The premier education and advocacy organization for the oncology team

ACCC
Association of Community Cancer Centers

September 14, 2007

Kerry Weems, 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

RE: CMS-1392-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates)

Dear Acting Administrator Weems:

On behalf of the Association of Community Cancer Centers (ACCC), I 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 August 2, 2007 (the "Proposed Rule").[1] We also thank CMS for meeting with us on September 10, 2007, and look forward to working with the agency in the future on important issues such as those raised by the Proposed Rule.

ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 650 member institutions and organizations treat 45 percent of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60 percent of all U.S. cancer patients.

[1] 72 Fed. Reg. 42627 (August 2, 2007).

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 are a crucial part of the cancer care delivery system, providing a significant portion of this country's cancer care. 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. 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. In addition, some patients require care in an outpatient department because they have numerous complications or histories of infusion reactions. Finally, hospital outpatient departments play an important role in the early adoption of new technologies and frequently serve patients who have recently completed participation in clinical trials.

Our members also play an important role in the health care safety net. In some cases, hospital outpatient departments are the only sites available for Medicare and uninsured patients who need cancer care. Hospital outpatient departments also increasingly 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. Continuing this alarming trend, CMS proposes to reduce payment for many separately paid drugs to average sales price (ASP) plus five percent in 2008. We strongly disagree with CMS' conclusion that these rates will be adequate to reimburse hospitals for both the costs of acquiring and preparing drugs for administration, and we urge the agency to address serious flaws in its calculations. It should be noted that this proposal was in place in last year's OPPS proposed rule, only to be criticized by a majority of stakeholders, and the Ambulatory Payment Classification (APC) Panel, all of which recommended the level to remain at at least ASP+6 percent. For CMS to once again make this proposal seems to discount all of the advice and recommendations CMS received last year from these esteemed stakeholders. At its September 2007 meeting, the

[2] We refer to drugs, biologicals, and radiopharmaceuticals collectively as "drugs" throughout our comments.

APC Panel again recommended that payment remain at ASP plus six percent. We urge CMS to heed this advice for 2008.

It is imperative to continued patient access in this crucial setting that the OPPS rates in 2008 adequately reimburse hospitals for the costs of providing advanced cancer therapies. Toward this end, ACCC recommends that CMS:

- Recalculate its payment rates for separately paid drugs by including charges for all drugs with Healthcare Common Procedure Coding System (HCPCS) codes and adjust for charge compression, and, in any event, set rates at no less than ASP plus six percent;
- Not instruct hospitals to report charges for pharmacy service on an uncoded revenue code line and continue to work with stakeholders to develop a simplified plan to properly reimburse for pharmacy overhead services, such as the three phased plan devised by the pharmacy stakeholder group or a similar alternative;
- Pay separately for all drugs with HCPCS codes, thus eliminating the packaging threshold for drugs;
- Continue to pay separately for all anti-emetics;
- Continue to use the current methodology for setting payments for all radiopharmaceuticals, but if CMS decides to implement packaging for diagnostic radiopharmaceuticals, we urge the agency to follow the APC Panel's recommendation to continue to use the current methodology for all therapeutic and diagnostic radiopharmaceuticals with per-day costs over $200;
- Continue to make separate payment for contrast agents;
- Implement the proposed increases to the drug administration APCs;
- Implement the APC Panel's March 2007 recommendation to make separate payment for concurrent infusions;
- Continue to make payment at the current rate for the pre-administration services associated with providing intravenous immune globulin (IVIG) and consider making an additional payment to protect access to this therapy;
- Continue to assign concurrent PET/CT scans to a New Technology APC for at least one more year to ensure appropriate reimbursement while CMS collects data on the cost of these procedures;
- Continue to pay separately for brachytherapy sources;
- Ensure that the increased packaging of services, especially ancillary services, will not reduce access to those services and related procedures, and in particular, exclude image guidance procedures related to radiation oncology from any expanded packaging; and
- Propose national guidelines for Evaluation and Management (E&M) coding for outpatient visits and provide six to twelve months notice before implementation.

These issues and others are described below.

I. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals [OPPS: Specified Covered Outpatient Drugs]

A. Payment for Drugs and Biologicals

1. CMS' proposed rates are not adequate to reimburse hospitals for their pharmacy acquisition and service costs

ACCC once again is disturbed by CMS' proposal to reimburse separately paid drugs without pass-through status at 105 percent of ASP.[3] CMS claims that these rates will be sufficient to cover hospitals' acquisition costs as well as pharmacy handling costs. A survey of our members conducted last year at this time, when a similar proposal was made by CMS, indicates that this may not be true. A majority of the respondents to the survey said that they would be underwater at the proposed rates of reimbursement for the costs of providing five commonly used oncology and supportive care drugs. As we discussed during our September 10, 2007 meeting, we plan to supplement these comments with the results of this year's survey when they are available.

One member hospital reported this year that Medicare's current payments at ASP plus six percent are less than acquisition cost for 93 out of 157 separately payable drugs on its formulary. In other words, Medicare payment is insufficient to cover the cost of purchasing the drug, much less the costs of preparing it for administration, for 59 percent of the separately payable drugs on that hospital's formulary. This situation only will worsen if reimbursement is lowered to ASP plus five percent.

We believe that CMS' methodology for determining payment rates for separately payable drugs and their handling costs is deeply flawed. Not only does the methodology fail to recognize that hospitals' charges might not include their substantial pharmacy handling costs, but, to the extent that those costs are included in hospitals' charges,[4] it also fails to capture them accurately. This result is due to two errors in CMS' methodology. First, CMS applies a constant cost-to-charge ratio (CCR) to pharmacy charges, although hospitals do not apply a constant markup to their charges. Contrary to CMS' expectations, hospitals tend to apply larger markups to charges for lower cost items than to higher cost items. A hospital might charge $10 for a drug with an acquisition cost of $2, a mark up of 400

[3] 72 Fed. Reg. at 42731.

[4] We note that although hospitals' aggregate charges for all drugs, including inpatient drugs and drugs that are packaged under the OPPS, may include handling costs, a hospital's charge for an individual drug is not likely to include the overhead attributable to that particular drug.

percent, while it would charge $2200 for a drug that costs $2000, a mark up of 10 percent. If CMS applies a single CCR to both drugs, it would overestimate the cost of the $2 drug and underestimate the cost of the $2000 drug. This effect is known as "charge compression." The payment rates based on these estimates could exceed the cost of the lower cost drug but would be below the cost of the higher cost drug.[5] The Government Accountability Office (GAO) found that this methodology "does not recognize hospitals' variability in setting charges, and, therefore, the costs of services used to set payment rates may be under or overestimated."[6]

The study CMS commissioned from RTI International also confirms that charge compression can produce inaccurate estimates of drug costs. This study of the effects of charge compression in calculating diagnosis-related group (DRG) relative weights found evidence of charge compression in the pricing for IV solutions when compared to therapeutic drugs.[7] The study found that drug costs could be calculated more accurately by disaggregating the CCRs for drugs and applying a smaller CCR to IV solutions than to other drugs charged to the patient.[8] CMS acknowledges that this study has "obvious importance" for the OPPS, as well as for the inpatient PPS.[9] CMS proposes to develop a model for analyzing future adjustments to the OPPS,[10] but CMS does not propose to make any adjustments for charge compression in its calculations of the payment rates for drugs in 2008.

A preliminary analysis of CMS' claims data indicates that, without any adjustments for charge compression, CMS' methodology for calculating payment rates for drugs produces inconsistent and unpredictable results. Application of a constant CCR to charges for drugs produces widely varying estimates of drugs' mean unit costs. As a percentage of ASP, these costs ranged from ASP minus 98 percent to ASP plus 715 percent. We believe that a methodology that produces such disparate estimates of costs cannot be relied upon to set accurate payment rates.

Second, in addition to failing to recognize the effects of charge compression, CMS appears to use claims data for only separately paid drugs in its comparison of the estimated total costs for drugs to ASP. CMS assumes that comparing the estimated costs, calculated from claims data, to ASP will capture the overhead costs associated with separately payable drugs. Because hospitals do not markup charges for drugs uniformly, however, a disproportionate share of overhead

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5 M.J. Braid, K.F. Forbes, and D.W. Moran, Pharmaceutical Charge Compression under the Medicare Outpatient Prospective Payment System, Journal of Health Care Finance, Spring 2004, p. 21-33.

6 GAO, Medicare: Information Needed to Assess Adequacy of Rate-Setting Methdology for Payments for Hospital Outpatient Services, GAO-04-772, September 2004, at 16.

7 Kathleen Dalton, A Study of Charge Compression in Calculating DRG Relative Weights, January 2007, at 10, http://www.cms.hhs.gov/reports/downloads/Dalton.pdf.

8 Id. at 11.

9 72 Fed. Reg. at 42642.

10 Id.

tends to be associated with the charges for lower cost drugs. Many of these lower cost drugs have HCPCS codes and ASPs, but are packaged into payment for other services under the OPPS, and others do not have codes or ASPs but are included in hospitals' pharmacy charges. Leaving the lower cost drugs out of the analysis means that a large portion of hospitals' handling costs are not reflected in the estimated costs. If the packaged drugs with HCPCS codes are included in CMS' calculations, the mean unit cost for all drugs with ASPs, on average, would be equal to ASP plus nine percent. If the lower cost drugs without codes and ASPs were included, the mean unit cost likely would be even higher.

We urge CMS to recalculate payment rates, including an adjustment for charge compression, using charges for all drugs with HCPCS codes, to ensure that all pharmacy costs are included in CMS' payment rates for drug acquisition and pharmacy service costs. If CMS cannot make an adjustment for charge compression for the 2008 final rule, CMS should continue to reimburse separately paid drugs at no less than ASP plus six percent, the rate applicable in physicians' offices, as recommended by the APC Panel at its September 2007 meeting.

2. CMS should not require hospitals to report charges for pharmacy service and overhead costs on an uncoded revenue code line and should adopt the APC Panel's recommendation to implement a simplified system for capturing pharmacy costs.

We especially are concerned that CMS again proposes to make no additional payments for pharmacy handling costs, even though the APC Panel in March 2007 and a group of stakeholders in the pharmacy community recommended specific approaches to making these payments. As we explained in our testimony to the APC Panel in 2007 and in subsequent meetings with CMS, the advanced drugs we use to help our patients fight cancer require careful handling by specially trained personnel. These costs include the services needed 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 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. These costs also include supplies, equipment, and facilities used in

preparing drugs. In recent years, these costs have increased substantially as many hospitals renovate their facilities to comply with the new sterile compounding standards of the United States Pharmacopeia Chapter 797. The remaining pharmacy service costs include contract negotiations, building and information systems maintenance and upgrades, transportation of drugs within the hospital, and disposal of unused products (that typically involve the housekeeping department) to comply with Environmental Protection Agency (EPA) and National Institute for Occupational Safety and Health (NIOSH) regulations.

When it enacted the MMA, Congress recognized that an acquisition cost-based reimbursement methodology might not account for these pharmacy service costs. The MMA allows the Secretary to adjust OPPS rates to reflect these costs, based on the results of a Medicare Payment Advisory Commission (MedPAC) study of pharmacy service and handling costs. MedPAC's report, released in June 2005, concluded that these costs are significant and that an adjustment is warranted. MedPAC cited studies that found pharmacy service overhead costs to make up 26 to 33 percent of pharmacy departments' direct costs, with the rest of the costs attributed to the acquisition cost of drugs.[11] Most of the overhead costs reflect ancillary supplies (gowns, booties, masks) and salaries and benefits of pharmacists and technicians. MedPAC also noted that hospitals do not have precise information about the magnitude of their pharmacy expenses,[12] and therefore are not likely to have included all of these costs into their charges for drugs. If CMS used the MedPAC report's lower estimate of overhead costs – 26 percent of direct costs – to adjust payments for drugs, it would result in a payment rate of ASP plus 39 percent, assuming that ASP is equal to acquisition cost for all hospitals.

Other studies have reported similarly large estimates of hospital's pharmacy service costs. A study commissioned by the National Patient Advocate Foundation found that the average cost per dose of chemotherapy administration, including all of the costs listed above, is $36.03, in addition to the acquisition cost of the drug.[13] Realizing that these are large numbers that may be difficult for CMS to implement, the stakeholder community developed a three-phase plan to properly reimburse for pharmacy services at a lower cost to CMS.

The pharmacy proposal has three phases. In phase one, a flat add-on payment that would be added automatically when a drug is billed. Every drug would be assigned to one of three categories – low, medium, or high – depending on how much time and effort is required to prepare the drug. Our calculations put the add-on payment at about 17 percent of total Medicare hospital outpatient pharmacy

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[11] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

[12] Id.

[13] Gary Oderda, Documentation of Pharmacy Cost in the Preparation of Chemotherapy Infusions in Academic and Community-Based Oncology Practices, http://www.npaf.org/pdf/gap/utah.pdf.

cost reimbursement; well below the 26-33 percent called for in the MedPAC study. In the phase two, CMS would conduct a survey to determine if the add-on payments were sufficient. In phase three, CMS would establish payments for pharmacy services and overhead costs based on claims data, using the same methodology as is used for other services under the OPPS.

The proposal also could be implemented in two phases, without the need for additional surveys. The first phase would be the same, but in phase two, hospitals would be required to report charges and costs for pharmacy services and overhead to receive additional payments. As in the plan described above, all drugs would be assigned to one of three categories, and hospitals would report costs and charges for those three categories. This plan could be implemented relatively easily by hospitals and by CMS. We expect that hospitals would need at least one year to adjust their chargemasters and billing systems. Hospitals also would need guidance from CMS on how to set charges, including identification of the items and services to be included, and on how to process crossover claims and comply with uniform charge requirements. This proposal likely would comply with the uniform charge requirements as long as the total charges to Medicare for the drug and pharmacy services equal the charge to other payers for the drug and pharmacy services combined. We ask CMS to implement this proposal and issue clear guidance on these issues.

We believe this proposal is consistent with CMS' long term vision of increasing the use of bundled and packaged payments in the OPPS. Under this plan, the add-on payment would be bundled with payment for drug acquisition costs. Over time, CMS would be able to collect high quality data for use in setting payment rates for both drug acquisition costs and pharmacy services and overhead costs.

In contrast, the CMS' proposal to report pharmacy service costs on an uncoded revenue code line would impose substantial burdens on hospitals without collecting useful data for CMS. Instead of combining payment for drug acquisition and pharmacy services, it would require hospitals to remove the pharmacy services costs from the costs of the drugs and report them separately, effectively unpackaging these services from drug payments. CMS would not make any additional payment for reporting this data, although hospitals would face significant costs and administrative burdens in reporting it. To implement this instruction, hospitals would have to conduct expensive time and motion studies to set charges for hundreds of drugs. Hospitals would need to complete these studies and make extensive changes to their chargemasters before January 1, 2008. This proposal would be extremely difficult and costly for hospitals to implement, yet it would not produce useful data for CMS. CMS proposes to allow hospitals to decide whether to report a charge per drug or per episode of drug administration

services.[14] As a result, the data provided to CMS would not reflect the costs associated with particular drugs and would be inappropriate to use for packaging payment for these services into payment for other procedures. We ask that CMS once again review the stakeholder community proposal and see that it fits more in line with the vision of bundling in the future of OPPS than their current proposal does.

3. Pay separately for all drugs with HCPCS codes and eliminate the packaging threshold [OPPS: Packaging Drugs and Biologicals]

CMS proposes to increase the packaging threshold to $60 per day.[15] ACCC is concerned that increasing the packaging threshold would harm beneficiary access to appropriate care. We believe that separate payment for all drugs helps to encourage hospitals to select therapies to offer based on clinical characteristics, not reimbursement rates. Additionally, unpackaging these drugs would help to improve the overall accuracy of the OPPS by encouraging hospitals to code more accurately for drugs. Although we recognize this is inconsistent with the agency's desire to increase packaging across the board, we believe paying separately for HCPCS-coded drugs would help ensure appropriate reimbursement to hospitals while the agency is working on more permanent fixes for charge compression and adequate payment for pharmacy services and overhead.

Paying separately for all drugs with HCPCS also would eliminate disparities between the hospital outpatient and physician office settings and would not provide financial incentives to use more costly separately paid drugs even when a bundled drug may be more clinically appropriate. Most of our hospitals currently code for bundled drugs, so billing for them separately would not create a substantial additional administrative burden.

ACCC commends CMS' proposal to continue to pay separately for anti-emetics.[16] We agree that separate payment for anti-emetics will help ensure that Medicare's payment rules "do not impede a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician."[17] We believe the same policy should apply to all drugs, and we recommend that CMS eliminate the packaging threshold accordingly.

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14 72 Fed. Reg. at 42735.
15 Id. at 42732.
16 Id. at 42733.
17 71 Fed Reg. at 49583.

B. Payment for Radiopharmaceuticals [OPPS: Payment for Therapeutic Radiopharmaceuticals; OPPS: Payment for Diagnostic Radiopharmaceuticals]

ACCC also is concerned that CMS' proposed prospective payment rates for radiopharmaceuticals will be inadequate to protect beneficiary access to important cancer therapies. Radiopharmaceuticals are extremely complex therapies to prepare and administer. Preparation and administration of each drug requires a unique collection of services, such as compounding, dosimetic and therapeutic infusions, and scanning of the patient to assess biodistribution of the therapy. The costs of these services vary for each therapy, and many of these costs are not reimbursed under the OPPS.

CMS proposes to establish rates for therapeutic radiopharmaceuticals based on the mean costs derived from 2006 claims data, using CMS' standard methodology.[18] This is a change from the current method of paying based on a hospital's charges reduced to cost using the hospital's overall CCR, but is virtually identical to the proposal CMS decided not to implement for 2007.[19]

Similar to CMS' calculations of unit costs for drugs, its proposed methodology for setting payments for radiopharmaceuticals is flawed because it fails to adjust for charge compression and relies on incomplete data. CMS first instructed hospitals to include acquisition, preparation, and handling costs in their charges for radiopharmaceuticals in the final rule for 2006,[20] but it is likely that many hospitals were not able to implement this instruction until 2007. Therefore, CMS has not collected two full years of data for use in ratesetting.

CMS' descriptions of its calculations also indicate that the data or the CCRs, or both, are flawed. CMS notes that median costs for some radiopharmaceuticals did not increase when CMS calculated median costs from the 2006 data.[21] This suggests that the data do not include all costs associated with providing these therapies, because if those costs were included, the median costs for all radiopharmaceuticals should have increased. If the data do include preparation and handling costs and CMS used an appropriate CCR, the proposed rates for 2008 should be higher than the rates proposed in 2007. However, the similarity between the proposed rates for 2008 and the proposed rates for 2007 calculated using claims data from 2005 – before hospitals were instructed to include preparation and handling costs – indicates that, if the preparation and handling costs were included, CMS applied an incorrect CCR to these therapies. We ask CMS not to change its

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18 72 Fed. Reg. at 42738.
19 Id.
20 70 Fed. Reg. at 68653.
21 72 Fed. Reg. at 42739.

methodology for calculating payment for radiopharmaceuticals until it has accurate data on acquisition, preparation, and handling costs for these therapies and appropriate CCRs to use in determining costs from charges.

CMS also proposes to package payment for diagnostic radiopharmaceuticals, regardless of their cost per day. Although we understand that payments for the diagnostic agent would be increased, we are concerned that the increase is not sufficient to cover the costs of the radiopharmaceutical or contrast agent. In particular, the errors in calculating drug costs described above raise doubts about whether CMS has packaged an appropriate amount of costs into the APC rate. Moreover, even if some of the proposed rates for 2008 are adequate, CMS will have difficultly setting appropriate rates in the future if hospitals lose the incentive to report charges for all radiopharmaceuticals.

ACCC is concerned that if the OPPS does not appropriately reimburse for all of the costs of providing radiopharmaceuticals, hospitals will not be able to continue to provide these advanced treatments, which is especially worrisome considering that hospitals are often the only site of service for Medicare beneficiaries to receive these treatments. We are particularly concerned about ensuring access to therapeutic radiopharmaceuticals, such as BEXXAR® and Zevalin®. The rates calculated through the proposed methodology will be substantially reduced from 2007 levels, below many of our members' acquisition costs. Faced with reduced payment for the radiotherapies, many hospitals may not be able to offer them in 2008.

We recommend that CMS continue to use the current methodology for setting payments for all radiopharmaceuticals. CMS should continue to work with stakeholders to develop a payment methodology for radiopharmaceuticals in 2009 that will account for charge compression and ensure that preparation and handling costs are appropriately reimbursed. If CMS decides to implement packaging for diagnostic radiopharmaceuticals, we urge he agency to follow the APC Panel's recommendation to continue to use the current methodology for all therapeutic and diagnostic radiopharmaceuticals with per-day costs over $200. CMS also should implement edits to correct the data on radiopharmaceuticals. Finally, to ensure that CMS can continue to collect charge data if the agency decides to package payment for diagnostic radiopharmaceuticals, we recommend that CMS instruct hospitals to continue to report charges for all of these products.

C. Payment for Contrast Agents

CMS also proposes to package payment for all contrast agents.[22] The concerns we noted above about packaged payment for drugs and radiopharmaceuticals also apply to contrast agents. We believe that the apparent errors in CMS' calculations of drug costs indicate that the full costs of packaged drugs are not reflected in the proposed rates for the associated procedures. We are particularly concerned about protecting access to procedures in which contrast agents rarely are used, but can significantly increase the costs of care when they are used. Under the packaging proposal, hospitals would not be reimbursed for the costs of these contrast agents, even though they are medically necessary. This will discourage hospitals from offering these services to Medicare beneficiaries, possibly delaying diagnosis of cancer or planning of appropriate cancer care. To the extent that the costs of packaged drugs are included in the proposed 2008 rule, CMS' ability to continue to calculate accurate rates in future years will be compromised if the packaging proposals discourage hospitals from submitting charges for all of the contrast agents they use. We urge CMS to continue to make separate payment for contrast agents in 2008 and beyond.

II. Drug Administration

ACCC strongly supports the proposal to increase reimbursement for many drug administration codes. In order to keep up with the increased needs of patients, and of the increasing complexity of administering certain types of drugs, this proposal is necessary. We appreciate CMS recognizing this need and acting to address this issue. ACCC cautions CMS not to use this increase as an offset for pharmacy overhead services, however. Drug administration and drug preparation and storage are completely separate, and each deserves its own reimbursement.

ACCC also urges CMS to adopt the APC Panel's March 2007 recommendation to make separate payment for concurrent infusions under Current Procedural Terminology (CPT) code 90768. CMS claims that the costs of this procedure are included in payment for other procedures, although it does not have claims data for this code for use in ratesetting.[23] Separate payment for this procedure will help to ensure that hospitals are reimbursed for all of the drug administration services they provide. Currently, when hospitals administer a concurrent administration of a packaged drug, they are reimbursed neither for the drug nor its administration. Separate payment also would promote parity across settings by providing separate payment for services that are separately reimbursed in physicians' offices.

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22 Id. at 42672.

23 Id. at 42751.

III. CMS should continue to make payment at the current rate for the pre-administration services associated with providing IVIG and consider making an additional payment to protect beneficiary access to this therapy. [IVIG Preadministration-Related Services]

We urge CMS to continue to make payment for the pre-administration services associated with providing IVIG. We ask CMS to keep the rate at the 2007 levels, however, as opposed to the rate proposed in the 2008 rule, potentially lowering the payment from $75.00 to $38.52.[24] IVIG is an important component of treatment regimens for certain types of cancers. In recent years, changes in Medicare's payment for IVIG may have affected beneficiary access to this therapy. Hospitals have faced challenges in obtaining IVIG, and in particular, it has been difficult for hospitals to acquire the exact brand best suited for each patient's needs. As recently as April 2007, the Office of Inspector General (OIG) found that only 56 percent of IVIG sales to hospitals by the three largest distributors occurred at prices below Medicare's payment rates.[25] We believe this is still the case and believe a payment if $38.52 is insufficient to cover these costs. We also think that the reported charges for these services may not be accurate, and we ask CMS to collect at least one more year of data before transitioning these services to a clinical APC. ACCC recommends that CMS continue to assign these services to new technology APC 1502, with a payment of $75.00 for CY 2008. In addition, we would support the implementation of a permanent add-on payment to protect access to IVIG by ensuring that hospitals are reimbursed at rates greater than their acquisition costs.

IV. Imaging Procedures

A. PET/CT Scans

CMS proposes to reassign concurrent PET/CT scans from New Technology APC 1511 to clinical APC 0308.[26] This proposal would increase payment for these scans to $1107.22, and this payment would include the packaged payment for FDG, a radiopharmaceutical that commonly is administered with PET/CT scans.[27] We appreciate CMS' efforts to ensure that these scans are assigned to a clinical APC with other services with comparable median costs, but we are concerned that the combined payment for the scan and the radiopharmaceutical may not be appropriate. Under the proposed APC assignment, concurrent PET/CT scans would be reimbursed at the same rate as conventional nonmyocardial PET procedures, although PET/CT scans use more advanced technology and have

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[24] Id. at 42705.

[25] OIG, Intravenous Immune Globulin; Medicare Payment and Availability, OEI-03-05-00404, April 2007, at ii.

[26] 72 Fed. Reg. at 42705.

[27] Id.

enhanced capabilities. We recommend that CMS continue to assign PET/CT scans to a New Technology APC that reflects the cost of the service for at least one more year while CMS collects data on its costs. We also are concerned about the accuracy of the packaged costs for the radiopharmaceuticals. Because CMS has not provided clear information on the amount of costs packaged into each APC, we cannot be certain that packaging of this radiopharmaceutical "fully maintains the clinical and resource homogeneity" of this APC, as CMS asserts.[28] As discussed above, we recommend that diagnostic radiopharmaceuticals be separately paid, or at a minimum, that CMS implement the APC Panel's recommendation to make separate payment for radiopharmaceuticals with per-day costs greater than $200. We also ask CMS to provide stakeholders with clear information about the attribution of packaged drug costs assigned to each APC.

B. Bundling of ancillary and related procedures

In the Proposed Rule, CMS clearly indicates that it wants to increase the use of bundling and packaging in the OPPS. We are concerned that this move without more study as to the impacts may negatively affect patients and hospitals. CMS has proposed to package together certain types of services that often are performed with other services, specifically guidance services, image processing, intra-operative services, imaging supervision, diagnostic radiopharmaceuticals, contrast media, and observation services.[29]

ACCC supports the APC Panel's recommendation to exempt image guidance procedures used with radiation oncology from any packaging of ancillary services. These services are critical to the safe and effective performance of radiation oncology. By helping to ensure that the maximum dose of radiation reaches the tumor site, with minimal doses reaching surrounding tissue, these services help ensure that patients receive the highest quality care. Packaging payment for these guidance procedures would encourage hospitals to provide older, less effective localization technologies and would impede investments in technologies that would offer continued improvements in the quality of cancer care available to Medicare beneficiaries. If CMS implements expanded packaging, we recommend that the following five codes for image guidance procedures continue to be paid separately:

- 76950 Ultrasonic guidance for placement of radiation therapy fields
- 76965 Ultrasonic guidance for interstitial radioelement application
- 77014 Computed tomography guidance for placement of radiation therapy fields
- 77417 Therapeutic radiology port films

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28 Id.

29 72 Fed Reg. 42814

- 77421 Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy

ACCC also would like more definitive information from CMS as to the exact impacts of its packaging proposal before it is implemented. For example, we request a crosswalk of packaged service codes to the independent procedures with which they are performed, the median costs of the independent APCs with the dependent codes packaged and without the packaging proposal, and the percentage of claims for each independent procedure with a packaged dependent procedure code. Without additional information from CMS about how it has included the costs of packaged services into other APCs, we cannot confirm that the rates are appropriate. Our concern is that the bundled rates may not be adequate to reimburse hospitals for all of the services they provide. If this is the case, it may cause hospitals to reduce the usage of these procedures, thus limiting access to patients.

V. Brachytherapy [OPPS: Packaged Services]

ACCC supports the proposal to continue to pay separately for brachytherapy sources, and we also are supportive of the plan to introduce a new composite APCs to pay for low dose rate prostate brachytherapy administration. Although we do not support the slight reduction in reimbursement ($3,166.52 in 2008 from $3,182.34 in 2007),[30] and would support a flat or minor increase in the APC payment, we understand CMS' desire to encourage greater efficiency and use multiple procedures claims in ratesetting by paying for encounters rather than individual services.[31] We hope that this approach will help to stabilize payment rates and facilitate necessary planning and budgeting by hospitals.

VI. Evaluation and Management Services (E&M)

ACCC recommends that CMS propose national guidelines for E&M coding for outpatient visits and provide six to twelve months notice before implementation. CMS continues to evaluate the draft American Hospital Association (AHA)/ American Health Information Management Association (AHIMA) guidelines and requests comment on whether national guidelines are needed.[32] For now, the agency instructs hospitals to continue to report visits using their own internal guidelines.[33] CMS also proposes additional principles for these internal guidelines. We appreciate the agency's efforts to clarify the standards for internal guidelines, but we continue to believe that national guidelines are needed

30 Id. at 42846.
31 Id. at 42652.
32 72 Fed. Reg. at 42765.
33 Id.

to provide clear instructions to hospitals on how to code for each type of visit and level of service. We believe that the guidelines also should describe services provided by non-nursing professionals, such as nutritionists and social workers, who are essential providers of cancer therapy support services. Although these professionals provide valuable services that help patients achieve the full benefits of their cancer therapies and avoid adverse events, saving Medicare program expenditures, it currently is not clear how hospitals can bill for these services in a manner that reimburses them appropriately for their costs. Hospitals need up-to-date guidelines on the use of the new E&M codes that address these important and potentially cost-saving services.

VII. Conclusion

ACCC urges CMS to protect Medicare beneficiaries' access to quality care in the most appropriate setting by providing appropriate reimbursement for cancer treatments under the OPPS. We believe it is imperative that CMS recalculate payments for separately paid drugs without pass-through status to ensure that all of the pharmacy service costs associated with those drugs are included in their reimbursement. At a minimum, payment for these drugs should be set at no less than ASP plus six percent.

We also recommend that CMS abide by the recommendations of the pharmacy stakeholder community and the APC Panel to reimburse hospitals for their pharmacy service costs. CMS should not implement its unworkable proposal to instruct hospitals to report charges for pharmacy service on an uncoded revenue code line. We have proposed an efficient plan that also fits with CMS' vision to use more bundling in the outpatient department better than the current pharmacy proposal. In addition, CMS should pay separately for all drugs with HCPCS codes, including anti-emetics. The agency should continue to provide separate reimbursement for radiopharmaceuticals based on the current methodology. If CMS decides to package any radiopharmaceuticals, it should adhere to the APC Panel's recommendation to pay separately for diagnostic radiopharmaceuticals with per-day costs greater than $200. CMS also should continue to pay separately for contrast agents and brachytherapy sources.

ACCC supports the proposed increases in payment for drug administration APCs, but we ask CMS to implement the APC Panel's March 2007 recommendation to make separate payment for concurrent infusions under CPT code 90768. We also support the continued payment for pre-administration services associated with providing IVIG, but we recommend that they continue at the current rate.

ACCC believes more study needs to be done in the area of increased packaging, especially in the area of imaging services. ACCC is concerned that an increase in packaging may lead to an inappropriate decrease in the usage of these procedures and their related services. Greater transparency and more analysis of these proposals is needed to ensure that the combined payments are accurate and do not encourage hospitals to eliminate procedures due to reductions in reimbursement. We also recommend that CMS continue to assign concurrent PET/CT scans to a New Technology APC for at least one more year to ensure appropriate reimbursement while CMS collects data on the cost of these procedures.

Finally, we recommend that CMS propose national guidelines for Evaluation and Management (E&M) coding for outpatient visits and provide six to twelve months notice before implementation.

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 this very important matter.

Respectfully submitted,

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President
Association of Community Cancer Centers (ACCC)