Submitter : **Dr. Klaus Mergener** **Date: 10/10/2006**

Organization : **American Society for Gastrointestinal Endoscopy**

Category : **Physician**

Issue Areas/Comments

Device-Dependent APCs

Device-Dependent APCs

See attachment

CMS-1506-P-492-Attach-1.DOC

October 10, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1506-P

Dear Dr McClellan:

The American Society for Gastrointestinal Endoscopy (ASGE), the American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) welcome the opportunity to comment on the proposed changes to the hospital outpatient prospective payment system for 2007.

Proposed Payment for APC 0384

Our specific concern relates to the proposed payment for APC 384, GI procedures with stents. For 2007, the rate for this APC is proposed to be reduced from $1,600 to $1,395.84. We do not readily understand the reason for the reduction. The median costs for each of the three highest volume codes in this APC (Code 43256, 43268 and 43269), representing over 95 percent of the total volume of single claims in this APC, appears to have increased from 2004 to 2005. Intuitively, it seems to us that the payment rate for this APC should not be reduced for 2007.

However, since this is considered a "device dependent" APC, an adjustment is made to include only claims that include a separate charge for a C code for the device. For 2006, the final rule indicated this step increased the median costs for this APC from $1,262 to $1,598. For the 2007 proposed rule, CMS did not provide specific information as to the impact this adjustment had on the calculation of the median costs of this APC. Nevertheless, it is our understanding that the C code edit was not applied to all the codes in this APC.

Specifically, were informed that three of the codes within APC 0384 do not require a C-code in order to be billed, and therefore are not subjected to the edit requirements. These three procedures, which account for over 90% of the claims used in rate setting, are:

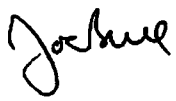
- Code 43268 - Endoscopic retrograde cholangiopancreatography (ERCP); with endoscopic retrograde insertion of tube or stent into bile or pancreatic duct
- Code 43269 - Endoscopic retrograde cholangiopancreatography (ERCP); with endoscopic retrograde removal of foreign body and/or change of tube or stent

- Code 43219 - Esophagoscopy, rigid or flexible; with insertion of plastic tube or stent

The device edits established for these codes indicates that a device code is optional in the case of some procedures reported under Codes 43219 and 43268. In the case of Code 43269, ERCP with endoscopic retrograde removal of foreign body and/or change of tube or stent, the use of a device is optional. The proportion of ERCP procedures performed under this code for removal of a foreign body that does not involve a change of tube or stent is, in our judgment, minimal. It is our professional opinion that a device is needed for virtually all services reported under Codes 43219, 43268 and 43269. We understand that if only claims including a separate charge for a device were included in the APC calculation, which was apparently the case for the 2006 rule, the proposed payment rate for this APC would be increased substantially. We therefore recommend that CMS recalculate the rate for this APC using only claims which included a separate charge for the device including claims for these three codes. This step is consistent with CMS' proposal for other device-dependent APCs, and reflects the APC Advisory Panel's August 2005 recommendation that the median costs for APC 0384 be determined using only those claims with C-codes. Moreover, we would point out that the Panel specifically expressed concern about the classification and payment for codes 43268 and 43269, which are the two highest volume codes in this APC (70 FR 68603 of the November 10, 2005, final rule).

We appreciate the opportunity to offer these comments.

Sincerely,



Joel V. Brill, MD
AGA representative to the CPT/RUC Advisory Committees

R. Bruce Cameron, MD
ACG/ASGE representative to the CPT Advisory Committee

Klaus Mergener, MD
ASGE representative to the RUC Advisory Committee

Submitter : Dr. Gregory Reaman **Date:** 10/10/2006

Organization : Children's Oncology Group

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-493-Attach-1.PDF

#1193

Children's Oncology Group

October 10, 2006

Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

RE: Proton Therapy Payment Rates

Dear Dr. McClellan:

We are writing to you on a matter of great importance to the proton therapy community. More than 40,000 cancer patients have been treated with proton therapy in many institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired biological effect on malignant tissue, has the clinical advantage of being significantly more precise in delivery. Positive clinical results at these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently two additional facilities opened in the United States this calendar year.

STATEMENT OF SUPPORT FOR THE PROPOSED CALENDAR 2007 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT RATES FOR PROTON THERAPY.

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which is as follows:

APC	CPT	CY'07 Proposed Payment Rate	CY'06 Payment Rate
0664	77520 and 77522	$1,136.83	$947.93
0667	77523 and 77525	$1,360.10	$1,134.08

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the National Payment rates for proton therapy are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States. Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

STATEMENTS OF CONCERN REGARDING FREESTANDING FACILITIES

For freestanding proton therapy centers the CMS has given its contracted Carriers significant latitude but limited guidance from which to determine payment rates for proton therapy.

We remain concerned with the manner in which contracted Carriers of the Centers have managed freestanding Proton Therapy Centers for Medicare and Medicaid Services in the State of Texas, Florida and Indiana. The existing or proposed proton therapy payment rates by State are as follows:

Group Chair
Gregory Reaman, M.D.

Group Vice Chair
Robert Castleberry, M.D.

Administrative Officer
Maura O'Leary, M.D.

Executive Officer
Anita Khayat, Ph.D., MBA

Group Statistician
James Anderson, Ph.D.

Group Chair's Office
4600 East West Highway, Suite 600
Bethesda, MD 20814-3457
Phone: (240) 235-2220
Fax: (301) 718-0047
greaman@childrensoncologygroup.org

Group Operations Center
440 E. Huntington Drive
Arcadia, CA 91006
Phone: (626) 447-0064
Fax: (626) 445-4334

Statistics & Data Center Headquarters
440 E. Huntington Drive
Arcadia, CA 91006
Phone: (626) 447-0064
Fax: (626) 445-4334

Gainesville Office
104 N. Main Street
Suite 600
Gainesville, FL 32601
Phone: (352) 273-0550
Fax: (352) 392-8162

Omaha Office
984350 University of Nebraska Medical Center
Omaha, Nebraska 68198-4350
Phone: (402) 559-4112
Fax: (402) 559-7259

A National Cancer Institute supported clinical cooperative group

Equal Opportunity Affirmative Action Institutions

Comparison of Freestanding Centers' Proton Therapy Rates by State			
	Indiana – Current	Florida – Proposed 9/11/06	Texas – 9/1/06
77520	—	$750.63	$652.75
77522	$496.83	$776.90	$653.90
77523	$811.33	$806.93	$783.79
77525	$856.12	$900.76	$954.41

As each State has its own CMS contracted Carrier, variations in existing CY'06 and proposed CY'07 proton therapy coverage and payment rates are occurring and are significant by comparison to CMS's National Payment Policy for protons as expressed in the OPPS rules.

Curtailing the development of proton beam therapy centers now through inadequate payment may have the negative long-term effect of precluding future cost reductions provided by proton beam therapy and not having this important therapy available to patients.

We are requesting that CMS direct its Carrier's on issues of payment proton therapy for Free-Standing centers so that their decisions are consistent with that of the CMS for HOPD.

It should be noted that due to the capital cost of proton therapy, both freestanding and HOPD centers have similar costs for patient treatments. The cost of treatment per fraction is consistent, if not higher, in both hospital based and freestanding facilities than the current 2006 APC payment rate. Given the great similarity of capital investment and operating costs of proton beam therapy centers, whether hospital-based or freestanding, this is an appropriate recommendation for CMS given the number of operating centers and patient demand for this valuable therapy.

In addition, we agree with the CMS that it is not appropriate for freestanding facilities to pursue a relative value unit (RVU) from the RUC for proton beam therapy. Due to the limited availability of this technology in the freestanding setting and the established coverage and payment policy established by CMS for hospital outpatient departments, we feel it is more appropriate to leverage the considerable work performed by CMS to establish payment for these setting across both hospital outpatient and freestanding facilities. The risk of not doing so may in effect limited the access of this technology to cancer patients around the country.

CONCLUSIONS

In conclusion, proton beam therapy has a recognized and desirable radiobiological effect on malignant tissue with the clinical advantage of being significantly more precise in the delivery, resulting in better health outcomes and fewer or less significant adverse side effects than other forms of radiation therapy.

We strongly agree with CMS's proposed CY'07 payment rule for proton beam therapy for Hospital Outpatient Departments.

We strongly urge CMS to direct its Carriers on matters concerning proton therapy payment so that CMS contracted Carriers determinations regarding proton therapy payment rates are in keeping with National Payment policy decisions, currently in effect for Hospital Outpatient Departments.

CMS thoroughly analyzes proton beam therapy claims and cost data in establishing payment rates for Hospital Outpatient Departments. CMS contracted Carriers should take advantage of vast work already performed on the part of the CMS when determining payment rates.

Sincerely,

Gregory H. Reaman, M.D.
Professor of Pediatrics
The George Washington University
School of Medicine and Health Sciences
Division of Hematology/Oncology
Children's National Medical Center
Chairman, Children's Oncology Group

Submitter : Ms. Kamenna Lee **Date:** 10/10/2006

Organization : American Red Cross

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Ms. Diana Blair** **Date: 10/10/2006**

Organization : **Wellmont Health System**

Category : **Hospital**

Issue Areas/Comments

OPPS: New HCPCS and CPT Codes

OPPS: New HCPCS and CPT Codes

IX. Proposed Hospital Coding and Payments for Visits

1. The proposed "G" codes for hospital EDs' and clinics' will continue to be another burdensome change and educational challenge for some providers. As we have currently 5 facility levels established we can allow some refinement within our own parameters for code defintion. But again CMS has had time to review claims data for several years and has not defined the guidelines for the proposed "G" codes. Each year hospital providers have asked for a national set of guidelines and yet CMS has not provided those to us. So we continue to see a discrepancy in how E&M/facility visits are billed and will continue to do so for another year.
2. The requirement that hospital coders will have to discern the amount of time spent on Critical CAre, each additional 30 minutes, is an unreasonable expectation for providers. Clinical staff have many areas of responsibility in an emergency department and this proposal will certainly be a burden on clinical, coding and billing staff.
3. I do concur that the establishment of Type A and Type B code sets is a reasonable proposal and will assist those providers who need to have better billing codes for the servics they provide.

Thank you,

Diana Blair
Billing Manager
Wellmont Health System

Submitter : Mr. Bruce McMaken **Date:** 10/10/2006

Organization : University of Texas, MD Anderson Cancer Center

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-496-Attach-1.PDF

#1196

MD ANDERSON CANCER CENTER
PROTON THERAPY CENTER

October 10, 2006

Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

RE: Proton Therapy Payment Rates

Dear Dr. McClellan:

We are writing to you on a matter of great importance to the cancer treatment community. More than 40,000 cancer patients have been treated with proton therapy in many institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired biological effect on malignant tissue, has the clinical advantage of being significantly more precise in delivery. Positive clinical results at these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently two additional facilities opened in the United States this calendar year.

1. STATEMENT OF SUPPORT FOR THE PROPOSED CALENDAR 2007 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT RATES FOR PROTON THERAPY

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for hospital-based proton beam therapy, which is as follows:

APC	CPT	CY'07 Proposed Payment Rate	CY'06 Payment Rate
0664	77520 and 77522	$1,136.83	$947.93
0667	77523 and 77525	$1,360.10	$1,134.08

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the national payment rates for proton therapy are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States. Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

2. STATEMENTS OF CONCERN REGARDING RATES FOR FREESTANDING FACILITIES

For freestanding (non hospital-based) proton therapy centers, the CMS has given its contracted carriers significant latitude but limited guidance from which to determine payment rates for proton therapy.

We remain concerned with the manner in which contracted carriers have dealt with rates for freestanding proton therapy centers in the states of Texas, Florida and Indiana. The existing or proposed proton therapy payment rates by state are as follows:

Comparison of Freestanding Centers' Proton Therapy Rates by State			
CPT	**Indiana – Current**	**Florida – Proposed 9/11/06**	**Texas – 9/1/06**
77520	-	$750.63	$652.75
77522	$516.36	$776.90	$653.90
77523	$782.43	$806.93	$783.79
77525	$782.43	$900.76	$954.41

As each state has its own CMS-contracted carrier, variations in existing CY'06 and proposed CY'07 proton therapy coverage and payment rates are occurring. Further, these carrier-determined rates are significantly less than under CMS's own National Payment Policy for protons as expressed in the OPPS rules.

Curtailing the development of freestanding proton beam therapy centers through inadequate payment rates may have the negative long-term effect of precluding future cost reductions provided by proton beam therapy and denying this important therapy to patients.

We are requesting that CMS direct its carriers regarding proton therapy rates for freestanding centers so that the rates are consistent with that of the CMS for hospital-based providers under the OPPS rules.

It should be noted that due to the capital cost of proton therapy facilities, both freestanding and hospital-based centers have similar costs for patient treatments. The cost of treatment per fraction is consistent, if not higher, in both hospital-based and freestanding facilities than the current 2006 APC payment rate. Given the great similarity of capital investment and operating costs of proton beam therapy centers, whether hospital-based or freestanding, this is an appropriate recommendation for CMS given the number of operating centers and patient demand for this valuable therapy.

In addition, we believe that it is not appropriate for freestanding facilities to pursue a relative value unit (RVU) from the RUC for proton beam therapy. Due to the limited availability of this technology in the freestanding setting and the established coverage and payment policy established by CMS for hospital outpatient departments, we feel it is more appropriate to leverage the considerable work performed by CMS to establish payment for these setting across both hospital-based and freestanding facilities. Not doing so may in effect limit access to this technology by cancer patients around the country.

3. CONCLUSIONS

In conclusion, proton beam therapy has a recognized and desirable radiobiological effect on malignant tissue with the clinical advantage of being significantly more precise in the delivery, resulting in better health outcomes and fewer or less significant adverse side effects than other forms of radiation therapy.

We strongly agree with CMS's proposed CY'07 payment rule for proton beam therapy for hospital outpatient departments.

We strongly urge CMS to direct its carriers regarding proton therapy payment rates for freestanding facilities so that these rates are consistent with national payment policy decisions currently in effect for hospital-based facilities.

Very truly yours,

Bruce R. McMaken
Managing Director

Submitter : Mr. Michael Romansky **Date:** 10/10/2006

Organization : Outpatient Ophthalmic Surgery Society

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P-497-Attach-1.PDF

#447

ASCRS OUTPATIENT OPHTHALMIC SURGERY SOCIETY, INC.

via Electronic Mail

October 10, 2006

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-P
P.O. Box 8013
Baltimore, MD 21244-8012

RE: CMS-1506-P; CMS-4125-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Ambulatory Surgical Center List of Covered Procedures; Ambulatory Surgical Center Payments System and CY2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient PPS Annual Payment Update Program—HCAHPS Survey, SCIP, and Mortality)

Dear Dr. McClellan:

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association representing over 1000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective outpatient surgical environments, particularly ambulatory surgical centers (ASC).

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing over 9,500 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures performed annually in ASCs and hospitals.

On behalf of OOSS and ASCRS, we are taking this opportunity to comment on the 2007 proposed Ambulatory Surgical Center Covered Procedures List, the New Technology Intraocular Lens (NTIOL) proposal, and elements of the Hospital Outpatient Prospective Payment System (HOPPS) rule, all of which were published in the August 23, 2006 Federal Register. We will provide further extensive comments on the FY 2008 ASC payment proposal, with respect to which comments are due on November 5, 2006.

New Technology Intraocular Lenses (NTIOL)

OOSS and ASCRS, as representatives of surgeons who operate in high-quality, lower-cost, and patient-friendly operative environments, are dedicated to ensuring that ophthalmologists are able to offer to our patients state-of-the-art vision-restoring technology, including intraocular lenses (IOL). Our organizations were integrally involved in the enactment of legislation and the promulgation of regulations to implement the NTIOL benefit that provides ASCs with an additional payment enabling ophthalmic surgeons to implant IOLs with advanced and innovative characteristics that offer patients improved surgical outcomes and quality of life. Through the NTIOL program, our patients have been afforded access to the Allergan AMO Array Multifocal lens, the STAAR Surgical Elastic Ultraviolet-Absorbing Silicone Posterior Chamber IOL with Toric Optic, and the AMO Tecnis and Alcon Acrysof IQ lenses, both of which reduce spherical aberration. Generally speaking, we support the changes CMS is proposing to modify the processes through the agency notifies the public regarding NTIOL approvals and revises the content of applications requesting NTIOL status. We do offer the following recommendations:

- OOSS and ASCRS agree that requiring additional information within the application for NTIOL status should enable CMS to more comprehensively assess the clinical benefits of applicants' NTIOL products, facilitating the adoption of appropriate designations and payment adjustments. However, application of these requirements by CMS should be guided by promoting, not inhibiting, access of patients to new technology.

- The enabling NTIOL regulation established a $50 additional payment for implantation of an NTIOL during cataract surgery. We believe that, in light of advances in cataract surgery technique and the availability of exceptional IOL products whose research, development and production costs exceed those of conventional lenses, the regulations should permit sponsors of new lens technologies to apply for payment adjustments that are greater than $50. Unless NTIOL payments adequately account for inflation in surgery centers' IOL acquisition costs, our patients will be denied optimal potential surgical outcomes. The proposed modifications to the NTIOL application and payment adjustment process should enable the agency to complete the requisite evaluation of an NTIOL's characteristics and costs. We would suggest that manufacturers of new lens products be afforded the opportunity of presenting to CMS dual submissions for agency review: (1) a request for approval of the applicant IOL to be approved for NTIOL status; and, (2) a request, based upon the submission of appropriate documentation, for the particular class of NTIOL to be eligible for a higher payment adjustment. In order to ensure maximum patient access to NTIOLs, the approval of a higher payment for a new NTIOL class, or a new lens within an existing class, should not affect the status of, or beneficiary access to, existing classes or lenses paid for at the standard $50 rate.

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY
P.O. Box 5256 • Johnson City, TN 37602-5256 • 866-246-9880 • Facsimile (423) 282-9712

- We are not recommending herein that an NTIOL category be extended beyond the five-year period embodied within the original regulation. However, it is imperative that, consistent with the HOPPS pass-through process, the base ASC facility payments for cataract surgery be upwardly adjusted after the five-year period, to appropriately reflect the adoption rates of these more costly lenses within the ASC setting.

- We support the agency's objective to codify the NTIOL review process to render it consistent with the annual notice and comment period that is proposed to be applied to the annual establishment of new payment rates for ASC services. We appreciate CMS' need for ample time to review NTIOL applications and support, where absolutely necessary, the extension of the NTIOL review period from 30 to 90 days. However, as discussed below, we would expect that NTIOL sponsor/agency contact during the course of new product development and study should mitigate the need for CMS to avail itself of review time in excess of 30 days. Regardless of the review time, upon completion of application review, patients should have immediate access to NTIOL products in the ASC. It appears that the agency is proposing that NTIOL application approvals be "batched" into one annual payment rule and effective date. To ensure timely beneficiary access to approved NTIOLs, our organizations believe that the agency should implement a process similar to the new technology pass-through system applicable to hospital outpatient surgical services under which newly designated NTIOLs are available to patients upon CMS approval throughout the course of the year.

- As noted above, it is imperative that patients enjoy expeditious access to advances in IOL technology; this is contingent upon manufacturers of these products being afforded timely access to all NTIOL submission requirements and a meaningful agency review of their applications. CMS is proposing to post NTIOL requirements on its website. We are concerned that lags in website updates may compromise an NTIOL sponsor's ability to design and implement requisite studies and generate data that will adequately support timely consideration and approval of an application. We would recommend that the proposed rule be reflective of CMS' practice of meeting with manufacturers throughout the study design and application processes to ensure that the agency's demands for documentation of an IOL's benefits are fully understood by applicants and are met upon submission of the application. Alternatively, the agency should review an NTIOL application under the criteria published on the CMS website at the time of submission. We believe any changes to the rule or criteria should be made only under notice and comment rulemaking as announced in the Federal Register.

CY 2007 Update to List of Covered Procedures

In our comments submitted to CMS with respect to the 2005 procedures list update, we objected to CMS' decision not to include **CPT Code 66990** (use of ophthalmic endoscope) on the list of

approved procedures. We reiterate our objection today with respect to the proposed rule. 66990 is an add-on code for a specific endoscopic surgical approach and does constitute surgery. It is reported on conjunction with many ophthalmic surgical services that are permitted and reimbursed in the ASC environment. Failure to include the code will result in these services being performed in the hospital inpatient or outpatient environments, at greater cost to the Medicare program and inconvenience to the beneficiary. We recommend that 66990 be added to the ASC list.

*****

Thank you for providing our organizations with the opportunity to present our comments on these important issues. We look forward to providing more extensive comments next month with respect to the proposed 2008 ASC payment system. Should you have any questions, please do not hesitate to contact our Washington representatives: Michael Romansky, Washington Counsel, OOSS at mromansky@ooss.org or at 302.332.6474; or Emily Graham, RHIT, CCS-P, CPC, ASCRS Manager of Regulatory Affairs at egraham@ascrs.org or 703-591-2220.

Sincerely,

Samuel Masket, MD
President, ASCRS

William Fishkind, MD
President, OOSS

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY
P.O. Box 5256 • Johnson City, TN 37602-5256 • 866-246-9880 • Facsimile (423) 282-9712

Submitter : Lynda Barton **Date:** 10/10/2006

Organization : South Texas Oncology and Hematology, PA

Category : Health Care Provider/Association

Issue Areas/Comments

New Technology APCs

New Technology APCs

SEE ATTACHED PDF DOCUMENT ... We appreciate the opportunity to submit comments on the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule published August 23, 2006 in the Federal Register Volume 71, No. 183 Part II 42 CFR Parts 410, 414, 416, 419, 421, 485, and 488 [CMS-1506-P; CMS-4125-P] RIN 0938-AO15, pages 49553 and 49544 New Technology APCs, Section c. Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

CMS-1506-P-498-Attach-1.PDF

#416

South Texas Oncology and Hematology, PA
7979 Wurzbach Road Suite U415
San Antonio, TX 78229

October 4, 2006

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

Re: New Technology APCs – Section c. Pages 49553 and 49554

We appreciate the opportunity to submit comments on the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule published August 23, 2006 in the Federal Register Volume 71, No. 183 Part II 42 CFR Parts 410, 414, 416, 419, 421, 485, and 488 [CMS-1506-P; CMS-4125-P] RIN 0938-AO15, pages 49553 and 49544 – New Technology APCs, Section c. Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

New Technology APCs

The Proposed Rule includes changes to the Ambulatory Payment Classifications (APCs) for G0339 (image-guided robotic stereotactic radiosurgery complete or first treatment) and G0340 (image-guided robotic stereotactic radiosurgery fractionated – treatments 2 through 5). Specifically the proposal is to move G0339 from APC 1528 to APC 0067 resulting in a reduction of ($1,190.39) per treatment. It is also proposed to move G0340 from APC 1525 to APC 0066 resulting in a reduction of ($833.32). These proposed revisions would result in a reduction in payment averaging ($2,857.03) per patient (based on the average treatment of three fractions per patient). A reduction of this magnitude for these codes would make it financially prohibitive for institutions to make this technology available to their patients. The proposed reductions were made based on the Center for Medicare and Medicaid Services (CMS) review of the Identifiable Data Set Hospital OPPS file for Calendar Years (CY) 2004 and 2005. We have serious concerns about this review, which we will enumerate in these comments. It is our hope that CMS will modify its proposed changes to payment codes and rates for both staged and single session image-guided robotic stereotactic radiosurgery, effective CY 2007. We request your assistance in setting reasonable Medicare rates for image-guided robotic stereotactic radiosurgery technology.

We want to acknowledge and applaud CMS' efforts over the past several years to continually improve its understanding of image-guided robotic stereotactic radiosurgery and maintain a process that allows for tracking of new technology claims. We would like to take this opportunity to further assist CMS in its efforts to establish appropriate payment rates for this technology and clarify the descriptor related to image-guided robotic stereotactic radiosurgery. To that end, we are supplying a brief overview of the development of the relevant codes and rates.

History of Medicare Coding and Payment for Image-Guided Robotic Stereotactic Radiosurgery (r-SRS)

CY 2002

In the November 30, 2001 Federal Register, CMS acknowledged that, "the APC assignment of (these) G codes and their payment rate was based on the understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session..."[1] Robotic radiosurgery treatment with the CyberKnife is, in fact, just the opposite – predominantly an outpatient staged treatment.

CMS also acknowledged that, "We did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services."[2]

Accordingly, in the November 30, 2001 Federal Register, CMS substantially altered the codes available for stereotactic radiosurgery and modified the then-existing code descriptors. The HCPCS Code used in CY 2001 for reporting stereotactic radiosurgery (for both Gamma Knife® and linear accelerator-based radiosurgery) was HCPCS Code G0173. In the November 30, 2001 Federal Register, CMS announced a modified descriptor for Code G0173 to limit its use to linear accelerator-based stereotactic radiosurgery. However, CMS did not distinguish between gantry-based and image-guided robotic radiosurgery systems because it did not have any data regarding the relative costs of image-guided stereotactic radiosurgery (e.g., the CyberKnife) and non-robotic LINAC-based stereotactic radiosurgery using more conventional technology. CMS assigned HCPCS Code G0173 to New Technology APC 0721 for CY 2002.

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum[3]. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery, fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 2002.

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[1] Federal Register, November 30, 2001, page 59865.
[2] Federal Register, November 30, 2001, page 59866.
[3] CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

CMS acknowledged in its Final Rule, published November 1, 2002, that there are significant fixed costs for all stereotactic radiosurgery, but they did not have enough cost data showing the current APC assignment for G0251 (APC 713) as inappropriate. In response, Georgetown University Hospital submitted cost data for CyberKnife treatment in December 2002. Stanford University Hospital submitted its cost data in January 2003. University of Southern California Keck School of Medicine submitted its cost data in February 2003.

CMS designated G0251 for treatment completed in stages, and priced the treatment using the payment for a single stage treatment (G0173), dividing the payment by 5, and allowing up to five payments. Under the payment methodology, each staged treatment was set at the national rate of $1,125, which did not reflect the consistent use and cost of resources for each treatment.[4] As a result of this initial payment rate calculation methodology, CyberKnife centers continued to be underpaid for treatments 2-5.

CY 2003

CMS agreed to revisit the APC assignments for all stereotactic radiosurgery procedures in 2003 when it had 2002 claims data available. The APC classification for G0173 was based on claims submitted in Calendar Year 2001, before the CyberKnife was used in any substantial way for clinical purposes in the United States. In CY 2001, there was only one HCPCS Code – G0173 – for stereotactic radiosurgery (complete course of treatment in one session), regardless of whether the treatment was provided using a LINAC or cobalt-based system (Gamma Knife®) and regardless of whether the treatment was performed in stages.

CY 2004

For 2004, CMS made certain changes to the HCPCS codes and APCs applicable to robotic stereotactic radiosurgery. CMS recognized new HCPCS codes for robotic stereotactic radiosurgery to distinguish these services from other linear accelerator-based (LINAC-based) SRS services that are substantially less resource-intensive. CMS established HCPCS G0339, which describes image-guided robotic LINAC-based SRS completed in one session (or the first of multiple sessions), and assigned this new code to New Technology APC 1528 -- the same APC used for other forms of SRS. CMS also established HCPCS G0340, which describes the second and any subsequent sessions of r-SRS (up to five sessions), and assigned this new code to New Technology APC 1525, with a rate that was approximately 70% of the rate for the first treatment or session. These decisions were made after a review of the available clinical, cost and other data. **We believe that the decisions that were made were – and are -- correct.**

CY 2005

For CY 2005, no changes were made to G0339 and G0340. In the OPPS final rule (69 FR 65711) CMS stated that ***"any SRS code changes would be premature without cost data to support a code restructuring"***. (CMS-1506-P, page 156).

[4] Federal Register November 30, 2001, page 59868

CY 2006

At the August, 2005 APC Panel meeting, stereotactic radiosurgery codes including G0339 and G0340 were discussed. The Data Subcommittee reported its analysis of the CY 2004 Identifiable Data Set Hospital OPPS file for all SRS codes. The data reflected significant cost differences among institutions billing the G0339 and G0340 codes, and resulted in the median costs of the procedures being lower than the current APC assignments warranted. The APC Panel's recommendation to CMS was to continue to reimburse G0339 and G0340 at their current APCs because of a lack of adequate and accurate data to assign a permanent APC. At the conclusion of the August, 2005 APC Panel meeting, the Panel recommended to CMS that no changes be made to SRS treatment delivery codes G0173. . . G0339, and G0340 (CMS-1506-P, page 157).

Proposed CY 2007 APC Changes

We believe that the changes proposed by CMS for CY 2007 are based on flawed methodology. The Hospital Outpatient Prospective Payment System (OPPS) was intended by Congress to be resource-based, as reflected in hospital cost and charge data. The question is ***whether the APC rates adopted by CMS for a covered service for which there is inadequate and inconsistent claims history appropriately reflect the relative clinical utility and whether the rate established by CMS reflects a reasonable estimate of the resources involved.***

There is no question that image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of LINAC-based SRS. In fact, it was for this reason that ***CMS created separate HCPCS codes to distinguish these two technologies in CY 2004. And yet for CY 2007 CMS proposes to place r-SRS and LINAC-based SRS back into the same APC.***

It is our understanding that CMS is required to have a minimum of two years of claims data before moving a HCPCS code from a new technology to a clinical APC. We believe that CMS does not have meaningful two-year data upon which to base the proposed changes to the APC placement of G0339 and G0340. We believe this for the following reasons:

1. The proposed APC classifications and rates are based on claims submitted in Calendar Years 2004 and 2005, before the CyberKnife® (the only true image-guided robotic stereotactic radiosurgery system on the market) was used in any substantial way for clinical purposes in the United States. In the beginning of CY 2004, there were only twelve (12) operational CyberKnife centers in the United States, with eight (8) of these centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

   By the end of CY 2005, there were thirty-five (35) centers operating: fifteen (15) of those centers began operations during that year. Forty-three percent (43%) of all operational CyberKnife centers submitted claims for less than a full calendar year.

Thus, although CMS looked at data from the years 2004 and 2005, they do not have claims data of two years' duration.

2. Further, our own analysis of the CY 2004 Identifiable Data Set Hospital OPPS file raises serious questions about the reliability of the claims as reported.

   The basis for determining the proposed APC rate for CY 2007 for image-guided robotic stereotactic radiosurgery was a review of claims data for G0339 and G0340. Of the 486 claims analyzed for 2004, 15% of the claims came from centers using the G0339 code which did not have an image-guided robotic stereotactic radiosurgery system. As a result, inclusion of their data in the calculation of the appropriate APC results in a lower median cost. The average cost, as indicated in the Identifiable Data Set Hospital OPPS file for CY 2004 for true image-guided robotic stereotactic centers (CyberKnife) is reported at $6,203.27 per unit. For non-CyberKnife centers, the average cost is $3,479.65. The range in costs and charges is not surprising since the code has been used by centers that do not provide image-guided robotic stereotactic radiosurgery services.

3. In addition, the 2004 Identifiable Data Set Hospital OPPS file does not include data for several of the most productive CyberKnife centers in the country which are also in large urban areas: Georgetown University Hospital had the 2nd highest procedure volume in the United States; Sinai Hospital in Baltimore, 6th highest procedure volume in the United States, and Miami CyberKnife Center with the 7th highest procedure volume in the United States. Other smaller, less urban centers are also not included.

   The total number of claims for both G0339 and G0340 in the CY 2004 Identifiable Data Set Hospital OPPS file is 1,311. The total CY 2004 Medicare claims for Georgetown University Hospital (an institution not included in the Identifiable Data Set Hospital OPPS file) was 282; Miami CyberKnife Center submitted 196 claims to Medicare in CY 2004. ***Georgetown and Miami's claims along with the other centers whose data was not included in the 2004 Identifiable Data Set Hospital OPPS file total, at a minimum, more than thirty-six percent (36%) of the total number of claims that were included in the 2004 Identifiable Data Set Hospital OPPS file for G0339 and G340 together.***

The CY 2004 Identifiable Data Set Hospital OPPS file clearly does not provide a sound basis for modifying the APC classification in light of the relatively low number of appropriate claims, the high number of centers contributing data for less than a full year for both CY 2004 and 2005, the number of claims not included in the Identifiable Data Set Hospital OPPS file that are nonetheless relevant when establishing median cost, and the extraordinary variation in costs caused by a mix of centers utilizing the G0339 and G0340 codes for all types of SRS procedures instead of exclusively for r-SRS procedures.

Historical Precedent – Gamma Knife New Technology Codes

We also note that CMS is proposing to assign the Gamma Knife to a higher APC, while reclassifying image-guided robotic radiosurgery to a lower APC. CMS noted that ***it is a "mature technology [with] stable median costs"*** (CMS-1506-P, p 157). This would be an accurate

reflection of the Gamma Knife, a technology in existence for 30 years with significant and mature data with which to establish an appropriate median cost.

Since the clinical process-of-care, resources utilized and related costs involved in providing intra- and extracranial image-guided robotic stereotactic radiosurgery using CyberKnife are at least as great as, if not greater than, the clinical process-of-care, resources utilized and related costs involved in the provision of intracranial radiosurgery using the Gamma Knife, the APC assignment should reflect a similar reimbursement. Gamma Knife was maintained in temporary APC status for nearly 30 years while data was collected for review and determination of final rate setting. The proposed APC assignment for image-guided robotic radiosurgery for CY 2007 is based on less than two full years of data as well as a small number of claims (a total of 486 single billed claims for G0339 and 940 billed claims for G0340 for CY 2004). The CY 2005 Identifiable Data Set Hospital OPPS file is not yet available to us for purchase and therefore has not been analyzed. However, we expect that these trends will be evident proportionally, and possibly exclude even more centers from the "common working file".

G0339 and G0340 Code Descriptors

Given the confusion of some centers in determining which code to use, a further refinement of the code language might distinguish the technologies. If non-robotic stereotactic radiosurgery centers continue to use the r-SRS codes in the future, it will be impossible for CMS to determine whether and to what extent the median costs for this service exceed the median cost of radiosurgery performed using modified LINACs, as we believe they do. We suggest that a more precise and accurate descriptor of ***image-guided robotic*** stereotactic radiosurgery is:

> Delivering radiobiologically ablative doses to stationary or moving planning target volume, in 1-5 fractions, with non-ablative radiation dose to non-target tissue, regardless of proximity to planning target volume. Identifying and correcting translational and rotational planning target volume targeting inaccuracy in real-time, through automated continuous feedback loop with <=0.5mm radial targeting error for stationary targets and <=1.5 mm radial targeting error for moving targets.

If the r-SRS code descriptors are not further refined it will be virtually impossible to determine appropriate APC rates in the future.

CY 2004 and CY 2005 Data Variability Summary

In 2004, 12 r-SRS centers were operating and 8 new centers started operation that that year. This was the first operational year for 67% of centers who had no established costs on which to set charges.

	# centers operating Jan 1st	New centers treating during year	% of centers in first year
2004 CY 2004	12	8	67%
2005 CY 2005	20	15	43%

Of the 25 centers reported in the 2004 Identifiable Data Set Hospital OPPS file using G0339 / G0340 – only 16 centers or 64% of those listed have dedicated image-guided robotic SRS equipment. The CY 2004 data is a mixture of data from all kinds of stereotactic radiosurgery procedures using various treatment modalities with vastly differing resource requirements. A clearer distinction among SRS codes through continued code descriptor refinement will help facilitate the collection of data for all types of SRS services and the eventual establishment of appropriate permanent rates for each, respectively.

Further, the CY 2004 Identifiable Data Set Hospital OPPS file for code G0339 for example, consists of only 486 claims with cost data ranging from $3,479.65 (non-robotic SRS centers) to $6,203.27 (for image-guided r-SRS centers).

We believe that this analysis establishes that the CY 2004 claims data available for image-guided robotic stereotactic radiosurgery do not currently provide a sound basis for modifying the APC classifications or the proposed CY 2007 payment rates for codes G0339 and G0340.

It was our hope to provide a similar analysis of the CY 2005 Identifiable Data Set Hospital OPPS file, which was to be released at the beginning of September. It was, however, recalled by CMS. We regret that the comment period was not adjusted to allow interested parties to review this important data in the preparation of their comments. As we have indicated, however, we expect the same problems will be evident in the CY 2005 Identifiable Data Set Hospital OPPS file and we urge CMS to review the 2005 data with our comments in mind.

Conclusion

The purpose of new technology HCPCS codes is to allow for collection of a comprehensive, stable data set with which to effect an analysis of the charges and costs associated with the new technology. We understand that two years is the statutory minimum amount of time for which CMS must have data before moving a covered service from a new technology code to a clinical code. In the case of CyberKnife, the minimum is insufficient. An analysis of two years of data is not enough due to the large number of new centers submitting less than a full year of data for 2004 and 2005 and the large number of centers with non-robotic equipment using the image-guided robotic stereotactic radiosurgery codes. Thus, while G0339 and G0340 are a vast improvement over the original SRS codes, they are still unclear and potentially misleading, resulting in a lower median cost as non-robotic SRS procedures are being billed using the image-guided robotic SRS codes. There is clear precedent for maintaining new technology codes well beyond the minimum two years. Gamma Knife, for example, was maintained in temporary new technology codes for the first thirty years of its use.

Image-guided robotic stereotactic radiosurgery is still developing, with the CyberKnife the only dedicated r-SRS system in use at this time. The majority of the centers are new, in full operation for one year or less. ***Thus the 2004 and 2005 Identifiable Data Set Hospital OPPS files result in an analysis of less than two full years of data. The data are not stable and do not accurately capture the resources used in r-SRS as is CMS's charge.*** We join the many stakeholders who urge you to look at external data in making your classification decisions. We have shared with

you the analysis the CyberKnife Coalition undertook, which we believe demonstrates the insufficiency of the CY 2004 and 2005 CMS data relative to SRS codes.

Recommendations

►No changes should be made in the APCs or payment rates for G0339 (APC 1528) and G0340 (APC 1525) for CY 2007.

►The code descriptor as proposed on page 16 for image-guided robotic stereotactic radiosurgery (r-SRS) could be used in a way that would promote more accurate capture of resources for all types of SRS procedures.

►CMS continue to work with CyberKnife centers to establish accurate and adequate reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Sincerely,

Lynn Kuhn, CPA
Chief Operating Officer
South Texas Oncology and Hematology, PA
South Texas Stereotactic Radiosurgery
Member CyberKnife Coalition

210-616-5763
lkuhn@ctrc.net

Submitter : Roger Sarao **Date:** 10/10/2006

Organization : New Jersey Hospital Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. Stephen McMillan **Date:** 10/10/2006

Organization : AstraZeneca Pharmaceuticals LP

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
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Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. Stephen Scannell **Date:** 10/10/2006

Organization : Jewish Hospital & St. Mary's HealthCare

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached

CMS-1506-P-501-Attach-1.PDF

#501

Jewish Hospital &
St. Mary's HealthCare

October 9, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-8011

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) & Calendar Year 2007 Payment Rates

The purpose of this correspondence is to submit Jewish Hospital & St. Mary's HealthCare, Inc.'s (JHSMH) comments and concerns regarding the proposed 2007 OPPS rule that was published in the Federal Register on August 8, 2006. JHSMS is a not-for profit health system with a network that encompasses 70 facilities and over 1900 inpatient beds. JHSMH recognizes the huge responsibility and amount of work borne by CMS to refine OPPS both to implement statutory requirements as well as to improve the system based on continuing experience and access to better data. We appreciate the efforts of CMS and the opportunity to provide input on proposed changes before they are finalized into policy. Please find below our comments, concerns, and suggestions related to specific provisions listed in the 2007 proposed rule.

APC Relative Weights
JHSMH supports the use of most recent claims and cost report data to set 2007 payment rates. We also support the expanded use multi-procedure claims or "pseudo" single claims, as we believe this practice will provide improved hospital cost estimates. However, when payment for a specific item or service drops precipitously and incongruently with easily demonstrable cost information, we urge that CMS use supplemental external cost sources to make appropriate adjustments in payment levels.

Outlier Payments
Outlier payments are important to supplement APC payment levels to hospitals to help offset hospital losses associated with high-cost cases. As a provider of many services involving new technology services with many involving high cost medical devices and drugs that may have payment rates that are, at least initially, inadequate to cover the costs of these services, we are concerned that increasing the fixed dollar outlier threshold to $1,825, $625 more than in 2006, will have a negative impact.

200 Abraham Flexner Way
Louisville, Kentucky 40202
(502) 587-4011 phone
(502) 587-4919 fax
www.jhsmh.org

Hyperbaric Oxygen Therapy
JHSMH, as a provider of hyperbaric oxygen services, is concerned that the CMS claims data does not accurately reflect the costs of this therapy because of potential hospital miscoding and use of hospital aggregate cost to charge ratios which do not reflect the accurate ratio for hyperbaric oxygen therapy. We believe the payment rate for C1300 is still inadequate as proposed and ask that the HBO2 payment rate be increased on the basis of external data provided by the Hyperbaric Oxygen Therapy Association to the APC Advisory Panel.

Device Dependent APCs
As Jewish Hospital performs a large number of outpatient procedures involving a medical device, we are very concerned that CMS use data sufficient to fairly project median costs. We support the packaging changes associated with APCs 107 and 108 which allowed more claims to be used in determining median costs and thus higher median values for these APSs.

E/M Services
JHSMH appreciates CMS taking steps to address the issue of national guidelines for evaluation and management services as the current lack of guidelines potentially puts hospitals at risk for lack of uniformity in coding as well as prevents CMS from being able to gather meaningful data that would assist in setting equitable and appropriate payment rates. We will monitor the development of draft national guidelines and appreciate CMS stated position to give hospitals ample time (6-12 months) to implement any new criteria.

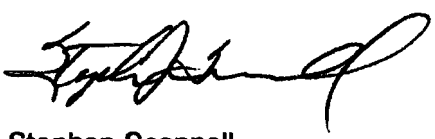
Inpatient-Only Procedures
JHSMH urges CMS to make policy modifications to allow for the procedure to be appealed and billed as an inpatient if the hospital is able to provide documentation as to the physician's intent, patient's clinical condition, and the circumstance that allowed the patient to be safely sent home with an admission. Inasmuch as physicians, not hospitals, determine where procedures can be safely performed, as well as whether the patient's condition warrants admission as an inpatient, it is unfair that the hospital is penalized if that procedure happens to be on the inpatient list.

CMS should also consider policy changes that would allow hospitals to change to the appropriate inpatient or outpatient status after patient discharge but before the patient or payor is billed. CMS' requirements should focus on ensuring that the beneficiary receives appropriate, quality care and the hospital bills correctly for the care given instead of relying on antiquated rules put in place when the inpatient prospective payment system was introduced and there was fear that some hospitals may try to game IPPS by making admissions outpatient and billing under what was, at that time, still a cost-based payment methodology. A change in this area would be applauded by the hospital industry and help smaller facilities to better focus limited utilization review resources on the quality of care instead of spending an inordinate amount of time chasing physicians different wording on a piece of paper before the patient is discharged.

Hospital Quality Data
JHSMH disagrees with CMS linking inpatient quality measures to the outpatient OPPS update. We believe that any link between quality improvement and payment for outpatient services should be based on outpatient quality measures.

Jewish Hospital & St. Mary's Healthcare, Inc., appreciates the opportunity to submit these comments. If you have any questions, please feel free to contact me.

Sincerely,



Stephen Scannell
Vice President of Finance/Associate Chief Financial Officer
Jewish Hospital & St. Mary's Healthcare, Inc.

CC: Mark B. Carter, Senior Vice President and Chief Financial Officer

Submitter : **Dr. Robert W. Glover** **Date: 10/10/2006**

Organization : **Nat. Asso. of State Mental Health Program Dir.**

Category : **Other Association**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

NASMHPD

National Association of State Mental Health Program Directors
66 Canal Center Plaza, Suite 302
Alexandria, Virginia 22314

October 10, 2006

Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Attention: CMS-1506-P

Subject: Partial Hospitalization

Dear Ms. Norwalk:

The National Association of State Mental Health Program Directors (NASMPD) appreciates the opportunity to comment on the Notice of Proposed Rulemaking (NPRM) regarding proposed payment for partial hospitalization programs (PHP) that may be provided by a hospital to its outpatients or by a community mental health center (CMHC).

NASMHPD represents the $26 billion public mental health service delivery systems serving 6.1 million people annually in all 50 states, four territories, and the District of Columbia. It is the only national association to represent state mental health commissioners/directors and their agencies. In addition, NASMHPD has an affiliation with the approximately 220 state psychiatric hospitals. Our members administer and manage community-based systems of care for the millions of individuals with serious mental illness who at times require immediate access to a variety of inpatient facilities and psychiatric units in general hospitals but are often cared for successfully on an outpatient basis.

NASMHPD commends the Centers for Medicare and Medicaid Services (CMS) for its long term efforts to structure a Medicare payment system that identifies the actual cost of providing services and pays for those services on a fair and equitable basis. The recent average 4 percent increase for inpatient psychiatric services is one example of bringing rates more into line with the true cost of providing services by taking into account changes in the costs of goods and services that have occurred over time.

On the other hand, the proposed decreases in payment for partial hospitalization programs (PHP) does not in our view reflect the actual changes in the cost of providing these services and could jeopardize their availability. Medicare payment policy should create incentives for the highest quality of care to be delivered in the most appropriate and cost effective setting. Partial hospitalization programs offer an excellent option for those individuals who do not require the level of intensity provided in an inpatient setting but need an array of services that are most efficiently and effectively provided in a partial hospitalization program. Partial hospitalization programs provide continuity of care for individuals being discharged from the hospital and also allow for shorter stays in the inpatient setting. Additionally, PHP provides a cost-effective alternative to inpatient hospitalization.

The multi-year decreases in payment for the PHP have already resulted in the closing of numerous community mental health center programs, placing additional stress on the overloaded inpatient hospital system. If the proposed 15 percent reduction in reimbursement for CY 2007 is adopted, it will have a devastating impact on PHP and the other acute care providers such as emergency departments that will experience increased demand.

NASMHPD strongly opposes these proposed cuts at a time when there is a deficit in acute care inpatient services of crisis proportions and encourages CMS to consider a positive update for CY 2007. We recommend that CMS convene a representative group of mental health providers and other experts to examine the current payment methodology and recommend improvements that ensure the availability of high-quality services at the most appropriate and cost effective level of care.

Sincerely,

Robert W. Glover
Executive Director

National Association of
State Mental Health Program Directors

Submitter : Roger Sarao **Date:** 10/10/2006

Organization : New Jersey Hospital Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. I forgot to save the attachment on my earlier submission (Temporary Comment Number 93456) -- please discard that one.

CMS-1506-P-503-Attach-1.DOC

#503

NJHA
NEW JERSEY HOSPITAL ASSOCIATION

October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W., Rm 445-G
Washington, DC 20201

Ref: [CMS-1506-P and CMS-4125-P] Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program - HCAHPS Survey, SCIP, and Mortality (71 Federal Register 49506), August 23, 2006.

Dear Dr. McClellan:

On behalf of the New Jersey Hospital Association's (NJHA) 114 member hospitals, health care systems and other health care organizations, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed rule establishing new policies and payment rates for the hospital outpatient prospective payment system (PPS) for calendar year (CY) 2007.

Our review of the proposed rule indicates that many ambulatory payment classification (APC) rates continue to fluctuate dramatically, with payments much lower or higher in 2007 than in 2006. These changes make it extremely difficult for hospitals to plan and budget from year to year. We would expect that four years after the start of the outpatient PPS, the payment rates and associated payment-to-cost ratios would be much more stable.

In addition to this instability, the entire outpatient PPS is underfunded, paying only 87 cents for every dollar of hospital outpatient care provided to Medicare beneficiaries. Hospitals must have adequate funds to address critical issues such as severe workforce shortages, increasing liability premiums, the rising cost of drugs and technologies, aging facilities, expensive regulatory mandates and more. The NJHA will continue to work with Congress to address inadequate payment rates and updates in order to ensure access to hospital-based outpatient services for Medicare beneficiaries.

OUTPATIENT PPS ISSUES

QUALITY REPORTING AND UPDATING OUTPATIENT PPS PAYMENTS

The NJHA and its member hospitals support the goal of public transparency of hospital quality information. For calendar year (CY) 2007, the Centers for Medicare & Medicaid Services (CMS) has proposed to use its authority under § 1833(t)(2)(E) of the *Social Security Act* to reduce the outpatient prospective payment system (PPS) update for those hospitals that fail to report quality data as required under the inpatient PPS. Specifically, CMS proposes to reduce the outpatient update by 2 percentage points for hospitals that fail to submit the quality data required for a full market basket update for the fiscal year (FY) 2007 inpatient PPS.

We are troubled by CMS' proposal for many reasons. First, it simply makes no sense to link outpatient payments to inpatient measures of quality. Second, linking a reduction in the conversion factor to the submission of inpatient PPS data that have already been reported and made public does nothing to further CMS' stated goals of encouraging hospital accountability and quality improvement. Third, linking payment to data submission that predates the outpatient PPS rule is unfair and tantamount to retroactive rulemaking. Fourth, in linking outpatient payments to the reporting of quality data, CMS has exceeded its statutory authority.

1. **CMS should not use inpatient quality measures in the outpatient setting.**
In the proposed rule, CMS asserts that the clinical quality measures for inpatient PPS are proxies for hospital outpatient performance measures and that outpatient-specific measures are needed for the outpatient setting. The inpatient PPS measures are not, in fact, appropriate proxies for outpatient PPS measures, for reasons articulated below.

The measures of heart attack, heart failure, pneumonia and surgical infection prevention are not appropriate proxies of outpatient care quality. These measures are based on solid scientific evidence about what constitutes effective treatment for patients with heart attack, who are undergoing major surgeries, or who are in heart failure or suffering from community-acquired pneumonia to the point that they require hospitalization. They reflect significant steps in the care of hospitalized patients that have been linked to clear medical evidence of improved patient outcomes if these steps are followed as the patients are admitted, during their hospitalization, and as they are discharged. In other words, the measures are specified in a manner that they apply only to patients who are admitted to the hospital. For example, we know that patients diagnosed with an acute myocardial infarction and who have no contraindications for receiving particular medications, have a better outcome if given aspirin and beta blockers within a short time of when they first present. We do not know whether patients who come to the emergency department with chest pain, are diagnosed with some condition other than a heart attack, and then go home, have a better outcome when they are given aspirin.

Furthermore, there is little or no relationship between the measures being used to assess the adequacy of care provided to an inpatient with a heart attack, heart failure, pneumonia and surgical care and an assessment of care to patients in the outpatient setting. In addition,

certain of the inpatient measures apply only during a hospitalization (e.g., whether the chosen antibiotic was discontinued after 24 hours if there is no indication of infection from surgery, or whether the patient was given medication to address his/her left ventricular systolic dysfunction) or when an inpatient is discharged (e.g., prescriptions for continuation of beta blockers). Effective quality measurement assesses whether the individual received the right care at the right time. While there may be some steps in caring for outpatients that are similar to those for patients requiring inpatient admission for heart failure and pneumonia, the guidelines overall will be different for the outpatient. **Linking the reporting of inpatient quality measures to outpatient payment creates a disconnect between the care setting and payment system.**

In the final inpatient PPS rule for FY 2007, CMS said "that stakeholder input is an essential part of the measure selection process." The Hospital Quality Alliance (HQA) and AQA (formerly known as the Ambulatory Quality Alliance) were established specifically to bring relevant stakeholders together to agree on effective measures of the quality of care for inpatient and ambulatory care settings and to find ways to make performance data available to the public.

We urge CMS to continue working with the HQA and AQA to identify and implement measures that truly assess aspects of outpatient care quality, and when appropriate measures have been identified, work with Congress to consider how the payment system should be altered to support the provision of high-quality care in the outpatient setting. **Because appropriate outpatient care measures have not been identified, CMS should eliminate any link between inpatient quality measures and outpatient hospital payments.**

2. The proposal does not further CMS' stated goals.
In the proposed outpatient rule, CMS said that "the collection and submission of performance data and the public reporting of comparative information about hospital performance can provide a strong incentive to encourage hospital accountability in general and quality improvement in particular." The NJHA agrees with this view. We disagree, however, with what appears to have been CMS' conclusion - albeit unstated - that linking outpatient payments to the submission of previously reported inpatient PPS quality data furthers CMS' stated goals.

Under CMS' proposal, outpatient payments would be reduced if a hospital failed to submit the data required for the inpatient PPS market basket update. Those data are based exclusively on inpatient quality measures. We see no way to encourage accountability or quality improvement in the outpatient setting by linking payment to inpatient performance measures. In addition, because obtaining the full market basket update under the inpatient PPS depends upon the submission of inpatient quality data, hospitals already have a very strong incentive to provide the inpatient PPS quality data to CMS. In fact, according to CMS' own data, 99 percent of affected hospitals share their data. Moreover, eligibility for the inpatient PPS market basket update has already been or will be determined before CMS publishes the outpatient PPS final rule. A hospital can do nothing now or once the final rule has been published to alter its eligibility for the inpatient PPS market basket update. Therefore, linking outpatient payments to the submission of inpatient PPS quality data provides no additional incentive for hospitals to submit those data.

3. Linking outpatient payments to the prior submission of inpatient data is tantamount to retroactive rulemaking.

As explained above, CMS has proposed to link payments under the outpatient PPS to eligibility for the full market basket update under the inpatient PPS; however, eligibility for the inpatient PPS market basket update has already been or will have been determined before CMS publishes its outpatient PPS final rule. Thus, hospitals can take no action now or, if CMS adopts this proposal in a final rule, in the future, to avoid a reduction in their CY 2007 outpatient PPS conversion factor. This is patently unfair and tantamount to retroactive rulemaking.

In the proposed outpatient PPS rule, CMS said the "determinations concerning which hospitals fail to meet the requirements for receiving the full update to the outpatient PPS conversion factor in CY 2007 will be available on or about September 1, 2006." That is long before the final outpatient PPS rule will be published. Thus, eligibility for CY 2007 outpatient PPS payments would be contingent on actions that occurred even before CMS established its CY outpatient PPS payment rules. Linking future reimbursement to actions that occurred in the past and which cannot be altered now is unjust and conflicts with the way in which CMS approached the submission of quality data under the inpatient PPS.

In responding to comments regarding the submission of quality data for the FY 2007 inpatient PPS update, CMS explained that its goal was to improve "quality through public reporting in an efficient manner that does not create an undue burden." (71 Fed. Reg. 48,032.) In the text that immediately followed, CMS went on to delay, by two calendar quarters from the quarter specified in the proposed rule, the date for requiring hospitals to submit quality data for an expanded set of inpatient PPS quality measures. CMS said that the delay "would afford hospitals adequate notice . . ." Id. at 48,033.

Because the inpatient PPS eligibility determination will have been made before the outpatient PPS rule is final, linking outpatient PPS payments to the inpatient PPS does nothing to improve data reporting; rather, it is simply a potential financial burden for hospitals. Similarly, if CMS wants to "afford hospitals adequate notice" in setting the date for requiring the submission of quality data under the outpatient PPS, then the agency should not now establish a rule that ties to a period in which hospitals lacked notice of CMS' plans. Doing so would be inequitable, at best.

4. CMS exceeded its statutory authority to "ensure equitable payments" in linking outpatient payments to eligibility for the inpatient PPS update.

In the preamble, CMS explained its proposal to link payment under the outpatient PPS to eligibility for the inpatient PPS market basket update. Specifically, CMS said:

> We are proposing to employ our equitable adjustment authority under section 1833(t)(2)(E) of the Act to adapt the quality improvement mechanism provided by the inpatient PPS . . . program for use in the outpatient PPS. As we have discussed above, failure to account at all for quality in payment systems raises a fundamental issue of payment equity. In the absence of mechanisms that provide incentives for higher quality care, Medicare's payment systems can direct more resources to hospitals that do not deliver high quality care to Medicare beneficiaries. (71 Fed. Reg. 49,667.)

In the NJHA's view, basing outpatient PPS payment on eligibility for the inpatient PPS update is anything but equitable. CMS goes to some lengths to argue in favor of accounting for quality in payment systems, but never explains how its outpatient PPS proposal would actually do that. In our view, the outpatient PPS discussion regarding "equitable adjustments" is a pretext for permitting CMS to do what Congress has never given the agency authority to do.

Congress expressly established the link between quality data reporting and the payment update in inpatient PPS and in the home health payment system. If Congress wanted outpatient PPS updates to be linked to reporting inpatient quality data, it would have made that change expressly. Because Congress did not explicitly authorize CMS to take such action, the agency has attempted to find authority for this unprecedented link elsewhere.

The NJHA believes that CMS has stretched too far in concluding that the "equitable payments" provision is that authority. CMS simply makes an unexplained and, we believe, inexplicable, leap in logic in concluding first, that the desirability of accounting for quality results in payment inequities in outpatient PPS, and second, that reducing the conversion factor is the means to address those inequities. This type of adjustment is not what Congress intended in enacting the "equitable payments" provision.

In the only case to have considered the breadth of the "equitable payments" provision, the U.S. Court of Appeals for the District of Columbia Circuit made clear that there is a legally significant distinction between an "adjustment" on the one hand and substantial departure from, or a restructuring of, a statutory scheme on the other hand. Amgen v. Smith, 357 F.3d 103 (D.C. Cir. 2004). The "equitable payments" provision permits the former and prohibits the latter.

Reducing the conversion factor as CMS proposes is a substantial departure from the statutory scheme and can hardly be called an "adjustment." As the D.C. Circuit said:

> Limitations on [CMS's] equitable adjustment authority inhere in the text of § [1833](t)(2)(E), which only authorizes "adjustments," not total elimination or severe restructuring of the statutory scheme." As in *MCI Telecommunications Corp. v. American Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994), where the Supreme Court held that the Federal Communications Commission's authority to "modify" certain requirements could not reasonably be read to encompass the power to make "basic and fundamental changes in the scheme" such as eliminating them entirely, similar limits inhere in the term "adjustments" to those the Supreme Court found in the word "modify." Id, at 117.

In this case, linking a reduction to the outpatient PPS conversion factor to submission of inpatient PPS quality data would be a "severe restructuring of the statutory scheme." The conversion factor is a crucial part of outpatient PPS and altering it can hardly be termed an "adjustment." CMS' authority under the "equitable payments" provision simply cannot "reasonably be read to encompass the power to make [such a] 'basic and fundamental change in the scheme.'" Id.

In summary, because Congress did not explicitly authorize CMS to link outpatient payment to inpatient data, CMS may not do so on its own. **Reliance on the "equitable payments"**

provision is misplaced and, as a result, CMS should not adopt the proposal to link outpatient PPS payments to eligibility for the inpatient PPS update.

PARTIAL HOSPITALIZATION

The NJHA is concerned that an additional proposed 15 percent reduction in the per-diem payment rate for partial hospitalization services could harm the financial viability of partial hospitalization services and could endanger Medicare beneficiary access to them. This will be the second consecutive year that the per-diem rate was reduced by 15 percent. Hospitals cannot sustain further reductions in the per-diem rates. These services are quite vulnerable, with many programs in recent years closing or limiting the number of patients they accept.

We share CMS' concern about the volatility of the community mental health center (CMHC) data and support the agency's intent to monitor and work with CMHCs to improve their reporting.

The NJHA recognizes that CMS made the proposal to avoid an even more significant reduction in the payment rate for these services that would be derived from using the combined hospital-based and CMHC median per-diem cost; however, hospitals offering partial hospitalization services should not be penalized for the instability in data reporting of CMHC-based services.

The NJHA recommends that in the final rule for 2007, CMS freeze payment rates for partial hospitalization services at the 2006 level of $245.65. This approach will provide payment stability for these services and protect beneficiary access while allowing CMS adequate time to address the instability in the CMHC data.

CLINIC AND ED VISITS

Background. Since April 2000, hospitals have been using the American Medical Association's (AMA) Current Procedural Terminology (CPT) evaluation and management (E/M) codes to report facility resources for clinic and emergency department (ED) visits. Recognizing that the E/M descriptors - designed to reflect the activities of physicians - did not adequately describe the range and mix of services provided by hospitals, CMS instructed hospitals to develop internal hospital guidelines to determine the level of clinic or ED services.

In the past several years, different models for national coding guidelines for reporting facility visit services have been proposed and reviewed by CMS. In 2002, CMS stated that it would not create new codes to replace existing CPT E/M codes for reporting hospital visits until national guidelines were developed, in response to the public's concern about implementing code definitions without national guidelines.

In 2003, the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) submitted recommended hospital E/M visit guidelines based on the work of an independent expert panel comprised of representatives with coding, health

information management, documentation, billing, nursing, finance, auditing and medical experience.

We appreciate CMS' consideration of the recommendations of the independent expert panel, and the posting of this recommendation for wider public input. While we have eagerly awaited national guidelines for hospital visits, we continue to support CMS' commitment to provide a minimum of 6-to-12 months notice prior to implementing national guidelines. Sufficient time is required for providers to make the necessary system changes and educate their staff.

Proposed Codes and Coding Policy for 2007. Despite CMS' previous assurances that it would not create new codes to replace existing CPT E/M codes until national guidelines were developed, in 2007 the agency proposes to establish new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, ED visits and critical care services. CMS proposes five levels of clinic visit G codes, five levels of ED visit G codes for two different types of EDs, and two critical care G codes. Until national guidelines are adopted, CMS states that hospitals may continue to use their existing internal guidelines to determine the visit levels to be reported with the new G codes, or they can adjust their guidelines to reflect the new codes and policies.

The NJHA opposes implementing new codes for hospital clinic and ED visits in the absence of accompanying national code definitions and national guidelines for their application. CMS should drop its proposal to create temporary level II G codes while requiring hospitals to apply their own internal guidelines to these codes. Instead, we recommend that CMS support the continued use of the current five level CPT codes, which would be assigned to the three existing APCs for hospital clinic and ED services until national coding definitions and guidelines are formally proposed, subjected to stakeholder review and finalized.

Creating temporary G codes without a fully developed set of national guidelines will increase confusion and require hospitals to manage two sets of codes - G codes for Medicare and CPT codes for non-Medicare payers - without the benefit of a standardized methodology or better claims data. In contrast, our approach would provide stability for hospitals in terms of coding and payment policy and allow CMS and stakeholders to focus on developing and fine-tuning a set of national hospital visit guidelines that could be applied to a new set of hospital visit codes in the future.

The NJHA recommends that once national guidelines are developed, a formal proposal should be presented to the AMA's CPT Editorial Panel to create CPT level I codes for hospital visits. Then hospitals could report these codes to all payers. We do not support the creation of temporary G codes as an interim step for a year or two, but prefer to wait for the implementation of CPT codes.

Proposed Payment Policy for 2007. CMS proposes to assign the new G codes to Ambulatory Payment Classifications (APCs) for payment purposes as follows:

- Five new clinic visit G codes would be assigned to five new clinic visit APCs.
- Five new type A ED visit G codes assigned to five new type A emergency visit APCs. (Type A = open 24 hours a day, seven days a week - 24/7)

- Five new type B ED visit G codes assigned to the five new clinic visit APCs. (Type B = not open 24/7)

- One new critical care G code (hosp critical care, 30-74 min) assigned to the new critical care APC. The other critical care G code (hosp critical care, additional 30 min) would be packaged into other services or procedures performed during the visit.

CMS asserts that paying for type B ED visits at the clinic visit rate is consistent with the agency's current policy for services furnished in EDs that have an *Emergency Medical Treatment and Labor Act* (EMTALA) obligation but do not meet the CPT definition of ED to be reported using clinic codes. The agency states, "Under the outpatient PPS, we have restricted the billing of emergency department CPT codes to services furnished at facilities that meet this CPT definition. Facilities open less than 24 hours should not use the emergency department codes."

In the proposed rule, CMS requests comments regarding this policy because the agency is concerned with ensuring that necessary ED services are available to rural Medicare beneficiaries, recognizing that rural EDs sometimes operate on a less than 24/7 basis. There are no EDs in New Jersey that are open less than 24/7. The NJHA believes that there are likely very few facilities that would currently meet the type B ED definition, and that most of these are remotely located EDs operated by hospitals with 24/7 on-site EDs. That said, the level of services in EDs varies based on the availability of other hospitals, general population size and availability of physician specialists.

In addition, in the proposed rule, CMS notes that the reporting of specific G codes for emergency visits provided in type B EDs will permit the agency to collect and analyze the hospital resource costs of visits to these facilities in order to determine whether a proposal of an alternative payment policy may be warranted in the future. The NJHA believes that CMS' proposed policy to establish different sets of ED visit codes for type A and type B facilities will not provide adequate data to allow a useful analysis of comparative costs to charges associated with the operation of these facilities. Hospitals that have both an on-site 24/7 ED as well as one or more remote non-24/7 EDs would report costs for both types of EDs under a single service category - emergency services. Rolling costs into the same cost report line would make it impossible to distinguish between the services provided in the type A versus type B ED.

We recommend that CMS create a unique revenue code for reporting non-24/7 ED services and modify the cost report to create another service category to allow separate reporting of those costs. With this structure, the billed services provided in the on-site 24/7 ED could be captured using a different revenue code from the billed services provided in the satellite non-24/7 ED. This would allow the matching of costs to charges. This approach also would make it unnecessary to establish a separate set of codes for type B EDs. Over time, reviewing cost report data combined with patient level-of-care data will help determine whether the costs of non-24/7 EDs are more similar to those of a clinic, a 24/7 ED, or somewhere in-between.

APC RELATIVE WEIGHTS

Proposed Recalibration of APC Relative Weights for 2007. Current law requires CMS to review and revise the relative payment weights for APCs at least annually. The NJHA continues to support the agency's use of hospital data, rather than data from other sources, to set the payment rates, as this information more accurately reflects the costs hospitals incur to provide outpatient services. However, since the August 2000 implementation of the outpatient PPS, payment rates for specific APCs have fluctuated dramatically. For 2007, the proposed rates continue to show significant volatility.

In the proposed rule, CMS uses the most recent claims data for outpatient services to set the 2007 weights and rates. The NJHA continues to support the use of the most recent claims and cost report data to set the 2007 payment weights and rates. We also continue to support the use of multi-procedure claims, as we believe these data improve hospital cost estimates. The NJHA also supports the expanded list of codes for bypass, as it appears unlikely that these codes would have charges that would be packaged into other services or procedures.

Proposed Revision to the Overall Cost-to-Charge Ratio (CCR) Calculation. The proposed rule includes a significant change in the way the overall hospital-specific CCR is calculated. CMS uses the overall hospital CCR to set outlier thresholds and to estimate outlier and pass-through payments and in other services paid based on charges reduced to costs. The fiscal intermediaries (FIs) use overall CCRs to determine outlier payments and payments for certain other services. CMS recently discovered that it calculates the overall hospital CCR differently than the FIs. Compared with the CMS "traditional" overall CCR calculation, the FIs' method includes allied health education costs and adds weighting by Medicare Part B charges. In the rule, CMS proposes to use features of both methods by excluding allied health education costs and adopting weighting by Medicare Part B charges.

It is important to have a consistent methodology for setting policy, modeling impacts and making outpatient PPS payments. In addition, the decisions to exclude allied health education costs and to adopt weighting by Medicare Part B charges are appropriate policy decisions. **Therefore, the NJHA supports CMS' proposal to adopt a single overall CCR calculation that incorporates weighting by Medicare Part B charges and excludes allied health costs for modeling and payment.**

Proposed Changes to Packaged Services. The NJHA commends CMS and the APC Packaging Subcommittee for continuing to address provider concerns that many packaged services ("N" status code services) could be provided alone, without any other separately payable services on the claim. In the rare circumstances in which a hospital provides services described by these "N" status codes alone, there is no way for the hospital to be reimbursed for the cost of providing these services.

The NJHA supports the proposed designation of specific CPT codes as "special packaged codes" with status indicator "Q" that will be used for separate payment of these services when they are billed on a date of service without any other separately payable outpatient PPS service. We encourage CMS to continue to work with the APC Packaging Subcommittee to further review "N" status codes and identify those services that should be paid separately.

OUTLIER PAYMENTS

Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. For 2007, CMS proposes to retain the outlier pool at 1 percent of total outpatient PPS payments. Further, CMS proposes to raise the fixed-dollar threshold to $1,875 - $625 more than in 2006 - to ensure that outlier spending does not exceed the reduced outlier target. This increase in the fixed-dollar threshold is largely due to the projected overpayment of outliers resulting from the change in the CCR methodology. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment amount and at least $1,875 more than the APC payment amount.

We are concerned that CMS has set the threshold for outliers too high. With the significant changes to outlier policies, including the methodology for calculating the hospital-specific CCR proposed for 2007, the NJHA is concerned that Medicare may not spend the targeted outlier pool.

NEW TECHNOLOGY APCS

CMS proposes to assign 23 services from new technology APCs to clinically appropriate APCs. CMS generally retains a service within a new technology APC group for at least two years, unless the agency believes it has collected sufficient claims data before that time. In the proposed rule, CMS proposes to assign some services that have been paid under the new technology APCs for less than two years to clinically appropriate APCs. For example, positron emission tomography (PET)/computed tomography (CT) scans, which had been assigned to new technology APC 1514 in 2005, is scheduled to move to a clinical APC in 2007. Some hospitals that adopt these new technologies may be unable to change their charge masters quickly, including changing codes and setting charges that reflect actual costs of the new service. Additionally, the data that CMS obtains in the first year or two of adoption of these technologies may not appropriately reflect the use and cost of these services because diffusion of new technologies can be slow, and waiting additional years for more hospitals to adopt and use new technology is important. **Therefore, the NJHA recommends that when CMS assigns a new service to a new technology APC, the service should remain a new technology APC for at least two years until sufficient claims data are collected.**

RADIOLOGY PROCEDURES

In the proposed rule, CMS indicates that it will continue to defer the implementation of a multiple imaging procedure payment reduction policy pending further analyses. **The NJHA supports CMS' decision not to implement this policy.** As we commented last year, the NJHA opposes this policy without better justification and more substantial hospital-based data analyses. Hospital cost data currently reflect efficiencies gained when multiple images are performed, leading to lower cost estimates across all procedures.

In the proposed rule CMS requests comments on ways that hospitals can uniformly and consistently report charges and costs related to all cost centers that also acknowledge the

tradeoff between a greater precision in developing CCRs and the administrative burden associated with reduced flexibility in hospital accounting practices.

The NJHA appreciates CMS' evenhanded presentation of this issue in the proposed rule. As CMS notes, any step taken to ensure greater uniformity in the reporting of costs and charges would have to carefully balance the additional administrative burden and loss of flexibility in a hospital's accounting system.

The difficulty in applying CCR ratios to arrive at cost is that it presupposes that there is consistency in how HCPCS procedure codes relate to the service categories indicated on the cost report. The cost report relies on service categories that reflect the general descriptor of a provider's service departments. But other departments can now safely and effectively perform services that were once performed by a specialized departmental unit. For instance, bedside lab tests are now performed in the ED; procedures can be furnished in an operating room, treatment room or outpatient surgery area; and supplies cross multiple departments. Consequently, inconsistencies occur when determining the cost of a service if the CCR assignment is made to a different cost report service category.

CMS also must recognize the current limitations and inconsistencies in preparing the cost report. Today, providers must reconcile the Medicare Provider Statistical & Reimbursement reports to determine how FIs not only paid the claim but also how they recorded the units and revenue code assignment to the billed services. Often the FI makes changes that affect how the services and revenue matches are made. Such changes by the FI, however, fail to match the revenue as reported by the provider on the cost report.

The NJHA urges CMS to proceed with care in this area. Hospitals need the flexibility to set charges and allocate costs in a manner that makes the most sense for the particular mix of services it offers. In addition, even relatively small changes in practices and procedures need to take into account the varying levels of sophistication of provider accounting systems. CMS must allow adequate time for dissemination of changes, and provider education on any changes is imperative.

DEVICE-DEPENDENT APC

Devices Replaced without Cost or with Credit to the Hospital. CMS proposes to reduce the APC payment and beneficiary copayment for selected APCs when an implanted device is replaced without cost to the hospital or with full credit for the removed device. This is in response to device recalls and field actions involving the failure of implantable devices for which manufacturers offer to replace devices without cost to the hospital or to offer credit for the device being replaced if the patient requires a more expensive one. CMS proposes to calculate the reduction to the APC payment rate using the same method it uses to calculate the pass-through rate for implanted pass-through devices. The adjustment would be implemented through the use of an appropriate modifier specific to a device that has been replaced.

Neither the Medicare program nor Medicare beneficiaries should be required to pay hospitals for devices that were provided to the hospital at no cost. In addition, while there are additional burdens on hospitals associated with imposing this new policy, hospitals have been

required since January 1 to use the FB modifier with the HCPCS code for a device that was furnished to the hospital without cost. Therefore, this is not an entirely new type of policy for hospitals. **The NJHA requests that CMS clarify whether and how this FB modifier would be used once the new policy goes into effect.**

Further, as CMS acknowledges in the proposed rule, the FB modifier may not be used appropriately if the replacement device is an upgrade from the device that is being removed from the patient. In any given recall, 10-20 percent of replaced devices could result in upgrades - the physician opts to use a higher functioning device over the one being replaced in order to meet the patient's current clinical needs. In these cases, the hospital would be responsible for paying the price difference between the upgraded device to be implanted and the replaced device that is being removed. This price difference may be significant. For instance, in the case of implantable cardiac defibrillators, the hospital payment for the difference between the upgraded and replaced device could range between $1,000 and $7,000.

The NJHA recommends that CMS revise its proposal to account for the additional cost that the hospital would bear in the event of a device upgrade. This could be accomplished through the use of a second modifier or another approach to identify when the replacement procedure involves an upgraded device. The APC offset for an upgraded device replacement should be set at a lower percentage than the APC offset made for an "even" device replacement.

OPPS: NONPASS-THROUGH DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Proposed Payment for Specified Covered Outpatient Drugs. The NJHA is concerned about CMS' proposal to reduce payments for specified covered outpatient drugs (SCODs) to the average sales price (ASP) plus 5 percent in 2007. This represents a 1 percent reduction from the ASP plus 6 percent rate in 2006. This payment reduction means that drugs and biologicals provided in hospital outpatient departments would be reimbursed at a rate less than the ASP plus 6 percent rate paid in a physician office. **Consistency in payment for drugs and biologicals across settings is important, which is why the NJHA recommends that CMS maintain the payment rates for drugs at the rate of ASP plus 6 percent for 2007.**

In addition, as we commented last year, the NJHA agrees with the Medicare Payment Advisory Commission that handling costs for drugs and biologicals delivered in the hospital outpatient department is significant and should be reimbursed by Medicare. We remain concerned that payments for SCODs at the proposed rate for 2007, or even at the 2006 rate of ASP plus 6 percent, does not adequately reimburse hospitals for drugs that have very high overhead and handling costs due to special equipment or procedures related to a drug's toxicity, special compounding or preparation requirements. **The NJHA recommends that CMS work with stakeholders to understand better the costs involved in the preparation of pharmaceutical agents, particularly those drugs that have very high handling costs.** CMS should develop a new payment methodology that acknowledges and provides appropriate payment for those costs.

Payment Policy for Radiopharmaceuticals. CMS proposes to no longer pay for radiopharmaceutical agents at the hospital charge reduced to cost and instead to pay for

them at aggregate hospital mean costs as derived from the 2005 claims data. For brachytherapy sources, CMS proposes to pay on the basis of claims-based median cost per source for each brachytherapy device. We believe the claims data still are incomplete and may be incorrect as a result of frequent code and descriptor changes for radiopharmaceuticals. **Therefore, the NJHA recommends that for 2007, CMS continue to use the current methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources.**

OPPS: Observation Services

For 2007, CMS proposes to continue applying the criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in 2006. The NJHA continues to support CMS' concept of allowing the Outpatient Claims Editor logic to determine whether observation services are separately payable. This has resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services.

In addition, now that the process for determining whether observation is separately payable is largely "automated," CMS should explore a narrow expansion in the diagnoses for which observation may be separately paid. **Therefore, the NJHA recommends that CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment.** This is consistent with a recent recommendation from the Advisory Panel on APC Groups.

Proposed Procedures that will be Paid Only as Inpatient Procedures

CMS proposes to remove eight codes from the inpatient-only list, which identifies services that are ineligible for payment if they are performed in an outpatient setting, and assign them to clinically appropriate APCs.

The NJHA remains concerned about the inconsistency between Medicare payment policy for physicians and hospitals with regard to procedures on the inpatient-only list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient-only list are performed in outpatient settings, physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, because the inpatient-only list changes annually, physicians may not always be aware that a procedure they have scheduled in an outpatient department is on the inpatient-only list. There also may be other reasonable, but rare, clinical circumstances that may result in these procedures occurring in the absence of an inpatient admission.

The NJHA continues to recommend that CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient-only list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent,

patient's clinical condition, and the circumstances that allow this patient to be sent home safely without an inpatient admission.

OTHER POLICY ISSUES

FY 2008 IPPS REPORTING OF HOSPITAL QUALITY DATA FOR ANNUAL PAYMENT UPDATE (RHQDAPU)

In the proposed rule, CMS announces the measures that hospitals paid under the Medicare acute care hospital inpatient PPS must submit in order to receive the full inpatient payment in FY 2008. Under the DRA, hospitals that fail to submit these measures and the other quality measures that are currently required would have their FY 2008 inpatient payments reduced by 2 percent.

The NJHA applauds CMS for adding to its requirements for obtaining full inpatient payment in FY 2008 measures that have been adopted by the HQA. These well-designed measures represent aspects of care that are important to patients and provide insights into the safety, efficiency, effectiveness and patient-centeredness of care. **We urge CMS to continue to align its choices of measures to link to payment with the measures chosen by the HQA.** This alignment will reinforce the importance of public transparency on quality and help focus quality improvement efforts on the chosen high-priority areas of care.

We also commend CMS for proposing in August the measures that hospitals will be required to report to receive their full FY 2008 inpatient payments. This early notice allows hospitals sufficient time to establish the proper data collection processes. We urge CMS to continue with this timely rulemaking - using the proposed rule for outpatient PPS or a freestanding quality reporting rule - as a mechanism to notify hospitals several months in advance of the inpatient PPS quality reporting requirements for the upcoming fiscal year.

The NJHA appreciates the opportunity to comment on the proposed rule establishing new policies and payment rates for the hospital outpatient PPS for CY 2007. If you have questions, please feel free to contact me or Roger Sarao, assistant vice president of Health Economics, at 609-275-4024.

Sincerely,

Sean Hopkins
Senior Vice President