ADVISORY PANEL
ON AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS

APC Panel Meeting Report

March 7–8, 2007

Centers for Medicare & Medicaid Services (CMS)

7500 Security Boulevard, Auditorium

Baltimore, MD 21244-1850

PANEL MEMBERS PRESENT AT THIS MEETING

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.

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

Russ Ranallo, M.S.

James Rawson, M.D.

Lou Ann Schraffenberger, M.B.A., R.H.I.A., C.C.S.

Judie S. Snipes, R.N., M.B.A., F.A.C.H.E.

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

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, M.M.S., *Designated Federal Official* (DFO)

Thomas Gustafson, Ph.D., Acting Director, Center for Medicare Management (CMM)

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

Kim Newman, M.A., Acting Deputy Director, DOC

Marjorie Baldo, LCDR, U.S.P.H.S., M.S., R.H.I.A., C.C.S., C.C.S.-P, Staff, DOC

Dana Burley, M.S.P.H., B.S.N., Staff, DOC

Anita Heygster, B.S., Staff, DOC

Heather Hostetler, J.D., Staff, DOC

Rebecca Kane, M.S., Staff, DOC

Marina Kushnirova, M.S., Staff, DOC

Chris 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

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. A list of presentations appears in Appendix C.)

Thomas Gustafson, Ph.D., Acting Director, CMM, welcomed the Panel on behalf of CMS leadership. Dr. Gustafson said that the Panel's sage advice over the years has contributed to better regulations and programs for those who use Medicare. He welcomed two new members to the Panel: Pat Spencer-Cisek and Russ Ranallo. Dr. Gustafson also thanked two outgoing members for their service: Frank Opelka, M.D., and Albert B. Einstein, Jr., M.D.

Dr. Hambrick briefly reviewed the Panel's Charter and defined the scope of issues that the Panel can address.

OVERVIEW OF FINAL RULE FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (OPPS) AND CALENDAR YEAR (CY) 2007 PAYMENT RATES

Carol Bazell, M.D., M.P.H., Acting Director, DOC, described some significant policy changes that took place with the publication of the final rule on November 24, 2006. Dr. Bazell said that a number of Healthcare Common Procedure Coding System (HCPCS) codes were assigned to different APC groups to address violations of the "two-times rule" (i.e., in a given APC, the median cost of the most costly service should be no more than two times the median cost of the

least costly service), and a number of services were moved out of New Technology APCs and into clinical APCs.

Dr. Bazell said that in accordance with the OPPS final rule, the following are applicable:

- CMS no longer pays for devices that are recalled and replaced by the manufacturer at no cost to the hospital.
- As mandated by the Tax Relief and Health Care Act of 2006, CMS pays brachytherapy sources using a formula of charges reduced to costs.
- As requested in comments from the public, CMS now pays drug administration services using CPT codes.
- In 2007, CMS pays separately for additional hours of drug infusion.
- CMS increased the threshold for packaging drugs with services from $50 per day to $55 per day.
- CMS continues to pay separately for drugs and biologicals at 106 percent of the average sales price and continues to pay for separately payable radiopharmaceuticals at charges reduced to cost for CY 2007.
- For the first time, Medicare pays separately for activation of a trauma-response team in association with critical-care services.
- Also for the first time, Medicare covers ultrasound screening for abdominal aortic aneurysms.

- For 2007 under OPPS, we pay for a number of procedures that were on the inpatient only list in CY 2006. They are identified like other codes that have status indicator (SI) changes in our Addenda B.
- In 2007, CMS pays for hospital outpatient visits under five levels of visit APCs, rather than the historical three levels of visit APCs, because the cost data show a significant difference in costs among visit codes.
- The Tax Relief and Health Care Act of 2006 extends the requirements for hospitals to report quality measures.
- The final rule explains that when a hospital fails to meet quality reporting standards established by the Secretary, its annual update will be reduced by 2 percent beginning in CY 2009.
- Finally, the OPPS final rule clarifies that rural essential community hospitals meet the definition of sole community hospitals for purposes of the rural hospital adjustment.

DATA ISSUES

CMS staff member Anita Heygster said that about 98.5 million claims were used to set rates for 2007, a significant increase over the previous year. She provided an overview of the methodology that CMS uses to evaluate data and to set median costs for 2007, and she noted that a detailed discussion is available in the 2007 Claims Accounting on the OPPS Web site. The Agency continues to consider how information from multiple-procedure claims could be added to data from single claims and used to set rates. CMS staff member Chris Smith-Ritter, Ph.D., explained how the Agency accounts for the costs of packaged codes in both multiple-procedure

and single claims. She said that, excluding the costs of services on the bypass list (which have limited or no packaging associated with them), packaged costs account for about 30 percent of the total costs in both the single bills and in all claims used to model median costs. Dr. Ritter then presented the Panel with data on the amount of packaging in the single bills for drug administration and proxy estimates of the amount of packaging associated with drug administration in the multiple bills. Most drug administration codes demonstrate some packaging, and for many, the median amount of packaging ranges from 10 to 30 percent of the total cost on each claim. For many codes, the amount of packaging specific to packaged drugs and pharmacy revenue codes ranges from 10 to 25 percent. Analysis of about 600,000 multiple-procedure claims, where drug administration codes are the only separately paid codes on the claim, suggests a similar proportion of packaging in the multiple bills.

Data Subcommittee's Report

Timothy Gene Tyler, Pharm.D., Chair, Data Subcommittee, said that the Subcommittee reviewed the Agency's examination of the packaging of drugs and services into drug administration APC payments and of packaged revenue codes. The Subcommittee also reviewed the 2007 final rule claims accounting; the median costs for all device-dependent APCs, specifically the median costs for APCs 0107, Insertion of Cardioverter Defibrillator, and 0108, Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads, based on CY 2006 data, and made the following recommendations that the Panel approved:

- **Recommendation:** The Panel recommends that the Centers for Medicare & Medicaid Services (CMS) edit and return for correction claims that contain a HCPCS code for a separately paid drug or device but do not also contain a HCPCS code assigned to a procedural APC (i.e., SI "S," "T," "V," or "X"). This process should improve the claims data and may increase the number of single bills available for ratesetting.

- **Recommendation**: The Panel recommends that CMS delete G0297, *Insertion of single chamber pacing cardioverter defibrillator pulse generator*; G0298, *Insertion of dual chamber pacing cardioverter defibrillator pulse generator*; G0299, *Insertion or repositioning of electrode lead for single chamber pacing cardioverter defibrillator and insertion of pulse generator*; and G0300, *Insertion or repositioning of electrode lead(s) for dual chamber pacing cardioverter defibrillator and insertion of pulse generator*, and require hospitals to report Current Procedural Terminology (CPT) codes 33240, *Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator*, or 33249, *Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator*, as applicable for the insertion of implantable cardioverter defibrillators. The requirement for reporting device HCPCS codes will enable CMS to continue identifying costs when different types of devices are implanted. Current Outpatient Code Editor (OCE) edits requiring providers to report device HCPCS codes for these procedures will enable CMS to continue isolating the costs of implanting different types of devices.

Public Presentations

Jugna Shah, on behalf of the Alliance of Dedicated Cancer Centers (ADCC), requested that CMS make data available on the total dollars associated with packaged codes (SI "N") and packaged revenue codes in the claims database, with specific subsets for drug administration further identified for public review and consideration (Presentation 1). She encouraged CMS to continue seeking ways to break down multiple-procedure claims into single or pseudo-single claims for ratesetting. She proposed "conditional-packaging" in which CMS would assign certain packaged charges to a separately payable line-item procedure when it is apparent that the packaged charge is distinctly associated with that specific procedure. Panel members briefly debated whether costs associated with a revenue code, but no HCPCS code, could be specifically and appropriately assigned to one of two drug administration procedures on a multiple-procedure claim. The Panel members agreed that CMS should consider the "conditional packaging" approach in its ongoing efforts to use more multiple bills in median cost estimates, but they did not make a formal recommendation.

Valerie Rinkle, representing the Provider Roundtable (PRT), asked that CMS make the list and definitions of packaged revenue centers consistent between the Outpatient Code Editor (OCE) software and the OPPS final rule (Presentation 2). She provided some examples of inconsistencies between the two.

- **Recommendation:** The Panel recommends that CMS review the list of packaged revenue codes for consistency with Outpatient Prospective Payment System (OPPS) policy and ensure that future versions of the OCE edit claims accordingly.

DRUGS, RADIOPHARMACEUTICALS, AND DRUG ADMINISTRATION

CMS staff member Rebecca Kane explained that the 2007 final rule reflects the Panel's recommendation that CMS use only the American Medical Association's CPT codes for drug administration. She noted that CMS had proposed a methodology for CY 2006 for capturing pharmacy overhead costs and received input on the proposal. However, CMS' analysis suggests—and a Medicare Payment Advisory Commission (MedPAC) report confirms—that hospitals build some pharmacy overhead costs into their drug prices. However, commenters objected to the administrative burden associated with the CY 2006 proposal, so the methodology was not finalized.

Ms. Kane said that the packaging threshold ($55 for 2007) would be updated annually using the producer price index as a guide and rounding to the nearest $5. In 2006, CMS continued to pay for drugs on the basis of average sales price (ASP, updated quarterly) plus 6 percent. In keeping with the Panel's recommendations from March 2006, CMS maintains separate payment for intravenous immunoglobulin (IVIG) preadministration-related services in CY 2007 and continues to evaluate appropriate payment rates for IVIG administration, with input from the Plasma Protein Therapeutics Association and other stakeholders.

For 2007, CMS continues to pay for radiopharmaceuticals by reducing hospital charges to cost using the hospital's overall cost-to-charge ratio. However, the Agency considers this approach temporary, and it intends to develop a prospective payment methodology for radiopharmaceuticals and continues to seek input from stakeholders.

Ms. Kane noted that for APC 1511, New Technology - Level XI ($900-$1000), which includes positron emission tomography (PET) procedures, only 84 percent of CY 2006 single claims included a radiopharmaceutical. Denise Merlino of the Society of Nuclear Medicine (SNM) said that her organization was working with hospitals and physicians' offices to clear up confusion about that particular billing issue.

Public Presentations

Ms. Shah of the ADCC pointed out that because the full set of CPT codes for drug administration services was not implemented until 2007, CMS will not have data from these codes on which to base rates until 2008. She further said that the rates would not go into effect until 2009 (Presentation 3) and that the current rates reflect 2005 data.

The 2005 CPT codes did not distinguish between hydration using prepackaged solutions and therapeutic, diagnostic, or prophylactic non-chemotherapy infusions. The 2007 CPT codes do distinguish between these procedures and also allow coding for sequential and concurrent infusions. Ms. Shah would like CMS to seek out additional data to determine more appropriate payment rates for hydration versus therapeutic, diagnostic, or prophylactic non-chemotherapy infusion. Payment for non-chemotherapy infusion should be increased, she said.

Ms. Shah also said that her organization is concerned that CPT 90768, *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure)*, was not assigned to a separately payable APC for 2007. She asked that CMS set the payment rate for this procedure at the same rate as

CPT 90767, *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion, up to 1 hour (list separately in addition to code for primary procedure*) for 2008.

Finally, Ms. Shah asked that CMS consider applying a dampening methodology to drug administration APC payment rates when wide fluctuations are noted.

- **Recommendation**: The Panel recommends that CMS pay separately for CPT 90768, *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure),* at the same rate as CPT 90767, *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion, up to 1 hour (list separately in addition to code for primary procedure*).

Judith Baker of The Resource Group explained why it is so difficult to determine pharmacy overhead costs (Presentation 4). She asked CMS to consider creating APC groups for multiple levels of pharmacy drug preparation and management services that would be paid separately, that these APCs align with appropriate levels of hospital resources consumed or the relevant duties required at each level, and that the coding be easy for providers to implement.

Jason Slotnik of the Biotechnology Industry Organization (BIO) asked that CMS eliminate the drug packaging threshold and pay separately for all drugs and biologicals that had been paid separately under OPPS in the past (Presentation 5). He added that hospitals should receive adequate payment for all aspects of providing drugs and biologicals, including pharmacy

services and handling costs. Mr. Slotnik said that CMS' conclusion regarding the adequacy of ASP plus 6 percent rests on a flawed analysis because most hospitals do not set complete charges and lack precise information on the aggregate handling costs of drugs and biologicals compounded in their pharmacies. He asked that CMS revise its method for calculating pharmacy handling costs.

Ernest Anderson, Jr., M.S., R.Ph., of the Association of Community Cancer Centers (ACCC) said that pharmacies play a key role in delivering cancer drugs, including preparing drugs, ensuring correct dosing, preventing drug interactions, and ensuring quality standards are met (Presentation 6). New standards under U. S. Pharmacopoeia Chapter 797 have contributed to increased pharmacy overhead costs. The ACCC proposed that CMS implement a three-phased approach: 1) Create categories of drugs according to the complexity of preparation and make a flat overhead payment for each category; 2) Survey providers to determine pharmacy overhead costs; and 3) Establish payment rates for pharmacy services on the basis of cost reports, charges, and claims data.

The ACCC further suggested CMS pay for all separately payable drugs using ASP plus 6 percent to ensure stable payment rates that cover acquisition and preparation costs. Finally, the ACCC requested that CMS pay separately for all HCPCS-coded drugs, instead of applying a packaging threshold.

David Chen of the American Society of Health System Pharmacists supported the recommendations of the ACCC (Presentation 7). Beth Roberts, speaking for the ACCC, said that her organization is working to determine specific numbers/categories of pharmacy overhead

services for CMS to consider if the Agency decides to implement the three-phase approach to pay for pharmacy overhead costs.

Ms. Rinkle, speaking on behalf of Asante Health System, said that her organization is experiencing a shift of patients receiving infusion services from physicians' offices to hospital outpatient departments because the offices do not want to incur the high costs of the drugs.

- **Recommendation:** The Panel recommends that CMS implement a three-phase plan to address OPPS payment pharmacy overhead costs:

  Phase 1: Work with appropriate stakeholders to develop a system of defined pharmacy overhead categories (e.g., low, medium, and high cost) for outpatient drugs requiring different levels of pharmacy resources and reimburse pharmacy overhead costs by set fees for the categories through New Technology APCs, keeping the CY 2007 Average Sales Price (ASP) plus 6 percent payment methodology for separately paid drugs intact. The Panel recommends that CMS consider gradual implementation of the categories, possibly beginning with the highest level.

  Phase 2: CMS should be cognizant of the Government Accountability Office and Medicare Payment Advisory Commission reports estimating pharmacy overhead costs and accept outside survey data from stakeholders.

  Phase 3: Establish payment rates for pharmacy overhead costs based on claims data (ultimately) for outpatient hospital administration of drugs (i.e., a hospital

pharmacy overhead category HCPCS code would need to be reported, along with the appropriate charge for each administration of a drug in the hospital outpatient department).

- **Recommendation**: The Panel recommends that CMS allow hospitals to report all HCPCS codes for drugs.

Gordon Schatz and Lisa Saake of the Council on Radionuclides and Radiopharmaceuticals recommended that CMS develop prospective payment amounts for the largest class of radiopharmaceuticals (encompassing diagnostic and some therapeutic radiopharmaceuticals with projected average acquisition costs ranging from $50 to $3,000) (Presentation 8). They suggested that CMS consider applying an editing or trimming methodology for hospital charges to ensure that unique overhead and preparation costs of radiopharmaceuticals are included in CMS cost data. Because a trimming methodology would not be feasible for some radiopharmaceuticals, they said that hospitals might need to supply invoices as a source of more accurate data on acquisition costs. Ms. Merlino asked that the Panel delay making recommendations on this issue until representatives of the SNM, the Nuclear Medicine APC Task Force, and the American College of Radiology (ACR) could evaluate the current data and issues more fully.

- **Recommendation**: The Panel recommends that CMS continue to work with stakeholders on issues related to payment for radiopharmaceuticals, e.g., evaluating claims data for different classes of radiopharmaceuticals and ensuring that a nuclear

medicine procedure claim always includes at least one radiopharmaceutical agent reported.

The Panel reviewed a letter from the SNM requesting that CPT 78492, *Myocardial imaging, positron emission tomography (PET), perfusion; multiple studies at rest and/or stress*, be moved to its own APC so that it is not included in the same APC as single myocardial PET studies (Presentation 9). The Panel agreed that multiple studies require more time and resources than single studies.

- **Recommendation**: The Panel recommends that CMS move CPT 78492, *Myocardial imaging, positron emission tomography (PET), perfusion; multiple studies at rest and/or stress*, into its own clinical APC.

The Panel reviewed a letter from the Daxor Corporation explaining that the dose listed for its Volumex radiopharmaceutical in the HCPCS descriptor remains incorrect despite efforts to correct it and that CMS has underpaid for Volumex as a result (Presentation 10). Ms. Merlino of the SNM said that her organization supports the use of external data for this and other codes for which the claims data are clearly flawed.

- **Recommendation**: The Panel recommends that CMS consider use of external data and work with stakeholders to determine the correct code-descriptor units for each radiopharmaceutical, including HCPCS A9524, *Iodine I-131 iodinated serum albumin, diagnostic, per 5 microcuries*.

MISCELLANEOUS APC ISSUES

Cardiac Computed Tomography (CT) and CT Angiography

CMS staff member LCDR Marjorie Baldo explained that for 2007, cardiac CT and CT angiography continue being assigned to clinical APCs. Analysis of claims data from the first 9 months of 2006 yielded 7,500 claims on which to base payment rates for 2008. LCDR Baldo presented to the Panel three possibilities for APC placement that CMS has developed for cardiac CT and CT angiography procedures.

Public Presentation

Gregory Thomas, M.D., M.P.H., speaking on behalf of the American College of Cardiology (ACC), asked CMS to assign the CPT codes for cardiac CT and CT angiography procedures to New Technology APCs (Presentation 11). He said that the procedures require hours of patient preparation and recovery time that are not adequately covered by the current payment rates and that the technology is progressing so rapidly that the real costs are difficult to pin down.

Pam Kassing of ACR agreed that the codes should move into New Technology APCs because they are clinically different from the nuclear medicine procedures currently assigned to the same clinical APCs. She further asked CMS to establish guidelines for how new technologies are assigned to APCs under the OPPS initially and over time. Panel member Louis Potters, M.D., agreed that the process for assigning new CPT codes to APCs seems arbitrary and carries the potential to create inappropriate financial incentives. Dr. Bazell noted that under the OPPS, if

CMS believes a new service or procedure could potentially be an appropriate covered outpatient hospital service, the Agency assigns it to an APC.

Ms. Merlino said that the SNM and the Nuclear Medicine APC Task Force supported a proposal put forth by the ACC in October 2006 to place the cardiac CT and CT angiography CPT codes into specific New Technology APCs. Audience member Michael Ross, M.D., said that his experience evaluating chest pain using CT angiography and nuclear imaging confirms that the services do not belong in the same APC. Panel member Kim Allan Williams, M.D., agreed. The Panel did not support any of the proposed APC placements that the CMS staff suggested.

- **Recommendation**: The Panel recommends that CMS work with stakeholders to determine more appropriate APC placements for the following CPT codes:
    - CPT 0144T, *Computed tomography, heart, without contrast material, including image postprocessing and quantitative evaluation of coronary calcium*
    - CPT 0145T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology*
    - CPT 0146T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium*

- CPT 0147T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium*

- CPT 0148T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium*

- CPT 0149T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium*

- CPT 0150T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology in congenital heart disease*

- CPT 0151T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing, function evaluation (left and right ventricular function, ejection-*

fraction and segmental wall motion) (list separately in addition to code for primary procedure)

Magnetic Resonance (MR) Guided Focused Ultrasound Ablation

LCDR Baldo said that CMS maintained for CY 2007 the HCPCS 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 or equal to 200 cc of tissue*, in the same clinical APCs as for 2006 (APC 0195, Level IX Female Reproductive Procedures, and 202, Level X Female Reproductive Procedures, respectively). The Agency received comments to the 2007 proposed rule requesting the procedures be moved into an APC for stereotactic radiosurgery on the basis of clinical homogeneity and resource use. However, the procedure treats uterine fibroids and is rarely performed in Medicare patients.

Public Presentation

Elizabeth Stewart, M.D., and Kathy Francisco of the Pinnacle Health Group asked that MR guided focused ultrasound ablation procedures be moved to a New Technology APC, adding that the treatment is unique and requires much more time than diagnostic MR imaging (Presentation 12). Ms. Francisco said that an independent analysis of the procedure in five hospitals found costs ranging from $7,000 to $8,500. Dr. Stewart pointed out that commercial insurers base their payment rates on Medicare payment rates. Ms. Francisco added that Medicare beneficiaries include individuals under age 65 who should have access to this New Technology. The Panel

agreed the procedures should move to an APC that better accounts for the time and resources involved.

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

Skin Repair Procedures

CMS staff member Heather Hostetler described a possible realignment of APCs for skin repair procedures to address violations of the two times rule evident in 2006 data. Panel member Robert Matthew Zwolak, M.D., Ph.D., questioned the integrity of the data for those codes that are add-on codes.

- **Recommendation:** The Panel supports CMS' possible reorganization of the skin repair APCs into five levels but urges CMS to give special consideration to the assignment of those codes listed as CPT add-ons.

Blood and Blood Products

Bonnie Handke, R.N., of the Advance Medical Technology Association (AdvaMed) expressed concern that CMS does not pay adequately for the ancillary services required to provide blood and blood products (Presentation 13). Ms. Rinkle of the PRT added that the costs identified by

hospitals' blood centers do not capture the considerable expense of nursing administration, which should be distinguished from blood product processing. Panel member Gloryanne Bryant noted that CMS does not pay for subsequent blood transfusions, as it does for subsequent administration of other products.

Recommendation: The Panel recommends that CMS investigate whether CPT 36430, *Transfusion, blood or blood components,* should identify when multiple units are transfused and trigger a discounted payment for the second and subsequent administrations of additional units of blood or blood components.

DEVICE-RELATED APC ISSUES

Ms. Heygster, CMS staff, explained how CMS has revised its approach to calculating the payment rates for device-dependent APCs. Beginning in 2007, the Agency no longer pays for devices that are recalled and replaced by the manufacturer at no cost to the hospital, and Ms. Heygster said that the device-dependent APC median costs should be more stable as a result. She also explained how CMS applies a wage-adjustment factor to account for the clinical labor associated with procedures assigned to device-dependent APCs, just as CMS does for other OPPS services.

Public Presentations

Ms. Handke of AdvaMed asked that CMS continue adjusting its calculations to better capture device costs and continue educating hospitals on correctly coding for devices and technologies (Presentation 13). She also asked that CMS incorporate external data when appropriate to

calculate payment rates for new technology services and that CMS allow procedures assigned to a New Technology APC to remain in that APC for at least 2 full years.

Jori Frahler of the Medical Device Manufacturers Association said that the lack of predictability and stability in the OPPS deters entrepreneurs from pursuing the development of new technology services (Presentation 14). She asked CMS to require device C-codes be reported for procedures assigned to all device-dependent APCs in 2008 and to maintain 2007 rates for 2008 or institute a payment floor when payment rates would decline by more than 10 percent. Ms. Frahler also recommended that CMS establish a 2-year minimum assignment of new services to New Technology APCs, consistent with the minimum 2 years of pass-through payment required for pass-through devices.

Mary Hayter of Smith & Nephew further supported a 2-year minimum placement of services in New Technology APCs (Presentation 15).

Dr. Tyler noted that very few OPPS services experienced payment reductions of more than 10 percent in 2006, and the Panel relies on CMS staff to identify specific cases for consideration. The Panel agreed that CMS should include external data in considering the costs of procedures for assignment to New Technology APCs. Some Panel members wondered whether basing New Technology APC payments on submitted external data results in overpayment for services while they are in New Technology APCs. Panel members pointed out that in some cases, the volume of services assigned to a New Technology APC after 1 year is high enough to provide significant data on which to justify clinical APC placement and ratesetting.

- **Recommendation**: The Panel recommends that CMS keep services in New Technology APCs until data are sufficient to assign them to a clinical APC, but for no longer than 2 years.

OBSERVATION ISSUES

Ms. Hostetler said that CMS was seeking input from the Panel on whether the CPT codes for consultation visits were useful. She also described the Agency's current coding and payment policy for observation services as well as criteria for paying separately for observation of patients admitted with asthma, chest pain, or congestive heart failure. Ms. Hostetler provided statistical data on the frequency and costs of observation for the three clinical conditions for which observation is currently separately paid, as well as for syncope and dehydration.

Ms. Hostetler also provided data on 2006 claims that included a procedure with SI of "T" that was billed along with a claim for observation services on the same day. She said that the most common procedures with "T" status were cardiac catheterization and angiography procedures, and CMS found it difficult to determine whether the observation services occurred before or after these procedures.

Ms. Hostetler added that CMS agreed to expand the scope of the Observation Subcommittee to include evaluating visits. Consequently, the Subcommittee is now called the Observation and Visit Subcommittee.

Observation and Visit Subcommittee's Report

Judie Snipes, R.N., Chair, Observation and Visit Subcommittee, thanked CMS staff for the data and assistance to the Subcommittee and presented the recommendations of the Observation and Visit Subcommittee.

Audience member John Settlemeyer of the Carolinas Health Care System said that CMS should standardize the guidelines for evaluation and management visits, eliminate the reporting and payment distinction between new and established patients, and pay for consultations based on the five levels of CPT codes.

Public Presentation

Jugna Shah of the ADCC said that her organization appreciated CMS' assessment of the data and recommended that CMS add syncope and dehydration to the list of conditions eligible for separate payment for observation (Presentation 16).

- **Recommendation**: The Panel recommends that CMS add syncope and dehydration to the list of clinical conditions eligible for separate observation payment.

- **Recommendation**: The Panel recommends that CMS make no changes to the criteria for separate observation payment related to the performance of "T" status procedures. However, if CMS adds syncope and dehydration to the list of conditions eligible for separate observation payment, the Panel requests that CMS re-examine the claims data

once CMS collects a year of observation claims data including the additional conditions so the Panel can reconsider this recommendation at a future meeting.

- **Recommendation**: The Panel recommends that CMS direct hospitals to report for payment the CPT codes for non-emergency department (ED) outpatient visits at five levels, making no distinction between reporting and payment for new and established patients.

- **Recommendation**: The Panel recommends that CMS eliminate the "new" and "established" patient distinctions in the reporting of non-ED outpatient visits.

- **Recommendation**: The Panel recommends that CMS *not* recognize the CPT consultation codes (CPT 99241; *Office consultation for a new or established patient, which requires these three key components: a problem focused history; a problem focused examination; and straightforward medical decision making;* CPT 99242, *Office consultation for a new or established patient, which requires these three key components: an expanded problem focused history; an expanded problem focused examination; and straightforward medical decision making*; CPT 99243, *Office consultation for a new or established patient, which requires these three key components: a detailed history; a detailed examination; and medical decision making of low complexity*; CPT 99244, *Office consultation for a new or established patient, which requires these three key components: a comprehensive history; a comprehensive examination; and medical decision making of moderate complexity*; CPT 99245, *Office consultation for a new or established patient, which requires these three key components: a comprehensive*

history; a comprehensive examination; and medical decision making of high complexity). CMS should instruct hospitals to build consultation services into their internal hospital guidelines related to reporting outpatient clinic visit levels based on the complexity and resources used for these outpatient visits.

- **Recommendation**: The Panel recommends that CMS continue to evaluate the types of diagnostic conditions that might qualify for separate observation payment in the future.

Ms. Bryant asked that CMS give hospitals and providers more information about how to apply consultation codes and clearly identify the different definitions of "consultation" for hospitals versus physicians.

PACKAGING ISSUES

CMS staff member Tamar Spolter explained that CMS packages certain codes with others when it determines that a service is almost always provided in conjunction with another separately payable service (SI "N"). CMS assigns SI "Q" to designate "special" packaged codes. "Special" packaged codes are usually packaged, but are separately paid when provided without another separately payable code on the same date of service. CMS will be studying the frequency of payment to these special packaged codes as soon as we have available data.

Ultrasound Guidance

Ms. Spolter said that CPT 76937, *Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (list separately in addition to code for primary procedure),* had been packaged since 2004. CMS has received requests to pay for this code separately. Ms. Spolter noted that if it were paid separately, the number of single claims used for ratesetting could be significantly reduced.

Public Presentation

Andrew Whitman of the Medical Imaging and Technology Alliance asked CMS to continue seeking ways to identify costs using multiple-procedure claims, specify a process for assigning New Technology services to APCs, and maintain services in New Technology APCs for a minimum of 2 years (Presentation 17). He also requested that CMS promote adequate payment for imaging technologies and postpone implementing the multiple imaging reduction policy. Mr. Whitman recommended that ultrasound guidance be paid separately and assigned to APC 0268, Level I Ultrasound Guidance Procedures.

- **Recommendation**: The Panel recommends that CMS place CPT 76937, *Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of*

vascular needle entry, with permanent recording and reporting (list separately in addition to code for primary procedure), on the list of special packaged codes (SI "Q").

Trauma Activation

Ms. Spolter said that CMS now pays differentially for critical care when associated with trauma activation. When trauma activation occurs in conjunction with services other than critical care, payment for the trauma activation is bundled into the payment for other services provided on that day.

Public Presentation

Ms. Rinkle and Janet Gallaspy of the Providers Roundtable asked that trauma activation be paid separately regardless of the level of emergency visit with which it occurs (Presentation 18). Ms. Gallaspy said that trauma activation occurs in accordance with state guidelines and that hospitals incur costs for every activation. Written testimony from Larry S. Gage, National Association of Public Hospitals and Health Systems (Presentation 19), and Connie J. Potter and Ron J. Anderson, National Foundation for Trauma Care (Presentations 20a, 20b), supported the recommendation.

- **Recommendation**: The Panel recommends that CMS evaluate providing separate payment for trauma response activation when it is reported on a claim for an ED visit, regardless of the level of the ED visit.

Chest X-Ray Computer Aided Detection

Ms. Spolter said that 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,* 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,* replaced CPT 0152T, which was packaged for 2006. CPT codes 0174T and 0175T are packaged for 2007. CMS has received requests to pay the codes separately. She asked the Panel to consider whether the codes should continue to be packaged in 2008, paid separately, or given "special" packaged status.

Public Presentation

Matthew Freedman, M.D., David Fryd, Ph.D., and Sam D. Finklestein of Riverain Medical asked CMS to move the two CPT codes for chest x-ray with CAD to New Technology APC 1492, New Technology—Level 1B ($10-$20) (Presentation 21). Because the provision of CAD is resource-intensive and is provided infrequently in proportion of the total number of chest x-rays performed, they believe it should be paid separately. Panel member and newly elected Chair of the Packaging Subcommittee James Rawson, M.D., said that the Subcommittee was leaning toward continued packaging of these codes. Panel member Lou Ann Schraffenberger said that separate payment should be considered for CAD performed remote from the primary

interpretation because providers who serve rural communities might otherwise not be paid for the service. Drs. Potters and Zwolak questioned whether early diagnosis of stage I lung cancer increased survival rates. Dr. Potters added that if CAD was being used as a screening technique, it should remain packaged.

- **Recommendation**: The Panel recommends that CMS place 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*, on the list of special packaged codes (SI "Q").

Acoustic Heart Sound Recording and Computer Analysis

Ms. Spolter said that CPT 0069T, *Acoustic heart sound recording and computer analysis; acoustic heart sound recording and computer analysis only*, had been packaged since 2005.

Public Presentation

Frank Smart, M.D., and Patty White, speaking on behalf of Inovise Medical, the manufacturer of an acoustic heart sound recording device, asked CMS to pay separately for CPT 0069T because it can be performed without other services (Presentation 22). They said that the procedure is underpaid by CMS and the costs are not packaged with any specific APC. They asked that it be moved to a New Technology APC or into APC 0096, Non-Invasive Vascular Studies, or 0097, Cardiac and Ambulatory Blood Pressure Monitoring, for clinical homogeneity. Dr. Smart added

that the procedure is less costly and faster than echocardiography but hospitals have been slow to implement the technology because it is not sufficiently recognized by CMS.

- **Recommendation**: The Panel recommends that CMS place CPT 0069T, *Acoustic heart sound recording and computer analysis; acoustic heart sound recording and computer analysis only*, on the list of special packaged codes (SI "Q") and that CMS exclude APC 0096, Non-Invasive Vascular Studies, as a potential placement for this CPT code.

Total Body Hypothermia

Ms. Spolter said that CMS had received few claims for CPT 99186, *Hypothermia, total body*, in the first 9 months of 2006 and that the code was never billed alone. She asked the Panel to consider whether the code should continue to be packaged in 2008, paid separately, or given special packaged status.

Public Presentation

Robert J. Freedman, Jr., M.D., and John McInnis of Life Recovery Systems, which manufacturers a whole-body emergency cooling suit, said that CMS payment does not adequately reflect new, faster, more expensive cooling technologies (Presentation 23). They presented published data indicating that cooling was associated with better patient outcomes. They asked that CMS pay separately to recognize the resource intensity of modern cooling technologies. Life Recovery Systems is in the process of applying for a distinct CPT code for its emergency cooling suit. The Panel noted that paying separately for CPT 99186 would also affect

the payment rates for the old cooling methods. The Panel discussed how and in what settings the cooling suit was used and requested more data on the technology.

- **Recommendation**: The Panel recommends that CMS reevaluate the packaged OPPS payment for CPT 99186, *total body hypothermia*, based on current research and availability of new therapeutic modalities.

Disposable Drug Delivery System

Ms. Spolter said that the SI for HCPCS A4306, *Disposable drug delivery system, flow rate of less than 50 mL per hour*, had been changed to N (packaged) for 2007. It had previously been considered to be durable medical equipment. According to CMS, this code represents a supply, and is therefore appropriately packaged, since supplies are packaged under the OPPS.

Roger Massengale and Steve Watkins of I-Flow Corporation said that CMS underpays for HCPCS A4306 (Presentation 24). They said that the disposable drug delivery system reduces postsurgical pain, reduces the length of the patient's stay, and increases patient satisfaction. They recommended that HCPCS A4306 be moved to its own APC.

- **Recommendation**: The Panel recommends that HCPCS A4306, *Disposable drug delivery system, flow rate of less than 50 mL per hour*, remain packaged and that CMS present additional data on this system to the Panel when available.

Packaging Subcommittee Report

Common Carotid Intima-Media Thickness Study

The Packaging Subcommittee reviewed the general principles of packaging and specific codes brought to the attention of CMS by the public. The Subcommittee discussed the issues identified for the Panel by Ms. Spolter but did not provide specific recommendations. The Subcommittee also discussed the appropriate placement of CPT 0126T, *Common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment*. The Panel believed that patients may come to the hospital for carotid IMT study and have no other separately payable services provided on the same date.

- **Recommendation**: The Panel recommends that CMS place CPT 0126T, *Common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment,* on the list of special packaged codes (SI "Q") and consider mapping the code to APC 340, Minor Ancillary Procedures.

INPATIENT-ONLY LIST

CMS staff member Dana Burley presented a list of procedures that CMS identified as possible services for removal from the inpatient-only list:

- **CPT 21360**, *Open treatment of depressed malar fracture, including zygomatic arch and malar tripod*

- **CPT 21365**, *Open treatment of complicated (e.g., comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches*

- **CPT 21385**, *Open treatment of orbital floor blowout fracture; transantral approach (Caldwell-Luc type operation)*

- **CPT 25931**, *Transmetacarpal amputation; re-amputation*

- **CPT 27006**, *Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)*

- **CPT 27720**, *Repair of nonunion or malunion, tibia; without graft, (e.g., compression technique)*

- **CPT 27722**, *Repair of nonunion or malunion, tibia; with sliding graft*

- **CPT 50580**, *Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive or radiologic service; with removal of foreign body or calculus*

- **CPT 51535**, *Cystotomy for excision, incision, or repair of ureterocele*

- **CPT 58805**, *Drainage of ovarian cyst(s), unilateral or bilateral, (separate procedure); abdominal approach*

- **CPT 60271**, *Thyroidectomy, including substernal thyroid; cervical approach*

- **CPT 61770**, *Stereotactic localization, including burr hole(s), with insertion of catheter(s) or probe(s) for replacement of radiation source*
- **CPT 69970**, *Removal of tumor, temporal bone*
- **CPT 64818**, *Sympathectomy, lumbar*
- **CPT 20660**, *Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure)*

Public Presentation

Kathy Austin of the PRT asked that CMS remove HCPCS 20660, *Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure)*, from the inpatient-only list and assign it to APC 0221, Level II Nerve Procedures (Presentation 25). She said that that in some cases, the stereotactic radiosurgery is aborted, but hospitals are unable to bill for the costs associated with preparing for the procedure. The Panel recognized the problem but was unwilling to recommend removing the procedure from the inpatient-only list because the procedure occurs relatively infrequently in the outpatient setting.

Ms. Shah, speaking on behalf of ADCC , suggested that CMS designate HCPCS 20660 a "special" packaged code, paying for it separately when it is not billed with a separately payable service.

Dr. Zwolak pointed out that CMS proposed to remove HCPCS code 64818, *Sympathectomy, lumbar*, from the inpatient-only list despite the fact that only 18 percent of procedures are performed in an outpatient setting.

Ms. Leon-Chisen of the American Hospital Association pointed out that physicians often make the decision about whether to perform surgery on an outpatient or inpatient basis, and hospitals must bear the facility costs when a physician performs outpatient surgery but the procedure is on the inpatient-only list.

- **Recommendation**: The Panel recommends that CMS remove the following CPT codes from the inpatient-only list:
    - CPT 21360, *Open treatment of depressed malar fracture, including zygomatic arch and malar tripod*
    - CPT 21365, *Open treatment of complicated (e.g., comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches*
    - CPT 21385, *Open treatment of orbital floor blowout fracture; transantral approach (Caldwell-Luc type operation)*
    - CPT 25931, *Transmetacarpal amputation; re-amputation*
    - CPT 27006, *Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)*

- CPT 27720, *Repair of nonunion or malunion, tibia; without graft, (e.g., compression technique)*
- CPT 27722, *Repair of nonunion or malunion, tibia; with sliding graft*
- CPT 50580, *Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive or radiologic service; with removal of foreign body or calculus*
- CPT 51535, *Cystotomy for excision, incision, or repair of ureterocele*
- CPT 58805, *Drainage of ovarian cyst(s), unilateral or bilateral, (separate procedure); abdominal approach*
- CPT 60271, *Thyroidectomy, including substernal thyroid; cervical approach*
- CPT 61770, *Stereotactic localization, including burr hole(s), with insertion of catheter(s) or probe(s) for replacement of radiation source*
- CPT 69970, *Removal of tumor, temporal bone*

The Panel ***does not*** recommend that CMS remove CPT codes 64818, *Sympathectomy, lumbar*; and 20660, *Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure)*. Rather, the Panel recommends that CMS continue to collect utilization data on CPT codes 64818 and 20660 for consideration at the next Panel meeting.

ADMINISTRATIVE BUSINESS

Panel members reviewed the collected recommendations and refined them following further discussion. At the request of the DFO, the Panel members considered whether the Subcommittees should continue to meet.

- **Recommendation**: The Panel recommends that the Observation and Visit, Data, and Packaging Subcommittees continue their work.

CLOSING

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 John O'Reilly (audio specialist) and Dana Trevas (reporter) for their assistance. Dr. Hambrick also thanked outgoing members Frank Opelka, M.D., and Albert Einstein, M.D., for their years of service to the Panel.

The meeting adjourned at 4:45 p.m. on Thursday, March 8, 2007.

Appendix A

AGENDA

March 7 and 8, 2007

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

DAY 1 - Wednesday, March 7, 2007

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

(NOTE: Afternoon break will be at the discretion of the Chair.) **TAB**

AGENDA **A**

01:00 **Opening** - Day 1
Welcome, Call to Order, and Opening Remarks
Thomas Gustafson, Ph.D., Acting Director, Center for Medicare Management

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

01:30 **CMS-1506-F:** Medicare Program; Final Rule for the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates, **Federal Register**

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

01:45 **DATA ISSUES**

Data Issues (continued)

1. **Overview**
   a. Anita Heygster, CMS Staff
   b. Chris Smith Ritter, Ph.D., CMS Staff

2. **Data Subcommittee's Report**
   a. Timothy Tyler, Pharm.D., Chair
   b. Discussion
   c. Panel's Comments

3. **Public Presentations**
   a. Jugna Shah, Consultant **B**
      Alliance of Dedicated Cancer Centers (ADCC)
   b. Valerie Rinkle, Provider Roundtable (PRT) **C**
   c. Discussion
   d. Panel Recommendation(s)

02:45 **DRUGS, RADIOPHARMACEUTICALS, AND DRUG ADMINISTRATION**

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

2. **Public Presentations/Comment Letter**

   a. Jugna Shah, Consultant, ADCC **D**
   b. Judith J. Baker, The Resource Group **E**
   c. Jason Slotnik, Biotechnology Industry Organization **F**
   d. Ernest R. Anderson, M.S., R.Ph. **G**
      Association of Community Cancer Centers
   e. Brian M. Meyer, M.B.A. - Comment Letter **H**
      American Society of Health System Pharmacists
   f. Gordan Schatz, Consultant **I**
      Council on Radionuclides & Radiopharmaceuticals, Inc.
   g. John Reyes-Guerra/Joseph Feldschuh, M.D., Daxor Corp. **J**
   h. Discussion
   i. Panel's Recommendation(s)

04:15 **MISCELLANEOUS APC ISSUES**

Cardiac Computed Tomography and Computed Tomographic Angiography

1. **Overview**
   Marjorie Baldo, LCDR, U.S.P.H.S., CMS Staff
2. **Public Presentation**
   a. Gregory S. Thomas, M.D., M.P.H., ACC **K**
   b. Discussion
   c. Panel Recommendation(s)

Magnetic Resonance Guided Focused Ultrasound Ablation

1. **Overview –** Marjorie Baldo, LCDR, USPHS, CMS Staff
2. **Public Presentation**
   a. Elizabeth Stewart, M.D., Pinnacle Healthgroup **L**
   b. Discussion
   c. Panel Recommendation(s)

Skin Repair Procedures

1. **Overview –** Heather Hostetler, CMS Staff
2. **Panel and Public Comments**
   a. Discussion
   b. Panel Recommendation(s)

05:00 **ADJOURN**

AGENDA

March 7 and 8, 2007

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

DAY 2 - Thursday, March 8, 2007

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

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

08:45 **DEVICE-RELATED APC ISSUES**

1. **Overview** - Anita Heygster, CMS Staff
2. **Public Presentations**
   a. Bonnie Handke, Advanced Medical Technology Association **M**
   b. Jori Frahler, Medical Device Manufacturing Association **N**
   c. Mary E. Hayter, Smith & Nephew, Inc. **O**
   d. Discussion
   e. Panel Recommendation(s)

09:30 **OBSERVATION ISSUES**

1. **Overview** – Heather Hostetler, CMS Staff
2. **Observation Subcommittee's Report**
   a. Judie Snipes, R.N., M.B.A., F.A.C.H.E., Chair
   b. Discussion
   c. Panel's Comments
3. **Public Presentation**
   a. Jugna Shah, Consultant, ADCC **P**
   b. Discussion
   c. Panel Recommendation(s)

10:15 *Break*

10:30 **PACKAGING ISSUES** **TAB**

1. Overview – Tamar Spolter, CMS Staff

2. Packaging Subcommittee's Report

a. Albert Brooks Einstein, Jr., M.D., Chair
b. Discussion
c. Panel's Comments

3. Public Presentations/Comment Letters

Trauma Activation

a. **Overview –** Tamar Spolter, CMS Staff
b. Valerie Rinkle/Janet Gallaspy, PRT **Q**
c. Larry S. Gage – Comment Letter **R**
National Association of Public Hospitals and Health Systems (NAPH)
d. Connie J. Potter & Ron J. Anderson – Comment Letter **S**
National Foundation for Trauma Care
e. Connie J. Potter & Ron J. Anderson, NAPH – Comment Letter **T**
f. Discussion
g. Panel Recommendation(s)

Chest X-Ray Computer Aided Detection

a. **Overview -** Tamar Spolter, CMS Staff
b. Matthew Freedman, M.D./Sam Finklestein/David Fryd, Ph.D. **U**
Riverain Medical
c. Discussion
d. Panel Recommendation(s)

12:00 *Lunch*

01:00 **Packaging Issues – Public Presentations/Comment Letters** (continued)

Acoustic Heart Sound Recording and Computer Analysis

a. **Overview -** Tamar Spolter, CMS Staff
b. Frank Smart, M.D./Paul W. Radensky, M.D. **V**
Morristown Memorial Medical Center
c. Discussion
d. Panel Recommendation(s)

Packaging Issues – Public Presentations/Comment Letters (continued) **TAB**

Total Body Hypothermia

a. **Overview -** Tamar Spolter, CMS Staff
b. Robert J. Freedman, Jr., M.D./John S. McInnis, M.D., J.D. **W**
   Life Recovery Systems
c. Discussion
d. Panel Recommendation(s)

Ultrasound Guidance

a. **Overview -** Tamar Spolter, CMS Staff
b. Andrew Whitman, Medical Imaging & Technology Alliance **X**
c. Discussion
d. Panel Recommendation(s)

Disposable Drug Delivery System

a. **Overview -** Tamar Spolter, CMS Staff
b. Roger Massengale, I-Flow Corporation **Y**
c. Discussion
d. Panel Recommendation(s)

02:15 **INPATIENT ONLY PROCEDURES**

1. Overview Dana Burley, CMS Staff

2. Public Presentation

a. Kathy Austin, PRT **Z**
b. Discussion
c. Panel Recommendation(s)

02:45 *Break* (Cumulative list of Panel's recommendations will be compiled.)

03:30 **Closing**

a. Summary of the Panel's Recommendations for 2008
b. Discussion
c. Final Remarks

04:30 **Adjourn**

(NOTE: There will be NO meeting tomorrow if all Panel business is completed today.)

Appendix B

CENTERS FOR MEDICARE & MEDICAID SERVICES

Advisory Panel on Ambulatory Payment Classification (APC) Groups

Recommendations: March 7–8, 2007

Data Issues

1. The Panel recommends that the Centers for Medicare & Medicaid Services (CMS) edit and return for correction claims that contain a Healthcare Common Procedure Coding System (HCPCS) code for a separately paid drug or device but do not also contain a HCPCS code assigned to a procedural APC (i.e., status indicators (SIs) "S," "T," "V," or "X"). This process should improve the claims data and may increase the number of single bills available for ratesetting.

2. The Panel recommends that CMS delete G0297, *Insertion of single chamber pacing cardioverter defibrillator pulse generator*; G0298, *Insertion of dual chamber pacing cardioverter defibrillator pulse generator*; G0299, *Insertion or repositioning of electrode lead for single chamber pacing cardioverter defibrillator and insertion of pulse generator*; and G0300, *Insertion or repositioning of electrode lead(s) for dual chamber pacing cardioverter defibrillator and insertion of pulse generator,* and require hospitals to report Current Procedural Terminology (CPT) codes 33240, *Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator,* or 33249, *Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator,* as applicable for the insertion of implantable cardioverter defibrillators. The requirement for reporting device HCPCS codes will enable CMS to continue identifying costs when different types of devices are implanted. Current Outpatient Code Editor (OCE) edits requiring providers to report device HCPCS codes for these procedures will enable CMS to continue isolating the costs of implanting different types of devices.

3. The Panel recommends that CMS review the list of packaged revenue codes for consistency with Outpatient Prospective Payment System (OPPS) policy and ensure that future versions of the OCE edit claims accordingly.

Drugs, Biologicals, and Radiopharmaceuticals

4. The Panel recommends that CMS pay separately for CPT 90768, *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure)*, at the same rate as CPT 90767, *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion, up to 1 hour (list separately in addition to code for primary procedure*).

5. The Panel recommends that CMS implement a three-phase plan to address OPPS payment pharmacy overhead costs:

   Phase 1: Work with appropriate stakeholders to develop a system of defined pharmacy overhead categories (e.g., low, medium, and high cost) for outpatient drugs requiring different levels of pharmacy resources and reimburse pharmacy overhead costs by set fees for the categories through New Technology APCs, keeping the CY 2007 Average Sales Price (ASP) plus 6 percent payment methodology for separately paid drugs intact. The Panel recommends that CMS consider gradual implementation of the categories, possibly beginning with the highest level.

   Phase 2: CMS should be cognizant of the Government Accountability Office and Medicare Payment Advisory Commission reports estimating pharmacy overhead costs and accept outside survey data from stakeholders.

   Phase 3: Establish payment rates for pharmacy overhead costs based on claims data (ultimately) for outpatient hospital administration of drugs (i.e., a hospital pharmacy overhead category HCPCS code would need to be reported, along with the appropriate charge for each administration of a drug in the hospital outpatient department).

6. The Panel recommends that CMS allow hospitals to report all HCPCS codes for drugs.

7. The Panel recommends that CMS continue to work with stakeholders on issues related to payment for radiopharmaceuticals, e.g., evaluating claims data for different classes of radiopharmaceuticals and ensuring that a nuclear medicine procedure claim always includes at least one radiopharmaceutical agent reported.

8. The Panel recommends that CMS consider use of external data and work with stakeholders to determine the correct code descriptor units for each radiopharmaceutical, including HCPCS A9524, *Iodine I-131 iodinated serum albumin, diagnostic, per 5 microcuries.*

Miscellaneous APC Issues

9. The Panel recommends that CMS move CPT 78492, *Myocardial imaging, positron emission tomography (PET), perfusion; multiple studies at rest and/or stress,* into its own clinical APC.

10. The Panel recommends that CMS work with stakeholders to determine a more appropriate APC placement for the following CPT codes:

10. *(continued)*

- CPT 0144T, *Computed tomography, heart, without contrast material, including image postprocessing and quantitative evaluation of coronary calcium*

- CPT 0145T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology*

- CPT 0146T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium*

- CPT 0147T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium*

- CPT 0148T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium*

- CPT 0149T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium*

- CPT 0150T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology in congenital heart disease*

- CPT 0151T, *Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing, function evaluation (left and right ventricular function, ejection-fraction and segmental wall motion) (list separately in addition to code for primary procedure)*

11. The Panel recommends that CMS move HCPCS 0071T, *Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue*; and HCPCS 0072T, *Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue*; to APC 0067, Level III Stereotactic Radiosurgery.

12. The Panel recommends that CMS investigate whether CPT 36430, *Transfusion, blood or blood components*, should identify when multiple units are transfused and trigger a discounted payment for the second and subsequent administrations of additional units of blood or blood components.

13. The Panel supports CMS' possible reorganization of the skin repair APCs into five levels but urges CMS to give special consideration to the assignment of those codes listed as CPT add-ons.

Devices

14. The Panel recommends that CMS keep services in New Technology APCs until data are sufficient to assign them to clinical APCs, but for no longer than 2 years.

Observation

15. The Panel recommends that CMS add syncope and dehydration to the list of clinical conditions eligible for separate observation payment.

16. The Panel recommends that CMS make no changes to the criteria for separate observation payment related to the performance of "T" status procedures. However, if CMS adds syncope and dehydration to the list of conditions eligible for separate observation payment, the Panel requests that CMS re-examine the claims data once CMS collects a year of observation claims data including the additional conditions so the Panel can reconsider this recommendation at a future meeting.

17. The Panel recommends that CMS direct hospitals to report for payment the CPT codes for non-emergency department (ED) outpatient clinic visits at five levels, making no distinction between reporting and payment for new and established patients.

18. The Panel recommends that CMS eliminate the "new" and "established" patient distinctions in the reporting of non-ED outpatient clinical visits.

19. The Panel recommends that CMS *not* recognize the CPT consultation codes (CPT 99241; *Office consultation for a new or established patient, which requires these three key components: a problem focused history; a problem focused examination; and straightforward medical decision making;* CPT 99242, *Office consultation for a new or established patient, which requires these three key components: an expanded problem focused history; an expanded problem focused examination; and straightforward medical decision making*; CPT 99243, *Office consultation for a new or established patient, which requires these three key components: a detailed history; a detailed examination; and medical decision making of low complexity*; CPT 99244, *Office consultation for a new or established patient, which requires these three key components: a comprehensive history; a comprehensive examination; and medical decision making of moderate complexity*; and CPT 99245, *Office consultation for a new or established patient, which requires these three key components: a comprehensive history; a comprehensive examination; and medical decision making of high complexity*). CMS should instruct hospitals to build consultation services into their internal hospital guidelines related to reporting outpatient clinic visit levels based on the complexity and resources used for these outpatient visits.

20. The Panel recommends that CMS continue to evaluate the types of diagnostic conditions that might qualify for separate observation payment in the future.

Packaging

21. The Panel recommends that CMS place CPT 76937, *Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (list separately in addition to code for primary procedure)*, on the list of special packaged codes (SI "Q").

22. The Panel recommends that CMS evaluate providing separate payment for trauma response activation when it is reported on a claim for an ED visit, regardless of the level of the ED visit.

23. The Panel recommends that CMS place 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*, on the list of special packaged codes (SI "Q").

24. The Panel recommends that CMS place CPT 0126T, *Common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment*, on the list of special packaged codes (SI "Q") and consider mapping the code to APC 340, Minor Ancillary Procedures.

25. The Panel recommends that CMS place CPT 0069T, *Acoustic heart sound recording and computer analysis only*, on the list of special packaged codes (SI "Q") and that CMS exclude APC 0096, Non-Invasive Vascular Studies, as a potential placement for this CPT code.

26. The Panel recommends that HCPCS A4306, *Disposable drug delivery system, flow rate of less than 50 mL per hour*, remain packaged and that CMS present additional data on this system to the Panel when available.

27. The Panel recommends that CMS reevaluate the packaged OPPS payment for CPT 99186, *total body hypothermia*, based on current research and availability of new therapeutic modalities.

Inpatient-Only List

28. The Panel recommends that CMS remove the following CPT codes from the inpatient-only list:

    - **CPT 21360**, *Open treatment of depressed malar fracture, including zygomatic arch and malar tripod*

    - **CPT 21365**, *Open treatment of complicated (e.g., comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches*

    - **CPT 21385**, *Open treatment of orbital floor blowout fracture; transantral approach (Caldwell-Luc type operation)*

    - **CPT 25931**, *Transmetacarpal amputation; re-amputation*

    - **CPT 27006**, *Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)*

    - **CPT 27720**, *Repair of nonunion or malunion, tibia; without graft, (e.g., compression technique)*

    - **CPT 27722**, *Repair of nonunion or malunion, tibia; with sliding graft*

    - **CPT 50580**, *Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive or radiologic service; with removal of foreign body or calculus*

    - **CPT 51535**, *Cystotomy for excision, incision, or repair of ureterocele*

- **CPT 58805**, *Drainage of ovarian cyst(s), unilateral or bilateral, (separate procedure); abdominal approach*

- **CPT 60271**, *Thyroidectomy, including substernal thyroid; cervical approach*

- **CPT 61770**, *Stereotactic localization, including burr hole(s), with insertion of catheter(s) or probe(s) for replacement of radiation source*

- **CPT 69970**, *Removal of tumor, temporal bone*

The Panel *does not* recommend that CMS remove CPT codes 64818, *Sympathectomy, lumbar*; and 20660, *Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure).* However, the Panel recommends that CMS continue to collect utilization data on CPT codes 64818 and 20660 for consideration at the next Panel meeting.

Panel Subcommittees

29. The Panel recommends that the Observation and Visit, Data, and Packaging Subcommittees continue their work.

Appendix C

Presentations

The following organizations provided written testimony for the Advisory Panel on Ambulatory Payment Classification Groups meeting March 7–8, 2007:

Presentation 1: Alliance of Dedicated Cancer Centers (ADCC)

Presentation 2: Provider Roundtable (PRT)

Presentation 3: ADCC

Presentation 4: The Resource Group

Presentation 5: Biotechnology Industry Organization

Presentation 6: Association of Community Cancer Centers

Presentation 7: American Society of Health System Pharmacists

Presentation 8: Council on Radionuclides and Radiopharmaceuticals, Inc.

Presentation 9: Society of Nuclear Medicine

Presentation 10: Daxor Corporation

Presentation 11: American College of Cardiology

Presentation 12: The Pinnacle Health Group

Presentation 13: Advanced Medical Technology Association (AdvaMed)

Presentation 14: Medical Device Manufacturers Association

Presentation 15: Smith & Nephew

Presentation 16: ADCC

Presentation 17: Medical Imaging and Technology Alliance

Presentation 18: PRT

Presentation 19: National Association of Public Hospitals and Health Systems

Presentation 20a: National Foundation for Trauma Care (NFTC)

Presentation 20b: NFTC

Presentation 21: Riverain Medical

Presentation 22: Inovise Medical

Presentations *(continued)*

Presentation 23: Life Recovery Systems

Presentation 24: I-Flow Corporation

Presentation 25: PRT