August 31, 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: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System
(CMS-1633-P)

Dear Administrator Slavitt:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment (OPPS) 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 committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to appropriate cancer therapies in the most appropriate setting. Advanced cancer treatments are often associated with considerable risk, and many are available only in the hospital setting. Hospital outpatient departments are a crucial part of the cancer care

[1] 80 Fed. Reg. 39199 (July 8, 2015).

delivery system. Hospitals face growing numbers of patients requiring cancer care, and their ability to provide care will depend on appropriate Medicare payment rates for cancer care, including drugs and other services. ACCC is pleased to provide the following recommendations in response to requests for comments on the Proposed Rule by the Centers for Medicare & Medicare Services (CMS):

- Wait until the effects of current policies have been thoroughly evaluated before expanding packaging to additional items and services;
- Extend CMS's process for gathering stakeholder input on, refining, and implementing any new packaging proposals and continue to work with stakeholders to ensure they have the data and other information they need to comment meaningfully on these proposals;
- Continue to make separate payment at average sales price (ASP) plus six percent for drugs without pass-through status and implement the proposal to reimburse biosimilars at the same rate as in physicians' offices;
- Review the proposed changes in payment for drug administration services;
- Not implement the proposed reduction in payment for multiple-session stereotactic body radiation therapy (SBRT) and proceed carefully with setting rates for single-session cranial stereotactic radiosurgery (SRS);
- Make separate payment for the two new Current Procedural Terminology (CPT®)[2] codes for advance care planning services;
- Incorporate provider input before finalizing new requirements for Chronic Care Management Services;
- Adopt proposed coverage of lung cancer screenings;
- Adopt the proposal to allow for comment on new and revised CPT codes prior to usage for payment purposes; and
- Expand proposed exceptions to the 2-midnight rule.

I. CMS Should Wait until the Effects of Current Policies Have Been Thoroughly Evaluated before Expanding Packaging to Additional Items and Services.

Following the substantial changes to the OPPS implemented in 2014, and another set of new policies implemented for calendar year (CY) 2015, CMS proposes to further expand its packaging policies, including expanded packaging of certain ancillary services, conditional packaging of laboratory tests, and creation of new comprehensive ambulatory payment classifications (C-APCs), as well as restructuring and renumbering many ambulatory payment classifications (APCs).[3] ACCC understands CMS's desire to transform the OPPS into more of a prospective payment system that "maximize[s] hospitals' incentives to provide care in the most efficient manner."[4] We ask CMS to employ a measured, gradual approach to this transformation, however, in order to ensure that these goals are met. Hospitals need the assurance of predictable, appropriate payments in order to plan for the future and invest in the personnel and technologies that are essential to providing high-quality cancer care. The OPPS is

[2] CPT codes are the copyright of the American Medical Association.
[3] 80 Fed. Reg. at 39206 (July 8, 2015).
[4] Id. at 39233.

a complicated system, and each change to the packaging policies raises questions about whether the proposed rates truly reflect the historic costs of care and whether they will be sufficient to protect access to care in the future. These questions can be difficult to answer, not only because the OPPS rate calculations are challenging to replicate, but also because the effects of a new payment policy are not reflected in the claims data until well after they are implemented.

CMS acknowledges this reality in the Proposed Rule, when it discusses its analysis of 2014 claims data and its discovery of "excess packaged payment" for laboratory services. CMS now proposes to make a 2.0 percent reduction to the conversion factor to offset this $1 billion error.[5] ACCC urges CMS to not implement this proposed reduction. ACCC is understandably concerned that similar errors might have happened with other recent packaging proposals, leading to swings in payment rates as CMS moves forward with packaging in one year and seeks to correct its mistakes in a later year. This instability and uncertainty about future payments will not provide hospitals the incentives CMS intends. We also are troubled by the possibility that CMS underestimated the packaged costs of other services, but is not proposing an offset to reflect that mistake.

Careful analysis of the Proposed Rule's policies and rates is needed to ensure that the proposed payment rates appropriately reflect the costs of providing cancer care and to prevent the need for future adjustments to offset any mistakes in setting payment rates. We thank CMS for releasing the OPPS data to consultants early in the comment period this year, and for working with those consultants to explain the agency's methodology and respond to questions about how to replicate it.

In all likelihood, it will take another year to begin to measure the effects of these policies. There typically is a two year lag in the data CMS uses to set payment rates under the OPPS. A substantial body of claims data that include services affected by these policies still is not available. CMS and its stakeholders cannot effectively estimate the effects of potential expansions of packaging, such as packaging for drug administration add-on codes or imaging services, until the data on the effects of the current policies have been collected and evaluated.

CMS needs to consider not only the effects of its proposals on access to each category of packaged services, but also on the full spectrum of cancer care. We are particularly concerned about hospitals' ability to provide the extensive support services that allow patients to achieve the full benefits of their treatment regimens. In addition to managing the course of treatment, our member hospitals offer social services, including planning for home care, hospice and long-term care; community agency referrals and referrals for transportation assistance; and nutrition services, including evaluating the patient's nutritional status, providing information about diet and cancer, and developing nutrition plans to meet the individual patient's needs. Cancer therapy support services also include patient and family education, which entails educating newly diagnosed patients and their families about their cancer, treatment options, support resources, self-care techniques, new prescribed treatments, and coping with and managing treatment side effects. Hospitals also provide psychosocial support to address the psychological and emotional aspects of cancer and cancer treatment. Many of these services were not fully

[5] Id. at 39239.

reimbursed under the OPPS prior to the expansion of packaging, and it remains to be seen whether the new payment rates will harm hospitals' ability to furnish these services.

We urge CMS to evaluate the effects of its recently-implemented policies before considering further expansions of its packaging policies. CMS, hospitals, and other stakeholders need time to learn from their experience with the newest policies before implementing any additional packaging proposals.

II. CMS Should Extend Its Process for Gathering Stakeholder Input on, Refining, and Implementing Any New Packaging Proposals and Continue to Work with Stakeholders to Ensure They Have the Data and Other Information They Need to Comment Meaningfully on The Agency's Proposals.

ACCC cautions CMS against proceeding with newly proposed packaging policies, including three new proposed APCs and conditionally packaged laboratory tests.[6] Providers need certainty in payments, and CMS already has demonstrated the inaccuracy of recent packaged payments. CMS should proceed cautiously with new packaging policies to ensure accurate payment rates.

In addition to taking time to assess the effects of the most recently implemented policies, CMS must provide sufficient time to evaluate, refine, and implement any new packaging proposals. As we learned during the comment periods on the last proposed rules, 60 days is not enough time for stakeholders to replicate CMS's calculations, analyze the results, and provide meaningful comments. This is particularly true when CMS's proposals involve increasingly complex packaging rules, such as conditional packaging and comprehensive APCs. We commend CMS for making the data available this year promptly after the Proposed Rule was released and for working with the small group of consultants who can perform this analysis to understand the agency's methodology. We also appreciate the additional detail CMS released regarding methodological issues. We ask the agency continue to work with stakeholders to ensure they have the data and other information they need to comment meaningfully and in a timely manner on CMS's proposals.

Even with this assistance from the agency, however, it is difficult for us to complete our analysis of the Proposed Rule during the comment period. Moreover, hospitals often need more than 60 days after the final rule is released to fully digest the changes and implement the required changes to their billing systems. CMS acknowledged this fact in the final rule for CY 2014, when it delayed implementation of the comprehensive APCs until 2015 to allow more time for hospitals and the agency to assess the impact of this change in policy and verify the accuracy of the payment rates.[7]

To facilitate thorough analysis of any new packaging proposals by all stakeholders, we ask CMS to extend its process for gathering comments on its proposals. Specifically, we recommend that CMS present its proposals at the first meeting of the Advisory Panel on Hospital Outpatient Payment (HOP Panel) of the year before publishing them in the proposed rule. This

[6] Id. at 39223-4, 39234-6.
[7] 79 Fed. Reg. 66769, 66799 (November 10, 2014).

would allow CMS to benefit from two rounds of comments on its ideas: one at the HOP Panel meeting and another in response to the proposed rule. If CMS finalizes the proposals, it should delay implementation for at least one year, as it did with the comprehensive APCs, to allow hospitals time to adjust to the proposals and permit the agency to verify the appropriateness of its methodologies by applying them to an additional year of data. This extended time period for the development and implementation of any new packaging proposals would be similar to CMS's process for the adoption of quality measures, which the agency frequently announces several years before implementation to allow ample time for evaluation and comment.

III. CMS Should Continue to Reimburse Hospitals for Acquisition Cost of Separately Payable Drugs at ASP Plus Six Percent and Should Implement the Proposed Payment Rate for Biosimilars.

To maintain stable and predictable reimbursement for important cancer therapies and other drugs, we ask CMS to finalize its proposal to continue to reimburse the acquisition cost of separately payable drugs at ASP plus six percent.[8] This payment rate helps ensure that hospitals can continue to provide high quality cancer care to Medicare beneficiaries. In addition, because this payment rate is equivalent to the rate provided for drugs in the physician office setting, it removes incentives to select one setting over another and helps protect access to care in the most clinically appropriate setting for each beneficiary.

For the same reasons, we support CMS's proposals to pay for biosimilar biological products at their physician office rates and to allow these therapies to be eligible for pass-through status.[9] ACCC supports the development of biosimilar biologics, which may provide greater access to innovative cancer treatment at lower costs to beneficiaries, providers, and the Medicare program. However, ACCC cautions that assigning biosimilars that share a reference product to the same code will impose administrative burdens on physicians and complicate their recordkeeping. We will address these issues in more detail in our comments on the Physician Fee Schedule (PFS) proposed rule.

ACCC also continues to be deeply troubled by CMS's expanded list of "policy packaged drugs" and proposed increase in the packaging threshold.[10] CMS also proposes to increase the packaging threshold for drugs, biological and radiopharmaceuticals from $95 to $100 per day.[11] This proposal would lead to an increase in packaging, as more drugs would fall under the threshold. ACCC cautions against the expansion of packaging policies, given the miscalculation in CY 2014. At a minimum, CMS should establish a clear process for addressing incorrect packaging payments. We believe these policies disregard the clear language of the statute and Congressional intent, and they make it increasingly difficult for hospitals to furnish critical therapies and diagnostic drugs. We ask that separate payment should be made for all drugs with Healthcare Common Procedure Coding System (HCPCS) codes just as payment is made for these drugs in physicians' offices. To the extent that certain drugs continue to be packaged, CMS should require hospitals to bill for them using HCPCS codes and revenue code 636.

[8] 80 Fed. Reg. at 39281.
[9] Id. at 39285.
[10] Id. at 39276.
[11] Id. at 39275-76.

IV. CMS Should Review the Proposed Changes in Payment for Drug Administration Services.

For CY 2016, CMS proposes to restructure many APCs, leading to significant changes in payment for many services. Several drug administration services that are critical to cancer care would see reductions of 13.6 percent, while payment for one code would increase by 74 percent, as described in the table below. We are concerned about these dramatic changes in payment and ask that CMS review these proposed changes to verify that they correctly reflect hospitals' costs, including the costs of packaged drugs.

Drug Administration Codes with Proposed Reductions in Reimbursement Greater than 10 Percent

HCPCS Code	Short Descriptor	SI	APC	Payment Rate	CI	SI	APC	Payment Rate	Change 2015-2016 (%)
96360	Hydration iv infusion init	S	0438	$108.24		S	5693	$93.48	-13.6
96370	Sc ther infusion addl hr	S	0437	$53.54	CH	S	5691	$34.34	-35.9
96371	Sc ther infusion reset pump	N				N			
96372	Ther/proph/diag inj sc/im	S	0437	$53.54		S	5692	$49.92	-6.8
96373	Ther/proph/diag inj ia	S	0438	$108.24		S	5693	$93.48	-13.6
96374	Ther/proph/diag inj iv push	S	0438	$108.24		S	5693	$93.48	-13.6
96401	Chemo anti-neopl sq/im	S	0438	$108.24		S	5693	$93.48	-13.6
96411	Chemo iv push addl drug	S	0437	$53.54	CH	S	5693	$93.48	74.6
96420	Chemo ia push tecnique	S	0438	$108.24	CH	S	5693	$93.48	-13.6
96423	Chemo ia infuse each addl hr	S	0438	$108.24		S	5693	$93.48	-13.6
96523	Irrig drug delivery device	Q1	0624	$78.82	CH	Q1	5733	$56.70	-28.1
96542	Chemotherapy injection	S	0438	$108.24		S	5693	$93.48	-13.6

ACCC supports CMS's proposal to continue to exclude certain services, including low-cost drug administration services, from ancillary services packaging policy.[12] ACCC cautions that CMS's revision of drug administration rates should not result in reduced overall payments for providers. Providers depend on stable payment rates to ensure their ability to provide high quality care to patients.

V. CMS Should Not Implement the Proposed Reduction in Payment for Multiple-Session SBRT and Should Proceed Carefully with Setting Rates for Single-Session Cranial SRS.

ACCC continues to be concerned about the reduction in payment for SBRT services in recent years. Payment rates for a multiple-session course of treatment declined by about 30 percent from 2013 to 2014, declined by another 1 percent this year, and are proposed to be reduced by another 11 percent for 2016. Although CMS's methods of estimating costs suggest that costs have fallen, review of the data show that many hospitals estimated costs are unrealistically low. These data should not be used for rate-setting when it is clear that the actual cost of providing these services has not declined. If these proposed rates are implemented, we are concerned that hospitals might not be able to continue to provide the most appropriate radiation therapy options for beneficiaries with cancer. We ask that CMS not implement this proposed reduction in payment and should instead assign these services to a temporary APC, such as a new technology APC, to provide stable, appropriate payment until better cost data can be collected.

ACCC is pleased that CMS proposes to revise its policies for the C-APC for single-session cranial SRS after observing differences in how hospitals bill for the planning and preparation services associated with Cobalt-60 and LINAC-based treatments.[13] CMS proposes to unpackage these services and use a modifier to collect data for use in setting a single payment for the C-APC in the future. We commend CMS for taking steps to provide appropriate payment for all of the services currently included in this C-APC and recommend CMS finalize this proposal. We are concerned about the proposed modifier, however, because it would be extremely difficult for hospitals to implement. Identifying related services across multiple days of care and hospital departments would require hospitals to manually review all claims and delay claims submission, postponing payment to the hospital. We urge CMS to work with hospitals to identify less burdensome methods of collecting the cost data the agency seeks. If CMS implements the modifier, we also recommend that CMS provide clear instructions to hospitals about use of the modifier to ensure that the agency collects accurate data on the costs of these services and how they are used.

VI. CMS Should Make Separate Payment for the Two New CPT Codes for Advance Care Planning Services.

For CY 2015, the CPT Editorial Panel created the following two new codes for advance care planning (ACP) services:

[12] Id. at 39234.
[13] Id. at 39227.

- 99497 – Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; first 30 minutes, face-to-face with the patients, family member(s) and/or surrogate)
- 99498 – Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; each additional 30 minutes (List separately in addition to code for primary procedure)

Although these codes were not paid by Medicare in 2015, the PFS Proposed Rule for CY 2016 now proposes to recognize and make separate payment for them, in recognition of the time required to furnish the services and their importance for the quality of care and treatment of the patient.[14] ACCC strongly agrees with CMS's proposal. As ACP services are equally important in the hospital outpatient setting, where they also take substantial time and resources and contribute significantly to the quality of patient care, ACCC urges CMS to pay separately for these two new CPT codes in the hospital outpatient setting as well. Payments for transitional care management (TCM) and chronic care management (CCM) could serve as a benchmark for establishing payment rates as we believe resource use for ACP is similar to these services.

ACP is an essential service for oncology patients and can have a significant, positive effect on quality of care. Discussions often are extensive, covering long and short-term options, pain management, hospice, and palliative care. Decisions may need to be revisited as prognosis changes and therapies fail. In addition, discussions often involve family members as well as the patient.

Overall, substantial facility resources are expended when these critically important ACP services are provided by non-physician practitioners in hospital outpatient departments. Accordingly, we urge CMS to pay separately for CPT codes 99497 and 99498 under the OPPS as CMS has proposed to do under the PFS, and as recommended by the HOP Panel.

VII. CMS Should Incorporate Provider Input before Finalizing New Requirements for Chronic Care Management Services.

CMS proposes new requirements for hospitals billing under CPT code 99490 for chronic care management (CCM) services.[15] In particular, CMS proposes to permit only one hospital to bill for CCM services during a calendar month. ACCC supports efforts to coordinate care of cancer patients with multiple chronic conditions, but we are concerned that CMS's rules for these services make it very difficult for hospitals to seek payment for them. Because cancer patients' care is highly multidisciplinary, it can be difficult to agree upon who should be the designated CCM physician. A single patient might have surgeons, medical oncologists, radiation oncologists, palliative care physicians, pulmonologists, primary care physicians, and others involved in his or her care. Depending on the disease site, any one of these physicians may be best to qualify for the CCM physician. This difficulty is compounded when a patient receives care in more than one hospital or hospital-based practices where there providers are not always

[14] 80 Fed. Reg. 41686, 41773 (July 15, 2015).
[15] 80 Fed. Reg. at 39288-90.

formally affiliated but are still a part of the patient's healthcare team. The restrictions on who can bill for CCM may further erode the relationships between hospitals and private practice oncologists as well. We urge CMS to continue to consult with hospitals and physicians on the best way to determine which entities should bill for these services.

VIII. ACCC commends CMS for coverage of lung cancer screenings.

ACCC strongly supports CMS's national coverage determination in February 2015 regarding coverage of lung cancer screening with low dose computed tomography, as well as counseling and shared decision-making.[16] ACCC also supports CMS's current proposal to establish HCPCS codes for payment of these services under the OPPS.

IX. CMS Should Adopt Its Proposal to Allow for Comment on New and Revised CPT Codes Prior to Usage for Payment Purposes.

ACCC commends CMS for proposing a comment period for new CPT codes before they are used for payment purposes under the ASC payment system.[17] Provider input prior to use of new and revised codes will lead to increased accuracy in payments, and reduce the need for adjustments. ACCC supports this effort which will encourage reliable and accurate payments.

X. CMS Should Expand Proposed Exceptions to the 2-Midnight Rule.

ACCC supports CMS's proposal to establish exceptions to the 2-midnight rule, allowing determination by the responsible physician, and subject to the review of Quality Improvement Organizations (QIO's).[18] ACCC is encouraged by CMS's willingness to engage stakeholders on the 2-midnight rule. We are also pleased that CMS has proposed to transfer review to QIO's, which have the capability of adequately determining whether an inpatient admission is medically reasonable and necessary.

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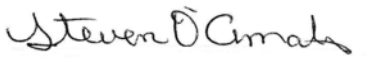
Thank you for this opportunity to comment on proposals regarding hospital care. ACCC encourages CMS to incorporate our recommendations into the final OPPS rule, and protect patients' access to care in the most appropriate setting. We look forward to continuing to work with CMS to address these critical issues in the future. 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 these very important matters.

[16] Id. at 39301.
[17] Id. at 39305-07.
[18] Id. at 39348-53.

Respectfully submitted,



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