Meeting Report

for

August 23–24, 2006

Advisory Panel on Ambulatory Payment Classification (APC) Groups

Centers for Medicare & Medicaid Services (CMS)

7500 Security Boulevard

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 Munger, M.D., F.A.C.C.
Frank G. Opelka, M.D., F.A.C.S.
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.
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

Edith Hambrick, M.D., J.D., CMS Medical Officer, *Chair*
Shirl Ackerman-Ross, *Designated Federal Official*
Herb Kuhn, Director, Center for Medicare Management
James Hart, Director, Division of Outpatient Care
Joan Sanow, Deputy Director, Division of Outpatient Care
Carol Bazell, M.D., CMS Medical Officer, Hospital and Ambulatory Policy Group
Dana Burley, Staff, Division of Outpatient Care
Anita Heygster, Staff, Division of Outpatient Care
Tamar Spolter, Staff, Division of Outpatient Care

WELCOME AND CALL TO ORDER

Edith 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.)

Herb Kuhn, Director of the Center for Medicare Management, welcomed the Panel on behalf of CMS leadership and said that comments on the Notice of Proposed Rulemaking (NPRM) on the Hospital Outpatient Prospective Payment System (HOPPS) will be accepted by CMS until October 10, making the current meeting a timely one. Mr. Kuhn noted that Panel meetings offer an opportunity for CMS to engage with the community and get real-time, thoughtful input from practitioners and stakeholders. He said that the NPRM reflects Medicare's current efforts to improve the quality of care, obtain better value, and pay for care more accurately. Mr. Kuhn noted that the rule demonstrates CMS' interest in translating its inpatient quality improvement approaches to the hospital outpatient setting. The Agency has projected that costs to the Medicare program in 2007 could increase by as much as 11 percent over the current year.

Mr. Kuhn praised Dr. Hambrick's wit, wisdom, and exceptional talent for leading the Advisory Panel, saying her focus on people, passion for performance, and innovation are evident in her work with the Advisory Panel and other programs. He then presented Dr. Hambrick with a Certificate of Appreciation "for outstanding performance as Chair of the Advisory Panel on APC Groups," signed by the Administrator, Dr. Mark McClellan.
Dr. Hambrick thanked Mr. Kuhn for the honor. She then briefly reviewed the Panel's charter. Dr. Hambrick referenced other proposed rules for the Inpatient Prospective Payment System (IPPS) and the Physician Fee Schedule. She pointed out that because the Agency is in the midst of the comment period for the HOPPS NPRM, staff are restricted in how they can respond to some queries.

PROPOSED CHANGES TO THE HOPPS AND CALENDAR YEAR (CY) 2007 PAYMENT RATES

Overview of Proposed Changes

James Hart, Director of the Division of Outpatient Care, highlighted some areas of the NPRM of particular interest to the Panel. He said that payment would increase overall by about 3 percent in 2007 as a result of revision of the conversion factor and other changes. The Office of the Actuary estimates that payments in 2007 will increase to $32.5 billion in the aggregate.

Mr. Hart said that the current NPRM represents a small step toward value-based purchasing. Hospitals that are required to report quality measures under the inpatient system will also be required to do so for the HOPPS. He added that those hospitals who are subject to quality reporting under the IPPS, and who are paid under the HOPPS for hospital outpatient hospital services and that fail to report such measures will suffer a 2 percent reduction in their payment update for 2007. Mr. Hart said that CMS plans eventually to incorporate OPPS quality measures

for those hospitals that are not currently required to report quality measures and to refine quality measures so they are more applicable to outpatient settings.

He informed the group that CMS is proposing new G-codes for clinic and emergency department outpatient visits that focus on hospital resource use. The proposed scenario would expand the APC structure to include five payment levels for emergency care, five levels for clinic visits, and one level for critical care, with significant increases in payment for the highest level services that are provided.

Mr. Hart also referred to changes in payment rates and APCs for drug administration, device-dependent procedures, radiopharmaceuticals, and brachytherapy—all of which would be discussed in more detail during presentations throughout the meeting. He went on to say that the 2007 NPRM presents a modest proposal for restructuring payment for ambulatory surgical centers, and -includes a more sweeping proposal for 2008. He concluded that the HOPPS for CY 2007 also addresses many issues that go beyond outpatient hospital services, such as reforms for Medicare contractors and conditions of participation for critical-access hospitals.

Observation Subcommittee's Report

Judie Snipes, R.N., M.B.A., F.A.C.H.E., presented the recommendations of the Observation Subcommittee. The Panel accepted the report of the Observation Subcommittee and made the following recommendations:

> **Recommendation:** The Panel recommends that CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment.
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> **Recommendation:** The Panel recommends that CMS perform claims analyses and present data that would allow CMS to consider revising criteria for separately payable observation services when certain procedures that are assigned status indicator T (e.g., insertion of bladder catheter or laceration repair) are reported on the same claim with an emergency department visit and observation and all other criteria for separate observation payment (e.g., qualifying diagnosis code, number of hours, etc.) are met.
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> **Recommendation:** The Panel recommends that CMS expand the scope (and change the name) of the Observation Subcommittee to include issues related to policies regarding emergency department and clinic visits.

Packaging Subcommittee's Report

Albert Einstein, Jr., M.D., said that the Packaging Subcommittee discussed several specific packaged codes. The Panel accepted the report of the Packaging Subcommittee and made the following recommendations:

> **Recommendation:** The Panel recommends that CMS continue to package revised CPT code 0069T, *Acoustic heart sound recording and computer analysis only*, for CY 2007.

Recommendation: The Panel recommends that CMS assign CPT code 96523, *Irrigation of implanted venous access device for drug delivery systems*, status indicator Q as a "special" packaged code for CY 2007.

Packaging Issues

"Special" Packaged Codes

A CMS staffer Tamar Spolter said that the NPRM addresses rare cases in which a service that is normally packaged is provided without another separately payable OPPS service on the same date (and, therefore, the hospital receives no payment). She said that CMS proposes using the status indicator Q to identify and provide payment for these rare cases and that the Agency has proposed six Current Procedural Terminology (CPT) codes for this "special" packaged code status:

- CPT 36540, *Collection of blood from a completely implantable venous access device*
- CPT 36600, *Arterial puncture, withdrawal of blood for diagnosis*
- CPT 38792, *Injection procedure; lymphangiography for identification of sentinel node*
- CPT 75893, *Venous sampling through catheter, with or without angiography (eg, for parathyroid hormone, rennin), radiological supervision and interpretation*
- CPT 94762, *Noninvasive ear or pulse oximetry for oxygen saturation; single determination by continuous overnight monitoring*
- CPT 96523, *Irrigation of implanted venous access device for drug delivery systems*

Chest X-Ray with Computer-Aided Detection (CAD)

Ms. Spolter noted that the 2006 HOPPS recognizes CPT 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 reported as an add-on code for chest x-ray and packaged (i.e., not separately payable). Beginning January 1, 2007, CPT 0152T will be replaced by CPT 0174T, *Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation (List separately in addition to code for primary procedure)*, and CPT 0175T, *Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation.* Ms. Spolter said that the new CPT codes were not included in the NPRM because of time constraints associated with the American Medical Association's (AMA) release of the codes, but the new codes will be included in the final rule, where they will be provided with interim assignments that are open to public comment in the final rule. She also added that CMS encourages those interested to submit written comments on these new CPT codes, even though they are not included in the NPRM.

Sam Finkelstein, Matthew Freedman, M.D., M.B.A., and David Fryd, Ph.D., of Riverain Medical, which produces a chest x-ray CAD system, described the system and requested that CPT codes 0174T and 0175T be assigned to the New Technology APC 1492, New Technology—Level 1B ($10-$20), with a payment rate of $15 (Presentation 1). The Riverain presenters noted that CAD is appropriate only for a small subset of the population of chest x-rays, and no nationally accepted clinical guidelines for its use have been produced.

> **Recommendation:** The Panel recommends that for CY 2007 CMS package new Current Procedural Terminology (CPT) codes 0174T, *Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation (List separately in addition to code for primary procedure)*, and 0175T, *Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation.*

Miscellaneous APC Issues

Positron Emission Tomography with Computed Tomography (PET/CT)

Ms. Spolter said that CMS proposes to move CPT codes 78814, *Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and alatomical localization; limited area (eg, chest, head/neck);* 78815, *Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and alatomical localization; skull base to mid-thigh;* and 78816, *Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and alatomical localization; whole body,* for PET/CT services from the New Technology APC 1514, New Technology—Level XIV ($1,200-$1,300), which has a payment rate of $1,250, to APC 308, Non-Myocardial Positron Emission Tomography (PET) Imaging, which has a median cost of $865. The Agency determined the median cost of PET/CT (on the basis of about 64,000 single claims) and found that it is comparable to that of non-myocardial PET scans.

Tom Grissom, representing the Academy of Molecular Imaging (Academy), requested that the PET/CT procedures remain in the current New Technology APC 1514 because CMS does not have sufficient data to support the move (Presentation 2). He said that procedures usually remain in a New Technology APC for at least 2 to 3 years, giving hospitals time to update their chargemasters and implement accurate coding strategies. He added that the hospital claims do not adequately represent the real costs of the procedure. Beth Roberts of the Association of Community Cancer Centers (ACCC), Jugna Shah of the Alliance of Dedicated Cancer Centers, and Denise Williams of Vanguard Health System also supported the Academy's request. Denise Merlino of the Society of Nuclear Medicine (SNM) said that her organization has provided education to hospitals on correctly coding and charging for PET/CT, but she does not believe the current CMS claims data are completely accurate. Therefore, SNM also supports the request.

The Panel discussed the challenges that hospitals face in implementing new codes and in updating chargemasters to reflect real costs more accurately. Panel members acknowledged that keeping these codes in the New Technology APC gives hospitals more time to work out coding and charging issues, but it does not incentivize hospitals to do so quickly.

> **Recommendation:** The Panel recommends that CMS maintain the CPT codes 78814, *Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area (eg, chest, head/neck)*; 78815, *Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid-thigh*; and 78816, *Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; whole body*, in New Technology APC 1514, New Technology – Level XIV ($1,200-$1,300), at the current payment rate of $1,250 for CY 2007.

Home Prothrombin Time/International Normalized Ratio (INR) Monitoring

Ms. Spolter explained that Healthcare Common Procedure Coding System (HCPCS) codes G0248, *Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstrating use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing,* and G0249, *Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; per four tests, to APC 0421, Prolonged Physiologic Monitoring, for CY 2007,* for home INR monitoring have resided in a New Technology APC for 5 years, paid initially at a rate of $75, and later paid at a rate of $150. Further, Ms. Spolter said that CMS received no single claims for these codes from 2002 to 2004 and a total of 15 single claims for both codes in 2005. On the basis of these claims, the Agency found the median costs below $150 and proposes moving them to APC 604, Level 1 Clinic Visits, which has a payment rate of $49.

Paul Radensky, M.D., of the Prothrombin-Time Self-Testing Coalition described the time and facility resources involved in educating patients on using home INR monitoring (G0248) and furnishing the materials for home INR monitoring (G0249). Dr. Radensky said that evidence supports the effectiveness of the technology in monitoring the adequacy of anticoagulation in patients taking warfarin, thus preventing major thromboembolic and bleeding events. However, providers have been slow to adopt the technology in part because they must purchase the monitors and materials, and essentially they must loan them to patients. He requested that the codes remain in the New Technology APC until use of the monitors increases and more data can be collected. Barring that, Dr. Radensky asked that the codes be moved to an APC that pays at a rate closer to the real costs associated with the services. The Panel agreed that paying at a higher

rate would encourage more use of home monitoring, which actively engages patients in their own care.

> **Recommendation:** The Panel recommends that CMS move HCPCS codes G0248, *Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstrating use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing,* and G0249, *Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; per four tests,* to APC 0421, Prolonged Physiologic Monitoring, for CY 2007.

Central Venous Access

Ms. Spolter said that CMS proposes moving CPT code 36566, *Insertion of tunneled centrally inserted central venous access device, requiring two catheters via two separate venous access sites; with subcutaneous port(s),* from the New Technology APC 1564, New Technology – Level XXVII ($4,500-$5,000), with a payment rate of $4,750, to APC 0623, Level III Vascular Access Procedures, with a median cost of $1,704. Ms. Spolter added that CMS believes that the procedure is rarely performed on Medicare beneficiaries in a hospital outpatient setting, and the median cost on the basis of 2004 claims data was $1,962.

Jerry Stringham of Medical Technology Partners said that the device alone costs $3,500 (Presentation 4). His organization believes that the claims used by CMS are miscoded because they do not all include the appropriate C-code for the device. He requested that a unique APC group be created for the procedure and that hospitals be required to report the appropriate C-code when inserting the device. The Panel members believed that the current payment rate may be too generous, but CMS' proposed move could underpay for the technology.

> **Recommendation:** The Panel recommends that for CY 2007 CMS move CPT code 36566, *Insertion of tunneled centrally inserted central venous access device, requiring two catheters via two separate venous access sites; with subcutaneous port(s),* to an APC with a payment rate no less than that of New Technology APC 1524, New Technology – Level XXIV ($3,000-$3,500), with a payment rate of $3,250 and no more than that of New Technology APC 1564, New Technology – Level XXVII ($4,500-$5,000), with a payment rate of $4,750 and also require that claims for the procedure be subject to a device edit for the device code C1881, *Dialysis access system (implantable).*

Keratoprosthesis

A CMS staffer Dana Burley said that CMS proposes moving CPT 65770, *Keratoprosthesis*, to APC 0293, Level V Anterior Segment Eye Procedures, at a payment rate of $3116, which is higher than that of the APC where the code currently resides.

Brian Regan of Addition Technology Inc., which makes the AlphaCor Keratoprosthesis, said that the claims on which CMS bases its proposal do not accurately reflect the actual cost of the device (Presentation 5). He said that many claims were not filed with the appropriate device C-code (C1818). Mr. Regan recommended working with CMS to identify data that better reflect the cost of the device. Jennifer Myers, a recipient of the AlphaCor Keratoprosthesis, said that the device has changed her life dramatically after seven failed cornea transplants. She and her husband, David Myers, said that they fought with their insurance provider for coverage of the device. They asked the Panel to take into account that many third-party payers use the Medicare system as a basis for payment.

> **Recommendation:** The Panel recommends that CMS consider external data to validate whether current claims data for CPT code 65770, *Keratoprosthesis*, were properly coded and, if necessary, adjust its payment rate from CY 2007 forward. The Panel further recommends that CMS implement a device edit for the procedure and the device code C1818, *Integrated keratoprosthesis*. The Panel requests that CMS staff report the findings from this data assessment to the Panel at its next full Panel meeting.

Critical Care Services

Ms. Spolter explained that the current evaluation and management (E&M) CPT codes do not adequately reflect the resources associated with outpatient hospital visits. Therefore, CMS proposes two new G-codes for critical-care services. The codes are distinguished by the amount of time required to provide the service.

Valerie Rinkle of the Provider Roundtable (PRT) suggested that CMS distinguish the two new codes on the basis of whether a trauma response team was activated (Presentation 6). Ms. Rinkle said that trauma response-team charges are captured under revenue code 68x. Ms. Williams of Vanguard Health System asked that the Panel not use time as the deciding factor. The Panel discussed the various criteria used to activate a trauma team response. Panel members agreed that the amount of time spent on critical care does not, by itself, accurately reflect the resources involved.

> **Recommendation:** The Panel recommends that CMS consider redefining the proposed new critical care G-codes as follows and that CMS use the presence or absence of claims charge data under revenue code 68x reported in association with critical care CPT codes 99291, *Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes,* and 99292, *Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service),* to determine payment rates for two new critical care APCs to which the two new G-codes would be assigned:
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> - Gccc1: Patient critically ill/injured and no trauma response team activation
> - Gccc2: Patient critically ill/injured with trauma response team activation

Spinous Process Distraction Device

Mary Corkins, St. Francis Medical Technologies (which makes the X-STOP Interspinous Process Decompression System), and Stuart Langbein, Consultant for St. Francis Medical Technologies, requested that new CPT codes for insertion of spinous process distraction devices (0171T, *Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance),* and 0172T, *Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level (List separately in addition to code for primary procedure*)) be placed in APCs 0061, Laminectomy or Incision for Implanation of Neurostimulator Electrodes, Excluding Cranial Nerve, and 0123, Bone Marrow Harvesting and Bone Marrow/Stem Cell Transplant, respectively (Presentation 7). The Panel believed that the codes would not be clinically consistent with other codes in the APCs suggested by the presenter.

> **Recommendation:** The Panel recommends that CMS review the resources required for new CPT codes 0171T, *Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level*, and 0172T, *Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level (List separately in addition to code for primary procedure*), and recommend appropriate APC assignments for them for CY 2007.

Extracorporeal Shockwave Therapy

The Panel reviewed written testimony from United Shockwave Therapies Inc., on the assignment of CPT 28890, *Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia*, to APC 1547, New Technology—Level X ($800-$900), with a payment rate of $850. The company claims the payment is not reasonable and requested the rate be raised (Presentation 8).

OPPS Inpatient List Issues

Ms. Burley of the CMS staff said that in addition to the eight services presented to the Panel in March as procedures that should be removed from the inpatient procedure list, a presenter had identified 10 other procedures that should be removed.

Gail Daubert of the Prolapse Repair Coalition said that the American Urogynecology Society supports the Coalition's request to remove a number of colpopexy and vaginal hysterectomy procedures from the inpatient list (Presentation 9). She cited evidence that these procedures are performed safely in an outpatient setting. Ms. Rinkle of the PRT said that her organization supports the recommendation. She added that because Medicare requires the procedures to be performed on an inpatient basis to qualify for payment, Medicare beneficiaries do not have the option of the outpatient setting. As a result, Ms. Rinkle believed that Medicare does not have data supporting the performance of the procedure in an outpatient setting. Marion G. Kruse of

the PRT added her opinion that Medicare inpatients do not stay in the hospital very long after these particular procedures.

Recommendation: The Panel recommends that CMS remove the following CPT codes for colpopexy and vaginal hysterectomy from the inpatient list and assign them to appropriate clinical APCs, e.g., APCs 194, Level VIII Female Reproductive Proc; 195, Level IX Female Reproductive Proc; and 202, Level X Female Reproductive Proc:

a. 57282, *Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus);*
b. 57283, *Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy);*
c. 58260, *Vaginal hysterectromy, for uterus 250 grams or less;*
d. 58262, *Vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s) and/or ovary(s);*
e. 58263, *Vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s), and/or ovary(s), with repair of enterocele;*
f. 58270, *Vaginal hysterectomy, for uterus 250 grams or less; with repair of enterocele;*
g. 58290, *Vaginal hysterectomy, for uterus greater than 250 grams;*
h. 58291, *Vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s);*
i. 58292, *Vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s), with repair of enterocele;*
j. 58294, *Vaginal hysterectomy, for uterus greater than 250 grams; with repair of enterocele.*

Data Subcommittee's Report

Timothy Gene Tyler, Pharm.D., said that the Data Subcommittee reviewed the following proposals related to the 2007 HOPPS:

- Setting rates for device-dependent codes using only claims that pass device edits
- Reducing payments when a device is furnished to the hospital at no cost or with full credit (e.g., in the case of a recalled device)
- Implementing reverse device edits that would return claims when a device is billed without a corresponding procedure code
- Paying brachytherapy sources separately on the basis of the median cost of the source
- Paying complex interstitial applications of brachytherapy sources on the basis of median costs calculated using single-procedure claims for CPT 77778

In addition, the subcommittee agreed to review codes (either via a conference call or at the next face-to-face subcommittee meeting) and suggested add-on codes that should be included in the bypass list for 2008. The subcommittee also agreed to review base and add-on code

combinations, developed by CMS based on assessment of CPT codes, with the goal of producing a file of permissible code pairs to analyze data further and to assist with correct coding.

Data Issues

CMS staffer Anita Heygster described changes to the median costs of OPPS services for 2007. Approximately 91.4 million claims were used to determine the median costs on which payment rates are based. She noted changes to the bypass list for 2007 included some codes for drug administration and radiologic guidance during surgery. Ms. Heygster said that the Agency is also changing how it calculates hospital cost-to-charge ratios. She added that the change will affect 700 hospitals, and CMS believes that the result will better reflect outpatient charges converted to costs. Lastly, she said that the Agency continues to consider how information from multiple-procedure claims could be added to data from single claims and used to set rates.

Device-Related APC Issues

Ms. Heygster said that CMS seeks the Panel's input on determining appropriate payment to a hospital when a device is recalled and replaced by the manufacturer. She further stated that CMS believes that no payment is necessary if neither the hospital nor the beneficiary is liable for any charges for the replacement device. Similarly, she said that the appropriate payment is not clear when a hospital implants an upgraded device, while receiving a credit from the manufacturer for a failed device. She added that CMS proposes reducing payment by the "offset" amount of an APC (in general, the portion of the APC's payment that is intended to cover the device itself).

Panel members questioned why manufacturers cover only the cost of the device when the device malfunctions and not the related costs of replacing it. The Panel agreed that until this particular question is resolved, CMS should pay hospitals for the administrative resources involved when a device is recalled and replaced.

> **Recommendation:** The Panel recommends that CMS evaluate the proposed percentage offsets related to recalled devices to ensure that they take into account administrative resources required to provide the replacement devices.

JoEllen Slurzberg of the Medical Device Manufacturers Association requested that CMS reinstitute a payment floor to ensure that payment for device-dependent APCs is no more than 10 percent below the median cost for the previous year (Presentation 10). She suggested the Agency seek more external data to support proposed changes when the claims data are not robust. She also asked that items remain in their assigned New Technology APC for at least 2 to 3 years to give hospitals time to work out all coding and charging issues and thus provide CMS with reliable data on which to base clinical APC assignments.

DeChane Dorsey of Advanced Medical Technology Association (AdvaMed) also suggested that CMS use more external data in its rate-setting decisions (Presentation 11). She said that AdvaMed supports mandatory reporting of all C-codes and asked that CMS continue educating

hospitals on appropriate coding. She recommended that CMS publish a chart that identifies the percentage of claims, by HCPCS code, with correctly reported C-codes. She asked that CMS examine the criteria and process for moving codes from New Technology to clinical APCs and that methods be implemented to prevent excessive reductions in payment. She suggested codes in New Technology APCs remain there for at least 3 years. Finally, Ms. Dorsey said that AdvaMed remains concerned that the low payment rates for blood and blood products will affect patient access and safety.

The Panel members agreed that device manufacturers can assist hospitals by providing education on coding for devices to those in various areas, not just in the department that purchases the device. Ms. Slurzberg noted that manufacturers are prohibited from providing specific charge advice. Panel members believed that CMS should continue identifying areas in which hospitals need more education. Theresa Lee of AdvaMed said that her organization is working with other organizations to improve education and would be interested in doing more.

Ms. Heygster said that because device-dependent procedure claims which do not contain the correct C-code are returned to the provider without payment, CMS does not have a database of incorrectly coded claims. Ms. Heygster also said that many device-dependent APCs contain CPT codes for which the use of devices is optional, so it is not possible to identify claims that should have contained a device code. Nelly Leon-Chisen of the American Hospital Association (AHA) added that her organization has approached coding education from numerous standpoints but still finds that it is problematic.

The Panel questioned whether the average sales price (ASP) methodology used for drug payment could be applied to devices. Dr. Hambrick noted the ASP methodology was mandated by Congress for drug payment only.

Ms. Heygster noted that CMS examines closely APCs in which the median costs change significantly from year to year. She added that the pass-through approach may artificially inflate total hospital payments for certain procedures, as can repeated use of a payment floor from year to year to buffer decreases in payments.

> **Recommendation:** The Panel recommends that CMS use readily available external data to validate costs determined by its claims data.
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> **Recommendation:** The Panel recommends that when CMS assigns a new service to a New Technology APC, the service should remain there for at least 2 years until sufficient claims data are collected.

The Panel reviewed written testimony from the Coalition for the Advancement of Brachytherapy requesting that CMS continue using the charges-adjusted-to-cost methodology for payment of brachytherapy sources (Presentation 12). It also asked that CMS implement mandatory code edits for brachytherapy procedures to require reporting of all brachytherapy sources used.

Blood and Blood Products

Ms. Heygster explained that a refined methodology was applied to establish the payment rates for blood products in the 2007 NPRM. She said that CMS applied actual hospital or simulated blood-specific cost-to-charge ratios to its claims data, yielding a more accurate reflection of true hospital costs for blood and blood products. The payment rates for 2007 are based on unadjusted median costs from 2005 claims data and based on this specific methodology.

Theresa Wiegmann of the American Association of Blood Banks (AABB) expressed concerns that the payment rates remain unrealistically low for some commonly used blood and blood products (Presentation 13). She noted that the Department of Health and Human Services (DHHS) is planning to publish national data demonstrating that the mean average cost for leukocyte-reduced red blood cells in 2004 was $201 and that CMS proposes to pay $177 in 2007 for the same product. Ms. Wiegmann requested that CMS apply to blood and blood products the same payment methodology currently used for specified-covered outpatient drugs, by employing simulated mean costs to develop payment rates rather than simulated median costs. Jerry Squires of the American Red Cross (ACR) echoed AABB's recommendations (Presentation 14).

John Carlsen of Covance Market Access Services, which is working with the ARC, added that he does not know how to reproduce a comprehensive simulated mean-cost methodology for comparison with the proposed simulated median costs, but he believes that it would mirror the observed differences in the mainline median versus mean costs for blood and blood products available on the Web for the 2007 NPRM.

The Panel noted that hospitals are extremely reluctant to mark up the cost of blood or blood products. Cathy Austin of Sisters of Mercy Health System said that her organization does not mark up blood costs but tries to capture some of its expenses in billing for transfusion procedures. The Panel suggested blood and blood products should be treated as pass-throughs. Dr. Hambrick said that the law defines what products should be treated as pass-throughs. Panel members questioned the usefulness of the DHHS survey data, which have not been published.

> **Recommendation:** The Panel recommends that CMS reconsider its methodology to develop payment rates for blood and blood products to more accurately reflect the true costs of blood and blood products to hospitals, including using external data.

Drugs, Radiopharmaceuticals, and Drug Administration

Mr. Hart said that 2007 payment rates for drug administration services are based on detailed claims data from 2005, the first year that hospitals were required to code separately for the first hour and each additional hour of drug administration. For 2007, CMS proposes six drug administration APC levels intended to mirror resource intensity. He said that CMS used the bypass methodology and per-unit method for developing median costs in order to propose a comprehensive payment methodology for drug administration.

Mr. Hart went on to say that CMS proposes raising the drug packaging threshold from $50 to $55. The Agency also proposes paying for drugs and biologicals at a rate of ASP plus 5 percent. Because radiopharmaceuticals are exempt from ASP, he said that CMS proposes paying for them using their mean costs from 2005 claims data, which were developed by applying hospital-specific cost-to-charge ratios. Mr. Hart described the specific development of the payment rate proposed for strontium-89 chloride.

Stanley Satz, Bio-Nucleonics Pharma, Inc., said that the proposed payment rate for strontium-89 chloride is half the actual cost (Presentation 15). He said the he believed that CMS' data are flawed because of miscoding resulting from misunderstanding of the code unit to be used for reporting. He requested that strontium-89 chloride be paid at a rate of ASP plus 5 percent. Ms. Merlino of the SNM confirmed that hospitals are confused about how to report doses of strontium-89 for coding purposes. Ms. Austin of Sisters of Mercy Health System agreed. Gordon Schatz, Consultant for the Council on Radionuclides and Radiopharmaceuticals (CORAR), said that external data are needed to account for recent changes to the HCPCS code descriptors for many radiopharmaceuticals.

Dr. Hambrick noted that the National HCPCS Coding Panel recently updated the code descriptors for many radiopharmaceuticals, which may address some concerns about units of measure. The Panel members voiced that they would welcome input from Louis Potters, M.D., F.A.C.R. (absent member of the Panel), on strontium-89.

> **Recommendation:** The Panel recommends that CMS consider external data in evaluating the proposed CY 2007 payment rate for HCPCS code A9600, *Strontium Sr-89 Chloride, therapeutic, per millicurie*.

John Siracusa of the Biotechnology Industry Organization (BIO) said that the ASP plus 5 percent payment rate does not sufficiently pay hospitals for pharmacy overhead costs (Presentation 16). He asked that CMS not package drugs and biologicals which had been paid separately in previous years, including all drugs and biologicals that ever had pass-through status. Paying separately for these items would also resolve the concern that CMS does not pay for second and subsequent intravenous pushes of drugs. Mr. Siracusa requested that CMS pay hospitals when both a hydration infusion and a non-chemotherapy infusion are provided in the same visit.

Ernest Anderson, Jr., of the ACCC echoed BIO's claim that the ASP plus 5 percent payment method does not cover both drug acquisition costs and pharmacy overhead, and he requested that CMS not package drugs and biologicals which had ever been paid separately (Presentation 17). He requested that CMS continue using the ASP plus 6 percent payment rate. Mr. Anderson asked CMS to work with stakeholders to determine pharmacy handling and overhead costs. Jennifer Ortiz of Our Lady of Lourdes Hospital confirmed Mr. Anderson's point that in 2007, hospitals would pay more to acquire and be paid less by the HOPPS for intravenous immunoglobulin. Ms. Roberts of ACCC said that the packaging threshold created the problem for drugs and biologicals because some are underpaid and some are not paid at all. Dr.

Hambrick reminded Ms. Roberts that packaged drugs are paid through payments for the codes with which the drugs are packaged.

The Panel discussed the Medicare Payment Advisory Commission's evaluation of pharmacy overhead costs. Mary Jo Braid of the Moran Company said that CMS calculates pharmacy overhead in a way that does not fully capture the costs. At its March 2006 meeting, the Panel asked CMS to work with stakeholders to gather more information about pharmacy overhead costs. Mr. Hart noted that no entities provided additional information to CMS. Ms. Heygster added that CMS considers all input from public and private entities and is open to meeting with any entity upon request.

The Panel noted that some proposals to address pharmacy overhead have been put forth, but none have been adopted. Ms. Shah of the Alliance of Dedicated Cancer Centers said that it is not clear how claims data support the ASP plus 5 percent rate for drugs administered in the hospital when the physician rate for drug payment remains at ASP plus 6 percent. The Panel members agreed that CMS should consider implementing a pharmacy handling fee.

Wendy Andrews of University Medical Center/Arizona Cancer Center said that her organization supports the testimony of the ACCC and believed that the ASP plus 5 percent rate is inadequate (Presentation 18). She asked that CMS pay separately for hydration therapy and therapeutic infusion and for second and subsequent intravenous pushes. She applauded the Agency's progress toward revising E&M codes and suggested that CMS work with stakeholders to further refine its proposal. The Panel discussed various approaches in order to identify and pay for intravenous pushes of drugs.

Ms. Shah of the Alliance of Dedicated Cancer Centers asked CMS to provide data to show the percentage of a drug administration APC payment that represents payment for the packaged drug (Presentation 19). She said that the HOPPS packaging approach creates inequality because physicians' offices receive separate payment for all drugs and biologicals. She requested that CMS eliminate the drug packaging threshold and pay for all drugs with HCPCS codes separately. Because some hospitals are required by other payers to use all the CPT codes for drug administration services, Ms. Shah asked that CMS adopt the full set of CPT drug administration codes. She said that CMS should also work with the AMA on descriptors to make the CPT drug administration codes more applicable to the hospital setting. However, if CMS does not adopt the CPT drug administration codes, it should establish a method for paying for both hydration and therapeutic infusion when they occur simultaneously.

Ms. Leon-Chisen of the AHA said that her organization is working with both CMS and the AMA on drug administration coding, and she sees the potential for better coding alignment in the future. Ms. Rinkle of the PRT described the conflicts that arose with Medicare payment when her state's Medicaid program and other payers required the use of CPT codes. John Settlemeyer of the Carolinas Health Care System said that the CPT codes for drug administration are not applicable in hospital settings because, for example, they do not account for separate drug

administration services provided to the same patient when the patient has been transferred from one department to another.

> **Recommendation:** The Panel recommends that CMS eliminate the drug packaging threshold for all drugs and radiopharmaceuticals with HCPCS codes.

The Panel reviewed the written testimony of the Nuclear Medicine APC Task Force requesting that CMS continue to apply the hospital-specific cost-to-charge ratio methodology for payment of radiopharmaceuticals. Mr. Schatz of CORAR agreed and asked that the same methodology be applied to brachytherapy sources. Mr. Schatz said that in both cases, because the coding has changed, he believed that CMS lacked sufficient data on which to base payment rates.

> **Recommendation:** The Panel recommends that CMS continue using the current CY 2006 methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources for 1 year.

> **Recommendation:** The Panel recommends that CMS maintain the payment rates for drugs at their ASP plus 6 percent for CY 2007.

> **Recommendation:** The Panel recommends that CMS recognize only the AMA's CPT codes for outpatient hospital reporting of drug administration services in CY 2007.

> **Recommendation:** If CMS does not recognize only the AMA CPT codes for drug administration services for CY 2007, the Panel recommends that CMS allow hospitals to separately bill and receive payments for therapeutic infusions and hydration infusions provided in the same encounter.

> **Recommendation:** The Panel recommends that CMS make payment for a second or subsequent intravenous push of the same drug by instituting a modifier, developing a new HCPCS code for the procedure, or implementing another methodology in CY 2007.

> **Recommendation:** The Panel recommends that CMS provide payments for all intravenous pushes and therapeutic injections for pain management and other clinical conditions, regardless of the setting (e.g., post-operative anesthesia care unit, cardiac catheterization laboratory).

> **Recommendation:** The Panel recommends that CMS work with stakeholders to better understand the costs involved in the preparation of pharmaceutical agents for chemotherapy, and that CMS develop a new payment methodology that acknowledges and provides appropriate payment for those costs. The Panel requests that CMS staff report their findings at the next full Panel meeting.

> **Recommendation:** The Panel recommends that CMS allow providers to use all available HCPCS codes for reporting drugs to reduce the administrative burden

associated with reporting drugs only using HCPCS codes with the lowest increments in their descriptors.

Recommendation: The Panel recommends that CMS provide claims analyses of the contributions of packaged costs (considering packaged drugs and other packaging) to the median cost of each drug administration service.

ADMINISTRATIVE BUSINESS

The Panel members considered whether the subcommittees should continue to meet.

Recommendation: The Panel recommends that CMS renew the Panel's existing Data, Observation, and Packaging Subcommittees.

CLOSING

The Panel reviewed the recommendations from the meeting. Dr. Hambrick noted that Marilyn K. Bedell, M.S., R.N., O.C.N., is resigning from the Panel effective January 1, 2007, and said that the Panel will miss Ms. Bedell's helpful, insightful, and level-headed comments. Dr. Hambrick thanked the Panel members for their service, and she thanked the CMS support staff for their hard work. She gave special thanks to Shirl Ackerman-Ross, the Designated Federal Official for the Panel, and to contractors John O'Reilly (audio specialist) and Dana Trevas (reporter) for their assistance.

Respectfully submitted,

Shirl Ackerman-Ross 9/15/2006
Designated Federal Official

Appendix A

AGENDA

August 23 and 24, 2006

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

DAY 1 - Wednesday, August 23, 2006

Notes:
[1]Public registrants may enter the CMS Central Office Building after 12:15 p.m.

[2]NO meeting is scheduled for Friday, August 25, 2006, as indicated in the **Federal Register** notice of December 30, 2004.

TAB

01:00 Opening - Day 1
- a. Welcome & Call to Order - E. L. Hambrick, M.D., Chair
- b. Opening Remarks - Herb Kuhn, Director Center for Medicare Management

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

01:30 Overview of CMS-1506-P, Proposed Rule for the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates **A**
- a. James Hart, Director, Division of Outpatient Care
- b. Panel's Comments/Recommendations

Page 2 – Day 1, August 23, 2006 – APC Panel Meeting **TAB PG**

02:00	Observation Issues		**B**	
	a. Observation Subcommittee's Report	- Judie Snipes, R.N., M.B.A. Chairperson Observation Subcommittee		
	b. Discussion			
	c. Panel's Recommendations			
02:30	Packaging Issues		**C**	
	a. Packaging Subcommittee's Report	- Albert Brooks Einstein, Jr., M.D. Chairperson Packaging Subcommittee		
	b. Overview	- Tamar Spolter, CMS Staff		
	c. Riverain Medical's Presentation	- Sam D. Finkelstein, President - Matthew Freedman, M.D., M.B.A. - David Fryd, Ph.D.	**1-66**	
	d. Bloomington Hospital's Comment Letter	- Evelyn Alwine, Director Revenue Cycle Mgt.	**67**	
	e. Discussion			
	f. Panel's Recommendations			

- **The option for an *Afternoon Break* is at the discretion of the Chair.**

03:10	Miscellaneous APC Issues		**D**	
	a. Overview of PET/CT	- CMS Staff		
	b. Academy of Molecular Imaging's Presentation	- Tom Grissom Health Policy Specialist	**68-82**	
	c. Overview of Home PT/INR Monitoring	- CMS Staff		
	d. Prothrombin-time Self Testing Coal.'s Present.	- Paul W. Radensky, M.D. Consultant	**83-95**	
	e. Overview of Central Venous Access Issue	- CMS Staff		
	f. Medical Technology Partners, Inc.'s Presentation	- Jerry Stringham, President	**96-107**	
	g. Overview of Keratoprosthesis	- Dana Burley, CMS Staff		
	h. Addition Technology, Inc.'s Presentation	- Brian Regan, Vice Pres. Sales & Marketing	**108-124**	
	i. Overview of Critical Care Services	- Tamar Spolter, CMS Staff		
	j. Provider Roundtable's Presentation	- Valerie Rinkle, Director Revenue Cycle	**125-129**	

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k. St. Francis Medical Technologies' Presentation	- Mary Corkins, Director Reimbursement	**130-136**
l. United Shockwave's Comment Letter	- F. Bruce Cohen, CFO	**137-139**
m. Discussion		
n. Panel's Recommendations		

05:15 Adjourn

AGENDA

August 23 and 24, 2006

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

DAY 2 - Thursday, August 24, 2006

Note: Public registrants may enter the CMS Central Office Building <u>after</u> 7:45 a.m.

			TAB	PG
08:30	Opening - Day 2 a. Welcome and Call to Order b. E. L. Hambrick, M.D., Chair			
08:35	OPPS Inpatient List Issues		**E**	
	a. Overview	- Dana Burley, CMS Staff		
	b. Prolapse Repair Coalition's Presentation			Gail
	Daubert, Consultant			**140-142**
	c. Discussion			
	d. Panel's Recommendations			
09:00	Data Issues		**F**	
	a. Data Subcommittee's Report	- Timothy G. Tyler, Pharm.D. Chairperson, Data Subcommittee		
	b. Overview of Data Issues	- Anita Heygster, CMS Staff		
	c. Discussion			
	d. Panel's Recommendations			
09:45	*Break*			

Page 2 – Day 2, August 24, 2006 – APC Panel Meeting **TAB PG**

10:00 Device-Related Issues **G**

- a. Overview - CMS Staff
- **b.** Medical Device Manufac. Assoc.'s Presentation - Jo Ellen Slurzberg, Almyra, Inc. **143-146**
- c. AdvaMed's Presentation - DeChane Dorsey, Assoc. VP **147a - d**
  - Teresa Lee, VP
- **d.** Coalition for the Advancement of Brachytherapy's Comment Letter - Lisa Hayden/Janet Zeman **148a – c** & **149**
- e. Discussion
- f. Panel's Recommendations

10:45 Blood & Blood Products **H**

- a. Overview - Anita Heygster, CMS Staff
- b. AABB's Presentation - Theresa L. Wiegmann, J.D. Director, Public Policy **150-155**
- c. American Red Cross' Presentation - Dr. Jerry Squires, Vice President and Chief Scientific Officer **156-160**
- d. Discussion
- e. Panel's Recommendations

11:45 *Lunch*

12:45 Drugs, Radiopharmaceuticals, and Drug Administration **I**

- a. Overview - CMS Staff
- b. Bio-Nucleonics Pharma, Inc.'s Presentation - Stanley Satz, President/Owner **161-242**
- c. BIO's Presentation - John Siracusa, Manager Medicare Reimburse. & Econ. Policy **243-250**
- a. ACCC's Presentation - Ernest R. Anderson, Jr. **251-257**
- b. University Medical Center/Arizona Cancer Ctr.'s
- c. Presentation Wendy Andrews, Director Oncology Services **258-263**
- d. Alliance of Dedicated Cancer Center's Pres. - Jugna Shah, M.P.H., Consultant **264-270**
- e. Nuclear Medicine APC Task Force's Comment Letter - Kenneth McKusick, M.D. **271-278**
- f. Discussion
- g. Panel's Recommendations

Page 3 – Day 2, August 24, 2006 – APC Panel Meeting **TAB**

02:45 *Break*

03:15 Closing
- a. Summary of the Panel's Recommendations for 2006 **J**
- b. Discussion
- c. Final Remarks

05:00 Adjourn

Appendix B

ADVISORY PANEL ON AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS

August 23–24, 2006

Panel Recommendations

Observation Subcommittee

1. The Panel recommends that CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment.

2. The Panel recommends that CMS perform claims analyses and present data that would allow CMS to consider revising criteria for separately payable observation services when certain procedures that are assigned status indicator T (e.g., insertion of bladder catheter or laceration repair) are reported on the same claim with an emergency department visit and observation services, and all other criteria for separate observation payment (e.g., qualifying diagnosis code, number of hours, etc.) are met.

3. The Panel recommends that CMS expand the scope (and change the name) of the Observation Subcommittee to include issues related to policies regarding emergency department and clinic visits.

Packaging Subcommittee

4. The Panel recommends that for CY 2007 CMS package new Current Procedural Terminology (CPT) codes 0174T, *Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation (List separately in addition to code for primary procedure),* and 0175T, *Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation.*

5. The Panel recommends that CMS continue to package revised CPT code 0069T, *Acoustic heart sound recording and computer analysis only,* for CY 2007.

6. The Panel recommends that CMS assign CPT code 96523, *Irrigation of implanted venous access device for drug delivery systems,* status indicator Q as a "special" packaged code for CY 2007.

Miscellaneous APC Issues

7. The Panel recommends that CMS maintain the CPT codes 78814, *Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area (eg, chest, head/neck)*; 78815, *Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid-thigh*; and 78816, *Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; whole body*, in New Technology APC 1514, New Technology – Level XIV ($1,200-$1,300), at the current payment rate of $1,250 for CY 2007.

8. The Panel recommends that CMS move HCPCS codes G0248, *Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstrating use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing,* and G0249, *Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; per four tests,* to APC 0421, Prolonged Physiologic Monitoring, for CY 2007.

9. The Panel recommends that for CY 2007 CMS move CPT code 36566, *Insertion of tunneled centrally inserted central venous access device, requiring two catheters via two separate venous access sites; with subcutaneous port(s),* to an APC with a payment rate no less than that of New Technology APC 1524, New Technology – Level XXIV ($3,000-$3,500), with a payment rate of $3,250 and no more than that of New Technology APC 1564, New Technology – Level XXVII ($4,500-$5,000), with a payment rate of $4,750 and also require that claims for the procedure be subject to a device edit for the device code C1881, *Dialysis access system (implantable).*

10. The Panel recommends that CMS consider external data to validate whether current claims data for CPT code 65770, *Keratoprosthesis*, were properly coded and, if necessary, adjust its payment rate from CY 2007 forward. The Panel further recommends that CMS implement a device edit for the procedure and the device code C1818, *Integrated keratoprosthesis*. The Panel requests that CMS staff report the findings from this data assessment to the Panel at its next full Panel meeting.

11. The Panel recommends that CMS consider redefining the proposed new critical care G-codes as follows and that CMS use the presence or absence of claims charge data under revenue code 68x reported in association with critical care CPT codes 99291, *Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes*, and 99292, *Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)*, to determine payment rates for two new critical care APCs to which the two new G-codes would be assigned:
    - Gccc1: Patient critically ill/injured and no trauma response team activation
    - Gccc2: Patient critically ill/injured with trauma response team activation

12. The Panel recommends that CMS remove the following CPT codes for colpopexy and vaginal hysterectomy from the inpatient list and assign them to appropriate clinical APCs, e.g., APCs 194, Level VIII Female Reproductive Proc; 195, Level IX Female Reproductive Proc; and 202, Level X Female Reproductive Proc:
    a. 57282, *Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus);*
    b. 57283, *Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy);*
    c. 58260, *Vaginal hysterectromy, for uterus 250 grams or less;*
    d. 58262, *Vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s) and/or ovary(s);*
    e. 58263, *Vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s), and/or ovary(s), with repair of enterocele;*
    f. 58270, *Vaginal hysterectomy, for uterus 250 grams or less; with repair of enterocele;*
    g. 58290, *Vaginal hysterectomy, for uterus greater than 250 grams;*
    h. 58291, *Vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s);*
    i. 58292, *Vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s), with repair of enterocele;*
    j. 58294, *Vaginal hysterectomy, for uterus greater than 250 grams; with repair of enterocele.*

13. The Panel recommends that CMS review the resources required for new CPT codes 0171T, *Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level*, and 0172T, *Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level (List separately in addition to code for primary procedure*) and recommend appropriate APC assignments for them for CY 2007.

14. The Panel again recommends that CMS use readily available external data to validate costs determined by its claims data.

15. The Panel recommends that CMS reconsider its methodology to develop payment rates for blood and blood products to more accurately reflect the true costs of blood and blood products to hospitals, including using external data.

16. The Panel recommends that CMS evaluate the proposed percentage offsets related to recalled devices to ensure that they take into account administrative resources required to provide the replacement devices.

17. The Panel recommends that when CMS assigns a new service to a new technology APC, the service should remain there for at least 2 years until sufficient claims data are collected.

18. The Panel recommends that CMS consider external data in evaluating the proposed CY 2007 payment rate for HCPCS code A9600, *Strontium Sr-89 Chloride, therapeutic, per millicurie*.

19. The Panel recommends that CMS eliminate the drug packaging threshold for all drugs and radiopharmaceuticals with HCPCS codes.

20. The Panel recommends that CMS continue using the current CY 2006 methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources for 1 year.

21. The Panel recommends that CMS maintain the payment rates for drugs at their average sales price (ASP) plus 6 percent for CY 2007.

22. The Panel recommends that CMS recognize only the American Medical Association's (AMA) CPT codes for outpatient hospital reporting of drug administration services in CY 2007.

23. If CMS does not recognize only the AMA CPT codes for drug administration services for CY 2007, the Panel recommends that CMS allow hospitals to separately bill and receive payments for therapeutic infusions and hydration infusions provided in the same encounter.

24. The Panel recommends that CMS make payment for a second or subsequent intravenous push of the same drug by instituting a modifier, developing a new HCPCS code for the procedure, or implementing another methodology in CY 2007.

25. The Panel recommends that CMS provide payments for all intravenous pushes and therapeutic injections for pain management and other clinical conditions, regardless of the setting (e.g., post-operative anesthesia care unit, cardiac catheterization laboratory).

26. The Panel recommends that CMS work with stakeholders to better understand the costs involved in the preparation of pharmaceutical agents for chemotherapy, and that CMS develop a new payment methodology that acknowledges and provides appropriate payment for those costs. The Panel requests that CMS staff report their findings at the next full Panel meeting.

27. The Panel recommends that CMS allow providers to use all available HCPCS codes for reporting drugs to reduce the administrative burden associated with reporting drugs only using HCPCS codes with the lowest increments in their descriptors.

28. The Panel recommends that CMS provide claims analyses of the contributions of packaged costs (considering packaged drugs and other packaging) to the median cost of each drug administration service.

29. The Panel recommends that CMS renew all of the Panel's existing Data, Observation, and Packaging Subcommittees.

Appendix C

Presentations

The following documents were presented at or submitted for the Advisory Panel on APCs meeting August 23–24, 2006:

Presentation 1: Riverain Medical

Presentation 2: Academy of Molecular Imaging

Presentation 3: Prothrombin-Time Self-Testing Coalition

Presentation 4: Medical Technology Partners

Presentation 5: Addition Technology, Inc.

Presentation 6: Provider Roundtable

Presentation 7: St. Francis Medical Technologies, Inc.

Presentation 8: United Shockwave Therapies

Presentation 9: Prolapse Repair Coalition

Presentation 10: Medical Device Manufacturers Association

Presentation 11: Advanced Medical Technology Association (AdvaMed)

Presentation 12: Coalition for the Advancement of Brachytherapy

Presentation 13: American Association of Blood Banks

Presentation 14: American Red Cross

Presentation 15: Bio-Nucleonics Pharma, Inc.

Presentation 16: Biotechnology Industry Organization

Presentation 17: Association of Community Cancer Centers

Presentation 18: University Medical Center/Arizona Cancer Center

Presentation 19: Alliance of Dedicated Cancer Centers

Presentation 20: Nuclear Medicine APC Task Force