The premier education and advocacy organization for the oncology team

ACCC
Association of Community Cancer Centers

October 6, 2006

BY ELECTRONIC FILING

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1506-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates)

Dear Administrator McClellan:

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 23, 2006 (the "Proposed Rule").[1] ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 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] 71 Fed. Reg. 49506 (August 23, 2006).

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. 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, 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 are becoming the only option for Medicare beneficiaries who lack supplemental insurance. In 2004, the Medicare Payment Advisory Commission (MedPAC) found that oncologists in some markets sent Medicare beneficiaries without supplemental insurance to hospitals to receive chemotherapy, rather than face the financial burden of unpaid coinsurance if they treated these patients in physicians' offices.[2] MedPAC recently testified to the House Ways and Means Subcommittee on Health that, in 2005, these practices increased the number of patients they sent to hospitals for care, and hospitals in those markets reported that they were treating more patients without supplemental insurance who required innovative therapies.[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. Since the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Medicare payments for cancer drugs

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[2] Statement of Mark Miller, Executive Director, MedPAC, to the House Ways and Means Subcommittee on Health, July 13, 2006.

[3] Id.

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

have been reduced significantly. When CMS introduced reimbursement based on average sales price (ASP) in the physician office setting, it also implemented new, revalued codes for drug administration services, the Improved Quality of Care for Cancer Patients Undergoing Chemotherapy Demonstration Project, and transition payment of 32 percent in 2004 and three percent in 2005. These adjustments helped to protect Medicare beneficiaries' continued access to cancer care in physician offices. Although the MMA's reforms are likely to produce similar reductions in OPPS reimbursement for cancer drugs, CMS has not made comparable adjustments in the hospital outpatient setting. As a result of these changes, many of our members are finding it difficult to continue to provide quality, multi-disciplinary cancer care. Several members were forced to close their infusion units and others have expressed concerns that they will not be able to offer outpatient cancer care if Medicare continues to reduce its payment rates.

We are disturbed that CMS proposes again to reduce payment for many separately paid drugs, to average sales price (ASP) plus five percent, in 2007. 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 is imperative to continued patient access in this crucial setting that the OPPS rates in 2007 and beyond 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 setting rates at no less than ASP plus six percent;
- Continue to study mechanisms to reimburse hospitals for their pharmacy service costs;
- Pay separately for all drugs with HCPCS codes;
- Continue to pay separately for anti-emetics;
- Continue to reimburse separately paid radiopharmaceuticals based on the hospital's charge adjusted to cost using hospital-specific cost to charge ratios;
- Implement the proposed new APCs for drug administration services and the changes recommended by the Advisory Panel on APC Groups to allow hospitals to be reimbursed appropriately for drug administration services.
- Continue to make payment for the preadministration services associated with providing intravenous immune globulin (IVIG).

- Implement the proposed new APCs and codes for evaluation and management services provided during clinic visits and continue to work to refine the draft guidelines for the use of those codes;
- Adopt codes, with appropriate reimbursement, to reflect coordinated care services provided by several professionals.
- Postpone the adoption of a policy to reduce payment for second and subsequent imaging procedures within the same family when performed in the same session;
- Implement the proposed payment rates for brachytherapy APCs;
- Delay the movement of positron emission tomography/computed tomography (PET/CT) scans to a clinical APC; and
- Reevaluate its proposal to assign nonmyocardial PET scans to a clinical APC.

These issues and others are described in depth below.

I. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals – NonPass-Throughs

A. Payment for Drugs and Biologicals

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

ACCC is disturbed by CMS' proposal to reimburse separately paid drugs without pass-through status at 105 percent of ASP.[5] CMS claims that these rates will be sufficient to cover hospitals' acquisition costs as well as pharmacy handling costs. A survey of our members indicates that this may not be true. Over half of the respondents to our survey said that the proposed rates would not be adequate reimbursement for the costs of providing five commonly used oncology and supportive care drugs. One member hospital reports 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 will only worsen if reimbursement is lowered to ASP plus five percent.

We especially are concerned that CMS again proposes to make no additional payments for pharmacy handling costs. As we explained in our comments on the OPPS proposed rule for 2006, the advanced drugs we use to

[5] 71 Fed. Reg. at 49585.

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 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.[6] 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,[7] 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 –

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

[7] Id. at 140.

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.[8] Our own calculations indicate that the cost of pharmacist interventions is not captured by CMS' reimbursement for the drug. One of our members reported an average of 3.1 pharmacist interventions per hour over a 15 month period. Most interventions lasted 15 to 30 minutes, and the average pharmacist salary and benefits at that hospital was $56 per hour, producing a per-intervention cost of $14 to $28. These costs are in addition to the time needed to prepare a drug when no intervention is necessary.

2. CMS' methodology for calculating the proposed rates is deeply flawed.

In spite of the evidence demonstrating the significant costs of safely preparing drugs in hospital outpatient departments and indicating that these costs are not reflected in hospitals' charges, CMS continues to assert that hospitals set charges for drugs high enough to include these costs. Working on the assumption that hospitals' charges in 2005 included charges for pharmacy service costs, CMS attempted to calculate the mean unit cost for separately payable drugs by applying a constant cost-to-charge ratio (CCR) to these charges.[9] It then compared the aggregate expenditures calculated from claims data to aggregate expenditures calculated based on ASPs.[10] CMS concludes that the mean unit costs for separately payable drugs are equal, on average, to ASP plus five percent.[11]

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

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[8] 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.

[9] 71 Fed. Reg. at 49584-85.

[10] Id.

[11] Id. at 49585.

included in hospitals' charges,[12] it also fails to capture them accurately. This result is due to two errors in CMS' methodology. First, CMS applies a constant 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 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.[13] 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."[14] CMS itself has recognized that charge compression could create inaccurate payment rates and has commissioned a study to determine how to address it in the inpatient prospective payment system.[15]

Analysis of CMS' claims data shows that applying 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 100 percent to ASP plus 2395 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 uses claims data for only separately paid drugs to 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 tends to be associated with the charges for lower cost drugs. Many of

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[12] 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.

[13] 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.

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

[15] 71 Fed. Reg. 47870, 47897 (August 18, 2006).

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 eleven percent. If the lower cost drugs without codes and ASPs were included, the mean unit cost likely would be even higher.

3. CMS should recalculate its payment rates for separately payable drugs and should set payment rates for these drugs at no less than ASP plus six percent.

To set appropriate payments for drugs in 2007, CMS should include all drugs with HCPCS codes, not just the drugs that currently are paid separately, in its calculations of total pharmacy costs. The study of charge compression in the inpatient PPS may provide useful insights for the OPPS, as well. Until CMS receives this report and develops a method to adjust for charge compression, CMS should include all of these drugs in the calculations to help ensure that all pharmacy costs, including acquisition and handling services, are reflected in its data. We urge CMS to recalculate payment rates and set payment in 2007 at no less than ASP plus six percent, the rate applicable in physicians' offices, as recommended by the Advisory Panel on APC Groups (the APC Panel) at its August meeting.[16]

4. CMS should continue to study and work with stakeholders to develop appropriate payments for pharmacy service costs.

For future years, CMS should continue to study mechanisms to reimburse hospitals appropriately for their pharmacy service costs. ACCC will continue to work with our members to help CMS learn more about the challenges hospitals face in measuring and reporting charges for these services. As MedPAC noted in its report, many hospitals are unaware of the magnitude of their pharmacy service costs and thus cannot set charges to include all of these costs. CMS should help hospitals set charges that could be used to calculate future payments by providing clear guidance on how to report costs and set charges for these services. We also recommend that CMS consider other options for making payment for pharmacy services, such as the use of codes similar to

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[16] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

those proposed by the agency last year[17] or payment for medication therapy management codes.

5. CMS should pay separately for all drugs with HCPCS codes.

CMS proposes to increase the packaging threshold to $55 per day.[18] ACCC is concerned that increasing the packaging threshold could reduce the number of drugs that are separately paid and could harm beneficiary access to appropriate care. We support the APC Panel's recommendation to pay separately for all drugs with HCPCS codes. This policy is consistent with CMS' payment policies for physician offices and would help eliminate financial incentives to choose one therapy or site of service over another. As discussed above, it also is consistent with our recommended method of calculating mean unit costs for 2007. Additionally, unpackaging these drugs would help to improve the overall accuracy of the OPPS. An analysis of the claims data found that only four percent of claims for packaged drugs are submitted with a drug administration claim and are used to set rates for these services. Over 40 percent of the claims for packaged drugs were submitted with claims for other services, and more than half of the claims for packaged drugs are not used in CMS' analysis. This indicates that the costs of packaged drugs are not actually included in payment for drug administration services, although they are included in the OPPS. Paying separately for these drugs would help CMS to calculate more accurate payments for all of the services in which drugs are used.

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 pay separately for anti-emetics.[19] 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."[20]

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17 70 Fed. Reg. 42674, 42730 (July 25, 2005).
18 71 Fed. Reg. at 49582.
19 Id. at 49583.
20 Id.

We also support CMS' decision not to apply an "equitable adjustment" to any drugs in 2007. As CMS noted last year, this decision will "permit market forces to determine the appropriate payment" for drugs.[21]

B. Payment for 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 bundle 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.

Instead of paying for these therapies based on each hospital's charge reduced to cost as it did in 2006, CMS proposes to establish payment for these therapies in 2007 using mean costs derived from calendar year 2005 claims data through the use of hospital-specific departmental CCRs.[22] 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. As we explained above, application of a constant CCR to hospital charges produces inaccurate estimates of cost because hospitals do not apply constant markups to the therapies they provide. Additionally, CMS plans to use 2005 claims data to set these rates, even though CMS issued guidance only last year for hospitals to set charges to include "all costs associated with the acquisition, preparation, and handling of these products."[23] CMS issued those instructions in the OPPS final rule for 2006 to ensure that "payments under the OPPS can accurately reflect all of the actual costs associated with providing these therapies to hospital outpatients."[24] We are disappointed that CMS is not waiting for hospitals to adjust their charges so it will have more accurate data on which to base payments. CMS' proposed rate setting methodology cannot produce accurate rates until it has accurate data on costs and charges.

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. We are

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21 Id. at 42727.
22 Id. at 49587.
23 Id. at 68653.
24 Id.

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 2005 levels, possibly below hospitals' acquisition costs. The proposed rate for Y-90 Zevalin® is 42 percent less than the 2005 rate and 38 percent less than the average purchase price reported by the GAO in 2005.[25] Payment for BEXXAR® would fall by 39 percent from the 2005 levels. CMS also proposes to move the codes for administration of these therapies from new technology APCs to clinical APCs, producing significant reductions in reimbursement. Faced with reduced payment for both the radiotherapies and their administration, many hospitals may not be able to offer these therapies in 2007.

We urge CMS to continue to use the 2006 payment methodology for radiopharmaceuticals for at least one more year. As CMS noted last year, this methodology protects against rapid reductions that could harm beneficiary access to these therapies.[26] In the Proposed Rule, CMS also acknowledges that this methodology is an acceptable proxy for average acquisition costs.[27] Additionally, the APC Panel recommends that CMS continue to use this methodology in 2007.[28] ACCC recommends that CMS use this methodology for 2007 and evaluate the data at the end of that year to determine how to set rates in the future.

II. Drug Administration

ACCC strongly supports the agency's decision to create six new drug administration APCs and to make separate payment for additional hours of drug administration services.[29] ACCC has long advocated for separate payment for these drug administration services under the OPPS. Under the current APCs, payment for second and subsequent hours of drug administration services is packaged into payment for the first hour. These rates do not reflect the true cost of providing drug therapies, particularly for the 40 percent of our patients who receive infusions of chemotherapy and other drugs that usually take two hours or more to administer. In 2006, hospital outpatient departments are paid significantly less than physicians' offices for administering chemotherapy infusions – 22 percent less than a physician's office for administering a 2-hour

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[25] GAO, Medicare: Radiopharmaceutical Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting, GAO-05-733R, July 14, 2005, at 6.

[26] 70 Fed. Reg. 68515, 68653 (November 10, 2005).

[27] 71 Fed. Reg. at 49587.

[28] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

[29] 71 Fed. Reg. at 49600.

chemotherapy infusion, 24.6 percent less for a 3-hour infusion, and 34.7 percent less for a four-hour infusion. By making separate payment for additional hours of drug administration services, CMS would close this payment gap and protect beneficiary access to care. This is particularly important for patients who require infusions administered over periods of eight hours, seven days a week, or in other situations that are outside normal physician office hours. Although we understand that other stakeholders have recommended that CMS use Current Procedural Terminology (CPT)[30] codes instead of C-codes for drug administration services, until hospital-specific CPT codes are developed, we believe that continued use of the C-codes is the most appropriate way to ensure that hospitals are adequately paid for these services. We urge CMS to finalize this proposal.

Although we support CMS' proposal to make separate payment for additional hours of infusion services, we are concerned by the significant decrease in payment for the first hour codes. We ask CMS to verify that its calculations are correct and that those rates are appropriate. We also recommend that the agency consider that only four percent of claims for packaged drugs are made with a claim for a drug administration service. If CMS does not make separate payment for all drugs with HCPCS codes – as the APC Panel recommends and we urge the agency to do – it must be aware that most of its claims data for drug administration services do not include the cost of packaged drugs.

To further improve equity between hospital outpatient departments and physicians' offices, we support the APC Panel's recommendation to allow hospitals to separately bill and receive payment for therapeutic infusions and hydration infusions provided in the same encounter.[31] Because these services share codes under the OPPS, a hospital that administers both a one-hour hydration infusion and a one-hour therapeutic infusion would be paid for the first hour of one infusion under APC 440 and a reduced rate for subsequent hour for the other infusion under APC 437. In contrast, under CMS' current guidance, hospitals can report a first hour code for each of other types of infusions, such as chemotherapy or therapeutic infusion, if both infusions meet the requirements for billing a first hour of each type of infusion.[32] We

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[30] Current Procedural Terminology or CPT is a trademark of the American Medical Association.

[31] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

[32] January 2006 Updated of Hospital Outpatient Prospective Payment System Manual Instruction: Changes to Coding and Payment for Drug Administration, Transmittal 785,

recommend that CMS adopt a similar policy for hospital outpatient departments and allow hospitals to be paid using the initial infusion code for both the hydration infusion and the therapeutic infusion.

We also continue to be concerned that the current drug administration codes do not allow additional payment for a second IV push of the same drug. If the drug is packaged, hospitals do not receive any payment for the second drug or its administration service. ACCC supports the APC Panel's recommendation to make payment for a second or subsequent intravenous push of the same drug by instituting a modifier, developing a new HCPCS code for the procedure, or implementing another methodology.[33] Paying separately for all drugs with HCPCS codes also would help to establish appropriate payment for all drugs and their administration services.

Additionally, we ask CMS to clarify its guidance on the use of the chemotherapy drug administration codes under the OPPS. CMS' guidance on these codes instructs hospitals to "report chemotherapy drug administration HCPCS codes when providing non-radionuclide anti-neoplastic drugs to treat cancer and when administering non-radionuclide anti-neoplastic drugs, anti-neoplastic agents, monoclonal antibody agents, and biologic response modifiers for treatment of noncancer diagnoses."[34] This guidance is consistent with the CPT's guidance for physician offices, but it does not state clearly that these codes should be used for administration of standard and specialty IVIG. Because IVIG is a biologic response modifier, its administration should be billed using the code for chemotherapy administrations, C8954, not C8950, the code for non-chemotherapy intravenous infusion for therapy or diagnosis. We also ask CMS to clarify that DNA or RNA based therapies are biologic response modifiers that should be billed under chemotherapy administration codes as well.

Finally, we recommend that CMS continue to make payment for preadministration-related services for standard and specialty IVIG. 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

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Change Request 4258, Dec. 16, 2005 (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2).

[33] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

[34] January 2006 Updated of Hospital Outpatient Prospective Payment System Manual Instruction: Changes to Coding and Payment for Drug Administration, Transmittal 785, Change Request 4258, Dec. 16, 2005 (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2.2).

IVIG, and in particular, it has been difficult for hospitals to acquire the exact brand best suited for each patient's needs. For 2006, CMS implemented a $75 payment for preadministration-related services for IVIG. We are disappointed that CMS proposes to eliminate this payment for 2007.[35] This proposal, combined with the proposed reduction in reimbursement, will make it even more difficult for hospitals to provide each patient with the appropriate brand IVIG for his or her treatment. We urge CMS to recognize that hospitals continue to bear extra costs in obtaining IVIG and to continue to make the payment for pre-administration services.

III. Evaluation and Management Services (Visits)

We also are pleased that CMS has made progress on new codes and APC assignments for evaluation and management services.[36] As we have explained in the past, improving payment rates and providing appropriate coding guidelines for evaluation and management services can help ensure appropriate payment for cancer therapy support services. The proposed new HCPCS codes for clinic visits and their APC assignments are an important step toward providing appropriate payment for cancer therapy support services, such as management of courses of treatment, nutritional counseling, counseling, patient and family education, and risk assessments.

We also ask CMS to adopt codes, with appropriate reimbursement, that describe clinic visits in which patients receive cancer care from several professionals. For example, in addition to an oncologist and nursing staff, a patient might meet with a nutritionist to discuss changes to the patient's diet, a social worker to plan for home care, and a counselor to address the psychological and emotional aspects of cancer treatment. In 2000, CMS created a code, G0175 (scheduled interdisciplinary team conference (minimum of three exclusive of patient care nursing staff) with patient present), to describe visits in which numerous physicians meet with the patient concurrently. When it created this code, CMS recognized that patients with complex conditions, such as cancer, require carefully coordinated care. Unfortunately, in practice it often is nearly impossible and an inefficient use of resources to have a patient's caregivers meet with the patient as a group. Currently, a facility can report only one evaluation and management code if the patient has sequential visits with several professionals in the same clinic setting, regardless of the amount of time the patient spends with each caregiver. Alternatively, the hospital could bill for each visit if it required the patient to visit separate clinics within the hospital, although the patient would experience greater inconvenience. Hospitals need to

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[35] 71 Fed. Reg. at 49604.

[36] 71 Fed. Reg. at 49607-12.

be reimbursed appropriately for providing coordinated cancer care services in a way that is efficient for the patient, the professionals, and the hospital.

We recommend that CMS revise the definition of G0175 to describe multidisciplinary care as it is actually provided in clinics for cancer and other serious illnesses, such as AIDS and diabetes – through the coordinated efforts of multiple professionals who meet with the patient individually. We also recommend that CMS assign the revised code to a new APC that would represent a sixth level of care. This level would be analogous to proposed APC 617 for critical care. Like critical care in an emergency room, multidisciplinary specialty care in a clinic setting requires more resources than the current highest level clinic visit, involves the work of numerous staff, and requires the patient to remain in the clinic for many hours. Setting payment for this APC at a level equal to the critical care APC would help hospitals continue to provide these important services in a manner that is most convenient and effective for patients and staff. It also would encourage the provision of high quality, coordinated patient care.

We also thank CMS for its efforts to refine the draft guidelines for use of these codes. We believe the guidelines identify helpful criteria for distinguishing each level of service. We believe that the guidelines will need additional examples to 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 evaluation and management codes that address these important and potentially cost-saving services.

IV. Multiple Diagnostic Imaging Procedures (Radiology Procedures)

ACCC supports CMS' proposal to postpone the adoption of a policy to reduce payment for second and subsequent imaging procedures within the same family when performed in the same session.[37] We commend CMS for deciding to conduct additional studies in order to determine the actual savings yielded from the performance of multiple imaging services in a single session before adopting payment reductions for those services. We remain extremely concerned, however, that CMS will implement an inappropriate payment reduction in the future. As we have indicated previously to CMS, diagnostic

[37] Id. at 49567.

imaging procedures are vital to the treatment of cancer. These services are essential both to diagnosing the disease and evaluating its treatment. A payment reduction for second and subsequent imaging procedures may impede beneficiary access to these essential imaging services. Furthermore, payment cuts could encourage greater use of invasive diagnostic procedures, unnecessarily exposing patients to potential complications resulting in additional costs to the beneficiary and to Medicare. A decrease in payment for multiple imaging procedures also may cause hospitals to perform each imaging procedure in a different session over an extended period of time, both inconveniencing the patient and delaying beneficiary access to important services. Finally, ACCC believes such a reduction may discourage investment by hospitals in essential new technologies.

As we have stated previously, there is no standard economy of scale when multiple procedures are performed. Technologist time and contrast material administered are not necessarily reduced by the performance of multiple procedures in one session. Rather, the requirements related to patient preparation for some imaging procedures may be different such that substantial time between each procedure may be necessary even if multiple procedures are performed in a single session. In addition, equipment costs, including depreciation and maintenance, are tied to the number of images produced and not the number of sessions in which those images are created.

In the event CMS adopts a payment reduction policy for multiple imaging services performed in a single session in the future, we encourage CMS to base that reduction upon the actual savings realized when more than one imaging procedure is conducted in a single visit and to apply a payment reduction only to those procedures for which the costs currently do not reflect efficiencies resulting from performance of multiple procedures in a single session.

V. Brachytherapy

ACCC strongly supports CMS' proposed payment rates for brachytherapy APCs, specifically the proposed rate for APC 0651 of $1025.37 (applicable to CPT code 77778) and the proposed rate for APC 0163 of $2160.59 (applicable to CPT code 55859).[38] Brachytherapy is an innovative and important cancer treatment that hospitals should be able provide to those patients who could benefit from it. Therefore, we are pleased that CMS followed the March 2006 APC Panel recommendation to reevaluate the proposed payment rates for brachytherapy APCs. We commend CMS for its recognition that the historical instability in the

[38] Id. at 49563.

payment rates for this vital service has caused difficulty for hospitals in planning and budgeting. Continued instability and unsuitable payment rates could jeopardize hospitals' ability to offer this life-saving therapy to patients. We believe the new rates proposed by CMS are more appropriate for this service and will help enable hospitals to offer brachytherapy to beneficiaries in need of the treatment. Moreover, greater stability in the payment rates will facilitate necessary planning and budgeting by hospitals.

VI. New Technology APCs

A. PET/CT Scans

ACCC is troubled by the agency's proposal to move concurrent PET/CT scans (specifically, CPT codes 78814, 78815, and 78816) from New Technology APC 1514, with a payment rate of $1250, to APC 0308, Nonmyocardial PET Imaging, with a proposed payment rate of $862.29.[39] We agree with the APC Panel's August 2006 recommendation that CMS maintain concurrent PET/CT scans in New Technology APC 1514 at the payment rate of $1250.[40] The innovative technology provided by concurrent PET/CT scans is dramatically improving diagnosis and treatment of cancer patients by offering diagnostic capability superior to PET scans alone. Concurrent PET/CTs can reduce diagnostic errors and the need for certain invasive procedures and can assist in assessing the effectiveness of cancer treatments. In addition, the service allows for more accurate localization of abnormalities, tumors and nodes and more precise prescription of radiation fields.[41] PET/CT scans therefore can decrease the incurrence by Medicare and beneficiaries of additional costs that may stem from diagnostic errors and less appropriate treatment. ACCC is greatly concerned that premature assignment of PET/CT scans to a clinical APC, resulting in a significant reduction in the reimbursement for such services, will hinder patient access to this life-saving technology. The reduction in payment for PET/CT scans may discourage hospitals from investing in this important new technology. Finally, the assignment could create an incentive for hospitals to perform PET and CT scans separately in order to receive payment for each, that not only would inconvenience cancer beneficiaries but also would prevent such patients from realizing the benefits associated with the concurrent scans.

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[39] Id. at 49553 and Addendum B.

[40] Advisory Panel on APC Groups, Meeting Report for August 23-24, 2006, available at http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp

[41] See PET/CT's High Accuracy Fuels Rapid Adoption, Community PET a Supplement to Diagnostic Imaging, available at http://www.diagnosticimaging.com/communitypet/4.jhtml.

We believe that CMS should make no changes to payment for this service until it has received more accurate claims data so that cancer patients may continue to receive those services most applicable to their condition. We strongly encourage CMS to delay the movement of PET/CT scans to a clinical APC, as recommended by the APC Panel, in order to provide hospitals additional time to adopt accurate coding and to modify their chargemasters to reflect the appropriate cost and charges for this exciting new procedure.

B. Nonmyocardial PET Scans

ACCC also is concerned by the agency's proposal to assign Nonmyocardial PET scans (in particular, CPT codes 78608, 78811, 78812, and 78813) to clinical APC 0308, Nonmyocardial PET Imaging, with a proposed payment rate of $862.29.[42] PET scans currently receive payment based on a 50/50 blend of the median cost of PET scans and the New Technology APC 1516 payment rate, resulting in a payment rate of $1150. The PET scan is a vital tool in the diagnosis of cancer and to evaluation of the effectiveness of treatment for cancer patients. We believe that lowered reimbursement for PET scans may deter hospital investment in this important technology and could diminish its availability to cancer beneficiaries. We recommend that CMS either reevaluate its proposal to assign Nonmyocardial PET scans to a clinical APC or reconsider the rate for APC 0308 in order to ensure continued access by Medicare beneficiaries.

VI. Conclusion

ACCC urges 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 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 recommend that CMS continue to study mechanisms to reimburse hospitals for their pharmacy service costs and pay separately for all drugs with HCPCS codes, including anti-emetics. CMS should continue to reimburse separately paid radiopharmaceuticals based on the hospital's charge adjusted to cost using hospital-specific cost to charge ratios, as well.

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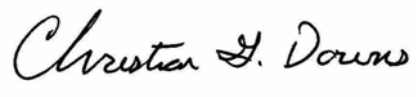
[42] 71 Fed. Reg. at 49552.

We support implementation of the proposed new APCs for drug administration services and the changes recommended by the Advisory Panel on APC Groups to allow hospitals to be reimbursed appropriately for drug administration services. We also recommend that CMS implement the proposed new APCs and codes for evaluation and management services provided during clinic visits and continue to work to refine the draft guidelines for the use of those codes. In addition, CMS should adopt codes, with appropriate reimbursement, that describe clinic visits in which patients receive cancer care from several different professionals. We agree that CMS should postpone the adoption of a policy to reduce payment for second and subsequent imaging procedures within the same family when performed in the same session. We also agree with CMS' proposed payment rates for brachytherapy APCs. Finally, we recommend that CMS delay the movement of PET/CT scans to a clinical APC and reevaluate its proposal to assign Nonmyocardial PET scans to a clinical APC.

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 me 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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Executive Director