# ADVISORY PANEL

# ON

# AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS

**APC Panel Meeting Report**

**February 18–19, 2009**

**Centers for Medicare & Medicaid Services (CMS)**

**7500 Security Boulevard, Auditorium**

**Baltimore, MD 21244-1850**

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**PANEL MEMBERS PRESENT AT THIS MEETING**

Gloryanne Bryant, B.S., R.H.I.T.

Kathleen M. Graham, R.N., M.S.H.A.

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

Judith T. Kelly, R.H.I.T., R.H.I.A.

Michael D. Mills, Ph.D.

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

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

Randall A. Oyer, M.D.

Beverly Khnie Philip, M.D.

Russ Ranallo, M.S.

James Rawson, M.D.

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

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

Kim Allan Williams, M.D., F.A.C.C., F.A.B.C.

Robert Matthew Zwolak, M.D., Ph.D., F.A.C.S.

**CMS STAFF PRESENT**

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

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

Amy Bassano, Director, Hospital and Ambulatory Policy Group

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

Christina Smith Ritter, Ph.D., Acting Deputy Director, DOC

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|---|---|
| Carrie Bullock, M.H.S. | Staff, DOC |
| Dana Burley, M.S.P.H., B.S.N. | Staff, DOC |
| Erick Chuang, M.S. | Staff, DOC |
| Anita Heygster | Staff, DOC |
| Heather Hostetler, J.D. | Staff, DOC |
| Rebecca Cole, M.S. | Staff, DOC |
| Barry Levi, M.B.A. | Staff, DOC |
| Tamar Spolter, M.H.S. | Staff, DOC |
| Raymond Bulls | Staff, DOC |
| Alberta Dwivedi | Staff, DOC |
| Gift Tee, M.P.H. | Staff, DOC |

## WELCOME AND CALL TO ORDER

E. L. Hambrick, M.D., J.D., Chair, welcomed the members, CMS staff, and the public. (The proceedings of the meeting follow. The agenda appears in Appendix A; a listing of only the recommendations appears in Appendix B. A list of presentations appears in Appendix C.) Amy Bassano, Director of the Hospital and Ambulatory Policy Group, welcomed the Panel members, noting that their broad expertise and input has been invaluable to CMS in rulemaking. Ms. Bassano offered a special welcome to the three new Panel members, Kathleen M. Graham, R.N., M.S.H.A.; Judith T. Kelly, R.H.I.T., R.H.I.A.; and Randall A. Oyer, M.D.

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

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

Carol Bazell, M.D., M.P.H., Director, DOC, briefly described the process CMS used to set the payment rates in the final rule, which was published in the *Federal Register* November 18, 2008. She noted that the market basket increase for CY 2009 is 3.6 percent, which will increase the overall OPPS payment to providers by approximately 3.9 percent. Significant changes discussed in the CY 2009 final rule include the following:

- **Outlier Payments**: The outlier threshold for hospitals for CY 2009 is set at 1.75 times the APC payment amount. The fixed-dollar outlier threshold for hospitals is $1,800. Hospital costs must exceed both thresholds to qualify for the outlier payment, which will trigger an outlier payment of 50 percent of the difference between the hospital's cost and the APC payment.

- **Quality Measures**: Beginning in CY 2009, hospitals that failed to report the seven required quality measures for CY 2008 will receive a 2-percentage point reduction to the update factor for CY 2009 payment.

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

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

- **Charge Compression**: To address the impact of charge compression (the hospital practice of assigning a lower markup to relatively high-cost items and a higher markup to lower-cost items within the same cost center), the FY 2009 final rule for the Inpatient Prospective Payment System creates separate cost centers on the Medicare cost report for high-cost implants and other medical supplies.

- **Composite APCs**: CMS created five new composite APCs for multiple imaging services provided during the same session within three imaging families:
    - Ultrasound
    - Computed tomography (CT) and computed tomographic angiography (CTA) without contrast
    - CT and CTA with contrast
    - Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) without contrast
    - MRI and MRA with contrast
- **Drugs and Biologicals (Except Radiopharmaceuticals)**: For CY 2009, CMS will pay for drugs and biologicals at a rate of the average sales price (ASP) plus 4 percent. The updated packaging threshold for drugs and biologicals will remain $60 per day.
- **Radiopharmaceuticals and Brachytherapy Sources**: In accordance with the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), therapeutic radiopharmaceuticals and brachytherapy sources will be paid at hospitals' charges adjusted to cost through December 31, 2009. Diagnostic radiopharmaceuticals will remain packaged for CY 2009. Brachytherapy sources are not eligible for outlier payments or rural SCH adjustment while they are paid at cost.
- **Drug Administration APCs**: For CY 2009, CMS drug administration services will be paid through a five-level APC structure that better aligns with costs determined from claims data and that eliminates unnecessary APCs. Preadministration-related services for intravenous immunoglobulin (IVIG) administration will be packaged in CY 2009.
- **Ambulatory Surgical Centers (ASCs)**: A budget-neutral ASC-specific conversion factor to determine payment rates for ASCs will be used for CY 2009, consistent with the final policies of the revised ASC payment system initially adopted for CY 2008.

## DATA ISSUES

CMS staff member Anita Heygster noted that the data construction method CMS uses for setting median costs for APCs changed very little for CY 2009. For the CY 2009 OPPS, CMS changed the revenue code-to-cost center crosswalk that CMS uses to match the charges on a claim to the cost-to-charge ratio for the applicable cost center for a specific revenue code (0904). The change is intended to conform to the crosswalk being used to calculate partial hospitalization program costs.

Ms. Heygster outlined how CMS categorizes claims for ratesetting, including the process of identifying "pseudo" single claims that can be assessed alongside "natural" single claims. About 99.3 million claims from CY 2007 were available to calculate median costs for CY 2009. After

determining median costs, CMS assesses APC assignments for violations of the two-times rule. Ms. Heygster said a notable number of Healthcare Common Procedure Coding System (HCPCS) codes were reassigned to different APCs as a result of updated claims or creation of composite APCs for imaging. Overall, 14 APCs violate the two-times rule in CY 2009, down from 20 in CY 2008. The Panel was asked to consider potential violations of the two-times rule for the proposed rule for CY 2010, bearing in mind that low-volume services are exempt from the two-times rule.

***Data Subcommittee's Report***

Kim Allan Williams, M.D., Chair of the Data Subcommittee, said that the Subcommittee met in conjunction with the Packaging Subcommittee for part of its meeting. The Subcommittee discussed CMS' assessment of the frequency and payment of services with expanded packaging from CY 2007 to CY 2008. The Subcommittee reviewed the claims data used by CMS to establish payment for CY 2009 and assessed the bypass list. It evaluated the revenue code-to-cost center crosswalk and the data on brachytherapy sources, drugs and biologicals, and radiopharmaceuticals developed in preparation for the CY 2010 OPPS.

- **Recommendation**: The Panel recommends that the work of the Data Subcommittee continue.

***Radiological Examination of Surgical Specimen***

Overview

CMS staff member Erick Chuang explained that the bypass list includes HCPCS codes that appear on claims with multiple other services and which CMS splits off from multiple procedure claims in order to develop so-called "pseudo" single claims for ratesetting purposes. CMS applies four criteria to determine whether a code is eligible for the bypass list, but not all codes on the bypass list meet all the criteria. Mr. Chuang noted that CMS has become more cautious about adding codes to the bypass list, particularly codes that do not meet CMS' criteria, because of the complications that may occur.

Mr. Chuang said the American College of Radiology requested that CMS move CPT code 76098, *Radiological examination, surgical specimen,* to APC 0260, *Level I Plain Film,* and place CPT code 76098 on the bypass list. CMS is concerned that moving CPT code 76098 into APC 0260 would result in a violation of the two-times rule. CMS notes that CPT code 76098 does not meet its criteria for the bypass list because there are too many single claims with packaging or too high a median packaged cost or both. Finally, Mr. Chuang said, including CPT code 76098 on the bypass list could result in other minor services being inappropriately or incorrectly packaged into the remaining major services on the claim.

Presentation

Pam Kassing, M.P.A., R.C.C., asked that CPT code 76098 be moved to APC 0260, which includes procedures that are more clinically similar (Presentation A). She further requested that CPT code 76098 be added to the bypass list, although it does not meet all of CMS' bypass criteria, because it would result in more single claims for major breast surgery procedures to be used in ratesetting. Ms. Kassing said that adding the code to the bypass list would also result in stripping out of cost estimation

for CPT code 76098 items that are inappropriately packaged with the code. Panel members agreed that the code would fit better in APC 0260.

- **Recommendation**: The Panel recommends that CMS reassign CPT code 76098, *Radiological examination, surgical specimen,* to APC 0260, *Level I Plain Film,* and place CPT code 76098 on the bypass list.

## PACKAGING ISSUES

### *Overview*

CMS staff member Tamar Spolter reiterated the CMS rationale for packaging, noting that it provides an incentive for providers to deliver services in the most efficient, cost-effective manner possible. Ms. Spolter said that for CY 2008, CMS significantly increased the number of services packaged. She reviewed and responded to recommendations made by the Panel over the past three meetings.

To evaluate the impact on beneficiaries of expanded packaging, as recommended by the Panel in September 2007, CMS staff compared the frequency of services billed before packaging was implemented with data from the first year of increased packaging. Because only data from the first 9 months of CY 2008 were available, they were compared with claims data from the first 9 months of CY 2007. Looking at contrast agents, diagnostic radiopharmaceuticals, guidance services, image processing services, imaging supervision and interpretation services, and intraoperative services, CMS found changes in frequency of billing ranging from –1 percent to 2 percent and changes in the numbers of hospitals reporting ranging from –1 percent to 2 percent. Therefore, Ms. Spolter concluded, in the aggregate, it does not appear that hospitals have changed their reporting or patterns of care in response to expanded packaging under the OPPS.

CMS staff assessed the impact of packaging on net payments for patient care by evaluating three areas of historical interest to the Panel, assessing the average changes in payment for 1) cardiac catheterization and other vascular procedures that would be accompanied by intravascular ultrasound (IVUS), intracardiac echocardiography (ICE), and fractional flow reserve (FFR); 2) radiation oncology services that would be accompanied by radiation oncology guidance; and 3) nuclear medicine procedures that would be accompanied by diagnostic radiopharmaceuticals. Again, the data reflect claims from the first 9 months of CY 2007 and CY 2008.

For cardiac catheterization and related procedures, CMS staff found an 8-percent increase in the number of services and items billed and a 25-percent increase in payment, as well as an increase of the average payment per service/item of 15 percent. On closer examination, Ms. Spolter explained, staff identified specific issues contributing to the overall increase in payment. For example, the frequency of implanting drug-eluting coronary stents nearly doubled between CY 2007 and CY 2008, and the payment for the stent insertion procedures increased as well. Therefore, it is difficult to determine how much of the 25-percent aggregate payment increase is attributable to packaging and how much to recalibration of payment rates, but both combined to contribute to the increase, said Ms. Spolter.

For radiation oncology and radiation oncology guidance services, CMS found a 5-percent decrease in the number of services and items billed and a 10-percent decrease in payment. Ms. Spolter pointed out that some radiation oncology services that were separately paid in both CY 2007 and CY 2008 decreased in frequency by 10 to 40 percent in some cases. She added that packaging led to decreases

in payments for some separately payable services and increases for other separately payable services. Again, it is difficult to determine how much of the decrease in aggregate payment is attributable to packaging and how much to recalibration of payment rates, but both combined to contribute to the decrease.

Similar conclusions applied to the evaluation of nuclear medicine procedures, which experienced minimal change in the number of services and items billed and a 3-percent decrease in overall payment. Ms. Spolter said that CMS identified few significant changes in the frequency and payment rates for the relevant HCPCS codes.

***Discussion***

Wendy Smith-Fuss of the Coalition for the Advancement of Brachytherapy asked whether payment for low dose rate (LDR) brachytherapy will decline by 10 percent in CY 2010. She asked that CMS evaluate the two APCs for LDR brachytherapy to determine whether the decrease could be more than 10 percent as a result of removing radiation oncology codes from the bypass list. Dr. Bazell explained that the intent of adding codes to the bypass is to identify more single claims for ratesetting; when codes are taken off the bypass list, CMS no longer uses claims that become multiple procedure claims, which may affect the median costs of certain services.

Some discussion revolved around factors that could have contributed to the decreased payment for nuclear medicine procedures. Jugna Shah of the Alliance of Dedicated Cancer Centers (ADCC) noted that payment for radiation oncology services declined by $60 million and asked the Panel to evaluate where that money went. The Panel commended CMS staff for their analysis but said further evaluation is needed.

- **Recommendation**: The Panel recommends that CMS pay separately for radiation therapy guidance services performed in the treatment room for 2 years and then reevaluate packaging on the basis of claims data.

- **Recommendation:** The Panel recommends that CMS continue to analyze the impact of increased packaging on beneficiaries, providing more detailed versions of the analyses presented at the February 2009 meeting of services initially packaged in calendar year (CY) 2008 at the next Panel meeting. The Panel requests that, in the more detailed analyses of radiation oncology services that would be accompanied by radiation oncology guidance, staff stratify the data according to the type of radiation oncology service, specifically, intensity modulated radiation therapy, stereotactic radiosurgery, brachytherapy, and conventional radiation therapy.

Packaging of Diagnostic Radiopharmaceuticals

CMS staff member Rebecca Cole responded to the Panel's March 2008 request that CMS provide data on usage and frequency, geographic distribution, and size and type of hospitals performing nuclear medicine examinations using radioisotopes to ensure that access is preserved for Medicare beneficiaries. To narrow the scope of the request, CMS first analyzed the number of hospitals performing such scans and the frequency of those scans, and then categorized the findings according to urban or rural location, teaching status (teaching or nonteaching hospital), and volume using CY 2007 and CY 2008 claims data. Overall, between CY 2007 and CY 2008, analysis showed that the number of hospitals performing nuclear medicine scans declined between 0 and 4 percent, and the frequency of claims for nuclear medicine scans declined between 3 and 6 percent.

Ms. Cole said the staff then looked in more detail at cardiac imaging and tumor imaging with diagnostic radiopharmaceuticals. Overall, the second analysis did not show that hospitals providing nuclear imaging scans have significantly changed their use of expensive radiopharmaceuticals as a result of CMS' packaging policy, Ms. Cole noted.

With the exception of notable increases in specific reporting of diagnostic radiopharmaceuticals potentially resulting from the introduction of claims processing edits in CY 2008 to ensure that a diagnostic radiopharmaceutical is included on claims for all nuclear medicine procedures, the analysis showed that hospital billing patterns for diagnostic radiopharmaceuticals associated with cardiac imaging did not change dramatically between CY 2007 and CY 2008, regardless of hospital type or location. The analysis of tumor imaging showed an increase in billing for the two most costly diagnostic radiopharmaceuticals, which could be attributed to improved reporting or to changes in practice. The largest observed increase in billing associated with tumor imaging was for a relatively inexpensive diagnostic radiopharmaceutical.

On the basis of these data, CMS believes that most hospitals have continued to provide nuclear medicine scans and to use more costly diagnostic radiopharmaceuticals as needed, said Ms. Cole.

Discussion

Denise Merlino of the Society for Nuclear Medicine pointed out that the most expensive radiopharmaceuticals do not appear to be included in the analysis, possibly because only teaching hospitals use them more than 2 percent of the time (and therefore they fell below the criteria for presentation this analysis). Dr. Bazell clarified that the analysis looked only at diagnostic radiopharmaceuticals and not other radiolabeled products that could be used in nuclear medicine studies.

- **Recommendation**: The Panel recommends that CMS continue to analyze the impact on beneficiaries of increased packaging of diagnostic radiopharmaceuticals, providing more detailed analyses at the next Panel meeting. The Panel requests that, in the more detailed analyses of packaging of diagnostic radiopharmaceuticals by type of nuclear medicine scan, the staff break down the data according to the specific CPT codes billed with the diagnostic radiopharmaceuticals.

Composite APCs

CMS staff member Carrie Bullock explained that composite APCs group services that are typically performed together during a single encounter and on the same date of service in order to provide a single payment. CMS sees the use of composite APCs as a method to promote efficiency, similar to packaging payment for certain items and services. CMS staff analyzed the effects of composite APCs by comparing CY 2008 claims for APC 8000, *Cardiac Electrophysiologic Evaluation and Ablation (ELA)*, and APC 8001, *Low Dose Rate Prostate Brachytherapy (LDR)*, with CY 2007 claims for the HCPCS codes that make up those composites. Data from all of CY 2007 and from the first 9 months of CY 2008 were used in the analysis.

For the ELA composite, Ms. Bullock pointed to a notable increase from a per unit payment of about $6,000 for all the components of the composite in CY 2007 to payment of about $8,400 for the ELA composite in CY 2008. For the LDR composite, the per unit payment increased by $128. Ms. Bullock said that CMS believes the data for both the ELA and LDR composites indicate that the composite methodology has not resulted in providers changing their patterns of practice and that payment for the services appears to have increased.

Packaging Subcommittee's Report

James Rawson, M.D., Chair of the Packaging Subcommittee, said that the Subcommittee reviewed packaging issues identified by the public, as well as data from CMS staff on the impact of packaging on net payments for patient care, diagnostic radiopharmaceuticals by class of provider, and the ELA and LDR composite APCs. The Subcommittee also reviewed the reporting instructions for CPT code 99291, *Critical care, evaluation and management of the critically ill or critically injured patient, first 30–74 minutes*.

- **Recommendation**: The Panel recommends that CPT code 36592, *Collection of blood specimen using established central or peripheral catheter, venous, not otherwise specified*, remain assigned to APC 0624, *Phlebotomy and Minor Vascular Access Device Procedures*, for CY 2010.

- **Recommendation**: The Panel recommends that the work of the Packaging Subcommittee continue.

## BRACHYTHERAPY SOURCES

### *Overview*

CMS staff member Barry Levi said that statute dictates that CMS pay for brachytherapy sources on the basis of hospital charges adjusted to cost through December 31, 2009. CMS is seeking input on payment for CY 2010. He provided claims data from the first 9 months of CY 2007 and CY 2008 on brachytherapy sources, noting that the data are relatively consistent across both years in both volume and median cost.

### *Discussion*

Ms. Smith-Fuss of the Coalition for the Advancement of Brachytherapy pointed out that, according to a previous CMS analysis, using hospitals' charges adjusted to cost saved the Medicare program money.

- **Recommendation**: The Panel recommends that, for CY 2010, CMS pay for brachytherapy sources using a prospective payment methodology based on median costs.

## VISITS AND OBSERVATION ISSUES

### *Overview*

CMS staff member Heather Hostetler explained that for CY 2009, CMS established a five-level APC structure for Type B ED visits by creating four new APCs for care defined as Levels 1–4 Type B ED Visits. The level 5 Type B ED visit is paid using the same APC as level 5 Type A ED visits. In addition, CMS added HCPCS code G0384, *Level 5 Hospital Emergency Department Visit Provided in a Type B Emergency Department,* to APC 8003, *Level II Extended Assessment and Management Composite*.

### *Visits and Observation Subcommittee's Report*

Michael Ross, M.D., Chair of the Visits and Observation Subcommittee, said the Subcommittee reviewed CY 2009 OPPS payment policies for ED visits and extended assessment and management composite APCs. It also reviewed frequency and median cost claims data for visits and the composite APCs, compared historical payment for visits and observation services under the composite methodology and prior payment policy, and evaluated data on observation services for longer lengths of stay by hospital-specific characteristics. The Subcommittee discussed packaging of critical care services and referred the issue to the Packaging Subcommittee for further consideration.

- **Recommendation**: The Panel recommends that CMS present at the next Panel meeting an analysis of the most common diagnoses and services associated with Type A and Type B ED visits, including analysis by hospital-specific characteristics.

- **Recommendation**: The Panel recommends that CMS issue guidance clarifying the correct method for reporting the start time of observation services.

- **Recommendation**: The Panel recommends that CMS present at the next Panel meeting an analysis of 2008 claims data for clinic, ED (Types A and B), and extended assessment and management composite APCs.

- **Recommendation**: The Panel recommends that the work of the Visits and Observation Subcommittee continue.

## INPATIENT LIST

### *Overview*

CMS staff member Dana Burley presented a list of procedures that CMS identified for possible removal from the inpatient list, as well as utilization data on CPT code 20660, *Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure),* and CPT 64818, *Sympathectomy, lumbar,* in response to the Panel's request for more data. In response to a question by one Panel member, Ms. Burley explained that removing a procedure from the inpatient list enables the physician to determine whether to perform the service in the inpatient or outpatient setting and allows payment to the hospital to be paid for the procedure regardless of whether it is performed in the inpatient or outpatient setting.

- **Recommendation**: The Panel recommends that CMS remove the following CPT codes from the inpatient list:

    - CPT code 21256, *Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (e.g., micro-ophthalmia)*

    - CPT code 27179, *Open treatment of slipped femoral epiphysis; single or multiple pinning of bone graft (includes obtaining graft); osteoplasty of femoral neck (Heyman type procedure)*

    - CPT code 51060, *Transvesical ureterolithotomy*

    In addition, the Panel recommends that CPT code 64818, *Sympathectomy, lumbar*, remain on the inpatient list for CY 2010.

## APC ISSUES

### *Multiple Imaging Composite APCs*

Overview

Ms. Bullock said that for CY 2009, CMS created five new composite APCs for multiple imaging procedures. Providers receive a single payment when multiple imaging procedures within a single family are performed on the same date of service. In the final rule, CMS responded to concerns that, under the composite payment methodology, sessions involving three or more CT scans of the chest, abdomen, and pelvis would be underpaid, thus having a disproportionately negative effect on cancer centers. CMS performed extensive analyses and determined that there is more variability in the number of scans for cancer patients than other patients and that cancer patients often have sessions involving more than two imaging procedures. However, the higher rate of variability was not so great that the mix of services hospitals provide to other types of patients would not balance out higher numbers of scans for cancer patients. Furthermore, CMS does not believe the small percentage of sessions involving three or more imaging services merits additional composite APCs, and doing so would remove some of the efficiency incentives of a single bundled payment, said Ms. Bullock.

In the final rule, CMS also held that composite payment is appropriate for multiple imaging procedures provided on the same date of service, even when provided during a different sitting, because hospitals do not expend the same facility resources for each distinct imaging sitting. Ms. Bullock added that higher costs associated with multiple imaging procedures performed on the same date but in a different sitting would be reflected in the claims data.

Presentation

Ms. Shah of ADCC asked that CMS apply the policy for other procedures such as multiple evaluation and management visits or multiple biopsies on the same date of service to multiple imaging services (Presentation B). She pointed out that hospitals use the modifier –59 to indicate that items or services were provided on a different site, during a different session, or during a different encounter. She asked that CMS enable multiple imaging services to be reported with modifier –59, and that the multiple imaging composite APCs not be applied to these procedures when reported with modifier -59.

Ms. Shah stated that the current composite methodology underpays providers who perform three or more imaging services in one session. She asked that CMS recalculate the median costs of the composite APCs for CTs after excluding claims with three or more CT scans of the chest, abdomen, and pelvis on the same date of service, and create two new composite APCs for sessions involving three or more CT scans of the chest, abdomen, and pelvis, with and without contrast.

Panel members discussed the technical components, time, and resources involved in performing multiple imaging procedures on the same date of service and among different types of patients. Thomas Munger, M.D., wondered whether CMS is moving toward paying lump sums for management of disease states over time instead of paying for individual services. Ms. Bullock said that CMS had proposed instituting a multiple procedure discount for multiple imaging sessions on the same date (as it does for some surgical procedures), but commenters complained that the approach was not based on costs from claims data. She added that payment for claims for other services reported with modifier –59 is calculated differently from payment for composite APCs. John Settlemeyer said the Provider Roundtable supports the recommendations of the ADCC.

- **Recommendation**: The Panel recommends that CMS continue to work with stakeholders to examine different options for APCs for multiple imaging sessions and multiple imaging procedures.

***Neurostimulator Implantation APCs***

Overview

Ms. Bullock said that for CY 2008, CMS revised the APCs for neurostimulator implantation to group payment for procedures that involve mainly nonrechargeable technology (that is, cranial, sacral, gastric, or other peripheral neurostimulator pulse generators) into two APCs and established a third APC for spinal neurostimulator pulse generator implantation, which commonly may use either rechargeable or nonrechargeable devices.

Presentation

Stan Jackson of Cyberonics requested that CMS reconfigure the neurostimulator implantation APCs, either by splitting APC 0039, *Level I Implantation of Neurostimulator*, into two APCs, one each for CPT code 61885, *Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array*; and CPT code 64590, *Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling* (Presentation C). Alternatively, he requested that CMS move CPT code 61885 to APC 0222, *Level II Implantation of Neurostimulator*, along with CPT code 63685, *Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling*. He noted that the service time for cranial and spinal procedures is nearly twice as long as that for gastric and peripheral procedures. Jeffery W. Cozzens, M.D., representing the American Association of Neurological Surgeons/Congress of Neurological Surgeons, echoed Mr. Jackson's assertion, saying that the pre-, intra-, and postoperative time for cranial and spinal neurostimulator implantation are similar.

Rachel Feldman, an analyst for the Moran Company, said that data show that the hospital resources required for CPT codes 61885 and 63685 are similar, so it makes sense to combine them into one APC. Jeff Farkas of Medtronic said the rechargeable and nonrechargeable devices require different resources and suggested further study before combining the two codes into one APC. In response to discussion about whether implantation of a device in the neck could be considered a central nervous system procedure, Linda Holtzman of Clarity Coding pointed out that the codes in question refer specifically to the neurostimulator pulse generators, not the leads, and pulse generators for both purposes are placed subcutaneously.

- **Recommendation**: The Panel recommends that CMS combine APC 0039, *Level I Implantation of Neurostimulator*, and APC 0222, *Level II Implantation of Neurostimulator*, into one APC, and maintain APC 0315, *Level III Implantation of Neurostimulator*, as is for CY 2010.

### *Implantation of Interspinous Device*

Overview

Mr. Levi said that for CY 2009, CMS assigned CPT code 0171T, *Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar, single level*, and CPT code 0172T, *Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar, each additional level*, to APC 0052, *Level IV Musculoskeletal Procedures Except Hand and Foot*. APC 0052 includes several spinal procedures that require implantable devices. CPT codes 0171T and 0172T both utilize a device described by HCPCS code C1821, *Interspinous process distraction device (implantable)*. Mr. Levi added that CMS typically does not implement procedure-to-device edits for APCs for which there are not HCPCS codes for all possible devices that could be used for procedures that always require a device and for APCs that are not device-dependent. Furthermore, CMS recognizes the additional administrative burden to hospitals when claims processing edits are implemented.

Presentation

Michael McCormack of Medtronic asked that CMS move CPT codes 0171T and 0172T to APC 0425, *Level III Arthroplasty or Implantation with Prosthesis,* which is device-dependent (Presentation D). The procedures are more clinically consistent with those in APC 0425, and the resources used are more similar. Among the reasons cited by CMS in the CY 2009 final rule against moving these procedures to APC 0425 was that the median cost of HCPCS code C1821 is lower than the median cost of APC 0052. Mr. McCormack pointed out that the device costs are only one component of the procedure costs. He added that 36 percent of claims involving CPT code 0171T were incorrectly billed because they did not include HCPCS code C1821, and the requested change would improve billing and result in more accurate cost data from claims.

Gloryanne Bryant, B.S., R.H.I.T., said that, in contrast to CMS' belief that device edits are burdensome, hospitals appreciate the quick feedback that such edits provide to coders, and Judith T. Kelly, R.H.I.T., R.H.I.A., agreed that hospitals do well with device edits.

- Recommendation: The Panel recommends that CMS continue the assignments of CPT code 0171T, *Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar, single level,* and CPT code 0172T, *Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar, single level, each additional level,* to APC 0052, *Level IV Musculoskeletal Procedures Except Hand and Foot,* for CY 2010; institute procedure-to-device claims processing edits for HCPCS code C1821, *Interspinous process distraction device (implantable)*; and then reevaluate the APC assignments of these CPT codes in one year.

*APC Ratesetting*

Presentations

DeChane Dorsey, Esq., of the Advanced Medical Technology Association (AdvaMed) asked that CMS monitor the impact of the multiple imaging composite APCs on beneficiaries (Presentation E). She also asked that CMS make available to the public the data it uses to establish payment for packaged codes and that CMS defer extending the packaging policy to any additional services for at least 2 years. AdvaMed supports continuing use of methodologies to improve estimates of the costs of devices included in multiple procedure claims and continued focus on coding education.

Ms. Dorsey said AdvaMed supports the creation of a new cost center for implantable devices and asked that CMS ensure that hospitals are educated about the new cost center and implement it in a timely fashion. She also asked that CMS validate the accuracy of the data from the new cost center. She called for continued education for hospitals on correct coding for devices and other technologies. Ms. Dorsey asked that CMS exclude claims with the –FC modifier from ratesetting calculations.

Finally, Ms. Dorsey requested that CMS create two new composite APCs for cardiac resynchronization therapy (CRT): one for CRT with a defibrillator and one for CRT with a pacemaker. This approach would increase the number of claims available for use in ratesetting.

Thomas Novelli of the Medical Device Manufacturers Association (MDMA) said that over time, expanded packaging and bundling may lead to artificial reductions in the complexity of services provided, with corresponding reductions in payment that will create barriers to access to complex and innovative items and services (Presentation F). He pointed out that, in outpatient settings, hospitals have an incentive to provide the lowest cost item or service in an APC, and , if necessary bring the patient back for a second visit or admit the patient for inpatient care for additional treatment. Furthermore, hospitals often do not submit HCPCS codes for services that do not directly affect payment, so packaging limits the amount of data that CMS collects for ratesetting.

Mr. Novelli asked that CMS require complete and correct coding for packaged services and that it study the effects of expanded packaging on utilization and beneficiary access before introducing any more packaging proposals.

Although MDMA supports CMS' methodology for calculating median costs of device-dependent APCs, Mr. Novelli said, the severe payment reductions to several device-dependent APCs in the CY 2009 final rule will significantly threaten medical technology innovation and patient access. He asked that CMS study the claims for any APC facing a payment reduction of more than 10 percent and take action to correct issues that may artificially reduce payments.

Dr. Munger said CMS should be aware of the need for appropriate beneficiary access to care but added that not every hospital need provide every service or technology. Dr. Williams pointed to dramatic changes in payment—both up and down—for several services over the past 5 years and said that such unpredictability makes it difficult to plan and budget for the future.

- **Recommendation**: The Panel recommends that CMS staff evaluate the implications of creating composite APCs for cardiac resynchronization therapy with a defibrillator or pacemaker and report its findings to the Panel.

- **Recommendation**: The Panel recommends that CMS study the claims data for any APC for which the calculated payment reduction would be greater than 10 percent and take action to correct any issues that may artificially reduce these payments. The Panel requests that CMS staff provide the Panel at the next meeting with a list of APCs with a proposed CY 2010 payment change of greater than 10 percent.

## DRUGS, BIOLOGICALS, RADIOPHARMACEUTICALS, AND PHARMACY OVERHEAD

### *Anticoagulant Therapy*

Overview

Ms. Cole described the drug packaging threshold, that is, payment for most drugs and biologicals with estimated per-day costs of $60 or less is packaged into payment their associated procedures, while those over $60 are paid separately. She noted some exceptions, including 5HT3 antiemetics, which are always paid separately. Ms. Cole said that CMS received requests for several more exceptions, particularly for anticoagulants. She said a commenter raised the concern that providers may have an incentive to use more expensive, separately paid drugs even though treatments are not interchangeable

and benefits vary by patient. Ms. Cole said CMS has no reason to believe its payment methodologies are creating access problems for beneficiaries or that providers make prescribing decisions on the basis of payment alone.

Presentation

Mark Coin of Sanofi Aventis asked that CMS pay separately for all anticoagulant therapies with unique Level II HCPCS codes, in addition to payment for their administration (Presentation G). By paying separately for fondaparinux sodium, Mr. Coin said, CMS creates an incentive to use this drug over other packaged anticoagulants that may be more appropriate for the patient. Daniel Yannicelli, M.D., reiterated the importance of individualizing the choice of treatment.

Dr. Oyer felt the Panel should address concerns that the OPPS creates incentives to use one therapy over another and suggested CMS seek data on the issue. He added that drug safety and the appropriate use of anticoagulants are being addressed through provider education. The Panel discussed the pros and cons of packaging payment for all anticoagulants and of changing the drug packaging threshold.

***Radioimmunotherapy***

Overview

Ms. Cole said that for CY 2009, CMS will continue to package payment for diagnostic radiopharmaceuticals into payment for their associated nuclear medicine procedures. The statute requires that CMS pay for brachytherapy sources and therapeutic radiopharmaceuticals at hospital charges adjusted to cost through December 31, 2009. CMS did not finalize its proposal to collect ASP data from manufacturers for separately payable therapeutic radiopharmaceuticals for CY 2009 payment purposes and instead implemented payment according to the statute.

Presentation

James Fong of Cell Therapeutics, Inc., requested that CMS use the "ASP-plus" methodology in CY 2010 to pay for its product, Zevalin (injectable ibritumomab tiuxetan), to improve beneficiary access to the therapy (Presentation H). He noted that his company plans to report ASP data to CMS quarterly. Mr. Fong added that stakeholders agree that the ASP-plus methodology is the appropriate method for paying for radiopharmaceuticals.

Dr. Bazell clarified that CMS is able to accept ASP data from manufacturers but cannot make the data public unless it is used for payment. She added that CMS put forth in the CY 2009 proposed rule a plan to use manufacturers' ASP data to determine payment for therapeutic radiopharmaceuticals, but federal legislation superseded that proposal. In some cases, Dr. Hambrick noted, manufacturers are not able to provide data on the products in patient-ready doses. In such cases, CMS would have used claims-based data to determine payment.

- **Recommendation:** The Panel recommends that CMS use the average sales price (ASP) methodology to pay for therapeutic radiopharmaceuticals and, where ASP data are not available, pay based on mean costs from claims data.

*Drugs, Biologicals, and Pharmacy Overhead*

Overview

Ms. Cole described the ASP-plus methodology for determining drug payment rates, which reflects both drug acquisition costs and associated pharmacy overhead. In the proposed rule for CY 2009, CMS sought public comment on a proposal put forth by the Pharmacy Stakeholder Group and subsequently recommended by the APC Panel that CMS package the costs of all drugs that are not paid separately at ASP plus 5 percent and use the difference between these costs and CMS' costs derived from charges to create a pool that funds payment for pharmacy services. Ms. Cole said the comments that CMS received were, in general, supportive of the proposal, particularly the administrative simplicity of its implementation compared with other proposals put forth by CMS. A few commenters were concerned about the redistributive effects and higher beneficiary copayments for separately payable drugs, said Ms. Cole.

CMS modeled the proposal using claims data from the first 9 months of CY 2008 and an estimated payment rate of ASP plus 6 percent. According to the model, CMS anticipated that the total amount of cost available for redistribution would approach $200 million using a full calendar year of 2008 claims. CMS also modeled the impact of reducing the costs of packaged drugs on its procedural APC median costs. Significant changes were observed for only a handful of APCs.

CMS has met with various stakeholders to discuss the effects of the proposed methodology on hospitals that participate in the federal 340B program, which allows some hospitals to obtain drugs for outpatients at substantially discounted prices. Notably, CMS determines aggregate drug costs using hospital claims data that include 340B discount pricing, but the aggregate drugs costs under CMS' current ASP methodology do not include 340B discount pricing. CMS requested information in the CY 2009 final rule about hospitals that participate in the 340B program. Most commenters felt that 340B hospitals should receive the same payment for drugs and biologicals as non-340B hospitals, because the intent of the program is to enable 340B hospitals to use the money they save on drug costs to pay for other services for the uninsured.

Presentations

The Pharmacy Stakeholder Group—represented by Ernest Anderson Jr., M.S., R.Ph., of the Lahey Clinic and President of Association of Community Cancer Centers (ACCC); Laurel Todd of the Biotechnology Industry Organization; Justine Coffey of the American Society of Health-System Pharmacists; Jay Greissing of the Plasma Protein Therapeutics Association; and Ms. Shah of ADCC—provided a joint presentation reiterating its proposal and responding to the final rule for CY 2009 (Presentation I).

Mr. Anderson said that despite the Panel's recommendation, CMS reduced the ASP rate to ASP plus 4 percent, which does not cover drug acquisition costs. Ms. Todd described flaws in the CMS ratesetting methodology, pointing out that both the Medicare Payment Advisory Commission

(MedPAC) and RTI International believe that some of the data CMS relies on are inaccurate. Ms. Todd said CMS includes the costs of drugs purchased at deep discounts by 340B hospitals, which penalizes non-340B hospitals. In addition, by calculating hospitals' charges adjusted to cost only to separately payable drugs in order to determine drug payment, CMS wrongly assumes that pharmacy overhead costs are evenly distributed across all drugs.

Ms. Coffey said that CMS should pay drugs at a rate of ASP plus 6 percent because it complies with federal statute and because it aligns with the rate for payment of drugs in the physician's office setting. In addition, ASP plus 6 percent is a reasonable payment rate when data from 340B hospitals are excluded, Ms. Coffey said. She added that the proposed methodology would pay for the costs of pharmacy services and handling, which can range from 25 to 33 percent of the department's costs.

Mr. Greissing pointed out that including data from 340B hospitals is a growing problem, as participation in the 340B program has increased dramatically over the past decade and is expected to climb further. He noted that CMS suggested using its equitable adjustment authority to establish separate payment rates for 340B and non-340B hospitals, which the Pharmacy Stakeholder Group opposes. Congress never intended for the 340B program to adversely affect the ability of non-340B hospitals to provide care by driving down the Medicare reimbursement rates, said Mr. Greissing.

Ms. Coffey reviewed the methodology proposed by the Pharmacy Stakeholder Group. It would pay for all separately payable drugs at a rate of ASP plus 6 percent. The difference between ASP plus 6 percent and CMS' costs derived from charges would be used to create a pool of funds to pay for pharmacy services. Pharmacy services would be categorized into three tiers by level of complexity. The Pharmacy Stakeholder Group proposed pharmacy payments for each tier of $12.50, $38, and $65, respectively. The proposal addresses concerns of stakeholders as well as issues raised at previous APC Panel meetings, is administratively simple to implement, results in more accurate APC payment rates and copayments, is budget-neutral with very little redistributive effect, and does not affect CMS' cost estimates for other services.

If the proposal is not accepted by CMS, Ms. Coffey continued, the Pharmacy Stakeholder Group requests that CMS exclude data from 340B hospitals from its ratesetting methodology for calculating payments for drugs and that CMS not adjust payments for separately paid drugs to 340B hospitals.

Each presenter from the Pharmacy Stakeholder Group also provided written presentations (Presentations J–N).

Stuart Yael Gordon of Safety Net Hospitals for Pharmacy Access said that the publication of the CY 2009 final rule was his organization's first notice that CMS was seeking comments about 340B hospitals (Presentation O). He supported the proposal of the Pharmacy Stakeholder Group and said that CMS should not adjust payments for separately payable drugs to 340B hospitals. Mr. Gordon explained that the 340B program was created to counter disincentives for drug manufacturers to provide discounted drugs to Medicaid programs.

Mr. Gordon described the purpose of the 340B program and some of the barriers 340B hospitals face trying to obtain discounted drugs from manufacturers. Strict rules are in place to prevent hospital outpatient departments from using drugs obtained through the 340B program for other programs, and hospitals must have tracking mechanisms to separate 340B drugs from non-340B drugs in their

inventories. When 340B hospitals cannot obtain discounted drugs, they must purchase them at retail prices and cannot use group purchasing organizations to negotiate lower prices.

Russ Ranallo, M.S., raised concerns about the redistributive effect of the proposed methodology on rural hospitals. Mary Jo Braid-Forbes, Braid-Forbes Health Research, said that she analyzed the proposal and found almost no redistributive effect because the changes to procedural APC payments were so small.

Agatha L. Nolen, M.S., D.Ph., suggested dropping the three-tiered categorization of complexity because the need to categorize all drugs could pose a burden and because the criteria for categorizing drugs are not clear. Mr. Anderson said that a group of pharmacists in his organization had already categorized all the drugs according to the proposed tiers of complexity. Ms. Shah reported that 245 drugs fell into the low-complexity tier, 192 in the medium-complexity tier, and 176 in the high-complexity tier.

Dr. Oyer noted some of the many factors associated with pharmacy services—such as drug disposal and other regulatory requirements —that make it difficult to get a good understanding of costs. Beth Roberts of ACCC said the proposed methodology has garnered support from a number of stakeholders, including hospital associations.

- **Recommendation**: The Panel recommends that CMS pay the acquisition cost of all separately payable drugs at no less than ASP plus 6 percent.

- **Recommendation**: The Panel recommends that CMS package payment for all drugs that are not separately payable at ASP plus 6 percent and use the difference between these rates and CMS' costs derived from charges to create a pool to fund payment for pharmacy service costs more appropriately. The Panel further recommends that CMS reimburse for pharmacy service costs using this pool and applying a tiered approach to payments based on some objective criteria of the work involved.

- **Recommendation**: If CMS does not implement the preceding recommendations, then the Panel recommends that CMS exclude data from hospitals that participate in the 340B program from its ratesetting calculations for drugs and that CMS pay 340B hospitals in the same manner as it pays non-340B hospitals.

## Closing

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

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'Leary (audio specialist) and Dana Trevas (reporter) for their assistance.

The meeting adjourned at approximately 3:15 p.m. on Thursday, February 19, 2009.

**Appendix A**


## Agenda

***February 18 & 19, 2009***

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

**DAY 1 - Wednesday, February 18, 2009**

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

**AGENDA**

01:00[2] **Opening** - Day 1
Welcome and Call to Order – E. L. Hambrick, M.D., J.D., Chair, APC Panel
Opening Remarks – Amy Bassano
Director, Hospital and Ambulatory Policy Group

01:15 **Panel Organization and Housekeeping Issues**
E. L. Hambrick, M.D., J.D., Chair, APC Panel

01:30 **CMS-1404-FC:** Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2009 Payment Rates, et al, **Federal Register**

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

**TAB**

01:50 **DATA**

1. **Overview** – Anita Heygster, CMS Staff
2. **Data Subcommittee's Report** – Kim Allan Williams, M.D., F.A.C.C., F.A.B.C., Chair
3. Discussion
4. Panel's Comments/Recommendations

02:45 *Break*

03:00 **DATA** *(continued)*

**RADIOLOGICAL EXAMINATION OF SURGICAL SPECIMEN (CPT CODE 76098)**

1. **Overview** – Erick Chuang, M.S., CMS Staff
2. **Presentation** – Pam Kassing, M.P.A., R.C.C. **A**
   American College of Radiology
3. Discussion
4. Panel's Comments/Recommendations

03:20 **PACKAGING**

1. **Overview** – Tamar Spolter, M.H.S., CMS Staff
   – Rebecca Cole, M.S., CMS Staff
   – Carrie Bullock, M.H.S., CMS Staff
2. **Packaging Subcommittee's Report** – James V. Rawson, M.D. – Chair
3. Discussion
4. Panel's Comments/Recommendations

04:45 **BRACHYTHERAPY SOURCES**

1. **Overview** – Barry Levi, M.B.A., CMS Staff
2. Discussion
3. Panel's Comments/Recommendations

05:05 **VISITS AND OBSERVATION**

1. **Overview** – Heather Hostetler, J.D., CMS Staff
   – Tamar Spolter, M.H.S., CMS Staff
2. **Visit and Observation Subcommittee's Report** – Michael Ross, M.D., Chair
3. Discussion
4. Panel's Comments/Recommendations

05:45 **ADJOURN**


**AGENDA**

***February 18 and 19, 2009***

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

**DAY 2 - Thursday, February 19, 2009**

**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 **INPATIENT LIST**
1. **Overview** – Dana Burley, M.S.P.H., CMS Staff
2. Discussion
3. Panel's Comments/Recommendations

09:00 **APC ISSUES**
**Public Presentations and Comments**

**MULTIPLE IMAGING COMPOSITE APCS**
1. **Overview** – Carrie Bullock, M.H.S., CMS Staff
2. **Presentation** – Jugna Shah, Consultant **B**
   Alliance of Dedicated Cancer Centers
3. Discussion
4. Panel's Comments/Recommendations

**NEUROSTIMULATOR IMPLANTATION APCS**
1. **Overview** – Carrie Bullock, M.H.S. , CMS Staff
2. **Presentation** – Stan Jackson & Jeffrey W. Cozzens, M.D. **C**
   Cyberonics
3. Discussion
4. Panel's Comments/Recommendations

**APC ISSUES** *(continued)* **TAB**

**IMPLANTATION OF INTERSPINOUS DEVICE**

1. **Overview** – Barry Levi, M.B.A., CMS Staff
2. **Presentation** – Michael McCormack **D**
   Medtronics
3. Discussion
4. Panel's Comments/Recommendations

**APC RATESETTING**

1. **Presentation** – DeChane L. Dorsey, Esq., **E**
   Advanced Medical Technology Association
2. **Presentation** – Thomas C. Novelli **F**
   Medical Device Manufacturers Association
3. Discussion
4. Panel's Comments/ Recommendations

10:45 *Break*

11:00 **DRUGS, BIOLOGICALS, RADIOPHARMACEUTICALS, AND PHARMACY OVERHEAD**

**ANTICOAGULANT THERAPY**

1. **Overview** – Rebecca Cole, M.S., CMS Staff
2. **Presentation** – Mark Coin **G**
   Sanofi Aventis US
3. Discussion
4. Panel's Comments/Recommendations

**RADIOIMMUNOTHERAPY**

1. **Overview** – Rebecca Cole, M.S., CMS Staff
2. **Presentation** – James A. Bianco **H**
   Cell Therapeutics, Inc.
3. Discussion
4. Panel's Comments/Recommendations

12:00 *Lunch*

Page 3 - Day 2, February 19, 2009 – APC Panel Meeting

01:00 **DRUGS, BIOLOGICALS, RADIOPHARMACEUTICALS, AND PHARMACY OVERHEAD** *(continued)*

**DRUGS AND PHARMACY OVERHEAD**

1. **Overview** – Rebecca Cole, M.S., CMS Staff
2. **Presentations** – Pharmacy Stakeholders **I**
   a. Ernest R. Anderson, Jr., M.S., R.Ph. **J**
      Pharmacy Dept., Lahey Clinic
   b. Justine Coffey **K**
      American Society of Health-System Pharmacists
   c. Jay Greissing **L**
      Plasma Protein Therapeutics Association
   d. Jugna Shah, Consultant **M**
      Alliance of Dedicated Cancer Centers
   e. Laurel Todd **N**
      Biotechnology Industry Organization
3. **Presentation-** Stuart Yael Gordon **O**
   Safety Net Hospitals for Pharmacy Access
4. Discussion
5. Panel's Comments/Recommendations

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

03:15 **Closing**

1. Summary of the Panel's Recommendations for 2010
2. Discussion
3. Final Remarks

04:00 **Adjourn**

**NOTE: There will be no meeting tomorrow, Friday, February 20, 2009.**

**Appendix B**

CENTERS FOR MEDICARE AND MEDICAID SERVICES

**Advisory Panel on Ambulatory Payment Classification (APC) Groups**
**February 18–19, 2009**

## Data Issues

1. The Panel recommends that CMS reassign CPT code 76098, *Radiological examination, surgical specimen*, to APC 0260, *Level I Plain Film*, and place CPT code 76098 on the bypass list.

2. The Panel recommends that the work of the Data Subcommittee continue.

## Packaging Issues

3. The Panel recommends that CMS pay separately for radiation therapy guidance services performed in the treatment room for 2 years and then reevaluate packaging on the basis of claims data.

4. The Panel recommends that CMS continue to analyze the impact of increased packaging on beneficiaries, providing more detailed versions of the analyses presented at the February 2009 meeting of services initially packaged in calendar year (CY) 2008 at the next Panel meeting. The Panel requests that, in the more detailed analyses of radiation oncology services that would be accompanied by radiation oncology guidance, staff stratify the data according to the type of radiation oncology service, specifically, intensity modulated radiation therapy, stereotactic radiosurgery, brachytherapy, and conventional radiation therapy.

5. The Panel recommends that CMS continue to analyze the impact on beneficiaries of increased packaging of diagnostic radiopharmaceuticals, providing more detailed analyses at the next Panel meeting. The Panel requests that, in the more detailed analyses of packaging of diagnostic radiopharmaceuticals by type of nuclear medicine scan, the staff break down the data according to the specific CPT codes billed with the diagnostic radiopharmaceuticals.

6. The Panel recommends that CPT code 36592, *Collection of blood specimen using established central or peripheral catheter, venous, not otherwise specified*, remain assigned to APC 0624, *Phlebotomy and Minor Vascular Access Device Procedures*, for CY 2010.

7. The Panel recommends that the work of the Packaging Subcommittee continue.

**Brachytherapy Sources**

8. The Panel recommends that, for CY 2010, CMS pay for brachytherapy sources using a prospective payment methodology based on median costs.

**Visits and Observation Issues**

9. The Panel recommends that CMS present at the next Panel meeting an analysis of the most common diagnoses and services associated with Type A and Type B emergency department visits, including analysis by hospital-specific characteristics.

10. The Panel recommends that CMS issue guidance clarifying the correct method for reporting the start time of observation services.

11. The Panel recommends that CMS present at the next Panel meeting an analysis of 2008 claims data for clinic, emergency department (Types A and B), and extended assessment and management composite APCs.

12. The Panel recommends that the work of the Visits and Observation Subcommittee continue.

**Inpatient List**

13. The Panel recommends that CMS remove the following procedures from the inpatient list for CY 2010:

    - CPT code 21256, *Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (e.g., micro-ophthalmia)*
    - CPT code 27179, *Open treatment of slipped femoral epiphysis; single or multiple pinning of bone graft (includes obtaining graft); osteoplasty of femoral neck (Heyman type procedure)*
    - CPT 51060 code, *Transvesical ureterolithotomy*

    The Panel recommends that CPT code 64818, *Sympathectomy, lumbar*, remain on the inpatient list for CY 2010.

**APC Issues**

14. The Panel recommends that CMS continue to work with stakeholders to examine different options for APCs for multiple imaging sessions and multiple imaging procedures.

15. The Panel recommends that CMS combine APC 0039, *Level I Implantation of Neurostimulator*, and APC 0222, *Level II Implantation of Neurostimulator*, into one APC, and maintain APC 0315, *Level III Implantation of Neurostimulator*, as is for CY 2010.

16. The Panel recommends that CMS continue the assignments of CPT code 0171T, *Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar, single level,* and CPT code 0172T, *Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar, single level, each additional level,* to APC 0052, *Level IV Musculoskeletal Procedures Except Hand and Foot,* for CY 2010; institute procedure-to-device claims processing edits for HCPCS code C1821, *Interspinous process distraction device (implantable)*; and then reevaluate the APC assignments of these CPT codes in one year.

17. The Panel recommends that CMS study the claims data for any APC for which the calculated payment reduction would be greater than 10 percent and take action to correct any issues that may artificially reduce these payments. The Panel requests that CMS staff provide the Panel at the next meeting with a list of APCs with a proposed CY 2010 payment change of greater than 10 percent.

18. The Panel recommends that CMS staff evaluate the implications of creating composite APCs for cardiac resynchronization therapy with a defibrillator or pacemaker and report its findings to the Panel.

**Drugs, Biologicals, Radiopharmaceuticals, and Pharmacy Overhead**

19. The Panel recommends that CMS use the average sales price (ASP) methodology to pay for therapeutic radiopharmaceuticals and, where ASP data are not available, pay based on mean costs from claims data.

20. The Panel recommends that CMS pay for the acquisition cost of all separately payable drugs at no less than ASP plus 6 percent.

21. The Panel recommends that CMS package payment at ASP plus 6 percent on claims for all drugs that are not separately paid and use the difference between these rates and CMS' costs derived from charges to create a pool to provide more appropriate payment for pharmacy service costs. The Panel further recommends that CMS pay for pharmacy service costs using this pool and applying a tiered approach to payments based on some objective criteria related to the pharmacy resources required for groups of drugs.

22. If CMS does not implement recommendations 20 and 21, then the Panel recommends that CMS exclude data from hospitals that participate in the 340B program from its ratesetting calculations for drugs and that CMS pay 340B hospitals in the same manner as it pays non-340B hospitals.

## Appendix C

### PRESENTATIONS

The following organizations provided written testimony for the Advisory Panel on Ambulatory Payment Classification Groups meeting February 18–19, 2009:

Presentation A: American College of Radiology

Presentation B: Alliance of Dedicated Cancer Centers

Presentation C: Cyberonics, Inc.

Presentation D: Medtronic

Presentation E: Advance Medical Technology Association

Presentation F: Medical Device Manufacturers Association

Presentation G: Sanofi Aventis

Presentation H: Cell Therapeutics, Inc.

Presentation I: The Pharmacy Stakeholder Group

Presentation J: Association of Community Cancer Centers

Presentation K: American Society of Health-System Pharmacists

Presentation L: Plasma Protein Therapeutics Association

Presentation M: Alliance of Dedicated Cancer Centers

Presentation N: Biotechnology Industry Organization

Presentation O: Safety Net Hospitals for Pharmaceutical Access