease in the time it takes to furnish these services. CMS proposes to establish the lower work RVUs for code 77332 by cross-walking the work RVUs from CPT code 93287 due to "its identical intraservice time, similar total time, and similar level of intensity." Because the work RVUs for codes 77333 and 77334 are based on an incremental increase from the work RVUs for code 77332, the work RVUs for those codes likewise would be reduced under the Proposed Rule.

We urge CMS not to finalize this additional cut in payment for radiation oncologists. Although the RUC did change its estimate of service time for these procedures, the amount of service time is not the only appropriate factor in determining the amount of physician work and appropriate work RVUs; among other things, the intensity of the physician work must be considered. Ultimately, the RUC recommended no change in the work RVUs for these codes, and the Proposed Rule does not identify any basis other than the change in estimated service time for disregarding this recommendation. Moreover, although the CPT code that CMS proposes to use as a crosswalk may involve "similar" service time and level of intensity to CPT code 77332, that code describes a procedure wholly unrelated to the radiation treatment device codes. It is inconsistent with the ordinary and appropriate procedure for valuing and reimbursing physician services under Part B to use an unrelated code as a crosswalk while disregarding the RUC's recommendation on the appropriate work RVUs for the actual codes at issue. We urge CMS to maintain the work RVUs for these codes at their current level, as the RUC recommended.

In addition to our concerns about how CMS arrived at each of the proposed RVUs above, we are concerned that the cumulative effect of these proposals will be to cut payment to radiation oncology providers to a level that threatens access to services for Medicare beneficiaries. ACCC is deeply concerned that cuts such as these, particularly in combination with other policies that CMS estimates will result in a net *reduction* in the conversion factor, will force some radiation

<sup>7</sup> 81 Fed. Reg. at 46251.

<sup>&</sup>lt;sup>6</sup> Comment Letter from AMA RUC to CMS, at 26 (Dec. 17, 2015) (emphasis added).

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oncologists, particularly those operating in rural and underserved areas, to cut services or cease operating entirely. As a result, Medicare beneficiaries who live in these areas and require radiation therapy to treat their life-threatening cancer may be unable to obtain the care that they need. In addition, the growing disparity between Medicare's payment rates for these services in hospitals and freestanding facilities also could cause physicians to choose settings of care based on reimbursement, or to sell their practices to hospitals, even if these options would be more costly for the beneficiary and the Medicare program.

We urge CMS not to finalize these unjustified and harmful reductions in reimbursement for important radiation treatment procedures. To the extent there are appropriate changes in radiation treatment delivery to be made in the future, ACCC and other cancer provider organizations stand ready to work with CMS to find ways to implement these changes over a period sufficient to allow providers to absorb the changes and ensure that Medicare beneficiaries continue to have access to these critical services.

III. CMS should finalize its cautious approach to setting Medicare payment for mammography and delay implementation of new inputs until stakeholders have an opportunity to submit a full record regarding the costs of providing mammography services.

CMS proposes to revise its payment policies for mammography to implement new CPT codes in accordance with changes made by the CPT Editorial Panel for CY 2017, but would delay proposing changes in the recommended inputs for these codes because the new inputs could result in drastic reductions in reimbursement for mammography services. ACCC strongly believes that mammography services are particularly important to continuing health and successful treatment of breast cancer for many Medicare beneficiaries and therefore agrees that CMS should exercise caution before reducing payment for these services. Consideration of further data is essential before CMS proposes and adopts new inputs and RVUs for the new CPT codes.

Since 2002, CMS has paid for digital mammography services using G-codes G0202, G0204, and G0206, and for film mammography services using CPT codes 77055, 77056, and 77057, with use of computer-aided detection (CAD) reported using CPT codes 77051 and 77052. For CY 2017, the CPT Editorial Panel decided to delete CPT codes 77051, 77052, 77055, 77056, and 77057, and to create three new CPT codes, 770X1, 770X2, and 770X3, to describe mammography services bundled with CAD. The RUC recommended work RVUs for each of the new CPT codes, as well as new PE inputs for use in developing resource-based PE RVUs for each code.

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<sup>&</sup>lt;sup>8</sup> <u>Id.</u> at 46252-53.

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We appreciate CMS's acknowledgement that adopting the new input values would result in "drastic" reductions in payment for mammography services, potentially up to 50 percent relative to current payment. We also agree with CMS that mammography services are of particular importance to Medicare beneficiaries and to the Medicare program. As a result, we strongly support CMS's proposal to delay implementation of the recommended resource inputs to protect against "disruptive" changes in payment, and its acknowledgement that the statute requires any significant reduction in RVUs in the future to be phased in. 9 We agree that CMS should not adopt new inputs until stakeholders have the opportunity to submit data on equipment inputs for mammography services, and CMS has an opportunity to carefully consider these data and propose revised PE values in subsequent rulemaking.

With respect to the CPT codes created in CY 2015 for digital breast tomosynthesis (codes 77061, 77062, and 77063), CMS also proposes to continue delaying implementation of CPT codes 77061 and 77062 and allow physicians to bill G-code G0279 as an add-on code to the diagnostic digital mammography codes (which now will be 770X1 and 770X2). The values for the add-on code would continue to be based on CPT code 77063. We appreciate and support these proposals.

## IV. CMS should finalize its proposal to make the requirement to consult appropriate use criteria for advanced diagnostic imaging services effective no earlier than January 1, 2018.

We appreciate CMS's new proposals to continue implementation of the requirement to establish appropriate use criteria (AUC) for certain advanced diagnostic imaging services (ADIS). As health care providers who rely on such imaging services to diagnose and treat cancer patients, ACCC and its members look forward to working closely with CMS to implement the new AUC requirements in a manner that is practical, achievable, and consistent with the statute.

We commend CMS for finalizing its definition of provider-led entity (PLE) and for announcing qualified PLEs in June. We strongly believe that AUC should be developed by physicians and providers who used advanced diagnostic imaging in their daily practice rather than by radiology benefit managers (RBMs) and other bodies who are primarily concerned with cost instead of delivering the high quality care that we strive to deliver to our patients.

<sup>&</sup>lt;sup>9</sup> <u>Id.</u> at 46253. <sup>10</sup> <u>Id.</u> at 46254.

<sup>&</sup>lt;sup>11</sup> Id. at 46386.

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We recommend that CMS finalize its proposal to make the requirement to consult AUC effective no earlier than January 1, 2018. We believe that this time will help ordering and furnishing professionals to put into place the necessary technical systems and clinical processes to promote compliance with the new law.

V. CMS should finalize its proposal to add advance care planning services to the telehealth list, with appropriate payment for such services, should work with ACCC and other stakeholders to establish broader coverage for telehealth services under the PFS, and should improve payment for advance care planning services.

We strongly support CMS's proposal to add the two CPT codes for advance care planning services (CPT codes 99497 and 99498) to the list of services that Medicare will cover when provided via telehealth, and we recommend that CMS finalize this proposal.<sup>13</sup> In addition. we urge CMS to work with ACCC and other health care providers to continue expanding Medicare coverage for telehealth services. We recognize that CMS has established by regulation a process for adding CPT codes to the list of Medicare telehealth services and that for certain codes and services, the stakeholders requesting coverage may not have demonstrated how a service meets the specific requirements for coverage as a telehealth service. However, we believe that broader Medicare coverage for physician services provided via telehealth is essential to ensuring access to care for Medicare beneficiaries in rural areas, allowing patients to receive care from specialists and sub-specialists who might otherwise be located too far away from the patient to participate in their care on a regular basis, and helping to meet increased demand for cancer care in our aging population. We urge CMS to work with ACCC and other provider organizations to promote increased Medicare coverage for telehealth. We also ask CMS to prioritize its consideration of any applications to add oncology-related services to the telehealth list.

We reiterate our concern that the payment rates proposed for CY 2017 for the advance care planning services, which closely resemble those finalized for CY 2016, do not adequately reflect the cost to physicians of providing advance care planning. These are complex consultative services that require significant physician time and work, and adequate reimbursement must be available to ensure that beneficiaries have access to advance care planning when such services are needed. We urge CMS to finalize payment for the first 30 minutes of advance care planning services, code 99497, at the same rate as a level 5 evaluation and management (E/M) code, 99215, to better account for the amount of time physicians spend preparing for and delivering these services. We also strongly recommend that CMS continue to work with physicians to ensure that Medicare provides appropriate reimbursement for all phases of a patient's care, including overseeing the patient's care after he or she enters hospice.

<sup>&</sup>lt;sup>12</sup> <u>Id.</u> at 46392.

 $<sup>^{13}</sup>$  Id. at 46180.

#### VI. CMS should finalize its proposal to establish payment for new care management and collaborative care services.

We applaud CMS for recognizing the importance of care management and collaborative care in the effective delivery of treatment to Medicare beneficiaries. In particular, we thank CMS for its proposal to establish payment rates for a new G-code for comprehensive assessment and care planning for patients who require chronic care management (CCM). <sup>14</sup> We also appreciate CMS's proposal to pay for additional CPT codes in the family of codes for CCM services and to adjust payment for the initial CCM visit to account for new care plan detail. 15

We encourage CMS to develop and pay for such codes to help ensure that primary care physicians and other health care professionals are reimbursed adequately for the work they perform in managing and coordinating care to patients with serious chronic conditions. In developing such codes and establishing values for the codes, CMS should ensure that physicians and other health care providers that routinely perform such services are given the opportunity to provide input. We encourage CMS to work with ACCC and other provider organizations to ensure that any new care management or collaborative care codes are structured and valued appropriately.

#### VII. CMS should assign a separate HCPCS code for each biosimilar product.

In the CY 2016 rulemaking, CMS finalized a payment methodology under which all biosimilars with the same reference product will be assigned to a single HCPCS code and reimbursed based on the volume-weighted Average Sales Price (ASP) for all products under the code, plus six percent of the reference product's ASP. ACCC reiterates its concerns that this policy will continue to impose unfair administrative burdens and care-compromising financial pressures on providers, and will make it more difficult for the Food and Drug Administration (FDA) to track safety information back to the manufacturer of the specific biosimilar product for which information is reported. ACCC strongly recommends that CMS adopt a reimbursement methodology that assigns each biosimilar product to a separate HCPCS code and calculates reimbursement separately for each biosimilar product. This approach will ensure effective monitoring of the safety of each biosimilar product following approval, and encourage providers to focus on providing the best and most appropriate beneficiary care.

<sup>14</sup> <u>Id.</u> at 46202. <sup>15</sup> <u>Id.</u> 46207-13.

 $<sup>\</sup>overline{80}$  Fed. Reg. at 71101.

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Thank you for this opportunity to share the oncology care provider perspective on your proposals in the PFS Proposed Rule. As the association representing the multidisciplinary cancer team, ACCC is uniquely suited to participate in this dialogue. Please feel free to contact Leah Ralph, Director of Health Policy, at (301) 984-5071 if you have any questions or need any additional information. Thank you again for your attention to this very important matter.

Respectfully submitted,

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President

Association of Community Cancer Centers