Report
of the
Advisory Panel on
Ambulatory Payment Classification
(APC) Groups

March 1-2, 2006

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)
7500 Security Boulevard, Auditorium
Baltimore, MD 21244-1850

PANEL MEMBERS PRESENT AT THIS MEETING:

Marilyn K. Bedell, M.S., R.N., O.C.N.
Gloryanne Bryant, B.S., R.H.I.A., R.H.I.T., C.C.S.
Albert B. Einstein, Jr., M.D., F.A.C.P.
Hazel Kimmel, R.N. C.C.S., C.P.C.
Sandra Metzler, M.B.A., R.H.I.A., C.P.H.Q.
Thomas M. Munger, M.D., F.A.C.C.
Frank G. Opelka, M.D., F.A.C.S.
Louis Potters, M.D., F.A.C.R.
James V. Rawson, M.D.
Lou Ann Schraffenberger, M.B.A., R.H.I.A., C.C.S.
Judie S. Snipes, R.N., M.B.A., F.A.C.H.E.
Lynn R. Tomascik, R.N., M.S.N., C.N.A.A.
Timothy Gene Tyler, Pharm.D.
Kim Allan Williams, M.D., F.A.C.C., F.A.B.C.
Robert Matthew Zwolak, M.D., Ph.D., F.A.C.S.

CMS STAFF PRESENT:

E. L. Hambrick, M.D., J.D., CMS Medical Officer, *Chair*
Shirl Ackerman-Ross, Designated Federal Official (DFO)

Herb Kuhn, Director, Center for Medicare Management (CMM)
Liz Richter, Director, Hospital and Ambulatory Policy Group (HAPG)
James Hart, Director, Division of Outpatient Care (DOC)
Joan Sanow, Deputy Director, DOC
Carol Bazell, M.D., CMS Medical Officer, HAPG
Kenneth Simon, M.D., CMS Medical Officer, HAPG

Sabrina Ahmed, Staff, DOC
Dana Burley, Staff, DOC
Anita Heygster, Staff, DOC
Heather Hostetler, Staff, DOC
Rebecca Kane, Staff, DOC
Barry Levi, Staff, DOC
Tamar Spolter, Staff, DOC
Gift Tee, Staff, DOC

WELCOME AND CALL TO ORDER

E. L. Hambrick, M.D., J.D., Chair of the APC Panel, welcomed the members, CMS staff, and the public to the meeting. (The proceedings of the meeting follow. The agenda appears in Appendix A; a cumulative listing of the recommendations appears in Appendix B.)

Dr. Hambrick introduced Herb Kuhn, Director, CMM. Mr. Kuhn welcomed everyone—especially the Panel—to CMS, and he indicated CMS' appreciation of the Panel's work, which helps CMS serve its beneficiaries. He especially spoke of the critical, key role of the Panel members to advise the Secretary and the Administrator on the weights and composition of APCs. In addition, he reviewed some new aspects of Mecicare benefits, and he concluded by reiterating his support of the Panel's thoughtful work in deliberating on complex hospital Outpatient Prospective Payment System (OPPS) issues.

Dr. Hambrick then asked each of the Panel members and the Panel's DFO, Shirl Ackerman-Ross, to introduce themselves and briefly describe their backgrounds. Dr. Hambrick reviewed the following routine guidelines:

- Presenters are given 5 minutes per presentation.
- Commenters from the floor are given 1-2 minutes per person and a maximum of 5 minutes per organization.
- The APC Panel's Charter was summarized, paying particular attention to what is/is not in the scope of the Panel's work.
- The Panel's purpose, authority, and function were discussed.
- When an organization has an issue—outside those included in the APC Panel scope—CMS welcomes a separate meeting between its staff and that organization's staff.
- There was an overview of how to use and interpret the 2 times rule data.

FINAL RULE FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (OPPS) AND CALENDAR YEAR 2006 PAYMENT RATES

Overview

James Hart, Director, DOC, welcomed back the Panel members and expressed appreciation for their hard work in the past. He gave an overview of the OPPS, highlighted significant issues for discussion during this Panel meeting, and gave a brief summary of these issues for the Panel. He reported that the CY 2006 final rule was published on November 10, 2005, in which payments were up 2.2 percent for 2006 due to changes in that final rule. Taking into account all factors (including enrollment and utilization changes), it is expected that the payments for 2006 will be up 5.2 percent. He reviewed key issues from last year's final rule, including:

- CY 2006 payments for drug acquisition costs and pharmacy overhead;
- CY 2006 payment methodology for radiopharmaceuticals;
- Proposed multiple imaging procedure reduction policy, which was not finalized; and
- Rural adjustment for sole community hospitals.

Mr. Hart stated that CMS is continuing to make good progress on increasing the proportion of claims data used for rate-setting and on enhancing the quality of claims data, especially related to ensuring the costs of devices are included in the median costs of procedures.

PACKAGING ISSUES

Overview

Tamar Spolter, CMS Staff, indicated that payments for packaged Healthcare Common Procedure Coding System (HCPCS) codes under the OPPS are bundled into the payments providers receive for separately payable services provided on the same day. This is consistent with the principles of a prospective payment system based upon groupings of services and in contrast to a fee schedule that provides an individual payment for each service billed. Ms. Spolter noted that CMS considers a variety of factors when deciding whether to package a service or to pay for it separately. These factors include:

- Whether the service is normally provided separately or in conjunction with other services
- How likely it is for the costs of the packaged code to be appropriately mapped to the separately payable services with which it is performed
- Whether the expected cost of the service is relatively low

Further, Ms. Spolter stated that Current Procedural Terminology (CPT) code 42550 (injection for salivary x-ray) would not be discussed in the Packaging Subcommittee report because CMS did accept the APC Panel's August 2005 recommendation in the CY 2006 final rule.

Packaging Subcommittee's Report

Albert B. Einstein, Jr., M.D., Chair of the Packaging Subcommittee, advised the attendees of the meeting that the Subcommittee had conducted for several hours prior to the public meeting in order to discuss codes pending for presentation and discussion.

He first discussed the Subcommittee's recommendations relating to codes that would not be discussed in any of the presentations:

- CPT codes 36500 (venous catheterization for selective organ blood sampling) & 75893 (venous sampling through catheter, with or without angiography, radiological supervision and interpretation). The Subcommittee reviewed the clinical scenarios submitted by a provider.
  Recommendation: Maintain the packaged status of CPT 36500 and pay separately for CPT code 75893 if there are no separately payable OPPS services on the claim.

- CPT codes 74328 (endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation), 74329 (endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation) & 74330 (combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation). The Subcommittee reviewed the data pertinent to these codes and discussed clinical scenarios.
  Recommendation: Maintain the packaged status of CPT codes 74328, 74329 & 74330.

- HCPCS code G0269 (placement of occlusive device into either a venous or arterial access site). The Subcommittee reviewed the data pertinent to this code and discussed clinical scenarios.
  Recommendation: Maintain the packaged status of code G0269.

- CPT codes 76937 (ultrasound guidance for vascular access) & 75998 (Fluoroscopic guidance for central venous access device placement, replacement, or removal). The Subcommittee reviewed the data pertinent for these codes and discussed clinical scenarios.
  Recommendation: Maintain the packaged status of CPT codes 76937 & 75998.

- CPT codes 76001 (fluoroscopy, physician time more than one hour), 76003 (Fluoroscopic guidance for needle placement) & 76005 (Fluoroscopic guidance and localization of needle or catheter tip). The Subcommittee reviewed the data pertinent to these codes and discussed clinical scenarios.
  Recommendation: Maintain the packaged status of CPT codes 76001, 76003 & 76005.

- CPT code 76000 (fluoroscopy, up to one hour physician time).
  The Subcommittee reviewed the data pertinent to this code and discussed clinical scenarios.
  Recommendation: Continue to pay separately for CPT code 76000.

- CPT code 94762 (noninvasive ear or pulse oximetry for oxygen saturation by continuous overnight monitoring). The Subcommittee reviewed the data pertinent to this code and discussed clinical scenarios.
  Recommendation: Pay separately for CPT codes 94760 (Noninvasive ear or pulse oximetry for oxygen saturation; single determination), 94761 (noninvasive ear or pulse oximetry for oxygen saturation; multiple determinations) & 94762 (noninvasive ear or pulse oximetry for oxygen saturation by continuous overnight monitoring) if there are no separately payable OPPS services on the claim.

- CPT code 38792 (sentinel node identification). The Subcommittee reviewed the data pertinent to this code and discussed clinical scenarios.
  Recommendation: Pay separately for CPT code 38792 if there are no separately payable OPPS services on the claim.

Final recommendations for these and other codes, on behalf of the full APC Panel, were postponed until after the following presentations.

Computer-Aided Detection (CAD), Chest Radiograph(s)
Matthew Freedman, M.D., M.B.A.; David Freed, M.D.; Sam Finklestein, CEO, Riverain Medical; and Alison Shuren, Arent Fox, requested a change to status indicator "S" and assignment to APC 1492 for CPT code 0152T, *Computer aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images, chest radiograph(s),* which is currently bundled into APC 0260.

***Discussion*:**
The presenters said that this procedure was not used for screening. Several Panel members believed that a radiologist should be able to identify areas of concern on x-rays without CAD; therefore, they did not see the added value of using CAD. The Panel members noted that if the frequency of this code increased, the median cost for the chest x-ray would include the cost of the CAD.

Riverain representatives indicated that they anticipate publication of additional clinical trials regarding the use of chest x-ray CAD to improve the diagnosis and clinical outcomes of patients with lung cancer, after which point they hope the technology will be more widely used. Panel members speculated about whether the use of CAD would result in better outcomes or earlier diagnoses, and under what clinical circumstances CAD should be most appropriately used. They also wanted to know if CAD eliminated the need for additional testing. Riverain representatives again noted that they would have more data after completion of the clinical trials. Panel members noted that this code is indicated as an add-on code to a chest x-ray in the CPT book.

Acoustic Heart Sound Recording and Computer Analysis

Patricia A. White, CEO of Inovise Medical, Inc., indicated that CPT code 0069T, *„Acoustic heart sound recording and computer analysis; acoustic heart sound recording and computer analysis only (List separately in addition to codes for electrocardiography*), is currently packaged into electrocardiogram (EKG) payment. The procedure is used to diagnose heart failure. To make her point, Ms. White reviewed the related procedures, CPT codes, costs, and potential financial impact on hospitals of various payment methodologies.

***Discussion*:**

The Panel applauded both Inovise and Riverain for obtaining Category III CPT codes for their new services. Several Panel members believed that acoustic heart sound recording is a separate service from an EKG, but they were conflicted as to whether it should be packaged or separately payable since the cost is relatively low. Ms. Spolter of CMS noted that the CPT instructions indicate that this is an add-on code to be reported in conjunction with CPT code 93005 for a routine EKG tracing with at least 12 leads and, therefore, should not be billed without also billing for the EKG. Some Panel members felt that even if the routine EKG service with at least 12 leads was not provided as CPT instructions indicate, a separately reportable EKG procedure would always be provided with CPT code 0069T. Nevertheless, the Panel concluded that the CPT status as an add-on code was possibly problematic, given the description of the service provided by the presenter.

Incidental or "N" Status HCPCS

Valerie Rinkle, MPA, Asante Health System, Representative for Provider Roundtable (PRT), indicated that the following HCPCS codes should be separately payable when they are the only services on a claim:

- CPT code 36540, blood collection from VAD; CPT 36600, arterial puncture for blood specimen
- CPT code P9612, catheterization for collection of specimen, single patient, all places of service
- CPT code 96523, irrigation of implanted venous access device

Ms. Rinkle discussed the costs of these procedures, as well as clinical scenarios describing when these codes are provided without a separately payable procedure on the same day.

Discussion:

The Chair of the Packaging Subcommittee, Dr. Einstein, said that the Subcommittee's recommendations are that CPT codes 36540, 36600, and 96523 be separately paid if there are no separately payable OPPS services billed on the claim. He also said that the Subcommittee recommends that P9612 change its payment status indicator to "A," so it would be payable under

the lab fee schedule. The Panel discussed P9612 in further detail, and it chose not to accept the Packaging Subcommittee's recommendation for this code.

PACKAGING ISSUES

1. **The Panel recommends** that CMS maintain the packaged status of HCPCS code 0152T, *Computer aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images, chest radiograph(s).*
2. **The Panel recommends** that CMS pay separately for HCPCS code 0069T, *Acoustic heart sound recording and computer analysis; acoustic heart sound recording and computer analysis only (List separately in addition to codes for electrocardiography*).
3. **The Panel recommends** that CMS pay separately for CPT code 96523, *Irrigation of implanted venous access device for drug delivery systems site, post surgical or interventional procedure (e.g. angioseal plug, vascular plug*, if there are no separately payable OPPS services on the claim.
4. **The Panel recommends** that CMS pay separately for CPT code 36540, *Collection of blood specimen from a completely implantable venous access device*, if there are no separately payable OPPS services on the claim.
5. **The Panel recommends** that CMS pay separately for CPT code 36600, *Arterial puncture, withdrawal of blood for diagnosis*, if there are no separately payable OPPS services on the claim.
6. **The Panel recommends** that CMS pay separately for CPT code P9612, *Catheterization for collection of specimen, single patient, all places of service,* if there are no separately payable OPPS services on the claim.
7. **The Panel recommends** that CMS maintain the packaged status of CPT code 36500, *Venous catheterization for selective organ blood sampling.*
8. **The Panel recommends** that CMS pay separately for CPT code 75893, *Venous sampling through catheter, with or without angiography (e.g., for parathyroid hormone, renin), radiological supervision and interpretation*, if there are no separately payable OPPS services on the claim.
9. **The Panel recommends** that CMS maintain the packaged status of the following:
   - CPT code 74328, *Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation*
   - CPT code 74329, *Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation*
   - CPT code 74330, *Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation*
10. **The Panel recommends** that CMS maintain the packaged status of HCPCS code G0269, *Placement of occlusive device into either a venous or arterial access site, post surgical or intervention procedure*.
11. **The Panel recommends** that CMS maintain the packaged status of the following:
    - CPT code 76937, *Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure)*

- CPT code 75998, *Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (List separately in addition to code for primary procedure)*

12. **The Panel recommends** that CMS maintain the packaged status of the following:
    - CPT code 76001, *Fluoroscopy, physician time more than one hour, assisting a non-radiologic physician (e.g., nephrostolithotomy, ERCP, bronchoscopy, transbronchial biopsy)*
    - CPT code 76003, *Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device)*
    - CPT code 76005, *Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural, transforaminal epidural, subarachnoid, paravertebral facet joint, paravertebral facet joint nerve or sacroiliac joint), including neurolytic agent destruction*
13. **The Panel recommends** that CMS continue to separately pay for CPT code 76000, *Fluoroscopy (separate procedure), up to one hour physician time, other than 71023 or 71034 (e.g., cardiac floruoscopy).*
14. **The Panel recommends** that CMS provide separate payment for the following:
    - CPT code 94760, *Noninvasive ear or pulse oximetry for oxygen saturation; single determination*
    - CPT code 94761, *Noninvasive ear or pulse oximetry for oxygen saturation; multiple determinations (e.g., during exercise)*
    - CPT code 94762, *Noninvasive ear or pulse oximetry for oxygen saturation by continuous overnight monitoring (separate procedure)*
15. **The Panel recommends** that CMS pay separately for CPT code 38792, *Injection procedure; for identification of sentinel node,* if there are no separately payable OPPS services on the claim.
16. **The Panel recommends** that CMS bring data to the next Panel meeting that show the following:
    - How the costs of packaged items and services are incorporated into the median costs of APCs
    - How the costs of these packaged items and services influence payments for associated procedures
17. **The Panel recommends** that the Packaging Subcommittee continue until the next APC Panel meeting.

OBSERVATION ISSUES

Overview

Heather Hostetler, CMS Staff, spoke about observation coding and policy changes, which were finalized in the November 10, 2005 OPPS final rule and were implemented January 1, 2006. She indicated that the criteria for separate payment had not changed, and the three G codes for observation services that were discontinued for CY 2006 were: G0244 (Observation care by facility to patient), G0263 (Direct Admission with CHF, CP, asthma) and G0264 (Assessment

other than CHF, CP, and asthma). Two new G codes were added to report observation services. These are G0378 (Hospital observation services, per hour) and G0379 (Direct admission of patient for hospital observation care). She went on to give an overview of CY 2006 payment rates and continued with an overview of August 2005 APC Panel recommendations to CMS. She indicated that internet-only manuals—in particular the sections related to hospital observation services—were updated in December 2005.

Observation Subcommittee's Report

Judie Snipes, R.N., M.B.A., F.A.C.H.E., Chair, reviewed CMS' changes to observation codes, automation of determining separately payable observation care, and CMS' recent clarifications to billing instructions. She stated that the Subcommittee appreciates CMS' continuing improvement efforts regarding observation services. The Subcommittee discussed the median cost of direct admission to observation, the possibility of expanding the list of diagnoses eligible for separate payment, and the relationship of procedures with status indicator "T" to observation services. However, the Subcommittee members declined to make formal recommendations on these issues until CMS is able to gather claims data for the new G codes for the Subcommittee's review.

Discussion

Valerie Rinkle posed the question:

> When a patient is in a post-anesthesia care unit after a surgical procedure, and observation care is ordered specifically for a condition that is separate from routine recovery from the surgical procedure, what should be done?

She said that the provider cannot bill G0378 because there is no associated Evaluation & Management (E&M) service; therefore, the provider cannot successfully submit the claim.

Dr. Carol Bazell, CMS staff, responded that there is no requirement that an E&M service must be billed in order to bill for observation services. She said that she was not aware of any national edit being in place. She stated that E&M services on the claim only come into play when the observation service may be eligible for separate payment.

Valerie Rinkle said that the logic of the Outpatient Code Editor (OCE) will not accept the claim. Joan Sanow, CMS staff, responded that incidents of specific claims should be forwarded to CMS or the fiscal intermediary (FI). Sandy Metzler, a member of the Panel, asked if the data presented to the Packaging Subcommittee regarding packaged observation show up on claims with surgical codes. She requested that CMS clarify in instructions the specific situations where G0378 CAN be reported. She said she believes that the OCE will allow G0378 to be reported in association with a surgical procedure.

John Settlemeyer praised CMS regarding the establishment and use of the new G codes, but he said that some FIs have interpreted that G0378 may be reported only when there are more than 8 hours (units) of observation services provided. Joan Sanow's response was that providers should discuss their local concerns with their regional offices.

PANEL'S RECOMMENDATIONS - OBSERVATION ISSUES

1. **The Panel accepts** the Observation Subcommittee's report, including the request to review additional data at the 2007 winter meeting of the APC Panel.

2. **The Panel recommends** that the Observation Subcommittee continue until the next APC Panel meeting.

DATA ISSUES

Overview

Anita Heygster, CMS Staff, described the data process used to develop median costs for HCPCS and APC codes. She discussed the role that medians play in payment rates under the OPPS and the OPPS system. Further, Ms. Heygster said that median costs are the best estimate of hospital resources for services. Ms. Heygster indicated that more information can be found regarding OPPS data development on CMS' Web site. She described the APC median calculation process, which is addressed in detail in the 2006 OPPS claims accounting narrative. The narrative is found on the CMS OPPS Web page under supporting documentation for the 2006 OPPS final rule. She also indicated that analysis of the APC Panel data found that some additional HCPCS codes met the empirical criteria for their addition to the bypass list based on the initial analysis of CY 2005 claims data. Lastly, Ms. Heygster indicated that CMS generally used the same data process and the CY 2006 drug packaging rules to develop median cost data for the Panel's review at the meeting.

Data Subcommittee's Report

Timothy Gene Tyler, Pharm.D., Chair, commended CMS for its continued work on extracting as much cost data from hospital claims as possible. He said the Subcommittee believed that there is need for more guidance up front to providers regarding their reporting of services and their associated charges. The Subcommittee made no official recommendations. They expressed general support for CMS' work to explore developing reverse device edits; that is, developing edits that would require an appropriate procedure for the insertion of a device to be on the claim if certain device codes were reported.

Subcommittee members were concerned about the following issues:

- The CMS may have reached the point of doing all it can do internally to improve the data being used for rate-setting, and it may be time for a concerted effort—perhaps, with the American Hospital Association (AHA), Federation of American Hospitals, and American Health Information Management Association (AHIMA)— to possibly correct the coding and charging practices of hospitals, so data will be improved at its source. (The CMS staff replied that they have entered into a coding clearinghouse arrangement with AHA and AHIMA aimed at providing more accurate coding of services.)
- More specific direction should be given on what revenue codes to use with certain HCPCS codes; this would improve data and would also be more readily accepted by hospitals than in the past as hospitals recognize the value of standardization. (The CMS staff indicated that CMS has, in general, given hospitals the latitude to select the revenue code that is appropriate for the service rendered, so each hospital can best accommodate its own accounting systems.)
- The CMS has looked at the issue in the past, but its proprietary nature is inconsistent with CMS' goal to be as transparent as possible—as a means of helping hospitals to code correctly.
- The OCE does not edit beyond the first 300 lines; therefore, claims may bypass device and other edits if certain codes fall after line 300. Apparently, the claim will pass even if it should fail the edit because the edit will not be applied.

- Improving the quality of the data available for rate-setting has to shift to the individual providers.

PANEL'S RECOMMENDATIONS – DATA ISSUES

1. **The Panel accepts** the Data Subcommittee's report.
2. **The Panel recommends** that the Data Subcommittee continue until the next APC Panel meeting.

DEVICE-RELATED APC ISSUES

Overview

Anita Heygster, CMS Staff, advised that CMS is seeking the Panel's input with respect to treatment of device-dependent APCs in the CY 2007 proposed rule. The CY 2005 claims data to be used for CY 2007 rate-setting show median costs for APCs in which a device must be used to perform the service. These costs appeared, in some cases, to be lower than the adjusted relative medians used as the basis for CY 2005, which is a chronic issue recurring with each new year. It was discussed how the medians were calculated for the CY 2006 OPPS, based upon CY 2004 claims data. In CY 2007, medians are going to be based on CY 2005 claims data.

The CMS first implemented device edits for many procedures assigned to device dependent APCs in CY 2005. Proposed device edits were maintained on the OPPS Web site for many months prior to their implementation. Some edits were implemented first on April 1, 2005, with the majority of the edits implemented October 1, 2005. Ms. Heygster also discussed the CY 2005 recall of devices by manufacturers and the related token device charges observed in CY 2005 claims data. She reviewed the median costs figures on the spreadsheet for device dependent APCs and their significance. Further, she went on to explain that preliminary data from a 9-month period can change as cost-to-charge ratios are updated and more complete claims data are available.

Cardiac Electrophysiological Procedures

Margaret Schwantes, Manager, Health Economics, Biosense Webster/Cordis (Johnson & Johnson), addressed the Panel about CPT codes 93609, 93613, and 93631. She focused on how APCs 0086 and 0087 are affected. Biosense believes that APC 0087 violates the 2 times rule. They recommend that CPT codes 93609, 93613, and 93631 should be reassigned to APC 0086 for improved clinical and resource alignment. They believe that electrophysiological mapping and ablation procedures that require similar hospital resources should not be assigned to different APCs.

Payment Rates for Device-Related Procedures

Jori Frahler, Director, Federal Affairs, Medical Device Manufacturers Association (MDMA), described MDMA and its missions. She emphasized that the OPPS system lacks stability and predictability for providers, innovators, and patients. Ms. Frahler indicated that the current OPPS payment methodology must be explored in order to ensure that CMS is basing payments on a substantial number of accurate and correctly coded hospital claims. Patients will suffer if companies continue to be subject to payment fluctuations. The MDMA believes that CMS should use the best available data in setting rates. External data has not been taken advantage of in order to improve payment adequacy. Ms. Frahler discussed that using external data gives CMS more complete information to use in setting rates. All external data must be kept private.

Adequate assurances of confidentiality must be given to hospitals and manufacturers, so they will release proprietary information to CMS.

Device-Related APCs

Bonnie Handke, Medtronic, Advanced Medical Technology Association (AdvaMed), addressed packaging device costs into APCs—including the methodology and effects on APCs, use of single- and multiple-procedure claims data, and other claims data issues. She also talked about the reconfiguration of APCs, including moving HCPCS codes from new technology APCs to clinical APCs. Ms. Handke reviewed continuing significant APC rate variations and related issues including the use of external data, reliance on single procedure claims, use of correctly coded claims, reporting of device codes, and setting a floor on payment rate decreases. She voiced AdvaMed's continuing concerns about bundling and device-related procedures.

PANEL'S RECOMMENDATIONS - DEVICE-RELATED APC ISSUES

1. **The Panel recommends** that CMS continue exploring the benefits of reverse editing for devices that are reported on claims without HCPCS codes for procedures describing their insertion or implantation.
2. **The Panel recommends** that the Data Subcommittee continue until the next APC Panel meeting.
3. **The Panel recommends** that CMS maintain the following in APC 0087, Cardiac Electrophysiologic Recording/Mapping:
   - CPT code 93609, *Intraventricular and/or intra-atrial mapping of tachycardia site(s) with catheter manipulation to record from multiple sites to identify origin of tachycardia (List separately in addition to code for primary procedure)*
   - CPT code 93613, *Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure)*
   - CPT code 93631, *Intra-operative epicardial and endocardial pacing and mapping to localize the site of tachycardia or zone of slow conduction for surgical correction*

INPATIENT ONLY PROCEDURES

Overview

Dana Burley, CMS Staff, introduced seven inpatient procedures that CMS identified as possibly appropriate for removal from the inpatient list, specifically CPT codes 16035, 21181, 57292, 57335, 61720, 62000, and 64804. According to claims for physician services, the majority of these procedures for CY 2004 and CY 2005 were performed in outpatient settings.

Discussion

Dr. Opelka said that he needed more information in order to form an opinion one way or another. He did say that he supports the removal of CPT codes 61720, 62000, and 64804 from the inpatient list as long as letter of support is provided by the neurosurgical professional association.

Valerie Rinkle commended the Panel for recognizing the issue of patient safety, but she indicated that a great concern is the losses that hospital suffer when procedures on the inpatient list are performed in the outpatient department. Physicians are paid regardless of the site of

service, but hospitals do not receive payment when procedures are performed in settings that are not allowed for Medicare payment.

It was the Panel 's consensus that CMS should consult with relevant societies before removing CPT codes 61720, 62000, 64804, 57292, 57335, and 16035 from the inpatient list. Dr. Zwolak wanted to know if there were any societies in support of these items being removed from the inpatient list. Ms. Burley said that, in general, procedures are brought to the Panel for their consideration prior to external review of the list.

Dr. Opelka said that these are small numbers of Medicare services that the Panel is considering, and it would be good to have the input of relevant specialty societies. He went on to say that it would be helpful to match these CPT codes to ICD-9 (International Classification of Diseases, 9th Edition) codes in order to ensure that they are not coding mistakes.

However, Marion Kruse from Ohio Health (and representing the Provider Roundtable) recommended that the Panel approve the list provided by CMS. She reminded the Panel that it has recommended the abolishment of the list in past years.

PANEL'S RECOMMENDATIONS - INPATIENT-ONLY LIST ISSUES

1. **The Panel recommends** that CMS consult with the relevant medical specialty societies before removing the following from the inpatient list:
   - CPT code 61720, *Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus*
   - CPT code 62000, *Elevation of depressed skill fracture; simple, extradural*
   - CPT code 64802, *Sympathectomy, cervicothoracic*
   - CPT code 57292, *Construction of artificial vagina; with graft*
   - CPT code 57335, *Vaginoplasty for intersex state*
   - CPT code 16035, *Escharotomy; initial incision*
2. **The Panel recommends** that CMS remove CPT code 21181, *Reconstruction by contouring of benign tumor of cranial bones (eg, fibrous dysplasia), extracranial*, from the inpatient list.

BRACHYTHERAPY

Overview

Barry Levi, CMS Staff, summarized brachytherapy source payments for the Panel and reviewed how the OPPS will pay for brachytherapy sources as of January 1, 2007. He also reviewed the statutory requirements. Then he summarized background on the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provisions and payments for brachytherapy sources prior to MMA. Mr. Levi indicated that a number of brachytherapy sources have been added through recommendations from the public, as well as through other means, such as pass-through applications.

He went on to say that CMS is currently paying for 12 brachytherapy sources on a cost basis under MMA. The Government Accountability Office (GAO) is required under MMA to submit a report with recommendations on its study of appropriate payment amounts for brachytherapy devices to Congress and to the Secretary.

Mr. Levi reviewed the brachytherapy data that were handed out. Some sources (e.g., HCPCS codes C1716, C1720, C2616, C2634, C2635, and C2636) show relatively consistent data—such as mean and median numbers and costs of sources—and some sources (e.g., HCPCS codes C1717, C1719, C2632, and C2633) demonstrate relatively inconsistent mean and median numbers of sources used.

Mr. Levi and Ms. Heygster spoke about some of the concerns surrounding the variability between the mean and median numbers of sources, such as possible coding confusion regarding billing of units. Mr. Levi also presented sample questions to request the insights of the Panel on what the data indicate. These questions were as follows:

- How would you explain the variability in mean and median numbers of sources per line?
- Does this reflect true variability in medical practice, or does it reflect differences in coding and billing by hospitals?
- How would one explain the variability in mean and median unit costs? Is this what one would expect?
- Do you have any observations regarding the differences in costs and payments per unit?

It was also noted that CMS would welcome any recommendations from the Panel on payment for brachytherapy sources for CY 2007.

Overview

Anita Heygster, CMS Staff, addressed APC 0651, Complex interstitial radiation source application, and specifically CPT code 77778, the Complex interstitial application of brachytherapy sources. The median cost for APC 0651 is not stable, and the instability is a source of concern, expressed Ms. Heygster. Ms. Heygster commented about the level of variation and how it is a problem for hospitals with regard to budgeting. She also discussed what other HCPCS codes would be expected to be seen on claims for CPT code 77778 and reviewed potential codes for special studies of packaging or bypassing that could increase the number of single bills available for APC 0651. Further, she said that CMS is interested in the Panel's comments on APC 0651 or any other thoughts the Panel has on these issues.

Brachytherapy Presentations

Michael Kuettel, M.D., Ph.D., M.B.A., member of American Society for Therapeutic Radiology & Oncology (ASTRO), addressed the Panel on the issue of APC payment reductions for radiation oncology procedures described by CPT codes 77778 and 57155, but he concentrated on CPT code 77778. CPT code 77778 is billed with CPT code 55859 in 87 percent of the time, and the resulting multiple-procedure claims are not used for payment rate calculations since they have many packaged revenue-code charges and include multiple procedures. Very few claims were used for CY 2006 to set the payment rate for APC 0651. Payment for CPT code 77778 has been highly unstable from year to year, largely due to the small numbers of single and likely miscoded claims used in the rate-setting process.

Mary Jo Braid-Forbes, consultant to ASTRO, reviewed the historical ASTRO code analysis, which was largely based on the HCPCS codes included in the CY 2003 OPPS G-code methodology for payment of prostate brachytherapy services, as applied to CY 2004 OPPS data toward a goal of developing more accurate payment rates as shown below:

- Ms. Braid-Forbes said that one way to deal with using the CPT codes was to apportion the

costs by figuring out what the total cost was with all the packaged items, and then just split that amount out between the two payable codes based upon their relative median costs. She said that's one way of getting around not using the G codes but still looking at full claims for both CPT codes.

- Another simple solution, she said, is possibly using a modification of the G code methodology. Ms. Braid-Forbes went on to say that CMS had come up with and used this method in 2003; however, at that time, the G code was not paid, and the system apportioned those costs between the two CPT codes. In her opinion, this method was "kind of the best of both worlds." "Other than that," she said, "I accepted the methodology."

Panel recommendations were tabled until the end of all presentations in this section.

W. Robert Lee, M.D., consultant to the Coalition for the Advancement of Brachytherapy (CAB), emphasized that brachytherapy is a generic term for a procedure to put a radioactive source or sources into or near a tumor. He also indicated that brachytherapy cannot be performed without a radioactive source. Therefore, he concluded that all correctly coded claims for brachytherapy procedures must have brachytherapy sources also reported on the claims. The problems with incorrect coding of brachytherapy services start at the hospital level. He reflected on what happens to claims for brachytherapy after they leave the Department of Radiation Oncology when codes for various aspects of the procedures, including HCPCS codes for devices of brachytherapy, may be erroneously removed from the claims prior to submission.

Wendy Smith Fuss, consultant to CAB, emphasized that it is important for hospitals to learn how to properly code brachytherapy services.

Gordon Schatz, Esq., legal counsel for CAB, briefly addressed the need to differentiate all different kinds of brachytherapy sources. He noted that CMS has made quick progress in this area, and it needs to continue moving forward.

Panel recommendations for this entire section are shown below.

Discussion

Dr. Potters said that the mean numbers of sources used and median costs look reasonable for most brachytherapy sources, especially the three most commonly used sources. Dr. Potters indicated that the median cost for the Cesium source looks a bit low, but he noted that the frequency is also low since it is a new source.

Dr. Einstein stated that clinically appropriate variations in therapy occur because of specific patient and practitioner considerations including the tumor type, size of the treatment area, and practitioner preference; therefore, a range of source numbers is to be expected. He thought that specific billing guidance for hospitals regarding the reporting of brachytherapy sources and services may be warranted because there may be some confusion, particularly about the reporting of numbers of sources for high intensity brachytherapy sources that may be used for many treatments.

PANEL'S RECOMMENDATIONS - BRACHYTHERAPY ISSUES

1. **The Panel recommends** that CMS reevaluate proposed payment for brachytherapy services in APC 0651, Complex Interstitial Radiation Source Application, for 2007.

2. **The Panel recommends** that CMS formally work with the Coalition for the Advancement of Brachytherapy, American Brachytherapy Society, and the American Society for Therapeutic Radiation and Oncology to evaluate the methodology for setting brachytherapy service payment rates in APC 0651, Complex Interstitial Radiation Source Application, going forward.

SPECIFIC APC ISSUES

Fracture/Dislocation Procedures

Heather Hostetler, CMS Staff, discussed APC 0046, which is made up of 106 CPT codes for open or percutaneous treatment of fractures and dislocations of the upper and lower body. Individual code-specific median costs range from $22 to $7,184. The range of median costs for significant procedures in APC is $1,332 to $3,701, and there are very few single bills for many of the services. Because CPT codes typically indicate with or without fixation in their descriptors, there is no way to specifically differentiate procedures based on their use of external fixation. APC 0046 was excepted from the 2 times rule for CY 2006. Ms. Hostetler requested that the Panel consider giving a recommendation on how to best reconfigure this large and very diverse APC. Ms. Hostetler referred to a handout showing a preliminary suggestion for how APC 0046 might be restructured into three levels.

Fracture/Dislocation Procedures

- **The Panel recommends** that CMS continue to evaluate the refinement of APC 0046, Open/Percutaneous Treatment Fracture or Dislocation, into at least three APC levels, with consideration of a fourth level should data support this additional level.

Update on Magnetoencephalography (MEG) Procedures

Tamar Spolter, CMS Staff, circulated a handout on MEG procedures showing their historical claims frequencies, median costs, and payment rates. She also provided an update per the APC Panel recommendation from the September 2005 APC Panel meeting, which also included a recommendation to maintain MEG services for CY 2006 in their CY 2005 new technology APCs. MEG is a non-invasive diagnostic tool that assists surgeons by measuring and mapping brain activities. For CY 2006, CMS maintained MEG procedures in new technology APCs, but it based their payments on a 50/50 blend of their claims-based median costs and their CY 2005 new technology payment rates. This lowered the payment rates for CY 2006 for all three MEG services. She explained that commenters have indicated that the median costs of these services are erroneous because hospitals are not providing accurate charges for the procedures. The CMS believes that some of the variations between years and between the observed and expected median costs may be due to differences in the numbers of cases performed used in amortization estimates, as costs of the equipment used to provide MEG procedures are significant. Ms. Spolter explained that the OPPS payment rates need to make appropriate payments for the services provided to Medicare beneficiaries, recognizing that the budget-neutral payment system under the OPPS does not pay the full hospital costs of services. The CMS expects that the payment rates will generally reflect the costs associated with providing care to Medicare beneficiaries in cost efficient settings.

MEG Procedures

The Panel recommends that CMS move the following from their current New Technology APCs to clinical APC(s):

- CPT code 95965, *Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (e.g., epileptic cerebral cortex localization)*
- CPT code 95966, *MEG, recording and analysis; for evoked magnetic fields, single modality (e.g., sensory, motor, language, or visual cortex localization)*
- CPT code 95967, *MEG, recording and analysis; for evoked magnetic fields, each additional modality (e.g., sensory, motor, language, or visual cortex localization) (List separately in addition to code for primary procedure)*

Mesh/Prosthesis Procedures

Tom Byrne, Director, Reimbursement & Outcomes Planning, Boston Scientific Corporation, made a presentation on the insertion of mesh for the repair of a pelvic floor defect, described by CPT code 57267 assigned to APC 0154, Hernia/Hydrocele Procedures. Because CPT code 57267 is an add-on code that is always reported in addition to another code for the primary procedure, the payment of $852—after the multiple procedure reduction—for APC 0154 for CY 2006 does not adequately cover the average hospital cost for the implant of $1,900. He recommended assigning CPT code 57267 to a new clinical APC, with a status indicator of "S," that fully recognizes the device costs and is not subject to the multiple surgical procedure reduction. Mr. Byrne said that inappropriate reimbursement could adversely affect access for Medicare beneficiaries, and there are better patient outcomes for pelvic floor repairs with mesh.

Mesh/Prosthesis Procedures

The Panel recommends that CMS move CPT code 57267, *Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure),* from APC 0154, Hernia/Hydrocele Procedures, to a clinically and resource-appropriate APC.

Skin Replacement & Skin Substitute Procedures

David Ahrenholz, M.D., F.A.C.S., presenting on behalf of the American Burn Association (ABA), discussed the assignments of APCs for the new skin substitute CPT codes for CY 2006. The four CPT codes previously used were not adequate to clinically describe what was being done. There are now 40 CPT codes to replace the previously existing four codes. He said that CMS did an excellent job in assigning a number of new codes to APC 0027 for CY 2006. However, nine codes initially placed in APCs 0024 and 0025 for CY 2006 should be moved to APC 0027 based on clinical coherence, and five codes—which were placed in APC 0024—should be moved to APC 0025. Further, Dr. Ahrenholz said that among the other codes currently assigned to APC 0024, most describe repair of nail beds or primary closure of skin wounds either as a simple or layered closure. These codes describe relatively simple procedures that are not consistent with skin graft procedures.

Mark Finkelstein, Administrator, Staten Island University Hospital Burn Center, Staten Island, New York, indicated that he supported moving these 14 codes from their CY 2006 APCs to higher paying APCs 0025 or 0027. The reason for this support is that significant hospital resources are expended from an administrative point of view to provide skin replacement products. Those resources include specialized equipment, refrigerators, alarm systems, and tracking and logging the whereabouts of products.

Dr. Frederick Cahn, CEO of BioMedical Strategies, LLC, explained that his company is a contractor to Integra Life Sciences that manufactures products used in burn treatment

procedures, which are being discussed. He made comments similar to those of the ABA, particularly concerning CPT codes 15170 and 15175.

Robert Kirsner, Vice Chairman of Dermatology, University of Miami, provided a handout to the Panel and made a recommendation to reassign CPT codes 15340 and 15341 to APC 0025, Level II Skin Repair.

Skin Replacement & Skin Substitute Procedures

1. **The Panel recommends** that CMS move the following CPT codes to APC 0027, Level IV Skin Repair:
   - CPT 15170, *Acellular dermal replacement, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children*
   - CPT 15175, *Acellular dermal replacement, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or less, or one percent of body area of infants and children*
   - 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 or less, or one percent of body area of infants and children*
   - CPT 15340, *Tissue cultured allogeneic skin substitute; first 25 sq cm or less*
   - CPT 15360, *Tissue cultured allogeneic dermal substitute; trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children*
   - CPT 15365, *Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or less, or one percent of body area of infants and children*
   - CPT 15420, *Xenograft skin (dermal), for temporary wound closure, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or less, or one percent of body area of infants and children*
   - CPT 15430, *Acellular xenograft implant; first 100 sq cm or less, or one percent of body area of infants and children*

2. **The Panel recommends** that CMS move the following to APC 0025 (Level II Skin Repair):
   - CPT 15171, *Acellular dermal replacement, trunk, arms, legs; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)*
   - CPT 15176, *Acellular dermal replacement, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)*
   - CPT 15321, A*llograft skin for temporary wound closure, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)*
   - CPT 15341, *Tissue cultured allogeneic skin substitute; each additional 25 sq cm*
   - CPT 15361, *Tissue cultured allogeneic dermal substitute; trunk, arms, legs; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)*

- CPT 15366, *Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or less, or one percent of body area of infants and children*

- CPT 15421, *Xenograft skin (dermal), for temporary wound closure, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)*
- CPT 15431, *Acellular xenograft implant; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary)*

Artificial Cornea Procedure

Michael Frost, Clinical Accounts Manager of CooperVision Surgical, Inc., made a presentation with regard to CPT code 65770 for implantation of a keratoprosthesis, a procedure assigned to APC 0244, Corneal Transplant, for CY 2006. AlphaCor provides an alternative to corneal transplant for certain patients who otherwise would become blind. In July 2003, C1818 was initiated for the keratoprosthesis device, which then received transitional pass-through payment through December 31, 2005. Mr. Frost explained that beginning in January 2006, payment for the device is bundled into the procedure payment for CPT code 65770. From CY 2005 to CY 2006, however, the CMS OPPS payment for APC 0244 only increased by $12.99. Mr. Frost said that providers are inadequately reimbursed by the APC rate for the hospital resources utilized for implantation or a keratoprosthesis, and there is a 2 times violation of APC 0244. The cost of the keratoprosthesis procedure is approximately four times the costs of other procedures also assigned to APC 0244. Mr. Frost suggested the creation of a distinct new clinical APC for CPT code 65700.

Artificial Cornea Procedure

The Panel recommends moving CPT code 65770, *Keratoprosthesis*, to a more appropriate APC in order to make appropriate payment.

Percutaneous Renal Cryoablation

Sharon Whalen, Senior Director, Reimbursement & Clinical Outcomes, Endocare, made a presentation with regard to percutaneous renal cryoablation. She explained that the procedure is described by CPT code 0135T, a new Category III CPT code effective in January 2006. The average CY 2006 APC payment is $1,999 for APC 0163, under which CPT code 0135T is currently assigned. APC 0163 does not include other ablation procedures. Ms. Whalen indicated that payment for APC 0163 does not reflect the hospital procedure costs, specifically the requirement for expensive cryoablation probes. There is a more appropriate clinical APC assignment that includes other percutaneous renal ablation procedures. Ms. Whalen suggested the reassignment of CPT 0135T from APC 0163 to APC 0423, Level II Percutaneous Abdominal and Biliary Procedures, which would group CPT 0135T with clinically similar procedures. Further, she indicated that the APC 0423 payment rate would more closely approximate estimated cryosurgery procedure costs.

John McGuinness, Encura, a manufacturer of cryoablation renal equipment, pointed out that this code is a brand new Category III code. He said that the AMA decided to give it a Category III code because it involves new technology. Currently there is a new technology APC application for the procedure pending before CMS.

Percutaneous Renal Cryoablation

The Panel recommends that CMS move CPT 0135T, *Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy,* from APC 0163, Level IV Cystourethroscopy and other Genitourinary Procedures, to APC 0423, Level II Percutaneous Abdominal and Biliary Procedures.

Medication Therapy Management

John Settlemyer, M.B.A., M.H.A., Director, Financial Services, Carolinas Health Care Systems, presenting on behalf of the Provider Round Table (PRT), spoke about Medication Therapy Management Services (MTMS). Mr. Settlemyer gave a brief history of reporting facility fees for E & M-type services under CPT code 99211 prior to the OPPS and under the OPPS. He referenced a CPT instruction, which indicated that a provider should report the code for a service that accurately identifies the service performed. He discussed the new CY 2006 Category III CPT codes for 2006, 0115T, 0116T and 0117T that describe Medication Therapy Management Services, and that are assigned status indicator "B" for CY 2006, indicating that they are not recognized under the OPPS. Mr. Settlemyer described the clinical significance of MTMS to patients. The PRT specifically requested that CPT code 0115T be assigned to APC 0601, that CPT code 0116T be assigned to APC 0600, and that CPT code 0117T be assigned status indicator "N" for purposes of further tracking and future analysis. The PRT also requested that the above actions be implemented during July 2006 in accordance with CMS' semi-annual update of the Category III codes.

Medication Management Therapy Services

1. **The Panel recommends** that CMS provide guidance to hospitals on how and when the these codes should be used, instruct hospitals to report the services under revenue code 940 on the UB-92, and create a new APC—with a nominal payment—for the following:
   - CPT 0115T, *Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, initial 15 minutes, with assessment and intervention if provided; initial encounter*
   - CPT 0116T, *Medication therapy management; subsequent encounter*
   - CPT 0117T, *Medication therapy management; each additional 15 minutes*
2. **The Panel recommends** that CMS implement the previous assignment in July, if possible; otherwise, implementation should be set for CY 2007 at the latest.

Radiology Services

John A. Patti, M.D., F.A.C.R., Chair, Commission on Economics, American College of Radiology (ACR), presented the Panel with an update of ACR's work with CMS on multiple imaging procedure discounting. The ACR has met with CMS and participated in detailed dialogue on whether economies exist when multiple computed tomography (CT), magnetic resonance imaging, and ultrasound procedures in the 11 code families that were defined in the CY 2005 OPPS and Medicare Physician Fee Schedule (MPFS) proposed rules are performed in a single session. The OPPS did not finalize multiple imaging procedure discounting for CY 2006, although this policy was finalized for the MPFS.

The ACR continues to advocate that hospital data for computed tomography angiography (CTA) are flawed, and the APC weight is subsequently too low in comparison with CT procedures. The ACR is also concerned with the inconsistency with which hospitals report their costs. Dr. Patti went on to discuss that CMS should implement uniformity in the system, so consistency would

improve the accuracy of the APC weights. In summary, the ACR made three requests of the Panel:

- First, the ACR would like the Panel to reaffirm its recommendation that CMS not implement the multiple procedure discount policy for imaging services in the OPPS until it has determined that any economies are not already captured by hospitals in their cost data and that no reduction should apply wherever the APC system is used for payments. The ACR would like the Panel to reaffirm its recommendation that CMS continue to work with the ACR to determine how economies are captured by hospitals in their cost data.
- Second, the ACR requested that the APC Panel recommend that CMS address the resource homogeneity of APC 662 and adjust the relativity of APCs for CT and CTA procedures so that payment levels are more accurate by analyzing the hospital data for CPT codes describing CT, CTA, and 3-dimensional reconstruction services.
- Third, ACR recommended that the APC Panel consider how hospitals can better report their costs in a more granular, consistent manner and thus improve the clinical and resource homogeneity of APCs. The ACR is ready to assist the APC Panel and CMS in their efforts in order to improve the clinical and resource integrity of the APC groups through data review, analysis, and education.

Bibb Allen, M.D., F.A.C.R., Co-Chair, Commission on Economics, ACR, Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR), submitted written comments within the letter of Lisa Saake, R.N., M.S.N., M.B.A., and William Regan, Co-Chairs, dated February 1, 2006.

Radiology

1. **The Panel reaffirms** the 2005 recommendation that CMS postpone implementation of the multiple procedure reduction policy for imaging services as included in the CY 2006 OPPS proposed rule for CY 2007, so CMS can gather more data on the efficiencies associated with multiple imaging procedures that may already be reflected in OPPS payment rates for imaging services.
2. **The Panel recommends** that CMS review payment rates for computed tomography and computed tomographic angiography procedures to ensure that their payment rates are comparatively consistent and that they accurately reflect resource use.
3. **The Panel recommends** that CMS invite comments on ways that hospitals can uniformly and consistently report charges and costs related to radiology services.

DRUGS AND DRUG ADMINISTRATION

Drug Acquisition & Pharmacy Overhead Payments

Sabrina Ahmed, CMS Staff, reviewed the major payment policies related to drugs, biologicals, and radiopharmaceuticals that were proposed in the CY 2006 OPPS proposed rule and later were implemented in the CY 2006 final rule. The MMA requires that separate payments be made in CY 2006 for drugs and biologicals with per-administration costs greater than $50. In the CY 2006 OPPS final rule, CMS finalized the policy of paying separately for items with per-day costs greater than $50 and packaging items with per-day cost less than $50. The CMS also allowed an exception to the packaging rule for injectable and oral forms of anti-emetic agents and is paying for them separately in CY 2006. The requirement to establish the packaging threshold at $50 per administration will expire at the end of CY 2006; therefore, CMS will be evaluating the appropriate packaging threshold for drugs, biologicals, and radiopharmaceutical for the 2007 OPPS update.

For CY 2006, the MMA requires that payments for almost all hospital outpatient drugs be equal to the average acquisition cost for the drug as determined by the Secretary. In making this determination, the law requires the Secretary to take into account an MMA mandated GAO survey of hospital drug acquisition costs. The MMA also authorizes the Secretary to determine additional payment amounts for pharmacy handling and overhead costs after reviewing a mandated Medicare Payment Advisory Commission (MedPAC) study of hospital pharmacy overhead costs.

In developing the payment policy for separately payable drugs and biologicals in CY 2006, CMS examined data from several sources such as: the hospital acquisition cost data collected by the GAO, the average sales price data submitted by the manufacturers, and the hospital outpatient claims data. In the CY 2006 proposed rule, CMS proposed to employ the average sales price (ASP) of a drug plus 6 percent as a proxy for the acquisition cost of each separately payable drug because CMS determined that the ASP methodology provided an accurate estimate of drug acquisition costs. The CMS proposed this level after comparing several sources of data including data from a survey of hospital acquisition costs by the GAO, which indicated that payment rates for separately payable drugs and biologicals would be equal to ASP+3 percent on average, and a computation of the mean costs of separately payable drugs from the OPPS claims data, which indicated that payment rates for separately payable drugs and biologicals would be equal to ASP+8 percent on average.

The CMS staff indicated that MedPAC reported that pharmacy overhead costs are already built into the charges for drugs and biologicals used to derive the mean costs; therefore, CMS staff states in the CY 2006 proposed rule that payment for drugs and biologicals at a combined rate of ASP + 8 percent would serve as a proxy for representing both the acquisition cost and overhead cost of each of these products, where ASP + 6 percent represented a drug's acquisition cost, and 2 percent of ASP represented additional costs associated with pharmacy overhead.

However, in the CY 2006 final rule, CMS implemented a policy to set total payment at ASP plus 6 percent for both the acquisition and pharmacy overhead costs of separately payable drugs and biologicals. For the CY 2006 final rule, CMS used updated claims data, updated cost-to-charge ratios, applied more recent ASP data, and recalculated the mean cost of separately payable drugs and biologicals. The CMS found that using average costs to set the payment rates for drugs and biologicals, which would be separately payable in 2006, was equivalent to basing their payment rates, on average, at ASP+6 percent. Consequently, CMS staff believed that it was appropriate to base payment for average acquisition and overhead cost for separately payable drugs and biologicals on ASP+6 percent for CY 2006 because both acquisition and overhead costs are reflected in the charges submitted by hospitals for these items. The final payment level for CY 2006 was, therefore, 2 percentage points less than that shown by the analysis of the data available at the time of the proposed rule. The CMS staff believed that a payment rate of ASP + 6 percent in CY 2006 would serve as the best proxy for the combined acquisition and overhead costs of separately payable drugs and biologicals under the OPPS.

Further, CMS is updating the ASP-based payment rates for separately payable drugs and biologicals on a quarterly basis during CY 2006 as more recent ASP data become available.

In the report of the MMA-mandated study of pharmacy overhead costs, MedPAC developed seven drug categories for pharmacy and nuclear medicine handling costs according to the

level of resources used to prepare the products. The MedPAC recommended that CMS establish separate, budget-neutral payments to cover the costs that hospitals incur for handling separately payable drugs, biologicals and radiopharmaceuticals, and also define a set of handling fee APCs that group these items based on attributes that affect their handling costs. The MedPAC further recommended that hospitals be instructed to submit charges for these APCs and that the payment rates for these APCs be based on submitted charges reduced to costs. In response to the MedPAC recommendations, CMS had proposed to establish three distinct HCPCS C codes and APCs in CY 2006 for drug handling categories to differentiate overhead costs for drugs and biologicals by combining several of the categories identified in the MedPAC report. The CMS also proposed to instruct hospitals to charge the appropriate pharmacy overhead C code for overhead costs associated with each administration of each separately payable drug. However, in the final rule for CY 2006, CMS did not implement these proposals.

Ms. Ahmed also indicated that CMS received comments from the hospital industry on these proposals. The hospital industry expressed strong opposition to CMS' proposal to institute new codes for the collection of pharmacy overhead costs because of the burden that would be imposed by requiring hospitals to separate charges for pharmacy overhead costs from their drug charges solely to bill Medicare. Furthermore, the APC Panel, during the August 2005 meeting, recommended delaying implementation of the new HCPCS codes so that further data and alternative solutions for making payments to hospitals for pharmacy overhead costs could be collected, analyzed, and presented to the Panel at the March 2006 meeting.

The CMS also received several comments with alternatives for it to consider in determining appropriate payment levels for drug-handling costs in CY 2006. The CMS did not adopt these proposals because its staff agreed with MedPAC and other commenters that hospital charges for drugs and biologicals are generally reflective of both their acquisition and overhead costs. Therefore, based on CMS' analysis of the ASP data and hospital outpatient claims data, CMS staff believed that a total ASP+6 percent rate served as the best proxy for the combined acquisition and overhead costs of these products in CY 2006.

Overview - Radiopharmaceuticals

The MMA exempted radiopharmaceuticals furnished in the physician office setting from payment under the ASP system and instituted an alternative methodology to pay for radiopharmaceuticals in physician offices. Because ASP data were not available for radiopharmaceuticals, CMS proposed in the CY 2006 proposed rule to temporarily pay for these products by converting their charges submitted on claims to costs, using the hospital-specific overall cost-to-charge ratio under the OPPS in CY 2006. Ms. Ahmed also indicated that CMS proposed to require ASP reporting by radiopharmaceutical manufacturers beginning in CY 2006 with a view to employing ASP-based prices for radiopharmaceuticals under the OPPS in CY 2007 and beyond.

In the CY 2006 final rule, CMS finalized that it will be paying hospitals for radiopharmaceuticals by adjusting submitted charges to costs using the hospital-specific overall cost-to-charge ratio. The CMS also indicated that it would not be requiring radiopharmaceutical manufacturers to submit ASP data at this time.

The CMS further indicated that the payment methodology for radiopharmaceutical agents, which it finalized for CY 2006, was intended to be only a temporary policy, and it requested suggestions about alternatives sources of radiopharmaceutical cost data and alternative payment methodologies for CMS to consider for the CY 2007 OPPS.

Please see the appropriate Panel recommendation(s) for Drug Acquisition, Pharmacy Overhead Payments, and Radiopharmaceuticals below each of the following sections..

Overview - Drug Administration APCs

Rebecca Kane, CMS Staff, said that prior to CY 2005, drug administration services performed in the hospital outpatient setting were reported using four HCPCS Q-codes as follows: Q0081, Q0083, Q0084, and Q0085 (discontinued in CY 2004). These four codes were each assigned to one of four drug administration APCs for payment purposes under the OPPS, and those are APCs 0115, 0117, 0118 (discontinued in CY 2004), and 0120.

Beginning in CY 2005, OPPS transitioned to the use of CPT codes that continued the chemotherapy, non-chemotherapy distinction and added concepts regarding duration of administration and method of administration. The CPT codes were mapped to the three existing drug administration APCs for payment purposes, and they continued to be paid on a per-visit basis.

In CY 2006, CPT drug administration codes were revised from the 2005 CPT codes to incorporate the concepts of initial, concurrent, and sequential. The OPPS implemented the majority of the 2006 CPT codes but did not implement the codes that incorporated the concept of initial, concurrent, and sequential. Instead, the OPPS implemented several C codes for this subset of services to simplify hospital reporting.

Ms. Kane went on to explain a methodology for unpackaging the three CPT codes for additional hours of infusion in order to obtain data reflecting an individual per-hour infusion rate for those three types of infusion services. Drug administration HCPCS median costs were created using a bypass methodology, and services were preliminarily grouped into six possible new clinical APCs—taking into account both HCPCS median costs and clinical coherence.

The six APC structure reflecting CY 2005 CPT codes was compared to both CY 2006 OPPS drug administration codes and CY 2006 CPT codes. The Panel was asked to comment on the six APC levels, the methodology used to arrive at this structure, and the placement of services within the six levels.

Please see the appropriate Panel recommendation(s) for Drug Acquisition below.

Presentations

Jason Slotnik, Director, Medicare Reimbursement & Economic Policy, Biotechnology Industry Organization (BIO), indicated that his testimony focused on several issues related to OPPS payments for drugs, pharmacy overhead, and drug administration services.

Mr. Slotnik went on to speak about the packaging threshold for separately paid drugs and biologicals including the payment and packaging status of drug administration services. Further, BIO asked the APC Panel to make the following recommendations:

- The CMS should implement adequate, additional payments for hospitals' pharmacy services and handling costs.
- The CMS should continue to pay separately for all drugs and biologicals paid separately in the past, including all therapies that ever had pass-through status.

- The CMS should provide separate payment for the second and subsequent hours of infusion services and should allow hospitals to be paid separately for administering both a hydration and non-chemotherapy infusion in the same visit.
- The CMS should assign the service of administering intravenous immune globulin (IVIG) to an APC that more accurately captures the resources involved in this service, such as APC 0117.

Please see the appropriate Panel recommendation(s) for Drug and Drug Administration, Biologicals & Radiopharmaceuticals below.

Dr. Hambrick indicated to the Panel that as far as the last recommendation, assigning IVIG administration to a specific APC, CMS does not tell hospitals how to bill that particular service.

Stuart Langbein, consultant, Plasma Protein Therapeutics Association (PPTA), focused on IVIG. The PPTA asked the Panel to take the following actions:

- Develop an alternative payment methodology for setting the CY 2007 payment rates for IVIG to hospital outpatient departments that includes product-specific rates.
- Increase the payment for preadministration-related services to capture more accurately the costs hospitals incur for such services and make this a permanent feature of the hospital OPPS.
- Assign the service of administering IVIG to an APC that more accurately captures the resources involved in this service, such as APC 0117.

Please see the appropriate Panel recommendation(s) for Drug and Drug Administration, Biologicals & Radiopharmaceuticals below.

Douglas J. Scheckelhoff, M.S., Director, Pharmacy Practice Sections, American Society of Health-System Pharmacists (ASHP), indicated that ASHP is the professional and scientific association representing pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, and other components of health systems. Further, ASHP provided comments to the APC Panel regarding the reimbursement rates for drugs under the OPPS. It also recommended that CMS work with stakeholders to ensure that separate and appropriate reimbursement for pharmacy handling costs in the OPPS.

Please see the appropriate Panel recommendation(s) for Drug and Drug Administration, Biologicals & Radiopharmaceuticals below.

Ernest R. Anderson, Jr., M.S., R.Ph., Director of Pharmacy, Lahey Clinic and Chairman, Association of Community Cancer Centers (ACCC), addressed the issues concerning reimbursement for drug therapies and APC assignments and payments for drug handling costs. The ACCC requested that the APC Panel recommend that CMS monitor access to drug therapies in hospital outpatient departments and adjust payments as needed to ensure beneficiary access to care. In addition, ACCC requested that CMS pay separately for all drugs, which have been paid separately in the past, and that CMS work with providers to ensure that all hospitals' pharmacy services and handling costs are represented accurately in CMS' data and to develop an appropriate payment methodology for these costs.

Please see the appropriate Panel recommendation(s) for Drug and Drug Administration, Biologicals & Radiopharmaceuticals below.

Wendalyn G. Andrews, Director, Oncology Services, University Medical Center (UMC), Arizona Cancer Center, commented on APC assignments and payments for drugs and drug administration services, as well as coding guidelines for E & M services. Additionally, UMC requested that the APC Panel recommend the following to CMS:

- Make adjustments to the OPPS drug administration rates similar to the adjustments that were made in the physician office setting
- Analyze the CY 2005 claims data to determine if additional new drug administration APCs are warranted and if so, make an adjustment accordingly
- Pay separately for the second and subsequent hours of infusion in CY 2007 and beyond Issue proposed coding guidelines for hospital outpatient E & M services

Please see the appropriate Panel recommendation(s) for Drug and Drug Administration, Biologicals & Radiopharmaceuticals below.

Judith J. Baker, Partner & Executive Director, The Resource Group (TRG), addressed two particular issues, those of drug administration APC groups and the reconsideration of payments for drug-handling services. Current APC groups for chemotherapy infusion (APC 0117) and non-chemotherapy infusion (APC 0120) comprise a wide bundle of services that do not sufficiently recognize the resources required to provide these services.

The TRG recommended that APC 0117 and APC 0120 each be split into two groups of services as follows: the first group representing the initial hour of infusion, and the second group representing each additional hour of infusion. Further, TRG recommended that payment for each additional hour be incremental. Ms. Baker went on to discuss the issue of drug-handling services. In summary, TRG recommended that APC groups for multiple levels of pharmacy drug-handling services be implemented for separate payment, that these groups be aligned with appropriate levels of hospital resources consumed for the relevant duties required at each level, and that the coding allow ease of implementation for providers.

Please see the appropriate Panel recommendation(s) for Drug and Drug Administration, Biologicals & Radiopharmaceuticals below.

Jugna Shah, consultant, Alliance of Dedicated Cancer Centers (Centers), discussed reconfiguration of drug administration APCs. The Centers asked the APC Advisory Panel to make the following recommendation to CMS:

- First, CMS should review the median cost data for each drug administration CPT code, whether currently assigned to an APC or not, and apply the 2 times rule to determine whether additional drug administration APCs should be created.
- Secondly, CMS should place packaged drug administration CPT codes 90781, 96412, and 96423 on the bypass list for the purpose of determining single/multiple procedure claims status.
- Third, if separate APCs are not created for CPT codes 90781, 96412, and 96423, CMS should assign the line item charges associated with these codes to the primary procedure codes associated with each.
- Finally, CMS should provide clear, consistent, and detailed coding guidelines to hospitals at least 45 days prior to the implementation of CPT codes for drug administration in CY 2007.

Please see the appropriate Panel recommendation(s) for Drug and Drug Administration, Biologicals & Radiopharmaceuticals below.

PANEL'S RECOMMENDATIONS - DRUG AND DRUG ADMINISTRATION, BIOLOGICAL & RADIOPHARMACEUTICAL ISSUES

Drug Administration

The Panel recommends that CMS use the bypass methodology presented for additional hours of drug infusion in developing a drug administration payment structure that includes a methodology to pay for infusion services by the hour.

Drugs and Biologicals

1. **The Panel recommends** that CMS examine pharmacy overhead cost issues and work with appropriate associations to study how to measure pharmacy overhead costs.
2. **The Panel recommends** that CMS also solicit feedback on how pharmacy overhead costs should be reimbursed in the future.
3. **The Panel recommends** that CMS maintain the $50 packaging threshold or, if the threshold is reevaluated, that CMS provide the Panel with data that indicate the costs of packaged drugs that are incorporated into drug administration payment rates.

Radiopharmaceuticals

The Panel recommends that CMS work with stakeholders to continue to develop a methodology to pay for radiopharmaceuticals.

IVIG

1. **The Panel recommends** that CMS work with the Plasma Protein Therapeutics Association and other stakeholders to develop appropriate payments for intravenous immunoglobulin (IVIG).
2. **The Panel recommends** that CMS maintain separate payment for IVIG preadministration-related services as long as it remains appropriate.
3. **The Panel recommends** that CMS reevaluate payments for IVIG administration, especially considering the resource intensity of IVIG infusions.

CLOSING

The Panel reviewed the recommendations from the meeting. Dr. Hambrick thanked the Panel members for their service and the CMS and its support staff for their assistance.

Dr. Hambrick adjourned the meeting at 6:18 p.m. on Thursday, March 2, 2006.

Appendix A

AGENDA

March 1, 2, and 3, 2006

ADVISORY PANEL ON AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS' MEETING

DAY 1 - Wednesday, March 1, 2006

TAB

Public registrants may enter the CMS Central Office Building <u>after</u> 12:15 p.m.

Agenda **A(1)**

Charter (Signed November 1, 2004) **(2)**

Security Information **B**

08:00 Subcommittee Meetings

Break (at the discretion of the Subcommittee Chair)

11:00 Subcommittees meet with full Panel

12:00 *Lunch*

01:00 Opening - Day 1
Welcome, Call to Order, and Opening Remarks
Herb Kuhn, Director, Center for Medicare Management

01:20 Panel Organization and Housekeeping Issues
E. L. Hambrick, M.D., Chair, APC Panel

01:30[2] **CMS-1501-fc:** Medicare Program; final rule for the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, Federal Register
- **Overview** - James Hart, Director, Division of Outpatient Care (DOC)
  a. Discussion
  b. Panel's Comments

01:45 **Packaging Issues**
1. **Overview** - Tamar Spolter, CMS Staff
2. **Packaging Subcommittee's Report**
   a. Albert Brooks Einstein, Jr., M.D., Chair
   b. Discussion
   c. Panel's Recommendations
3. **Computer-Aided Detection, Chest Radiograph(s)**
   a. Riverain Medical **C**
      - Matthew Freedman, M.D., M.B.A., Radiologist
        Associate Professor of Oncology, Georgetown University
   c. Discussion
   d. Panel's Recommendations
4. **Acoustic Heart Sound Recording and Computer Analysis**
   a. Inovise Medical, Inc. **D**
      - Patricia A. White, CEO
   b. Discussion
   c. Panel's Recommendations
5. **Incidental or "N" Status HCPCS**
   a. Provider Roundtable **E**
      - Valerie Rinkle, Revenue Cycle Director, Asante
   b. Discussion
   c. Panel's Recommendations

03:00 **Break**

03:15 **Observation Issues**
1. **Overview** – Heather Hostetler, CMS Staff
2. **Observation Subcommittee's Report**
   a. Judie Snipes, R.N., M.B.A., F.A.C.H.E., Chair
   b. Discussion
   c. Panel's Recommendations

03:45 **Data Issues**

1. **Overview** - Anita Heygster, CMS Staff
2. **Data Subcommittee's Report**
   a. Timothy Tyler, Pharm.D., Chair
   b. Discussion
   c. Panel's Recommendations

04:15 **Device-Related APC Issues**

1. **Overview** - Anita Heygster, CMS Staff
2. **Cardia Electrophysiological Procedures**
   a. Biosense Webster, Inc./Cordis (Johnson & Johnson) **F**
   - Margaret Schwantes, Manager, Health Economics
   b. Discussion
   c. Panel's Recommendations
3. **Payment Rates for Device-Related Procedures**
   a. Medical Device Manufacturers Association (MDMA) **G**
   - Jori Frahler, Director, Federal Affairs
   b. Discussion
   c. Panel's Recommendations
4. **Device-Related APCs**
   a. Advanced Medical Technology Association (AdvaMed) **H**
   - Bonnie Handke, Medtronic
   b. Discussion
   c. Panel's Recommendations

05:15 **Inpatient Only Procedures**

1. **Overview** - Dana Burley, CMS Staff
2. Discussion
3. Panel Recommendations

05:45 **Adjourn**

AGENDA

March 1, 2, and 3, 2006

ADVISORY PANEL ON AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS' MEETING

DAY 2 - Thursday, March 2, 2006

Public registrants may enter the CMS Central Office Building <u>after</u> 7:45 a.m.
(NOTE: The Chair will determine the appropriate time for a morning break.)

TAB

08:30 Opening - Day 2
Welcome and Call to Order
E. L. Hambrick, M.D., Chair, APC Panel

08:40 **Brachytherapy**

1. **Overview** - Anita Hegyster, CMS Staff
   - Barry Levi, CMS Staff
2. **Brachytherapy Issues**
   a. American Society for Therapeutic Radiology & Oncology (ASTRO) **I**
      - Michael Kuettel, M.D., Ph.D., M.B.A., Member
      - Mary Jo Braid-Forbes, Consultant
   b. Coalition for the Advancement of Brachytherapy (CAB) **J**
      - W. Robert Lee, M.D., Consultant
      - Gordon Schatz, Esq., Legal Counsel
      - Wendy Smith Fuss, Consultant
   c. Discussion
   d. Panel Recommendations

09:15 **Specific APC Issues**

1. Fracture/Dislocation Procedures
- a. **Overview -** Heather Hostetler, CMS Staff
- b. Discussion
- c. Panel Recommendations

2. Update on MEG Procedures
- a. **Overview -** Tamar Spolter, CMS Staff
- b. Discussion
- c. Panel Recommendations

3. **Mesh/Prosthesis Procedures**
- a. Boston Scientific Corporation **K**
  - Tom Byrne, Director, Reimbursement & Outcomes Planning
- b. Discussion
- c. Panel Recommendations

4. **Skin Replacement & Skin Substitute Procedures**
- a. American Burn Association (ABA) **L**
  - David Ahrenholz, MD, FACS
  - David Levinsohn, CEO, Sherman Oaks Hospital
- b. BioMedical Strategies, LLC **M**
  - Dr. Frederick Cahn, CEO
- c. Discussion
- d. Panel Recommendations

5. Artificial Cornea Procedure
- a. CooperVision Surgical, Inc. **Mc**
  - Michael Frost, Clinical Accounts Manager
  - R. Doyle Stulting, M.D., Ph.D., Professor, Emory University
- b. Discussion
- c. Panel Recommendations

6. Percutaneous Renal Cryoablation
- a. Endocare **N**
  - Sharon Whalen, Senior Director, Reimbursement & Clinical Outcomes
- b. Discussion
- c. Panel Recommendations

7. **Medication Therapy Management**
- a. Provider Roundtable **O**
  - John Settlemyer, MBA, MHA, Director, Financial Services, Carolinas HC Systems
- b. Discussion
- c. Panel Recommendations

8. **Radiology Services**
   a. American College of Radiology (ACR) **P**
      - John A. Patti, M.D., FACR, Chair, Commission on Economics
      - Bibb Allen, M.D., FACR, Co-Chair, Commission on Economics
   b. Council on Radionuclides and Radiopharmaceuticals, Inc.'s (CORAR) **Q**
      Written Comments
   c. Discussion
   d. Panel Recommendations

11:15 **Drugs and Drug Administration**

1. Drug Acquisition & Pharmacy Overhead Payments
- Overview - Sabrina Ahmed, CMS Staff

2. Radiopharmaceuticals
- Overview - Sabrina Ahmed, CMS Staff

3. Drug Administration APCs
- Overview - Rebecca Kane, CMS Staff

12:15 *Lunch*

01:15 **Drug Acquisition, Pharmacy Overhead, and Drug Administration Issues**

1. Biotechnology Industry Organization (BIO) **R**
   - Jason Slotnik, Director, Medicare Reimbursement & Economic Policy
2. Plasma Protein Therapeutics Association (PPTA) **S**
   - Stuart Langbein, Consultant
3. American Society of Health-System Pharmacists (ASHP) **T**
   - Douglas J. Scheckelhoff, M.S., Director, Pharmacy Practice Sections
4. Association of Community Cancer Centers (ACCC) OPEN Advisory Board **U**
   - Ernest R. Anderson, Jr., M.S., RPh., Director of Pharmacy, Lahey Clinic and Chairman, ACCC
5. University Medical Center, Arizona Cancer Center **V**
   - Wendalyn G. Andrews, Director, Oncology Services
6. The Resource Group **W**
   - Judith J. Baker, Partner & Executive Director
7. Alliance of Dedicated Cancer Centers **X**
   - Jugna Shah, Consultant
8. Discussion
9. Panel Recommendations

03:30 *Break* (Cumulative list of Panel's recommendations will be compiled.)

04:00 **Closing**

a. **Summary of the Panel's Recommendations for 2007**
b. Discussion
c. Final Remarks

05:00 **Adjourn**

Appendix B

ADVISORY PANEL ON AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS

Bi-Annual Meeting - March 1-2, 2006

APC Panel Recommendations

PACKAGING ISSUES

1. **The Panel recommends** that CMS maintain the packaged status of HCPCS code 0152T , *Computer aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images, chest radiograph(s).*
2. **The Panel recommends** that CMS pay separately for HCPCS code 0069T, *Acoustic heart sound recording and computer analysis; acoustic heart sound recording and computer analysis only (List separately in addition to codes for electrocardiography*).
3. **The Panel recommends** that CMS pay separately for CPT code 96523, *Irrigation of implanted venous access device for drug delivery systems site, post surgical or interventional procedure (e.g. angioseal plug, vascular plug*, if there are no separately payable OPPS services on the claim.
4. **The Panel recommends** that CMS pay separately for CPT code 36540, *Collection of blood specimen from a completely implantable venous access device*, if there are no separately payable OPPS services on the claim.
5. **The Panel recommends** that CMS pay separately for CPT code 36600, *Arterial puncture, withdrawal of blood for diagnosis,* if there are no separately payable OPPS services on the claim.
6. **The Panel recommends** that CMS pay separately for CPT code P9612, *Catheterization for collection of specimen, single patient, all places of service,* if there are no separately payable OPPS services on the claim.
7. **The Panel recommends** that CMS maintain the packaged status of CPT code 36500, *Venous catheterization for selective organ blood sampling.*
8. **The Panel recommends** that CMS pay separately for CPT code 75893, *Venous sampling through catheter, with or without angiography (e.g., for parathyroid hormone, renin), radiological supervision and interpretation*, if there are no separately payable OPPS services on the claim.
9. **The Panel recommends** that CMS maintain the packaged status of the following:
   - CPT code 74328, *Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation*
   - CPT code 74329, *Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation*
   - CPT code 74330, *Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation*
10. **The Panel recommends** that CMS maintain the packaged status of HCPCS code G0269, *Placement of occlusive device into either a venous or arterial access site, post surgical or intervention procedure*.

11. **The Panel recommends** that CMS maintain the packaged status of the following:
    - CPT code 76937, *Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure)*
    - CPT code 75998, *Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (List separately in addition to code for primary procedure)*
12. **The Panel recommends** that CMS maintain the packaged status of the following:
    - CPT code 76001, *Fluoroscopy, physician time more than one hour, assisting a non-radiologic physician (e.g., nephrostolithotomy, ERCP, bronchoscopy, transbronchial biopsy)*
    - CPT code 76003, *Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device)*
    - CPT code 76005, *Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural, transforaminal epidural, subarachnoid, paravertebral facet joint, paravertebral facet joint nerve or sacroiliac joint), including neurolytic agent destruction*
13. **The Panel recommends** that CMS continue to separately pay for CPT code 76000, *Fluoroscopy (separate procedure), up to one hour physician time, other than 71023 or 71034 (e.g., cardiac floruoscopy).*
14. **The Panel recommends** that CMS provide separate payment for the following:
    - CPT code 94760, *Noninvasive ear or pulse oximetry for oxygen saturation; single determination*
    - CPT code 94761, *Noninvasive ear or pulse oximetry for oxygen saturation; multiple determinations (e.g., during exercise)*
    - CPT code 94762, *Noninvasive ear or pulse oximetry for oxygen saturation by continuous overnight monitoring (separate procedure)*
15. **The Panel recommends** that CMS pay separately for CPT code 38792, *Injection procedure; for identification of sentinel node,* if there are no separately payable OPPS services on the claim.
16. **The Panel recommends** that CMS bring data to the next Panel meeting that show the following:
    - How the costs of packaged items and services are incorporated into the median costs of APCs
    - How the costs of these packaged items and services influence payments for associated procedures
17. **The Panel recommends** that the Packaging Subcommittee continue until the next APC Panel meeting.

OBSERVATION ISSUES

18. **The Panel accepts** the Observation Subcommittee's report, including the request to review additional data at the 2007 winter meeting of the APC Panel.
19. **The Panel recommends** that the Observation Subcommittee continue until the next APC Panel meeting.

DATA AND DEVICE-RELATED APC ISSUES

20. **The Panel recommends** that CMS continue exploring the benefits of reverse editing for devices that are reported on claims without HCPCS codes for procedures describing their insertion or implantation.
21. **The Panel recommends** that the Data Subcommittee continue until the next APC Panel meeting.
22. **The Panel recommends** that CMS maintain the following in APC 0087, Cardiac Electrophysiologic Recording/Mapping:
    - CPT code 93609, *Intraventricular and/or intra-atrial mapping of tachycardia site(s) with catheter manipulation to record from multiple sites to identify origin of tachycardia (List separately in addition to code for primary procedure)*
    - CPT code 93613, *Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure)*
    - CPT code 93631, *Intra-operative epicardial and endocardial pacing and mapping to localize the site of tachycardia or zone of slow conduction for surgical correction*

INPATIENT-ONLY LIST ISSUES

23. **The Panel recommends** that CMS consult with the relevant medical specialty societies before removing the following from the inpatient list:
    - CPT code 61720, *Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus*
    - CPT code 62000, *Elevation of depressed skill fracture; simple, extradural*
    - CPT code 64802, *Sympathectomy, cervicothoracic*
    - CPT code 57292, *Construction of artificial vagina; with graft*
    - CPT code 57335, *Vaginoplasty for intersex state*
    - CPT code 16035, *Escharotomy; initial incision*
24. **The Panel recommends** that CMS remove CPT code 21181, *Reconstruction by contouring of benign tumor of cranial bones (eg, fibrous dysplasia), extracranial*, from the inpatient list.

BRACHYTHERAPY ISSUES

25. **The Panel recommends** that CMS reevaluate proposed payment for brachytherapy services in APC 0651, Complex Interstitial Radiation Source Application, for 2007.
26. **The Panel recommends** that CMS formally work with the Coalition for the Advancement of Brachytherapy, American Brachytherapy Society, and the American Society for Therapeutic Radiation and Oncology to evaluate the methodology for setting brachytherapy service payment rates in APC 0651, Complex Interstitial Radiation Source Application, going forward.

SPECIFIC APC ISSUES

Fracture/Dislocation Procedures

27. **The Panel recommends** that CMS continue to evaluate the refinement of APC 0046, Open/Percutaneous Treatment Fracture or Dislocation, into at least three APC levels, with consideration of a fourth level should data support this additional level.

MEG Procedures

28. **The Panel recommends** that CMS move the following from their current New Technology APCs to clinical APC(s):
    - CPT code 95965, *Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (e.g., epileptic cerebral cortex localization)*
    - CPT code 95966, *MEG, recording and analysis; for evoked magnetic fields, single modality (e.g., sensory, motor, language, or visual cortex localization)*
    - CPT code 95967, *MEG, recording and analysis; for evoked magnetic fields, each additional modality (e.g., sensory, motor, language, or visual cortex localization) (List separately in addition to code for primary procedure)*

Mesh/Prosthesis Procedures

29. **The Panel recommends** that CMS move CPT code 57267, *Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure)*, from APC 0154, Hernia/Hydrocele Procedures, to a clinically and resource-appropriate APC.

Skin Replacement & Skin Substitute Procedures

30. **The Panel recommends** that CMS move the following CPT codes to APC 0027, Level IV Skin Repair:
    - CPT 15170 *Acellular dermal replacement, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children*
    - CPT 15175 *Acellular dermal replacement, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or less, or one percent of body area of infants and children*
    - 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 or less, or one percent of body area of infants and children*
    - CPT 15340 *Tissue cultured allogeneic skin substitute; first 25 sq cm or less*
    - CPT 15360 *Tissue cultured allogeneic dermal substitute; trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children*
    - CPT 15365 *Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or less, or one percent of body area of infants and children*
    - CPT 15420 *Xenograft skin (dermal), for temporary wound closure, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or less, or one percent of body area of infants and children*
    - CPT 15430 *Acellular xenograft implant; first 100 sq cm or less, or one percent of body area of infants and children*

31. **The Panel recommends** that CMS move the following to APC 0025 (Level II Skin Repair):
    - CPT 15171 *Acellular dermal replacement, trunk, arms, legs; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)*
    - CPT 15176 *Acellular dermal replacement, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)*
    - CPT 15321 *Allograft skin for temporary wound closure, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)*
    - CPT 15341 *Tissue cultured allogeneic skin substitute; each additional 25 sq cm*
    - CPT 15361 *Tissue cultured allogeneic dermal substitute; trunk, arms, legs; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)*
    - CPT 15366 *Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or less, or one percent of body area of infants and children*
    - CPT 15421 *Xenograft skin (dermal), for temporary wound closure, face, scalp, eyelids, mouth neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)*
    - CPT 15431 *Acellular xenograft implant; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary)*

Artificial Cornea Procedure

32. **The Panel recommends** moving CPT code 65770, *Keratoprosthesis,* to a more appropriate APC in order to make appropriate payment.

Percutaneous Renal Cryoablation

33. **The Panel recommends** that CMS move CPT 0135T, *Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy,* from APC 0163, Level IV Cystourethroscopy and other Genitourinary Procedures, to APC 0423, Level II Percutaneous Abdominal and Biliary Procedures.

Radiology

34. **The Panel reaffirms** the 2005 recommendation that CMS postpone implementation of the multiple procedure reduction policy for imaging services as included in the CY 2006 OPPS proposed rule for CY 2007, so CMS can gather more data on the efficiencies associated with multiple imaging procedures that may already be reflected in OPPS payment rates for imaging services.

35. **The Panel recommends** that CMS review payment rates for computed tomography and computed tomographic angiography procedures to ensure that their payment rates are comparatively consistent and that they accurately reflect resource use.
36. **The Panel recommends** that CMS invite comments on ways that hospitals can uniformly and consistently report charges and costs related to radiology services.

Medication Management Therapy Services

37. The Panel recommends that CMS provide guidance to hospitals on how and when the these codes should be used, instruct hospitals to report the services under revenue code 940 on the UB-92, and create a new APC—with a nominal payment—for the following:

- CPT 0115T, *Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, initial 15 minutes, with assessment and intervention if provided; initial encounter*
- CPT 0116T, *Medication therapy management; subsequent encounter*
- CPT 0117T, *Medication therapy management; each additional 15 minutes*

38. **The Panel recommends** that CMS implement the previous assignment in July, if possible; otherwise, implementation should be set for CY 2007 at the latest.

DRUG & DRUG ADMINISTRATION, BIOLOGICAL & RADIOPHARMACEUTICAL ISSUES

Drug Administration

39. **The Panel recommends** that CMS use the bypass methodology presented for additional hours of drug infusion in developing a drug administration payment structure that includes a methodology to pay for infusion services by the hour.

Drugs and Biologicals

40. **The Panel recommends** that CMS examine pharmacy overhead cost issues and work with appropriate associations to study how to measure pharmacy overhead costs.
41. **The Panel recommends** that CMS also solicit feedback on how pharmacy overhead costs should be reimbursed in the future.
42. **The Panel recommends** that CMS maintain the $50 packaging threshold or, if the threshold is reevaluated, that CMS provide the Panel with data that indicate the costs of packaged drugs that are incorporated into drug administration payment rates.

Radiopharmaceuticals

43. **The Panel recommends** that CMS work with stakeholders to continue to develop a methodology to pay for radiopharmaceuticals.

IVIG

44. **The Panel recommends** that CMS work with the Plasma Protein Therapeutics Association and other stakeholders to develop appropriate payments for intravenous immunoglobulin (IVIG).
45. **The Panel recommends** that CMS maintain separate payment for IVIG preadministration-related services as long as it remains appropriate.
46. **The Panel recommends** that CMS reevaluate payments for IVIG administration, especially considering the resource intensity of IVIG infusions.