ADVISORY PANEL

ON

AMBULATORY PAYMENT CLASSIFICATION (APC)

GROUPS

APC Panel Meeting Report

August 27–28, 2008

Centers for Medicare & Medicaid Services (CMS)

7500 Security Boulevard, Auditorium

Baltimore, MD 21244-1850

PANEL MEMBERS PRESENT AT THIS MEETING

Patrick A. Grusenmeyer, Sc.D., F.A.C.H.

Michael D. Mills, Ph.D.

Thomas M. Munger, M.D., F.A.C.C.

Agatha L. Nolen, M.S., D.Ph.

Beverly Khnie Philip, M.D.

Louis Potters, M.D., F.A.C.R.

Russ Ranallo, M.S.

James Rawson, M.D.

Michael A. Ross, M.D., F.A.C.E.P.

Patricia Spencer-Cisek, M.S., A.P.R.N.-B.C., A.O.C.N.®

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

Kerry Weems, Acting Administrator, CMS

E. L. Hambrick, M.D., J.D., CMS Medical Officer, *Chair*

Shirl Ackerman-Ross, M.M.S., *Designated Federal Official* (DFO)

Jeffery Rich, M.D., Director, Center for Medicare Management (CMM)

Carol Bazell, M.D., M.P.H., Director, Division of Outpatient Care (DOC)

CMS STAFF PRESENT (continued)

Stephanie Kaminsky, J.D.	Deputy Director, DOC
Sheila Roman, M.D., M.P.H.	Medical Officer, HAPG
Marjorie Baldo, LCDR, U.S.P.H.S., M.S., R.H.I.A., C.C.S. C.C.S.-P	Staff, DOC
Carrie Bullock, M.H.S.	Staff, DOC
Dana Burley, M.S.P.H., B.S.N.	Staff, DOC
Erick Chuang, M.S.	Staff, DOC
Alberta Dwivedi	Staff, DOC
Anita Heygster	Staff, DOC
Rebecca Cole, M.S.	Staff, DOC
Barry Levi, M.B.A.	Staff, DOC
Christina Smith Ritter, Ph.D.	Staff, DOC
Tamar Spolter, M.H.S.	Staff, DOC
Gift Tee, M.P.H.	Staff, DOC

WELCOME AND CALL TO ORDER

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

Kerry Weems, Acting Administrator for CMS, welcomed the members and stressed that the Agency values the work of the Panel. He emphasized the importance of keeping the interests of beneficiaries in mind as the Panel offers advice on improving CMS' payment systems to achieve more efficient delivery of care.

Jeffrey Rich, M.D., Director, CMM, said that the Agency takes the Panel's recommendations very seriously. He noted that the Agency appreciates the Panel members taking time out from their busy schedules to give CMS valuable input.

Dr. Hambrick briefly reviewed the Panel's Charter and defined the scope of issues that the Panel can address. She welcomed Dr. Beverly Philip back to the Panel, and she noted that Louis Potters, M.D., and Judie S. Snipes complete their terms on the Panel in September 2008.

OVERVIEW OF PROPOSED CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (OPPS) AND CALENDAR YEAR (CY) 2009 PAYMENT RATES

Carol Bazell, M.D., M.P.H., Director, DOC, briefly described the that process CMS used to set the payment rates noted in the proposed rule, which went on public display July 3, 2008. She noted that the proposed market basket increase for CY 2009 is 3 percent, and the proposed rule would increase overall OPPS payment to providers by approximately 3.2 percent. Significant issues discussed in the CY 2009 proposed rule include the following:

- **Quality Measures**: The CY 2009 proposal would require hospitals to report on 11 quality measures in CY 2009 to achieve full payment in CY 2010 (the seven measures currently required plus four new imaging efficiency measures). CMS is proposing to validate quality measures in 2010 by surveying 800 randomly selected hospitals that reported CY 2009 data.

- **Cost Estimation**: CMS seeks long-term solutions to improve cost estimation, including addressing charge compression (i.e., the result of assigning a lower markup to high-cost items and higher markup to lower-cost items within one cost center). The CY 2009 proposal would establish separate cost centers for drugs on the basis of pharmacy overhead costs (high vs. low).

- **Partial Hospitalization Program (PHP)**: CMS proposes two separate APCs for the PHP on the basis of the number of services provided per day (three vs. four or more).

- **Type B Emergency Department (ED) Visits**: CMS proposes to create four new APCs for Type B ED visits (identified as levels 1–4) and to pay for level 5 Type B ED visits using the same APC as level 5 Type A ED visits.

- **Composite APCs**: CMS proposes five new composite APCs for multiple imaging services provided during the same session within three imaging families:
  - Ultrasound
  - Computed tomography (CT) and computed tomographic angiography (CTA) without contrast
  - CT and CTA with contrast
  - Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) without contrast
  - MRI and MRA with contrast

- **Drugs and Biologicals (Except Radiopharmaceuticals)**: CMS proposes to pay for drugs and biologicals at a rate of the average sales price (ASP) plus 4 percent. The updated packaging threshold for drugs and biologicals would remain $60 per day.

- **Radiopharmaceuticals and Brachytherapy Sources**: In accordance with the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), therapeutic radiopharmaceuticals and brachytherapy sources will be paid at hospitals' charges adjusted to cost through December 31, 2009. (The CY 2009 proposed rule does not reflect MIPPA because it was issued before the law was enacted.) Diagnostic radiopharmaceuticals are proposed to remain packaged for CY 2009.

- **Drug Administration APCs**: CMS proposes to reconfigure the six-level APC structure for payment of drug administration services to five APCs that better align with costs determined from claims data and that eliminate unnecessary APCs.

- **Ambulatory Surgical Centers (ASCs)**: CMS will apply a budget-neutral ASC-specific conversion factor to determine payment rates for ASCs.

DATA ISSUES

CMS staff member Anita Heygster described proposed changes to the revenue code-to-cost center crosswalk that CMS uses to match the charges on a claim to the cost-to-charge ratio for the applicable cost center. The proposed rule supporting data files include a crosswalk based on revisions suggested by RTI International, which CMS commissioned to study cost estimation under the OPPS.

Ms. Heygster outlined how CMS categorizes claims for ratesetting, including the process of identifying "pseudo" single claims that can be assessed alongside "natural" single claims. About 91 million claims from CY 2007 were identified (30 million single claims and 61 million "pseudo" single claims), of which 89 million were used to calculate median costs for 2009. Ms. Heygster said that in the proposed rule for 2009, the number of violations of the "two-times rule" (i.e., in a given APC, the median cost of the most costly significant service should be no more than two times the median cost of the least costly significant service) decreased to 12 (from 20) in 2008. A notable number of Healthcare Common Procedure Coding System (HCPCS) codes were proposed for reassignment to different APCs as a result of updated claims data or as a result of the proposal to create composite APCs for imaging procedures.

Data Subcommittee's Report

Dr. Potters, Chair of the Data Subcommittee, said that the Subcommittee discussed information provided by CMS staff on median cost development, the RTI report, calculations upon which the proposed 2009 payment of separately payable drugs was based, and the proposal to categorize pharmacy costs into two cost centers on the Medicare cost report on the basis of overhead costs. The Subcommittee deferred making recommendations in anticipation of presentations and Panel discussion to come.

Valerie Rinkle of Asante Health System asked the Subcommittee to evaluate the effect on device-dependent APCs of CMS' new policy adopted in the FY 2009 Inpatient Prospective Payment System (IPPS) final rule to establish separate cost centers for implantable devices and other medical supplies on the Medicare cost report.

PACKAGING ISSUES

Packaging Subcommittee's Report

James Rawson, M.D., Chair of the Packaging Subcommittee, said that the Subcommittee reviewed information provided by CMS on HCPCS code A4306, *Disposable drug delivery system, flow rate of less than 50 mL per hour*, and a number of CPT codes for intravascular ultrasound (IVUS), intracardiac echocardiography (ICE), fractional flow reserve (FFR), and intravenous immune globulin (IVIG) preadministration-related services. The Subcommittee deferred making recommendations in anticipation of presentations and Panel discussion to come.

Disposable Drug Delivery Devices

Overview

CMS staff member Tamar Spolter reiterated the CMS rationale for packaging, noting that it provides an incentive for providers to deliver services in the most efficient, cost-effective manner possible. Ms. Spolter said that for 2009, CMS proposes to continue packaging HCPCS code A4306, *Disposable drug delivery system, flow rate of less than 50 mL per hour*, as recommended by the Panel at a previous meeting, because it views the items reported under this code as supplies.

Public Presentation

Roger Massengale of I-Flow, Inc., said that some disposable drug delivery devices used to treat postoperative pain have more components and cost much more than those used for simple antibiotic infusion (Presentation A). He believes that by reporting HCPCS code A4306, *Disposable drug delivery system, flow rate of less than 50 mL per hour*, providers may be miscoding the multi-component kit and reporting only the drug-delivery device in the kit. He requested that CMS create a new APC for such postoperative pain drug-delivery devices. Deborah Williams of Baxter Healthcare pointed out that her company has had difficulty understanding the coding for drug-delivery devices. She noted that the CPT codes do not adequately distinguish drug-delivery devices from saline infusion devices. Kathy Dorale of Avera Health suggested that hospitals may include charges for such devices under a supply revenue code but would not necessarily report them with the HCPCS code, so the data may not reflect the real costs of the devices.

Coronary Flow Reserve Management

Overview

Ms. Spolter said that CMS proposes to maintain packaging for several IVUS, ICE, and FFR CPT codes for 2009. Although at a previous meeting the Panel recommended paying separately for a number of IVUS and ICE CPT codes, CMS believes these technologies and FFR are always used ancillary and supportive to another procedure that is separately paid under the OPPS. Neither resource cost nor frequency of use are specifically factored into packaging decisions.

Public Presentation

James Archetto of Radi Medical Systems, Inc., argued that FFR is neither ancillary nor dependent because it is performed before other interventional procedures to aid decision making (Presentation B). He added that more use of FFR might result in fewer unnecessary interventions, but packaging limits payments so much that hospitals avoid using the technology. Panel members expressed concern about the lack of data about quality on which to base cost-benefit decisions for this and other technologies. There was consensus that when items are packaged too soon, it may be difficult to obtain sufficient data on their use. Panel members felt CMS should establish some threshold of use of new technology before packaging is considered.

- **Recommendation**: The Panel recommends that CMS pay separately for the following IVUS, ICE, and FFR CPT codes:

  - CPT code 37250, *Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel*

  - CPT code 37251, *Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel*

  - CPT code 92978, *Intravascular ultrasound (coronary vessel or graft) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel*

  - CPT code 92979, *Intravascular ultrasound (coronary vessel or graft) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel*

  - CPT code 93662, *Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation*

  - CPT code 93571, *Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, initial vessel*

  - CPT code 93572, *Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, each additional vessel*

  The Panel further recommends that CMS establish a threshold (e.g., a proportion of cases in which the service is provided ancillary and dependent to another service, rate of change in utilization over time, market penetration) when packaging will be considered. The Panel also recommends that CMS reconsider packaging these codes after 2 years' worth of claims data are available from their period of separate payment.

IVIG Preadministration-Related Services

Overview

Ms. Spolter noted that from 2006 through 2008, CMS paid separately for HCPCS code G0332, *Services for intravenous infusion of immunoglobulin prior to administration*. She emphasized that separate payment had always been considered a temporary approach to address instability in the marketplace that caused providers to spend a great deal of staff time procuring IVIG and rescheduling patient visits because of unpredictable supplies of IVIG. CMS proposes to package HCPCS code G0332 in 2009 because market conditions appear to have improved.

Public Presentation

Jay Greissing of the Plasma Protein Therapeutics Association (PPTA) urged CMS to continue paying separately for IVIG preadministration-related services, saying that 44 percent of hospitals are unable to purchase IVIG at or below the Medicare payment rate (Presentation C). He pointed to continued barriers faced by Medicare beneficiaries receiving IVIG. John Settlemyer of the Carolinas Healthcare System noted that providers have difficulty maintaining patients on the same brand of IVIG over time because of supply problems. Beth Roberts of the Association of Community Cancer Centers (ACCC) echoed that same point.

Laurel Todd of the Biotechnology Industry Organization (BIO) said her organization supports the request for continued separate payment of HCPCS code G0332. Jugna Shah of the Alliance of Dedicated Cancer Centers (ADCC) said that the Alliance polled its member institutions: about half felt IVIG supply problems had been resolved, and half said that supply problems had worsened. Janet Gallaspy of Forrest General Hospital related her family member's experience with unpredictable IVIG supplies. Jennifer Artigue of Our Lady of the Lake Hospital System said her hospital kept the charge for IVIG preadministration-related service especially low to avoid increasing the cost of the service to beneficiaries. Panel members were unaware of data documenting widespread barriers to IVIG access.

Radiation Therapy Guidance

Overview

Ms. Spolter said that CMS sees no reason to treat radiation therapy guidance differently from other guidance because it is always performed ancillary to and dependent on radiation therapy. CMS proposes to maintain the packaging of radiation therapy guidance for 2009.

Public Presentation

Grant Bagley, M.D., speaking on behalf of Calypso Medical Technologies, reiterated the concern that when CMS packages new technologies too soon, providers face a disincentive to use them; consequently, he felt that CMS never receives sufficient data upon which to base median costs (Presentation D). He asked that CMS continue to pay separately for newer radiation guidance technologies, so it may collect more data on their use and costs on which to base packaging decisions. Trisha Crishock of the American Society for Therapeutic Radiology and Oncology said that few of the costs associated with image-guided radiation therapy are captured in CMS' ratesetting methodology.

Ms. Shah of ADCC said that CMS' claims processing logic allows for some incongruous packaging. Instituting a packaging threshold would not help as long as services are packaged inappropriately, she noted.

- **Recommendation**: The Panel recommends that CMS pay separately for radiation therapy guidance for 2 years and then reevaluate packaging on the basis of claims data. The Panel further recommends that CMS evaluate possible models for threshold levels for packaging radiation therapy guidance and other new technologies.

MULTIPLE IMAGING AND DEVICE-DEPENDENT APCS

Overview

CMS staff member Carrie Bullock said that for CY 2009, CMS proposed to continue using its current methodology to set payment rates for device-dependent APCs. Among other criteria, claims must pass a procedure-to-device edit as well as a device-to-procedure edit. Ms. Bullock noted that payment for device-dependent APCs appears to have stabilized over the past few years. However, median costs declined significantly for three APCs in the CY 2009 calculations, all involving implantation of electrode leads. Most notably, APC 0225, *Implantation of Neurostimulator Electrodes, Cranial Nerve*, declined from a median of approximately $13,889 to approximately $6,633. CMS determined that the steep decline for APC 0225 resulted from the initiation of a device-to-procedure edit (in 2007) that ensures that claims reflect both the procedure and its correlating device, whether implantation of the lead or the pulse generator. Therefore, the 2009 proposed payment rates are appropriate and expected. CMS staff applied similar analyses to claims for APC 0106, *Insertion/Replacement of Pacemaker Leads and/or Electrodes*, and APC 0418, *Insertion of Left Ventricular Pacing Electrodes*, for which median costs also decreased significantly, and came to similar conclusions.

Ms. Bullock described the history of the APC assignment of percutaneous renal cryoablation. For CY 2009, CMS proposes maintaining CPT code 50593, *Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy*, in APC 0423, *Level II Percutaneous Abdominal and Biliary Procedures*.

CMS proposes five new composite APCs for multiple imaging procedures. Providers would receive a single payment when multiple imaging procedures within a single family are performed on the same date of service. The composite APCs for procedures with contrast will be applied when at least one of the imaging services requires the use of contrast. The payment rates would be determined on the basis of median costs calculated using claims data for the specific combination of services.

In response to Panel members' concerns, Denise Williams of Vanguard Health System said there would be little incentive for providers to game the system by requiring patients to have imaging services on separate days because the work required for multiple patient visits would be more than the additional payment is worth. Mr. Settlemyer added that many patients who require multiple imaging services have emergency conditions, so returning for imaging on another day would not be an option.

Public Presentations

Beth Halpern, speaking for the Medical Device Manufacturers Association (MDMA), said that expanded packaging creates artificial reductions in payment and limits beneficiaries' access to care (Presentation E). Experience shows that hospitals do not code for items for which they are not paid separately, she said, and recommended that CMS require complete and correct coding for all packaged services. Ms. Halpern said that packaging payment for new technologies decreases providers' ability to offer innovative treatments and asked that CMS pay separately for IVUS and ICE procedures. She questioned CMS' calculation of rates for the "with contrast" composite APCs for multiple imaging services. To prevent problems with provider payment and beneficiary access, Ms. Halpern recommended that CMS limit any reduction in a given device-dependent APC to no more than 10 percent per year. Finally, she asked CMS to stabilize the payment for APC 0225 at the 2008 rate.

Ms. Bullock pointed out that in determining rates for the proposed multiple imaging services composite APCs, CMS applied the methodology that it would use for 2009 to 2007 claims data. Claims with multiple imaging services within the same imaging family were evaluated, and if one imaging service involved contrast, the claim was categorized in the corresponding "with contrast" composite APC.

Panel member, Kim Williams, M.D., supported the concept of requiring providers to submit complete and correctly coded claims for all packaged services. Pam Kassing of the American College of Radiology (ACR) suggested that CMS identify claims for multiple imaging services when all are performed with contrast to more appropriately estimate the cost of the imaging session. She added that her organization's analysis of the data found that payments would be significantly reduced when three or more imaging services are provided in a single session, providing incentive to spread imaging services out over multiple days. Ms. Shah of ADCC said her organization came to a similar conclusion, with significant financial impact when providers perform three or more CT services, commonly performed in trauma care or cancer staging. She suggested that CMS consider establishing composite APCs that take into account the number of services provided, as it is proposing for PHP payments.

- **Recommendation**: The Panel recommends that CMS work with stakeholders to review the proposed multiple imaging composite APCs and to assess the potential impact of the proposal on Medicare beneficiaries affected by trauma or cancer.

Gregory Krauss, M.D., said that the Vagus Nerve Stimulation (VNS) Therapy System is used to reduce seizures in patients with epilepsy for whom antiepileptic medications are not effective (Presentation F). The proposed decrease in payment for APC 0225, which includes the VNS system, would make the therapy too expensive for providers and beneficiaries, said Dr. Krauss. He asked that CMS look only at the claims data on APC 0225 for patients with epilepsy. Stanley Jackson of Cyberonics, Inc., which makes the VNS Therapy System, suggested that CMS do the following:

1) reassign CPT code 64553, *Percutaneous implantation of neurostimulator electrodes, cranial nerve*, to APC 0040, *Percutaneous Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve*, leaving CPT code 64573, *Incision for implantation of neurostimulator electrodes, cranial nerve*, as the only code in APC 0225; and then

2) recalculate the payment rate for APC 0225 using only claims for patients with epilepsy.

Dr. Bazell pointed out that the OPPS rates typically apply regardless of the medical condition for which a device is used, so APC median costs are typically developed based on claims for all patient diagnoses.

Stephanie Mensh from Neocure said that her organization is in the process of evaluating CMS' claims data for APC 0225. She said that hospitals would be underpaid if the proposed payment decrease takes effect and suggested that CMS maintain APC 0225 at its current payment rate for CY 2009 and base future payment rates on correctly coded claims. She added that it is difficult to identify single or "pseudo" single claims for a procedure that always involves implantation of two devices (a lead and a generator).

- **Recommendation**: The Panel recommends that CMS reassign CPT code 64553, *Percutaneous implantation of neurostimulator electrodes, cranial nerve,* to APC 0040, *Percutaneous Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve.*

- **Recommendation**: The Panel recommends that CMS recalculate the median cost of APC 0225, *Implantation of Neurostimulator Electrodes, Cranial Nerve,* based solely on CPT code 64573, *Implantation of neurostimulator electrodes, cranial nerve (vagal nerve stimulation).*

DeChane Dorsey, Esq., of the Advanced Medical Technology Association (AdvaMed) said the organization withdrew its comments on multiple imaging services composite APCs (Presentation G). She asked that CMS establish a new, device-dependent APC for higher-cost percutaneous renal cryoablation procedures and continue educating hospitals on accurate coding for devices and other technologies. Ms. Dorsey asked that CMS exclude claims with the FC modifier from ratesetting calculations, just as it already excludes claims with the FB modifier. She also called for stabilization of payment for APC 0225 for CY 2009 and asked that CMS conduct a detailed analysis of claims and external data to determine the payment rate for future years.

Dr. Bazell said that she believes that CMS has implemented edits for as many device-dependent APCs as appropriate although suggestions for further edits are welcome. In response to a question about why percutaneous renal cryoablation costs $1,200 more than percutaneous radiofrequency ablation, Lisa Hayden of Galil Medical said cryoablation involves more monitoring, among other resource and supply differences. She said that cryoablation always involves a probe, so the reporting of a C code to capture the use of the device on claims should be required.

Ms. Rinkle of Asante Health System expressed concern that CMS was basing its calculations on an artificially low number of claims because only single or "pseudo" single claims were used for ratesetting.

Dr. Bazell noted that CMS had not yet addressed whether it would exclude claims using the FC modifier from ratesetting methodologies because data on the modifier's use will only be first reflected in CY 2008 claims.

Mr. Settlemyer, speaking on behalf of the Provider Roundtable, urged CMS to delay the implementation of the proposed multiple imaging services composite APCs. Ms. Kassing of ACR said her organization is against the proposed multiple imaging services composite APCs, noting that many issues require further study.

VISITS AND OBSERVATION ISSUES

Overview

CMS staff member Heather Hostetler explained that for CY 2009, CMS proposes to establish a five-level APC structure for Type B ED visits by creating four new APCs for care defined as levels 1–4. The level 5 Type B ED visit would be paid using the same APC as level 5 Type A ED visits and would be included in the composite APC 8003, *Level II Extended Assessment and Management Composite*.

Visits and Observation Subcommittee's Report

Michael Ross, M.D., Acting Chair of the Visits and Observation Subcommittee, thanked CMS staff for the data and assistance provided to the Subcommittee. He noted that after reviewing the data provided on length of stay, the Subcommittee requested more detailed data from CMS to evaluate why lengths of stay for observation peak at 12–24 hours and again at 48 hours and to evaluate lengths of stay over 48 hours.

- **Action Item**: The Panel requests that data on observation services with longer lengths of stay, analyzed by hospital characteristics, be presented at the next meeting of the Panel.

The Subcommittee reviewed the proposed APCs for Type B ED visits and requested to review relevant CY 2008 claims data at the next Panel meeting.

- **Action Item**: The Panel requests that an analysis of CY 2008 claims data for clinic visits, ED visits (Type A and Type B), and extended assessment and management composite APCs be presented at the next meeting of the Panel.

Ms. Rinkle of Asante Health System requested that the Subcommittee assess whether there is some correlation between the decrease in 1-day hospital inpatient admissions and an increase in longer lengths of stay in outpatient observation that could be a result of pressure to eliminate 1-day inpatient stays. Ms. Williams of Vanguard Health System raised concerns that CMS is not capturing all the relevant HCPCS codes in its claims data for critical care services. Ms. Williams and Nelly Leon-Chisen of the American Hospital Association said hospitals are confused about correct coding for critical care because no clear guidance is available. Ms. Rinkle added that hospitals would prefer the previous approach of billing separately for ancillary services because they feel those services are not adequately captured and included in ratesetting by CMS for critical care.

- **Recommendation**: The Panel recommends that CMS adopt the proposed APC assignments and payment rates for Type A and Type B ED visits for CY 2009.

- **Recommendation**: The Panel recommends that CMS adopt the CY 2009 proposals related to the extended assessment and management composite APCs, especially in reference to the inclusion of the level 5 Type B ED visit HCPCS code in APC 8003, *Level II Extended Assessment and Management Composite*.

INPATIENT LIST

Overview

CMS staff member Dana Burley presented a list of 11 procedures that CMS identified for possible removal from the inpatient list. She briefly described the procedures and the data on which CMS' proposal was made.

Public Presentation

Stephanie Stinchcomb of the American Urological Association (AUA) said her organization agreed with the CMS proposal to remove three urological procedures from the inpatient list and also recommended three others (Presentation H). She noted that these six procedures can be performed safely in outpatient settings but supporting claims data are limited because hospitals only receive payment when they are performed on an inpatient basis.

- **Recommendation**: The Panel recommends that CMS remove the following CPT codes from the inpatient list:
    - CPT code 50727, *Revision of urinary-cutaneous anastomosis (any type urostomy)*
    - CPT code 54332, *One stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap*
    - CPT code 54535, *Orchiectomy, radical, for tumor, with abdominal exploration*
    - CPT code 51845, *Abdomino-vaginal vesical neck suspension, with or without endoscopic control (e.g., Stamey, Raz, modified Pereyra)*
    - CPT code 51860, *Cystorrhaphy, suture of bladder wound, injury of rupture; simple*
    - CPT code 54336, *One stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap*

Ms. Artigue of Our Lady of the Lake Hospital System pointed out that when, in the course of performing a procedure on an outpatient basis, a provider finds it necessary and appropriate to perform an additional procedure that is limited to CMS' inpatient list, CMS denies payment for the entire encounter. She requested that CMS create a modifier to identify such claims and to provide payment.

DRUGS, BIOLOGICALS, RADIOPHARMACEUTICALS, AND PHARMACY OVERHEAD

Drugs, Biologicals, and Pharmacy Overhead

Overview

CMS staff member Rebecca Cole described the methodology for determining payment rates, noting that for CY 2009, CMS proposes to continue using a packaging threshold of $60 per day. She pointed out that the 2008 payment rate of ASP plus 5 percent for separately payable drugs was intended to serve as a transition between the CY 2007 payment of ASP plus 6 percent and CMS' claims-based cost estimates of ASP plus 3 percent for 2008. In CY 2009, CMS proposes to pay for drugs and biologicals at a rate of ASP plus 4 percent, consistent with the costs on claims.

Ms. Cole said that hospitals include pharmacy overhead costs in the charges for a drug, regardless of whether the drug is paid separately or packaged. In the past few years, CMS has proposed and the Panel has recommended various methods to better capture and pay for pharmacy overhead costs, but none have been implemented. At the March 2008 meeting of the Panel, a group of stakeholders proposed a methodology that they believed would capture drug and pharmacy overhead costs more accurately. The methodology included recalculating the ASP on the basis of both separately paid and packaged drugs, which would result in an excess pool of money that could be redistributed, for example, to pay for pharmacy overhead costs. In the proposed rule for CY 2009, CMS has requested public comment on the methodology suggested, while noting its concerns about the implementation, accuracy, and challenges of redistribution. CMS also expressed concerns about substituting external data for costs on claims to develop payment rates.

In accordance with the recommendations made by RTI, Ms. Cole said, that CMS proposes to create two cost centers under which hospitals would report drug acquisition and overhead costs: drugs with high overhead cost charged to patients and drugs with low overhead cost charged to patients. The Agency believes this approach would address the underlying issues that affect ratesetting for drugs by allowing for more accurate cost estimation.

Radiopharmaceuticals

Overview

Ms. Cole said that CMS proposes to continue packaging payment for diagnostic radiopharmaceuticals into payment for their associated nuclear medicine procedures. While CMS had proposed for CY 2008 to make separate payment for therapeutic radiopharmaceuticals with a per-day cost over $60, the Medicare, Medicaid, and State Children's Health Insurance Program Extension Act of 2007 required CMS to pay for therapeutic radiopharmaceuticals at hospital charges adjusted to cost through June 30, 2008. Furthermore, MIPPA requires CMS to continue this methodology through December 31, 2009. Ms. Cole pointed out that MIPPA supersedes CMS' published proposal to provide payment for therapeutic radiopharmaceuticals at a rate of ASP plus 4 percent.

Public Presentations

James Bianco, M.D., of Cell Therapeutics, Inc., said that his company's product, Zevalin, is a radiopharmaceutical used to treat patients with non-Hodgkin's lymphoma who fail immunotherapy (Presentation I). He said CMS underpays for Zevalin, thereby limiting beneficiaries' access to it. Dr. Bianco expressed support for the CMS' proposal to use the ASP methodology and said his company would provide ASP data quarterly. He said that the exemption from the ASP methodology under MIPPA allows manufacturers time to prepare for reporting ASP data.

Dr. Potters said that whenever CMS proposes a methodologic change to fix the payment rates for radiopharmaceuticals, the industry lobbies Congress for an exemption, and he found this approach disruptive, inappropriate, and a disservice to those who use radiopharmaceuticals and brachytherapy. He also pointed out to Dr. Bianco that it might not be an efficient use of the Panel's time to hear a presentation when the industry had already secured congressional intervention to prevent CMS' proposal from taking effect. Audience member Ann Marie Williams echoed the comments of Dr. Bianco.

Christopher Hogan, Ph.D., of Direct Research, LLC; John McKnight of PPTA; Ernest Anderson Jr., M.S., R.Ph., of the Lahey Clinic and President of ACCC; Ms. Todd of BIO; Justine Coffey of the American Society of Health-System Pharmacists; and Ms. Shah of ADCC provided a joint presentation in which they proposed a revised methodology for setting payment rates for drugs and biologicals that better accounts for pharmacy overhead costs (Presentation J).

Mr. Anderson said the current rate of ASP plus 5 percent does not cover acquisition costs (Presentation K). He also spoke against the CMS proposal to create two pharmacy overhead cost centers. Ms. Todd said that Congress required CMS to pay for drugs at their average acquisition costs so that CMS would move away from the flawed system of estimating costs from charges (Presentation L). She said the ASP methodology does not comply with Congress' intent. Ms. Coffey pointed out that analysis of cost reports shows that pharmacy overhead accounts for at least 25 percent of a department's costs for a drug, and these costs are not adequately reflected in the ASP methodology (Presentation M). Ms. Todd noted that 2005 Medicare Payment Advisory Commission (MedPAC) findings concur with this analysis of pharmacy overhead costs and that the RTI report stated that CMS underestimates those costs.

Dr. Hogan gave his analysis of how CMS applies the ASP methodology, stating that the rate of ASP plus 4 percent is arbitrarily set on the basis of the packaging threshold. Because CMS has no policy for allocating drug costs between separately paid and packaged drugs, the current allocation represents a random interaction between hospital markup practices and the CMS packaging threshold. Dr. Hogan said the CMS method is flawed and consistently underpays for separately payable drugs. He added that CMS' method does not comply with the statute and therefore should be replaced by the drug payment rates that are paid in the physician's office setting (ASP plus 6 percent) or under the Competitive Acquisition Program.

Mr. McKnight pointed out that when CMS compares drug costs from claims with ASP, CMS includes claims from hospitals that purchase drugs at a deeply discounted rate under the 340B program, although sales under the 340B program are excluded from the ASP calculation. Thus, CMS underestimates the aggregate cost of drugs for most hospitals.

Ms. Shah explained how this group of stakeholders had been working with CMS to craft an alternative to its previous proposal (described by Ms. Cole) (Presentation N). She recommended that CMS: 1) pay for separately payable drugs at a rate no less than ASP plus 6 percent, 2) package payment for all HCPCS-coded drugs that are not separately paid at a rate of ASP plus 6 percent, and 3) apply the difference between ASP plus 6 percent and CMS' costs derived from charges to pay for pharmacy services. She also asked that CMS not implement the proposal to create two pharmacy cost centers. This group of stakeholders has developed a system to categorize pharmacy overhead costs according to the complexity of services required.

Panel Member Agatha Nolen, D.Ph., M.S., a pharmacist, pointed out that the stakeholder methodology would primarily affect payment for cancer drugs, which are used by only 3 percent of the Medicare population. While she appreciated the need to address pharmacy overhead costs, she raised concerns about the effect the proposal would have on beneficiaries' copayments.

Ms. Rinkle of Asante Health System raised concerns about CMS' piecemeal approach to revising the cost centers on the Medicare cost report and said hospitals need more prescriptive directions from CMS. She asked that CMS not implement the proposal to create two pharmacy cost centers and supported the use of ASP plus 6 percent for drug payment. Panel member Patrick Grusenmeyer, Sc.D., felt the two cost center approach could not be implemented.

Dr. Bazell reiterated that CMS had requested comment in the proposed rule on the methodology suggested by this group of stakeholders at the March 2008 meeting. She clarified that in the proposed rule, CMS discussed four possible ways in which hospitals could allocate pharmacy overhead costs to the proposed two cost centers but specifically proposed one approach.

Ms. Roberts of the ACCC said that if all HCPCS-coded drugs were paid separately instead of packaged, the current methodology would yield a payment rate of ASP plus 13 percent. This finding supports Dr. Hogan's contention that packaging drives the equivalent ASP-based payment rate down. She supported the suggestion that CMS apply a payment rate of ASP plus 6 percent or conduct a detailed cost survey as required by statute.

While Ms. Shah felt the current system disproportionately affects cancer hospitals, Dr. Ross raised concerns that the new proposal would discriminate against small, non-cancer hospitals. Mr. Anderson said the proposal applied to all drugs, including other high-cost therapies, such as those for rheumatoid arthritis. Ms. Rinkle added that hospitals cannot continue to absorb the costs of providing care when cancer drugs are underpaid. Panel member Patricia Spencer-Cisek, M.S., A.P.R.N.-B.C., A.O.C.N.®, concurred, saying that because of the underpayment for drugs, physicians are sending patients to the hospital for treatment, which can pose a burden to patients as well as to the hospital.

In response to a question about including drug costs from hospitals using the 340B program, Dr. Bazell said CMS uses data from all hospitals in ratesetting. She indicated that there are a variety of discounts hospitals may receive on products used in the care of hospital outpatients, and CMS has no way of identifying in most cases those discounts that may affect hospitals' costs as calculated from claims.

- **Recommendation**: The Panel recommends that CMS *not* implement the proposed change to the cost center for drugs on the Medicare cost report.

- **Recommendation**: The Panel recommends that CMS continue to pay for drugs at a rate of the ASP plus 5 percent, that CMS continue to look at refining the methodology for payment of pharmacy overhead and handling costs, and that CMS work with stakeholders to find a feasible approach for payment of drugs and pharmacy overhead.

Ms. Roberts of the ACCC said the proposed solution described by the stakeholders at this meeting represented the culmination of discussions between stakeholders and CMS and that it could be implemented by January 1, 2009. Dr. Nolen felt the Panel needed more time to evaluate the proposal. Panel member Thomas Munger, M.D., said the proposal, while laudable, represents a temporary fix that still fails to provide CMS adequate data on drug costs. Ms. Shah countered that the two cost center approach might be appropriately implemented in the future.

Panel members discussed the pros and cons of the stakeholder proposal, including the ASP plus 6 percent payment rate, the three-tier system suggested by the stakeholders for categorizing pharmacy overhead costs by drug, and the effect on beneficiaries' copayments. Dr. Rawson expressed concern that if CMS implemented a methodology that redistributed money to pay for pharmacy overhead costs, other hospital services would demand the same treatment.

- **Recommendation**: The Panel recommends that CMS:

  - Pay the acquisition cost of all separately paid drugs and biologicals at no less than ASP plus 5 percent.

  - Package the cost of all drugs that are not separately paid at ASP plus 5 percent. Use the difference between these costs and CMS' costs derived from charges to create a pool that funds payment for pharmacy services. In applying this methodology, CMS should take into consideration the impact on beneficiaries' copayments.

  - Pay hospitals for pharmacy service costs using this pool by making payments based on some system of categorization determined by CMS.

APC ASSIGNMENT ISSUES

Insertion of Prostatic Urethral Stent

Overview

CMS staff member Alberta Dwivedi said that for CY 2009, CMS proposes to maintain CPT code 0084T, *Insertion of temporary prostatic urethral stent*, in APC 0164, *Level II Urinary and Anal Procedures*, at a payment rate of approximately $145. She noted that for the past 3 years, CMS received 20 or fewer claims per year containing this CPT code, with fewer than 10 per year used for ratesetting. Because of the low volume of procedures, the median cost for this CPT code does not violate the two-times rule.

Public Presentation

Randy Hansen of AbbeyMoor Medical, Inc., described how the Spanner Prostatic Stent is used and said the device is packaged as part of a kit (with an insertion tool and a surveyor) priced at $575 (Presentation O). Jolayne Fisher, speaking on behalf of AbbeyMoor Medical, requested that CPT 0084T be moved to APC 165, *Level IV Urinary and Anal Procedures*. Ms. Stinchcomb said the AUA supports the request. Panel member Robert Zwolak, M.D., pointed out that this device has had a Category III CPT code for 3 years, yet the cost of the device is still not accounted for in CMS data.

Magnetic Resonance Guided Focused Ultrasound (MRgFUS)

Overview

CMS staff member LCDR Marjorie Baldo reminded the Panel that CMS agreed with the Panel's recommendation to move CPT codes 0071T, *Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue,* and 0072T, *Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater than or equal to 200 cc of tissue,* to APC 0067, *Level III Stereotactic Radiosurgery, MRgFUS, and MEG,* in CY 2008. CMS proposes to maintain the current placement of CPT codes 0071T and 0072T in APC 0067 for CY 2009. LCDR Baldo pointed out that MRgFUS is used primarily to treat uterine fibroids and thus is not commonly used in the majority of Medicare beneficiaries, so CMS has few claims for it.

Public Comment Letter

In a letter, Kathy Francisco of The Pinnacle Health Group asked that CMS reassign CPT codes 0071T and 0072T to APC 0127, *Level IV Stereotactic Radiosurgery, MRgFUS, and MEG* (Presentation P). Dr. Zwolak noted that these procedures have Category III CPT codes and that their Medicare claims data are limited. Speaking from the audience, Ms. Francisco said that a request for a Category 1 CPT code is under consideration by the CPT Panel.

- **Recommendation**: The Panel recommends that CMS maintain CPT code 0071T, *Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue,* and CPT code 0072T, *Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater than or equal to 200 cc of tissue,* in APC 0067, *Level III Stereotactic Radiosurgery, MRgFUS, and MEG.*

Placement of Endorectal Intracavity Applicator for High-Dose-Rate Brachytherapy

Overview

LCDR Baldo said that for CY 2009, CMS proposes to move HCPCS code C9725, *Placement of endorectal intracavitary applicator for high-intensity brachytherapy,* out of the New Technology APC where it has been assigned for the past 3 years and into APC 0164, *Level II Urinary and Anal Procedures,* with a payment rate of about $145. Very few claims were available for evaluation, she said.

Public Comment Letter

In a letter, Ms. Francisco of The Pinnacle Health Group requested that CMS assign HCPCS code C9725 to APC 0155, *Level II Anal/Rectal Procedures*, because the procedure is more similar clinically and in terms of resource use to other procedures in APC 0155 (Presentation Q). Dr. Potters pointed out that the procedure in question is performed in an office treatment room, not an operating suite, and does not require anesthesia. He and others thought a device-dependent APC might be a better fit for HCPCS code C9725. Wendy Smith Fuss of the Coalition for the Advancement of Brachytherapy noted that the median cost of APC 0164 is less than the cost of the device used in HCPCS code C9725.

- **Recommendation**: The Panel recommends that CMS reassign HCPCS code C9725, *Placement of endorectal intracavitary applicator for high-intensity brachytherapy*, to an appropriate device-dependent APC on the basis of median cost data.

Magnetoencephalography (MEG)

Ms. Heygster described a comment received by CMS from Michael Funke, M.D., Ph.D., of University of Utah Health Care about the decreased proposed payment for CPT code 95965, *Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (e.g., epileptic cerebral cortex localization)* (Presentation R). For CY 2009, CMS proposes to maintain CPT code 95965 in APC 0067, *Level III Stereotactic Radiosurgery, MRgFUS, and MEG*, at a payment rate of about $3,600. Ms. Heygster said the payment rate is a modest decline from 2008 rates but appears to be appropriate on the basis of claims data.

Public Comment Letter

In a letter, Dr. Funke expressed his concern over the small number of claims for CPT code 95965 available for ratesetting and the proposed decrease in payment. Furthermore, he expressed specific concern about the cost-to-charge ratio applied to charges on claims.

- **Recommendation**: The Panel recommends that CMS maintain CPT code 95965, *Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (e.g., epileptic cerebral cortex localization)*, in APC 0067, *Level III Stereotactic Radiosurgery, MRgFUS, and MEG*.

Insertion of Interpositional Thumb Spacer

Overview

CMS staff member Barry Levi said that for CY 2009, CMS proposes to maintain CPT code 25447, *Arthroplasty, interposition, intercarpal or carpometacarpal joints*, in APC 0047, *Arthroplasty without Prosthesis*, at a CY 2008 payment rate of about $2,287 and a proposed CY 2009 payment rate of about $2488.

Public Presentation

Charles Schneider, speaking on behalf of Small Bone Innovations, Inc., asked that CMS move CPT code 25447 to APC 0048, *Level I Arthroplasty or Implantation with Prosthesis*, to cover the cost of the implant (Presentation S). Dr. Zwolak noted that CPT code 25447 does not involve a prosthetic and may not be accurate for the interpositional spacer manufactured by Small Bone Innovations. Panel members agreed that the manufacturer should work with the CPT Panel to secure more appropriate CPT coding for their product.

- **Recommendation**: The Panel recommends that CMS maintain CPT code 25447, *Arthroplasty, interposition, intercarpal or carpometacarpal joints*, in APC 0047, *Arthroplasty without Prosthesis*.

CLOSING

Panel members reviewed the collected recommendations and refined them following further discussion.

- **Recommendation**: The Panel recommends that the work of the Visits and Observation Subcommittee (chair: Michael Ross, M.D.), the Packaging Subcommittee (chair: James Rawson, M.D.), and the Data Subcommittee (chair: Kim Williams, M.D.) continue.

Dr. Hambrick thanked the Panel members for their service and the CMS support staff for their hard work. She gave special thanks to Shirl Ackerman-Ross (DFO for the Panel) and to contractors Flawn Williams (audio specialist) and Dana Trevas (reporter) for their assistance. Dr. Hambrick also thanked outgoing members Dr. Potters and Ms. Snipes for their years of service to the Panel.

The meeting adjourned at approximately 3:00 p.m. on Thursday, August 28, 2008.

Appendix A

AGENDA

August 27, 28, and 29[1], 2008

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

DAY 1 - Wednesday, August 27, 2008

Public registrants may enter the Centers for Medicare & Medicaid Services' (CMS) Central Office Building after 12:15 p.m.

AGENDA

01:00[2] **Opening** - Day 1
Welcome, Call to Order, and Opening Remarks
Kerry Weems, Acting Administrator, CMS

01:30 **Panel Organization and Housekeeping Issues**
E. L. Hambrick, M.D., J.D., Chair, APC Panel

01:45 **CMS-1404-P:** Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2009 Payment Rates, et al, **Federal Register**

1. **Overview** - Carol Bazell, M.D., M.P.H., Director, Division of Outpatient Care (DOC)
2. Discussion
3. Panel's Comments

TAB Pages

02:00 **DATA**

1. **Overview** - Anita Heygster, CMS Staff
2. **Data Subcommittee's Report** - Louis Potters, M.D., F.A.C.R., Chair
3. Discussion
4. Panel's Comments/Recommendations

02:20 **PACKAGING**

1. **Packaging Subcommittee Report** - James V. Rawson, M.D. – Chair
   a. Discussion
   b. Panel's Comments/Recommendations

2. **Disposable Drug Delivery Device**
   a. **Overview –** Tamar Spolter, M.H.S., CMS Staff
   b. **Presentation** – Roger Massengale, Vice President **A 01-07**
      Business Development & Clinical Research
      I-Flow Corp., Inc.
   c. Discussion
   d. Panel's Comments/Recommendations

3. **Coronary Flow Reserve Measurement**
   a. **Overview –** Tamar Spolter, M.H.S., CMS Staff
   b. **Presentation–** James Archetto, President **B 08-18**
      RADI Medical Systems, Inc.
   c. Discussion
   d. Panel's Comments/Recommendations

4. **Intravenous Immune Globulin Preadministration-Related Services**
   a. **Overview –** Tamar Spolter, M.H.S., CMS Staff
   b. **Presentation** – Jay Greissing, Director, Federal Affairs **C 19-30**
      Plasma Protein Therapeutics Association
   c. Discussion
   d. Panel's Comments/Recommendations

5. **Radiation Therapy Guidance**
   a. **Overview –** Tamar Spolter, M.H.S., CMS Staff
   b. **Presentation –** Grant Bagley, Consultant **D 31-32**
   c. Discussion
   d. Panel's Comments/Recommendations

03:45 *Break*

Page 3 - Day 1, August 27, 2008 – APC Panel Meeting

		TAB	Pages
04:00	**MULTIPLE IMAGING AND DEVICE-DEPENDENT APCs**		
	1. **Overview** – Carrie Bullock, M.H.S., CMS Staff		
	2. **Presentation** – Mark Leahey, Executive Director Medical Device Manufacturers Association – Jo Ellen Slurzberg, Vice President Reimbursement & Health Policy Almyra, Inc. – Beth Halpern, Attorney at Law Hogan & Hartson a. Discussion b. Panel's Comments/Recommendations	**E**	**33-41**
	3. **Presentation** – Richard Rudolph, M.D., Special Advisor Clinical & Medical Affairs, Cyberonics – Stanley D. Jackson National Director, Reimbursement, Cyberonics a. Discussion b. Panel's Comments/Recommendations	**F**	**42-53**
	4. **Presentation** – DeChane L. Dorsey AVP, Payment & Health Policy AdvaMed a. Discussion b. Panel's Comments/Recommendations	**G**	**54-57**
05:00	**ADJOURN**		

AGENDA

August 27, 28, and 29, 2008

Advisory Panel on Ambulatory Payment Classification (APC) Groups' Meeting

DAY 2 - Thursday, August 28, 2008

Public registrants may enter the CMS Central Office Building after 7:45 a.m. **TAB** **Pages**

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

08:45 **VISITS AND OBSERVATION**

1. **Overview –** Heather Hostetler, J.D., CMS Staff
2. **Visits and Observation Subcommittee's Report** - Judie Snipes, R.N., M.B.A., Chair
   a. Discussion
   b. Panel's Comments/Recommendations

09:15 **INPATIENT LIST**

1. **Overview –** Dana Burley, R.N., M.S.P.H., CMS Staff
2. **Presentation –** Stephanie N. Stinchcomb, American Urological Association **H** **58-61**
   a. Discussion
   b. Panel's Comments/Recommendations

09:45 **DRUGS, BIOLOGICALS, RADIOPHARMACEUTICALS, AND PHARMACY OVERHEAD**

1. **Overview –** Rebecca Cole, M.S., CMS Staff

		TAB	Pages
2.	**Therapeutic Radiopharmaceuticals**		
a.	**Presentation –** James A. Bianco President/CEO Cell Therapeutics, Inc.	**I**	**62-70**
b.	Discussion		
c.	Panel's Comments/Recommendations		
3.	**Drugs and Pharmacy Overhead**		
a.	**Presentation –** Christopher Hogan, Ph.D. President, Direct Research, LLC **–** Jay Greissing, Director, Federal Affairs Plasma Protein Therapeutics Association (PPTA)	**J**	**71-95**
b.	**Presentation –** Ernest R. Anderson, Jr., M.S., R. Ph. Director of Pharmacy, Lahey Clinic & President, Association of Community Cancer Centers (ACCC)	**K**	**96-104**
c.	**Presentation –** Laurel Todd, Director Reimbursement and Economic Policy Biotechnology Industry Organization (BIO)	**L**	**105-116**
d.	**Presentation –** Justine Coffey, Director, Federal Regulatory Affairs American Society of Health-System Pharmacists (ASHP)	**M**	**117-120**
e.	**Presentation –** Jugna Shah, MPH, Consultant	**N**	**120-128**
f.	Discussion		
g.	Panel's Comments/Recommendations		

12:00 *Lunch*

Page 3 - Day 2, August 28, 2008 – APC Panel Meeting

		TAB	Pages

1:00 **APC ISSUES**

1. **Insertion of Prostatic Urethral Stent**

   a. **Overview** – Alberta Dwivedi, CMS Staff
   b. **Presentation** – Jolayne Fisher, Senior Advisor Argenta Reimbursement
      – Randy Hansen, Chief Financial Officer AbbeyMoor Medical, Inc. **O** **128-141**
   c. Discussion
   d. Panel's Comments/Recommendations

2. **Magnetic Resonance Guided Focused Ultrasound (MRgFUS)**

   a. **Overview** – LCDR Marjorie Baldo, USPHS, M.S., CMS Staff
   b. **Comment Letter** – Kathy Francisco, Principal & Managing Partner The Pinnacle Health Group **P** **142-145**
   c. Discussion
   d. Panel's Comments/Recommendations

3. **Placement of Endorectal Intracavity Applicator for High Dose Rate Brachytherapy**

   a. **Overview** – LCDR Marjorie Baldo, USPHS, M.S., CMS Staff
   b. **Comment Letter** – Kathy Francisco, Principal & Managing Partner The Pinnacle Health Group **Q** **146-148**
   c. Discussion
   d. Panel's Comments/Recommendations

4. **Magnetoencephalography (MEG)**

   a. **Overview** – Anita Heygster, CMS Staff
   b. **Comment Letter** – Michael E. Funke, M.D., Ph.D. Program Director, Magnetic Source Imaging University of Utah Health Care **R** **149-150**
   c. Discussion
   d. Panel's Comments/Recommendations

	TAB	Pages

5. **Insertion of Interpositional Thumb Spacer**

   a. Overview – Barry Levi, M.B.A., CMS Staff
   b. Presentation – Charles E. Schneider, Vice President **S** **151-164**
   Musculoskeletal Clinical Regulatory Advisers, LLC
   c. Discussion
   d. Panel's Comments/Recommendations

02:30 *Break* (Cumulative list of Panel's recommendations will be compiled.)

03:00 **Closing**
1. Summary of the Panel's Recommendations for CY 2009
2. Discussion
3. Final Remarks

04:00 **Adjourn**

Appendix B

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Advisory Panel on Ambulatory Payment Classification (APC) Groups
August 27–28, 2008

Final APC Panel Recommendations

Packaging Issues

1. The Panel recommends that CMS pay separately for the following intravascular ultrasound, intracardiac echocardiography, and fractional flow reserve CPT codes:

   - CPT code 37250, *Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel*
   - CPT code 37251, *Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel*
   - CPT code 92978, *Intravascular ultrasound (coronary vessel or graft) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel*
   - CPT code 92979, *Intravascular ultrasound (coronary vessel or graft) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel*
   - CPT code 93662, *Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation*
   - **CPT code 93571, *Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, initial vessel***
   - **CPT code 93572, *Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, each additional vessel***

   The Panel further recommends that CMS establish a threshold (e.g., a proportion of cases in which the service is provided ancillary and dependent to another service, rate of change in utilization over time, market penetration) when packaging will be considered. The Panel also recommends that CMS reconsider packaging these codes after 2 years' worth of claims data are available from their period of separate payment.

2. The Panel recommends that CMS pay separately for radiation therapy guidance for 2 years and then reevaluate packaging on the basis of claims data. The Panel further recommends that CMS evaluate possible models for threshold levels for packaging radiation therapy guidance and other new technologies.

Inpatient List

3. The Panel recommends that CMS remove the following CPT codes from the inpatient list:

   - CPT code 50727, *Revision of urinary-cutaneous anastomosis (any type urostomy)*
   - CPT code 54332, *One stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap*
   - CPT code 54535, *Orchiectomy, radical, for tumor, with abdominal exploration*
   - CPT code 51845, *Abdomino-vaginal vesical neck suspension, with or without endoscopic control (e.g., Stamey, Raz, modified Pereyra)*
   - CPT code 51860, *Cystorrhaphy, suture of bladder wound, injury of rupture; simple*
   - CPT code 54336, *One stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap*

Drugs, Biologicals, Radiopharmaceuticals, and Pharmacy Overhead Issues

4. The Panel recommends that CMS *not* implement the proposed change to the cost center for drugs on the Medicare cost report.

5. The Panel recommends that CMS continue to pay for drugs at a rate of the average sales price (ASP) plus 5 percent, that CMS continue to look at refining the methodology for payment of pharmacy overhead and handling costs, and that CMS work with stakeholders to find a feasible approach for payment of drugs and pharmacy overhead.

6. The Panel recommends that CMS:

   - Pay the acquisition cost of all separately paid drugs and biologicals at no less than ASP plus 5 percent
   - Package the cost of all drugs that are not separately paid at ASP plus 5 percent. Use the difference between these costs and CMS' costs derived from charges to create a pool that funds payment for pharmacy services. In applying this methodology, CMS should take into consideration the impact on beneficiaries' copayments.
   - Pay hospitals for pharmacy service costs using this pool by making payments based on some system of categorization determined by CMS.

APC Assignment Issues

7. The Panel recommends that CMS reassign CPT code 64553, *Percutaneous implantation of neurostimulator electrodes, cranial nerve,* to APC 0040, *Percutaneous Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve.*

8. The Panel recommends that CMS recalculate the median cost of APC 0225, *Implantation of Neurostimulator Electrodes, Cranial Nerve*, based solely on CPT code 64573, *Implantation of neurostimulator electrodes, cranial nerve (vagal nerve stimulation).*

9. The Panel recommends that CMS maintain CPT code 0071T, *Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue*, and CPT code 0072T, *Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater than or equal to 200 cc of tissue*, in APC 0067, *Level III Stereotactic Radiosurgery, MRgFUS, and MEG.*

10. The Panel recommends that CMS reassign HCPCS code C9725, *Placement of Endorectal Intracavitary Applicator for High Intensity Brachytherapy*, to an appropriate device-dependent APC on the basis of median cost data.

11. The Panel recommends that CMS maintain CPT code 95965, *Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (e.g., epileptic cerebral cortex localization)*, in APC 0067, *Level III Stereotactic Radiosurgery, MRgFUS, and MEG.*

12. The Panel recommends that CMS maintain CPT code 25447, *Arthroplasty, interposition, intercarpal or carpometacarpal joints*, in APC 0047, *Arthroplasty without Prosthesis.*

Multiple Imaging Composite APCs

13. The Panel recommends that CMS work with stakeholders to review the proposed multiple imaging composite APCs and to assess the potential impact of the proposal on Medicare beneficiaries affected by trauma or cancer.

Visits and Observation Issues

14. The Panel recommends that CMS adopt the proposed APC assignments and payment rates for Type A and Type B emergency department (ED) visits for calendar year (CY) 2009.

15. The Panel recommends that CMS adopt the CY 2009 proposals related to the extended assessment and management composite APCs, especially in reference to the inclusion of the Level 5 Type B ED visit HCPCS code in APC 8003, *Level II Extended Assessment and Management Composite.*

Administrative Issues

16. The Panel recommends that the work of the Visits and Observation Subcommittee (chair: Michael Ross, M.D.), the Packaging Subcommittee (chair: James Rawson, M.D.), and the Data Subcommittee (chair: Kim Williams, M.D.) continue.

Action Items

Visits and Observation Issues

1. The Panel requests that data on observation services with longer lengths of stay, analyzed by hospital characteristics, be presented at the next meeting of the Panel.

2. The Panel requests that an analysis of CY 2008 claims data for clinic visits, ED visits (Type A and Type B), and extended assessment and management composite APCs be presented at the next meeting of the Panel.

Appendix C

PRESENTATIONS

The following organizations provided written testimony for the Advisory Panel on Ambulatory Payment Classification Groups meeting August 27–28, 2008:

Presentation A:	I-Flow Corporation, Inc.
Presentation B:	Radi Medical Systems, Inc.
Presentation C:	Plasma Protein Therapeutics Association
Presentation D:	Calypso Medical Technologies
Presentation E:	Medical Device Manufacturers Association
Presentation F:	Cyberonics, Inc.
Presentation G:	Advance Medical Technology Association
Presentation H:	American Urological Association
Presentation I:	Cell Therapeutics, Inc.
Presentation J:	Association of Community Cancer Centers; American Society of Health-System Pharmacists; Plasma Protein Therapeutics Association; Direct Research, LLC; Biotechnology Industry Organization; and Alliance of Dedicated Cancer Centers (Joint Presentation)
Presentation K:	Association of Community Cancer Centers
Presentation L:	Biotechnology Industry Organization
Presentation M:	American Society of Health-System Pharmacists
Presentation N:	Alliance of Dedicated Cancer Centers
Presentation O:	AbbeyMoor Medical, Inc.
Presentation P:	The Pinnacle Health Group
Presentation Q:	The Pinnacle Health Group
Presentation R:	Michael E. Funke, M.D., Ph.D., University of Utah Health Care
Presentation S:	Musculoskeletal Clinical Regulatory Advisors, LLC, on behalf of Small Bone Innovations, Inc.