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Association of Community Cancer Centers

August 29, 2011

Donald Berwick, MD
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-1525-P: (Medicare and Medicaid Programs; Hospital Outpatient Prospective Payment)

Dear Administrator Berwick:

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 18, 2011 (the "Proposed Rule").[1]

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

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. Because advanced cancer

[1] 76 Fed. Reg. 42170 (July 18, 2011).

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 healthcare safety net. In some cases, HOPDs are the only sites available for Medicare and uninsured patients who need cancer care. HOPDs also are becoming the only option for Medicare beneficiaries who lack supplemental insurance. 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[2] and the services required to prepare and administer them are critical to ensuring patient access to care. Since the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Medicare payments for cancer drugs have been reduced significantly. Although we are encouraged to see that CMS has recognized the need to account for inflation in the reimbursement of drugs,[3] we remain concerned that the methodology to determine this rate remains flawed, and that the proposed payment rate of Average Sales Price (ASP) plus four percent may not be sufficient to cover the cost of drug acquisition and related pharmacy overhead services costs.

Over the past few years, ACCC and other stakeholders have presented CMS with data showing that the OPPS rates are inadequate and are based on a deeply flawed methodology. We greatly appreciate that CMS has continued to recognize the problems inherent in its rate-setting methodology, including the effects of charge compression, and that the agency has made significant adjustments to its methodology accordingly. However, we believe that CMS must make additional changes in order to achieve stable and appropriate payment rates for drugs and related pharmacy services.

It is imperative to continued patient access in this crucial setting that the OPPS rates in 2012 and beyond adequately reimburse hospitals for the costs of providing advanced cancer therapies. Toward this end, ACCC recommends that CMS:

- Reimburse hospitals for the acquisition cost of separately payable drugs at no less than ASP plus six percent;
- Reallocate a larger portion of pharmacy overhead costs from packaged drugs to separately payable drugs;

[2] We refer to drugs, biologicals, and radiopharmaceuticals collectively as "drugs" throughout our comments.
[3] 76 Fed. Reg. at 42260-61.

- Remove data for drugs purchased under the 340B program from the calculation of drug payment rates while continuing to reimburse all hospitals at the same rate;
- Make separate payment for all drugs with Healthcare Common Procedure Coding System (HCPCS) codes, or, at a minimum, not increase the packaging threshold for drugs;
- Reinstate separate payment for diagnostic radiopharmaceuticals and contrast agents;
- Not implement an "equitable adjustment" to cap payment for any outpatient procedures at the rates calculated under the inpatient prospective payment system (IPPS);
- Implement the proposed payment rates for low dose rate prostate brachytherapy;
- Continue to apply the current policy for establishing payment for new brachytherapy sources;
- Reinstate separate payment for radiation oncology guidance services and monitor access to these services;
- Implement the proposed new Ambulatory Payment Classification (APC) assignments for combined Computed Tomography (CT) of the abdomen and pelvis;
- Implement the proposal to allow the Advisory Panel on APC Groups (APC Panel) to make suggestions to CMS on the correct level of supervision for selected procedures;
- Implement the adjustment to payments for cancer hospitals exempt from the OPPS in a truly budget neutral manner; and
- Work with providers and specialty societies to determine which new measures to add to the quality reporting requirement.

Our comments on these issues and others are presented below.

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

A. Proposed payment for drugs and biologicals

We are concerned once again that CMS proposes to reimburse all separately paid drugs without pass-through status at ASP plus four percent.[4] ACCC has recommended for several years that CMS reimburse all separately paid drugs at no less than ASP plus six percent – the rate applicable in physicians' offices. Establishing reimbursement at this rate would protect access to care in the most clinically appropriate setting.

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

[4] Id. at 42262.

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.

In recent years, pharmacy service costs have increased due to the growing number of drugs subject to Risk Evaluation Mitigation Strategies (REMS) by the Food and Drug Administration (FDA). These heightened regulatory requirements increase pharmacists' work and require the drugs to be acquired only from specialty distributors, often at cost plus a handling fee that exceeds six percent of ASP. CMS's assumptions about the pharmacy overhead associated with separately payable drugs do not appear to account for these costs. In addition, because the number of drugs subject to REMS has increased in recent years, these costs are not reflected in the claims and cost report data used to calculate payment rates. It is critical that Medicare's reimbursement amounts reflect the current costs of providing care.

We are pleased that CMS continues to recognize that it is appropriate to redistribute pharmacy overhead costs from packaged drugs to separately payable drugs to avoid underpayment for separately payable drugs to achieve more equitable payment for all drugs under the OPPS. We are also pleased that CMS has recognized the rising costs due to inflation, and has introduced an inflation adjustment to the amount of overhead to transfer to separately paid drugs. We believe CMS has made steps toward establishing more appropriate payment for the acquisition and pharmacy overhead costs of drugs in the past, and we hope that CMS will continue to review this policy in order to achieve the most appropriate reimbursement possible.

Overall, however, ACCC believes the proposed methodology continues to include flaws that produce unstable estimates of drug costs and could lead to inadequate payment. We believe that CMS's methodology can be improved to produce more stable payment rates and better recognize the costs associated with providing drugs to hospital outpatients. Specifically, we offer the following recommendations to help ensure appropriate reimbursement for drugs administered in HOPDs:

1. **CMS should reimburse hospitals for the acquisition cost of separately payable drugs at no less than ASP plus six percent, as required by the statute.**

Once again, in the Proposed Rule, CMS proposes to reimburse separately payable drugs at ASP plus four percent.[5] CMS arrives at this proposed rate by using a slightly revised version of the methodology it used in 2010 and 2011. First, CMS calculates the estimated aggregate cost of separately paid and packaged drugs relative to ASP. This step produces estimated acquisition and pharmacy overhead cost for separately payable drugs of ASP minus two percent and ASP

[5] Id.

plus 188 percent for packaged drugs.[6] Second, CMS reallocates $215 million in overhead costs from packaged drugs to separately payable drugs.[7] CMS arrived at the $215 million figure by adjusting the $200 million redistribution amount used in 2010 and 2011 by the Producer Price Index (PPI) for Pharmaceuticals for Human Use.[8] As a result of CMS's proposed reallocation of overhead costs from packaged drugs to separately paid drugs, CMS proposes to reimburse separately paid drugs at ASP plus four percent. The agency also notes that CMS's experience has been that the use of updated ASP, claims, and cost report data produces payment rates that may be lower in the final rule than in the Proposed Rule.[9] Therefore the final payment rate under CMS's methodology could be less than ASP plus four percent.

As CMS explains the history of its payment rates for separately payable drugs in recent years in the Proposed Rule, it is hard not to notice that the CMS's methodology, even with recent refinements, has not produced stable reimbursement amounts for these therapies. Final payment rates have varied from ASP plus four percent to ASP plus six percent, and CMS's estimates of cost for separately payable drugs have ranged from ASP plus three percent to ASP minus two percent. These variations do not reflect changes in hospitals' actual costs, and they indicate that the core methodology is flawed. In addition, the methodology is very sensitive to changes in the underlying data and assumptions used, as illustrated by the reduction by at least one percentage point between past proposed and final rules, producing results that appear to be arbitrary. We disagree with CMS's belief that its methodology based on ASP data and hospital claims data is a "proxy for the sum of the average hospital acquisition cost that the statute requires for payment of [specified covered outpatient drugs] and the associated pharmacy overhead cost." A more appropriate and stable approach would be to set payment for acquisition and overhead costs of drugs at no less than ASP plus six percent.

ACCC has conducted an informal survey of our members and the results show that reduced reimbursement would lead to decreased access. Our survey found that nearly 80 percent of respondents report that ASP plus four percent would not be adequate to cover both drug acquisition cost and the pharmacy overhead. In addition, when asked if the member has had to make any changes to drug administration services in the past several years due to lowered drug reimbursement, 50 percent responded yes, with 88 percent of those responders reporting that they have limited their drug formulary. Finally, when asked what, if any, additional changes the member would make to its outpatient services if CMS finalized the proposal to reduce drug reimbursement to ASP plus four percent, 100 percent of those saying they would change their services reported that they will have to limit their formulary. Respondents feel that overall, these reductions will lead to patients experiencing the following: increased out of pocket costs (79 percent), reduced access to therapies (76 percent), and reduced access to injectable therapies (72 percent).

Payment for the acquisition and overhead costs of drugs at no less than ASP plus six percent will help to protect patients' access to care in the most clinically appropriate setting. It

[6] Id. at 42260.
[7] Id.
[8] Id. at 42261.
[9] Id.

also would create parity with the physician office setting. Moreover, this rate is consistent with the statute, which requires use of data on "average acquisition cost" or payment at the rates applicable in physicians' offices.[10] To provide for stable, appropriate payment, CMS should reimburse drugs provided under the OPPS at no less than ASP plus six percent.

2. CMS should reallocate a larger portion of the pharmacy overhead costs associated with packaged drugs to the separately payable drugs.

Over the past few years, CMS has established two parameters for redistribution of overhead costs. First, CMS believes that one-third to one-half of the overhead cost associated with coded packaged drugs is the appropriate amount for redistribution. Second, CMS estimates that at least eight percent of the total cost of uncoded packaged drugs is overhead cost inappropriately associated with those drugs. Although we appreciate CMS's flexibility within these parameters, we continue to believe that CMS significantly underestimates the amount of overhead associated with packaged drugs.

In particular, although CMS concludes that about 35 percent of the overhead associated with coded packaged drugs – or about 23 percent of the total cost of those drugs – is an appropriate amount to reallocate, CMS proposes to reallocate only 11 percent of the total cost of uncoded packaged drugs.

Comparison of Proposed Reallocated Overhead Amounts as a Share of Total Costs

	Total Cost	**Reallocated Overhead**	**Reallocated Overhead/ Total Cost**
Uncoded packaged drugs	$502 million	$54 million	11%
Coded packaged drugs	$705 million	$161 million	23%

This approach incorrectly assumes that overhead is a smaller share of total costs of uncoded packaged drugs than of the coded drugs. In reality, hospital pharmacies' overhead is spread across all drugs and the amount of overhead, as a proportion of the drug's cost, allocated to each drug varies with cost for all drugs. Therefore, the same assumptions should be applied to uncoded drugs as to coded drugs and CMS should reallocate a similar proportion of costs from the uncoded drugs as from the coded packaged drugs.

Indeed, the proportion of overhead associated with uncoded drugs appears to have increased compared to the coded drugs due to CMS's proposed increase in the packaging threshold from $70 to $80 and packaging of contrast agents and diagnostic radiopharmaceuticals regardless of cost. As a result of these policies, the pool of coded packaged drugs includes many higher cost products that have less overhead included in their charges. In fact, as the packaging threshold has increased, the share of total costs of coded packaged drugs attributed to overhead declined. In 2010, when the packaging threshold was $65, overhead accounted for 72 percent of the total cost of coded packaged drugs. In 2011, the packaging threshold was increased to $70

[10] Social Security Act (SSA) § 1833(t)(14)(A)(iii)(I).

and overhead accounted for 75 percent of the total cost of coded packaged drugs. In the Proposed Rule, CMS proposes to increase the packaging threshold to $80 and overhead accounts for only 65 percent of the total cost of coded packaged drugs.

CMS's Estimated ASP Dollars, Total Cost, and Overhead for Coded Packaged Drugs (in millions)

Year	ASP Dollars	Overhead	Total Cost	Overhead/ Total Cost
2010	$172	$444	$616	.72
2011	$155	$457	$612	.75
2012	$244	$461	$705	.65

In each of these years, CMS's estimated overhead for all coded drugs has remained within a narrow range of 10 to 13 percent, and the estimated overhead for separately payable drugs has been negative. Because overhead represents a smaller share of the total cost of coded packaged drugs, while the overhead associated with all drugs has not declined, it appears that the proportion of overhead associated with uncoded drugs has increased.

Applying the reasonable assumption that packaged drugs not billed with HCPCS or without ASPs have the same ratio of acquisition cost to overhead cost as drugs with HCPCS codes and ASPs, produces a substantial, additional overhead pool. It is clear that CMS's proposed reallocation of $54 million significantly underestimates the overhead associated with uncoded packaged drugs. CMS should transfer a similar share of overhead from uncoded drugs and coded drugs. We urge CMS to reallocate a larger share of overhead costs from uncoded packaged drugs to separately payable drugs in the final rule.

ACCC also understands that CMS's ability to calculate more accurate payments in future years will depend on the quality of data available. Under current billing guidance, hospitals may have used different, but permissible, approaches to reporting packaged drugs. These practices have resulted in CMS not collecting complete and detailed data on the costs of all packaged drugs. We appreciate CMS's continued encouragement for hospitals to "bill all drugs and biologicals with HCPCS codes, regardless of whether they are separately payable or packaged," and believe the agency should continue to urge hospitals to bill all drugs with HCPCS codes under revenue code 0636. ACCC has urged its members to follow this recommendation, but we also believe that CMS should now *require* hospitals to bill all drugs with HCPCS codes under revenue code 0636.

3. CMS should remove data for drugs purchased under the 340b program from the calculation of drug payment rates, while continuing to reimburse all hospitals at the same rate.

ACCC also requests that CMS remove data from hospitals that participate in the 340B program from its rate-setting methodology for drugs. The APC Panel has recommended in the past that these data should not be included in the calculation of drug reimbursement rates under

the OPPS because sales under the 340B program are excluded from the calculation of ASP. To include data from 340B hospitals, as CMS currently does, unfairly penalizes non-340B hospitals by artificially lowering drug reimbursement rates. Removing these data would help to establish more appropriate reimbursement rates. An analysis by The Moran Company found that if CMS excluded data from 340B hospitals from its calculations for calendar year 2012, the estimated aggregate cost for separately payable drugs would increase from ASP minus two percent to ASP plus 3 percent, before any reallocation of overhead. This effect could be even greater in future years as the 340B program continues to grow. Given this, along with the other flaws in CMS's methodology for setting payment rates for drugs, ACCC believes that CMS's calculations do not accurately reflect hospitals' drug acquisition and pharmacy overhead costs. CMS should take a significant step toward more accurate reimbursement rates by removing data from 340B hospitals from its drug payment calculations.

ACCC does not believe that there should be two separate reimbursement rates – one for 340B hospitals and one for non-340B hospitals. We believe that all hospitals should be paid the same. Reducing reimbursement to 340B hospitals would be inconsistent with the clear intent of Congress and the Health Resources and Services Administration (HRSA) for participating hospitals to use savings on drug costs to expand care for their patients. It also would be unfair to those patients who might see reductions in services available from these safety net hospitals if reimbursement is reduced. Therefore, we ask CMS to remove the 340B drug data from the calculation of drug payment rates, while continuing to reimburse both types of hospitals at the same rate.

4. CMS should make separate payment for all drugs with HCPCS codes, or, at a minimum, not increase the packaging threshold for drugs.

For 2012, CMS proposes to increase the packaging threshold to $80 and to continue to package payment for all diagnostic radiopharmaceuticals and contrast agents.[11] We are concerned that continued use of any threshold and the implementation of expanded packaging could harm hospitals' ability to provide essential cancer care. Even if CMS implements our other recommendations to establish appropriate payment for acquisition and pharmacy overhead costs, we remain concerned that packaging may discourage hospitals from providing appropriate care.

As in previous years, we continue to be troubled by CMS's policy of packaging payment for contrast agents and diagnostic radiopharmaceuticals. CMS explains that it believes these drugs function as supplies and are not subject to the statutory payment requirements for specified covered outpatient drugs. 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. For these reasons, we recommend that CMS make separate payment for all 5-HT3 anti-emetics, contrast agents, diagnostic radiopharmaceuticals, and all other drugs

[11] Id. at 42252.

with HCPCS codes. At a minimum, CMS should maintain the packaging threshold at no more than the current level of $70.

B. 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.[12] Although we understand that CMS has increased payments for many diagnostic and imaging services as a result of its expanded packaging policies, we are concerned that the increase might not be sufficient to protect beneficiary access to important cancer therapies and diagnostic services. Radiopharmaceuticals are extremely complex therapies to prepare and administer. Preparation and administration of each drug requires a unique bundle 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.

II. CMS should not implement an "equitable adjustment" to cap payment for any outpatient procedures at the rates calculated under the IPPS.

For the first time, CMS proposes to use its authority under section 1833(t)(2)(E) of the Social Security Act, which allows CMS to make "adjustments as determined to be necessary to ensure equitable payments," to cap payment for procedures under the OPPS at the rate calculated for a Medicare Severity-Diagnosis Related Group (MS-DRG) for similar procedures under the IPPS. Specifically, CMS proposes to limit payment for APCs 0108 (Insertion/Replacement/Repair of Cardioverter Defibrillator Leads) and 8009 (Cardiac Resynchronization Therapy with Defibrillator Composite) to the rates calculated for MS-DRGs 227.[13] CMS would set aside the rates calculated using its standard OPPS methodology and OPPS claims data for rates calculated using different data under a different payment system. CMS does not identify any problems with the data or the standard methodology, however, noting only that the payment rate calculated under the OPPS is slightly higher than the rate under the IPPS. CMS proposes to reduce the payment to HOPDs to ensure that Medicare does "not create an inappropriate payment incentive" to provide these services in the outpatient setting.[14] We believe this proposal is misguided, would set a harmful precedent, and should not be implemented.

As we explained in section I, above, we generally support payment equity across settings of care when appropriate and indeed encourage CMS to use the statutory payment mechanism to ensure that payments for drugs are equitable across the physician office and HOPD settings of

[12] Id. at 42255.
[13] Id. at 42205, 42241.
[14] Id. at 42205.

care.[15] We do not, however, support the proposal to set aside the rates calculated under the OPPS methodology in favor of lower IPPS payment rates when neither CMS nor stakeholders have identified any errors in the OPPS data or methodology. CMS's proposal would not achieve the goals of protecting access and providing predictable reimbursement. To the contrary, this proposal would create uncertainty about payment rates that ultimately will discourage hospitals from offering care in the most clinically appropriate setting. It also fails to protect against unpredictable changes in reimbursement that inhibit innovation and investments in improved care. We urge CMS to not implement the proposed reduction of payments under the OPPS to the rates calculated under the IPPS.

III. CMS should implement the proposed payment rates for low dose rate (LDR) prostate brachytherapy.

For 2012, CMS proposes to increase the proposed payment for composite APC 8001 for LDR prostate brachytherapy due to increased median costs for the procedure.[16] Brachytherapy is an important treatment option for prostate cancer, and ACCC appreciates CMS's work to ensure that payment for this composite APC reflects hospitals' costs. We ask CMS to implement the proposed payment increase for this composite APC.

IV. CMS should continue to apply its current policy for establishing payment for new brachytherapy sources.

CMS proposes to continue the policy it implemented for 2010 regarding payment for new brachytherapy sources for which the agency has no claims data.[17] Under this policy, CMS assigns new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on CMS's consideration of "external data and other relevant information regarding the expected costs of the sources to hospitals."[18] ACCC supports CMS's efforts to establish appropriate payment rates for new brachytherapy sources in a timely manner, and CMS should finalize this proposal.

V. CMS should reinstate separate payment for radiation oncology guidance services and monitor access to these services.

ACCC recognizes CMS's desire to continue to expand bundling and packaging in the OPPS. We remain concerned, however, that CMS's continued expansion of packaging, including packaging of guidance services, may negatively affect patients and hospitals. In the proposed rule for 2011, CMS presented the results of its analysis of billing for radiation oncology guidance services in 2007, before expanded packaging, and in 2009, after expanded packaging. CMS reported increases in the number of intensity modulated radiation therapy (IMRT), stereotactic radiosurgery (SRS), and brachytherapy services billed and total payments for those procedures, but found a 20 percent reduction in the frequency of billing for

[15] SSA § 1833(t)(14)(A)(iii)(I).
[16] 76 Fed. Reg. at 42199.
[17] Id. at 42197.
[18] Id.

conventional radiation therapy services and a 10 percent reduction in total payment for those services.[19] We urge CMS to continue to monitor use of and payment for these services and share these reports with stakeholders, so we can verify that Medicare's payment policies do not harm access to care. ACCC urges CMS to reinstate separate payment for radiation oncology guidance procedures. These services are vital to the safe provision of radiation therapy, and unconditionally packaging payment for them may discourage hospitals from providing them.

VI. CMS should implement the proposed new APC assignments for combined CT of the abdomen and pelvis.

For 2011, new CPT codes were created for combined CT of the abdomen and pelvis. CMS made interim APC assignments for these codes for 2010, but after reviewing historic claims data for the predecessor codes, CMS now proposes to create new APCs and revised composite APC assignments for these codes.[20] CMS proposes to assign CPT code 74176 to new APC 0331 (Combined Abdominal and Pelvis CT Without Contrast) and to assign CPT codes 74177 and 74178 to new APC 0334 (Combined Abdominal and Pelvis CT With Contrast).[21] As a result of these new assignments, payment for these services would increase in 2012. CMS also is proposing to assign CPT code 74176 to imaging composite APC 8005 (CT and CTA Without Contrast) when it is reported with codes that describe CT services for other regions of the body other than the abdomen and pelvis in which contrast is not used.[22] CPT codes 74177 and 74178 would be assigned to APC 8006 (CT and CTA With Contrast) when they are reported with CT codes for other regions of the body with contrast. ACCC agrees with the assignment of these codes and urges CMS to implement these proposals.

VII. CMS should implement the proposal to allow the APC Panel to make suggestions to CMS on the correct level of supervision for selected procedures.

ACCC appreciates CMS' willingness to work with providers and the APC Panel in order to determine the proper supervision levels for certain treatments within the HOPD. ACCC recognizes how difficult it can be to determine different levels of supervision, and we feel that having the input of experts such as the APC Panel members, as well as the opportunity for public testimony and comment, will make it easier for CMS to determine appropriate levels. We support the proposal to use the APC Panel, with some modifications to its scope and composition, as the independent review entity for supervision levels.[23] We agree that it is essential that the Panel include members with relevant expertise about the services under review, and we urge CMS to continue to accept nominations for Panel members from stakeholders.

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[19] 75 Fed. Reg. 46170, 46222 (Aug. 3, 2010).
[20] 76 Fed. Reg. at 42235.
[21] Id.
[22] Id. at 42236.
[23] Id. at 42282.

VIII. CMS should implement the adjustment to payments to PPS-exempt cancer hospitals in a truly budget neutral manner.

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 are 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 has brought up a revised proposal in the 2012 rule.

In the Proposed Rule, CMS discusses last year's study and an update for 2011 and the findings that the PPS-exempt cancer hospitals have higher costs than other hospitals. CMS estimates that on average, the OPPS payments to the 11 cancer hospitals, not including transitional outpatient payments (TOPs, or hold harmless payments), are approximately 65 percent of reasonable cost (a payment-to-cost ratio (PCR) of 0.647) compared to average OPPS payments to other hospitals of approximately 90 percent of reasonable cost (PCR of 0.901).[24] Individual cancer hospitals' OPPS PCRs range from approximately 56 percent to approximately 82 percent.[25] CMS concludes that the cancer hospitals are more costly than other hospitals paid under the OPPS and that an adjustment is warranted. CMS again proposes to make hospital-specific adjustments ranging from 10.1 percent to 61.8 percent, with an aggregate adjustment of 38.8 percent, before application of the TOPs, or a net impact of 9 percent.[26] This adjustment would be offset by a 0.6 percent reduction in payments to all other hospitals.[27]

ACCC appreciates CMS's efforts to compare the costs of the 11 PPS-exempt cancer hospitals to other hospitals and make the adjustment required by the ACA. We are concerned, as we were in last year's comments, however, that the proposed adjustment is not budget neutral, as required by the ACA. Currently, the TOPs for PPS-exempt cancer hospitals are approximately $158 million.[28] CMS estimates that none of the 11 cancer hospitals would continue to receive TOPs if the agency finalizes its proposal to calculate the cancer hospital adjustment without considering the current effect of the TOPs.[29] When Congress required the cancer hospital adjustment to be budget neutral, it did not intend for CMS to reduce spending by nearly $158 million. This interpretation is supported by the Congressional Budget Office analysis of section 3138 of the ACA as having no effect on spending.[30] To be consistent with Congressional intent and to ensure appropriate payment to PPS-exempt cancer hospitals with minimal effect on other

[24] Id. at 42219.
[25] Id. at 42220.
[26] Id. at 42221, 42376
[27] Id. at 42376.
[28] 2012 OPPS NPRM Cancer Adjustment Analysis File, http://www.cms.gov/HospitalOutpatientPPS/Downloads/CMS-1525-P_OPPS_NPRM_cancer_adjustment_file.zip.
[29] 76 Fed. Reg. at 42221.
[30] CBO, Cost estimate for H.R. 3590, the Patient Protection and Affordable Care Act, as passed by the Senate on December 24, 2009, March 11, 2009, at 19, http://cbo.gov/ftpdocs/113xx/doc11307/Reid_Letter_HR3590.pdf.

hospitals, we recommend that CMS calculate the adjustment by including the TOPs for PPS-exempt cancer hospitals. This would require a smaller additional payment to PPS-exempt cancer hospitals and a significantly smaller offset for other hospitals and would be budget neutral.

Hospitals across the country are facing difficult financial circumstances in these trying economic times. Decreasing the 0.6 percent payment reduction will help us maintain the high quality care that our patients deserve.

IX. CMS should work with providers and specialty societies to determine which new measures to add to the quality reporting requirement.

ACCC supports the proposal to retain the existing Hospital Outpatient Quality Reporting (OQR) Program measures for the CY 2012, 2013, and 2014 payment determinations.[31] ACCC suggests that CMS continue to work with the oncology specialty societies, providers, and other quality societies in determining the best measures to add to the program. Oncology measures can be vital in determining the true quality of care, and ACCC supports their inclusion in this initiative.

X. 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 at least ASP plus six percent for the acquisition cost of separately payable drugs and to make an appropriate adjustment for pharmacy overhead. In addition, we urge the agency to implement the adjustment to payments to PPS-exempt cancer hospitals in a truly budget neutral manner that will reduce the payment reduction to other hospitals as much as possible. ACCC appreciates the opportunity to offer these comments. 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,

Thomas Whittaker, MD, FACP
President
Association of Community Cancer Centers (ACCC)

[31] 76 Fed. Reg. at 42315.