

Submitter : Dr. Frederick Cahn
Organization : BioMedical Strategies LLC
Category : Device Industry

Date: 01/09/2006

Issue Areas/Comments

**Classification assignments of
HCPCS codes identified in
Addendum B with comment
indicator NI.**

Classification assignments of HCPCS codes identified in Addendum B with comment indicator NI.

See Attachment regarding classification assignments of HCPCS codes identified in Addendum B with comment indicator NI

CMS-1501-FC-17-Attach-1.DOC

January 9, 2006

Mark McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244

Re: CMS-1501-FC, New CPT codes 15170, 15171, 15175 and 15176 and their assignments to APC classifications.

Dear Dr. McClellan:

I wish to submit a comment on the Final Rule With Comment Period for the Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates. This Final Rule was published in the Federal Register, Vol. 70, No. 217 on November 10, 2005.

Effective in 2006, the CPT codes regarding skin grafts and related procedures were updated in a section of the CPT now titled "Skin Replacement Surgery and Skin Substitutes." In CPT 2006, the codes 15342 and 15343 that described skin substitutes as well as codes 15350 and 15351 that described allograft were deleted. Codes 15300 and 15320 now describe application of allograft skin for the first 100 sq cm or less at different anatomic locations, and add-on codes 15301 and 15321 describe allograft skin for each additional 100 sq cm at these anatomic locations. Also, new codes 15170 and 15175 describe acellular dermal replacement for the first 100 sq cm or less, and new add-on codes 15171 and 15176 describe acellular dermal replacement for each additional 100 sq cm at different anatomic locations.

I am concerned about the assignment of new CPT codes for skin replacement to APC classifications in the Final Rule. My concern is based on my experience as chairman of ASTM International subcommittee F04.41, Terminology and Classification of Tissue Engineered Medical Products. My subcommittee developed and published ASTM International standard F2311-03, "Standard Guide for Classification of Therapeutic Skin Substitutes," which presents useful background information on procedures utilizing skin substitutes as well as a classification system for skin substitutes. The standard F2311-03 was one of the resources used by a committee at the American Burn Association to create these new codes for the AMA.

In "Addendum B" of the Final Rule the new and changed codes for skin allograft, skin replacements and substitutes were assigned to APC classifications without the benefit of claims data. In some cases, I believe that the APC assignments of the new codes do not adequately represent the outpatient hospital resources required to perform these procedures.

CPT 15300, "allograft skin for temporary wound closure, trunk, arms, legs, first 100 sq cm," was assigned to APC 27 and its add-on code of 15301 was assigned to APC 25, but CPT 15320, "allograft skin for temporary wound closure, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, first 100 sq cm," and its add-on code 15321 were both assigned to APC 25. Moreover, CPT codes 15170 and 15175, "acellular dermal replacement for the first 100 sq cm or less" and their add-on codes 15171 and 15176 are all assigned only to APC 24.

However, the hospital resources required to perform all of these procedures are very similar. For allograft, as well as for the skin replacements, the anatomic location has little effect on hospital

resources. Also, hospital resources to apply the acellular dermal graft are very similar to the application of allograft skin for temporary wound closure. Both procedures are used in skin replacement surgery to accomplish immediate wound closure and healing by first intention. In both cases the graft material must be trimmed to the wound margins and anchored using suture, staple, or other fixation means. The operating time required is similar and similar anesthesia, dressings and postoperative care would be required. The resources required for these procedures should be similar to those described by the discontinued allograft codes, 15150 and 15151, for which CMS should have claims data. Similar considerations may apply to procedures to apply other skin substitutes, when they are used for healing by first intention.

I believe that the hospital resources and thus the APC assignment for 15170, 15175 and 15320 should be the same as that for 15300, APC 27. The APC assignment for add-on codes 15171 15176 and 15121 should be the same as that for 15301, APC 25. Placing CPT codes 15170 and 15175 and add-on codes 15171 and 15176 in APC 24, for which the payment is only \$92.32, when the resources required are similar to those of 15300 and 15301, for which payments for APC 27 and 25 are \$1,082.84 and \$315.71, respectively, may have the effect of denying Medicare beneficiaries access to these procedures, since hospitals may discourage physicians from performing them in their outpatient facilities. I urge CMS to correct this problem in the 2006 HOPPS payments.

Sincerely yours,

Frederick Cahn, Ph.D.

BioMedical Strategies LLC

Submitter : Dr. William Van Decker
Organization : American Society of Nuclear Cardiology
Category : Health Care Professional or Association

Date: 01/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1501-FC-18-Attach-1.DOC



AMERICAN SOCIETY OF
NUCLEAR CARDIOLOGY

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January 9, 2006

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

File Code: CMS-1501-FC

Re: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and Calendar Year 2006 Payment Rates: Final Rule

Dear Dr. McClellan:

The American Society of Nuclear Cardiology (ASNC) is pleased to submit these comments in response to the Final Rule for the 2006 Hospital Outpatient Prospective Payment System (HOPPS) published in the November 10, 2005 Federal Register. ASNC is a greater than 5,000 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology, develops standards and guidelines for training and practice, promotes accreditation and certification in this sub-specialty field, and is the principal advocacy voice for nuclear cardiology.

The Society would first like to thank the Centers for Medicare & Medicaid Services (CMS) for their thoughtful consideration of our HOPPS comments over the past few years – in particular the agency's actions over the past year regarding Adenosine and cardiovascular positron emission tomography diagnostic procedures. We believe that the consensus changes that have occurred through dialogue have played a vital role in supporting quality and maintaining access to the powerful clinical tools of nuclear cardiology.

The primary issues that ASNC will discuss in these comments involve CMS' changes for radiopharmaceutical payment policy and the agency's classification of Dipyridamole as a bundled service.

Proposed Changes in Payment Policy for Radiopharmaceuticals (RPs)

ASNC appreciates the agency's specification in the final rule that the overall hospital charge adjusted to cost (CCR) will be used for calculating separate payable RPs as well as clarifying language that CMS intends for hospitals to include RP overhead costs in the hospital charge for each radiopharmaceutical. We will be updating ASNC members about these changes and will be monitoring hospital implementation of this payment policy.

There are a number of issues that CMS may wish to consider during 2006 as the agency mulls over proposed changes for RP payment policy for 2007. We understand that hospitals encounter three barriers that prevent them from fully accounting for their RP costs: (1) is external non-Medicare contracts, which are in place and preclude some hospitals from contractually raising their prices more than a specific percentage each year. This restriction limits the hospital's ability to raise the price such that their actual RP costs will be accounted for when reduced by the hospital CCR; (2) is a perception that the 20 percent co-payment may be based on the hospital charge and not the hospital cost; there is a concern that high co-payments may place undue financial burdens on Medicare beneficiaries, and hospitals are reluctant to significantly raise their rates; (3) is a disconnect and lack of communication or identified path in some hospitals where the costs including overhead are identified by the nuclear medicine department but the charges are set independently by the finance or other hospital department which does not fully understand all the costs associated with the different RPs.

ASNC encourages CMS to analyze the claims data regarding the actual implementation of the American Hospital Association radiopharmaceutical revenue codes 0343 and 0344 that became effective for hospital use in October 2004. We believe it is critical to understand the effect these codes could have on the department specific cost to charge ratios in the future. At present, we would not support use of the department specific CCR for radiopharmaceuticals reimbursement rates until we can analyze adoption and impact, which we would not expect to be accurately done for several years.

We also remain concerned regarding the effect of cost compression using any CCR method. This will result in under payment for more expensive RPs -- those costing greater than \$350. ASNC recommends that CMS use external data to verify and pay for radiopharmaceuticals based on invoice acquisition costs plus overhead and handling fees.

ASNC urges CMS to clarify CY 2006 and any proposed 2007 radiopharmaceutical payment policy as it relates to the cost report and final settlement to the hospitals. We have received reports that the department specific CCR is also used during the Fiscal Intermediaries year-end final settlement and that the overall hospital CCR is only used for interim payments to the hospitals. CMS should clarify this process. We are uncertain about the implication of using two different CCRs; one to set payment (overall hospital CCR) to the individual hospital, and a different department specific CCR to establish the costs for RPs to classify by status indicator, "N" separately paid, and for the potential implications in final settlements with hospitals, and even for setting payment rates in future years. We request that the CMS use one CCR for RP payment rates and cost calculations, rather than two.

For reasons mentioned earlier we are concerned regarding future radiopharmaceutical payments based on charge-based payment rates or mean costs from hospital claims data. We appreciate that CMS will consider other options and methodologies, such as alternate sources of data, or developing a payment methodology using the invoice data submitted to carriers in the physician office setting. Clearly, CMS is trying to come forth with an equitable solution for all radiopharmaceuticals based on cost of acquisition. We recognize that there are many factors that complicate an easy solution.

Co-Insurance for Radiopharmaceuticals with Status Indicator "H"

In the final rule, CMS states that for separately payable radiopharmaceuticals in CY 2006 that the APCs will be subject to a 20% coinsurance. We did follow up with CMS staff regarding this statement and we were told that the 20% patient coinsurance is based on the hospital charges reduced to cost by the overall all hospital CCR. We respectfully request CMS clarify the statement in the final rule regarding coinsurance and publish this information in future transmittals. Some hospitals believe that the 20% coinsurance will be based on the hospital charge alone and they therefore are reluctant to raise their charges consistent with the new radiopharmaceuticals payment policy for CY 2006.

Appropriate Classification of Dipyridamole (J1245)

We would like to echo our previous concerns that we included in our comments on the proposed rule regarding the agency's classification decision regarding Dipyridamole. Currently, nuclear cardiology procedures utilize three major pharmacological stress agents: Adenosine (J0152 & C9223), Dipyridamole (J1245) and Dobutamine (J1250). While Dobutamine is a low cost stress agent that is used under very specific clinical indications, Adenosine or Dipyridamole is administered to the vast majority of cardiovascular patients undergoing pharmacological stress. In the 2005 HOPPS, both Adenosine and Dipyridamole were classified with a K status indicator and were therefore paid for separately outside of the procedure APC.

ASNC remains extremely concerned over CMS' decision to bundle Dipyridamole into the procedure in 2006, when the reported median cost is just under fifty dollars (\$48.85). While we understand that a threshold (\$50) was set for bundling certain items into the procedure APC, CMS should be receptive to making exceptions in cases where arbitrary payment policy may limit access and create perverse incentives to change medical practices based on factors other than individual clinical patient care. ASNC recommends that the agency move quickly in early 2006 and provide an exception for Dipyridamole so that patients are able to receive the stress agent that is most clinically effective for them.

The Society thanks CMS for the opportunity to submit these comments. Should you have any questions, please contact me or Christopher Gallagher, Director of Health Policy, at 301-493-2310 or via email at gallagher@asnc.org

Sincerely,

William Van Decker, MD, FACC,
Chair, ASNC Government Relations Committee

CMS-1501-FC-19

Submitter : Kitty Vineyard
Organization : American Burn Association
Category : Association

Date: 01/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-FC-19-Attach-1.PDF

January 9, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
C5-01-17
US Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244

Re: CMS-1501-FC. Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates
Assignment of new CPT codes for skin replacement surgery and skin substitutes to APC classifications.

Dear Dr. McClellan:

The American Burn Association (ABA) sincerely appreciates the opportunity to comment on the 2006 Medicare Hospital Outpatient Prospective Payment System (HOPPS) final rule. The American Burn Association represents the nation's burn surgeons, nurses, therapists, and other members of the burn team, and the nation's leading medical institutions with burn centers who together provide therapeutic and surgical services for burn patients and other patients diagnosed with extensive and/or life-threatening skin diseases.

Following careful review of the 2006 HOPPS final rule, the ABA would like to comment on the assignment of APC classifications for new 2006 CPT codes for skin replacement surgery and skin substitutes which are listed with an "NI" indicator in the Final Rule. Our comments fall into two categories: hospital resource utilization and clinical coherence of the APCs to which the new codes have been assigned on an interim basis.

Background

The American Burn Association initiated, developed and proposed the new codes to the AMA with collaboration of other interested specialty societies. The ABA also participated in the assignment of RVU values for the new codes. We believe that our member surgeons and burn center hospitals are familiar with these procedures as well as the skin replacements and skin substitutes, and the physician effort and hospital resources needed to perform them.

As a result of the AMA revisions, certain codes were deleted. They are codes 15342-15343 that described both tissue cultured and acellular skin substitutes and codes 15350-15351 that described skin allograft. New codes were added to more specifically describe skin allograft, skin replacements, and skin substitutes. The new codes for skin allograft, skin replacements, and skin substitutes are:

15150-15157 describe tissue cultured epidermal autografts; 15170-15176 describe acellular dermal replacement; 15300-15321 describe allograft skin for temporary wound closure; 15330-15336 describe acellular dermal allograft;

15340-15341 describe tissue cultured allogeneic skin substitute;

15360-15366 describe tissue cultured allogeneic dermal substitute;

15430-15431 describe acellular xenograft implant.

Hospital Resource Utilization

The ABA believes that several of the interim assignments substantially underestimate the hospital resources required to perform these procedures in an outpatient setting. Hence, the resultant payment reduction for hospitals could adversely affect the availability of these skin replacement and skin substitute procedures for Medicare beneficiaries.

CPT code 15300 (Apply skin allograft trunk, arms, legs) is assigned to APC 27, with a payment rate of \$1082.84. In contrast, code 15320 (Apply skin allograft face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits) is assigned to APC 25 with the lower payment rate of \$315.71. The anatomic areas included in code 15320 represent greater difficulty and time for allograft application and, therefore, increased hospital resource consumption for them. Hence, the ABA believes code 15320 should be moved to APC 27 to reflect this fact.

CPT codes 15170 and 15175 (acellular graft) are assigned to APC 24 with the low payment rate of \$92.32. Hospital resources to apply the acellular graft are quite similar to those for code 15300 (Apply skin allograft). The ABA believes these codes should be moved to APC 27 as well.

In summary and based on the opinion of our members who were involved in the development of the new CPT codes, we believe that the resources required for CPT codes 15170, 15175, 15320, 15340, 15360, 15365, 15420, and 15430 are essentially equivalent to that for 15300 (Apply skin allograft) which is assigned to APC 27 and for which utilization of resources can be estimated from deleted code 15350. The ABA believes, therefore, that the foregoing primary codes should be moved to APC 27.

As well, the resources required for add-on codes 15171, 15176, 15321, 15341, 15361, 15366, 15421 and 15431 would be essentially similar to those for code 15301 (Apply skin allograft, add on) which is assigned to APC 25 and can be estimated by using claims data for deleted code 15151. The ABA believes, therefore, that the foregoing add-on codes should be moved to APC 25.

Clinical Homogeneity or Coherence

APC 24 currently includes procedures involving repair and reconstruction of nail bed (11760, 11762), repair of superficial wounds and layer closure of wounds (12001-12046) (12051-12056) and many of the new skin substitute and skin replacement codes discussed above. The ABA strongly believes the placement of the new skin substitute or skin replacement codes in APC 24 violates the clinical homogeneity rule which requires procedures or services in each APC group to relate generally to a common organ system or cause of disease, have the same degree of extensiveness, and use the same method of treatment (surgical, etc.).

While the new codes do involve the same organ system as others in APC 24 and do involve the same type of treatment (surgical), we believe the rule is violated regarding the extensiveness provision. The new codes represent procedures that require application of a purchased product, which themselves require specific resources and care prior to application. In addition, the clinical content of these procedures is essentially commensurate or nearly commensurate to harvest and application of an autogenous skin graft,

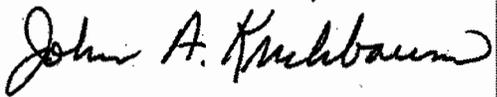
albeit without the use of a dermatome or blade. They are not at all comparable in extensiveness to the nail bed or wound repair procedures currently included in APC 24.

Further, the grouping of the new skin substitute or skin replacement codes with code 15040 (Harvest cultured skin graft) in APC 24 is inconsistent with the clinical homogeneity rule. Code 15040 involves removal of a very small piece of tissue followed by surgical closure of the wound, a procedure that a) is quite minimal and not nearly as extensive as the application of a skin substitute or replacement procedure and b) is seldom performed at all and rarely performed on an outpatient basis.

In summary, we believe the new skin substitute and skin replacement codes should be moved to the above-recommended APCs for the reasons listed.

Thank you for the opportunity to comment on this final rule. The ABA looks forward to contributing its expertise to CMS in order to foster proper payment for 2006 and in the future. If you have any questions on the issues discussed in this comment letter, please contact us. We will be happy to provide the information you require.

Respectfully submitted,

A handwritten signature in black ink that reads "John A. Krichbaum". The signature is written in a cursive style and is positioned to the left of a vertical line.

John A. Krichbaum, JD
Executive Director
American Burn Association

Submitter : Mr. James Greenwood

Date: 01/09/2006

Organization : BIO

Category : Health Care Professional or Association

Issue Areas/Comments

**Classification assignments of
HCPCS codes identified in
Addendum B with comment
indicator NL**

Classification assignments of HCPCS codes identified in Addendum B with comment indicator NL.

Please see attached.

GENERAL

GENERAL

Please see attached.

CMS-1501-FC-20-Attach-1.PDF



January 9, 2006

BY ELECTRONIC DELIVERY

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-1501-FC (Medicare Program; Changes to the Hospital
Outpatient Prospective Payment System and Calendar Year
2006 Payment Rates)**

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) final rule with comment period regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal

Register on November 10, 2005 (the "Final Rule").¹ BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

Representing an industry that is devoted to discovering new therapies and ensuring patient access to them, BIO supports CMS' ongoing efforts to address patients, providers, and manufacturers' concerns about access to quality care under the OPSS. This Final Rule implements many payment provisions that we believe will help protect beneficiary access to drugs and biologicals. We support CMS' decisions to reimburse vaccines at reasonable cost, apply a \$50 per administration threshold for separately-paid drugs and biologicals as required by the statute, make separate payment for all 5HT3 anti-emetic therapies even if they do not meet the packaging threshold, and allow market forces to determine appropriate payment for two biological therapies that CMS previously linked using the "equitable adjustment" authority. We also approve of the agency's implementation of most of the new drug administration Current Procedural Terminology[®] (CPT) codes under the OPSS.

BIO supports CMS' decision to reimburse most separately paid drugs, biologicals, and radiopharmaceuticals without pass-through status, including the specified covered outpatient drugs, at 106 percent of average sales price (ASP). We are disappointed, though, that CMS did not implement its proposal to make an additional payment for pharmacy handling costs. We also are concerned that the add-on payment for the pre-administration-related services associated with infusions of intravenous immune globulin (IVIG) will not be sufficient to ensure access to this therapy. Finally, we appreciate CMS' recent guidance regarding use of the new drug administration CPT codes but continue to be concerned about the payment rates for these services because they are set using two-year old data that lacks the granularity necessary to set appropriate rates. We also ask CMS to clarify that administration of IVIG should be billed using the chemotherapy infusion codes and to allow separate payment for infusions of hydration and non-chemotherapy drugs during the same visit. Most important, we ask

¹ 70 Fed. Reg. 68515 (November 10, 2005).

CMS to monitor access to drug and biological therapies in hospital outpatient departments and adjust rates as necessary to protect patient access to care. We discuss these issues in more detail below.

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

A. Payment for Drugs and Biologicals and Pharmacy Handling Costs

In the Final Rule, CMS explains that its data “indicate that payment for drugs and biologicals and pharmacy overhead at a combined ASP plus 6 percent rate would serve as the best proxy for the combined acquisition and overhead costs of each of these products.”² We disagree with this conclusion. Although we generally believe that ASP +6% is a reasonable proxy for hospitals’ average acquisition cost, we are concerned that it may not reflect the substantial costs associated with safely furnishing advanced therapies.

As the Medicare Payment Advisory Commission reported in June 2005, pharmacy handling costs are significant, making up 25-28 percent of hospital pharmacies’ direct costs, with drug acquisition costs accounting for the remaining 75-72 percent.³ These costs include salaries and benefits for the pharmacists and pharmacy technicians, as well as the supplies and equipment that are essential to patient safety and high quality care. Pharmacy professionals not only prepare drugs and biologicals for administration, but they also consult with physicians about the appropriate selection, dosage, and administration of drugs; perform quality assurance measures to verify that therapies are correctly prepared; and safely dispose of any unused medications. These safety measures are particularly important for preparing complex biologicals because many of these therapies must be stored and prepared under carefully controlled conditions to protect them from changes caused by changes in temperature and light. Without these quality and safety protections, errors involving these therapies are likely to occur.

² Id. at 68642.

³ Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

We are deeply concerned that CMS' decision to not make an additional payment for pharmacy handling costs will threaten hospitals' ability to continue to provide drugs and biologicals safely. Hospitals currently use reimbursement for drugs and biologicals to support these services, but as Medicare's reimbursement for most separately paid drugs drops to ASP plus 6 percent, hospitals will have less income to fund pharmacy salaries and benefits. Because their services are not separately reimbursed, hospitals could choose to reduce the number of pharmacists and pharmacy technicians they employ to make up for revenue shortfalls. As a result, pharmacies could be pressured to prepare more therapies in less time, and the number of medication errors could increase.

We urge CMS to reconsider this decision and to implement an additional payment for hospitals' pharmacy service and handling costs. We recommend that CMS work with hospitals to accurately measure the costs of providing these services and to develop an appropriate mechanism for capturing these significant costs. An appropriate payment mechanism must be developed for them, both now and in the future.

B. Payment for IVIG

BIO also remains concerned that ASP plus 6 percent may not be adequate to protect patient access to certain types of drugs and biologicals. IVIG is one of these therapies. As CMS discussed in the Final Rule, many providers have reported difficulty in acquiring enough of the various brands of IVIG to meet their patients' needs.⁴ In response to these comments, CMS created an add-on payment of \$75 for the pre-administration-related services associated with infusion of IVIG.⁵ We appreciate CMS' effort to protect access to IVIG, but we are concerned that this payment is not adequate to compensate hospitals for all of the costs associated with acquiring this important therapy. We recommend that CMS work with providers and the manufacturers of IVIG to identify the costs that remain uncompensated and to do what is necessary to ensure patient access to this critical therapy.

We also recommend that CMS create a unique Healthcare Common Procedure Coding System (HCPCS) code for each brand name IVIG product. Currently, there are only two HCPCS codes for IVIG, even though

⁴ 70 Fed. Reg. at 68648.
⁵ Id. at 68649.

the products are not interchangeable. As a result, the ASP calculation methodology reflects the prices of all brands of IVIG, not the specific brand that is best suited for a particular beneficiary. We believe that Medicare reimbursement for one brand of IVIG should not be based on another brand that is used for different indications and may be inappropriate for the patient. Creating unique HCPCS codes for each brand would help to protect beneficiary access by ensuring that Medicare's reimbursement is appropriate for each brand. This step also would help CMS better track the supply of each brand in the marketplace.

C. Packaging Threshold for Separately-Paid Drugs and Biologicals

BIO supports CMS' decision to set the threshold for establishing separate APCs for drugs and biologicals at \$50 per administration in 2006 as required by statute.⁶ We believe this threshold will help to maintain beneficiary access to appropriate drugs and biologicals. We also support the decision to pay separately for all 5HT3 anti-emetic therapies even if they do not meet the \$50 packaging threshold because it will protect beneficiaries' access to the particular anti-emetic that is most effective for them as determined by themselves and their physicians.

D. CMS' Decision to Not Apply an "Equitable Adjustment"

Finally, we support CMS' decision to not apply an "equitable adjustment" to certain biologicals.⁷ Instead of linking payment for one biological to another, as CMS has done in the past, the Final Rule uses the ASP methodology, which is based on market prices, to determine rates for these therapies. Using the ASP-based rates for these therapies is consistent with Congress' intent, in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, to use market-based payment systems, not arbitrary government price setting. We thank CMS for implementing this proposal in the final rule.

II. Vaccines

⁶ Id. at 68637.

⁷ Id. at 68652.

BIO supports CMS' decision to continue to reimburse influenza and pneumococcal vaccines at reasonable cost.⁸ We share CMS' concern for protecting beneficiary access to these important vaccines, and we agree that payment at reasonable cost helps to ensure that hospitals are adequately reimbursed for providing them. We also are pleased that CMS implemented the APC Panel's recommendation to reimburse FluMist[®], the intranasal influenza vaccine, on a reasonable cost basis as well and to assign it to status indicator "L" (paid at reasonable cost; not subject to coinsurance or deductible). In addition, we appreciate CMS' clarification that "vaccine administration codes other than G0008 for administration of influenza virus vaccine are not exempted in the [Outpatient Code Editor] from charging beneficiary deductible and coinsurance and they should not be used to report these services which are exempt from copayment."⁹ This clarification will ensure that Medicare beneficiaries can receive any appropriate influenza vaccine, including FluMist[®], without liability for coinsurance and deductibles.

III. Drug Administration

BIO is pleased that CMS decided to implement 20 of the 33 new CPT codes for drug administration services.¹⁰ Instead of recognizing the 13 new codes that require determinations of initial, sequential, and concurrent infusions or intravenous pushes, CMS created 6 new C-codes that describe these services.¹¹ These codes are a significant improvement over the old codes because they offer more specific descriptions of the types of services offered. As charge data are collected using these codes, CMS should be able to set more appropriate rates for these procedures in the future. BIO continues to be concerned that reimbursement for these services may not be appropriate because they are set using two-year old data that lack the granularity necessary to set rates for all the codes. These potentially inadequate rates, combined with the transition to ASP-based payment for almost all separately paid drugs and biologicals, raise concerns about hospitals' ability to provide essential therapies in outpatient departments. We urge CMS to monitor access to drug and biological therapies in hospital outpatient settings and adjust rates as needed to protect access to care.

⁸ Id. at 68670.

⁹ Id. at 68682.

¹⁰ Id. at 68679.

¹¹ Id. at 68880.

We also appreciate the guidance recently issued by CMS on the use of the new codes in hospital outpatient departments,¹² and we ask CMS to make two additional clarifications. First, consistent with the CPT's guidance for the chemotherapy codes used in physician offices, the guidance explains that "hospitals are 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."¹³ We appreciate this instruction and recommend that CMS clarify that it also applies to IVIG. IVIG is a biologic response modifier, and thus its administration should be billed using C8954, not C8950, the code for non-chemotherapy intravenous infusion for therapy or diagnosis.

Second, the guidance explains that hospitals may report a first hour for each different type of infusion provided when the infusions can be reported using different codes and they meet the requirements for billing an hour of each type of infusion.¹⁴ This would allow a hospital to report and be paid for both a hydration service and a chemotherapy service. Because CMS has assigned one code for both hydration infusions and non-chemotherapy infusions in hospital outpatient departments, however, a hospital would not be paid separately for both infusions. Instead, payment for the hydration service would be packaged into payment for the drug infusion. In physician offices, these services have different CPT codes and both services are separately reimbursed. We recommend that CMS also allow hospitals to be paid for administering both a hydration infusion and a non-chemotherapy infusion in the same visit.

VI. Conclusion

In conclusion, BIO commends CMS for making important improvements to the OPSS, and we urge the agency to continue to make patient access to quality care its primary focus as the OPSS is refined. We hope our suggestions will help CMS address these important issues in the final rule. Please contact Jayson Slotnik at 202-962-9200 if you have any

¹² January 2006 Update of the Hospital Outpatient Prospective Payment System (OPSS) Manual Instruction: Changes to Coding and Payment for Drug Administration, Transmittal 785, Change Request 4258, December 16, 2005.

¹³ Id. (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2.2).

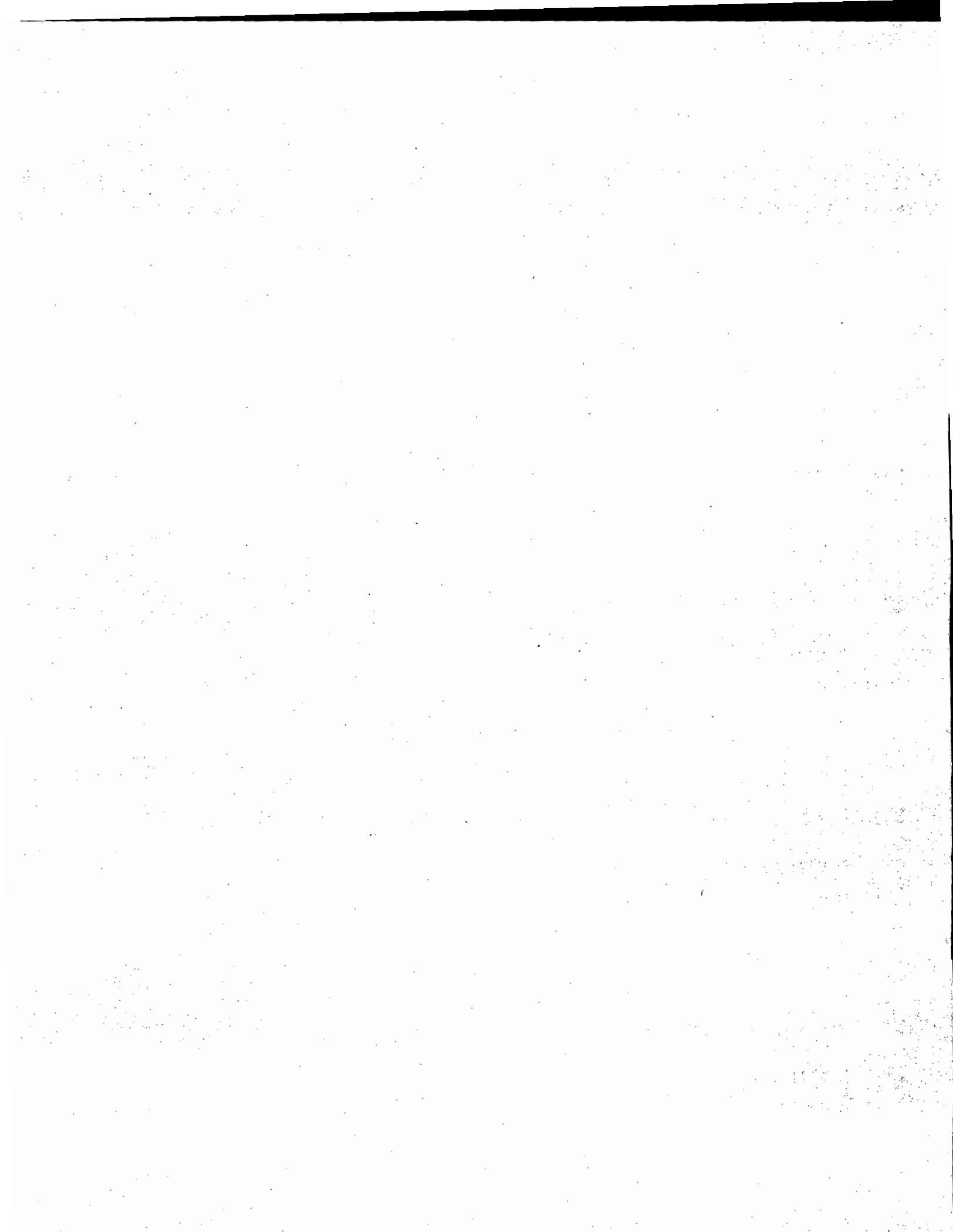
¹⁴ Id. (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2).

questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

James C. Greenwood
President & CEO
Biotechnology Industry Organization



Submitter : Kitty Vineyard
Organization : American Burn Association
Category : Association

Date: 01/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-FC-21-Attach-1.DOC



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March 31, 2008

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Centers for Medicare and Medicaid Services

C5-01-17

US Department of Health and Human Services

7500 Security Boulevard

Baltimore MD 21244

Re: CMS-1501-FC. Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates
Assignment of new CPT codes for skin replacement surgery and skin substitutes to APC classifications.

Dear Dr. McClellan:

The American Burn Association (ABA) sincerely appreciates the opportunity to comment on the 2006 Medicare Hospital Outpatient Prospective Payment System (HOPPS) final rule. The American Burn Association represents the nation's burn surgeons, nurses, therapists, and other members of the burn team, and the nation's leading medical institutions with burn centers who together provide therapeutic and surgical services for burn patients and other patients diagnosed with extensive and/or life-threatening skin diseases.

Following careful review of the 2006 HOPPS final rule, the ABA would like to comment on the assignment of APC classifications for new 2006 CPT codes for skin replacement surgery and skin substitutes which are listed with an "NI" indicator in the Final Rule. Our comments fall into two categories: hospital resource utilization and clinical coherence of the APCs to which the new codes have been assigned on an interim basis.

Background

The American Burn Association initiated, developed and proposed the new codes to the AMA with collaboration of other interested specialty societies. The ABA also participated in the assignment of RVU values for the new codes. We believe that our member surgeons and burn center hospitals are familiar with these procedures as well as the skin replacements and skin substitutes, and the physician effort and hospital resources needed to perform them.

As a result of the AMA revisions, certain codes were deleted. They are codes 15342-15343 that



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described both tissue cultured and acellular skin substitutes and codes 15350-5351 that described skin allograft. New codes were added to more specifically describe skin allograft, skin replacements, and skin substitutes. The new codes for skin allograft, skin replacements, and skin substitutes are:

15150-15157 describe tissue cultured epidermal autografts; 15170-15176 describe acellular dermal replacement; 15300-15321 describe allograft skin for temporary wound closure; 15330-15336 describe acellular dermal allograft;

15340-15341 describe tissue cultured allogeneic skin substitute;

15360-15366 describe tissue cultured allogeneic dermal substitute;

15430-15431 describe acellular xenograft implant.

Hospital Resource Utilization

The ABA believes that several of the interim assignments substantially underestimate the hospital resources required to perform these procedures in an outpatient setting. Hence, the resultant payment reduction for hospitals could adversely affect the availability of these skin replacement and skin substitute procedures for Medicare beneficiaries.

CPT code 15300 (Apply skin allograft trunk, arms, legs) is assigned to APC 27, with a payment rate of \$1082.84. In contrast, code 15320 (Apply skin allograft face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits) is assigned to APC 25 with the lower payment rate of \$315.71. The anatomic areas included in code 15320 represent greater difficulty and time for allograft application and, therefore, increased hospital resource consumption for them. Hence, the ABA believes code 15320 should be moved to APC 27 to reflect this fact.

CPT codes 15170 and 15175 (acellular graft) are assigned to APC 24 with the low payment rate of \$92.32. Hospital resources to apply the acellular graft are quite similar to those for code 15300 (Apply skin allograft). The ABA believes these codes should be moved to APC 27 as well.

In summary and based on the opinion of our members who were involved in the development of the new CPT codes, we believe that the resources required for CPT codes 15170, 15175, 15320, 15340, 15360, 15365, 15420, and 15430 are essentially equivalent to that for 15300 (Apply skin allograft) which is assigned to APC 27 and for which utilization of resources can be estimated from deleted code 15350. The ABA believes, therefore, that the foregoing primary codes should be moved to APC 27.

As well, the resources required for add-on codes 15171, 15176, 15321, 15341, 15361, 15366, 15421 and 15431 would be essentially similar to those for code 15301 (Apply skin allograft, add on) which is assigned to APC 25 and can be estimated by using claims data for deleted code 15151. The ABA believes, therefore, that the foregoing add-on codes should be moved to APC 25.



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Clinical Homogeneity or Coherence

APC 24 currently includes procedures involving repair and reconstruction of nail bed (11760, 11762), repair of superficial wounds and layer closure of wounds (12001-12046) (12051-12056) and many of the new skin substitute and skin replacement codes discussed above. The ABA strongly believes the placement of the new skin substitute or skin replacement codes in APC 24 violates the clinical homogeneity rule which requires procedures or services in each APC group to relate generally to a common organ system or cause of disease, have the same degree of extensiveness, and use the same method of treatment (surgical, etc.).

While the new codes do involve the same organ system as others in APC 24 and do involve the same type of treatment (surgical), we believe the rule is violated regarding the extensiveness provision. The new codes represent procedures that require application of a purchased product, which themselves require specific resources and care prior to application. In addition, the clinical content of these procedures is essentially commensurate or nearly commensurate to harvest and application of an autogenous skin graft, albeit without the use of a dermatome or blade. They are not at all comparable in extensiveness to the nail bed or wound repair procedures currently included in APC 24.

Further, the grouping of the new skin substitute or skin replacement codes with code 15040 (Harvest cultured skin graft) in APC 24 is inconsistent with the clinical homogeneity rule. Code 15040 involves removal of a very small piece of tissue followed by surgical closure of the wound, a procedure that a) is quite minimal and not nearly as extensive as the application of a skin substitute or replacement procedure and b) is seldom performed at all and rarely performed on an outpatient basis.

In summary, we believe the new skin substitute and skin replacement codes should be moved to the above-recommended APCs for the reasons listed.

Thank you for the opportunity to comment on this final rule. The ABA looks forward to contributing its expertise to CMS in order to foster proper payment for 2006 and in the future. If you have any questions on the issues discussed in this comment letter, please contact us. We will be happy to provide the information you require.

Respectfully submitted,

John A. Krichbaum, JD
Executive Director
American Burn Association

Submitter : Dr. Edward Coleman
Organization : Academy of Molecular Imaging
Category : Physician

Date: 01/09/2006

Issue Areas/Comments

**Classification assignments of
HCPCS codes identified in
Addendum B with comment
indicator NI.**

Classification assignments of HCPCS codes identified in Addendum B with comment indicator NI.

See Attachment

GENERAL

GENERAL

See Attachment

CMS-1501-FC-22-Attach-1.DOC



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January 9, 2006

The Honorable Mark McClellan
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200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1501-FC

**Re: Medicare Program; Changes to the Hospital Outpatient
Prospective Payment System and Calendar Year 2006
Payment Rates**

Dear Administrator McClellan:

The Academy of Molecular Imaging (AMI) is pleased to comment on the final rule, CMS-1501-FC, Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, published in the Federal Register on November 10, 2005. AMI is comprised of academicians, researchers, and radiologists and nuclear medicine physicians utilizing positron emission tomography (PET) technology. Through its educational programs, its journal, *Molecular Imaging & Biology*, and its annual meeting, AMI serves as a nexus of PET education, training, research and clinical practice.

AMI comments specifically on two aspects of the final rule: 1) the hospital outpatient payment rate for PET/CT scans, and 2) reimbursement for fluorodeoxyglucose (FDG) and other radiopharmaceuticals. First, AMI is concerned that the payment rate of \$1,250 for PET/CT, as provided by the final rule, will not adequately cover hospitals' true costs of providing PET/CT scans. The final rule does not articulate a persuasive rationale for such a payment rate, and AMI urges CMS to reconsider this decision. AMI respectfully requests that this issue be addressed at the Advisory Panel on Ambulatory Payment Classifications in March, 2006. Second, AMI supports CMS's decision to pay for FDG and other radiopharmaceuticals in FY 2006 based on hospital charges reduced to costs by the hospital-wide cost to charge ratio (CCR), and is eager to

collaborate with CMS and with other stakeholders in developing sound radiopharmaceutical payment policies for FY 2007 and beyond.

Payment Rate for PET/CT

The final rule's payment rate for PET/CT of \$1,250 will not adequately cover the costs to hospitals of providing PET/CT services. Because the PET/CT CPT codes and payment rate were first implemented in April 2005, there was no available Medicare claims data for PET/CT during the CY 2006 rule making process. Therefore, for the final hospital outpatient rule for CY 2006, CMS should base the New Technology payment rate for PET/CT on external data and economic analysis. In the final rule CMS acknowledges that there was no available claims data and PET/CT is set "at a payment rate of \$1,250, based on input claiming that the costs associated with PET/CT technology are higher than the costs of PET technology alone." (70 Fed. Reg. 68581)

The most comprehensive external data submitted during the comment period was an economic analysis submitted by AMI with its comment on the proposed rule that places the true average cost of providing PET/CT at \$1,717. This economic analysis was based on a national hospital utilization rate for PET/CT at approximately 3.8 scans per day. CMS has provided no persuasive rationale for adopting a payment rate that is \$467, or nearly 30%, below that figure. The final rule makes passing reference to the analysis, but dismisses it on the ground that it lacked "the level of detail that would have allowed us to verify the claims data" ¹ In the following sentence, however, the final rule relies on the assertion of a "leading mobile provider" that its average cost of providing PET/CT scans was only \$1,485, including FDG—a cost that is consistent with a payment rate of \$1,250, excluding FDG. The final rule does not explain why CMS believes it is appropriate to rely, in the absence of any supporting evidence, on a cost figure reported by a single provider to corroborate the payment rate established in the final rule, yet to disregard a detailed economic analysis based on external data that supports a substantially higher rate.

AMI is willing to work with CMS in 2006 to collect external data on PET/CT's cost and hospital resource use. The attached paper shows the hospital cost of providing a PET/CT scan, based on the extrapolation of a published economic cost model. According to its authors, the model is based on average national utilization rates in the hospital outpatient department, and is adjusted for PET/CT equipment and operational requirements. Based on this economic analysis, the costs for a PET/CT scan are approximately \$1,717. The present PET/CT payment rate is therefore far below the true costs of providing the service in hospital outpatient departments.

Finally, the final rule "acknowledge[s] that PET/CT scanners may be more costly to purchase and maintain than dedicated PET scanners," but emphasizes that "a PET/CT scanner is versatile

¹ 70 Fed. Reg. 68516, 68581 (Nov. 10, 2005).

and may also be used to perform individual CT scans [in the event that] PET/CT scan demand is limited.² The implication appears to be that the high capital and maintenance costs associated with PET/CT scanners can be offset by their supplemental performance of CT-only scans. This suggested utilization is not supported by how PET/CT scanners are actually used in practice. In fact, precisely because of their relatively greater operational costs, most hospitals do not use PET/CT scans to perform CT-only scans. A payment rate of \$1,250 will therefore force hospitals to absorb the additional fixed costs associated with PET/CT.

Payment for FDG

The final rule pays for FDG and other radiopharmaceuticals on the basis of hospital charges reduced to costs by the hospital CCR. AMI supports CMS's decision to use hospital-wide (as opposed to department-specific) CCRs in calculating FDG payment. Hospitals employ a wide range of mark-up policies for radiopharmaceuticals and other drugs, and it is critical that they understand that when converting charges to cost it is proper to include overhead and acquisition costs. AMI intends to educate hospitals about the new payment methodology in order to ensure that they apply the correct CCR.

In the final rule, CMS states that for separately payable radiopharmaceuticals in CY 2006 that the APCs will be subject to a 20% coinsurance. We respectfully request CMS clarify the statement in the final rule regarding coinsurance and publish this information in future transmittals. We are concerned that some hospitals believe that the 20% coinsurance will be based on the hospital charge alone and they therefore are reluctant to raise their charges consistent with the new radiopharmaceuticals payment policy for CY 2006.

Finally, as CMS develops payment policies for FY 2007, the question of whether CMS should use average sales price (ASP) to determine payment for radiopharmaceuticals warrants close study. In light of the difficulties involved in reporting and calculating ASP for FDG and other radiopharmaceuticals, CMS's consideration of this question will benefit from significant stakeholder input, including public comment.

AMI is committed to collaborating with CMS and with other stakeholders on this important issue. AMI would be very pleased to meet with CMS in February 2006 to discuss the development of sound payment policies for FDG and other radiopharmaceuticals for FY 2007 and beyond.

Thank you for consideration of these issues.

Sincerely,

² *Id.*

The Honorable Mark McClellan

January 9, 2006

Page 4 of 4

A rectangular box containing a handwritten signature in cursive script that reads "R. Edward Coleman".

Dr. R. Edward Coleman

Immediate Past President

Academy of Molecular Imaging