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October 9, 2006

Via Hand Delivery
Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
7500 Security Boulevard
Baltimore, Maryland 21244

RE: CMS-1506-P: Proposed Changes to Medicare Hospital Outpatient PPS for CY 2007 Prostate Laser Vaporization, Prosthetic Urology, and Vaginal Prolapse/Hysterectomy Procedures

Dear Dr. McClellan:

American Medical Systems ("AMS") is pleased to submit comments in response to the Centers for Medicare & Medicaid Services' ("CMS") Medicare hospital outpatient prospective payment system ("HOPPS") proposed rule for calendar year 2007 (the "Proposed Rule"). [1]

AMS is a leading manufacturer of medical devices used to treat urological and gynecological disorders such as urinary incontinence and menorrhagia. Although not life-threatening, these disorders can greatly affect one's quality of life and social relationships. As such, AMS is keenly interested in the changes recommended in the Proposed Rule concerning payment rates for procedures involving our technologies. Our comments this year primarily relate to the use of "Green Light" Laser for photoselective vaporization of the prostate ("PVP") to minimize urethral obstructions related to benign prostatic hyperplasia ("BPH"). As more fully described below, our comments are intended to ensure that HOPPS payments for these procedures adequately reflect the costs of even the most complicated and lengthy procedures, supporting access to high quality care for Medicare patients.

AMS is also a member of both the Coalition for the Advancement of Prosthetic Urology ("CAPU") and the Prolapse Repair Coalition ("PRC"). CAPU and the PRC are national organizations that include leading clinical experts and researchers in prosthetic urology and gynecologic products for prolapse repair, respectively. AMS supports the comments filed by CAPU and the PRC on the Proposed Rule and wishes to emphasize the following points.

Payment Increases for Prosthetic Urology Procedures

AMS appreciates the attention CMS has given over the past several years to ensure that reimbursement for prosthetic urology devices and procedures better reflects the actual costs incurred by our hospital customers when these procedures are performed in the outpatient department. We are pleased that CMS has proposed to increase 2007 HOPPS payment rates for several key APCs, including APC 0385 Level I Prosthetic Urology Procedures, APC 0386 Level II Prosthetic Urology Procedures, and APC 0181 Penile Procedures. We urge CMS to

[1] Proposed Changes to the Hospital Outpatient Prospective Payment System Calendar Year (CY) 2007 Payment Rates, 71 Fed. Reg. 49506 (August 23, 2006).

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adopt these proposed payment increases in the final HOPPS rule for calendar year 2007. Adequate payment levels for prosthetic urology procedures are critical to ensure that hospitals continue to offer these important therapies to Medicare beneficiaries in the outpatient setting.

Status Indicator Changes for Certain Vaginal Prolapse/Hysterectomy Procedures

AMS supports recommendations by the APC Advisory Panel and PRC that CMS change the status indicator ("SI") for certain colpopexy (prolapse repair) and vaginal hysterectomy codes as follows:

- Change the status indicators to "T" and assign CPT 57282 *Colpopexy, vaginal; extra-peritoneal approach* and CPT 57283 *Colpopexy, vaginal; intra-peritoneal approach* to APC 0202 or create a new APC for vaginal repair procedures with a payment rate of $3,000.

- Change the status indicators to "T" and create a new APC for the vaginal hysterectomy procedures listed below and use APC 0132 as the benchmark for the level of payment assigned to the new APC.

  58260 *Vaginal hysterectomy, for uterus 250 grams or less*
  58262 *Vaginal hysterectomy, ...; with removal of tube(s) and/or ovary(s)*
  58263 *Vaginal hysterectomy, ...; with removal of tube(s) and/or ovary(s), with repair of enterocele*
  58270 *Vaginal hysterectomy, ...; with repair of enterocele*
  58290 *Vaginal hysterectomy, for uterus greater than 250 grams*
  58291 *Vaginal hysterectomy, ...; with removal of tube(s) and/or ovary(s)*
  58292 *Vaginal hysterectomy, ...; with removal of tube(s) and/or ovary(s), with repair of enterocele*
  58294 *Vaginal hysterectomy, ...; with repair of enterocele*

Redesignating these two sets of CPT codes in this manner would remove them from the inpatient only list, thus making the procedures eligible for payment in the outpatient setting.

Such changes would be clinically appropriate and are supported by recent literature. More specifically, recent advances in vaginal colpopexy and hysterectomy techniques and new instruments have made it possible to furnish these procedures effectively in the hospital outpatient setting with good results (see for example, Levy, BS, MD, Outpatient Vaginal Hysterectomy is Safe for Patients and Reduces Institutional Cost, Journal of Minimally Invasive Gynecology (2005) 12, 494-501).

With respect to APC assignment, vaginal prolapse repair procedures are clinically similar to the procedures in APC 0202 and involve similar resources. Therefore, AMS encourages CMS to assign CPT 57282 *Colpopexy, vaginal; extra-peritoneal approach* and CPT 57283 *Colpopexy, vaginal; intra-peritoneal approach* to APC 0202. Alternatively CMS could create a new APC for vaginal repair procedures with a payment rate of $3,000.

Likewise, vaginal hysterectomy procedures are clinically similar to the procedures in APC 0132 Level III Laparoscopy and involve similar resources. However, rather than trying to

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fit these procedures into an existing APC, such as APC 0202[i], AMS suggests using APC 0132 as the benchmark for CMS to create at least one new APC, as follows:

APC 013x – Vaginal Hysterectomy Procedure with a proposed payment of $4,363[ii]

Changing the status indicators to "T" and assigning prolapse repair and vaginal hysterectomy procedures to the codes described above would be consistent with CMS's overall policy for APCs and the agency's goal to ensure Medicare patients have access to the appropriate procedure in the appropriate practice setting. Accordingly, AMS encourages CMS to adopt these recommendations in its final HOPPS rule for 2007. These actions are in the best interests of Medicare patients throughout the country. Otherwise, hospitals may be reluctant to furnish prolapse repair procedures and vaginal hysterectomies in the outpatient setting.

Payment Increases for PVP/Green Light Laser Procedures for Prostate Vaporization

Having recently acquired the Green Light Laser technology, AMS was not involved in the earlier discussions regarding reimbursement for the BPH laser procedures. We are, however, aware that for 2006, the AMA CPT Panel revised CPT code 52648 to clarify that the code reflects "laser vaporization of prostate, including control of postoperative bleeding, complete (including vasectomy, ..., internal urethrotomy and transurethral resection of prostate are included if performed)." As a result of this CPT coding change, CMS reassigned PVP/Green Light Laser procedures from HCPCS Code C9713, which was assigned to a new technology APC, to CPT 52648 which crosswalks to APC 0429, Level V Cystourethroscopy and other Genitourinary Procedures. Consequently, HOPPS payment for laser vaporization of the prostate performed with Green-Light Laser technology dropped almost $1,250, from $3,750 in 2005 to $2,504 in 2006.

For 2007, CMS is proposing to keep CPT 52648 in APC 0429 with the payment increasing slightly - about $139, although payment will still be significantly lower than the 2005 payment level and thus, fail to cover hospitals' costs. We understand that the part of the problem may relate to the claims used for rate-setting:

For example, of the 11,530 claims containing 52648 (only), the median charges were $9,347.48 and median costs were $2,731.67.

In contrast, the 719 claims that contained both 52648 and C9713 had median charges of $9,738.63 and median costs of $3,153.76. This is a $400 increase in costs.

Claims with CPT 52648 and C9713, however, are more appropriate to use for payment setting. As CMS has noted, claims for procedures that include C-codes are much more likely to include the costs for the related devices – in this instance, the laser fiber(s) required for photo vaporization treatment. For this reason, we urge CMS to --

- Assign CPT 52648 to a device-dependent APC;
- Require hospitals to report a C-code for the laser fiber (establish a device-edit) and .

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- Recommend CMS **use only claims that include both CPT code 52648 and C code C9713 in establishing the APC assignment and payment for these procedures .**

In addition, while many of the 52648 claims were classified as Single Major claims, all of the 719 claims containing 52648 and C9713 were classified as multi-major (data provided by Medical Technology Partners). It is possible that CMS' methodology ***may have excluded consideration of all correctly coded claims*** (if median cost calculation was based upon only single major claims). This is important for establishing the methodology in the future that all correctly coded claims be considered.

Finally, while in some cases the resources and clinical aspects of Green Light Laser may be similar to those of other prostate procedures reported under CPT code 52648, more complex and lengthy cases involving PVP are not adequately reflected in the HOPPS payment rate assigned to APC 0429. More specifically, we wish to emphasize—

- Physicians report that in approximately 15% of cases involving the use of Green Light Laser technology, two laser fibers are required due to either the large volume of the prostate, or because of the fibrous nature of the gland.[iii]
- However, because hospitals bill the CPT code for procedure (not the device) it is not possible to reflect the use of two laser fibers on a hospital outpatient claim, unless specific edits are adopted to recognize existing C-codes that represent the laser fibers and allow the hospitals to accurately capture the costs for all the devices used in these procedures.
- Therefore, as an interim measure, AMS urges CMS to adopt a weighted average cost for laser fibers for this APC, which recognizes that 15% of cases involving the use of Green Light Laser technology require the use of two optic fibers. CMS has taken a similar approach with other devices, including drug eluding stents. Accordingly, adopting a weighted average for APC 0429 follows precedent and should be implemented to ensure that payments under the HOPPS system for PVP/Green Light Laser technology accurately reflect the true resource costs involved in all cases.

* * *

As always, we are grateful for the opportunity to provide comment to CMS on the proposed HOPPS rule. If you have any questions about these comments, or if you would like additional information, feel free to contact Gary Goetzke at 952-930-6155 or our reimbursement counsel, Gail Daubert, Esq. at 202.414.9241.

Sincerely,

Gary Goetzke

Gary Goetzke
Senior Director
Health Care Affairs

cc: Carol Bazell, M.D., CMS
John Mulcahy, Chairman, CAPU
Robin Hudson, American Urological Association

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[i] APC 0202 includes quite different procedures that involve different resources than vaginal hysterectomy procedures. Moreover, based on initial cost estimates, the proposed payment for APC 0202 at $2,639 would fall far short of appropriate payment (~$4,500) for the vaginal hysterectomy procedures.

[ii] The payment rate for the new APC is based on cross-walking payment for the Level III Laparoscopy procedures which have similar hospital costs.

[iii] Literature on the use of lasers to treat BPH commonly distinguishes prostates based upon size. For example, Sandu JS, et.al. (Sandhu JS, Ng C, Vand.erBrink BA, Egan E Kaplan SA, Te AE (2004), Urology 64:1155-1159) label prostate volumes of at 60 ml as "large" high volume prostates (mean prostatic volume for the study was 101 ml), and in a peer reviewed article published in 2005 Sandhu et.al. (Sanhu JS, AE Te (2005), J Urol 173(4):366) describe a modified surgical technique for treating large volume prostatectomy with the 80W KTP laser, where additional incisions are made to accommodate vaporization along the median and lateral lobes and the apex of the prostate.

The published literature also commonly references the fact that large volume prostates require the use of two (2) single use optic fibers, as opposed to one fiber for smaller prostates.

Malek RS, et.al. (Malek RS, Kuntzman RS, Barrett DM (2005), J Urol, 174: 1344-1348) document extended time involved for laser procedure based upon prostate size, noting laser lasing time of 48 minutes for 60 ml glands and 94.7 minutes for 90 ml glands with KTP laser energy at 60 watts. (Baseline data reflects lasing time ranging from 10 to 99 minutes.)

The data further reflects the use of a higher powered energy source (the KTP 80 watt laser) first introduced in 2001, noting a lasing time of 99 minutes for the largest prostate of 136 ml treated with the 80 watt device. The Malek study sites Stovsky et.al.(Stovsky MD, Laskin CR, and Griffiths RI (2004), J Urol, suppl., 171: 103, abstract 393) to infer that these larger prostate cases require the use of two (2) laser fibers. Malek writes that positive outcomes associated with use of the KTP laser leads to "...reducing the health care costs despite the additional cost of a single use laser fiber and the one time initial cost of a laser generator."

The more recently published literature continues to validate the stratification of the prostate based upon volume. For example, Wong C et. al. (Wong C, Lam PN, Sulley GM, Culkin DJ, (2006), Can J Urol 13: (3)) write that using KTP laser to treat large volume BPH (greater than 75 cm) lead to initial results demonstrating that KTP laser is safe and effective for treatment of symptomatic large volume BPH, obviating the need for open surgery. And, in the 2006 Journal of Urology, Yakupoglu et. al. (Yakupoglu YK, Donmezer S, Mestci B, Saglam R, Simsek US (2006), J Urol 175 (4) suppl. P. 463) describe a study of KTP to treat large prostates (over 100 ml) concluding that KTP laser vaporization of the prostate can be safely and effectively used in men with large prostates over 100 ml.

NORWALK HOSPITAL

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October 9, 2006

Filed Electronically and Via Hand Delivery

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1506-P -- Changes to Hospital Outpatient Payment System for 2007
Support Proposed Increased Payment for Kyphoplasty Procedures – APC 052

Dear Dr. McClellan:

I am pleased to submit comments on the Centers for Medicare & Medicaid Services' (CMS) Medicare hospital outpatient prospective payment system (HOPPS) proposed rule for calendar year 2007 which was published in the Federal Register on August 23, 2006.

I am an orthopedic surgeon, the Immediate Past President of the Connecticut State Orthopaedic Society and the Chief of Staff at Norwalk Hospital in Connecticut. I have been performing kyphoplasty procedures since June 2001. In my leadership role with the Orthopaedic Society, I was pleased to work with CMS staff as they moved forward and established new C-codes for the kyphoplasty procedures in 2005. More recently, I have worn my "hospital administrator" chief of staff hat when communicating and working with CMS staff on payment and coding related matters for kyphoplasty. Because of my involvement with the coding process and my role as a hospital administrator, I am keenly interested in CMS proposed changes to the Hospital Outpatient PPS for 2007.

In brief, I recommend CMS finalize (or increase) the Medicare hospital outpatient payment rates ($4,055) for kyphoplasty procedures in the final 2007 HOPPS rule.

By way of background, balloon kyphoplasty is a minimally invasive surgical treatment which restores the height of pathologically fractured vertebrae whether by osteoporosis or cancer. Using specialized equipment and devices we can stabilize the fracture and correct the spinal deformity. As a result, patients generally report a significant reduction in pain as well as improved mobility. In turn, this reduces (1) the number of days they spend in bed (bedrest), (2) the amount of pain medication they need, and (3) potential complications related to bedrest and inactivity. Overall, patients report an increase in their quality of life following kyphoplasty. Most patients who need kyphoplasty are over 65 so Medicare is the primary payer and appropriate Medicare reimbursement is important to ensure that Medicare patients have full access to to this procedure.

For 2007, CMS has proposed increasing the payment to $4,055 for kyphoplasty procedures described by CPT codes 22523, 22524, and 22525. These three kyphoplasty CPT codes became effective on January 1, 2006. In the 2006 final HOPPS rule, CMS considered comments and moved the kyphoplasty procedures to APC 052 because APC 052 was a better fit and maintained the clinical and resource homogeneity of the APC procedure groupings. At that time, CMS also indicated that they would review claims data and evaluate the APC assignment again for 2007. I appreciate the attention that Ken Simon and the staff in CMS's Outpatient Care Division have given to kyphoplasty procedures to ensure that the procedures are assigned to the correct APC both from a clinical perspective and a

resource consumption standpoint. They have carefully reviewed and examined the hospital charge data that I provided for kyphoplasty procedures and I am pleased that, as a result of the coding changes, CMS now has charge data for kyphoplasty in their hospital claim file.

In closing, addressing reimbursement, including payment and coding for kyphoplasty to ensure that Medicare patients have access to this important procedure in all practice settings, is one of my primary goals, and achieving this goal involves a concerted effort on the part of all interested parties, especially CMS staff and the CMS medical officers. I sincerely appreciate CMS's efforts and look forward to continuing to work with CMS on this important matter.

Thank you for your time, attention, and consideration. If you have any questions or need additional information, please feel free to contact me.

Sincerely,

Michael Marks MD MBA

Michael R. Marks, M.D., MBA
Norwalk Hospital

cc: Carol Bazell, M.D., CMS
Edith Hambrick, M.D., J.D., CMS
Ken Simon, M.D. CMS
Gail Daubert, R.N., Esq.

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The Coalition for the Advancement of Prosthetic Urology
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October 10, 2006

Filed Electronically and Via Hand Delivery

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1506-P - Proposed Changes to Medicare Hospital Outpatient PPS for CY 2007
Device-Dependent APCs, Prosthetic Urology – APCs 181, 385 and 386

Dear Administrator McClellan:

The Coalition for the Advancement of Prosthetic Urology ("CAPU") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Medicare hospital outpatient prospective payment system ("HOPPS") proposed rule for calendar year 2007 (the "Proposed Rule").[1] CAPU is a national organization that includes leading clinical experts and researchers in prosthetic urology and the nation's leading manufacturers and developers of innovative prosthetic urology devices. CAPU has worked closely with CMS in the past in developing policies on adequate payment for prosthetic urology procedures under the HOPPS that support high quality care for Medicare patients. Our comments and recommendations are as follows:

1. CAPU appreciates the efforts CMS has made in the development of the proposed HOPPS rule. In particular, we are pleased that CMS has proposed to increase payment rates for several key prosthetic urology devices and procedures, including:
   - APC 385 Level I Prosthetic urology procedures –proposed payment $4,885,
   - APC 386 Level II Prosthetic urology procedures –proposed payment $8,354,
   - APC 181 Penile procedures–proposed payment $2,031.

   We strongly encourage CMS to adopt these proposed payment increases in the final 2007 HOPPS rule.
2. The Prosthetic Urology APCs are device-dependent APCs and CMS has created device coding edits to ensure that hospitals are reporting all the costs/charges for the devices.
3. **CAPU strongly supports CMS's proposal to use only claims that meet the device edits and contain actual charges for devices rather than "token" charges** for device-dependent APCs. Table 18 demonstrates that when CMS uses only hospital claims that meet the device edit and contain device charges, the median costs calculated for the procedures are several hundred dollars higher, as would be expected.
4. With regard to the offset adjustment in cases of replacement or full credit for failed or recalled device, we recommend that CMS change the proposed offset for APC 385 to 60%. The ratio of device costs to overall procedure costs is basically identical for APC 386 and APC 385. Therefore, offsets for both APC 385 and 386 should be 60%.

[1] See 71 Fed. Reg. 49506 (August 23, 2006).

Adequate payment levels for prosthetic urology procedures are critical to ensure that hospitals can continue to offer these important therapies to Medicare beneficiaries in the outpatient setting

As always, we thank CMS for the opportunity to provide comments on the proposed 2007 HOPPS rule.

If you have any questions about these comments, or if you would like additional information, feel free to contact me at 480.699.3378, or CAPU's counsel, Gail Daubert at 202.414.9241.

Sincerely,

John Mulcahy

John Mulcahy, M.D., Ph.D., F.A.C.S.
Diplomate, American Board of Urology
Chairman, CAPU

cc: Carol Bazell, M.D., CMS (vial email)
Robin Hudson, American Urological Association (via email)
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October 3, 2006

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Washington, DC 20201

Re: **CMS-1506-P** Proposed Changes to the Hospital Outpatient PPS and 2007 Payment Rates

Recommendation for New CPT Code for Percutaneous Intradiscal Electrothermal Annuloplasty to be Classified into APC 51

Dear Dr. McClellan:

Thank you for this opportunity to comment on the Proposed 2007 Medicare Hospital Outpatient Prospective Payment System (OPPS) rule. I am the Immediate Past President of the American Society of Interventional Pain Physicians (ASIPP), which represents more than 3,500 physicians nationwide who provide interventional pain management services. I am also a Diplomate and Board Certified with the American Academy of Pain Management and the American Board of Anesthesiology with a Subspecialty Certification in Pain Management. Most importantly, I am an interventional pain management physician in Danbury, Connecticut who treats several patients suffering from discogenic low back pain by using intradiscal electrothermal annuloplasty.

I am writing to recommend that CMS place the new CPT procedure codes for intradiscal electrothermal annuloplasty (i.e., IDET) into APC 51, Level III Musculoskeletal Procedures. As you may know, the American Medical Association (AMA) has established new CPT codes for IDET, effective January 1, 2007. I sponsored the application for these new codes, and want to follow this through and make sure that the new codes are assigned to the appropriate APC.

For this reason, I am writing to recommend that CMS place the new codes in an appropriate clinical APC where payment will accurately reflect the hospital resources involved. Based on the costs for the equipment and necessary supplies, I recommend assigning the new CPT codes to APC 51, which has a proposed payment rate of $2,539.

Mark McClellan, M.D., Ph.D.
Re: CMS-1506-P
October 3, 2006

IDET is a surgical procedure for the treatment of chronic discogenic low back pain. It is indicated for coagulation and decompression of disc material to treat patients with annular disruption of contained herniated disc. When performing IDET, a physician inserts a catheter with a two inch thermal resistive coil into the posterior annual wall of the disc. The catheter then delivers electrothermal heat to the intervertebral disc for about 20 minutes. The total operative room time is about 1.5 hours.

APC 51, Level III Musculoskeletal Procedures, is an appropriate placement for IDET. Other procedures in this APC involve performance of similar clinical activities and require a similar commitment of hospital resources. This APC will neither under nor over reimburse hospitals for the procedure and will group IDET with several other procedures of the spine.

IDET was for formerly described by CPT 0062T, which was assigned to APC 50 (payment rate of $1,542.47). However, CMS data published in the proposed 2007 rule notes that the average cost for all 0062T procedures was approximately $2,230. (In my experience IDET generally has higher costs than other procedures described by 0062T.) APC 51 therefore is a very appropriate fit. Such an assignment will establish an accurate reimbursement rate and will ensure that hospitals can offer this procedure to Medicare patients without encountering adverse financial pressure.

Thank you for considering these comments to the proposed rule. I share CMS' desire to create an accurate Medicare reimbursement system that eliminates both financial incentives and financial disincentives from the medical decision making process. Assigning the new CPT codes for percutaneous intradiscal annuloplasty to APC 51 will advance this goal.

If you have any questions, please do not hesitate to contact me at the telephone number above.

Sincerely,

David Kloth, M.D.

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Jim Bechtold, Executive Director
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October 9, 2006

Filed Via Hand Delivery and Electronically

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Baltimore, Maryland 21244

RE: CMS-1506-P Proposed Changes to Medicare Hospital Outpatient PPS for CY 2007
New APCs for Orthopedic Procedures that Involve Fixation Devices Better Reflect Hospital Costs

Dear Administrator McClellan:

On behalf of the Alliance for Orthopedic Solutions (the "Alliance"), we welcome the opportunity to submit comments on the Centers for Medicare & Medicaid Services' ("CMS") Medicare hospital outpatient prospective payment system ("HOPPS") proposed rule for calendar year 2007 (the "Proposed Rule").[1] Alliance members include leading clinical experts dedicated to high quality clinical care, education, and research in Orthopedics, as well as the leading developers and manufacturers of orthopedic devices.

The Alliance is pleased with several of CMS's proposed changes for HOPPS and particularly supports CMS's efforts to split APC 0046 (Open/ Percutaneous Treatment Fracture or Dislocation) into three separate new APCs. This is an important development for the Alliance and its hospital outpatient customers in achieving more accurate payment rates for fracture procedures involving external fixation devices. Our comments on this issue are discussed in detail below.

New APCs Better Distinguish the Costs of Procedures Involving the Use of External Fixation Devices

In the past, many varieties of procedures have fallen under APC 0046, Open/ Percutaneous Treatment Fracture or Dislocation, including those that involve casting and those that involve internal and external fixation devices. Due to the more costly nature of the fixation devices, however, APC 0046 has significantly underpaid the procedures that involve their use.

As a result, in considering the 2006 proposed HOPPS rule, the Alliance asked CMS to distinguish procedures containing "with or without external fixation" in the descriptors falling under APC 0046. While CMS declined to undertake this reassignment in the CY 2006 final rule, the agency did ask the APC Panel to consider a possible reconfiguration of APC 0046 during the APC Panel's March 2006 meeting.[2]

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1 Proposed Changes to the Hospital Outpatient Prospective Payment System Calendar Year (CY) 2007 Payment Rates, 71 Fed. Reg. 49506 (August 23, 2006).

2 We understand that the AMA CPT Panel / RUC is evaluating the codes to determine whether the costs of the devices are valued in the practice expense file and/or whether additional modifications are needed.

Earlier this year, the APC Panel recommended that CMS continue to evaluate the refinement of APC 0046 into at least three APC levels, with consideration of a fourth level should data support this. Accordingly, in the 2007 proposed HOPPS rule, CMS has proposed to eliminate APC 0046 and split the codes it previously covered into three new APCs[3]:

- APC 0062 (Level I Treatment Fracture/ Dislocation);
- APC 0063 (Level II Treatment Fracture/Dislocation); and
- APC 0064 (Level III Treatment Fracture/Dislocation).

As a result, HOPPS payment will increase significantly for the highest level of treatment for fractures and dislocations, decrease for the lowest level, and remain relatively stable for the middle level.

The Alliance supports this proposal and commends CMS for taking action to distinguish the more resource- intense fracture fixation procedures from the less costly casting procedures. Restructuring APC 0046 into these three new APCs is an important first step and will also help to eliminate 2 times rule violations in the Fracture/Dislocation series. These actions are in the best interests of both the Alliance's hospital customers and Medicare patients throughout the country who may otherwise be denied access to appropriate treatment for fracture fixation.

In closing, the Alliance appreciates the attention CMS staff have given to making HOPPS reimbursement for orthopedic procedures more equitable and appropriate. We encourage CMS to adopt its proposal to refine the APC configuration to better reflect the actual costs of fracture and dislocation procedures and to consider a fourth APC level in this series if future data so warrants. We appreciate the opportunity to submit these comments and we look forward to working with CMS to implement these important changes. Please feel free to contact me at 202.414.9241, if we can provide further information.

Sincerely,

Gail Daubert

Gail L. Daubert, Esq.
Counsel for the Alliance

cc: Carol Bazell, M.D., Acting Director, Division of Outpatient Care (email)
Edith Hambrick, M.D., J.D. CMS Medical Officer (email)
Alliance Members (email)

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3 CMS has decided against proposing a fourth APC level in this series (as recommended by the APC Panel) because claims data are not robust and consistent enough from year to year to support differential payment for another service level.

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KYPHON

Richard W. Mott
President and Chief Executive Officer

Via Overnight Mail

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1506-P -- Proposed changes to Hospital Outpatient PPS for 2007
Updated Kyphoplasty (APC) Payment Rates Better Reflect Hospital Costs
Bypass List: Request Addition of CPT code 88307 Tissue exam by pathologist

Dear Dr. McClellan:

Kyphon welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Medicare hospital outpatient prospective payment system ("HOPPS") proposed rule for 2007 (the "Proposed Rule").[1]

Kyphon is the leading manufacturer of innovative medical devices used during balloon kyphoplasty procedures to restore spinal function and treat vertebral compression fractures. These procedures may be performed in a hospital outpatient setting. Balloon kyphoplasty is a minimally invasive treatment which restores the height of vertebrae fractured by osteoporosis or cancer. By achieving fracture stabilization and correction of spinal deformity, patients experience significant reduction in pain and improvement in mobility, thus reducing the number of days in bed, the use of analgesics and other medicines for managing pain and increasing overall quality of life. Appropriate Medicare reimbursement for balloon kyphoplasty is important to ensure that elderly patients have access to this procedure.

For this reason, Kyphon commends CMS for recognizing and proposing to increase the HOPPS payment rates for Kyphoplasty procedures. Our comments and recommendations are summarized below and discussed in greater detail in the following sections. In brief:

- Kyphon encourages CMS to finalize (or increase) the APC payment rates for APC 052 which include kyphoplasty procedures in the final 2007 HOPPS rule.

- Kyphon also recommends adding CPT code 88307 Tissue exam by pathologist to the list of bypass codes for creating "pseudo" single claims for calculating median costs. Adding 88307 to the bypass list would increase the number of single claims used to establish the median costs for kyphoplasty and establish relative weights for APC 052. CPT code 88304 Tissue exam by pathologist and CPT code 88305 Tissue exam by pathologist are on the bypass list. CPT code 88307 involves a nearly identical procedure (i.e., tissue exam by a pathologist). Thus, adding CPT 88307 to the bypass

[1] Proposed Changes to the Hospital Outpatient Prospective Payment System Calendar Year (CY) 2007 Payment Rates, 71 Fed. Reg. 49506 (August 23, 2006).

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list would be consistent with CMS's practice of bypassing tissue exam procedures to create more pseudo single claims to use for rate-setting purposes.

Support APC Assignment and Payment for Kyphoplasty Procedures

Under the Proposed Rule, the payment rates for APC 052 (which include kyphoplasty procedures described by CPT codes 22523, 22524, and 22525) would increase in 2007. As you may recall, the three kyphoplasty CPT codes became effective on January 1, 2006. In the 2006 final HOPPS rule, CMS considered comments and moved the kyphoplasty procedures to APC 052 because APC 052 was a better fit and maintained the clinical and resource homogeneity of the APC procedure groupings. At that time, CMS also indicated that they would review claims data and evaluate the APC assignment again for 2007.

Kyphon appreciates the attention that CMS staff has given to kyphoplasty procedures over the past several years. We note that hospital charge data for the procedures, which generally lags by two years, is likely to expand over the next few years as this innovative technology has recently become better known and more frequently utilized. In this regard, we believe that next year and beyond, the charge data may reflect even higher median hospital costs. Accordingly, in the best interests of both our hospital customers and the many Medicare patients that will benefit from access to kyphoplasty procedures in the hospital outpatient setting, we encourage CMS to continue to consider future refinements to the HOPPS payment amounts if hospital charge data demonstrates such need.

Add CPT 88307 Tissue Exam by Pathologist to Bypass List

Kyphon appreciates and supports CMS's efforts to make use of as many "single" claims as possible in setting outpatient payment rates for procedures. We understand that when more than one separately paid procedure appears on a claim with other supplies, the "multiple procedure" claim is not used. Thus, we engaged The Moran Company to help us understand the claim file data and to better understand what, if any, procedures are billed on the same claim with Kyphoplasty procedures. The analysis demonstrated that the C9718 Kyphoplasty was often billed together with the following procedures:

	Frequency with C9718 on claims not used
20225 Bone biopsy, trocar/needle	1,025
88307 Tissue exam by pathologist	805

Looking ahead, we expect that at least about 1,000 additional claims may be used for rate setting next year as the hospital claim data will include the new CPT codes which include the bone biopsy in the code descriptor. As a result, we also expect that the hospital charges will reflect higher median hospital costs due to the inclusion of the "bone biopsy" procedure. Because the new CPT codes include the "bone biopsy" procedure, we are not recommending

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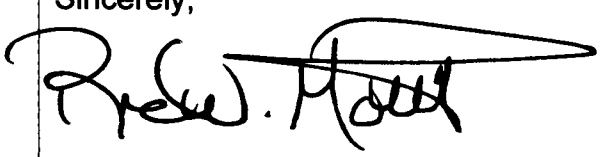
that CMS add CPT 20225 Bone biopsy to the bypass list. However, we do believe that CPT code 88307 Tissue exam by pathologist should be added to the bypass list. At minimum, it would appear that adding CPT 88307 to the bypass list could increase, by about 800, the number of single claims that CMS could use for calculating the median costs of kyphoplasty procedures and establishing the APC payment rates next year.

Accordingly, because adding CPT 88307 Tissue exam is consistent with CMS's policy to increase the number of "pseudo" single claims used for establishing median costs, we recommend that CMS add this procedure to the bypass list effective January 1, 2007. We believe that this additional refinement would, in turn, benefit our hospital customers because CMS would be able to use more claims and charge data for Kyphoplasty in future rate setting.

In closing, Kyphon believes that the proposed 2007 HOPPS payment rates are more reflective of the actual costs incurred by our hospital customers. We would, however, continue to encourage CMS to review hospital data as it expands over the next few years in order to ensure that any additional payment needs are captured and Medicare patients continue to have access to kyphoplasty procedures in the hospital outpatient setting. We appreciate the opportunity to submit these comments and to work with CMS to implement these important changes. Please feel free to contact Mary Hailey at 715.246.6013 or our reimbursement counsel, Gail Daubert at 202.414.9241, if we can provide further information.

Sincerely,



Richard W. Mott
President and Chief Executive Officer
Kyphon Inc.

cc: Carol Bazell, M.D., CMS
Edith Hambrick, M.D., J.D., CMS
Ken Simon, M.D. CMS
Mary Hailey
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Duplicate Copy filed via Hand Delivery

October 10, 2006

Mark McClellan, M.D., Ph.D.
Administrator, CMS
Department of Health and Human Services
Attn: CMS – 1506-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: **CMS-1506-P** Proposed Changes to the Hospital Outpatient PPS for 2007
New CPT Code Percutaneous Intradiscal Electrothermal Annuloplasty to be Classified into APC 51

Dear Dr. McClellan:

Thank you for this opportunity to comment on the Proposed 2007 Medicare Hospital Outpatient Prospective Payment System (OPPS) rule. I am an interventional neuroradiologist at the Mayo Clinic in Jacksonville, Florida and I am writing to recommend that CMS place the new CPT procedure codes for intradiscal electrothermal annuloplasty into APC 51 Level III Musculoskeletal Procedures. Earlier this year, I sponsored an application to the American Medical Association (AMA) for the creation of new CPT codes for percutaneous intradiscal electrothermal annuloplasty (also known as IDET). I understand that the AMA CPT Editorial Panel viewed this application favorably and new CPT codes will be established and effective January 1, 2007.

Therefore, it is important for CMS to recognize the new CPT codes in the final 2007 OPPS rule and assign these procedures to the appropriate clinical APC with reasonable payment based on the hospital resources involved. Based on the costs for the equipment and necessary supplies, I am writing today to recommend that the new CPT codes be placed in APC 51 with a proposed payment rate of $2,539. Such an assignment will ensure appropriate reimbursement for this important surgical procedure.

IDET is a surgical procedure for the treatment of chronic discogenic low back pain. It is indicated for coagulation and decompression of disc material to treat patients with annular disruption of contained herniated disc. When performing IDET, a physician inserts a catheter with a two inch thermal resistive coil into the posterior annual wall of the disc. The catheter then delivers electrothermal heat to the intervertebral disc for about 20 minutes. The total operative room time is about 1.5 hours. I also wish to point out that in at least 50% of cases, we use a second thermal catheter, and the catheter alone costs over $1,000.

APC 51, Level III Musculoskeletal Procedures, is an appropriate placement for IDET both in terms of clinical activities performed and resources required. This APC includes several procedures that involve similar resources and also covers conditions of the spine. Moreover, it reimburses hospitals at a rate that reflects the hospital's surgical resources required for this procedure.[1]

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[1] In 2006, IDET was described by 0062T and assigned to APC 50 with a payment rate of $1,542.47. CMS data published in the proposed 2007 rule notes that the median hospital cost for 0062T procedures was over $2,000 and the mean cost is about $2,230. We believe that IDET, which is one of several procedures billed under CPT 0062T, may actually have resources higher than reflected in CMS's cost data. For example, we expect that hospitals costs for IDET are closer to $3,500 to $4,000.

I believe that this assignment will establish an accurate reimbursement rate for hospitals that perform IDET and will ensure that hospitals can offer this procedure to Medicare patients without encountering adverse financial pressure.

Thank you very much for considering these comments to the proposed rule. If you have any questions, I would be happy to further discuss the IDET procedure with you. Please feel free to contact me at the telephone number above.

Very truly yours,

Douglas Fenton M.D.

Douglas Fenton, M.D.

AMERICAN ASSOCIATION OF EYE & EAR HOSPITALS

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October 9, 2006

Hand Delivered

The Honorable Mark B. McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule; (71 Federal Register No. 163), August 23, 2006 (CMS-1506-P)

Dear Dr. McClellan:

The American Association of Eye and Ear Hospitals (AAEEH) respectfully submits its comments on the Centers for Medicare & Medicaid Services' (CMS) proposed regulation to make changes to the hospital outpatient prospective payment system and to set the calendar year 2007 payment rates.

We extend our support for the rate increases in several ophthalmology areas. However, several aspects of the proposed rule could potentially have a detrimental affect on eye and ear specialty hospitals and the patients we serve. After carefully reviewing the proposed rule, we believe it raises substantive issues and concerns directly affecting eye and ear specialty hospitals that need to be fully addressed prior to implementation.

Background

The AAEEH is comprised of the world's premier centers for specialized eye and ear procedures. Eye and ear specialty hospitals have led the way as providers of high-quality, cost-effective outpatient health care services. The mission of these specialty institutions requires that they maintain leading edge technologies, enabling them to provide highly specialized services not available in general hospitals. AAEEH member facilities serve as models of cost efficiency and high-quality care when surgery and services are rendered by specialty hospitals on an outpatient basis. Association members are major nation-wide referral centers with a commitment to teaching, research and hands-on patient care of the highest level of quality. These specialty hospitals routinely treat the most severely ill eye and ear patients.

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Eye and ear specialty hospitals experience large outpatient volumes and are heavily dependent on Medicare outpatient revenues. They are also the premier teaching settings for surgical residents specializing in ophthalmology and otolaryngology. Because eye and ear hospitals provide cutting edge expertise, they often incur higher costs. Despite these high costs, specialty eye and ear hospitals often have difficulty breaking even financially, leaving many Medicare beneficiaries without access to tertiary level eye care surgery and services. A compelling and disturbing fact is there are now only half the number of specialty eye and ear hospitals in the country than there was just over a decade ago.

Despite unprecedented pressures, eye and ear specialty hospitals remain the premier teaching settings for surgical residents specializing in ophthalmology and otolaryngology. Teaching institutions are under extreme pressure to maintain their academic programs while taking on Medicare payment cuts and added regulatory oversight. Payment rates must be maintained at least on par with medical inflation. If not, more of these specialty institutions will be forced to avoid utilization of the latest technologies and procedural advancements that can improve patient outcomes.

We urge CMS to maintain its appreciation of the value that eye and ear specialty hospitals provide to Medicare beneficiaries and set the payment rates accordingly.

Today, eye and ear specialty hospitals experience large outpatient volumes and are heavily dependent on Medicare outpatient revenues. As such, they are uniquely qualified to comment on certain aspects of the CMS's proposed hospital outpatient prospective payment system update. Clearly, there are implications this proposed rule will have on eye and ear specialty hospitals.

Calendar Year 2007 Payment Rates

The AAEEH extends our support for the increases in calendar year 2007 payments for the following services: APC 242 Level V Repair Plastic Eye procedures (21% increase); APC 245 Cataract Procedures without IOL insert (13% increase); APC 246 Cataract Procedures with IOL insert (4.5% increase); APC 247 Laser Eye Procedures Except Retinal (5.5% increase); APC 248 Laser Retinal procedures (10% increase); APC 673 Level IV Anterior Segment Eye procedures (32.5% increase); and, APC 699 Level IV Eye Tests and Treatment (61% increase). Analysis by the AAEEH members indicates that these increases will help lessen the impact that the previous rates had on the financial viability of treating these types of cases.

While supportive of the aforementioned increases, there were three notable proposed double-digit decreases in the proposed rule: APC 241 Level IV Repair and Plastic Eye Procedures (-15.3 percent), APC 235 Level I Posterior Segment Eye Procedures (-12 percent); APC 232 Level I Anterior Segment Eye Procedures (-10.5 percent). Analysis by the AAEEH members could provide no reasoning to support payment decreases of this magnitude for these three procedures. To the contrary for APC 235 and 232, our facilities maintain that costs per procedure for these two procedures have actually increased over the last year in the range of (4.1% increase). The AAEEH respectfully requests that CMS reexamine the payment adequacy for both APC 235 and 232.

2 Times Rule

The AAEEH and the eye community are pleased with the agency's recommendation to exempt the Level I Cataract Procedures without IOL insert from the 2 Times Rule and to keep these procedures in APC 245.

Conclusion

While is appears that the outpatient prospective payment system continues to mature, some of the outpatient payment rates continue to fluctuate. These changes make it extremely difficult for hospitals to appropriately plan and budget from year to year. While the agency proposes a number of policies that would help stabilize these rate changes, we are concerned that some issues remain. Not surprisingly, some of our institutional providers have evaluated the impact of the reimbursement changes on their slim operating margins and indicate that they may be forced to make decisions with negative consequences for Medicare beneficiaries.

Eye and ear specialty hospitals must have adequate funds to address critical issues they face, such as severe worker shortages, skyrocketing liability premiums, expensive drugs and technologies, aging facilities and expensive regulatory mandates. Because of our focus in ophthalmology and due to our patient mix, our hospitals today are some of the most efficient in the country when it comes to ambulatory procedures for Medicare beneficiaries. The American Association of Eye and Ear Hospitals has consistently argued that Medicare should pay adequate rates for efficiently provided care.

The AAEEH appreciates the opportunity to comment on this proposed rule. We respectfully request that consideration be given to the issues we raised while you finalize the regulation and offer to assist you in any way that we can. If you have any questions regarding our comments, please contact me at (703) 243-8848.

Sincerely,

Robert Betz, Ph.D.
Executive Director

BrainLAB

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October 6, 2006

Via Electronic Filing and Hand Delivery

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1506-P -- Comments to the HOPPS Proposed Rule:
APC Assignment for Stereoscopic X-ray Guidance: HCPCS Code C9722 / CPT 77421

Dear Dr. McClellan:

BrainLAB appreciates this opportunity to submit comments on the proposed rule updating the Medicare hospital outpatient prospective payment system ("HOPPS") as set forth in the Proposed Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2007, 71 Fed. Reg. 49506 (August 23, 2006).

BrainLAB develops, manufactures, and markets software-driven medical equipment to provide advanced radiotherapy, radiosurgery, and neurosurgery services, among other things. Accordingly, the company is keenly interested in the impact CMS's proposed changes to HOPPS payments for 2007 would have on its products and on patient access to the medical services performed using its technologies.

Specifically, BrainLAB wishes to comment on the insufficient payment rate proposed for CPT Code 77421 Stereoscopic x-ray guidance which describes our ExacTrac x-ray guidance system. As many of the CMS medical officers may recall, BrainLAB and a distinguished group of neurosurgeons from across the country worked with the Division of Outpatient Care, Dr. Bill Rogers (Director, PRIT Team), and various staff in the Administrator's office to obtain a new code for stereoscopic Kv x-ray (C9722 Stereoscopic Kv X-ray). CMS medical officers and staff made a trip to Philadelphia to see the Stereoscopic Kv x-ray technology and how it is used to more accurately guide radiation treatment for cancer patients. Subsequently for 2005, CMS established C9722 to describe the technology. C9722 transitioned to CPT code 77421, effective January 1, 2006.

Unfortunately, this first year of claim data for C9722 is at striking odds with the reality of the hospitals' costs. For the reasons explained in greater detail below, we **respectfully request that CMS reassign CPT 77421 to APC 296 Level II Therapeutic Radiologic Procedures to more accurately reflect the true costs associated with providing this very important service to cancer patients.**

Background on Technology and Procedure

The ExacTrac stereoscopic Kv x-ray guidance system uses a combination of Kv x-ray imaging and infrared tracking to correlate the exact location of internal tumors being treated with

radiation. The ability to visualize the exact location of a moving target in real-time enables more precise, respiration-triggered dose delivery of radiation therapy. As a result, significantly more normal tissue may be spared from radiation, leading to reduced side effects and better treatment outcomes for patients. This technology also permits verification of images at any time during treatment delivery.

In the HOPPS final rule for 2005, CMS recognized the value of stereoscopic Kv x-ray guidance with infrared tracking and established a temporary C code – C9722 –which became effective on January 1, 2005. Moreover, CMS encouraged the specialty societies to establish a new CPT code for this procedure and to "evaluate the resources necessary to provide this service" (see 69 Fed. Reg. at 65,714). The medical community and the AMA CPT worked together, and effective January 1, 2006 stereoscopic Kv x-ray was assigned a new CPT code, 77421 Stereoscopic x-ray guidance.[1] As part of this process, the specialty societies surveyed physicians using the technology and gathered data on the practice expense components (costs of supplies and equipment). In turn, this data was conveyed to CMS and staff further evaluated the practice expense data for the "technical' component. After this extensive process in 2006, CMS established that the costs related to the technical component for stereoscopic x-ray guidance should be valued at about $130 per procedure. BrainLAB's technology is currently the only procedure described by CPT code 77421.

Proposed Change and New APC Assignment

Under the HOPPS proposed rule for 2007, CMS proposes to assign CPT code 77421 to APC 257 Level I Therapeutic Radiologic Procedures. The $60.14 payment rate for APC 257, however, severely under-represents the true costs associated with providing ExacTrac Kv x-ray guidance services. APC 257 is designed for much simpler and less resource-intense procedures than ExacTrac stereoscopic Kv x-ray, which is far more sophisticated and technologically complex.

As you may recall, CPT 77421 stereoscopic Kv x-ray guidance for tumor localization requires, at minimum,

- Two infrared cameras;
- Computerized data system and image analysis system;
- Two 80-100 kiloelectron volt (Kv) x-ray tubes;
- Infrared sensitive tissue markers; and
- Specialized treatment planning software.

The procedure requires a radiation technician in addition to the physician and takes at least 15 to 30 minutes, per procedure.

Under the Medicare physician fee schedule (MPFS) for calendar year 2006, the global payment rate for CPT 77421 is $151.59, of which $131.13 represents the technical component for providing the service. As you know, in establishing payment under the MPFS for the technical component, the relevant specialty societies surveyed the physicians using this technology and carefully mapped out all the practice expense inputs. This cost information was

[1] Previously, ExacTrac was assigned to HCPCS code C9722.

then closely examined and reviewed by CMS staff prior to establishing the practice expense relative value units (RVUs) for stereoscopic Kv x-ray guidance, last year.

Given the extensive research and review that went into establishing the practice expense RVUs, we believe that in this particular instance, for this new and very sophisticated technology, it would be inappropriate to ignore the MPFS practice expense cost information. Thus, rather than using the very limited hospital claim data, we recommend that CMS use the cost data developed and reviewed for the MPFS to establish (or benchmark) payment for stereoscopic Kv x-ray. CMS has implemented a variety of buffering mechanisms and/or alternate data sources when proposed changes would result in significant reductions in payment. Therefore using the MPFS practice expense data to avoid radial reductions would be consistent with CMS's overall policy to preserve access to services potentially threatened by precipitous payment decreases.

Unintended Consequences–Impact of Improper APC Assignment and DRA Cap on MPFS

In the Deficient Reduction Act of 2005, Congress mandated that the MPFS payment for certain imaging services not exceed the HOPPS payment rate. Thus, in this instance, the proposed assignment of CPT 77421 to APC 257 with a payment rate of $60.14 also would result in more than a 50% cut in payment under the MPFS for this new therapeutic imaging guidance service, if the DRA cap is applied as proposed. For this reason, it is especially important for CMS to properly assign new imaging guidance technologies such as stereoscopic Kv x-ray guidance to the most appropriate APC.[2] We also believe that when CMS has more accurate cost information, as in this case, it is appropriate to use that information to avoid precipitous reductions in payment.

Wide Variation in Median Costs Supports using Mid-Point or Other CMS Data

CMS has based the proposed 2007 HOPPS payment for CPT 77421 on a small number of single claims from a very limited number of hospitals. We understand that the proposed payment is based on the "median" costs derived from these claims. However, taking a broader perspective on the claims file one sees that CMS's calculated costs for this procedure range from $15 to $316. Thus, we believe that the APC payment could be more accurately reflected by a payment amount in the $150 range (which is closer to the cost data reviewed under the MPFS).

Reassignment to Clinically Similar APC with Similar Resources

For all the reasons discussed above, BrainLAB encourages CMS to reassign CPT code 77421 to APC 296 Level II Therapeutic Radiologic Procedures. Assignment to this APC will be more appropriate clinically and will correspond to a much greater extent to the resources hospitals use to furnish stereoscopic Kv x-ray guidance procedures. The proposed payment rate for APC 296 in 2007 is $166.84. Other procedures under APC 296 include:

- 74480 X-ray control, cath insert, and

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[2] We support ACR and other specialty societies recommendations and feel that when imaging guidance is used to facilitate a surgical procedure or treatment, those codes should not be defined as diagnostic imaging nor included on the list of codes subject to the DRA provisions.

- 74485 X-ray guide, GU dilation.

Both of these procedures are similar in resource use (costs) and clinical complexity to stereoscopic Kv x-ray guidance to localize tumor/target volume.

Federal regulations state that APCs should include clinically similar procedures that involve similar resources. When, as with ExacTrac, hospitals are under-reimbursed because a CPT code has been incorrectly assigned, there is financial pressure not to perform the procedure. This is inconsistent with CMS' goal of ensuring access to clinically-appropriate care for all Medicare beneficiaries.

CMS can easily correct the problems caused by inadequate payment rates for ExacTrac X-ray guidance by reassigning CPT code 77421 to APC 296 or another APC which more accurately reflects the true costs associated with providing ExacTrac X-ray guidance services to cancer patients.

BrainLAB's ExacTrac X-ray product allows physicians to provide a more accurate treatment that improves medical outcomes for cancer patients undergoing radiation therapy. Therefore, we respectfully request that CMS act now to preserve patient access to this clinically valuable and economical technology by placing it into a more appropriate payment category such as APC 296 in 2007.

* * * *

We appreciate your attention to this important matter. Please contact me at 440.213.3951 or Gail Daubert at 202.414.9241 for any further information you may need.

Sincerely,

Jason Chandler

Jason Chandler
Director of Business Development, BrainLAB

cc: American College of Radiology, Pam Kassing, Director
Elizabeth Richter, Director, Hospital and Ambulatory Policy Group, CMS
Terry Kay, Deputy Director, Hospital and Ambulatory Policy Group, CMS
Carol Bazell, Director, Division of Outpatient Care, CMS
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October 10, 2006

VIA Hand Delivery and Email

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: **CMS-1506-P**
7500 Security Boulevard
Baltimore, Maryland 21244

RE: **CMS-1506-P** Proposed Changes to Hospital Outpatient Prospective Payment System for CY 2007 - Vaginal Prolapse/Hysterectomy Procedures: Inpatient Only and Insertion of Mesh

Dear Administrator McClellan:

On behalf of the Prolapse Repair Coalition (the "Coalition"), we welcome the opportunity to submit comments on the Centers for Medicare & Medicaid Services' ("CMS") Medicare hospital outpatient prospective payment system ("HOPPS") proposed rule for calendar year 2007 (the "Proposed Rule").[1] The Coalition is comprised of physicians who focus their practices on issues regarding pelvic prolapse and other disorders of the pelvic region and leading developers and manufacturers of gynecologic products, including American Medical Systems, Boston Scientific, C.R. Bard, and Gynecare/Ethicon, a Johnson & Johnson Company.

The Prolapse Repair Coalition encourages CMS to revise the status indicators and APC assignments of certain vaginal prolapse/mesh procedures so that they are eligible for payment under the Medicare program when performed in the hospital outpatient setting or assigned to more clinically appropriate APCs. Specifically, consistent with the APC Advisory Panel's recommendations from the March and August 2006 meetings, we urge CMS to:

Under the "Inpatient Only Procedures:

- Change the status indicators to "T" and assign CPT 57282 *Colpopexy, vaginal; extra-peritoneal approach* and CPT 57283 *Colpopexy, vaginal; intra-peritoneal approach* to APC 202 or create a new APC for Vaginal repair procedures with a payment rate of $3,000.
- Change the status indicators to "T" and create a new APC for certain vaginal hysterectomy procedures (listed below) and use APC 0132 as the benchmark for payment for the new APC.

Hospitals may be reluctant to furnish prolapse repair procedures and vaginal hysterectomies in the outpatient setting if CMS continues to list these services on the "Inpatient Only" list. Recognizing these procedures for HOPPS payments will provide patients with access to important treatment options in the most appropriate clinical setting.

Under the "Insertion of Mesh or Other Prosthesis:

- Assign CPT code +57267 to a clinically appropriate APC with a status indicator of "S" that is device dependent, and has a payment rate of at least $1,300.

[1] See Proposed Rule, 71 Fed. Reg. 49506 (August 23, 2006).

Inpatient Only Procedures and APC Panel Recommendations

In August 2006, the APC Advisory Panel unanimously agreed to support the Coalition's recommendations to designate selected colpopexy (prolapse repair) and vaginal hysterectomy codes as eligible for payment in the hospital outpatient setting by removing these two sets of CPT codes from the inpatient only list through a change of status indictor from "C" to "T".

Adopting these changes in the 2007 Final HOPPS Rule would be an important development in the care of women by allowing access to these procedures in a hospital outpatient setting. Specific details on the Coalition and APC Panel recommendations are outlined below.

Specific Recommendations Regarding Status Indicators for Prolapse Repair Procedures

Vaginal colpopexy procedures (CPT codes 57282 and 57283) have been performed in the United States since 1971. Subsequent modifications of the original technique together with new instruments to facilitate suture placement have made it possible to furnish this procedure in the hospital outpatient setting. More specifically, vaginal colpopexy procedures are performed under general or spinal anesthesia with the procedure lasting on average 65 minutes. In a prospective study of over 300 patients, only two had complications during surgery and only 7 had complications during the post-operative period (see M.A. Hefni, et. al.), leading to the conclusion that vaginal colpopexy is effective in the long-term restoration of vaginal apical support with a low complication rate.

The Coalition recommends changing the status indicator ("SI") from "C" to "T" for CPT codes 57282 and 57283 and assigning these procedures to APC 202 Level X Female Reproductive Procedures. CPT 57282 *Colpopexy, vaginal; extra-peritoneal approach* and CPT 57283 *Colpopexy, vaginal; intra-peritoneal approach* are clinically similar to other procedures used to address pelvic floor disorders, such as CPT code 57284 *Paravaginal defect repair.* CPT code 57284 has a status indicator of "T" and is assigned to APC 0202.

All three of these colpopexy/paravaginal defect repair procedures can be done through a vaginal incision. In the instance of CPT codes 57282 and 57283 the surgeon is performing a procedure to fixate ligaments, such as the sacrospinous ligament, for the purpose of correcting a vaginal vault inversion. This is similar clinically to the elements being performed in a paravaginal defect repair, CPT code 57284, where the paravaginal defect results from a disruption of the fibromuscular connective tissue. As is the technique with CPT codes 57282 and 57283, for CPT code 57284 the surgeon is seeking to fixate tissue, in this case, muscular tissue that comprises the anterior lateral edge of the vaginal wall.

In addition to being clinical similar to the procedures in APC 202, the procedures involve similar resources. Thus, changing the status indicators to "T" and assigning CPT 57282 *Colpopexy, vaginal; extra-peritoneal approach* and CPT 57283 *Colpopexy, vaginal; intra-peritoneal approach* to APC 202 is consistent with CMS's overall policy regarding APC assignment and the agency's goal of ensuring that Medicare patients have access to the appropriate procedure in the appropriate practice setting.

With regard to payment, the APC Panel recommended that CMS place these procedures in an appropriate paying APC based on extremely limited median cost data from two or three claims or zero claims for some procedures. The APC Advisory Panel indicated that the appropriate paying APC could include APC 202, among others. However, we wish to emphasize that for CPT 57282

Repair of vaginal prolapse, CMS had four claims with a median cost of $3,149. This would suggest that assignment to APC 202 with a payment of $2,639 would result in underpayment by about $500. For this reason, the Coalition would support creating a new APC for vaginal prolapse procedures with a payment rate of $3,000 for 2007.

Specific Recommendations Regarding Status Indicators for Vaginal Hysterectomy Procedures

Approximately 500,000 hysterectomies are performed each year in the United States. Subsequent modifications of the original technique (vaginal and laproscopic-assisted vaginal) together with new instruments have made it possible to perform vaginal hysterectomy procedures in the hospital outpatient setting with good results. More specifically, a large study with over four years of data and more than 400 procedures has shown that outpatient vaginal hysterectomy is a safe and effective treatment option for most women (See Levy, BS, MD, Outpatient vaginal hysterectomy is safe for patients and reduces institutional cost, Journal of Minimally Invasive Gynecology (2005) 12, 494-501). Moreover, the average direct cost for outpatient vaginal hysterectomy is lower than for inpatient vaginal hysterectomy.

The clinical literature clearly supports performing vaginal hysterectomy in the outpatient setting. For this reason, the Coalition recommends that CMS change the status indicator from "C" to "T" for the following CPT codes and assigning these procedures to a new APC with its payment based on APC 0132 – Level III Laparoscopy.

58260 Vaginal hysterectomy, for uterus 250 grams or less;
58262 Vaginal hysterectomy, ...; with removal of tube(s) and/or ovary(s)
58263 Vaginal hysterectomy, ...; with removal of tube(s) and/or ovary(s), with repair of enterocele
58270 Vaginal hysterectomy, ...; with repair of enterocele
58290 Vaginal hysterectomy, for uterus greater than 250 grams;
58291 Vaginal hysterectomy, ...; with removal of tube(s) and/or ovary(s)
58292 Vaginal hysterectomy, ...; with removal of tube(s) and/or ovary(s), with repair of enterocele
58294 Vaginal hysterectomy, ...; with repair of enterocele

APC 0132 includes laproscopic hysterectomy procedures that are clinically similar to vaginal hysterectomy procedures. With respect to resources including, devices, equipment and OR time, the costs/resources involved with the vaginal hysterectomy procedures are also similar to the costs of procedures in APC 0132. Therefore, using APC 0132 as the benchmark, the Coalition requests that CMS create at least one new APC as follows:

APC 013x – Vaginal Hysterectomy Procedure with a proposed payment of $4,363[2]

After a careful review of the existing APC, the Coalition feels that creating a new APC, which could directly follow APC 0132, is the best approach. The newly created APC would include, at least initially, the eight vaginal hysterectomy procedures listed above. It simply makes sense from both a clinical and resource perspective to group these procedures together in the new APC rather than trying to "fit" these procedures into an existing APC, such as APC 0202 which includes quite different procedures that involve different resources.

Further, based on initial cost estimates, the proposed payment for APC 202 at $2,639 would fall far short of appropriate payment (~$4,500) for the vaginal hysterectomy procedures.

[2] The payment rate for the new APC was based on cross-walking payment for the Level III Laparoscopy procedures which have similar hospital costs.

Insertion of Mesh or Other Prosthesis

The Coalition appreciates CMS addressing the issue raised at the March 2006 APC Panel Meeting regarding CPT code 57267 (Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site. We agree with CMS that APC 0154 (Hernia/Hydrocele Procedures) was an inappropriate APC assignment for CPT code 57267 from a clinical stand point and appreciate CMS proposing to assign the code to APC 0195 with other gynecologic surgical procedures. We would also continue to argue that the payment level of 50% of APC 0154 is too low and does not cover the cost of the mesh or other prosthesis. CPT code 57267 was implemented in 2005 as an add-on code. As such, it is never billed as a stand alone procedure and when assigned to an APC with a status indicator of "T" is subject to the multiple procedure discounting rules resulting in payment at 50% of the applicable APC rate. 50% of the payment rate for APC 0195 is similar to 50% of payment rate for APC 0154.

In reviewing the analysis performed by CMS regarding the median costs associated with CPT Code 57267, we would assert that an incorrect device code was used and thus the final product of the analysis understates the costs of the mesh or other prosthesis devices. CMS looked at claims billed with both CPT code 57267 and C1781-Mesh (implantable), but the devices mapped to C1781 are for hernia repair mesh (Transmittal A-01-41 from March 22, 2001), not for mesh devices used in pelvic floor repair procedures.

The two c-codes describing mesh devices used in pelvic floor graft augmentation procedures would be correctly billed under:

- C1762- Connective Tissue, human
- C1763- Connective Tissue, non-human

OPPS Data Shows Significantly Higher Median Costs

Since 57267 is an add-on CPT code and can never be billed alone, single coded claims are an inappropriate measure of median costs. CPT code 57267 is typically billed with the following cystocele and rectocele CPT codes:

- 57240 - Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele
- 57250 - Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy
- 57260 - Combined anteroposterior colporrhaphy;
- 57265 - Combined anteroposterior colporrhaphy; with enterocele repair

Since a correctly coded claim for a pelvic floor repair procedure with graft augmentation would include one cystocele/rectocele CPT code (from list above), CPT code 57267 and either C1762 or C1763, examining claims data showing those coding combinations is the only accurate way to measure costs for the add-on procedure. (The c-codes are needed to accurately reflect the device burden of correctly coded claims.)

Coalition member, Boston Scientific, conducted a 2005 OPPS claims data analysis using the parameters outlined above to demonstrate the true median cost for correctly coded pelvic floor repair procedures with graft insertion. Because cystocele/rectocele procedures can also be done without graft augmentation, we compared those procedures without graft insertion with those correctly coded claims where a graft or prosthesis was used. The table below details their results:

Procedure	Median Claim Cost		Dollar Difference	Percent Difference
	Without 57267 and either C1762 or C1763	With 57267 and either C1762 or C1763		
57240 - Cystocele repair	$2,914	$3,860	$946	32%
57250 - Rectocele repair	$2,370	$3,756	$1,386	59%
57260 - Combined A&P repair	$2,969	$4,182	$1,213	41%
57265 - Combined A&P repair w/enterocele	$3,200	$4,665	$1,465	46%
Average Difference			$1,254	45%

The average median claim cost for correctly coded cystocele/rectocele repair with graft insertion s $1,254 or 45% higher than for those same procedures performed without the graft insertion procedure. The proposed 2007 payment of $885 ($1,769.04 * 50%) falls well short of adequately covering the median costs for correctly coded claims. We believe this analysis demonstrates both the inadequacy of CMS' proposed payment and the device-intensive nature of 57267. Therefore, the Coalition would urge CMS to assign CPT code 57267 to an APC with a status indicator of "S" with a payment rate of $1,300 or to an APC with a status indicator of "T" where 50% of the payment is approximately $1,300.

Conclusion

In summary, the APC Advisory Panel has concurred with the Coalition's recommendations regarding removing the selected colpopexy and vaginal hysterectomy CPT codes from the inpatient only list by reassigning them from status indicator "C" to status indicator "T" and the change in APC assignment for CPT code 57267. Adoption of the APC panel's recommendation would ensure that vaginal hysterectomy and colpopexy procedures would be eligible for payment when furnished as outpatient procedures.

We appreciate the opportunity to submit these comments and we look forward to working with CMS to implement these important changes. Please feel free to contact me at 202.414.9241, if we can provide further information.

Sincerely,

Gail Daubert

Gail L. Daubert, Esq.
Counsel for the Coalition

cc: Carol Bazell, M.D., CMS
PRC members via email