August 31, 2009

Charlene Frizzera
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-1414-P: (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates)

Dear Acting Administrator Frizzera:

On behalf of the Association of Community Cancer Centers (ACCC), we appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on July 20, 2009 (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 900 member institutions and organizations treat 60 percent of all U.S. cancer patients when combined with our physician membership.

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.

[1] 74 Fed. Reg. 35231 (July 20, 2009).

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Hospital outpatient departments (HOPDs) are a crucial part of the cancer care delivery system, providing a significant portion of this country's cancer care. Because advanced cancer treatments often are associated with considerable risk, several are available only through hospital-based oncologists, nurses, and pharmacists. Patients receiving these treatments must have substantial on-site clinical support in case of adverse reactions. ACCC members often serve patients who have numerous complications or histories of infusion reactions. In addition, some treatments, such as those involving radiopharmaceuticals, are available only in hospitals because they require specialized equipment and handling that is only available in that setting. Finally, HOPDs play an important role in the early adoption of new technologies and frequently serve patients who recently have completed participation in clinical trials.

Our members also play an important role in the health care safety net. In some cases, HOPDs are the only sites available for Medicare and uninsured patients who need cancer care. HOPDs also 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. We remain concerned that CMS proposes to continue payment for separately payable drugs without pass-through status at average sales price (ASP) plus four percent in 2010, a payment rate that is not sufficient to cover the cost of the drug and the related pharmacy overhead services costs.

Over the past few years, ACCC and other stakeholders have presented CMS with data showing that the OPPS rates are inadequate and are based on a deeply flawed methodology. Beginning with the 2005 Medicare Payment Advisory Commission (MedPAC) report on pharmacy overhead and handling costs, through last year's RTI International study, with our own analysis in between, it has become clear that payment for drugs without pass-through status at rates lower than ASP plus six percent is not justified and that an adjustment is needed to reimburse hospitals for pharmacy service costs. We are very pleased that CMS finally has recognized the problems inherent in its rate-setting methodology,

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

including the effects of charge compression; however, we believe that CMS must make additional changes in order to achieve appropriate rates.

It is imperative to continued patient access in this crucial setting that the OPPS rates in 2010 and beyond adequately reimburse hospitals for the costs of providing advanced cancer therapies. Toward this end, ACCC recommends that CMS:

- Reimburse the acquisition cost of separately payable drugs without pass-through status at no less than ASP plus six percent;
- Reallocate a larger share of costs for pharmacy overhead from packaged drugs to separately payable drugs;
- Use an ASP file that is better aligned with its claims and cost report data for its drug payment calculations;
- Remove 340B hospital data from the ASP + X percent calculation and continue to pay 340B hospitals at the same rate as non-340B hospitals;
- Reimburse the acquisition cost of separately payable drugs at ASP plus six percent; package payment for packaged drugs at ASP plus 100 percent; calculate the pharmacy overhead pool using the proposed methodology, with the corrections addressed above; and then allocate the pool to reimburse for the pharmacy services of separately payable drugs.
- Make separate payment for all drugs with Healthcare Common Procedure Coding System (HCPCS) codes, or, at a minimum, keep the packaging threshold for drugs at $60;
- Continue to pay separately for all anti-emetics;
- Reinstate separate payment for diagnostic radiopharmaceuticals and contrast agents;
- Institute reimbursement for therapeutic radiopharmaceuticals based on ASP, using data reported voluntarily by manufacturers;
- Not implement the proposed change to the definition of the pass-through eligibility period for new drugs;
- Continue to reimburse brachytherapy sources at charges adjusted to cost and retain APC 0182T for high dose rate electronic brachytherapy in New Technology APC 1519;
- Reinstate separate payment for radiation oncology guidance services;
- Institute the proposal to allow non-physician practitioners to supervise outpatient therapeutic services, but do not implement the proposed definition of "in the hospital" and the proposed interpretation of "immediately available" and clarify that its direct supervision amendments do not apply to services furnished in a department of a hospital that is located on the campus of that hospital;
- Work with providers and specialty societies in determining which new measures to add to the quality reporting requirement;

- Change the date of service regulations for certain laboratory tests from the date of collection of a specimen to the date of performance of the test to ensure proper reimbursement.

These issues and others are described below.

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

A. Payment for Drugs and Biologicals

1. CMS should reimburse hospitals for the acquisition cost of separately payable drugs without pass-through status at no less than ASP plus six percent.

Once again, ACCC is troubled by CMS's proposal to reimburse separately payable drugs without pass-through status at 104 percent of ASP.[3] ACCC appreciates that CMS did not reduce the drug reimbursement rate based on its estimated costs from claims data, as it has in previous years; however, we remain concerned that CMS's flawed methodology fails to reimburse our members appropriately for the therapies they provide to Medicare beneficiaries.

In the Proposed Rule, CMS continues to use claims data to calculate estimated aggregate average acquisition and pharmacy service costs for separately payable drugs by applying constant cost-to-charge ratio (CCR) to reported charges for drugs. As we have explained in comments on prior years' rules, this methodology does not produce accurate estimates of drug cost because, although hospitals may include much of their pharmacy overhead costs in their charges for drugs in the aggregate, they do not allocate even amounts of overhead to each drug. Instead, hospitals apply smaller percentage markups to higher cost items than to lower cost items. In the Proposed Rule, CMS acknowledges that its current rate-setting method "has the potential to 'compress' the calculated costs to some degree."[4] We agree with this conclusion, and we share CMS's belief that its estimated acquisition and pharmacy overhead costs of ASP minus two percent for separately payable drugs is too low, and ASP plus 247 percent for packaged drugs appears to be too high.[5]

Our analysis has found CMS's cost estimate methodology to be very sensitive to changes in the underlying data and assumptions used. The results, therefore,

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[3] 74 Fed. Reg. at 35254.
[4] Id at 35327.
[5] Id. at 35328.

appear to be arbitrary. CMS itself acknowledges that it does not have "ASP information specifically for [drug and biological] sales to hospitals."[6] Because CMS does not have data on hospitals' average acquisition cost, we believe the statute requires CMS to reimburse the acquisition cost of separately payable drugs at no less than ASP plus six percent, the rate applicable in physician's offices, plus an adjustment for pharmacy overhead.[7] This rate is consistent with the Social Security Act (SSA) and Congressional intent and will help to protect patients' access to care in the most clinically appropriate setting. It also would lessen the financial burdens on hospitals that experience increased demand due to shifts in site of care.

2. CMS should reallocate a larger share of costs for pharmacy overhead from packaged drugs to separately payable drugs.

In the Proposed Rule, CMS proposes to allocate $150 million from packaged drugs to be used to cover pharmacy overhead services.[8] Even though CMS does not propose to implement the APC Panel's recommendation to use the Pharmacy Stakeholder Group's proposed method of reimbursing hospitals more appropriately for the cost of acquiring and handling separately payable drugs without pass-through status, we appreciate CMS's proposal to reallocate some of the pharmacy overhead costs from packaged drugs to separately payable drugs, producing a payment rate for separately payable drugs of ASP plus four percent.[9] We applaud CMS for recognizing that an adjustment is needed, but we are concerned that this proposal does not provide enough reimbursement for the acquisition and pharmacy handling costs of separately payable drugs.

As we have explained in prior comments and conversations with CMS, the advanced drugs we use to help our patients fight cancer require careful handling by specially trained personnel to ensure that each patient receives the correct dosage of each drug, in the correct sequence, and through the safest administration method. Hospitals employ complex medication use processes in which physicians, nurses, and pharmacists review drug choices at each step of their prescribing, dispensing, and administration. Pharmacists make essential contributions to these processes by using a sequence of activities commonly referred to as "safety through redundancy." Registered pharmacists consult with physicians to determine drug interactions and contraindications, toxicity management and verification of therapy appropriateness, and dosing before and during administration of chemotherapy to a patient. Pharmacists also perform critical quality assurance tasks during the preparation of drug, such as labelling, recording, and tracking mixed drugs for

[6] Id. at 35327.
[7] SSA § 1833(t)(14)(A)(iii)(I).
[8] 74 Fed. Reg. at 35326.
[9] Id. at 35328.

safety purposes, sampling drugs at random to verify quality, and developing and reviewing protocols to flag potential interactions. The costs of these services, plus necessary supplies, equipment, and facilities used in preparing drugs, are significant.

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

When it enacted the MMA, Congress recognized that an acquisition cost-based reimbursement methodology might not account for hospitals' substantial 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.[10]

CMS proposes to reallocate $150 million of the $395 million in pharmacy overhead costs attributed to packaged drugs to separately payable drugs.[11] CMS claims that this amount represents a "middle ground" between its current methodology and the methodology recommended by the APC Panel and the pharmacy stakeholder group.[12] CMS determined that this figure would be appropriate after analyzing two methods of allocating pharmacy overhead to drugs by categories of overhead. In the first analysis, based on categories recommended by MedPAC, CMS calculated an allocation of $165 million to separately payable drugs.[13] In the second analysis, based on the pharmacy stakeholder proposal, CMS calculated a reallocation of $153 million, and later $157 million.[14] Both analyses produced an estimated cost of separately payable drugs equal to ASP plus four percent.[15] CMS cites these analyses as evidence that $150 million would be an

[10] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.
[11] 74 Fed. Reg. at 35328.
[12] Id.
[13] Id. at 35331.
[14] Id.
[15] Id.

appropriate amount to reallocate from packaged to separately payable drugs. We have not been able to replicate this analysis, however, because the agency has not made its overhead assignments public. We ask CMS to release this information if the agency decides to rely on this analysis for its payment methodology for drugs in the future.

Our analysis of CMS's methodology found that CMS should reallocate more than $150 million in pharmacy overhead to separately payable drugs. When CMS estimated the total pool of pharmacy overhead associated with packaged drugs to be $395 million, it used only drugs with HCPCS codes and ASPs. A significant number of drugs that account for a large portion of overhead do not have HCPCS codes or ASPs, however, and by excluding these drugs from the analysis, CMS identified no more than half of the total pool of overhead costs. In fact, although surveys indicate that pharmacy overhead should be at least 25 percent of total pharmacy costs, CMS's estimated $395 million pool of overhead costs is only 12.7 percent of its total estimated costs of drugs. If CMS measured the size of the pool correctly, it would be able to allocate more than $150 million of it to separately payable drugs.

In addition, through conversations with our members and a review of the OPPS claims data, we found that significant variations in hospital billing practices also may contribute to CMS's underestimation of the size of the overhead pool. We found that 41 percent of hospitals have no cost data in CMS's claims data file where line items were reported with HCPCS codes and revenue code 250, the standard revenue code used by many hospitals to report packaged drugs. It appears that hospitals may have used different, but permissible, approaches to billing for packaged drugs. For example, under one approach, hospitals may have reported their packaged drugs with revenue code 250 and the associated charges and units and no HCPCS codes because HCPCS codes are not required to be reported for packaged drugs. Under another approach, hospitals may have reported their packaged drugs and the associated HCPCS codes using revenue code 250, but the actual HCPCS codes may not have printed on the claim due to the settings on the provider billing systems. Under yet a third approach, hospitals have indicated that they have been instructed by their Medicare contractors that they are not permitted to report HCPCS coded drugs using revenue code 250. These hospitals likely would have removed the HCPCS codes from their claims and resubmitted them for payment. Under all of these approaches, CMS would not receive cost information associated with the packaged drugs with HCPCS codes. In contrast, hospitals that reported their packaged drugs with HCPCS codes and revenue code 636 would have printed the HCPCS codes on the bill, and CMS would have received the cost information from all hospitals that report in this manner. CMS also would have received cost data for packaged drugs with HCPCS codes from hospitals who have changed their billing systems to allow HCPCS codes to print on the bill when reported with revenue code 250.

This variety of approaches exists because CMS's guidance gives hospitals flexibility to use whatever revenue codes most appropriately reflect internal accounting of revenues and expenses. CMS also has permitted its contractors flexibility in implementing edits and other measures that they deem appropriate, even though CMS historically has indicated that contractors should not edit for HCPCS and revenue code combinations unless specified by CMS.[16]

CMS's failure to recognize this variation in billing approaches contributes to its underestimation of the size of the overhead pool. CMS seems to assume that its analysis captures the costs for all packaged drugs with HCPCS codes and ASPs, even though CMS permits billing for these packaged drugs without detailed coding. A substantial number of claims for packaged drugs are not included in CMS's analysis because the HCPCS codes were not on the bills. We recommend that CMS instruct hospitals to report all HCPCS-coded drugs with revenue code 636 and explain to hospitals why following this instruction and submitting HCPCS codes for packaged drugs will help produce more accurate payment rates. This also is consistent with the National Uniform Billing Committee's (NUBC) guidance on the issue and will help provide CMS with the data it needs to calculate accurate estimates of the total acquisition and overhead costs of drugs in the future.

Because it is clear that CMS has underestimated the size of the overhead pool, CMS should reallocate substantially more than the $150 million it proposes. We recommend that at least half of the $395 million pool be reallocated for 2010.

3. CMS should use an ASP file that is better aligned with its claims and cost report data to determine the ASP + X percent for drugs in the final rule for 2010.

We also found that CMS's choice of ASP file to use in its analyses causes it to underestimate the costs of separately payable drugs. CMS compares costs derived from 2008 claims data and 2007 cost reports to ASP data from the fourth quarter of 2008 (the April 2009 ASP file), although the 2008 ASPs reflect drug price increases that are not included in hospitals' cost and claims data. We compared CMS's estimated costs from the claims data to ASP data from the first quarter of 2008 (the July 2008 ASP file), a data files that more accurately reflects hospitals' acquisition costs at the time of the claims data were submitted to CMS. This comparison produced a payment rate for separately payable drugs of ASP plus zero percent, as opposed to the CMS calculation of ASP minus two percent, before reallocating the pharmacy overhead pool. Therefore, CMS should use an ASP file that is better

[16] See, e.g., Claims Processing Manual, ch. 17, sec. 70 ("On claims to FIs the drug is identified by the appropriate HCPCS code for the drug administered and billed under revenue code 0636 unless specific instruction states otherwise."); we understand that some contractors have instructed hospitals to report packaged drugs with revenue code 250 and no HCPCS codes.

aligned with its claims and cost report data to determine the percentage over ASP for reimbursement of drugs in the final rule for 2010. CMS also should continue to update payment rates quarterly using the current ASP file.

4. CMS should remove 340B hospital data from the ASP + X percent calculation and continue to pay 340B hospitals at the same rate as non-340B hospitals.

We have identified an additional problem with CMS's methodology. CMS compares its estimated mean unit costs to ASP to determine a payment rate for all hospitals. CMS includes hospitals that purchase drugs under the 340B program in its analysis, although the deeply discounted prices available to these hospitals are excluded from the ASP calculation. As a result, CMS underestimates the aggregate costs of drugs for most hospitals, and the ASP-based rate that CMS produces by comparing aggregate costs to ASP is too low. When the 340B hospitals are excluded from CMS's analysis, the mean unit cost rises to ASP plus three percent from ASP minus two percent. ACCC believes the 340B program helps participating hospitals serve poor and uninsured patients, but we also believe that the program was not intended to harm other hospitals' ability to provide care by reducing their Medicare reimbursement.

5. CMS should reimburse the acquisition cost of separately payable drugs at ASP plus six percent; package payment for packaged drugs at ASP plus 100 percent; calculate the pharmacy overhead pool using the proposed methodology, with the corrections addressed above; and then allocate the pool to reimburse for the pharmacy services of separately payable drugs.

We understand that CMS would like specific recommendations on a revised method of reimbursing acquisition and overhead costs of separately payable drugs. The following approach combines the recommended changes discussed above into an accurate payment methodology with minimal administrative burdens for CMS or hospitals.

1. Reimburse the acquisition cost of separately payable drugs at no less than ASP plus six percent. As discussed above, this rate is consistent with the statute's requirements for reimbursement in the absence of acquisition cost survey data.

2. Package payment for drugs that are not separately payable at ASP plus 100 percent. In the Proposed Rule, CMS explains that it assumes that "packaged drugs and biologicals, as a group,

typically have an aggregate absolute pharmacy overhead cost (direct and indirect) that exceeds the acquisition cost of the packaged drugs and biologicals." In general, we believe that packaging payment for drugs below the current packaging threshold at ASP plus 100 percent would sufficiently reflect the acquisition and overhead costs of those drugs, on average.

3. Calculate a pool of pharmacy overhead using CMS's proposed methodology, incorporating the corrections recommended in our comments.

4. Allocate the pharmacy overhead pool to separately payable drugs as reimbursement for pharmacy services and handling. There are several administratively simple ways CMS could allocate this pool. It could make a flat payment per separately payable drug administered, make payment based on the three tiers of pharmacy services as recommended previously in the stakeholder proposal, or add the allocation from the pool to the drug payment as a percentage of ASP, as CMS proposes to do with the $150 million reallocation in the Proposed Rule. This payment would be packaged with the payment for the drug and would be made automatically with the drug payment. It would not require CMS to unbundle payment, and hospitals would not be required to bill additional codes.

We urge CMS to implement this simple, stable, and appropriate approach in 2010.

6. CMS should make separate payment for all drugs with HCPCS codes, or, at a minimum, freeze the packaging threshold for drugs at the current level of $60, and continue to pay separately for anti-emetics.

In 2010, CMS proposes to raise the packaging threshold to $65.[17] We are concerned that the continued use and increase of any threshold could harm hospitals' ability to provide essential cancer care. We ask CMS to make separate payment for all drugs with HCPCS codes as it does in physician offices. At a minimum, CMS should freeze the packaging threshold at no more than $60.

[17] 74 Fed. Reg. at 35309.

ACCC also is concerned with CMS's proposal to no longer pay separately for anti-emetics.[18] 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.[19] Some of our members already have told us that if this proposal were to go into effect, hospitals likely would choose to give patients the separately payable anti-emetic instead of the packaged therapies. Some members of the Advisory Panel on APC Groups (APC Panel) echoed this concern.

B. Payment for Radiopharmaceuticals

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

CMS proposes to continue to package payment for diagnostic radiopharmaceuticals and contrast agents, regardless of their cost per day. Although we understand that CMS has increased payments for many diagnostic and imaging services as a result, we are concerned that the increase might not be sufficient to protect beneficiary access to important cancer therapies and diagnostic services. Radiopharmaceuticals are extremely complex therapies to prepare and administer. Preparation and administration of each drug requires a unique bundle of services, such as compounding, infusions, and scanning of the patient to assess bio-distribution of the therapy. The costs of these services vary for each therapy, and many of these costs are not reimbursed adequately under the OPPS. Contrast agents also vary in cost and may not be compensated adequately through the OPPS rates for imaging services.

CMS explains that it believes these drugs function as supplies and are not subject to the statutory payment requirements for specified covered outpatient drugs (SCODs).[20] This interpretation disregards both the plain language of the statute and Congressional intent behind the detailed statutory payment requirements for SCODs. We urge the agency to comply with the statute and reinstate separate payment for diagnostic radiopharmaceuticals and contrast agents.

2. CMS should reimburse therapeutic radiopharmaceuticals based on ASP, using data reported voluntarily by manufacturers.

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[18] Id. at 35320-21.
[19] Id.
[20] Id.

CMS again proposes to allow manufacturers to submit ASP information for any separately payable therapeutic radiopharmaceutical in order for therapeutic radiopharmaceuticals to be paid based on ASP beginning in 2010 under the OPPS.[21] This recommendation is in line with previous APC Panel recommendations and also recommendations from ACCC and other stakeholders in the past. ACCC recommends CMS to institute this proposal for 2010, but we also recommend that CMS provide a transition period of at least six months, using the current reimbursement methodology, until manufacturers have submitted ASP data for use by CMS.

CMS also proposes to require the ASP data to be submitted for a "patient-specific dose" or "patient-ready form" of the radiopharmaceutical. It is not clear how "patient-ready form" would be defined, however. We request that CMS work with manufacturers to determine how best to define this term.

II. Proposed Payment for Drugs with Pass-Through Status

A. CMS should not implement the proposed change to the definition of the pass-through eligibility period for new drugs

CMS proposes to revise the regulation governing the eligibility period for pass-through status for new drugs because it believes the current regulation is inconsistent with the statute.[22] Rather than beginning the pass-through payment eligibility period for "new" drugs on the first date on which pass-through payment is made for the item,[23] CMS proposes that the pass-through payment eligibility period for a drug would begin on the date on which payment first is made for a drug as an outpatient hospital service under Part B.[24] Under the proposal, pass-through status would expire on a quarterly basis, rather than on an annual basis.[25] CMS also would use the date of first sale for a drug in the U.S. following FDA approval as a proxy for the date of first payment under Part B.[26]

ACCC believes that these proposals are contrary to the statute and Congressional intent to protect access to new drugs, and we are dismayed that CMS proposes changes that would weaken this protection by shortening the period of eligibility for pass-through status. CMS correctly recognizes that the proposed policy "could have the effect of a shorter period of pass-through payment for some

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[21] Id. at 35309.
[22] SSA § 1833(t)(6)(C)(i)(II).
[23] 42 C.F.R. § 419.64(c)(2).
[24] Id. at 35314-15.
[25] Id. at 35316.
[26] Id. at 35315.

drugs and biologicals than would be the case under our current policy."[27] CMS also notes that the pass-through eligibility period and pass-through payment period currently are the same but would be different under the proposed rule.[28] The statute does not establish an eligibility period that is different from the payment period, however; it establishes a single "limited period of payment."[29] In addition, the "limited period of payment" under the pass-through provisions does not include the period between the date of first sale of a drug and the approval of an application for pass-through payment and issuance of a code for that new drug. Congress established a different payment methodology for that initial period for new drugs for which a HCPCS code has not yet been assigned,[30] therefore the period of pass-through payments begins once a pass-through application is approved and a new code is issued. CMS's current regulation correctly recognizes that the period of payment begins "on the date that CMS makes its first pass-through payment for the drug or biological."[31] This regulation is consistent with the SSA and should not be changed.

We also are concerned that CMS incorrectly assumes that Medicare beneficiaries are "among the first" to use new drugs and payment would be made for these drugs under the OPPS on the date of first sale.[32] CMS fails to recognize that some drugs are used primarily in populations not covered by Medicare, such as patients under age 65. Therefore, Medicare beneficiaries would not be "among the first" to use these drugs. In addition, delays in distribution and manufacturing mean that the first payment for a drug under the OPPS can be long after the date of first sale.

For these reasons, the date of first sale should not be used as a proxy for the date on which Medicare begins to collect data on these drugs. CMS should continue to use the date on which pass-through payment is first made as the beginning date of eligibility for pass-through status and continue to make pass-through payments expire on an annual basis.

III. CMS should continue to reimburse brachytherapy sources at charges adjusted to cost and should retain APC 0182T for high dose rate electronic brachytherapy in New Technology APC 1519.

Through December 31, 2009, CMS is statutorily required to reimburse brachytherapy sources as charges adjusted to cost, as it has done for the past five

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[27] Id. at 35316.
[28] Id. at 35315.
[29] SSA § 1833(t)(6)(C).
[30] SSA § 1833(t)(15).
[31] 42 C.F.R. § 419.64(c)(2).
[32] 74 Fed. Reg. at 35313.

and a half years.[33] For 2010, CMS proposes to adopt the general OPPS prospective payment methodology for brachytherapy sources.[34] However, there are a number of problems with the claims data that CMS would use to set the relative payment weights for brachytherapy services. As CMS itself recognizes, there is high variability in payment rates for brachytherapy sources.[35] Such variability calls into question the validity of the claims data on which CMS would rely to establish median costs. So does the fact that half of the current brachytherapy APCs have proposed payment rates based on 50 or fewer hospitals reporting cost data. Finally, anomalies in the claims data for brachytherapy services indicates that the data are inaccurate. Because instability in payment rates resulting from the use of invalid data to set the relative payment weights could jeopardize hospitals' ability to provide this important treatment option, ACCC urges CMS to continue to reimburse brachytherapy sources at charges adjusted to cost.

CMS also proposes to reassign Current Procedural Terminology (CPT) code 0182T, High dose rate electronic brachytherapy, per fraction, from New Technology APC 1519 to APC 313 for Brachytherapy.[36] CMS states that its claims data are sufficient to propose this reassignment; however, CPT 0182T became effective on July 1, 2007, providing only 1.5 years of OPPS claims data. As we have said repeatedly in the past, it often takes our members over a year to change their charge masters and billing systems to reflect services using new technologies. Indeed, CMS's proposed reassignment of 0182T is based upon very limited claims data – 100 single claims or less than one percent of total 2008 claims in APC 313. Because many patients receive multiple fractions, these data likely reflect even fewer total patients. The CMS median claims file indicates that there were 11 hospitals that reported data for CPT 0182T in 2008, and only three of the 11 hospitals had single procedure claims that CMS used for calculating the median cost.

CMS states that based on hospital claims data for 0182T, "its hospital resource costs are similar to those of other services assigned to APC 0313."[37] The brachytherapy procedures currently included in APC 313 do not include the cost of the Iridium-192 brachytherapy device, however, that is paid separately in addition to the procedure. The current payment for electronic brachytherapy includes the cost of the device. As there is no separate payment for the electronic brachytherapy source, the high resource cost required to perform electronic brachytherapy is not similar to the other brachytherapy procedures included in APC 313. Because of this – and the paucity of claims data – CMS should retain CPT code 0182T in New

[33] SSA § 1833(t)(16)(c).
[34] 74 Fed. Reg. at 35342.
[35] Id.
[36] Id. at 35304.
[37] Id.

Technology APC 1519 until it collects appropriate and sufficient claims data to place it in another permanent APC that is more similar clinically and with respect to resource use.

IV. CMS should reinstate separate payment for radiation oncology guidance services.

ACCC recognizes CMS's desire to continue to transform the OPPS into a system comprised mostly of bundled and packaged services. We remain concerned, however, that CMS's recent expansion of packaging, including packaging of guidance services, may negatively affect patients and hospitals. CMS proposes to continue to package payment for guidance and other ancillary services that often are performed with other services.

ACCC urges CMS to reinstate separate payment for radiation oncology guidance procedures. These services are vital to the safe provision of radiation therapy, and unconditionally packaging payment for them may discourage hospitals from providing them. ACCC also would like definitive information from CMS as to the exact impacts of expanded packaging based on CMS's experience to date. For example, we request the APC values and volume comparisons for these packaged services and their comparison to the levels when they were paid separately. We remain concerned that packaged payment may discourage use of appropriate services, such as guidance procedures, that are critical to providing quality care.

V. CMS should institute the proposal to allow certain non-physician practitioners to supervise outpatient therapeutic services, but should not implement its proposed interpretation of "in the hospital" and the proposed interpretation of "immediately available" and should clarify that its direct supervision amendments do not apply to services furnished in a department of a hospital that is located on the campus of that hospital.

CMS proposes to allow non-physician practitioners – specifically physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse-midwives – to directly supervise all hospital outpatient therapeutic services that they may perform themselves in accordance with their State law and scope of practice and hospital-granted privileges, provided that they continue to meet all additional requirements, including any collaboration or supervision requirements as specified in the regulations.[38] ACCC supports this proposal because it will help protect access to quality care, provided in an efficient manner, while also protecting

[38] Id. at 35362-35363

patient safety. We thank CMS for proposing it and urge its implementation in the final rule.

In the 2009 OPPS final rule, CMS made a "clarification" of the physician supervision requirement. This "clarification" was actually a change from what CMS rules actually required since 2000. It also proved to be confusing, difficult to implement, and a barrier to patient access. ACCC and other stakeholders held meetings with CMS with the hopes of making the new requirements less burdensome on patients and providers. CMS now proposes to "refine the definition of direct supervision of hospital outpatient therapeutic services for those services furnished in a hospital and in on-campus [provider-based departments] PBDs of a hospital."[39] "Direct supervision" would mean that "the supervisory physician or nonphysician practitioner must be present on the same campus, in the hospital or the on-campus PBD of the hospital as defined in [the provider-based regulations at 42 CFR] §413.65, and immediately available to furnish assistance and direction throughout the performance of the procedure."[40] "In the hospital" would be defined as "areas in the main building(s) of a hospital that are under the ownership, financial, and administrative control of the hospital; that are operated as part of the hospital; and for which the hospital bills the services furnished under the hospital's CCN."[41]

We appreciate CMS's efforts to clarify its regulations, but we disagree with the definition of "in the hospital." We believe this definition is arbitrary, difficult to apply, and likely to inhibit the efficient provision of safe, quality care. CMS expresses concern about the ability of physicians to provide supervision on "extensive hospital campuses" where the physician could be "far away from the location where hospital outpatient services are being furnished that he or she could not intervene right away."[42] This concern may be valid, but it is not addressed by requiring the supervising physician to be located in space under the hospital's control. In many hospitals, parts of the hospital campus that meet CMS's proposed definition are immediately adjacent to parts that do not. For example, a physician could lease office space from the hospital that is across the hall from an infusion suite. While working in that leased space, a physician could be immediately available to provide assistance and direction, regardless of whether the office is under the hospitals' control. It would not be logical to prohibit that physician from providing supervision simply because he or she is on the other side of the hall. At a time when the need for physicians and hospitals to provide care most efficiently is of utmost importance, CMS's proposed definition would require hospitals to forgo the most logical supervision arrangements and spend their limited resources on hiring

[39] Id. at 35366.
[40] Id. at 35366-67.
[41] Id. at 35367.
[42] See Id.

additional physicians to be available to provide supervision. We recommend that CMS not implement its proposed definition of "in the hospital" and revise the definition of "direct supervision" to require instead that the supervising physician be immediately available to furnish assistance and direction, without regard for whether the physician is on hospital-controlled property at all times.

We also ask that CMS not adopt the proposed interpretation of "immediately available" as meaning that "the physician or nonphysician practitioner must be prepared to step in and perform the service, not just to respond to an emergency."[43] In the event that a patient suffers an adverse event, the most likely response will be to stop the therapeutic intervention and stabilize the patient. It would not be necessary, therefore, for the supervising physician to perform the service. We ask CMS to remove this statement from its final guidance because it is not necessary and will impede hospitals' ability to provide appropriate supervision of outpatient therapeutic services.

Finally, we ask CMS to once again clarify its statements about its interpretation of the physician supervision requirements. CMS's restatements and clarifications only have created more confusion and concern about unfair enforcement actions for hospitals. We ask CMS to reiterate in the final rule that the following statement about the supervision rules from the April 7, 2000 final rule with comment period remains the agency's policy: "Our proposed amendment of Sec. 410.27 to require direct supervision of hospital services furnished incident to a physician service to outpatients does not apply to services furnished in a department of a hospital that is located on the campus of that hospital."[44]

VI. CMS should work with providers and specialty societies in determining which new measures to add to the quality reporting requirement.

ACCC supports the proposal to add oncology related measures to the quality reporting requirements for 2010.[45] ACCC also supports the addition of more oncology related measures for 2011 and suggests that CMS continue to work with the oncology specialty societies, providers, and other quality societies in determining the best measures to add to the program. Oncology measures can be vital in determining the true quality of care, and ACCC supports their inclusion in this initiative.

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[43] Id.
[44] 65 Fed. Reg. 18433, 18525 (April 7, 2000).
[45] 74 Fed. Reg. at 35395.

VII. CMS should revise the DOS regulations to provide that the date of service for certain complex diagnostic laboratory tests is the *date of performance* rather than the *date of collection*.

Finally, we ask CMS to revise its regulations on the DOS for certain complex diagnostic laboratory tests. Under Medicare regulations, the date of service for laboratory tests is the date on which the specimen was collected (*e.g.,* when the biopsy was performed that harvested the tissue specimen), unless the test is performed on a specimen stored for at least 14 days following the date the patient was discharged from the hospital.[46] If a test is performed on a specimen obtained during a hospital procedure within 14 days of discharge, it is deemed to have been provided on the date the specimen was collected, *i.e.,* the date on which the patient was a hospital patient. As a result, under Medicare regulations, such a test is treated as if it was furnished by the hospital, even though the hospital may not have ordered, performed, or used the test.[47] These regulations create disincentives for hospitals to provide access to a narrow class of advanced diagnostics.

To protect access to these complex laboratory tests, ACCC asks CMS to revise the regulation at 42 C.F.R. § 414.510 to establish that the date of service for certain advanced diagnostics would be the *date of performance* rather than the *date of collection*. This revised treatment should apply only to advanced diagnostic tests that meet the following criteria:

- The test is an analysis of DNA, RNA, chromosomes, proteins, or metabolites that detects, identifies or quantitates genotypes, mutations, chromosomal changes, biochemical changes, cell response, protein expression, or gene expression or similar method, or is a cancer chemotherapy sensitivity assay or similar method, but not including methods principally consisting of routine chemistry or routine immunology;
- The specimen was collected while the patient was undergoing a hospital procedure;
- The test was performed after the period during which the individual was a patient of the hospital and the specimen was collected;
- The results of the test do not guide the treatment provided during the hospital stay or encounter when the specimen was collected;
- The test was reasonable and medically necessary for the treatment of an illness;
- The test is developed and performed by a laboratory that is independent of the hospital in which the specimen was collected; and

[46] 42 C.F.R. § 414.510.
[47] 42 C.F.R. §§ 411.15(m) and 410.42.

- The test is not furnished by the hospital where the specimen was collected to a patient of such hospital, directly or under an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the hospital's patients.

VIII. 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. We particularly urge CMS to pay at least ASP plus six percent for the acquisition cost of separately payable drugs and to make an appropriate adjustment for pharmacy overhead. ACCC appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact Matthew Farber at (301) 984-9496, if you have any questions or if ACCC can be of further assistance. Thank you for your attention to these very important matters.

Respectfully submitted,

Luana R. Lamkin

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