September 2, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave. SW
Washington, DC 20201

RE: CMS-1613-P: (Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs)

Dear Administrator Tavenner:

On behalf of the Association of Community Cancer Centers (ACCC), we appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on July 14, 2014 (the "Proposed Rule").[1]

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 the most appropriate cancer therapies in the most appropriate settings. Hospital outpatient departments (HOPDs) are a crucial part of the cancer care delivery system, providing a significant portion of this country's cancer care. In fact, according to ACCC's annual Trends report, the amount of care given in the HOPD department has

[1] 79 Fed. Reg. 40915 (July 14, 2014)

grown in recent years, compared to care delivered in the physician office setting.[2] Because advanced cancer treatments often are associated with considerable risk, several are available only through hospital-based oncologists, nurses, and pharmacists. Patients receiving these treatments must have substantial on-site clinical support in case of adverse reactions. ACCC members often serve patients who have numerous complications or histories of infusion reactions. In addition, some treatments, such as those involving radiopharmaceuticals, are available only in hospitals because they require specialized equipment and handling that is only available in that setting. Finally, HOPDs play an important role in the early adoption of new technologies and frequently serve patients who recently have completed participation in clinical trials.

Our members also play an important role in the health care safety net. In some cases, HOPDs are the only sites available for Medicare and uninsured patients who need cancer care. HOPDs also can be the only option for Medicare beneficiaries who lack supplemental insurance. Since the inception of sequestration cuts to Medicare providers, more ACCC members have had to employ this practice, according to a November, 2013 survey.[3] As hospitals face growing numbers of patients who need care for cancer and other serious illnesses, but have nowhere else to turn, their ability to continue to provide care will depend on Medicare's payment rates.

Adequate OPPS payment rates for cancer drugs[4] and the services required to prepare and administer them are critical to ensuring patient access to care. We once again are encouraged that CMS has maintained its alternative methodology and proposed a payment rate of average sales price (ASP) plus six percent to cover the cost of drug acquisition and related pharmacy overhead services costs.

It is imperative to continued patient access in this crucial setting that the OPPS rates in 2015 and beyond adequately reimburse hospitals for the costs of providing advanced cancer therapies. Toward this end, ACCC recommends that CMS:

- Implement the proposal to reimburse hospitals for the acquisition cost of separately payable drugs at ASP plus six percent;
- Make separate payment for all drugs with Healthcare Common Procedure Coding System (HCPCS) codes, or, at a minimum, implement the proposal to maintain the current threshold at $90;
- Reinstate separate payment for diagnostic radiopharmaceuticals and contrast agents;
- Not implement the proposed reductions in payment for low dose rate (LDR) brachytherapy;
- Review the proposed ambulatory payment classification (APC) assignments and reimbursement rates for stereotactic radiosurgery (SRS) to ensure that the payment rates reflect the costs of these services and protect access to care;
- Revisit the policy change from last year that reduced clinic Evaluation and Management (E&M) codes from five levels to one;

[2] http://www.accc-cancer.org/surveys/CancerCareTrends-2014-Overview.asp.
[3] http://mynetwork.accc-cancer.org/blogs/sydney-abbott/2013/12/05/new-accc-survey-shows-sequester-impacting-all-cancer-patients.
[4] We refer to drugs, biologicals, and radiopharmaceuticals collectively as "drugs" throughout our comments.

- Use caution when establishing the comprehensive APCs (C-APCs) to ensure adequate reimbursement levels for all services within the C-APC;
- Implement the proposal to continue to pay separately for stem-cell transplants;
- Do not implement the proposal to package ancillary services under $100;
- Implement the proposal for PPS-exempt cancer hospitals payments in the same manner as 2014;
- Work with ACCC and other stakeholders before developing any drug administration packaging proposals; and
- Work with ACCC and other organizations on the implementation of the "off-campus" modifier.

Our comments on these issues and others are presented below.

I. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

A. CMS should implement the proposed payment rate of ASP plus six percent for separately paid drugs without pass-through status.

We are encouraged that CMS proposes to reimburse all separately paid drugs without pass-through status at ASP plus six percent.[5] ACCC is very pleased that CMS proposes to continue this payment rate from 2014, providing predictable and stable reimbursement for these vital therapies.

In our comments on prior years' proposed rules, we have explained the importance of appropriate payment for pharmacy overhead and service costs to hospitals' continued ability to provide cancer drugs to patients. The advanced drugs we use to help our patients fight cancer require careful handling by specially trained personnel to ensure that each patient receives the correct dosage of each drug, in the correct sequence, and through the safest administration method. Hospitals employ complex medication use processes in which physicians, nurses, and pharmacists review drug choices at each step of their prescribing, dispensing, and administration. Pharmacists make essential contributions to these processes by using a sequence of activities commonly referred to as "safety through redundancy." Registered pharmacists consult with physicians to determine drug interactions and contraindications, toxicity management and verification of therapy appropriateness, and dosing before and during administration of chemotherapy to a patient. Pharmacists also perform critical quality assurance tasks during the preparation of a drug, such as labelling, recording, and tracking mixed drugs for safety purposes, sampling drugs at random to verify quality, and developing and reviewing protocols to flag potential interactions. The costs of these services, plus necessary supplies, equipment, and facilities used in preparing drugs, are significant. It is critical that Medicare's reimbursement amounts reflect the current costs of providing care, and with the proposed continuation of reimbursement at ASP plus six percent, we appreciate that CMS has recognized this need.

[5] 79 Fed. Reg. at 41003.

Payment for the acquisition and overhead costs of drugs at ASP plus six percent will help continue to protect patients' access to care in the most clinically appropriate setting. It also maintains parity with the physician office setting. To provide for stable, appropriate payment, CMS should continue to reimburse drugs provided under the OPPS at ASP plus six percent.

B. CMS should make separate payment for all drugs with HCPCS codes, or, at a minimum, implement the proposal to maintain the packaging threshold for drugs at $90.

For 2015, CMS proposes to maintain the packaging threshold at $90.[6] We support the proposal to not increase the threshold for 2015. We remain concerned, however, that continued use of any threshold and the implementation of expanded packaging could harm hospitals' ability to provide essential cancer care and discourage hospitals from investing in new treatment options.

ACCC also continues to be deeply troubled by CMS's expanded list of "policy packaged drugs." CMS also asserts that it "has the statutory authority to package the payment of any drugs, biologicals, and radiopharmaceuticals, including those that meet the statutory definition of a [specified covered outpatient drug] SCOD."[7] This interpretation disregards both the plain language of the statute and Congressional intent behind the detailed statutory payment requirements for SCODs. Congress enacted these provisions after CMS set a high packaging threshold in 2003, and we believe that Congress intended for CMS to continue to protect access to care by keeping the packaging threshold low. Due to the well-known inaccuracies associated with estimating the cost of drugs using cost-to-charge ratios, we are concerned that expanded packaging will result in less accurate payment rates for the drugs and the procedures with which they are used. For these reasons, we recommend that CMS make separate payment for all drugs with HCPCS codes. At a minimum, CMS should maintain the packaging threshold at no more than the current level of $90.

C. CMS should reinstate separate payment for diagnostic radiopharmaceuticals and contrast agents.

CMS proposes to continue to package payment for diagnostic radiopharmaceuticals and contrast agents, regardless of their cost per day.[8] As we have stated in previous years, radiopharmaceuticals are extremely complex therapies to prepare and administer. Preparation and administration of each drug requires a unique combination of services, such as compounding, infusions, and scanning of the patient to assess bio-distribution of the therapy. The costs of these services vary for each therapy, and many of these costs are not reimbursed adequately under the OPPS. Contrast agents also vary in cost and may not be compensated adequately through the OPPS rates for imaging services. We urge the agency to reinstate separate payment for diagnostic radiopharmaceuticals and contrast agents.

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[6] Id. at 40997.
[7] Id. at 40949.
[8] Id. at 41004.

II. CMS should not implement the proposed reduction in payment for LDR prostate brachytherapy.

For CY 2015, CMS proposes to continue paying for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2013.[9] The proposed payment rate achieved through this methodology is a reduction of 8.9 percent from the CY 2014 payment. Brachytherapy is an important treatment option for prostate cancer, and ACCC asks that CMS work to ensure that payment for this composite APC does not experience significant reductions from year to year.

III. CMS should review the proposed APC assignments and reimbursement rates for SRS to ensure that the payment rates reflect the costs of these services and protect access to care.

In the CY 2014 final rule, CMS replaced the longstanding HCPCS codes for stereotactic radiosurgery with Current Procedural Terminology (CPT®)[10] codes and revised the APC assignments for those CPT codes.[11] These changes resulted in significant reductions in payment for the services formerly identified with codes G0339 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of treatment in one session or first session of fractionated treatment) and G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment) when used for fractionated treatment. CMS proposes to continue to assign these codes to APC 0066 and to use the historical claims data for the HCPCS codes to establish payment rates, although CMS acknowledges a "2 times rule" violation for this APC.[12] Specifically, the geometric mean cost for G0339 is more than three times the costs of code G0251 (Linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment), but the costs of both of these codes are used to set the payment rate for APC 0066. The historic claims data for the HCPCS codes used to calculate the payment rate for this APC clearly indicate that the procedures assigned to this APC have significant differences in resource costs.

We ask CMS to protect access to care by reviewing the APC assignments for these services and the use of historic claims data that violate the 2 times rule to calculate the payment rate for this APC. In particular, we recommend that CMS remove the claims data for G0251 from the calculations of the payment rate for APC 0066.

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[9] Id. at 40954.
[10] CPT copyright 2013 American Medical Association (AMA). All rights reserved. CPT® is a registered trademark of the AMA.
[11] 78 Fed. Reg. 74826, 74989 (Dec. 10, 2013).
[12] 79 Fed. Reg. at 40981.

IV. CMS should revisit the policy change from last year that reduced clinic E&M codes from five levels to one.

CMS proposes to continue to use a single code to "represent any and all clinic visits under the OPPS."[13] For the CY 2014 proposed rules, ACCC commissioned a study of ACCC hospital members to determine what level of E&M code is most often used with a cancer diagnosis. As we expected, most hospitals bill level 4 and 5 E&M codes a majority of the time that a cancer diagnosis also appears on the claim. We remain extremely concerned that CMS's continued use of a single code for all levels of clinic visits will harm cancer centers and their patients due to the reduction in payment for services that were previously reimbursed at higher levels. ACCC requests that CMS revisit this change from CY 2014 and reinstate payment for different levels of clinic visits that better accounts for the costs of the services provided to cancer patients.

V. CMS should use caution when establishing the comprehensive APCs (C-APCs) to ensure adequate reimbursement levels for all services within the C-APC.

In the CY 2014 OPPS final rule, CMS finalized a policy with a delayed implementation date of CY 2015 under which certain covered outpatient services would be designated as "primary services" and assigned to C-APCs. For CY 2015, CMS proposes to continue to define the services assigned to C-APCs as primary services and to define a comprehensive service as a classification for the provision of a primary service and all adjunctive services and supplies provided to support the delivery of the primary service.[14] The C-APC payment bundle would include all hospital services reported on a claim that typically are covered under Medicare Part B, with the exception of excluded services or services requiring separate payment by statute, such as mammography services and ambulance services; brachytherapy seeds; pass-through drugs, biologicals, and devices; recurring therapy services; certain preventative services; and self-administered drugs that are not otherwise packaged as supplies.[15]

ACCC appreciates CMS's delay in implementing the C-APCs for one year so that the agency could refine this proposal and seek additional comment on it. As we learned during the comment period on the CY 2014 proposed rule, 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 C-APCs. We commend CMS for making the data available this year soon 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 urge CMS to continue to allow additional time for review, analysis, and commenting on any proposals to expand packaging, including C-APCs, so that all stakeholders can fully understand the proposals and provide meaningful comments.

[13] Id. at 41008.
[14] Id. at 40940.
[15] Id.

ACCC continues to be concerned at the expansion of CMS's packing proposals. As we noted above, CMS's methods of estimating costs from hospitals' charges have well-known flaws that tend to result in "charge compression," or overestimates of the costs of lower cost services and underestimates of the cost of more resource-intensive services. The effects of this phenomenon on estimated costs of drugs have been thoroughly documented, and stakeholders also have raised concerns about the accuracy of cost estimates for imaging services. CMS's proposal to package payment for all non-pass-through drugs and all imaging services into comprehensive APCs renews our concerns about whether the costs of these services are accurately represented in the proposed payment rates.

We note that the geometric mean costs of services included in some of the C-APCs varies widely, often exceeding the "2 times" variation permitted by statute. Under CMS's criteria for identifying a 2 times rule violation, codes at least 99 claims but fewer than 1000 claims must represent 2 percent of single major claims in the APC in order to be considered when evaluating whether an APC violates the 2 times rule.[16] Because some codes assigned to a C-APC have a very high volume of claims, many codes with fewer than 1000 claims do not meet the threshold for consideration under the 2 times rule and are included in the C-APC despite having costs well in excess of 2 times the lowest cost service in the C-APC. For example, the codes assigned to C-APC 0622 have geometric mean costs ranging from $1,182 to $16,950, yet CMS concludes that this does not violate the 2 times rule because each of the 9 highest cost services have a total volume of single major claims that is less than 2 percent of the total for the C-APC. Although these assignments may not be a technical violation of the 2 times rule, we are concerned that they result in grossly inadequate payment for the highest cost procedures in the C-APC.

We also are concerned about the potential for confusion about billing and reimbursement for recurring chemotherapy and radiation therapy services when the patient also receives a service that is assigned to a C-APC. In response to comments on last year's proposed rule regarding whether other services furnished during the 30-day window surrounding the primary service in the C-APC would be packaged into the C-APC, CMS said:

> We remind hospitals that we have previously issued manual guidance in the Internet Only Manual at 100–4, Chapter 1, Section 50.2.2 that only recurring services should be billed monthly. Moreover, we have further specified that in the event that a recurring service occurs on the same day as an acute service that falls within the span of the recurring service claim, hospitals should bill separately for recurring services on a monthly claim (repetitive billing) and submit a separate claim for the acute service.[17]

The guidance in the manual identifies certain services, including physical therapy, occupational therapy, and speech-language pathology, as "repetitive services" that must be billed monthly, and it permits "recurring" chemotherapy and radiation therapy services to be billed either on separate claims for each date of service or on a single bill, "as though they were repetitive services."[18] We are concerned that providers may be confused about how these recurring

[16] Id. at 40937.
[17] 78 Fed. Reg. at 74865.
[18] Claims Processing Manual, ch. 1, § 50.2.2.

services will be treated when furnished to a patient who also receives a service assigned to a C-APC. We ask CMS to clarify its guidance so that hospitals understand how to bill for these services and that they continue to be reimbursed appropriately for providing critical cancer treatments.

VI. CMS should implement the proposal to continue to pay separately for stem-cell transplants.

CMS declined a commenter's request to apply the C-APC concept to outpatient stem cell transplants. Instead, the agency proposed to continue to pay separately for allogeneic transplantation procedures under APC 0111 (Blood Product Exchange) and APC 0112 (Apheresis and Stem Cell Procedures) with proposed rule geometric mean costs of approximately $1,127 and $3,064 respectively.[19] ACCC supports this proposal and asks that it be finalized for 2015.

VII. CMS should not implement the proposal to package ancillary services under $100.

For CY 2015, CMS proposes to conditionally package certain ancillary services for CY 2015. CMS proposes to limit the initial set of APCs that contain conditionally packaged services to those ancillary service APCs with a proposed geometric mean cost of less than or equal to $100.[20] CMS proposes to limit the initial set of packaged ancillary service APCs as a result of concerns expressed in public comments that certain low volume but relatively costly ancillary services would have been packaged into high volume but relatively inexpensive primary services. CMS notes that this limit is not intended as a threshold above which ancillary services will not be packaged but rather is intended to be used as the methodology for selecting the initial set of conditionally packaged ancillary service APCs under the proposed packaging policy.

As with drugs, ACCC remains concerned about the increased utilization of packaging and the impacts it may have on access to cancer therapies in the future. Therefore, ACCC asks that CMS not implement the proposal to package ancillary services under a $100 threshold.

VIII. CMS should implement the proposal for PPS-exempt cancer hospitals payments in the same manner as 2014.

Section 3138 of the Patient Protection and Affordable Care Act (ACA) required the Secretary of Health and Human Services to study whether the 11 PPS-exempt cancer hospitals incur greater outpatient costs than other hospitals. If the cancer hospitals' costs were determined to be greater than the costs of other hospitals paid under the OPPS, as CMS found in 2010, then the Secretary shall provide an appropriate adjustment to reflect these higher costs. Section 3138 also requires that this adjustment be budget neutral, and it was to have been effective for outpatient services provided at cancer hospitals on or after January 1, 2011. After the proposal received numerous comments last year, CMS tabled the change in payment, and then brought up

[19] 79 Fed. Reg. at 40950.
[20] Id. at 40960.

a revised proposal in the 2012 rule. The proposal was further refined after the comment period and finalized by providing additional payments to cancer hospitals so that the hospital's payment-to-cost ratio (PCR) with the payment adjustment is equal to the weighted average PCR for the other OPPS hospitals using the most recent submitted or settled cost report data.

For 2015, CMS is proposing to continue the adjustment to these hospitals in a manner similar to that in 2014.[21] ACCC agrees with this proposal and requests CMS to implement it. ACCC supports increasing the payments to these hospitals, but at the same time, we believe that the impact to all other hospitals should be as minimal as possible.

IX. CMS should work with ACCC and other stakeholders before developing any drug administration packaging proposals.

ACCC appreciates that CMS did not include a proposal to package drug administration in the 2015 proposal, as it had in the 2014 proposed rule. CMS says that it is "examining various alternative payment policies for drug administration services, including the associated drug administration add-on codes."[22] As we stated in comments last year, ACCC is greatly concerned about the packaging of chemotherapy administration. Given the complexity of many cancer regimens, we fear that a bundled payment may not accurately account for all of the services being offered during treatment. Therefore, ACCC requests that CMS work with us and other stakeholders before developing any drug administration packaging policies in the future.

X. CMS should work with ACCC and other organizations on the implementation of the "off-campus" modifier.

ACCC thanks CMS for considering the comments it received in 2013 regarding the best method for collecting information that would allow the agency to analyze the frequency, type, and payment for services furnished in off-campus provider-based hospital departments. Based on its review of these comments, CMS proposes to create a HCPCS modifier to be "reported with every code for physician and hospital services furnished in an off-campus provider-based department of a hospital."[23] ACCC believes this is a less administratively-burdensome method for capturing data from off-campus departments than other mechanisms CMS could use, but we have a number of concerns that we would like CMS to address in the final rule.

First, CMS's definition of "campus" is "the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office."[24] Given the variety of designs of hospital campuses, and the potential for case-by-case exceptions, hospitals may not be certain if a particular department is on campus or off-campus. For example, it may not be clear whether the physicians' office building is "immediately adjacent" to a cluster of "main buildings." We

[21] Id. at 40968.
[22] Id. at 40960.
[23] Id. at 41013.
[24] 42 C.F.R. § 413.65(a)(2).

urge CMS to provide clear guidance to help physicians identify whether their office is on-campus or off-campus.

Second, CMS says that it is seeking "a better understanding regarding the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments affects payments under PFS and beneficiary cost-sharing."[25] When a physician practice is acquired by a hospital, however, the provider number could change, making it difficult to track data for that practice before and after the acquisition. CMS should work with ACCC and other organizations to develop a mechanism that will collect the data needed to help CMS understand how these transactions affect Medicare payments and beneficiary cost sharing.

XI. Conclusion

ACCC encourages CMS to protect cancer patients' access to quality care in the most appropriate setting by providing appropriate reimbursement for cancer treatments under the OPPS. Toward this end, we urge CMS to pay ASP plus six percent for the acquisition cost of separately payable drugs. We also highly recommend that CMS implement our other comments in this letter. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact Matthew Farber at (301) 984-9496, 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,

Rebecca L. DeKay

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[25] 79 Fed. Reg. at 40333-34.