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September 8, 2015

Andrew M. Slavitt
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

BY ELECTRONIC DELIVERY

**Re: Medicare Program; Revisions to Payment Policies Under the
Physician Fee Schedule and Other Revisions to Part B for CY 2016;
Proposed Rule (CMS-1631-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").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 represents more than 20,000 cancer care professionals from approximately 1,100 hospitals and more than 1,000 private practices nationwide. These include Cancer Program Members, Individual Members, and members from 32 state oncology societies. It is estimated that 60 percent of cancer patients nationwide are treated by a member of ACCC.

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

- Use caution in reviewing and modifying codes proposed for review as "potentially misvalued;"

¹ 80 Fed. Reg. 41685 (July 15, 2015).

- Develop new add-on codes to fully account for the work involved in care management and collaborative care services and seek input from physicians and other stakeholders on appropriate payment policies;
- Not finalize proposals related to payment for radiation treatment delivery, or delay or extend implementation of these proposals, to avoid drastic cuts in payment and threats to continued access to care;
- Finalize its proposal to create new codes and payment rates to implement its National Coverage Determination (NCD) on lung cancer screening and counseling;
- Work with ACCC and other stakeholders to establish broader Medicare coverage for telehealth services;
- Educate and communicate with physicians about new requirements for billing for “incident to” services to ensure that they fully understand these new requirements;
- Not finalize its coding and payment methodology for biosimilar products and instead adopt separate codes for each biosimilar product to minimize administrative burden for physicians and allow for adequate traceability;
- Finalize its proposal to establish payment for advance care planning services but increase the payment rate to adequately reimburse providers for the cost of such services;
- Align current and proposed implementation of the Physician Quality Reporting System (PQRS) and Value-Based Payment Modifier (VBPM) with anticipated implementation of the Merit-Based Incentive Payment System (MIPS) required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA); and
- Finalize its proposed definition of “provider-led entity” for purposes of the new appropriate use criteria (AUC) for advanced diagnostic imaging services to ensure certifying organizations are familiar with using and providing advanced diagnostic imaging services.

We discuss these recommendations in depth below.

I. CMS should use caution in reviewing and modifying codes proposed for review as “potentially misvalued.”

In the Proposed Rule, CMS proposes to evaluate approximately 118 Current Procedural Terminology (CPT)² codes as potentially misvalued because they represent high expenditure services across specialties with Medicare allowed charges of \$10 million or more that CMS identifies as a prioritized subset of the new statutory category “codes that account for the majority of spending under the physician fee schedule.”³ CMS arrived at this list by identifying the top 20 codes for each specialty in terms of allowed charges, then removing any codes proposed as potentially misvalued since calendar year (CY) 2010 and any

² CPT copyright 2014 American Medical Association (AMA). All rights reserved. CPT is a registered trademark of the AMA.

³ 80 Fed. Reg. at 41705-06.

evaluation/management (E/M) codes. ACCC is concerned about this proposal because the list of codes proposed for review includes the codes for several drug administration services:

- 96372 (Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular);
- 96374 (Therapeutic, prophylactic, or diagnostic injection; intravenous push; single or initial substance/drug);
- 96375 (Therapeutic, prophylactic, or diagnostic injection; each additional sequential intravenous push of a new substance/drug);
- 96401 (Chemotherapy administration; subcutaneous or intramuscular; non-hormonal anti-neoplastic);
- 96402 (Chemotherapy administration; subcutaneous or intramuscular; hormonal anti-neoplastic);
- 96409 (Chemotherapy administration; intravenous, push technique, single or initial substance/drug); and
- 96411 (Chemotherapy administration; intravenous; push technique; each additional substance/drug).

These drug administration services are at the core of many cancer treatment regimens. Given the increasing incidence of cancer in the Medicare population, it is understandable that these codes have high utilization simply because there are more patients being treated for cancer. Physicians will be able to treat cancer patients effectively only if these codes are valued to reflect the true costs of care, including the costs of safely handling complex drugs and biologicals and complying with the growing burden of Risk Evaluation and Mitigation Strategies (REMS) for many of them. We urge CMS to exercise caution in reviewing these codes and ensure that the payment rates continue to appropriately reflect the substantial costs of safely and effectively providing these important services.

II. CMS should develop new add-on codes to fully account for the work involved in care management and collaborative care services and seek input from physicians and other stakeholders on appropriate payment policies.

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 acknowledgement in the Proposed Rule that Medicare's payment rates for the CPT codes for transitional care management (TCM) and chronic care management (CCM) do not fully account for the cognitive work that primary care physicians and other practitioners perform in managing and delivering care, particularly to chronically ill beneficiaries.⁴ CMS identifies add-on codes as one potential means of establishing payment rates that appropriately value the additional time and intensity of physicians' cognitive work often involved in delivering care management services.

We encourage CMS to develop 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

⁴ Id. at 41709.

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 add-on codes are structured and valued appropriately.

III. CMS should not finalize proposals related to payment for radiation treatment delivery, or delay or extend implementation of these proposals, to avoid drastic cuts in payment and threats to continued access to care.

In the Proposed Rule, CMS proposes several significant changes to payment for radiation oncology procedures,⁵ which would collectively result in drastic cuts in reimbursement for radiation oncology providers and risk severely limiting Medicare beneficiaries' access to life-saving cancer treatments.

First, CMS proposes to implement payment rates for the new CPT codes developed by the American Medical Association (AMA) to describe radiation treatment delivery, including new codes for intensity modulated radiation treatment (IMRT). The proposed payment rates for the new CPT codes will effectively reduce Medicare reimbursement for IMRT and other radiation treatment delivery services. In addition, and at the same time as this previously anticipated reduction in payment, CMS also proposes to remove several essential direct practice expense inputs from the new radiation treatment delivery codes, including the on-board imaging equipment that is essential to providing safe and accurate radiation treatment. Finally, CMS also proposes to adjust the equipment utilization rate assumption for the linear accelerator used in image guidance from 50 percent of available time to 70 percent of available time over two years. This proposed change also would effectively reduce reimbursement to radiation oncology providers for services that use this equipment.

CMS itself estimates that the cumulative effect on reimbursement if all of these proposals are finalized will amount to a three percent reduction for radiation oncology providers and a nine percent reduction for radiation therapy centers. Radiation oncology providers themselves estimate an even more significant negative impact on Medicare payments based on the cumulative proposals related to radiation treatment delivery, particularly as their costs to provide these services continue to increase. ACCC is deeply concerned that these deep and simultaneous cuts in reimbursement will have the effect of forcing some cancer care providers, particularly those operating in rural and underserved areas, to close their doors. 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 to recognize the significant threat that its combined proposals would pose for Medicare beneficiaries seeking access to radiation treatment. CMS should take the necessary steps to mitigate this threat, for example, by not implementing the proposed increase in the

⁵ Id. at 41769.

equipment utilization rate. The proposed 70 percent utilization rate is not supported by facilities' experience. A recent survey by the Radiation Therapy Alliance found an average utilization rate of 50 percent. If CMS decides to move forward with an increase in the utilization rate in spite of these data, it should extend the proposed two-year phase-in period for the increase in the equipment utilization rate. CMS also should delay the proposal to remove the direct inputs so that the cuts in reimbursement that would result do not come immediately on top of the already significant reductions as a result of the new CPT codes. ACCC and other cancer provider organizations stand ready to work with CMS to find ways to implement any appropriate changes in payment for radiation treatment delivery over a period sufficient to allow providers to absorb the changes and ensure that Medicare beneficiaries continue to have access to these critical services.

IV. CMS should finalize its proposal to create new codes and payment rates to implement its NCD on lung cancer screening and counseling.

We support CMS's proposal to establish two new G-codes to implement payment rates for lung cancer screening and lung cancer screening counseling services, as described in the NCD issued in February 2015.⁶ We believe that the new G-codes appropriately describe the screening and counseling services for which CMS established Medicare coverage in the NCD. CMS proposes to set the work relative value units for the low-dose computed tomography (CT) service equal to the value for 71250 (computed tomography, thorax; without contrast material). We recommend that this value be increased to account for the additional time and intensity associated with reading low-dose CT images as well as the effort needed to fulfill the additional documentation requirements established by the NCD. These images are more challenging to interpret because low-dose CT, intended to protect the patient from additional radiation, produces less clear images than a normal chest CT, yet these patients are more likely to have abnormalities than the average patient receiving a chest CT. We look forward to working with CMS to establish final values to ensure that these important services are reimbursed appropriately under the PFS.

We also ask CMS to clarify two points regarding the shared decision-making visit. First, CMS should clarify that this visit will not be subject to beneficiary coinsurance. As part of the preventive service described by the NCD, it should be exempt from coinsurance along with the low-dose CT service. Second, CMS should clarify that the visit can be billed on the same day as an E/M visit.

V. CMS should work with ACCC and other stakeholders to establish broader coverage for telehealth services under the PFS.

The Proposed Rule addresses a number of CPT codes that stakeholders submitted for proposed addition to the list of services that Medicare will cover when provided via telehealth. Although CMS proposes to add two CPT codes for prolonged inpatient services and four CPT codes for home dialysis services, CMS declines to propose several other CPT codes recommended by commenters for inclusion in the list of telehealth-eligible services.⁷

⁶ *Id.* at 41779.

⁷ *Id.* at 41781.

We urge CMS to work with ACCC and other health care providers to establish broader 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, where there is a growing shortage of providers, especially if they are physically or financially unable to obtain care in person. Telehealth can be particularly valuable at 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. It also could be a creative solution to the challenges of meeting 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, which will help to ensure that all Medicare beneficiaries have regular access to high-quality care from primary care and specialty providers alike. We also ask CMS to prioritize its consideration of any applications to add oncology-related services to the telehealth list.

VI. CMS should educate and communicate with physicians about new requirements for billing for “incident to” services to ensure that they fully understand these new requirements.

We appreciate CMS’s concerns about billing for items and services provided incident to the professional services of a physician. We believe that the ability to provide and bill for such “incident to” services is an important part of many physicians’ practices and agree that these services should continue to be billed according to sensible, well-understood criteria. In the Proposed Rule, CMS proposes to require that the physician or other provider who bills for an “incident to” service must also be the physician or other provider who directly supervises the auxiliary personnel in providing the “incident to” service.⁸ CMS also proposes to amend the regulation to explicitly prohibit auxiliary personnel from providing incident to services if they have either been excluded from Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General or if they have had their enrollment revoked for any reason.⁹ If CMS finalizes these requirements, we ask and encourage CMS to provide education to physicians and other providers on the revised regulation to ensure that providers do not experience unwarranted disruption in billing for appropriate “incident to” services.

VII. CMS should not finalize its coding and payment methodology for biosimilar products and instead should adopt separate codes for each biosimilar product to minimize administrative burden for physicians and allow for adequate traceability.

CMS proposes to clarify its payment methodology for biosimilar products by stating that all biosimilars with the same reference product would be assigned to a single Healthcare Common Procedure Coding System (HCPCS) code and reimbursed based on the volume-

⁸ Id. at 41785.

⁹ Id.

weighted Average Sales Price (ASP) for all products under the code plus six percent of the reference product's ASP.¹⁰

ACCC urges CMS not to finalize this proposal. Instead, CMS should assign each biosimilar product to a separate HCPCS code and calculate a separate reimbursement rate for that product based on its own ASP data and the ASP date for the reference product. Assigning multiple biosimilar products to a single HCPCS code would create new and unnecessary administrative burdens for physicians and other providers when treating patients with biosimilar products. Physicians will need to track the exact therapy each patient receives because biosimilars are not identical to each other or their reference biological products and may cause different side effects. Because a HCPCS code that encompasses multiple biosimilar products would not identify the specific biosimilar administered to the patient, providers would need to enter into the medical record not only the HCPCS code, as they do now, but also the specific biosimilar therapy used for the patient. This administrative burden, and the resulting potential for errors or omissions in the medical record, could be avoided by assigning each biosimilar product to a separate code.

For the same reasons, and as other commenters have explained in detail, assigning multiple biosimilar products to a single HCPCS code would significantly impede effective tracking of safety information and other information about patient experience with specific biosimilar products after they enter the market. To protect patient safety, prescribers and pharmacies must be able to easily report to the Food and Drug Administration (FDA) any information that they receive about the safety of specific therapies that their patients receive. If multiple biosimilar products are assigned to a single HCPCS code, however, it will be difficult if not impossible for FDA to trace safety information back to the appropriate biosimilar product because FDA's tracking systems rely on billing records, including reported HCPCS codes. In this respect, biosimilars are different from single-molecule drug products with multiple sources. Even biosimilar products that are based on the same reference product often exhibit important differences in efficacy and patient response; multiple-source drugs do not exhibit such differences and thus a single code is sufficient to ensure adequate collection of safety information for those products.

We urge CMS to promote effective tracing of safety information and minimize administrative burdens on providers who prescribe biosimilars by finalizing a payment methodology that assigns each biosimilar product to a separate HCPCS code.

VIII. CMS should finalize its proposal to establish payment for advance care planning services but should increase the payment rate to accurately reflect the cost of providing such services.

We strongly support CMS's proposal to establish payment rates for the two CPT codes adopted by the AMA CPT Editorial Panel to describe advance care planning services.¹¹ Establishing Medicare payment for these services is essential in promoting the provision of these

¹⁰ Id. at 41801-02.

¹¹ Id. at 41773.

services for chronically ill beneficiaries or in other circumstances where such services are appropriate.

However, we are concerned that the payment rates proposed for these services in the Proposed Rule do not adequately reflect the cost to physicians of providing advance care planning. As CMS is aware, 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 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.

IX. CMS should align implementation of the MIPS with existing policies and measures under the PQRS and VBPM, and should ensure that providers and other stakeholders have sufficient notice to allow preparation for the transition to the MIPS.

We thank CMS for its proposals to begin implementation of the MIPS as required by MACRA.¹² ACCC and its members look forward to working closely with CMS as it implements this important and complex new payment system.

As CMS begins to transition to the MIPS and prepares for the sunset of the existing PQRS and VBPM at the end of CY 2018, we encourage CMS to align its proposed policies with anticipated MIPS policies to the maximum extent possible. The potential adjustments to payment under the existing PQRS and VBPM are significant – for CY 2016, CMS proposes to increase the penalty for failure to report under the PQRS to two percent and expand the potential four percent adjustment under the VBPM to all solo practitioners and groups of eligible professionals. These significant potential adjustments would continue and increase under the MIPS.

It is essential that CMS's proposals related to the PQRS and VBPM anticipate and align with future policies under the MIPS. Providers have spent considerable time and resources developing systems, purchasing equipment, training staff, and making other changes in their practices to comply with the existing quality reporting requirements and to maximize the quality and cost-efficiency of the treatment they deliver. Moreover, providers have carefully tailored their preparations to the specific policies that CMS has adopted to implement the PQRS and VBPM, including particular quality measures or measures groups, criteria for satisfactory reporting, and calculation methodologies for composite value-based scoring. We urge CMS to transition existing policies, including existing quality measures, as directly as possible to the MIPS, to minimize the further time and resources providers must spend adjusting to the mechanics of a new payment system. Maximizing alignment and transition of existing quality measures is also consistent with Congress's intent to allow for continuity between current

¹² Id. at 41815.

systems and the MIPS; indeed, existing quality measures are to be automatically included in the list of quality measures for the MIPS unless specifically removed.¹³

In addition, we urge CMS to give providers as much notice as possible of the regulatory schedule for implementation of the MIPS, as well as any additional incentives under eligible alternative payment models (APMs). We appreciate the preliminary information that CMS provided in the Proposed Rule about the anticipated timing for the next steps of implementation of the MIPS. As we move toward sunset for the existing systems and the effective date of the MIPS on January 1, 2019, it will be extremely important that providers have early notice of the expected dates on which various aspects of the MIPS and APMs will go into effect, allowing the time necessary to make any adjustments, improvements, or other changes to promote high-quality, cost-efficient care as intended by Congress.

X. CMS should finalize its proposed definition of “provider-led entity” to ensure certifying organizations are familiar with using and providing advanced diagnostic imaging services.

We appreciate CMS’s initial proposals to implement the requirement to establish appropriate use criteria (AUC) for certain advanced diagnostic imaging services.¹⁴ 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 particular, we support CMS’s proposed definition of “provider-led entity” as a national professional medical specialty society, or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare.¹⁵ This definition is consistent with the language of the statute and will promote the development of AUC that are informed by the expertise of physicians and other providers who use advanced diagnostic imaging every day. As the Proposed Rule indicates, organizations that may qualify to develop or endorse AUC should be comprised of health care providers who understand advanced imaging technology and the process and context for providing advanced diagnostic imaging services. On the other hand, AUC that is developed by other bodies, such as radiology benefit managers (RBMs), would lack the clinical consensus that Congress intended. We are confident that CMS’s proposed definition, in conjunction with careful implementation of the remaining statutory requirements in consultation with providers and other stakeholders, will promote “high quality, evidence-based AUC” in accordance with Congress’s intent, and we urge CMS to finalize it.¹⁶

* * *

Thank you for this opportunity to share the oncology care provider perspective on chronic care treatment reform policies. As the association representing the multidisciplinary cancer team,

¹³ Social Security Act § 1848(q)(1)(D)(vii), as added by MACRA.

¹⁴ 80 Fed. Reg. at 41802.

¹⁵ *Id.* at 41961.

¹⁶ *Id.* at 41805-06.

ACCC is uniquely suited to participate in this dialogue. Please feel free to contact Leah Ralph, Manager, Provider Economics and Public 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,

A handwritten signature in cursive script that reads "Steven D'Amato".

Steven D'Amato, BSPHarm, BCOP
President
Association of Community Cancer Centers