Submitter : Mr. Dan Rode **Date:** 10/05/2006

Organization : American Health Information Management Association

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-280-Attach-1.DOC

October 5, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
PO Box 8011
Baltimore, Maryland 21244-1850

Re: File Code CMS-1506-P
File Code CMS-4125-P

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule (71 *Federal Register* 49506)

Dear Dr. McClellan:

The American Health Information Management Association (AHIMA) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed changes to the Hospital Outpatient Prospective Payment System (OPPS) and calendar year 2007 Rates, as published in the August 23, 2006 *Federal Register*. Our comments focus on those areas of particular interest to our members.

AHIMA is a not-for-profit professional association representing more than 50,000 health information management (HIM) professionals who work throughout the healthcare industry. AHIMA's HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, reporting, and utilizing data vital for patient care, while making it accessible to healthcare providers and appropriate researchers when it is needed most.

Consistency in medical coding and the use of medical coding standards in the US is a key issue for AHIMA. As part of this effort, AHIMA is one of the Cooperating Parties, along with CMS, the Department of Health and Human Services' (HHS) National Center for Health Statistics (NCHS), and the American Hospital Association (AHA). The Cooperating Parties oversee correct coding rules associated with the *International Classification of Diseases Ninth Revision, Clinical Modification* (ICD-9-CM).

1730 M Street, NW, Suite 502, Washington, IL 20036
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AHIMA participates in a variety of coding usage and standardization activities in the US and internationally, including the American Medical Association's (AMA's) Current Procedural Terminology® (CPT®) Editorial Panel.

AHIMA and its members also participate in a variety of projects with other industry groups and agencies of the Health and Human Services Department related to the use of secondary data for a variety of purposes including quality monitoring, reimbursement, public health, patient safety, biosurveillance, and research.

VIII-B: Proposed CY 2007 Drug Administration Coding Changes (71FR49600)

Currently, a combination of CPT and HCPCS level II codes are required by Medicare for facility reporting of drug administration services. Many private payers require the reporting of only CPT codes, resulting in a situation whereby hospitals are required to use different coding schemes to report drug administration services to different payers. Dual coding systems for drug administration services is administratively burdensome for hospitals and also results in data incomparability.

While we recognize that the CPT codes for drug administration services were designed for physician reporting purposes and have been somewhat confusing and difficult to apply in the facility setting, we do not believe that creation of a separate set of codes for Medicare use is a satisfactory solution, since many other payers require the use of the full set of CPT codes for drug administration services.

Consistent coding practices across payers would be less administratively burdensome and would result in improved data accuracy and comparability. We also believe that the HIPAA regulations for electronic transactions and code sets were intended to ensure that multiple code sets wouldn't be used to report the same service.

AHIMA recommends that CMS adopt the full set of CPT drug administration codes for use under the OPPS. Hospitals are already using the full set of CPT codes for reporting to many non-Medicare payers. Currently, however, the CPT codes are not intuitive and easily applicable to the hospital setting. Clarification of definitions, code descriptions, and instructions is necessary in order for hospitals to be able to report these codes accurately and consistently. CMS should work with AHIMA, the American Hospital Association and the American Medical Association to provide additional guidance to hospitals on the proper use of these codes for facility reporting, including instructions for the application of the terms "initial," "subsequent," "sequential," and "concurrent." If necessary, CMS should also work with these three organizations to develop proposed CPT code modifications to address specific issues pertaining to facility reporting of drug administration services.

IX: Proposed Hospital Coding and Payment for Visits (71FR49604)

We appreciate CMS' consideration of the facility visit coding guidelines developed by the American Hospital Association (AHA)/AHIMA Expert Panel and posting these guidelines for wider

public input. We also appreciate CMS' acknowledgement that the AHA/AHIMA guidelines are the most appropriate and well-developed guidelines for use in the OPPS. AHIMA looks forward to working with AHA and the Expert Panel to refine the guidelines to address concerns and suggestions raised by CMS and the public. We support CMS' commitment to provide a minimum of 6 to 12 months notice to hospitals prior to implementation of national guidelines. This timeframe will allow adequate education of hospital staff on the proper application of these guidelines and the documentation requirements necessary to support code levels.

We note that the AHA/AHIMA guidelines were submitted to CMS over three years ago, and some of the specific revisions CMS chose to make in their modified version, as well as other suggestions for modifications, could be a reflection of changes in clinical practice since the AHA/AHIMA guidelines were originally developed. If these guidelines had been implemented soon after their development, undoubtedly refinements would have been made since then.

CY 2007 Proposed Coding: **AHIMA opposes the creation of new G-codes to replace hospitals' reporting of the CPT emergency department and clinic evaluation and management (E/M) codes for CY 2007.** We believe that CMS should not implement new codes in the absence of accompanying national code definitions and national guidelines for their application. The CPT E/M codes should continue to be used until national guidelines are ready for implementation. Creating new codes without a set of national guidelines will increase confusion and add a new administrative burden requiring hospitals to manage two sets of codes – the proposed G-codes for Medicare and CPT E/M codes for non-Medicare payers – without the benefit of a standardized methodology or improved data.

Even when national guidelines are developed, AHIMA does not believe that temporary G-codes should be created for facility visit coding. A formal proposal should be presented to the American Medical Association's CPT Editorial Panel to create CPT codes for hospital emergency department and clinic visits. These codes could then be used by all payers. New codes and the accompanying national guidelines should not be implemented until CPT codes have been implemented.

CMS' Contracted Study to Validate AHA/AHIMA guidelines: In response to concerns raised by CMS' contracted study of the AHA/AHIMA guidelines, we would like to point out that these guidelines were never intended to be used as a stand-alone document without additional explanation and educational materials. We expected to develop supplemental materials, in conjunction with AHA, to clarify proper application of the guidelines after they were adopted by CMS for implementation under the OPPS. Therefore, in the absence of this additional guidance, it is not surprising that the contractor identified elements in the guidelines that were difficult to interpret or poorly defined. Also, it is not clear, by CMS' own admission, whether the contractor had access to the complete medical records.

CMS noted that they were unable to draw conclusions about the relationship between the distribution of current hospital reporting of visits using CPT E/M codes that are assigned according to each hospital's internal guidelines and the distribution of coding under the AHA/AHIMA guidelines. These findings reflect the fact that there is no set of national guidelines or a standard methodology for hospitals to develop their own guidelines. Through our participation on the AHA/AHIMA Expert Panel, we re-coded a sample of emergency department and clinic visit

records using several different hospitals' methodologies. This review revealed considerable variability in the levels of service reported, depending on which methodology was used.

Distinction Between Type A and Type B Emergency Departments: **AHIMA does not believe that the facility visit codes should distinguish between different types of emergency departments.** This is not a coding issue. The facility visit codes should be limited to describing the patient complexity and resource utilization. Other information, such as the type of emergency department where the visit occurred, should be captured through a separate methodology.

Other comments in response to CMS' concerns with the AHA/AHIMA guidelines can be found in a separate joint letter submitted by AHA and AHIMA as a result of our task force meetings.

XVIII-B-1-a: Proposed Revised ASC Payment System for Implementation January 1, 2008 – Proposed Definition of Surgical Procedure (71FR49636)

AHIMA supports the expansion of the definition of surgical procedure under the Ambulatory Surgical Center (ASC) payment system to include HCPCS level II and CPT category III codes which directly crosswalk to, or are clinically similar to, procedures in the CPT category I surgical range.

XX: Reporting Quality Data for Improved Quality and Costs Under the OPPS (71FR49665)

As AHIMA has noted in previous comments to CMS, we agree with the agency's desire to achieve a goal of value-based purchasing and promoting higher quality services. We acknowledge that taking the next step toward ambulatory care as offered by hospitals makes sense so long as it is recognized that eventually, sooner rather than later, any comparisons conducted on an ambulatory basis will have to cover non-hospital entities as well.

AHIMA is actively engaged in projects independently, with the Agency for Healthcare Research and Quality (AHRQ) and others to ensure that as standards for "performance data" and quality indicators are developed, implemented, and improved, the data and measures will be consistent and uniform geographically and across all sectors of the healthcare industry. We note CMS' comments on a "Hawthorne effect" coming from existing data and measure collection for hospitals. However, in the long run, it will be the ease of data collection, data uniformity, and trusted results that provide strong support for such data collection efforts. Consistency also permits those building the functional and data standards for the electronic health records to ensure appropriate secondary data is available for such purposes.

Everyone involved in the current efforts to develop an effective means for secondary data collection through paper records, the EHR, and hybrid environments, recognizes the difficulty of beginning and expanding the data collection efforts and the subsequent quality payment system that CMS and others are seeking. Until outpatient measures are developed and approved it appears acceptable in the short term to adapt the quality improvement mechanism provided by the IPPS (Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) and the proposed IPPS surgical

care improvement project (SCIP) measures. We are concerned, however, that adoption of the IPPS measures might delay work necessary for outpatient measures. CMS should work with the industry and other federal agencies to develop a strategic plan for outpatient measure standards. Input to this process needs time and must occur outside of a response to this NPRM. AHIMA's HIM professionals stand ready to work with CMS, AHR, HQA, AQA, NQF and others to ensure that appropriateness and consistency are developed across the outpatient sectors of the healthcare industry. As CMS has often noted, care rendered in hospital-based ambulatory needs to be compared to the same care that can be rendered in ambulatory surgical centers, physician offices, and other sites of service.

XXI: Promoting Effective Use of Health Information Technology (71FR49670)

AHIMA agrees that there is a mixed message regarding the potential of health information technology (HIT) to reduce costs. As alluded to in our comments on quality data reporting, we believe that is in the development, adoption, and implementation of standards that will lower costs and improve quality. Standards, consistency, and uniformity are necessary for software now, and as the industry moves forward in the implementation of a standard EHR and health information exchange (HIE); this includes standards for data, data definitions, terminologies, and classifications. The industry has started on the road toward President Bush's 2014 health information goal, however if we are to achieve this goal, the introduction of standards and requirements must take into account the paper to electronic transition currently under way and ensure that the development of secondary uses of data – like quality measurement – can be followed by organizations as they mature toward the EHR.

It is also important to note that with standards, quality measurement reporting or any secondary data reporting effort will be much easier, more accurate and much less costly once standard EHRs are in place. Before full use of EHRs is achieved collection of information in a paper or hybrid system remains a high consumer of human resources. The higher volume of outpatients as opposed to inpatients will also significantly inflate the costs and burdens of facilities, in as much as the same burden is often experienced with much lower reimbursement per encounter.

Development of a standard EHR and HIEs will not provide the full answer. Beyond the standardization of quality measures, for instance, CMS must take aggressive steps to ensure terminologies and classification standards are in place so that the quality or performance measurements can be evaluated with the condition of the patient. AHIMA urges the Health and Human Services Department (HHS) and the American Health Information Community (the Community), which include CMS, to adopt and provide for the implementation of modern terminologies such as those identified in the Consolidated Health Informatics (CHI), and especially the SNOMED-CT® adopted by CHI and approved by the National Committee on Vital and Health Statistics.

A standard EHR, with a SNOMED-CT terminology and functional standards and architecture designed to provide adequate and appropriate secondary data, will allow for achieving the goal of lowering costs and improving quality, but more is needed. The US must upgrade its primary

diagnoses classification system ICD-9-CM (volumes 1 and 2) to a 21st century standard ICD-10-CM.

The need for this change has been known for 13 years and the potential to resolve this need has been available since the turn of the century. But now, six years later, we have not moved to make the changes. Without the use of the ICD-10-CM classification, providers, health plans, QIOs, and others will continue to either rely on incomplete data coming from the claim, or demand additional data from providers – which translates into an inefficient use of resources and increased administrative costs for all.

It has been suggested that CMS finalize a rule for HIPAA attachments. AHIMA suggests instead that steps be taken to improve the initial data provided on the claims: the diagnosis and procedure codes. In addition, now that the industry has achieved electronic claims processing, AHIMA joins others and recommends that CMS and other payers accept and promote the transmission of all diagnostic and procedure codes associated with an encounter or stay, and not to limit this data (codes) to standards developed for paper claims in the 1980s (nine diagnoses on the UB-92).

XXII: Health Care Information Transparency Initiative (71FR49671)

While AHIMA supports the goal of transparency and the ability of healthcare consumers to have data on which to make choices, we must note that only through receiving and reviewing quality (appropriate, clear, consistent) information can a consumer make decisions to purchase quality healthcare. If data standards are not updated to reflect the contents of 21st century health records, and provide for consistent evaluation, the data provided to individuals is suspect. Much of the data used currently in quality measurement and payment comes from the claim. Yet the claim data is currently not capable of providing the detail necessary to accurately determine the diagnoses and procedures related to the patient's care. If transparency is the goal we must improve the data, not just the mechanisms to provide data.

XXIII: Additional Quality Measures and Procedures for Hospital Reporting of Quality Data for the FY 2008 IPPS Annual Payment Update (71FR49672)

Re: File Code CMS-4125-P

Most of AHIMA's comments on quality, above, also apply to this section. While we applaud CMS' further development of quality measures, we suggest they all be done in concert with the current AQA-HQA effort, and the recent recommendations of the Secretary for uniform measures across the industry. AHIMA is actively engaged in the goal of evaluating measures and highlighting gaps as well as working to ensure an appropriate standard EHR capable of producing secondary data that can support the uniform efforts and data collection mention here and above.

Since item 4 [71FR49674] relates to mortality, AHIMA must note that at some point CMS should consider the comparison of US mortality and morbidity data in its quest for quality measurement. Until ICD-10-CM and ICD-10-PCS are in use, such a comparison could be approached with a crosswalk between ICD-9-CM morbidity data, and ICD-10 mortality data. The additional

information contained in the US mortality database at the National Center for Health Statistics may prove most useful for full outcome information.

Conclusion

We appreciate the opportunity to comment on the proposed modifications to the Hospital OPPS. If AHIMA can provide any further information, or if there are any questions or concerns with regard to this letter and its recommendations, please contact Sue Bowman, RHIA, CCS, AHIMA's director of coding policy and compliance at (312) 233-1115 or sue.bowman@ahima.org, or myself at (202) 659-9440 or dan.rode@ahima.org.

Sincerely,

Dan Rode, MBA, FHFMA
Vice President, Policy and Government Relations

cc. Sue Bowman, RHIA, CCS

Submitter : Mr. Juan Carr **Date:** 10/05/2006

Organization : DAPA Family Recovery Programs

Category : Other Health Care Professional

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

See Attachment

CMS-1506-P-281-Attach-1.DOC

Juan A. Carr
2121 Tannehill #1160
Houston, Texas 77008

September 6, 2006

U.S. Senator John Cornyn
517 Hart Senate Office Bldg.
Washington, DC 20510

RE: Partial Hospitalization Services Proposed Changes to the Hospital Outpatient PPS-CMS-1506-P

Dear Senator:

I am a concerned citizen from your home state, Texas, asking you to take notice of an issue that deeply concerns me and asks for your attention in an urgent matter. CMS (Center for Medicare and Medicaid Services) has published a document, CMS 1506-P, proposing another reduction in reimbursement to providers of outpatient services, to be effective January 1, 2007, the second dramatic reduction in the past 13 months.

One of the proposed services **[APC 0033 Partial Hospitalization]** emerges as unique in that it does not represent a simple procedure such as a nail clipping or an injection. It represents an entire ***level of care***, known as PHP, which is a full day of intensive psychiatric treatment, minimally four psychotherapies per day, to be delivered from four to seven days per week, to a very *special population*. These programs are delivered by hospital systems through their outpatient departments, and by CMHCs (Community Mental Health Centers) which are designed specifically for the purpose of treating the mentally ill in their communities, in outpatient programs: the **severely and persistently mentally ill (SPMI).** These Medicare beneficiaries are in dire need of these services in order to remain out of institutional settings such as psychiatric hospitals, local emergency rooms, and even jails and prisons. The SPMIs are arguably the most disenfranchised, the most disabled because of the impact of their chronic and severe mental conditions, and the most voiceless in our political system, relying almost entirely on advocates who have the faculty to watch over and protect them. It is critical to note, too, that the impact against minorities is devastating, as a recent 2006 survey by AABH (Association for Ambulatory Behavioral Healthcare) indicates that fully **37% of the consumers of PHP services are of minority status**, 32% being African American. The disproportionately negative effects of the de-access to services upon minorities begs our special attention!

The proposed cut in reimbursement for 2007 is 15%, reducing the rate from $245.91, down to $208.27. This follows last year's cut from $281.33 down to $245.91. The effect of last year's cut was to **close many programs in CMHCs and hospitals across the nation** because the figures do not cover the actual costs of treatment that CMS recognizes. The providers who have been able to continue to provide are now facing the very real possibility of closing their doors. This one service represents not a mere procedure, but *entire treatment programs*, an *entire level of care*, and therefore requires special consideration and treatment due to the impact of potentially ***eliminating the services and access from the communities, completely***.

I am asking you to review this issue, to meet with individuals who are attempting to speak with you in your Washington office the week beginning September 11th, and to urge the Secretary of Health and Human Services, Mike Leavitt, to suspend the proposed reduction of APC 0033 pending further scrutiny of the uniquely devastating effect it may have on our mentally ill, aged, disabled, and largely minority consumers of partial hospitalization psychiatric treatment.

Sincerely yours,

_____

Juan A. Carr

Juan A. Carr
2121 Tannehill #1160
Houston, Texas 77008

September 6, 2006

U.S. Senator Kay Bailey Hutchison
961 Pickle Federal Building
Austin, TX 78701

RE: Partial Hospitalization Services Proposed Changes to the Hospital Outpatient PPS-CMS-1506-P

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Sincerely yours,

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2121 Tannehill #1160
Houston, Texas 77008

September 6, 2006

Congressman John Culberson
1728 Longworth House Office Building
Washington, DC 20515

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2121 Tannehill #1160
Houston, Texas 77008

September 6, 2006

Congressman Sheila Jackson Lee
2435 Rayburn House Office Building
Washington, DC 20515

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Juan A. Carr
2121 Tannehill #1160
Houston, Texas 77008

September 6, 2006

Senator Mario Gallegos
P.O. Box 12068
Austin, Texas 78711

RE: Partial Hospitalization Services Proposed Changes to the Hospital Outpatient PPS-CMS-1506-P

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2121 Tannehill #1160
Houston, Texas 77008

September 6, 2006

Senator John Whitmire
P.O. Box 12068
Austin, Texas 78711

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Dear Senator:

I am a concerned citizen from your home state, Texas, asking you to take notice of an issue that deeply concerns me and asks for your attention in an urgent matter. CMS (Center for Medicare and Medicaid Services) has published a document, CMS 1506-P, proposing another reduction in reimbursement to providers of outpatient services, to be effective January 1, 2007, the second dramatic reduction in the past 13 months.

One of the proposed services **[APC 0033 Partial Hospitalization]** emerges as unique in that it does not represent a simple procedure such as a nail clipping or an injection. It represents an entire ***level of care***, known as PHP, which is a full day of intensive psychiatric treatment, minimally four psychotherapies per day, to be delivered from four to seven days per week, to a very *special population*. These programs are delivered by hospital systems through their outpatient departments, and by CMHCs (Community Mental Health Centers) which are designed specifically for the purpose of treating the mentally ill in their communities, in outpatient programs: the **severely and persistently mentally ill (SPMI).** These Medicare beneficiaries are in dire need of these services in order to remain out of institutional settings such as psychiatric hospitals, local emergency rooms, and even jails and prisons. The SPMIs are arguably the most disenfranchised, the most disabled because of the impact of their chronic and severe mental conditions, and the most voiceless in our political system, relying almost entirely on advocates who have the faculty to watch over and protect them. It is critical to note, too, that the impact against minorities is devastating, as a recent 2006 survey by AABH (Association for Ambulatory Behavioral Healthcare) indicates that fully **37% of the consumers of PHP services are of minority status**, 32% being African American. The disproportionately negative effects of the de-access to services upon minorities begs our special attention!

The proposed cut in reimbursement for 2007 is 15%, reducing the rate from $245.91, down to $208.27. This follows last year's cut from $281.33 down to $245.91. The effect of last year's cut was to **close many programs in CMHCs and hospitals across the nation** because the figures do not cover the actual costs of treatment that CMS recognizes. The providers who have been able to continue to provide are now facing the very real possibility of closing their doors. This one service represents not a mere procedure, but *entire treatment programs*, an *entire level of care*, and therefore requires special consideration and treatment due to the impact of potentially ***eliminating the services and access from the communities, completely***.

I am asking you to review this issue, to meet with individuals who are attempting to speak with you in your Washington office the week beginning September 11th, and to urge the Secretary of Health and Human Services, Mike Leavitt, to suspend the proposed reduction of APC 0033 pending further scrutiny of the uniquely devastating effect it may have on our mentally ill, aged, disabled, and largely minority consumers of partial hospitalization psychiatric treatment.

Sincerely yours,

_____

Juan A. Carr

Submitter : **Dr. Kathleen Eve** **Date: 10/05/2006**

Organization : **Dr. Kathleen Eve**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-282-Attach-1.DOC

Attach
282

Office of The Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System (OPPS) and CY 2007 Payment Rates

Dear Administrator,

I appreciate the opportunity to share my concerns on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I am concerned with the Proposed reassignment of CPT codes 19296 and 19297 to an APC code that will not reflect the true costs to provide Breast Brachytherapy services.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. The proposed re-assignment of these codes from New Technology APCs to clinical APCs in 2007 will have a negative affect on my opportunity to provide Medicare patients brachytherapy. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment for the hospital that would make it difficult for them to purchase the needed catheters. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

Breast brachytherapy CPT codes 19296 and 19297 are classified as device-dependent procedures since they are reliant on the use of a high cost device that is bundled into the procedure payment. APC 648 Breast Reconstruction with Prosthesis includes other similar procedures to those of 19296 and 19297. The similarities not only are clinical, but also in the cost of the device. Should CMS discontinue the assignment of 19296 and 19297 in new tech APCs, an alternative request is for both CPT codes to be reclassified to APC 648.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data and charge data from the hospital to determine the true costs.

Finally, I recommend that CPT codes 19296 and 19297 be assigned to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the group title from Breast Reconstruction with Prosthesis to Level IV Breast Surgery.

Thank you again for allowing comment on this important issue.

Sincerely,

Kathleen Eve, MD

Kathleen Eve, M.D.
Surgeon
1541 Florida Avenue, Suite 200
Modesto, CA 95350

cc: Senator Barbara Boxer, CA (D)
Senator Diane Feinstein, CA (D)
Congresswoman Nancy Pelosi (D)

cc: Carolyn Mullen, Deputy Director,
Division of Practitioner Services

cc: American Brachytherapy Society
W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : **Dr. Sabrina Frierson** **Date: 10/05/2006**

Organization : **Dr. Sabrina Frierson**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-283-Attach-1.DOC

282

Office of The Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System (OPPS) and CY 2007 Payment Rates

Dear Administrator,

Thank you for providing me with the forum to voice my comments on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I am concerned with the proposed reassignment of CPT codes 19296 and 19297 to an APC code that is not appropriate for Breast Brachytherapy services.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523. The proposed re-assignment of these codes from New Technology APCs to clinical APCs in 2007 could hinder my ability to offer Breast Brachytherapy to Medicare patients. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment for the hospital. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
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CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

Breast brachytherapy CPT codes 19296 and 19297 are classified as device-dependent procedures since they are reliant on the use of a high cost device that is bundled into the procedure payment. APC 648 Breast Reconstruction with Prosthesis includes other similar procedures to those of 19296 and 19297. The similarities not only are clinical, but also in the cost of the device. Should CMS discontinue the assignment of 19296 and 19297 in new tech APCs, an alternative request is for both CPT codes to be reclassified to APC 648.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data and charge data from the hospital to determine the true costs.

Finally, I recommend that CPT codes 19296 and 19297 be assigned to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the group title from Breast Reconstruction with Prosthesis to Level IV Breast Surgery.

I appreciate your careful review of this matter and strongly urge CMS to reconsider the significant impact the proposal may have for your Medicare beneficiaries. Thank you for your time.

Sincerely,

Sabrina Frierson, MD

Sabrina Frierson, MD
Surgeon
1541 Florida Avenue, Suite 200
Modesto, CA 95350

cc: Senator Barbara Boxer, CA (D)
Senator Diane Feinstein, CA (D)
Congresswoman Nancy Pelosi (D)

cc: Carolyn Mullen, Deputy Director,
Division of Practitioner Services

cc: American Brachytherapy Society
W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : **Kathy Francisco** **Date: 10/05/2006**

Organization : **The Pinnacle Health Group, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

See Attached Comments regarding OPPS proposed payment for Brachythearpy sources.

CMS-1506-P-284-Attach-1.PDF

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257

THE PINNACLE HEALTH GROUP
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215 369 9290 • 866 369 9290
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October 3, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Hospital Outpatient Prospective Payment System and CY07 Payment Rates

Dear Dr. McClellan:

The Pinnacle Health Group is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule.

The Pinnacle Health Group provides coding and reimbursement support for hospitals, physicians and medical device manufacturers across the country. Ninety percent of the services provided by facilities across the country are for the support of cancer treatments. This comment letter specifically addresses the proposed payment methodology for brachytherapy sources, including the proposed changes in brachytherapy payment for 2007.

Payment Methodology for Brachytherapy Sources

We believe that it would be inappropriate to implement a new payment system for 2007 that would establish set payment rates for brachytherapy sources based upon median costs. The variations in cost of each source require a unique payment methodology for radioactive sources. One source may have a cost variation of over 10 times based upon the intensity of the source. This is due to the fact that HDR sources vary significantly from hospital to hospital based upon the number of fractions used during a period of time.

The CMS claims data shows large variations in per unit cost reported (see table below) on claims across hospitals, which further validates the concerns regarding the data that CMS proposes to use to set brachytherapy device payments in 2007.

HCPCS and Description	Variation of Cost per Unit (2005 Hospital Claims)
C1716 Gold-198	$3 - 943
C1717 HDR Iridium-192	$0 – 4,746
C1718 Iodine-125	$0 - 14,632
C1719 Non-HDR Iridium-192	$3 – 1,761
C1720 Palladium-103	$0 - 20,825
C2616 Yttrium-90	$1,676 - 62,071
C2632 Iodine-125 solution	$0 – 7,253
C2633 Cesium-131	$28 - 15,797
C2634 High Activity Iodine-125	$2 – 4,526
C2635 High Activity Pd-103	$3 – 5,212
C2636 Linear Palladium-103	$0 -1,690

The recommended payment methodology will not appropriately capture the variation of brachytherapy source configurations.

The Pinnacle Health Group recommends that CMS continue the current HOPPS payment methodology of hospital charges adjusted to cost for all brachytherapy devices. This recommendation also was made by the APC panel at the August 24, 2006 meeting.

High Dose Rate (HDR) Brachytherapy Sources

High Dose Rate brachytherapy utilizes a unique brachytherapy source that requires allocation of the quarterly source cost by each hospital. The actual cost of the source is based upon the number of treatments or fractions that are administered to patients over the life of the source.

CMS claims data shows a huge variation in cost per unit reported on claims data across hospitals for the source:

APC	Number of Hospitals	Number of Claims	Variation of Cost per Unit
1717	283	4740	$0-$4,746

In addition to the large variation of cost per unit across the hospitals and claims in the CMS data, the highest utilization hospital should have the lowest cost for the HDR source and hospital cost from there should increase in numeric succession. An analysis of the top five volume hospitals, per CMS claims data, indicates significant anomalies in the data. Clearly this information should cause CMS to question the accuracy of the data when considering payment based upon the claims data.

HCPCS	Hospitals	Median	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5
C1717	283	$135	$3	$9	$479	$118	$95

In addition, there were over 100 diagnosis codes reported on claims with C1717 (Ir-192) and each treatment with Ir-192 requires a different protocol. This adds to the claims data confusion as well.

Treatment Site	Average treatments (fractions)	Average HDR Source Runs	Average Treatment Days	Average Number of Catheters per Treatment
Breast	10-12	18-36	5-6	1-36
Uterine	3-5	3-18	5	1-18
Prostate	3-4	16-18	2	24-36
Vaginal	3-5	1-3	3-5	1-2
Lung	2-4	1-3	3-5	2-5

To further validate the variation in cost per unit, Pinnacle worked with the HDR manufacturers to survey eighty hospitals regarding the actual cost of the HDR source to the hospital. This survey was originally conducted in 2002 and was updated using 2005 hospital specific costs and actual source runs. The findings indicated that the variation in cost per unit among these 80 hospitals ranges from $4-$5,775. These findings validate the CMS claims data that indicate variation in cost per unit of ($0-$4,746).

Number of Hospitals	Total ACUTAL Source Runs	Average Quarterly Unit Cost	Average Quarterly Source Service Cost	Average Quarterly Source Cost	Variation of Cost per Unit
80	47,050	$17,500	$7,150	$10,000	$4-$5,775

In addition to the variation in HDR source cost in the CMS claims data and the actual hospital survey, the GAO had an opportunity to review the HDR source cost as part of the report published by the agency this year. The GAO stated "data from 8 hospitals was determined to be usable to evaluate Ir-192 causing the GAO to recognize there was too much variability in Ir-192 source cost and therefore no recommendations could be made."

The cost of the HDR source is a fixed cost. Hospitals must purchase the source and have it available to treat cancer patients at any time. HDR cost varies from other diagnostic imaging technologies that may also have associated fixed costs. The HDR source must be on hand at all times and the hospital absorbs the cost of the equipment on a daily basis. For imaging services, the cost of the imaging agent is only incurred by the hospital if a study is performed or ordered by the physician. The cost of the source is incurred by the hospital even if a patient is not treated.

Based upon this data and the validation by the GAO report, it is recommended that CMS continue to reimburse hospitals for HDR brachytherapy sources based upon charges adjusted to cost.

In addition to the proposed payment methodology for HDR source, CMS requested recommendations regarding the payment methodology for HDR sources. The HDR source is ordered by the physician and used by the hospital based upon a 'per fraction' basis. The source runs from the afterloader into each catheter on a per fraction treatment basis.

The CMS claims data in 2002 indicated that only a very small number of hospitals reported the use of the HDR source. The primary reason for this low reporting by hospitals was due to confusion regarding the reporting of the source use and cost. Claims data now indicates that over 60% of hospitals are reporting the HDR source on the claim form with HDR procedures. This would indicate that hospitals are beginning to understand the methodology required to report the HDR source accurately. A change in the methodology for reporting the source at this point may cause confusion in reporting requirements which will lead to increased inaccuracies in the CMS claims data. This will limit the usefulness of future claims data for decision-making purposes as much of it will be suspect.

The HDR treatment protocols, as indicated above, vary significantly from daily to weekly treatment regimens. Due to the significant treatment variations in patient protocols, payment for the HDR source should remain on a per treatment basis and not be changed to per treatment day. Continued changes in hospital reporting requirements will confuse providers and will lead to inconsistency in claims data making future payment rates unstable.

The Pinnacle Health Group recommends that CMS continue to reimburse hospitals for HDR sources at charges reduced to cost. Further, we recommend that CMS continue to require hospitals to report the use of HDR sources per fraction or treatment.

High Activity Brachytherapy Sources

The data used by CMS to establish proposed payment rates for high activity iodine and palladium sources for 2007 (see table below) shows a huge variation in per unit cost reported on claims by hospitals across the county. This variation validates our concern regarding the data that CMS is using to establish payment rates for fiscal year 2007.

HCPCS and Descriptor	Variation of Cost per Unit (2005 Hospital Claims)
C2634 High Activity Iodine-125	$2 - $4,526
C2635 High Activity Palladium-103	$3 - $5,212

In addition to the variations in cost reported by the data, high activity source proposed payment rates have been established based upon claims data from a small number of hospitals. A combination of data from the manufacturers that supply high activity iodine sources indicates that approximately 112 hospitals across the country ordered high activity sources in 2005. The data reflects information based upon less than 50% of these hospitals.

HCPCS and Descriptor	Hospitals Reporting (2005 Hospital Claims)
C2635 High Activity Palladium-103	20
C2634 High Activity Iodine-125	50

CMS data outlined in the table below indicates rank order anomalies in proposed payments for high activity brachytherapy devices. High Activity Iodine-125 sources (C2634) always cost more than low activity sources (C1718). Typically, High Activity sources are 2 to 10 times more expensive than loose sources. CMS has proposed to establish payment values for high activity sources at a lower value than loose iodine sources.

HCPCS and Descriptor	Median Cost (2005 Hospital Claims)
C1718 Iodine-125	$35.54
C2634 High Activity Iodine-125	$25.77

Based upon a review of the data, we do not believe that the recommended payment methodology will appropriately capture the variation of brachytherapy source configurations.

The Pinnacle Health Group urges CMS to continue the current payment methodology for brachytherapy sources based on hospital charges adjusted to cost for each brachytherapy device and abandon the proposed payment methodology.

Iodine-125 Solution (C2632)

The GliaSite Radiation Therapy System (RTS) is an innovative system to treat individuals with malignant brain cancer. Designed to be placed inside the brain tumor resection cavity, the GliaSite RTS delivers radiation with Iotrex®, a proprietary I-125 therapeutic liquid brachytherapy source placed inside a balloon catheter. The targeted tissue receives a high dose of radiation, while exposure to healthy tissue is minimized. In clinical trials, the GliaSite System has demonstrated improved median survival time, preservation of cognitive function and improvement of overall quality of treatment. In addition, the GliaSite System allows for radiation treatment to be completed within three to six days, often as an outpatient therapy.

Since January 1, 2004, CMS has established Medicare HOPPS reimbursement for this treatment based on hospital charges adjusted to cost, as mandated by the Medicare Modernization Act (MMA) of 2003. This payment policy has been successful in safeguarding patient access to this important treatment for malignant brain cancer, while providing an appropriate reimbursement mechanism for hospitals and the Medicare program.

Under the proposed 2007 methodology based on median 2005 charges, CMS would set the reimbursement rate for C2632 at $19.32 per mCi. This reimbursement level is less than half of the actual hospital charge for Iotrex. CMS's proposed payment level is insufficient to compensate hospitals for their costs, which in turn would jeopardize access to this critical therapy for beneficiaries with brain cancer.

Iotrex is supplied in a 150mCi vial, and appropriate coding requires reporting one unit per mCi, or 150 units per vial. Hospital confusion regarding the correct unit of billing undermines the accuracy of data on which CMS is relying in establishing the proposed median cost level for this therapy. In fact, CMS itself noted this confusion at the March 1-2, 2006 meeting of the APC Panel that "some sources (e.g., HCPCS codes C1717, C1719, C2632, and C2633) demonstrate relatively inconsistent mean and median numbers of sources used."

The CMS cost data for C2632 indicates a large variance in the costs and the methodology reported by hospitals for units of Iotrex, which points to unreliable cost data on which to base median payments for 2007.

APC	Units	Minimum Unit Cost	Maximum Unit Cost
2632	4,106	$0.31	$7,252.56

CMS's proposed median payment level is clearly insufficient for hospitals and implementation of this payment rate for 2007 will jeopardize access to this critical therapy for beneficiaries with brain cancer.

The Pinnacle Health Group recommends that CMS continue to base reimbursement for C2632 on hospital charges adjusted to cost to assure patients with brain cancer access to this critical cancer treatment.

Ytterbium-169 (C2637)

Ytterbium-169 is a High Dose Rate (HDR) brachytherapy source that was approved by the FDA in 2005. As required by the MMA, CMS assigned a HCPCS code for Ytterbium so hospitals could appropriately report the cost of the source to CMS. This source will be available in 2007 and we understand that CMS does not have hospital claims data to determine an appropriate cost for Ytterbium-169.

CMS considered four (4) options in establishing payment for Ytterbium-169. CMS proposes to assign Ytterbium-169 (C2637) to its own APC with a payment rate set at or near the lowest proposed payment rate for any brachytherapy source paid on a per source basis (Option 2).

Ytterbium-169 is a HDR source with unique characteristics and differences in application than other sources. Ytterbium-169 (C2637) has a shorter half-life than HDR Iridium-192 (C1717) and requires source replacement every 32 days vs. 90 days for HDR Iridium-192. In addition, Ytterbium-169 requires different shielding and has a unique target activity compared to HDR Iridium-192.

Since there are no other sources that are comparable to this new brachytherapy source, the most appropriate payment methodology for Ytterbium-169, and any new brachytherapy source, would be to establish a charge reduced to cost (CCR) methodology in order to collect cost data from hospitals. This option would be similar to the CMS policy for New Technology APCs.

The Pinnacle Health Group recommends that CMS adopt Option 1 proposed by CMS and reimburse Ytterbium-169 (C2637) at charges adjusted to cost, consistent with the payment methodology that should be used for all brachytherapy sources.

Payment for NEW Brachytherapy Sources

In the proposed rule, CMS solicited comments regarding establishing payment amounts for new brachytherapy sources eligible for separate payment when no hospital claims-based cost data are available. The only effective way for CMS to capture cost data regarding new brachytherapy sources is for CMS to establish payment to hospitals for new brachytherapy sources at hospital charges reduced to cost when no hospital claims-based cost data is available.

The Pinnacle Health Group recommends that CMS implement a three year payment policy for new brachytherapy sources at hospital's charges adjusted to cost.

HCPCS Codes for Stranded Sources

The claims data indicates large variances in the data for iodine, palladium and cesium sources. Some of the variance is due to the clinical distinctions among different types of brachytherapy sources. The 2005 CMS claims data does not reflect the important clinical differences that have emerged with these brachytherapy sources. The increased clinical use of stranded sources and the ability to track these costs separately will allow CMS to capture more relevant and reliable cost data for brachytherapy sources in the future.

Stranded brachytherapy sources are embedded into the stranded suture material and separated within the strand by an absorbable material at prescribed intervals based upon the patient need. This ensures the initial and long-term position of each source when implanted in and around cancerous tumors. This special stranded source is manufactured prior to delivery to the customer and is not a process which can be performed by a hospital.

The GAO survey noted that one professional society recommended that the data used to establish reimbursement rates should reflect the increased clinical use of stranded brachytherapy devices. The increased use of stranded sources combined with the professional society's recommendation underscore the need to track the cost of these stranded sources separately in the CMS data set.

Published clinical literature supports that stranded sources are distinct from traditional brachytherapy devices in a number of ways including the clinical use of this technology. In addition, stranded sources have increased costs of production and thus present a higher cost to the hospital. These products are FDA approved and HCPCS codes should be established for each of these sources to permit better cost data in the CMS system.

Three brachytherapy sources are provided to hospitals in a stranded suture material: iodine, palladium and cesium. In the proposed rule, CMS requests recommendations for new codes to describe new brachytherapy sources in a manner reflecting the number, isotope and radioactive intensity of the sources.

The Pinnacle Health Group recommends that CMS establish three new stranded brachytherapy source codes to reflect the isotopes that hospitals currently purchase:

- **Brachytherapy device, Stranded Iodine-125, per source**
- **Brachytherapy device, Stranded Palladium-103, per source**
- **Brachytherapy device, Stranded Cesium-131, per source**

Proposed Definition of Brachytherapy Source

CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a "seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."

The Social Security Act, SEC. 1833, also states that "The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services)." Under this section, current cancer therapy drugs and biologicals and brachytherapy are defined as "A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and device of brachytherapy..."

The above definition does not require that a device of brachytherapy to consist of "a seed or seeds (or radioactive source)" as proposed by CMS. Furthermore, because the definition clearly states "**but not limited to,**" the list of above agents used to describe "a drug or biological" is **not** exclusionary and therefore meant be inclusive of ALL drugs and biologicals used in cancer therapy.

The evolution of technology requires one to reexamine understandings and definitions once thought to be clear and defined. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. This demands one to reconsider conventional understanding and accept technological advances that demonstrate that a brachytherapy source dose not have to be radioactive to deliver a therapeutic radiation dose.

Brachytherapy is derived from the ancient Greek words for short distance (brachy) and treatment (therapy). The procedure is most often an outpatient procedure used in the treatment of different kinds of cancer. Brachytherapy sources are carefully placed inside of the cancerous tissue and positioned in a manner that will attack the cancer most efficiently. Brachytherapy has now been used for over a century to treat prostate cancer, cervical cancer, breast cancer, endometrial cancer, and coronary artery disease. Brachytherapy has been proven to be very effective and safe, providing a good alternative to surgical removal of the prostate, breast, and cervix, while reducing the risk of certain long-term side effects.

In the treatment of cancer using brachytherapy, sources give off radiation that travels only a few millimeters to kill nearby cancer cells. There are two types of brachytherapy: Permanent, when the source remains inside of the body; and temporary, when the source is inside of the body and then removed. Brachytherapy is not defined by the type of source used to treat the cancer, but by the treatment method that is used delivered a source of radiation to the patient.

Furthermore, through discussions with legislators, it is our understanding that the intent of the legislation was to provide separate payment for <u>all</u> devices of brachytherapy and to better define and categorize those devices; it was to not to exclude any specific devices.. New innovative, electronic (non-radioactive) brachytherapy radiation sources meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA. By excluding the non-radioactive brachytherapy radiation sources from separate payment, CMS is eliminating access to FDA approved new technology for Medicare beneficiaries.

The Pinnacle Health Group recommends that CMS reconsider their definition of brachytherapy sources as consisting of a seed or seeds (or radioactive source) and include non-radioactive brachytherapy sources.

CPT 77799 Assignment

Ambulatory Payment Classification Groups (or APCs) are composed of groups of services that are comparable clinically and with respect to the use of resources. CMS has proposed to move CPT 77799 from APC 313 to APC 312 for CY2007. CPT 77799 is the unlisted procedure code for clinical brachytherapy. APC 312 (Radioelement Application) is comprised of CPT codes that are described as radiation source applications and APC 313 (Brachytherapy) includes CPT codes that are described as remote afterloading high intensity brachytherapy. In keeping with the intent of APC classifications to group procedures that are similar clinically and resources utilized, unlisted brachytherapy code CPT 77799 would be more appropriately included in APC 313 with other brachytherapy procedure codes.

CMS has classified CPT 77799 appropriately as a brachytherapy procedure from the inception of the APC system in 2002. Since this time CPT 77799 (clinical brachytherapy) has been placed into APC 313 with other brachytherapy procedures. In following with the APC assignment of miscellaneous procedures, the assignment to the lowest paying brachytherapy APC is the most appropriate for 77799. The only brachytherapy APC that is appropriate for placement of 77799 would be APC 313.

The Pinnacle Health Group recommends that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.

Summary of Recommendations

Brachytherapy offers important cancer therapies to Medicare beneficiaries. Appropriate payment for brachytherapy sources is required to ensure that hospitals can continue to offer Medicare beneficiaries the highest quality of cancer care.

In summary, The Pinnacle Health Group recommends that CMS:

- **Continue the current HOPPS payment methodology of hospital charges adjusted to cost for all brachytherapy devices;**
- **Continue to reimburse hospitals for HDR sources at charges reduced to cost;**
- **Continue to require hospitals to report the use of HDR sources per fraction or per treatment NOT per treatment day;**
- **Continue to base reimbursement for C2632 on hospital charges adjusted to cost to assure patients with brain cancer access to this critical cancer treatment;**
- **Establish three new stranded brachytherapy source codes to reflect the isotopes that hospitals currently purchase:**
  - **Brachytherapy device, Stranded Iodine-125, per source;**
  - **Brachytherapy device, Stranded Palladium-103, per source; and**
  - **Brachytherapy device, Stranded Cesium-131, per source;**
- **Adopt Option 1 proposed by CMS and reimburse Ytterbium-169 (C2637) at charges adjusted to cost, consistent with the payment methodology that should be used for all brachytherapy sources;**
- **Implement a three year payment policy for NEW brachytherapy sources at hospital's charges adjusted to cost;**

- **Reconsider the definition of brachytherapy sources as consisting of a seed or seeds (or radioactive source) and include non-radioactive brachytherapy sources; and**

- **Retain unlisted brachytherapy CPT 77799 in the appropriate brachytherapy APC 313 for CY2007.**

Thank you for your consideration of these important issues.

Sincerely,
THE PINNACLE HEALTH GROUP, INC.

Kathy A. Francisco
Principal
kfrancisco@thepinnaclehealthgroup.com

cc: Carol Bazell, MD, Acting Director, Division of Outpatient Care (email)