

CMS-1501-P-561

Submitter : Dr. Michael F. Hogan
Organization : Ohio Department of Mental Health
Category : State Government

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-561-Attach-1.PDF

CMS-1501-P-561-Attach-2.PDF



Ohio Department of Mental Health

30 East Broad Street
Columbus, Ohio 43215-3430

September 16, 2005

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Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-CMS-1501-P

Thank you for the opportunity to provide comments regarding CMS' proposed Out Patient Psychiatric Service rates concerning Partial Hospitalization Services.

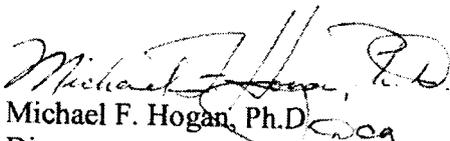
Intensive out-patient and partial hospitalization programs are a less restrictive and less costly alternative to inpatient hospitalization. We believe the current supply of Intensive Outpatient and Partial Hospitalization services is not adequate. Additionally, Ohio and national trends (as documented by The President's New Freedom Commission on Mental Health) demonstrate acute inpatient services are increasingly stressed.

We are concerned that the proposed cuts to the reimbursement rates will further strain outpatient and then inpatient hospitals, and shift patients and costs to state supported mental health systems. Acute care hospital capacity is already showing a swing due to the deterioration of access from closure of private psychiatric units. I have attached a report documenting this trend in Ohio.

We respectfully ask that you reconsider the proposed 15 percent cut. These important programs need to be supported by reasonable reimbursement rates, and I know of no evidence suggesting that current rates are excessive or that the supply of these services is too great.

Thank you for your consideration. Please let me know if you have questions or would like further information regarding this issue. I would be happy to discuss this with you.

Sincerely,


Michael F. Hogan, Ph.D.
Director

Submitter : Mr. Robert Saner
Organization : Pain Care Coalition
Category : Health Care Professional or Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-562-Attach-1.DOC

PAIN CARE COALITION

A National Coalition for Responsible Pain Care

American Academy of Pain Medicine • American Headache Society • American Pain Society
American Society of Anesthesiologists

September 16, 2005

Mark McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, D.C.

Attn: CMS-1501-P

Dear Dr. McClellan:

I am pleased to submit these comments on behalf of the Pain Care Coalition in connection with the agency's proposed hospital outpatient rule for FY 2006. The constituent members of the Pain Care Coalition represent practitioners, researchers and educators dedicated to advancing responsible pain care policies at the federal level which insure patient access to appropriate diagnosis and treatment for acute and chronic pain.

Pain is a tremendous public health problem in this country. It imposes an enormous toll of human suffering on patients and their families. It is well documented that pain is often under treated across demographic groups and care settings. It is a leading cause of lost productivity in the work place and often leads to partial or total disability. It accompanies a wide array of diseases and conditions that are heavily represented in the Medicare population, including arthritis, diabetes, and cancer. For other Medicare beneficiaries, pain is the disease or condition as is the case with migraine or chronic back pain. Given the prevalence of pain in the beneficiary population, it is critically important that Medicare coverage and reimbursement policies insure appropriate access to the wide range of diagnostic and therapeutic modalities now available in different care settings to alleviate suffering and improve health and disability outcomes for acute and chronic pain patients.

One policy area of tremendous consequence to pain patients and those who serve them is the area of new technologies. As new devices are proven safe and effective for the treatment of pain, their dissemination through care settings and ultimately their availability to patients depends on fair treatment in the agency's various payment systems. The comments below focus on certain technology issues in the hospital outpatient rule. Similar considerations should apply under the inpatient PPS system and in ambulatory surgery centers where these same technologies are utilized.

Pass-Through Device Categories and Criteria

Implantable devices represent important weapons in the arsenal of effective pain care. While appropriate for relatively modest numbers of patients at the current time (given the tens of millions who suffer from acute or chronic pain), these devices hold great promise for many. As various technologies reach the market, they often provide significant advances in clinical care as well as different cost considerations from those built into the current APC rates, even if they represent only enhancements to previously utilized technologies. Eligibility for transitional pass through treatment for such technology enhancements is critical to making them available to the Medicare population.

For this reason, the Coalition **strongly supports** the proposed change to section 419.66 (c) of the regulations and the suggested method of applying this new test in the creation of new pass through categories as set forth at 70 Fed Reg 42721. The Coalition encourages CMS to reach out to professional organizations in the pain field, as well as to device manufacturers, as it assesses specific devices to determine whether a new or modified device seeking pass through treatment represents a significant clinical improvement relative to other devices already in use.

The development of implantable neurostimulators with rechargeable technology is a good example of a device that should benefit from this change. The existing category for neurostimulators, C1767, does not appropriately describe the new rechargeable devices. As CMS has already determined in the context of the inpatient PPS rule for 2006 that rechargeable IPG neurostimulators provide a substantial clinical improvement over previous technologies, there should be no reason for delay in creating a new device category for purposes of outpatient pass through payments in 2006.

“2 Times Rule”

The Coalition **does not support** the proposed reassignment of CPT 63655 from APC 0225 (*Level II Implantation of Neurostimulator Electrodes*) to APC 0040 (*Level I Implantation of Neurostimulator Electrodes*). This reclassification would result in a dramatic drop in payment for that code, the justification for which was not adequately explained in the proposed rule. If CMS does not reverse this decision in the final rule, patient access to these services may well be jeopardized. A preferable approach for categorizing different neurostimulator electrode implantation services into APC groupings would appear to be that recently recommended by the APC Advisory Panel, and I urge CMS to carefully consider those recommendations.

As with decisions on new technologies, CMS should reach out to professional associations in the pain field whenever it grapples with appropriate classification of pain-related procedures within the basic construct of either the inpatient or outpatient PPS systems, and the Coalition would be happy to facilitate input to CMS on such issues in the regulatory development process.

“Device-Dependent APCs”

Another aspect of the proposed rule which could jeopardize patient access to pain care services is the proposed reduction in device-dependent APC payments, e.g. the proposed reduction for APC 0222 *Implantation of Neurological Device*. If payment rates for device-dependent codes do not adequately cover hospital acquisition costs, as industry alleges for this APC, hospitals will be unfairly penalized for these services in the short run, and patient access will be curtailed in the longer run as hospitals decline to offer these services to Medicare patients at a loss. The Coalition **urges CMS** to gather additional cost data on the devices included in this APC group, and to recalculate the relative weight for the APC using the best and most recent data available.

I appreciate your consideration of these views as CMS formulates final payment policies for 2006. If the Pain Care Coalition can be of assistance to you and your staff, please contact me at any time.

Respectfully submitted,

Robert J. Saner
Washington Counsel
Pain Care Coalition

Submitter : Mr. Michael Powe
Organization : American Academy of Physician Assistants
Category : Physician Assistant

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Resubmission of AAPA comments on "Physician Oversight of Nonphysician Practitioners" See attachment (Previous submission did not acknowledge attachment)

CMS-1501-P-563-Attach-1.DOC



American Academy of Physician Assistants

Attachment #563

950 North Washington Street ■ Alexandria, VA 22314-1552 ■ 703/836-2272 Fax 703/684-1924

September 16, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

File Code: CMS-1501-P

RE: Proposed Changes to the Hospital Outpatient Prospective Payment System

Physician Oversight of Non-Physician Practitioners

On behalf of the more than 55,000 clinically practicing physician assistants (PAs) who are represented by the American Academy of Physician Assistants (AAPA), we appreciate this opportunity to comment on a proposed change to the Hospital Outpatient Prospective Payment System dealing with physician oversight of non-physician practitioners (*Federal Register*, Vol. 70, No. 141, July 25, 2005).

AAPA is the only national professional organization representing PAs in all medical and surgical specialties. It is estimated that in 2004 approximately 206 million patient visits were made to PAs. Many of those patients were Medicare beneficiaries.

The PA profession began nearly 40 years ago. The profession was created by physicians who were guided by a desire to respond to patient health care needs caused by a mal-distribution of physicians in rural areas of the country. Today, large numbers of PAs can be found practicing in rural and underserved communities, delivering needed health care services in rural health clinics, community health centers, and Critical Access Hospitals.

Recognizing the importance of extending medical care to underserved areas, the Centers for Medicare and Medicaid Services (CMS) has been an advocate for creating a regulatory environment that encourages health care professionals to deliver care in underserved communities. The proposed revision to regulation 485.631(b)(iv), which would defer to state law regarding the review of outpatient medical records in Critical Access Hospitals when services are provided by PAs, is yet another example of efforts by CMS to provide increased access to care for Medicare beneficiaries. AAPA strongly supports the proposed change because it will provide greater flexibility to physician-PA teams in meeting the medical needs of senior citizens in underserved communities.

We do have an important concern about one aspect of the interpretation of the proposed revised regulation. It deals with the use of the term "independent practice." CMS proposes to make a distinction between those states that allow NPs and PAs to practice "independently" and those that do not. We

Mark B. McClellan, MD, PhD

September 16, 2005

Page Two

believe that the intent of this language rather should be to draw a distinction between those states that allow non-physician practitioners to practice with a high degree of autonomy in patient care and medical decision making. An example would be a state in which PAs are authorized to deliver care without the on-site presence of their supervising physician and without the requirement for chart co-signature. Under fee-for-service Medicare, PAs have their own statutory benefit for providing care in hospitals. Under that program, a PA's supervising physician is not required to be on-site, nor is chart co-signature required. Thus, PAs deliver autonomous care but are not independent practitioners.

PAs are not considered independent practitioners because they always work with physician supervision. However, supervision is typically defined as PAs and physicians having the ability to immediately contact one another via electronic communication (e.g., cell phone), if necessary. We encourage CMS to interpret the proposed revised regulation, if adopted, in a manner that fully recognizes the ability of PAs to care for Medicare beneficiaries.

As the CMS research verifies, numerous studies over a number of years have concluded that services delivered by PAs, working within their scope of practice, are equivalent in quality to similar services provided by physicians. In addition, existing state law has been shown to provide appropriate oversight of PA practice.

Critical Access Hospitals, by their nature, provide health care services in communities that have a fragile health care infrastructure. The availability of both health care professionals and resources is already strained. PAs continue to be an integral part of the medical "safety net" in underserved communities. We encourage CMS to promulgate regulations and make interpretations that appropriately recognize PAs as important members of the health care team.

Again, we appreciate the opportunity to share our views on this important issue. If we can be helpful in supplying additional information or details on this matter, please don't hesitate to contact us.

Sincerely,



Stephen C. Crane, PhD, MPH
Executive Vice President and Chief Executive Officer

SCC:mp/ng

Submitter : Mr. Michael Nuccio
Organization : Albert Einstein Healthcare System
Category : Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1501-P-564-Attach-1.DOC

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Medicare Program-Proposed Changes to the Hospital Outpatient Prospective
Payment System 2006

Dear Dr. McClellan:

Our hospital, Albert Einstein Medical Center, is a large urban teaching hospital located in Philadelphia. We are a disproportionate share hospital and serve a significant Medicare and Medical Assistance population. Our comments focus on the proposed payment discounts for multiple diagnostic imaging procedures.

Albert Einstein Medical Center agrees that when some of the procedures within the 11 families are performed in the same session, some of the resource costs may not be incurred twice. However, any cost savings would be historically reflected in the hospital's Medicare cost report and would result in a lower ratio of cost to charges (RCC) for procedures in the radiology department. Since the APC rates were developed using RCC's, any economies of scale the hospital would experience are already reflected in the APC rates. To apply the proposed payment discounts for multiple diagnostic imaging procedures would unfairly penalize the hospitals since the lower APC rates already reflect any cost savings for multiple procedures.

We estimate that the reduction in Family 2 alone (Family 2 - CT and CTA (Chest/Thorax/Abdomen/Pelvis) will reduce our annual hospital outpatient Medicare net revenue by \$165,000. Other hospitals will experience similar revenue reductions. With the severe negative impact of the proposed change, hospitals will be unfairly disadvantaged relative to other imaging facilities. This may affect patient access. Also, hospitals may consider having patients return to the hospital on a subsequent day for a diagnostic imaging procedure in the same family.

Because any cost savings are already reflected in the APC rates and because many hospitals would experience a severe financial impact if this proposed regulation is finalized, we respectfully urge CMS to rescind the proposal to discount multiple diagnostic imaging procedures.

Sincerely,

Mickey Nuccio
Associate Vice-President, Revenue Cycle

Submitter : Dr. Thomas Balkany
Organization : University of Miami Miller School of Medicine
Category : Physician

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

"See attachment"
September 14, 2005

Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attn: CMS-1501-P
PO Box 8016
Baltimore, MD 21244-8018

Re: File Code CMS-1501-P
Issue Identifier: Device-dependent APCs

Dear Sir/Madam:

The CMS proposed rule change for calendar year 2006 proposes to reduce payment for cochlear implantation from \$25,307 in 2005 to \$21,739 in 2006. The 2005 amount is already so much less than actual costs to hospitals that many programs have stopped providing cochlear implants to Medicare recipients. To do so, they have had to close their programs entirely, thus creating a domino effect overflowing from Medicare recipients to the entire hearing impaired public.

If the proposed cuts are adopted they would have a severe impact on Medicare beneficiary access to cochlear implantation. Cochlear implants provide extraordinary benefits to my patients and the proposed cuts would create a severe hardship for them.

Cochlear implants have been proven to be highly cost-effective based on a large body of evidence-based literature.

We respectfully request that CMS substitute accurate external device-cost data as determined in a careful study by the Lewin Group and recalculate the relative weight of APC 0259. If this is not possible, I would alternatively request that CMS set the 2006 OPPS payment no lower than 100% of the 2005 payment rate, plus the rate of inflation and other update factors applied to all APCs.

Thank you for your consideration on behalf of my patients.

Sincerely,

Thomas J. Balkany, MD, FACS, FAAP
Hotchkiss Professor and Chairman
Phone: (305) 585-7129
Fax: (305) 326-7610
E-mail: tbalkany@miami.edu
See our cochlear implant web site at www.cochlearimplants.org

cc: Donna Sorkin
John McClanahan
Cochlear Corporation

Submitter : Mr. Anthony Santangelo
Organization : Partners Healthcare System
Category : Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-566-Attach-1.DOC

CMS-1501-P-566-Attach-2.PDF

Electronic:

September 16, 2005

Mark McClellan M.D., Ph. D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**Re: CMS-1501-P; Medicare Program, Changes to the Hospital Outpatient
Prospective Payment Systems and Calendar Year 2006 Rates**

Dear Dr. McClellan:

Partners HealthCare System, Inc. is pleased to comment on the Proposed Rule for Medicare Prospective Payment System for Hospital Outpatient Services, 42 CFR Part 419 and 485, et al., July 25, 2005 Federal Register, on behalf of its member institutions providing hospital outpatient services:

<u>Institution</u>	<u>Provider Number</u>
Brigham & Women's Hospital	220110
Faulkner Hospital	220119
Massachusetts General Hospital	220071
McLean Hospital	224007
North Shore Medical Center	220035
Newton-Wellesley Hospital	220101
Rehabilitation Hospital of the Cape and Islands	223032
Shaughnessy-Kaplan Rehabilitation Hospital	222026
Spaulding Rehabilitation Hospital	222035

Mark McClellan MD, PhD, Administrator, CMS
Comments to 2006 Medicare OPSS Proposed Rule

I. Introduction

As we enter the sixth full year of OPSS, Partners HealthCare System's hospitals remain concerned about the payment levels and administrative burden under OPSS:

Payment levels: Payment levels under OPSS continue to concern us greatly. Payments under OPSS are only 75 percent of the cost of the outpatient care we provide to Medicare beneficiaries. *In aggregate, our annual loss under OPSS exceeds \$60 million*, a huge amount that we must recover from private payers. Amidst this enormous payment deficit, it is no surprise that we are especially concerned about the impact the payment reductions in this proposed rule would have:

- Reductions to payments for drugs, particularly oncology drugs;
- Proposed discounting of imaging services;
- Proposed reductions in outlier payments.

These payment reductions, coupled with an update factor that lags our actual input cost inflation, will further increase the magnitude of our loss under OPSS. While we understand the statutory constraints under which CMS must implement the OPSS, it is more incumbent upon CMS than ever to ensure that aggregate payments under OPSS are the maximum allowable by statute and that these payments are distributed in the most equitable manner, recognizing the costs providers incur in providing this care.

Administrative Burden: OPSS continues to present significant administrative challenges to our institutions. Considerable resources are devoted to working the system, particularly precious staff time and Information System resources. It is imperative that CMS continue to make every effort to reduce the administrative burden associated with the OPSS. For example, the proposal to require hospitals to implement a new, separate code for drug handling charges should be withdrawn.

Finally, Partners HealthCare System remains committed to working with CMS to ensure the greatest extent of payment stability and administrative simplification possible under statute.

Multiple Diagnostic Imaging Procedures

We strongly oppose the proposed discounting of multiple imaging procedures because the fundamental rationale on which CMS is basing this proposal *does not pertain to hospital outpatient payment rates*. Furthermore, the APC Panel, at its recent meeting, recommended that CMS postpone implementing this proposal for 1 year to gather more data on the implications for hospitals of these changes.

The rationale cited in the CMS opening discussion of this proposal is as follows:

Mark McClellan MD, PhD, Administrator, CMS
Comments to 2006 Medicare OPPS Proposed Rule

“MedPAC pointed out that Medicare’s payment rates are based on each service being provided independently and that the rates do not account for efficiencies that may be gained when multiple studies using the same imaging modality are performed in the same session.”

We believe this rationale to be flawed for the following reasons:

1. OPPS payment rates are based on the weights established for each procedure (within an APC);
2. These weights are based on the actual costs of each provider;
3. Any efficiencies providers gain in performing multiple imaging procedures in the same session are already included in their cost base;
4. Therefore, contrary to the above rationale, OPPS rates *do account* for all efficiencies gained when multiple studies using the same imaging modality are performed in the same session.

The attached hypothetical example of single scan and double scan encounters at “Hospital A” illustrates this. (See Attachment I) In this example, a single scan cost \$500; a second contiguous scan in the same session costs 50 percent less (to be consistent with CMS proposed payment assumption), or \$250. The charge for each scan is \$1,000. Under the OPPS cost weight determination methodology:

- Hospital A’s costs are determined using the *total, or weighted average, RCC* – 42.8% in this example. Put another way, if multiple image efficiencies were not reflected in the rate, the applicable RCC would be the single scan RCC of 50.0%
- To extend the example further, assume every other hospital in the country is identical to Hospital A, yielding a national median cost equal to Hospital A’s overall cost of \$427.63. Furthermore, assume the resulting national payment rate, after scaling, is \$400.00.
- Under the current OPPS payment methodology, Hospital A experiences a moderate 6.5 percent loss of \$105,000: the loss on single scan encounters of \$160,000 is partially offset by the \$55,000 gain on double scan encounters.

Under the proposed discounting, the loss more than triples to \$325,000, 20 percent lower than cost. For Partners five acute care hospitals, reductions from current payment levels *would average around 15 percent under the proposed discounting, exceeding \$2 million dollars a year.*

Again, we emphasize that whatever level of efficiencies are gained when performing multiple contiguous scans in the same session, these efficiencies are built into the OPPS rates. However, for the record, we note that the Medicare Physician Fee Schedule data

Mark McClellan MD, PhD, Administrator, CMS
Comments to 2006 Medicare OPPS Proposed Rule

and methodology are not, in our opinion, appropriate proxies by which to estimate the magnitude of any such efficiencies in hospitals.

In closing then, we urge CMS to withdraw this proposal and heed the recommendation of the APC Panel to gather more data on the impact of this proposal and work with the American College of Radiology and other stakeholders. *We strongly believe this data will confirm what we have demonstrated in the above example – that efficiencies realized by performing multiple scans are already accounted for in the OPPS rates.*

Outlier Payments

We have reservations regarding CMS proposal to reduce outlier payments by 50 percent beginning in CY 2006. CMS argues that this reduction is justified for the same reasons MedPAC has put forth in their recommendation to eliminate outlier payments entirely. In response, we raise the following points:

- Reduced cost variability because of narrow definition of many services under OPPS: We agree that at the individual service level, cost variability is likely less within individual APCs than it is under individual DRGs. This reduced variability does not, in our opinion, justify the elimination of outliers. Furthermore, it may not justify the proposed reduction as well – it only justifies the current lower proportion of outlier payments under OPPS than under IPPS.
- Distribution of outlier payments favors some hospital groups more than others: We do not understand this. It is known and accepted that one group of hospitals, tertiary care hospitals, generally receives higher levels of outlier payments under the IPPS than general community hospitals because they attract sicker than average patients (over and above that accounted for by the case mix adjustment.). Why would this be different under OPPS?

In the absence of data, we can't specifically argue that the outlier percentage should be greater than the proposed one percent. We urge CMS to closely monitor the impact of this reduction and report its findings in the CY 2007 OPPS proposed rule.

Pharmacy Overhead and Drug Handling Payment Rate Adjustment

CMS proposes to establish three distinct HCPCS C-codes and corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals and instructs hospitals to charge the appropriate pharmacy overhead C-code for overhead costs associated with each administration of each separately payable drug and biological based on the code description that best reflects the service the hospital provides to prepare the product for administration to a patient. In the absence of separate hospital charge data on pharmacy overhead, CMS is proposing a 2 percent payment "add-on" to reimburse for

Mark McClellan MD, PhD, Administrator, CMS
Comments to 2006 Medicare OPPS Proposed Rule

the costs of pharmacy handling and overhead. (The 2 percent add-on is based on CMS findings that costs using claims data are 2% greater than the costs using ASP data.)

We agree that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We support CMS' interim methodology that determined the 2% add-on for handling costs of separately payable drugs. Furthermore, we recommend that CMS work with hospitals to study methodologies for determining handling costs that create minimal administrative burden for both CMS and hospitals, such as cost report data or a survey.

We strongly disagree with the methodology proposed to collect overhead charge data. CMS' proposal to require new C-codes for separately payable drugs and biologicals will create a significant administrative burden for providers. Of particular concern is that Medicare providers are required to maintain uniform charges for all payers. In order to comply with the proposed policy hospitals will have 2 choices:

- a) Bill handling charges (i.e. \$2.00) separate from drug acquisition charges (i.e. \$98.00) when the payer is Medicare and bill the total charges (\$100.00) to all other payers, or,
- b) Bill handling charges (\$2.00) and acquisition charges (\$98) separately for all payers.

Neither choice, in our opinion, is viable: option A would leave hospitals non compliant with Medicare's rule of maintaining uniform charges for all payers, and option B would lower hospitals' reimbursement from some payers. Even assuming that hospitals could provide differential charges, other concerns include:

- Hospital pharmacies will have to maintain a separately payable drug schedule, evaluate the normal mark-up formula, and strip out the handling charges for only the items on the separately payable list. This would be an extremely complex and time-consuming process.
- For most hospitals, drug pricing is generated via a pharmacy charging system that is located outside the hospital's normal charging system. Most standard pharmacy systems cannot accommodate dual-code billing proposed by CMS.
- Many hospitals use the same charge system for inpatient and outpatient services. If the handling charge must be separated out of the drug charge for the outpatient setting, there are questions about how CMS will expect providers to report drug charges in the inpatient setting versus the outpatient setting.

Finally, we agree with APC Panel's recommendations to delay the implementation of proposed codes for drug handling costs until further studies can be done on alternative solutions. We strongly urge CMS to adopt this recommendation.

Mark McClellan MD, PhD, Administrator, CMS
Comments to 2006 Medicare OPPS Proposed Rule

Partial Hospitalization

Due to the wide fluctuation in the cost data of community mental health centers (CMHCs), CMS proposes not to base CY06 partial hospitalization payment on the most recent claims data available. We share CMS' concern that drastic payment reductions may limit beneficiary access to mental health services. However, we believe the proposed 15% reduction is especially significant to mental health providers because partial hospitalization services are a substantial portion of many mental health providers overall Medicare services. As a result, there are fewer other services available to "cover" such a significant reduction. We fear patient access could be limited.

We recommend that CMS maintain payment for partial hospitalization services at the CY 2005 payment level until better data are available. If CMS chooses to implement a reduction from CY05 payment, however, we ask CMS to base the reduction percent on the percent change in average hospital-based cost from CY05 to CY06, or -2.8%. Because hospital-based cost data have been consistent in the past 4 years, we feel this will provide a fair proxy for the overall cost trend.

New Technology APCs

MRgFUS

(Please note: The proposed rule does not address MRgFUS specifically in the preamble such that it is not clear what caption should be referred to for this comment. Hence, we have used what we believe to be the most applicable caption.)

By way of background: Magnetic Resonance Guided Focused Ultrasound Surgery (MRgFUS) is a new technology for treating uterine fibroids that offers dramatic benefits over the traditional treatment of hysterectomy: The patient returns home 1 to 2 hours after MRgFUS treatment, rather than several days after the hysterectomy. Furthermore, most patients resume normal activities in the home or work within 1 to 2 days, compared to several weeks following a hysterectomy. The AMA assigned CPT codes 0071T ("simple") and 0072T ("complex") for MRgFUS effective July 1, 2004. Shortly thereafter (October, 2004), the FDA granted its approval of MRgFUS. In the CY 2005 OPPS final rule published in November, 2004, CMS assigned both of these codes to APC 0193, Level V Female Reproductive Procedures. CMS continues the assignment of these codes to APC 0193 in the CY 2006 proposed rule.

Because OPPS codes for MRgFUS were not assigned by CMS until November, 2004, *CMS has no claims data available to place MRgFUS in APCs that are both clinically and resource appropriate for both the current CY 2005 OPPS (based on CY 2003 claims data) nor the proposed CY 2006 OPPS (based on CY 2004 claims data.)* As documented in a New Technology Application submitted in July, 2005 (summary

Mark McClellan MD, PhD, Administrator, CMS
Comments to 2006 Medicare OPPS Proposed Rule

schedule in Attachment II), the average cost of MRgFUS exceeds the CY 2006 proposed payment of \$861.66 by 5.8 times for “simple” MRgFUS (0071T) and 8.2 times for “complex” MRgFUS (0072T). This clearly demonstrates, we believe, that the proposed assignment of both MRgFUS codes to APC 0193 is inappropriate.

Conversely, assignment of these CPT codes to the appropriate New Technology APCs is not only appropriate – *it is precisely the purpose of New Technology APCs*, that is, to ensure that payment for a new technology is adequate to cover the resources required until sufficient claims data is available to properly group and price the new technology. *Furthermore, the APC Panel concurs:* At its August, 2005 Biannual Meeting, the panel recommended that “CMS work with stakeholders to assign CPT 0071T and 0072T, focused ultrasound ablation of uterine leiomyomata including magnetic resonance guidance, to an appropriate New Technology APC(s)”.

We are very concerned that the continued assignment of MRgFUS codes 0071T and 0072T to APC 0193, with its very inadequate payment rate, will limit access of patients to this important new technology in the treatment of uterine fibroids. We therefore urge CMS to remove MRgFUS CPT codes 0071T and 0072T from their current APC assignment of APC 193, Level V Female Reproductive Procedures, and assign CPT code 0071T to New Technology APC 1529 and CPT code 0072T to New Technology APC 1534.

Proton Beam Therapy

Partners Health Care System agrees that the CY 2004 claims data more accurately reflect the high capital and operating costs of proton beam facilities and, specifically, the cost of Level II (or “complex”) proton beam radiation therapy. We support CMS’ proposal to move CPT codes 77523 and 77525 from New Technology APC 1510 to clinical APC 0667. More importantly, the resulting national payment rate of \$914.92 for complex proton beam therapy will ensure access to this valuable therapy for Medicare and other patients as well.

Finally, on behalf of the Northeast Proton Therapy Center at Massachusetts General Hospital, we thank CMS for its reasoned and thoughtful transition of payment for proton beam therapy from New Technology APCs to proton beam specific clinical APCs. By maintaining payment for proton beam therapy in New Technology APCs until sufficient claims data was available to reflect the true cost of this therapy, CMS has both ensured continued access to this valuable therapy in existing proton therapy centers and, as importantly, supported the development of new centers.

Drug Administration

Mark McClellan MD, PhD, Administrator, CMS
Comments to 2006 Medicare OPPTS Proposed Rule

We urge CMS to continue using CPT codes to bill for drug administration services provided in the hospital outpatient department. Reverting back to HCPCS codes will force providers to maintain two separate sets of codes for the same services, thus creating unnecessary administrative burden. We understand that under the proposed methodology, payment for services within the same APC would be collapsed by the OCE into a single per-visit APC payment, just as it currently does, until 2005 claims data becomes available and CMS is able to provide further refinement and recognize resources associated with drug administrations lasting several hours.

Because of the significant changes expected with the new 2006 CPT codes for drug administration, hospitals will need instruction and clarification on the application of these new codes. For example, clarification will be needed regarding the following:

- How the code application may be similar or different for the hospital outpatient department as compared to the physician setting—especially with regards to non-oncology providers of infusion and injection services since they often cross departments.
- Definitions of what constitutes an “initial” vs. subsequent infusion vs. concurrent infusion.
- Definition of “hydration” and how is it different from a hydration that is given for therapeutic reasons. In other words, hydration is a therapeutic infusion.
- How should infusions or titrations be reported? Many times they are established with a documented start time and are administered via pump. As such, many infusions are maintained by equipment function rather than manual intervention. In these cases, even though a nurse may be aware of the start and end time of an infusion, the actual time is not currently captured by the hospital information system.

Observation Services

CMS proposes to discontinue the current 3 G-codes and to create 2 new G-codes for observation services: GXXXX for observation services, per hour and GYYYY for direct admission of patient for hospital observation care. CMS would shift the responsibility of determining if an observation service is separately payable from hospital billing department to the outpatient PPS claims processing logic contained in the Outpatient Code Editor (OCE) system.

We appreciate CMS’ proposal to relieve the burden from the hospital billing department by allowing the OCE logic to determine whether the services are separately payable. However, we believe that the OCE logic could be used even more efficiently so as to make the HCPCS code GYYYY unnecessary. An observation service billed that does not include a 45X (emergency department) or 516 (urgent care center) revenue codes, the OCE logic should determine it as direct admission to observation care.

Mark McClellan MD, PhD, Administrator, CMS
Comments to 2006 Medicare OPPS Proposed Rule

We also believe that GXXXX code is unnecessary. CMS should allow providers to follow standard coding practice that uses 99218, 99219 and 99220. Because Medicare payment for observation depends upon number of hours, CMS can require hospitals to provide hour information in the unit field when one of the 3 observation codes is used.

Inpatient List

The “inpatient only” list continues to be of a challenge to hospitals, especially teaching hospitals that are involved in research to advance the method and setting of providing care. We understand that the list intends to protect patient safety and that CMS reviews the appropriateness of the list on a quarterly basis. However, we feel that CMS should allow providers to appeal, on a case-by-case basis, when an inpatient-only case, having met all best care standards, was treated as an outpatient. Furthermore, the additional clinical and cost information that can be collected by establishing an appeals process can be helpful during the quarterly review of the inpatient list.

Status Indicator

CMS proposes to change the status CPT code 85060, blood smear interpretation, from X to B, and CPT codes 90465, 90466, 90467 and 90468 (vaccine administration codes) from N to B. We recommend changing the status of code 85060 from X to N and maintaining the status N for the vaccine administration codes. Currently these codes are billable to all payers; however, the OCE would disallow them under the new status B, resulting in return of the entire claim even if other services on the claim are covered services. To encourage administrative efficiency, providers would prefer to maintain uniform billing practice across all payers; thus changing a billing logic for a specific payers is a time consuming process and creates additional administrative burden.

X. Conclusion

On behalf of all the hospital providers of Partners HealthCare System, I thank you for the opportunity to comment on this proposed rule. Please feel free to contact me by phone (617-726-5449) or email (asantangelo@partners.org.) should you or your staff have any questions or would like more information.

Sincerely,

Mark McClellan MD, PhD, Administrator, CMS
Comments to 2006 Medicare OPPS Proposed Rule

Anthony J. Santangelo, Jr.
Corporate Manager, Government Revenue

Cc: Member Hospitals
Peter Markell

Attachment I: Multiple discounting example

	Single-scan encounters	Double-scan encounters	Total
1. Hospital A Imaging Costs and Charges			
Assumption: Two different scans, e.g., pelvis and abdomen, both cost \$500 if done alone. If done together, cost of second scan is \$250.			
Cost for 1st scan	500	500	
Cost for 2nd scan *		250	
total cost per encounter	500	750	
# encounters	1,600	1,100	2,700
Total Cost	800,000	825,000	1,625,000
Charge per scan	1,000	1,000	
# scans / encounter	1	2	
# encounters	1,600	1,100	
Total charges	1,600,000	2,200,000	3,800,000
Ratio of Cost to Charges	50.0%	37.5%	42.8%

2. Medicare Payment Methodology

a. Determination of Median Cost

Median Charge Per Scan	1,000
RCC	42.8%
Net Median Cost	427.63

Assume every other hospital in the country has same median charge, RCC and median cost. Therefore, \$427.63 = national median cost. Assume national payment rate is \$400.00 (after scaling)

3. Current Payment for Hospital A

payment per scan	400.00	400.00	400.00
# scans per encounter	1	2	
# encounters	1,600	1,100	
Total payments	640,000	880,000	1,520,000
Payment per encounter	400.00	800.00	
Cost per encounter	500.00	750.00	
Gain (Loss) per encounter	(100.00)	50.00	
Total Gain / Loss	(160,000)	55,000	(105,000)

3. Proposed Payment for Hospital A

Payment for 1st scan	400.00	400.00	
Payment for 2nd scan		200.00	
payment per patient	400.00	600.00	
proposed margin per patient	(100.00)	(150.00)	
Total margin	(160,000)	(165,000)	(325,000)
		Net Reduction in Payments	(220,000)
		Percent reduction in payments	-14.5%

* For illustration, cost of second scan reduced by 50 percent to be consistent with 50 percent proposed payment reduction.

Attachment II: MRgFUS

Revised Technical Cost to Provide MRgFUS in an Hospital Outpatient Setting

	Hospital A	Hospital B
Salaries and benefits	\$67,673.00	\$137,937.00
Supplies (consumables)	\$92,000.00	\$100,800.00
Equipment/Maintenance		
Depreciation	\$158,588.00	\$212,432.00
Maintenance	\$32,398.00	\$78,024.00
Space	\$3,949.00	\$3,360.00
Total Equip/Maintenance	\$194,934.00	\$293,816.00
Total Costs	\$354,279.00	\$532,553.00
Overhead	\$142,927.00	\$153,300.00
Total Costs	\$497,206.00	\$685,853.00
Simple cost	\$4,072.00	\$5,849.00
Complex cost	\$5,873.00	\$8,200.00

Cost Assumptions Used in Worksheet

Total # of cases per Year	100
Estimated Simple Cases	50
Estimated Complex Cases	50

Submitter : Mrs. Valerie Rinkle
Organization : Asante Health System
Category : Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Please accept the attached comments.

CMS-1501-P-567-Attach-1.DOC



September 16, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

Submitted Electronically: <http://www.cms.hhs.gov/regulations/ecomments>

**Re: File Code CMS-1501-P
July 25, 2005 OPPTS Proposed Rule**

Asante Health System (Asante) includes two acute care hospitals in Southern Oregon. This letter addresses many specific coding, billing and payment concerns regarding the Outpatient Prospective Payment System (OPPS). These comments are in relation to the changes discussed in the Proposed Rule published in the Federal Register on July 25, 2005.

You may call our Revenue Cycle Director at 541-789-4923 should you have any questions concerning these comments.

Packaged Services

Asante agrees with the proposal to move bladder catheterization codes into separately payable APCs. We also agree with assigning APCs to vaccine administration CPT codes. Asante asks CMS to consider the following services for payment in 2006, particularly when they are the only services rendered at an outpatient hospital visit.

- Non-selective Debridement CPT 97602. From the outset, CMS assigned status indicator "N" for packaged services to this code. The rationale was published in Transmittal A-02-129 where CMS states: "CPT code 97601 is a physical therapy service and is paid under the Medicare Physician Fee Schedule. Payment for CPT code 97602 is recognized under the OPPTS as a packaged service (i.e., the service is not separately paid under OPPTS); however, the cost of the service is packaged into whatever other service is provided on that date. It is common for 97602 to be performed at the time of another physical therapy service in which case payment for 97602 is packaged into payment for the other physical therapy service. If a service coded under 97602 is performed at the time of a clinic or emergency visit, the E/M service must be documented in accordance with the hospital's documentation guidelines for clinic and emergency visits. If the only service provided to a beneficiary is 97602, the hospital may bill outpatient visit code 99211. Payment for 97602 will be packaged into the payment for 99211. If a hospital provides

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and bills for 97601 or 97602 and a clinic or emergency department visit, the clinic or emergency visit must be separately identifiable and documented in accordance with the hospital's guidelines for documenting clinic and emergency visits."

CMS views these codes as physical therapy codes. These codes are not merely physical therapy codes, but also registered nurse codes. At Asante, registered nurses perform wound management care and rarely do therapy providers perform that care. Physicians order patients to come to the hospital for wound care management services from nurses. Non-selective debridement is the only service the patient receives. A typical visit takes the nurse between 30-45 minutes to assess the patient's wound, make the dressing change, and then instruct the patient. The only procedure performed is non-selective debridement, which is reported with CPT code 97602 along with billable supplies. Since no other service was provided, we are reluctant to report another service, even though CMS has stated that CPT code 99211 can be reported in order to generate reimbursement for the packaged services. Reporting 99211 and 97602 is problematic because non-Medicare payers only want to see the CPT code reported for the service actually rendered which is 97602.

Last year, CMS changed this code to the Physician Fee Schedule (MPFS) where in 2005 it has a status indicator of "B". This further complicates matters because now the code cannot even be reported. Language in the 2006 NPRM (on page 42962) states: "under the MPFS, a separate payment is never made for a 'bundled' service and, because of this designation, the provider does not receive separate payment for non-selective wound care described by CPT 97602. While this code now falls under the MPFS rules, payment policy for this 'bundled' service has not changed and separate payment is not made." We are confused because Medicare compliance rules do not allow the hospital to render services to Medicare beneficiaries and simply not charge for those services.

Asante asks CMS to carefully review the use of this code and how non-selective wound care meets the definition of coverage of outpatient therapeutic services under OPSS.

42 CFR 210.2 Defines Hospital Outpatient. *Outpatient* means a person who has not been admitted as an inpatient but who is registered on the hospital or Critical Access Hospital (CAH) records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH. *Non-selective wound care patients are registered outpatients of the hospital.*

42 CFR 210.2 Defines Outpatient Hospital Encounter. *Encounter* means a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient. *The nurse has direct personal contact with the patient to treat the patient. This falls under scope of practice for nurses. Medical staff physicians order wound care services from the nurse on behalf of their patient that they are managing in their offices. Wound care nurses report the care back to the ordering physician. There is a nurse specialty with certification for wound management.*

Publication 100-02, Chapter 6. Section 20.4.1 - Coverage of Outpatient Therapeutic Services. Therapeutic services which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians in the treatment

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of patients. Such services include clinic services and emergency room services. *Non-selective wound care patients meet the definition of covered outpatient therapeutic hospital services.*

Asante asks that CMS assign the newly proposed status indicator "Q" to CPT code 97602 so that separate payment can be made when this is the only payable service provided under OPSS. The OCE can package payment for 97602 when there is another APC-payable service on the claim, and generate a separate APC payment, using the same payment assigned to APC 600. This will allow CMS to track this service appropriately.

- Collect Blood Venous Device 36540. Physician's offices order patients to the hospital for blood work in cases where the patient has a venous access device. Drawing blood for lab work from a venous device requires that a registered nurse assess the patient, and then use a sterile kit with a needle to access the device, draw the blood, and flush the port afterwards to ensure patency. It typically takes 15-20 minutes to perform this procedure. This is a much more resource-intensive service than a simple venipuncture, yet venipuncture is paid separately under the Clinical Lab Fee Schedule, while CPT code 36540 is considered packaged. Venipuncture can be performed by phlebotomists that clinical labs employ, but hospitals employ registered nurses that are required to perform this service.

When this is the sole service provided, we are forced to report an E/M visit code to receive any payment for a legitimate outpatient encounter. Private payers and Medicaid programs only want the hospital to report the actual service provided -- in this case, CPT code 36540 and not the E/M code. It is extremely difficult to take a single service and break it into two charges (99211 and 36540) just to report that 36540 was the only service rendered.

Therefore, Asante asks that CMS assign the newly proposed status indicator "Q" to CPT code 36540 so that separate payment can be made when this is the only payable service provided under OPSS. The OCE can package payment for 36540 when there is another APC-payable service on the claim, and generate a separate APC payment, using the same payment assigned to APC 600.

- Injection Procedure for Sentinel Node ID 38792. This X-ray injection code is assigned status indicator "N" and separate reimbursement is not made. At times, this procedure is performed and the injection is the only service provided because surgery is provided by a different facility/provider and the nuclear medicine department merely performs the injection with no X-ray. In this case, we should be able to recoup reimbursement for these services without being forced to report a lymphangiography code with a modifier -52 for reduced services. Radiologists do not want to dictate a report for a service not performed or ordered. We ask that CMS assign the newly proposed status indicator "Q" to CPT code 38792 so that separate payment can be made when this is the only payable service provided under OPSS. The OCE can package payment for 38792 when there is another APC-payable service on the claim, but can generate a separate APC payment using the same rate as proposed for Level I injection codes when this is the only billed service.

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- Irrigation of implanted venous access device for drug delivery systems – (expected 2006 CPT code 96523). Irrigation of implanted venous access device for drug delivery systems – (expected 2006 CPT code 96523). In Table 27, page 42739, CMS proposes to assign this new service/code a status indicator “N”. Often, particularly in smaller and rural communities, private practice physicians often send patients to the hospital with an order to “flush the venous access device”. Under this order, a Registered Nurse assesses the patient and the device. A sterile kit with sterile needle is used to access the device to ascertain whether the device is patent by receiving blood flow with aspiration and flushing of the device. In the instance of a new device, there is additional time spent to remove the original dressing and redress the site. If allowed to go untreated, these conditions could lead to more invasive and expensive procedures, including removal of the existing device and implantation of a new device. This service would not be expected to generate separate reimbursement when it is provided on the same day as other services such as IV infusion therapy, IV push medications, blood transfusions, or blood draws. In fact, it is likely that this service will be a component NCCI edit to the above procedures and will not be able to be reported or billed when the other services are provided. Currently, hospitals must report the flush service when it is the only service provided during the visit with an E/M code in order to receive payment for the resources expended.

Asante is excited to see the new CPT code for this service and we ask that CMS assign the newly proposed status indicator “Q” to CPT code 96523 so that separate payment can be made when this is the only payable service provided under OPSS. The OCE can package payment for 96523 when there is another APC-payable service on the claim, and generate a separate APC payment, using the same payment assigned to APC 600.

- Fluoroscopy Greater than One Hour 76001. Hospitals should be able to report fluoro over one hour and receive separate reimbursement for this service, since it takes more time and resources than are required for fluoro under one hour (which is represented by CPT code 76000). CPT code 76001 initially started as “N” status, then was changed to “S” status and paid, then changed back to “N” again. There are cases where fluoro is required for over an hour, and we report this code to all other payers. Asante believes CMS incorrectly thinks CPT 76001 is an add-on code – it is not. A fluoroscopy procedure is either under one hour (and the provider reports 76000) or over one hour (and the provider reports 76001). The codes are mutually exclusive. Asante cannot think of any reason why CMS would not want to change the status indicator of CPT code 76001 from “N” to “X” and assign it to APC 0272.
- Bladder Catheterization for Specimen P9612. In keeping with CMS’ excellent decision to separately pay for bladder catheterizations under OPSS, Asante urges CMS to do the same for CPT code P9612. This procedure occurs in the Emergency and other Departments when the patient is unable to perform the steps necessary for a “clean catch” sample and the nurse catheterizes to obtain a clean urine sample for clinical lab testing. This service requires the same level of effort and resource use as CPT code 51701. Therefore, Asante asks that CMS treat it in the same manner as CPT code 51701 by assigning it to APC 0340 and making separate payment for this service.

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- Placement of occlusive device G0269. HCPCS code G0269 is a procedure which has a specific device associated with it. CMS has packaged both the procedure code G0269 and the device C-code (C1760) into endovascular APCs. This makes an assumption that this device and procedure are performed 100% of the time with other endovascular procedures. The reality is that this is one option for sealing the entrance site at the conclusion of an endovascular procedure. Asante believes that payment would be more accurate if separate payment for the G0269 was allowed. We also believe that G0269 should be classified as a device-dependent APC, requiring the reporting of both G0269 and C1760 on the claim. C1760 would be appropriately packaged into G0269. This would enable CMS to create an edit for claims so that G0269 and C1760 must both be reported and paid separately through an APC payment.
- Continuous Overnight Oximetry Monitoring 94762. Asante asks that the status indicator for CPT code 94762 -- Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure) -- be changed from "N" for packaged service to "X" and assigned to APC 0369 (Level III Pulmonary Tests). This test is a pre-requisite for proving medical necessity for home oxygen therapy. Physicians order patients to receive this test from hospitals. This is the only service performed. When pulse oximetry is the only service provided to a patient in the outpatient setting, we must report an E/M service in order to receive payment. This is problematic for the reasons discussed above and therefore, we ask that CMS assign CPT code 94762 to APC 0369 for 2006.

Inpatient-Only List

Asante approves of CMS' proposal to remove 25 procedure codes from the Inpatient-only List. We ask that CMS post the Inpatient-only List on the physicians' web-page of the CMS web-site and provide background detail on the Inpatient-only List. We also request that CMS discuss this issue on the Physician Open Door Forum and in the MPFS proposed and final rules. We suggest that CMS require carriers to post the Inpatient-Only list in their educational materials. In this fashion, CMS will educate physicians and facilitate hospitals' education efforts with physicians.

Please note that our FI has instructed Asante hospitals to move the Inpatient-Only CPT and charge to the non-covered column of the UB92 claim and re-submit the claim to allow payment for the other services under OPSS. This contradicts what Asante understands is OPSS policy. The FI states that this is their interpretation when both an OPSS procedure and an inpatient-only procedure are performed during the same session. Asante asks CMS if this instruction is valid since we can find no transmittal to support it and the FI states that since the claim will process and pay in this fashion, it is alright to do this.

New Procedure Codes

Please review and include all CPT Category III codes that will become effective on January 1, 2006 (codes 0089T – 0154T as published on the AMA website) in the final Addendum B and designate the codes to the most appropriate APC. We specifically request your careful review of the following codes:

0115T – Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, initial 15 minutes, with assessment, and intervention if provided; initial encounter

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0116T – subsequent encounter

0117T – each additional 15 minutes (add-on code for either of the above)

According to Daniel Buffington, a pharmacist on the CPT editorial panel's Health Care Professionals Advisory Committee, these codes were created to “articulate pharmacy services in general, **regardless of the payer type or practice setting**” and the “CPT editorial panel themselves struggled making sure that what was produced in terms of coding was not to be confused as being limited to a Medicare Part D beneficiary”.

Medicare beneficiaries frequently need medically necessary, medication management and pharmacist monitoring for optimal safe and therapeutic drug efficacy and this service is provided by licensed pharmacists under order from a treating physician. This service is direct, face-to-face patient care that, in the long run reduces additional inpatient and outpatient expenditures.

These services do not need to be assigned to New Technology APCs, and CMS has even instructed providers to bill for this type of service as a low-level clinic visit. CMS previously posted an FAQ on its website (Answer ID 2101, which is no longer available) that states “when a face-to-face medication therapy management is provided by qualified hospital staff...a hospital may bill CPT 99211 if the services are medically necessary and constitute a distinct, separately identifiable E/M service that is consistent with the hospital's criteria for a low-level clinic visit.”

We recommend the following designation:

0115T	SI “V”	APC 601
0116T	SI “V”	APC 600
0117T	SI “N”	

Device-Dependent APCs

Asante suggests that CMS freeze payment rates for device-dependent APCs at the current 2005 payment rates because there are still problems with correctly coded claims. By freezing the payment rates at the 2005 level, CMS may prevent even greater payment rate fluctuation in 2007 when device C-coded claims data from 2005 are used to set payment rates. We hope that CMS is eliminating claims data with device C-codes with a nominal line item charge (i.e., \$1.00) because claims subject to a device recall should not be used to develop median costs and relative weights.

Drugs

Asante has serious concerns about the proposal to pay an additional 2% of ASP for handling costs and CMS' proposal that hospitals be required to report new drug handling C-codes starting January 1, 2006 in order to capture drug handling charge data which CMS may use to create separate drug handling APCs in the future.

Asante understands that CMS has requested comments on how to package drugs starting in 2007. We appreciate the opportunity to comment and strongly believe CMS should provide separate payment for all infused and injectable drugs regardless of the “per day median” cost, and only continue to package oral drugs and possibly pre-packaged hydration solutions. This approach would create consistency in payment policy

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between the hospital and physician settings. CMS has already begun this process by aligning payment for many separately payable drugs this year (and even more so in 2006), as well as by proposing to require the same drug administration CPT codes in both settings starting in 2006.

Asante believes that CMS cannot intend to create consistency in some areas while leaving large differentials in others. For example, physicians receive higher payments for drug administration services and are paid for multiple administrations and hours of infusion service while hospitals are not. Particularly when hospitals treat more complex patients and are at physician's disposal to receive any patient referred.

Asante understands the rationale behind CMS proposal to use ASP+6% to set the average acquisition cost. We are concerned, however, about CMS's proposal to reimburse providers' handling costs and overhead expenses at 2% of ASP. Given that MedPAC found that pharmacy handling costs represent 26% to 28% of the total cost of providing drugs, it seems unreasonable for CMS to allocate just a fraction of that estimate to the drug payment rate to cover hospital handling costs/overhead expenses. We believe that separately payable drugs "acquisition costs" plus the handling costs should be paid by drug or together with the drug payment. Furthermore, the payment rates for drugs should be dampened like CMS has dampened blood products and device-dependent APCs.

We also wish to comment on the proposal to require hospitals report the newly proposed drug handling C-codes to reflect separate line item drug handling charges. This proposal has serious financial and operational consequences and we ask that CMS delay this until further study. Please recall that Medicare participating hospital providers must charge all payers in the same way. This is specified in Provider Reimbursement Manual (Publication 15, Part I, Chapter 22, §2204). It is impossible for hospitals to report a drug J-code with one charge that includes handling and a different charge that excludes handling to Medicare using the same J-code. Hospitals will not risk lowering drug prices to acquisition cost to Medicare and non-Medicare payers. This will force hospitals to violate either the new drug billing rules proposed by CMS or the current Medicare Provider Reimbursement Manual Instruction.

CMS should recognize that pharmacy handling costs are already built into the overall drug charges from hospitals. For this reason, the use of special codes to capture only the handling charge will create additional work for hospitals. It is not clear if CMS expects the handling charge reported to only reflect the "handling effort/expense" of the pharmacist or total overhead (direct and indirect) for pharmacy. Any change in drug pricing will take careful planning and time, far more than is available between publication of the final rule and the codes' proposed implementation date on January 1, 2006.

The proposed use of the drug handling C-codes also raises a number of operational questions that CMS must consider before moving forward with implementation. Does CMS expect multiple line- items to be reported per date of service if multiple drugs from the same drug handling family are provided? Does CMS expect only one drug handling C-code from each category on a given date of service with multiple units of service if multiple drugs from the same category are administered? Claims processing systems allow reporting of items under revenue codes in one of two ways: either by rolling up all items into one line item that reflects the total quantity and total charge billed under that revenue code; or by reporting a detailed listing of charges on individual line items. The revenue code assignment for these new handling C-codes will dictate whether the handling codes are rolled up into one line item with everything else reported in that revenue code, or detailed

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out on the claim in a single line item per C-code with multiple quantities on a particular date of service. Depending on the revenue code(s) required for these handling codes, the claim could become very long and burdensome for both the provider and payers.

Our pharmacists say that the C-code charge will have to be added manually on the back end of the billing cycle to each claim. We have point-of-service charging for medications. Requiring an additional charge to be entered for handling the medications will create a high compliance risk. Adding a handling charge will require manual intervention, since our system cannot produce an automated handling charge.

For drugs reported with a HCPCS code, is the handling charge reported per dose of the drug, per vial/amp of drug used, or per billing increment based on the HCPCS code description? When a drug is prepared but not administered to a patient, due to a change in condition or physician order, will providers be allowed to report the drug handling charge since resources were expended to prepare the drug? In other words, will CMS allow a handling charge to be reported without a corresponding drug HCPCS code? Does CMS only expect providers to only report a handling charge for separately payable drugs? Will CMS make a handling payment for packaged drugs? How will CMS determine what this payment should be if the drugs are not reported with HCPCS?

How does CMS define “handling” or “pharmacy overhead”? According to the MedPAC report, the dimensions of handling costs considered include: management, including regulatory compliance; storage, including inventory management; preparation, including review of drug orders and dosage calculations; transport within the hospital; and disposal of products. Within each of those categories are labor, benefits, space, equipment, supplies, and support contracts (to provide services such as waste disposal). It is not clear where other costs should be reported, such as: hospital administration, human resources, information technology, continuing education, hospital housekeeping, utilities, interest expenses, and other costs not directly related to pharmacy but which are currently spread over all hospital departments.

Asante is concerned that the terminology used by CMS about “expenses above and beyond acquisition expense” may inadvertently lead to the exclusion of certain categories of legitimate overhead expenses. Conversely, it might inadvertently include direct expenses that are not handling/overhead expenses. For example, the indirect expense of maintaining electronic medical records for medication administration records is crucial and valid as a pharmacy expense, especially given the Institute of Medicine initiatives to automate pharmacy drug dispensing to prevent errors. This is clearly a legitimate pharmacy handling or overhead expense. An example of another legitimate expense that should not be categorized as handling/overhead is a face-to-face pharmacist consultation with patients for medication therapy management as discussed above. CMS will need to carefully define what is drug handling.

Self-Administered Drugs

Asante asks that CMS clarify two issues related self-administered drugs. The first has to do with whether or not handling C-codes must be reported for these items, and if the costs will be considered non-covered similarly to the drugs themselves being non-covered. If the drug handling C-codes are non-covered, we seek clarification if CMS sees the beneficiary being financially responsible for this service.

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Our second issue, with respect to self-administered drugs, concerns beneficiary questions that may arise from the new Part D coverage beginning on January 1, 2006. The Medicare Online Manual Publication 100-04, Chapter 1 Section 60 gives hospitals two choices for billing non-covered self-administered drugs: 1) bill A9270 with modifier -GY in the non-covered column of the claim with other covered services to communicate that this is a statutory non-covered charge for which the patient is liable; or 2) separate the non-covered charges onto a separate claim with condition code 21.

The UB-92 claim form will contain the same minimal drug detail regardless of which billing method the hospital chooses. Drug line-items will show the revenue code, the date of service, units of service, and the total charge for the line-item. There will be no specific detail related to the actual drug that was administered if HCPCS code A9270 is billed. Furthermore, when the denial is obtained from Medicare and the liability reported on the beneficiary's explanation of benefits (EOB), the statement that the hospital sends the beneficiary will not (as it does not today) contain any detail on the actual drug that was administered.

For example, a beneficiary has an outpatient visit and receives aspirin for pain and atenolol for high blood pressure. Both of these drugs are non-covered, self-administered drugs. The hospital chooses to submit these charges on a separate claim form (option 2, described above). The UB-92 claim form submitted to Medicare shows the following:

Revenue Code	Revenue Code Description	Date of Service	Units	Charges
637	Pharmacy Self Administered	9/1/2005	4	\$5.00

The beneficiary will receive a hospital statement showing the following:

Date	Service Description and Quantity	Total Amount
9/1/2005	Pharmacy Quantity 4	Amount \$5.00

With the new Part D prescription drug benefit beginning January 1, 2006, patients will expect their prescription drugs to be covered. Indeed, CMS has confirmed that prescription drugs will be covered, with its statement on page 4268 of the January 28, 2005 Final Rule.

How can we help beneficiaries understand that they will continue to receive hospital statements for prescription drug charges when the beneficiary has the new prescription drug Part D benefit and believes that their prescription drugs are covered under Part D?

Drug Administration

Asante supported CMS' proposal to use CPT codes to report drug administration services. CMS proposes to continue requiring hospitals to report CPT codes and Asante agrees with this concept, in principle, but is significantly concerned about the new 2006 drug administration CPT codes and how they will be difficult to operationalize in a hospital setting if CMS adopts the AMA CPT definitions as currently stated.

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The 2006 CPT book will have many more drug administration codes and that the new codes and descriptions are completely different in their application. These codes and definitions may make sense in a physician office setting, but are very problematic for a 24/7 hospital setting. Note that in a hospital, drug administration services are generally assigned (“charged”) at the departmental level or at the point of service. Thus, drug administration CPT codes are embedded in the hospital Charge Description Master (CDM) and departmental staff (often clinical staff) are responsible for charging the appropriate codes based on the services provided to the patient under their care while the patient is in their department. Given these facts, Asante asks CMS to consider the following very carefully:

- The new drug administration codes were created to provide physicians with a way to bill for each and every instance, or combination, of drug administration service(s) provided in order to off-set the significant drug payment decreases required by the Medicare Modernization Act (MMA). Physicians in their private settings receive payment for almost every single G-code today and will receive payment for every 2006 CPT code billed. Furthermore, physicians receive separate payment for each drug administered. This is not the case in the hospital setting.
- CMS already concedes that there are exceptions to the application or use of CPT codes in the hospital setting. Old Hospital Manual Section 442.7 carried language to “ignore any wording in the CPT-4 codes that indicates that the service must be performed by a physician” – In fact, the absence of this language in the Online Manual still confuses hospitals in the application of CPT codes in the hospital setting. This discrepancy between use and application of CPT codes in the hospital setting versus physician offices exists with many different codes including the conscious sedation bulls-eye codes in Addendum I, evaluation and management codes, critical care codes, modifiers and others. CMS has been forced to provide separate guidance to hospitals on how to “interpret”, “use”, and even “ignore” certain CPT codes (or parts of the CPT description) because the codes are not applicable in the hospital setting. Asante asks CMS to keep this history in mind as it reviews recommendations below. Furthermore, we think all such exceptions should be published in the AMA CPT manual as a separate section regarding applicability of CPT in hospital outpatient settings. This section would be like the E/M Guidelines section. It would consolidate all exceptions and qualifiers to the use of CPT in general and with regard to specifics in the hospital setting, including the necessary re-emphasis that hospitals can ignore any wording in the CPT –4 codes that indicates the service must be performed by the physician and that they can be reported when qualified health care personnel perform the service under their State scope of practice.
- It will be impossible for our hospitals to implement separate codes for initial, subsequent, and concurrent injections and infusions, since outpatients – in particular observation patients - “flow” through hospitals in a way that is fundamentally different from how they are treated in a physician’s private setting. Patients move from one department to another and charges are entered by each department based on the services rendered in that department without regard to the charges entered from the previous department. Each department charges their own services and the departments do not know what services other departments have already charged. The concept of “initial” as the primary reason for the visit is impossible to automate using the CDM.

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- The new codes and descriptions are not easy for clinical and coding staff to understand or apply in the hospital setting. One example is the concept of only reporting one “initial” service code, where initial means the “primary reason for the visit”. A second example is reporting an additional hours’ code or an additional sequential injection code when the first hour or first injection have not been reported. These requirements simply do not make sense and are artifacts of codes created and defined by physicians for physicians’ office use last year. Clinical staff charging at the point of service will not comprehend charging for an additional hour’s hydration code when the first hour hydration code has not been charged. In fact, hospitals will have to “un-train” staff because CMS has previously stated that an additional hour code (i.e., 90781) should not be reported without the first hour code (i.e., 90780). The new 2006 CPT codes rely on the concept of “initial service”, which means that all other services provided must automatically be reported as “additional” “subsequent”, or “concurrent”. The fundamental problem hospital charging staff will have with this concept is that it crosses routes of drug administration and will therefore be intuitively difficult to accept.
- Two new CPT codes, 90767 and 90768, for sequential and concurrent infusion respectively, do not follow the hourly structure of the other infusion, hydration, and chemotherapy infusion codes. The proposed 2006 CPT code narrative, released early by the AMA for review, states: “these codes are reported once per sequential infusion or once per encounter for concurrent infusion”. It will be burdensome for hospital staff to apply four different sets of definitions for similar services: initial, additional, sequential, and/or concurrent.
- Can a hospital code CPT 36000 with modifier 59 for those cases where an IV start is complex. This means the patient has used up many resources with numerous IV start attempts. Typical hospital policy is that one nurse tries two times and if unsuccessful, a second nurse tries to start the IV. At times, two or more nursing staff try and then a physician is called in. This requires significant IV start supplies and nurse effort. This is documented in the medical record. Asante believes that this is an appropriate circumstance to report 36000 with modifier 59. We understand that this service is packaged and there is no separate APC payment.

If the descriptions and rules for these CPT codes are implemented in the hospital setting without exception, and as written in the 2006 CPT drug administration section, it will be impossible to implement them without heavily involving medical records staff and coders. These staff are in short supply nationally and this would increase administrative costs. This is hard to justify when the reporting of additional hours of infusion does not generate additional payment and will only do so in concept for 2007. The most difficult issue to accept as a result of the “initial service” concept is that CMS could inadvertently stop paying for services in the future that they currently pay for. We offer an example below, followed by our recommendation for how to handle it:

A patient is scheduled for a one-hour chemotherapy infusion visit. During the course of that visit, an emergency medical condition arises and the patient is taken to the emergency department where hydration is provided, followed by an intravenous injection. The patient is then stabilized but needs to be observed. The physician orders two hours of observation and orders another two hours of hydration to continue. In this example, drug administration services are charged in three different departments. Even if we accept that

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each department will know what the others provided and charged, and are able to comply with the concept of “initial service”, hospitals continue to face a payment reduction given the status indicators that CMS assigned to the descriptions of drug administration services in the 2006 proposed OPSS rule for expected new codes. Using the 2006 codes, the 90761 code for additional hours of hydration are reported with no payment, whereas today we would report 90780 and receive payment for this service.

If the 2006 CPT codes are implemented without exceptions and clarification, the nomenclature will result in non-payment for services that hospitals currently are paid for today, resulting in a significant decrease in payment as shown above which we do not believe is what CMS intended. Asante asks CMS to allow hospitals to ignore the concept and word “initial” in each CPT drug administration code. We believe that this will solve most of the issues problematic with the application of the 2006 CPT drug administration codes in hospital settings.

CMS should clearly define all concepts associated with the terms “sequential”, “concurrent”, “diagnostic”, “prophylactic”, and “therapeutic”. CMS should also define what solutions are administered as hydration with codes 90760/90761 and confirm that these solutions should be reported under revenue code 258 for IV solutions. This will improve packaging the cost of solutions into these codes on future claims.

CMS should clearly define what is meant by the administration of “single or initial substance/drug” (e.g. as in 90774), and provide examples of when it would be inappropriate to report these codes. Today, our hospitals report an administration for each medically necessary drug administered. For example, if two drugs are mixed together and administered via one syringe, then only one administration code is reported. If the same drug is injected more than once in a period of time due to medically necessary reasons, then multiple administrations are charged, even though the same drug is being given.

Without the benefit of a grace period, it is essential that CMS think about the implementation effects of this massive coding/billing change. Given that these services are Charge Master driven, we need time to either make any necessary process changes, update and test charging and billing systems, create charges for the new codes, update charge forms, and train staff at the point of service about how to select the new codes to report the services provided.

One continued question CMS has not addressed is how to code and bill for a Pain Control Pump (PCP) -- In this situation, an IV is started to infuse pain medicine that is loaded into a pain control pump. The nurse loads in the cassette of medication and programs the pump. When the medication is used up, a new cassette of medication is loaded and the nurse re-programs the pump based upon physician order. This service does not match to any of the 2006 drug administration codes. We need new HCPCS codes or CMS should provide guidance as to how to bill for this resource intensive service that is commonly provided to observation patients. This may be a valid place for a HCPCS code – one for initiation of a pump and another for each pump refill – note that there are HCPCS codes for chemotherapy provided through pumps, but not for pain management drugs.

Blood and blood products

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Asante appreciates the detailed guidance CMS released earlier this year. We ask that CMS explicitly state that hospitals should be charging for blood transfusion/administration the same way to both inpatients and outpatients. Please do not say that this is not a topic for OPSS -- note that OPSS does impact how services are charged and billed to inpatients because of existing Medicare regulations on cost apportionment contained in the Provider Reimbursement Manual: (1) (Publication 15, Part I, Chapter 22, §2203) which states: "so that its charges may be allowable for use in apportioning costs under the program, each facility should have an established charge structure which is applied uniformly to each patient as services are furnished to the patient" and (2) (Publication 15, Part I, Chapter 22, §2204) which states: "Medicare charges refer to the regular rates for various covered services which are charged to beneficiaries for inpatient or outpatient services. The Medicare charge for a specific service must be the same as the charge made to non-Medicare patients (including Medicaid, CHAMPUS, private, etc.), must be recorded in the respective income accounts of the facility, and must be related to the cost of the service. (See §2202.4.)"

According to the rules above, blood administration services should be separately charged in the same manner to patients seen both in the inpatient and outpatient setting. Please clarify this important issue for hospitals.

Observation Services

Asante sincerely thanks CMS and the APC Advisory Panel's Observation Subcommittee for the continued and thoughtful work they have performed in studying the administrative issues related to coding and billing and the payment criteria for the separately payable observation APC and for taking additional steps to propose a set of changes that will result in further streamlining the reporting of these services. The proposed changes will help Asante to streamline the billing and charging for this service, not only to Medicare, but to all payers.

Payment Reduction of Diagnostic Imaging Services

Asante understands the CMS proposal to apply a 50% discount when two or more diagnostic imaging procedures from the same family of codes are provided during one session because CMS assumes the provider gains economies to scale. Asante strongly disagrees with CMS' proposal to reduce the payment rate of the second and subsequent APCs by 50%. This reduction ignores the fact that economies of scale are already reflected in the cost-to-charge ratio used by CMS to arrive at the median cost data. CMS states in the proposed rule that private payers are already discounting in the same manner as proposed by CMS. Asante does not have any payers that apply this reduction.

Asante has questions about the family of codes CMS proposes, for example, CT Abdomen and CT Angio Abdomen. These services are never provided during the same session, yet CMS has assigned them to the same family of codes. What does CMS mean by separate "session"? The term "session" must be explicitly defined so that we know when we should use modifier -59 to signify that multiple diagnostic radiology procedures were performed on the same date of service, but NOT during the same session. CMS will need to define "session" in a way that distinguishes it from other terms, such as "encounter" or "visit", so that we will use modifier -59 appropriately in order to be paid 100% for both or all of the subsequent procedures provided (if done during different sessions).

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Asante asks CMS to delay implementation of this proposal in order to work with the AMA to simply create new CPT codes that describe commonly combined procedures so that data can be more systematically collected and payment rates naturally be set from provider charges for these combined procedures as reported through the claims data. Furthermore, this would ensure that the ordering physician intended for both exams to be performed and a single radiologist report would be produced that addresses the combined exams.

Interrupted Procedures (modifiers -52, -73, & -74)

Since implementation of the OPPI in 2000, CMS has required hospitals to report modifiers -52, -73, -74 to indicate procedures that were terminated before their completion. Clarification on this issue was released earlier this year was helpful, but there are still concerns about the use of the modifiers. For CY 2006, CMS proposes to decrease payment for services when modifiers -52 and -74 are reported. Asante strongly disagrees with this proposal.

Modifier -52

Asante asks CMS to continue making full payment (100% of the APC payment) for services reported with modifier -52. Asante never charges for procedures that are cancelled or discontinued at the very start due to patient's being nervous or worried. We only charge for procedures when the patient is clinically prepared for the procedure. In many cases where modifier 52 is used, even more resources are consumed than would be required to complete the normal procedure. This is true both for modifier -52, and even more so for modifiers -73 and -74.

Modifier -73

Asante strongly believes that CMS should make full APC payment for services reported with modifier -73 because of significant use of hospital resources in preparing the patient for the treatment or operating room. We have asked in our comments for the last several years that CMS remove the language "taken into the treatment room," from the current policy because, in many cases, it prevents the legitimate application of modifier -73. Patients are prepared for surgery in various settings of hospital based on space availability, including pre-operative and holding areas. Preparation in these areas incurs the same costs as if the preparation occurred in the treatment or operating room. The current definition of modifier -73 requires the surgery to be cancelled in the room where the surgery is to occur. Although the patient may not go to the treatment room, sterile surgical supplies have been opened and other resources (such as staff time and scheduling) consumed; providers cannot recoup these costs because modifier -73 is not allowed in this situation. Some hospitals bill nothing in these case since the patient was not taken into the procedure room, while others are reporting an E/M visit code to recoup some of their costs.

Asante asks that CMS allow providers to use modifier -73 for cancellation of procedures for patients in a holding room or a pre-operative suite when the patient is clinically prepared for surgery and resources have been utilized. When a procedure is cancelled prior to clinical preparation of the patient, there is little resource utilization and modifier -73 would be inappropriate and providers should not charge. If CMS does not change the description of modifier -73 to allow hospitals to report it with procedures cancelled prior to the

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patient entering the treatment room, then will CMS clarify that hospitals are allowed to report an appropriate E/M visit code to recoup some of the costs incurred?

Modifier -74

Asante strongly recommends that CMS continue with the current policy of paying for procedures with modifier -74 at 100% of the APC. Hospitals incur full and often increased costs when modifier -74 is used. In many circumstances when -74 is used, a procedure is cancelled due to the patient's anatomy or a complication of the patient's condition. This circumstance extends the procedure time beyond the normal period and often the recovery time.

Hospitals do their best to manage their resources by screening patients for possible complications that may cause the procedure's cancellation. Because each patient is unique, however, it would be impossible to anticipate and avoid all complications. Complications include -- but are not limited to -- excessive bleeding, hypotension, hypertension, tachycardia, bradycardia, and reactions to anesthesia drugs or gases. The physician and/or anesthesiologist attempt to manage complication(s) and complete the procedure, but there are times when it is in the patient's best interest to discontinue the procedure. The decision point for discontinuation will vary based on the individual situation. If a patient has a reaction to an anesthesia drug or gas, the procedure may be discontinued before an incision is made, however, significant resources have already been expended.

Once anesthesia is initiated, the hospital has every expectation that a procedure will be completed and, therefore, supplies are opened and ready for use during the procedure. (Note that the most expensive supplies like implants are not usually opened until the physician is sure which implant will be used when the patient is already in the surgery/treatment room.) Once the case supplies are opened and the patient has entered the room, the supplies cannot be used for a different case. To wait to open each item until the physician is ready to use it would increase procedure time, require additional staff in the procedure room to anticipate the physician's needs, and could cause the patient to be anesthetized longer than necessary. Once anesthesia is administered, there is no turning back in terms of hospital resources being expended. The post-procedure care of the patient does not change: anesthesia must be reversed, the patient must be recovered, and post-operative pain control managed. In fact, complications that cause a procedure to be interrupted often require longer recovery times than would be necessary for a completed procedure, which results in increased cost to the hospital that is not covered.

Supplies and recovery time are all packaged services and the costs are covered by the APC for the procedure; therefore, reducing the reimbursement when modifier -74 is appended will negatively impact hospitals. Many hospitals bill for surgical procedures based on the time the patient is actually in the surgical suite or procedure room. These facilities are already reporting any decrease in procedure time which will be reflected with decreased charges on the claims used by CMS to set APC payment rates. Does CMS exempt claims with modifier -74 from the calculation of median costs?

Also, we are confused by CMS' assertion that additional services are separately payable under OPSS and therefore the hospital's costs need not be paid through the APC payment for the planned procedure. Initiation of other APCs that are currently separately payable will not recoup costs for the cancelled

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procedure. Most of the services required to stabilize a patient are the same charges inherent to the procedure, such as anesthesia, recovery, staff, related supplies, and drugs (which are packaged).

Services provided that generate separate APC payment would simply cover the cost of providing those other APC services, not the cost of the surgical procedure and recovery time. Moreover, certain services that are provided as part of a surgical procedure (such as injections and infusions) are inherent to the procedure and are not separately reportable under CPT guidelines.

Finally, CMS should recognize that the majority of the upfront costs in providing a service occur in the procedure's first hour. When the physician reaches a point at which a procedure cannot be completed, the bulk of resources have already been expended. Again, CMS' own data shows that the use of modifier -74 is infrequent. Therefore, Asante urges CMS to continue making 100% APC payment for services that are discontinued in order to provide hospitals adequate reimbursement to cover the costs they have incurred.

Application of OPSS to Hospital Encounters

Please explain Medicare coverage and OPSS payment for nutrition/dietary evaluation and treatment services to a hospital outpatient who does not have renal or diabetic conditions. In other words, the medical nutrition therapy codes do not apply. An appropriate clinical scenario to give context to the question is as follows. A Medicare patient with cancer who is losing weight is ordered by the patient's treating physician to be evaluated by a licensed dietitian at the hospital as an outpatient. The patient is registered by the hospital as an outpatient and goes to a specific outpatient hospital department staffed with licensed dietitians for an outpatient visit to evaluate diet, weight, symptoms and propose supplements, changed diet, etc. and advise the patient. A written medical record is maintained and the results of the evaluation and recommendations are provided in writing to the ordering physician. The ordering physician may or may not order follow up visits. This service meets the definition of coverage at COV 80.1, the definition of an outpatient encounter at 42 CFR 210.2, and the definition of outpatient therapeutic services incident to a physician. The question is whether the service (dietary/nutrition evaluation and counseling) is covered and payable under OPSS. If covered, is it billable under an E/M visit code since no other HCPCS code exists for the service? If the answer is non-covered, please confirm that the hospital should then obtain a waiver of liability from the patient to bill the patient for the charge.

Thank you for this opportunity to comment.

Very truly yours,

Valerie A. Rinkle
Revenue Cycle Director

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Submitter : Dr. Michael F. Hogan
Organization : Ohio Department of Mental Health
Category : State Government

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See CORRECTED Attachment

CMS-1501-P-569-Attach-1.PDF

CMS-1501-P-569-Attach-2.PDF



Ohio Department of Mental Health

30 East Broad Street
Columbus, Ohio 43215-3430

September 16, 2005

Phone: (614) 466-2596
TDD: (614) 752-9696
Fax: (614) 752-9453
www.mh.state.oh.us

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-CMS-1501-P

Thank you for the opportunity to provide comments regarding CMS' proposed Outpatient Prospective Payment System concerning Partial Hospitalization Services.

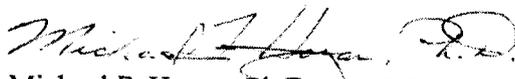
Intensive out-patient and partial hospitalization programs are a less restrictive and less costly alternative to inpatient hospitalization. We believe the current supply of Intensive Outpatient and Partial Hospitalization services is not adequate. Additionally, Ohio and national trends (as documented by The President's New Freedom Commission on Mental Health) demonstrate acute inpatient services are increasingly stressed.

We are concerned that the proposed cuts to the reimbursement rates will further strain outpatient and then inpatient hospitals, and shift patients and costs to state supported mental health systems. Acute care hospital capacity is already showing a swing due to the deterioration of access from closure of private psychiatric units. I have attached a report documenting this trend in Ohio.

We respectfully ask that you reconsider the proposed 15 percent cut. These important programs need to be supported by reasonable reimbursement rates, and I know of no evidence suggesting that current rates are excessive or that the supply of these services is too great.

Thank you for your consideration. Please let me know if you have questions or would like further information regarding this issue. I would be happy to discuss this with you.

Sincerely,


Michael F. Hogan, Ph.D.
Director

Submitter : Dr. Thomas Balkany
Organization : University of Miami Miller School of Medicine
Category : Physician

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1501-P-570-Attach-1.DOC

September 14, 2005

Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attn: CMS-1501-P
PO Box 8016
Baltimore, MD 21244-8018

Re: File Code CMS-1501-P
Issue Identifier: Device-dependent APCs

Dear Sir/Madam:

The CMS proposed rule change for calendar year 2006 proposes to reduce payment for cochlear implantation from \$25,307 in 2005 to \$21,739 in 2006. The 2005 amount is already so much less than actual costs to hospitals that many programs have stopped providing cochlear implants to Medicare recipients. To do so, they have had to close their programs entirely, thus creating a domino effect overflowing from Medicare recipients to the entire hearing impaired public.

If the proposed cuts are adopted they would have a severe impact on Medicare beneficiary access to cochlear implantation. Cochlear implants provide extraordinary benefits to my patients and the proposed cuts would create a severe hardship for them.

Cochlear implants have been proven to be highly cost-effective based on a large body of evidence-based literature.

We respectfully request that CMS substitute accurate external device-cost data as determined in a careful study by the Lewin Group and recalculate the relative weight of APC 0259. If this is not possible, I would alternatively request that CMS set the 2006 OPPS payment no lower than 100% of the 2005 payment rate, plus the rate of inflation and other update factors applied to all APCs.

Thank you for your consideration on behalf of my patients.

Sincerely,

Thomas J. Balkany, MD, FACS, FAAP
Hotchkiss Professor and Chairman
Phone: (305) 585-7129
Fax: (305) 326-7610
E-mail: tbalkany@miami.edu
See our cochlear implant web site at www.cochlearimplants.org

cc: Donna Sorokin
John McClanahan

Cochlear Corporation

CMS-1501-P-571

Submitter : Mr. Paul Sahney
Organization : Trinity Health
Category : Health Care Professional or Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-571-Attach-1.DOC

September 16, 2005

Mark B. McClellan, M.D., Ph.D.
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Centers for Medicare and Medicaid Services
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www.trinity-health.org

REF: CMS-1501-P

RE: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar 2006 Payment Rates; Proposed Rule.

Dear Dr. McClellan:

We write on behalf of Trinity Health regarding the proposed calendar year 2006 Medicare Outpatient Prospective Payment Regulations, which appeared in the July 25, 2005 *Federal Register*, Vol. 70, No. 141, pp. 42,674-43,011.

Trinity Health is an integrated health care system that provides acute hospital, long term, hospice, home health and related care services in **California** (Fresno); **Idaho** (Boise and Jerome); **Indiana** (Mishawaka, Plymouth and South Bend); **Iowa** (Clinton, Dubuque, Mason City, New Hampton, Primghar, and Sioux City); **Maryland** (Silver Spring); **Michigan** (Ann Arbor, Battle Creek, Cadillac, Grand Rapids, Grayling, Howell, Livonia, Macomb County [Clinton Township], Muskegon, Oakland County [Pontiac], Port Huron, and Saline); and **Ohio** (Columbus and Westerville). Our services extend from large inner city to remote rural areas. Our comments, which derive from this perspective, follow:

I. Multiple Diagnostic Imaging Procedures
(*Federal Register pages 42748 - 42751*)

Currently, hospitals receive a full APC payment for each diagnostic imaging procedure on a claim, regardless of how many procedures are performed using a single imaging modality and whether or not contiguous areas of the body are studied during the same encounter.



2004 Award Winner

For 2006, the CMS is proposing to pay 100 percent for the diagnostic imaging procedure with the highest APC payment rate, and pay only 50-percent for each additional imaging procedure when all the procedures are performed during a single patient encounter and all are within an identified “family” of procedures that are commonly billed on the same day. The CMS identified 11 “families” of imaging procedures by imaging modality and by contiguous body area. The agency is proposing to apply the multiple imaging procedure reduction to individual services described by codes within one Family, not across Families. For example, no reduction would apply to an MRI of the brain (CPT code 70552) in code Family 5, when performed in the same session as an MRI of the spinal canal and contents (CPT code 72142) in code Family 6. The CMS is proposing to make full payment for the procedure with the highest APC payment rate, and payment at 50 percent of the applicable APC payment rate for each additional procedure, when performed in the same session. In developing this policy, the CMS did not examine hospital cost data but relied on Medicare physician fee schedule practice expense data for determining the discount level. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the appropriate level of efficiencies obtained by hospitals, if they even exist.

Under the proposal, Trinity Health will incur significant OPPS payment reductions and opposes moving forward with this policy without solid justification, and more substantial, hospital-based data to support the policy. We note that the APC Advisory panel came to the same conclusion. Additional concerns include:

- The proposed rule does not specify how the reduced payments will be considered to assure overall budget neutrality.
- Historically, relative weights and hence payments for imaging were established using historical charge and cost data. By reducing payment for multiple procedures, imaging procedures as a whole will be paid below the cost of operations and will disproportionately disadvantage facilities.
- The proposed rule lacks detail and justification for the 50 percent discount.
- The proposed rule does not define “same session”. In some circumstances a patient may have a procedure performed earlier in the day and subsequently on the same day have another procedure that may fall within the same family and incorrectly be subject to the discount.

II. Conversion Factor

(Federal Register Page 42694-42695)

The hospital update is based on a “market basket” factor that is intended to reflect the average change in the price of goods and services hospitals purchase to furnish patient care. These price changes must be projected forward to estimate increases for the subsequent year so that an appropriate market basket update can be determined in advance of payment.

For the hospital inpatient PPS, the FY 2006 inpatient proposed rule included a 3.2 percent update, with the actual increase in the final rule set at 3.7 percent, based upon a change in methodology. Trinity Health requests that the CMS revise the market basket update included in the final OPPS rule to include a 3.7 percent market basket update, consistent with the inpatient final rule.

III. Rural Hospital Adjustment

(Federal Register pages 42698 – 42701)

Under section 411 of Public Law 108-173, the Secretary is given authorization to provide an appropriate adjustment to rural hospitals by January 1, 2006, if rural hospital costs are determined to be greater than urban hospital costs. Based upon its analysis the CMS proposes a 6.6% payment increase for rural Sole Community Hospitals for CY 2006.

Trinity Health supports the proposed increase for Sole Community Hospitals. Sole Community Hospitals play a vital role in providing access to care in rural areas and the payment increase will help offset their higher cost levels. The additional payment will also help offset payment reductions related to expiration of the transitional corridor payments for rural Sole Community Hospitals.

In closing, Trinity Health thanks you for the opportunity to comment on the proposed Hospital Outpatient Prospect Payment System rule. We look forward to working with you on the above issues.

Sincerely,

Paul Sahney
Vice President, Revenue Management

Timothy J. Eckels
Vice President of Public Policy

Submitter :

Date: 09/16/2005

Organization :

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Outlier Payments. _____ CMS Should Not Reduce the Outlier Payment Pool _____ Outlier payments are an important component of the OPSS because they provide some financial stop loss when hospitals provide high cost services. Currently, CMS targets these payments to be 2 percent of total outpatient payments, with a proposal to decrease to 1 percent. This reduction is achieved increasing the fixed dollar threshold by \$400. Payment would remain 50 % of the service cost above the threshold. _____ CMS has provided no data to support the proposed reduction or its impact on various classes of hospitals; the only rationale provided is a MedPAC recommendation to eliminate the outlier pool. _____

We believe these data must be made available to allow providers to make meaningful comments as to whether the outlier pool should be increased or decreased. _____

MedPAC's reasons and our reaction to MedPAC's comments are as follows: _____ The narrow definition of many of the services provided in hospital outpatient departments suggests that variability in costs should not be great. _____ While this is true to some extent, there is a significant amount of packaging of services in the OPSS that creates differences in cost. Most notably, payment for surgical procedures are based on average cost, while there can be enormous variances in OR time, packaged supplies and devices, recovery time, and when warranted, extended recovery or observation following complex surgery. It should also be noted that the OPSS outlier target of 2% is the lowest target under any of the various Medicare prospective payment systems ? the narrower definition of services is already reflected in the outlier policy. _____ The distribution of outlier payments benefits some hospital groups more than others. This is one of the main benefits of the outlier policy ? it reduces the loss that certain hospital groups incur in providing high-end services to the Medicare population. According to the CMS impact file, 40% of outlier payments are received by major teaching hospitals. There are a number of reasons for this including often being the first adapters of expensive state of the art technology, and more complex patients. _____

The outlier policy is susceptible to ?gaming? through charge inflation. _____ As CMS demonstrated with its inpatient outlier policy changes, there are ways to address charging practice ?gaming? without penalizing the facilities that require the outlier payments. _____

The OPSS is the only ambulatory payment system with an outlier policy. _____ The OPSS is the only ambulatory payment system targeted to hospitals where the variability in patient condition can be enormous. Freestanding providers subject to ASC and other ambulatory payment systems will often not even accept the more complex patients. If the outlier payment were to be removed or diminished to an extent where it is essentially removed, OPSS would be the only prospective payment system without an outlier policy. _____

We continue to believe that outpatient services that qualify for outlier payments should receive 80 percent of their costs above the threshold, rather than the current level of 50 percent. While teaching hospitals would still incur significant unreimbursed costs, increasing the payment level would help ameliorate the level of these losses for hospitals, such as teaching hospitals, that provide complex outpatient services. Increasing the payment level would also make the OPSS consistent with the policy under the inpatient PPS.

Submitter : Mr. Andrew Loman
Organization : Spring Harbor Hospital
Category : Health Care Provider/Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1501-P-573-Attach-1.DOC



September 15, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-CMS-1501-P

Spring Harbor Hospital is a hospital and psychiatric provider in Maine. As a long-standing provider of Partial Hospitalization services, the initial shock of CMS-1501-P and a 15% rate reduction for CY2006 was overwhelming. The very existence of this service will be threatened for the future if our facility must absorb this amount of revenue reduction. It is very difficult to convince boards and administrative authorities to continue programs year after year on a break-even basis at best. A \$40/day reduction will be an impossible task. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited.

As a member of the Association of Ambulatory Behavioral Healthcare, our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1501-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of \$289.00. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas. A daily per diem of \$241.57 cannot be justified with these expenses.
2. CMS identified the Median cost of group therapy at \$82.31. Our program offers 4 services per day at a minimum. This summarizes to a median cost of \$329.24. A per diem of \$241.57 cannot be justified with these expenses.

CMS Letter- Page 2.

3. Many of our patients are Medicare and Medicaid recipients. Medicaid cuts are strongly threatened here in Maine. If the 20% co-pay is unavailable, the per diem would shrink even further and eliminate any consideration for these programs to exist. This would virtually reduce the per diem to \$193.26 ($\$241.57 \times .80$). A daily per diem of \$241.57 cannot be justified with this situation.
4. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally tow years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two year periods.
5. Based on the above issues, Spring Harbor Hospital asks that CMS leave the per diem unchanged from the CY 2005 rate of \$281.33. The proposed rate is not sufficient to cover the costs needed for our intensive program.

If rates are slashed and our program cannot continue, the inpatient demands will grow substantially as there are no other alternative services for this needy population in our community. Our PHP program has had 242 admissions so far in CY 2006, and every one would be a high-risk candidate for inpatient admission without the PHP availability.

Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,



Dennis P. King
Chief Executive Officer

CMS-1501-P-574

Submitter : Ms. John Manzi
Organization : New Jersey - Healthcare Financial Mgt. Assoc.
Category : Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1501-P-574-Attach-1.DOC

September 16, 2005

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 21244

Sent via e-mail to: <http://www.cms.hhs.gov/regulations/ecomments>

RE: 2006 Hospital Outpatient PPS Proposed Rule [CMS-1501-P]

Dear Mr. McClellan:

The New Jersey Chapter of the Healthcare Financial Management Association appreciates this opportunity to comment on the 2006 OPSS Proposed Rule that was published in the July 25, 2005 Federal Register and corrected in the August 26, 2005 Federal Register. We wish to address the following Proposed Rule changes:

OPSS Payments for Drugs, Biologicals and Radiopharmaceuticals

The Center for Medicare and Medicaid Services (CMS) has recognized that expensive and rarely used drugs, biologicals and radiopharmaceuticals need to be paid separately in order to prevent insufficient payments to hospitals. CMS has also created APCs for certain products, rather than packaging them with their associated outpatient procedures. These items include: orphan drugs, blood and blood products, certain vaccines, and devices of brachytherapy consisting of a seed or seeds.

Payment for most Part B drugs (primarily injectable drugs administered by clinicians and used to treat cancer and other conditions), biologicals and radiopharmaceuticals administered in hospital outpatient departments will be based on competitive market prices. Rather than being paid at the current 83% of the average wholesale price (AWP), the proposed payment will be 106% of the average sales price (ASP). This mirrors the methodology already used for drugs administered in physicians' offices. Further, CMS is proposing to add an additional 2 percent to cover handling cost incurred by hospitals' pharmacy departments when administering separately payable drugs and biologicals.

CMS's proposal for CY2006 is for brand and generic drugs to be paid similarly, with a single ASP-based payment rate that considers the process for both forms of the

drug. However consideration of ASP plus 8 percent payment rate is in-line based on claims data to set the payment rate at mean costs.

It should also be noted that there is a wide variation in handling costs, depending upon the type of drug involved (example: oral tablet vs. compounded preparation). An additional 2 percent to cover handling cost incurred by hospitals' pharmacy departments does not seem to be sufficient.

Recommendation: We recommend that no change be made.

Multiple Diagnostic Imaging Procedures

Hospitals billing for outpatient imaging services have, under the current OPSS rule, received full reimbursement for all imaging procedures performed on the same date of service, regardless of the number of procedures performed. For example: if a CT of the chest, abdomen and pelvis were to be performed, the hospital would receive full reimbursement for all three procedures.

CMS is proposing "to apply the multiple imaging procedure reduction to individual services described by codes within one family {e.g. CT, Ultrasound}, but not across families. Reductions would apply when more than one procedure within the family is performed in the same session. {CMS} is proposing to make full payment for this procedure with the highest APC payment rate, and payment at 50% of the applicable APC payment rate for every different procedure, when performed in the same session."

CMS has identified 11 families of imaging procedures, based on the type of imaging modality used and contiguous body area that will be affected by the proposed policy.

Recommendation: Based on this proposal, hospitals that perform multiple diagnostic imaging procedures will have a dramatic decrease in their outpatient revenue. For this reason, we recommend that this change not be implemented.

If you or your staff would like to discuss our comments, please contact John Manzi at (609) 918-0990 ext. 124 or Lee Gordon at (201) 996-3373.

Sincerely,

John Manzi, President

Lee Gordon, Co-Chairperson
Reimbursement/Proactive Committee

Rea Zagaglia, Co-Chairperson
Reimbursement/Proactive Committee

Submitter : Dr. Ernst Valfer
Organization : La Cheim Adult Behavioral Health Services
Category : Other Health Care Provider

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1501-P-575-Attach-1.DOC

CMS-1501-P-575-Attach-2.DOC

September 15, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-
CMS-1501-P

La Cheim Adult Behavioral Health Services is a freestanding Community Mental Health Center in California. As a long-standing provider of Partial Hospitalization services, the initial shock of CMS-1501-P and a 15% rate reduction for CY2006 was overwhelming. The very existence of this service will be threatened for the future if our facility must absorb this amount of revenue reduction. It is very difficult to convince boards and administrative authorities to continue programs year after year on a break-even basis at best. A \$40/day reduction will be an impossible task. CMS must reconsider this position or we would have to close.

As a member of the Association of Ambulatory Behavioral Healthcare, our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1501-P refers to the CY2005 combined hospital-based and CMHC median per diem base costs of \$289.00. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in the San Francisco Bay Area. A daily per diem base of \$241.57 cannot be justified with these expenses.
2. CMS identified the Median cost of group therapy at \$82.31. Our program offers 5 services per day at a minimum. This summarizes to a median cost of \$411.55. A per diem base of \$241.57 cannot be justified with these expenses.
3. Many of our patients are Medi-Medi's. Medicaid cuts are strongly threatened here in California. If the 20% copay is unavailable, the per diem would shrink even further and eliminate any consideration for these programs to exist. This would virtually reduce the per diem base to \$193.26 ($\$241.57 \times .80$). A daily per diem base of \$241.57 cannot be justified with this situation.
3. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally tow years or more after the actual

year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two year periods.

4. Based on the above issues, La Cheim Adult Behavioral Health Services asks that CMS leave the per diem base unchanged from the CY 2005 rate of \$281.33. The proposed rate is not sufficient to cover the costs needed for our intensive program.

If rates are slashed and our program cannot continue, the inpatient demands will grow substantially as there are no other alternative services for this needy population in our community. Our PHP program has had 151 admissions so far in CY 2006, and every one would be a high risk candidate for inpatient admission without the PHP availability.

Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,

Victor G. Prada
CEO

CMS-1501-P-576

Submitter : Ms. JoAnne Mandel
Organization : Innerwisdom, inc
Category : Health Care Professional or Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1501-P-576-Attach-1.TXT

CMS-1501-P-576-Attach-2.RTF

September 15, 2005



InnerWisdom, Inc.
Counseling Centers

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

**Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient
PPS-CMS-1501-P**

InnerWisdom, Inc. is a freestanding Community Mental Health Center located in Houston Texas. We have been providing Partial Hospital Program (PHP) services since 1994. Since that time we have gone through many changes, both internally and as a result of changes in the benefit's administration and the reimbursement rate.

Initially, providers of services had no formal way of receiving information from HCFA, regarding regulations and provision of services for this level of care. Then providers were then put on 100 % review of medical records for post-pay evaluation. Finally, after extensive meetings with HCFA personnel and Congressional representatives, from 1997 through 2002, the benefit was revised, payment of services were changed from fee for service to prospective pay (2000), and some Fiscal Intermediaries (FI) posted Local Medical Review Policies (LMRP) on their websites, giving providers some direction by formally stating their regulations for the PHP benefit.

The years between 1997 and 2002 were difficult for all providers of PHPs. Most providers closed their programs. Few of the original providers still remain intact. Those of who have survived, however, have learned to provide adequate services with a much reduced reimbursement rate. We are just now beginning to stabilize under the new system. We remain aware of the problems of the past, and vividly remember those days. Yet most of us who remain active providers did find ways to cut costs and to treat our patients with reduced staff.

The information regarding CMS-1501-P and a 15% rate reduction for CY2006 was shocking. Providers think that we are already providing PHP services as efficiently as possible while trying to provide adequate services. It is very true that the very existence of this service will be threatened if PHPs must absorb this amount of revenue reduction. It is impossible to convince boards and administrative authorities to continue programs year after year on a break-even basis at best. A \$40/day reduction will be an impossible task.

Providers of PHPs in Community Mental Health Centers (CMHC) have heard that CMS has found information from recent Cost Reports showing a reduction in the cost of providing services in our facilities. There are many reasons why this information is unreliable. Most Cost Reports although reviewed, are not closed for up to four years after being filed, as providers and FIs do not agree on final numbers; initial information is most often flawed. It does not appear that CMS takes the final Cost Report information into account when reviewing information used in setting the daily reimbursement rate.

CMS must reconsider their position. Patients depend on us to provide these services. In some cases, we are their only hope for an even somewhat normal life. With a reduction of any amount, many facilities and providers will have to take extreme action, which will likely result in the closure of many programs, or to severely limit their already reduced services.

I am a provider of PHP services, but I am also a member of the Association of Ambulatory Behavioral Healthcare (AABH). Our organization stands firmly behind the comments they submitted under different cover.

In addition, the following key points represent views that we see differently than CMS:

1. CMS-1501-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of \$289.00. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas. A daily per diem of \$241.57 cannot be justified with these expenses.
2. CMS identified the Median cost of group therapy at \$82.31. Our program offers five services per day at a minimum. This summarizes to an above median cost of \$329.24. A per diem of \$241.57 cannot be justified with these expenses.
3. Many of our patients are Medi-Medi's. Medicaid cuts have already occurred in Texas. More are already proposed. If the 20% copay is unavailable, the per diem would shrink even further and eliminate any consideration for these programs to exist. This would virtually reduce the per diem to \$193.26 ($\$241.57 \times .80$). A daily per diem of \$241.57 cannot be justified with this situation.
4. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally two to four years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two to four year periods.

5. Based on the above issues, InnerWisdom, Inc. asks that CMS leave the per diem unchanged from the CY 2005 rate of \$281.33. The proposed rate is not sufficient to cover the costs needed for our intensive program.

If rates are slashed and our program cannot continue, the inpatient demands will grow substantially as there are no other alternative services for the mentally ill population in our community.

Lastly, due to recent events and the catastrophe that occurred in the Gulf Coast area, we are looking at increased needs throughout the country. The mentally ill population has been moved from their home states to other areas. Their needs are greatly increased.

Thank you for your consideration of our comments. I look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,

JoAnne Mandel

JoAnne D. Mandel, LMSW, RN, CNS
CEO
InnerWisdom, Inc.

Submitter : Dr. K. Todd Houston
Organization : Alexander Graham Bell Association
Category : Other Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Sec Attachment

CMS-1501-P-578-Attach-1.DOC

Alexander Graham Bell

ALEXANDER GRAHAM BELL
ASSOCIATION FOR THE DEAF AND HARD OF HEARING

September 16, 2005

Attachment #578

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1501-P (Device-Dependent APC's)
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and calendar year 2006 Payment Rates; Proposed Rule; (70 Federal Register 42674), July 25, 2005 (CMS-1501-P)

Dear Dr. McClellan:

The Alexander Graham Bell Association for the Deaf and Hard of Hearing (AG Bell) welcomes the opportunity to submit comments in response to CMS proposed rule 1501-P (Device Dependent APCs) to revise the outpatient prospective payment system (OPPS) for calendar year 2006.

AG Bell is the world's oldest and largest membership organization promoting the use of spoken language by children and adults with hearing loss. Members include parents of children with hearing loss, adults who are deaf or hard of hearing, educators, audiologists, speech-language pathologists, physicians, and other professionals in fields related to hearing loss and deafness. Through advocacy, publications, financial aid and scholarships, and numerous programs and services, AG Bell promotes its mission: *Advocating Independence through Listening and Talking!*

AG Bell is very concerned that reimbursement rates for cochlear implants continue to be significantly under funded, impacting accessibility to a life-enhancing technology for persons who are deaf or hard of hearing. Cochlear implants dramatically improve the quality of life, self-sufficiency and independence of the Medicare population who receive them, and are cost effective as demonstrated by evidence-based literature and their acceptance among medical professionals and insurance providers.

Our members appreciate CMS' willingness to work with implant providers and manufacturers in ensuring that payment rates are responsive to actual CI device costs, which are much higher than the proposed rate. If adopted, the proposed reimbursement level of \$21,739 would have a devastating effect on Medicare beneficiary access to cochlear implantation surgery and follow up care.

Mark B. McClellan, M.D., Ph.D.
September 16, 2005
Page Two

The limited number of implant centers and specialty hospitals that now provide cochlear implantation could and will reduce the number of surgeries performed due to inadequate reimbursement rates and others will close their doors altogether. This will, in turn, cause shortages of qualified clinical personnel to perform audiological services and (re)habilitation necessary for cochlear implant recipients to achieve maximum benefit from implantation.

We appreciate and commend the agency's willingness to work with the cochlear implant community and acknowledge the issues with hospital outpatient payment system methodology that makes it difficult for CMS to accurately track actual device costs. However, we urge you to increase payment rates for cochlear implants to more accurately reflect cochlear implantation costs.

We request and urge CMS to substitute accurate external device cost data as determined by a recent Lewin Group study and recalculate the relative weight of APC 0259. Alternatively, we request that CMS set the 2006 OPPI payment no lower than 100 percent of the 2005 payment rate plus the inflation and other update factors applied to all Ambulatory Payment Classifications (APCs).

Cochlear implants enhance the quality of life for individuals who are deaf and hard of hearing. Please take the necessary steps outlined above to ensure that more people with hearing loss have access to this hearing technology.

Sincerely,

A handwritten signature in cursive script that reads "K. Todd Houston".

K. Todd Houston, Ph.D.
Executive Director/CEO

Submitter : Ms. Trina Buettner
Organization : Defiance Regional Medical Center
Category : Pharmacist

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Regarding CMS-1501-P

Please consider complex biologicals under APC 0117. Monoclonal antibody preparations require intermittent swirling of the vial to get the product to go into solution. This is very time-intensive.

We are a small hospital providing services to Northwest Ohio residents. Reimbursement for Outpatient Services was at breakeven for medications like Remicade(R), Xolair(R), and IVIG during 2004. I am concerned about not being able to purchase medications at the median of the ASP. I can't operate on the same economies of scale as a larger facility.

Thank-you for the chance to comment,
Trina Buettner, Director
DRMC Pharmacy
Defiance, OH 43512

Submitter : Mr. James Greenwood
Organization : Biotechnology Industry Organization
Category : Health Care Professional or Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
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. Abbey Meyers
Organization : National Organization For Rare Disorders
Category : Consumer Group

Date: 09/16/2005

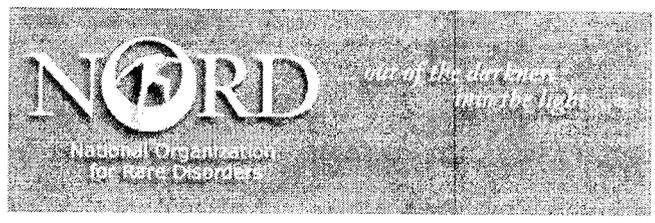
Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments.

CMS-1501-P-580-Attach-1.PDF



September 16, 2005

Via electronic submission at <http://www.cms.hhs.gov/regulations/ecomments>

Mark B. McClellan, M.D., Ph.D.
 Administrator
 Centers for Medicare and Medicaid Services
 Room 445-G, Hubert Humphrey Building
 200 Independence Avenue, SW
 Washington, DC 20201

RE: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates
[CMS-1501-P]
Comments on Orphan Drugs

Dear Dr. McClellan:

On behalf of the National Organization for Rare Disorders (NORD), we are pleased to provide comments on this Proposed Rule.

NORD is a federation of approximately 130 voluntary health organizations and approximately 60,000 individual patients, healthcare providers and clinical researchers. We are all committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research and service.

We are concerned about the marginalization of orphan drugs and biologicals provided under the Outpatient Prospective Payment System (OPPS) and other CMS programs. Access problems are a constant threat to rare disease patients and yet CMS has taken no actions to monitor this potential problem nor have they acknowledged the breadth of orphan products upon which Medicare beneficiaries are dependent.

Prior to 2002 (Calendar Year 2003 regulations), CMS's OPPS policy provided special payments for orphan drugs and made access to care for rare disease patients a priority. In 2002, CMS reversed this policy and approach and determined that the ambit of CMS concern would be limited. Ultimately, the new rules have recognized only 14 orphan products as eligible for special

Mark B. McClellan, M.D., Ph.D.
September 16, 2005
Page 2

consideration in the OPPS setting, ignoring about 80 other orphan products used in this setting that may also experience access difficulties.

This is unacceptable because it excludes the majority of rare disease therapies, undermines Congressional intent in enacting the Orphan Drug Act, and fails to give full weight to the scientific expertise of the Food and Drug Administration ("FDA") in making orphan designations.

The anomalous CMS definition of orphan drugs remains in the OPPS regulations and has started to take on a life of its own (e.g. in the final rules for the CAP program). Whether in the OPPS regulations or elsewhere, using the CMS definition relieves CMS of obligations to the entire rare disease population, something it should not be doing, both on legal and moral grounds. Our recommendations and further discussion will focus on the inappropriate CMS definition of "orphan drugs."

To be clear, under the predominant OPPS payment methodology proposed for CY2006, we are not anticipating access problems generally for orphan products used in this setting during the next year. We are aware of concerns raised about Intravenous Immune Globulin (IVIG), and we urge CMS to listen to the concerns, evidence and suggestions of the IVIG "community" with regard to a potential patient access issue under OPPS. We would also urge CMS to listen to concerns, evidence and suggestions from other members of the rare disease community if they identify potential access issues with other orphan drugs and biologicals.

The lack of a process and criteria for judging these situations is a problem, especially if the proposed rulemaking is the only means to raise access issues. What if there is a problem that doesn't emerge until March of next year? In response to this, our second recommendation calls for prospective criteria, ample opportunity to formally raise access concerns throughout the year and specific access determinations by CMS based on the prospective criteria.

RECOMMENDATIONS

CMS has never developed prospective criteria for designating orphan drugs and biologicals based upon utilization data or review of evidence about access to orphan drugs. Nor has CMS provided stakeholders with a written explanation—supported by examples—of the Agency's rationale for the criteria it has used to designate orphan drugs and biologicals.

Absent this, the statutory definition should prevail and not CMS's unsupported regulatory interpretation.

Therefore, we recommend that:

1. For the purposes of identifying drugs and biologicals that are treatments for rare diseases, CMS should adopt the definition of "orphan drugs" used in the Food, Drug and Cosmetics Act;¹
2. For the purpose of determining whether rare disease patients utilizing specific orphan drugs are subject to access problems under CMS programs, CMS should:
 - accept orphan products designated by FDA as a valid class for initial consideration,
 - develop prospective criteria to determine which orphan drugs should not be part of this class for a specific regulation or guidance because patients with rare diseases do not experience problems with access to these orphan drugs under the specific program controlled by the regulation or guidance,
 - work with stakeholder organizations, such as the National Organization for Rare Disorders, to identify any access problems that may occur or are likely to occur in the near future and
 - provide patients and pharmaceutical companies an opportunity to present data and receive a written explanation with examples before making a final decision that an orphan drug is not subject to access problems.

¹ Under the Orphan Drug Act (Pub. L. 97-414), an orphan drug is one that is designated as a drug for a rare disease or condition and for which a marketing approval for such disease or condition is obtained. The relevant statutory text is:

(a) Request by sponsor; preconditions; "rare disease or condition" defined

(1) The manufacturer or the sponsor of a drug may request the Secretary to designate the drug as a drug for a rare disease or condition. A request for designation of a drug shall be made before the submission of an application under section 355 (b) of this title for the drug, or the submission of an application for licensing of the drug under section 262 of title 42. If the Secretary finds that a drug for which a request is submitted under this subsection is being or will be investigated for a rare disease or condition and—

(A) if an application for such drug is approved under section 355 of this title, or

(B) if a license for such drug is issued under section 262 of title 42,

the approval, certification, or license would be for use for such disease or condition, the Secretary shall designate the drug as a drug for such disease or condition. A request for a designation of a drug under this subsection shall contain the consent of the applicant to notice being given by the Secretary under subsection (b) of this section respecting the designation of the drug.

(2) For purposes of paragraph (1), the term "rare disease or condition" means any disease or condition which

(A) affects less than 200,000 persons in the United States, or

(B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under this subsection is made.

(21 U.S.C. § 360bb(a).)

Using our recommended approach will end an ever-present threat to Medicare beneficiaries with rare diseases as they look for assurance that the drugs that they need will be available to them. Our approach is also the one that is consistent with the Orphan Drug Act.

DISCUSSION

In enacting the Orphan Drug Act (ODA) twenty years ago, Congress established the fundamental principle that the high costs and low returns associated with orphan products must not be allowed to impede the availability of such products to rare disease patients. Consistent with the policy, Congress exempted orphan products as a class from the HOPPS bundling, claims-based payment methodology for the first three years after the payment system was established. See Pub. Law 106-113 § 201(b).

Under this exemption, Congress provided that (1) orphan products were to be paid separately under “pass-through” status, rather than being bundled for payment into APCs; and (2) the payment for orphan products was to be established in accordance with the policy governing payment for drugs administered in the physician office, rather than by applying the HOPPS claims-based methodology. **During this timeframe (1999 to 2002), the use of the term “orphan drugs” by CMS was consistent with, and supportive of, FDA policy. The FDA policy emanates directly from statutory Congressional direction expressed in the ODA.**

In the HOPPS Rule for 2003, and in subsequent HOPPS rules and proposed rules, CMS chose a much narrower definition of “orphan drugs.” The new definition applied the orphan-specific payment rate safeguard only to products that are:

- designated as an orphan drug by the FDA;
- approved by the FDA for treatment of only one or more orphan conditions, and
- for which the United States Pharmacopoeia Drug Information “shows that the drug has neither an approved use nor an off-label use for other than the orphan condition(s).

This definition is wholly without precedent. To our knowledge, it was not developed based on statute, Congressional report, GAO report, correspondence with policymakers or discussion with the rare disease community. In fact, under commonly used standards of legislative interpretation, CMS should have extended their previous ODA-based definition into the 2003 to 2006 period.

Over the last three calendar years, CMS has identified a total of 14 products as “orphan drugs” under the agency’s definition. This has the effect of omitting the vast majority of orphan products administered in the outpatient setting (approximately 90 to 100).

CMS’s policy of recognizing only a small number of orphan drugs as eligible for special protection has broad and fundamental implications that are of great concern to the rare disease community. On its face, the policy seems more concerned with controlling the businesses of drug companies than with ensuring that the needs of patients can be met under OPSS payment policy and other CMS programs.

Mark B. McClellan, M.D., Ph.D.
September 16, 2005
Page 5

Moreover, by applying the orphan-specific safeguard so narrowly, CMS ignores the many orphan-designated products whose "non-orphan indications" under USP-DI are also for truly rare diseases. Thus, from the perspective of the rare disease community, this rule of exclusion threatens to undermine the incentives provided to companies under federal law that are so critical to the continued research and development of rare disease therapies.

CONCLUSION

We believe CMS's continuing policy of focusing on only 14 orphan products in the outpatient setting erodes the important principle that orphan products must be given special consideration as a class in order to ensure that the needs of the rare disease community are met.

Orphan drugs and biologicals provide important benefits to the health and quality of life of Medicare beneficiaries with rare diseases. Without special consideration under the Federal Food, Drug and Cosmetic Act and under the Medicare statute, these agents would not be available for these patients. As the representative for the rare disease community, we urge CMS to redefine "orphan drugs" to match the statutory definition and establish an evaluation process to determine which orphan products may need special status or assistance in order to assure access.

We appreciate the opportunity to provide comments on this Proposed Rule. It is vital to the rare disease community for CMS to reconsider its definition of "orphan drugs." NORD is eager to work with you to develop a more appropriate policy in HOPPS and other Medicare programs for assessing access to all orphan drugs and not just the 14 designated by CMS.

Please do not hesitate to contact me or Diane Dorman of our Washington office (202-496-1296, ddorman@rarediseases.org) to pursue this matter further.

Sincerely,



Abbey S. Meyers
President

cc: Diane E. Dorman, Vice President, Public Policy

MIA 300297-2.020980.0048

Submitter : Mr. Peter Diestel
Organization : The Valley Hospital
Category : Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

September 16, 2005

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

Ref: [CMS-1501-P] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2006 Payment Rates (70 Federal Register 42673), July 25, 2005.

Dear Dr. McClellan:

Thank you for the opportunity to comment on the proposed changes to the Hospital Outpatient Prospective Payment System. On behalf of Valley Hospital in Ridgewood, New Jersey, I would like to specifically comment on the proposal to reduce payment for multiple imaging procedures.

CMS proposes reducing payment when multiple imaging services are provided on the same day, with full payment for the costliest imaging service and a 50 percent reduction in payment for additional procedures from the same family of procedures performed in the same session. The proposed rule outlines 11 families of imaging procedures by imaging modality and by contiguous body area. In developing this policy, CMS did not examine hospital cost data, but relied on Medicare physician fee schedule practice expense data. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the right level of efficiencies obtained by hospitals, if they even exist.

Valley Hospital opposes moving forward with this policy without a better justification and more substantial, hospital-based data to support the policy. It should be noted that the APC advisory panel came to the same conclusion. We also are concerned with the lack of implementation detail provided in the proposed rule, such as defining the same session. Finally, we would like clarification on how CMS would ensure that this change is budget neutral. The proposed rule provides no detail on how the impact of the multiple imaging procedures discount was calculated or how the budget neutrality factor was adjusted.

Again, Valley Hospital appreciates the opportunity to comment on this proposal.

Sincerely,

Peter W. Diestel
Vice President, Administration
Attachment

CMS-1501-P-582

Submitter : Mr. Jim Hayes
Organization : Allergan Inc.
Category : Drug Industry

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1501-P-582-Attach-1.PDF

#582

ALLERGAN

2525 Dupont Drive, P.O. Box 19534, Irvine, CA 92623-9534 • (714) 246-4500

September 16, 2005

VIA ELECTRONIC SUBMISSION

Mark McClellan, M.D., Ph.D. Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule CMS-1501-P "NonPass-Throughs" and "New Procedure Codes"

Dear Dr. McClellan:

On behalf of Allergan Inc. ("Allergan"), we are pleased to submit comments in response to the above-captioned Proposed Rule ("NPRM") on the hospital Outpatient Prospective Payment System ("OPPS"). Allergan develops and manufactures BOTOX[®] (Botulinum Toxin Type A) Purified Neurotoxin Complex. BOTOX[®] is a biological used to treat patients with blepharospasm (a disorder involving involuntary closure of the eyelids), strabismus (a disorder of muscles that move the eyes), cervical dystonia (abnormal movements of the neck muscles) and severe primary axillary hyperhidrosis (disorder of sweat glands).¹ Botulinum toxin type A is administered by physicians in their offices and in hospital outpatient departments. Botulinum toxin type A is covered as a biological provided incident-to a physician's service under Medicare Part B.²

We were pleased to see the Centers for Medicare and Medicaid Services' ("CMS") careful consideration of available sources of hospital acquisition cost data for "specified covered outpatient drugs" ("SCODs"). We support the Agency's proposal to use average sales price (ASP) plus 6-percent as the best estimate for current average hospital acquisition cost for SCODs. We know that the Agency has struggled for a number of years to develop a payment method for drugs and biologicals under OPPS that accurately reflects hospital acquisition costs to assure patient access while at the same time preserving administrative efficiency and predictability. We believe the NPRM makes a significant advance in achieving these

¹ The current package labeling includes the following indications for BOTOX[®]:

BOTOX[®] is indicated for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.

BOTOX[®] is indicated for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents. BOTOX[®] is indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.

The efficacy of BOTOX[®] treatment in deviations over 50 prism diopters, in restrictive strabismus, in Duane's syndrome with lateral rectus weakness, and in secondary strabismus caused by prior surgical over-recession of the antagonist has not been established. BOTOX[®] is ineffective in chronic paralytic strabismus except when used in conjunction with surgical repair to reduce antagonist contracture.

In addition, BOTOX[®] Cosmetic, which has distinct labeling, packaging and NDC-coding, has been approved by the FDA for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients ≤65 years of age. BOTOX[®] Cosmetic is never covered by Medicare.

² Soc. Sec. Act §§ 1861(s)(2)(A),(B).

goals. We offer our comments below to support several proposals in the NPRM as well as to make certain specific recommendations for the Final Rule.

In summary, our comments are as follows:

- We are pleased with the decision to use the manufacturer-reported ASP plus 6-percent to estimate hospital acquisition costs for SCODs, including botulinum toxin type A (HCPCS code J0585³). We believe ASP plus 6-percent appropriately reflects current average hospital acquisition cost for botulinum toxin type A.
- We also agree with the proposal to adjust payment rates on a quarterly basis consistent with updated manufacturer reported ASPs.
- We support CMS' proposal to provide separate payment to cover pharmacy handling costs. As reported by many authoritative sources, pharmacy handling costs can be significant, and these costs should be reimbursed separate from payments to cover hospital acquisition costs for drugs and biologicals. At the same time, we agree with the recommendation of the Advisory Panel on Ambulatory Payment Classification Groups ("APC Panel") that it is premature to implement a series of new pharmacy handling codes in 2006. CMS should further refine the proposed codes based upon comments from hospitals, industry and other interested stakeholders, and CMS should provide detailed instructions to hospitals on the use of these codes before implementation.
- Several new Physicians' Current Procedural Terminology ("CPT") codes have been approved for CPT 2006 that are relevant to administration of botulinum toxin type A.
 - At least 2 new CPT codes have been developed to report chemodenervation of eccrine glands for the treatment of patients with severe focal hyperhidrosis. We would recommend that CMS assign these new codes to APC 0204 "Level I Nerve Injections" consistent with the assignment of other chemodenervation procedure codes.
 - Two new CPT codes have been developed to report needle electromyography ("EMG") and electrical stimulation as guidance for chemodenervation procedures. We would recommend that CMS assign these new codes to clinically and economically coherent APCs. It would appear that either APC 0215 "Level I Nerve and Muscle Tests" or APC 0218 "Level II Nerve and Muscle Tests" would be appropriate APCs consistent with the assignment of similar EMG procedures.

These points are explained more fully below.

1. Average Sales Price Plus 6-Percent is a Reasonable Estimate of Current Average Hospital Acquisition Costs for Specified Covered Outpatient Drugs and Biologicals, Including Botulinum Toxin Type A

Under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173 [the "MMA"]), payment for a SCOD in 2006 and subsequent years is to be equal to the average acquisition cost for the drug or, if such data are not available, the average price for the drug established

³ The descriptor for code J0585 is: "botulinum toxin type A, per unit."

for payment in the physician office setting.⁴ A SCOD is a covered outpatient drug for which a separate payment classification group (APC) has been established and that is either a radiopharmaceutical or a drug or biological which was paid as a pass-through drug on or before December 31, 2002.⁵ Botulinum toxin type A (HCPCS J0585) qualifies as a SCOD having a separate APC group (APC 0902⁶) and having been paid as a pass-through biological from August 1, 2000 through December 31, 2002.

In the NPRM, CMS identifies three sources of data for determining average hospital acquisition costs for SCODs: (1) survey data reported by the Government Accountability Office (GAO), (2) manufacturer-reported average sales price data used to determine payment rates for Part B drugs and biologicals in the physician office setting and (3) mean and median cost data from hospital claims.⁷ In the NPRM, CMS discusses the appropriateness and limitations of these data sources and proposes ASP-plus-6-percent as the best estimate of average acquisition cost for purposes of OPSS rate setting. We agree with this proposal.

The GAO report on hospital acquisition costs included data on only 55 drugs. To help GAO verify the data it received from surveyed hospitals, Allergan provided GAO with a comprehensive summary of all hospital sales of botulinum toxin type A⁸ for the period July 1, 2003 through June 30, 2004. The data GAO found for botulinum toxin type A were not reported publicly, however, so we cannot comment on the accuracy of these data.

The claims data posted by CMS to support the NPRM show a mean cost for botulinum toxin type A of \$4.05-per unit and a median cost of \$3.21-per unit. Although the mean cost is closer to actual acquisition cost than the median, these claims-based costs are substantially below actual hospital acquisition cost for botulinum toxin type A. Allergan provided CMS with comprehensive summaries of all hospital sales for botulinum toxin type A as part of our comments to Proposed Rulemaking for OPSS for 2003, 2004 and 2005. These "external" data showed that the claims-based costs for botulinum toxin type A were substantially below actual acquisition cost. CMS indicated in the Final Rule for OPSS 2004 that it found our external data credible and concluded that payments based on the claims-based cost data could provide a disincentive for hospitals to offer this biological.⁹ Therefore, we strongly support CMS' decision not to use claims-based costs as estimates of average hospital acquisition cost for SCODs, like botulinum toxin type A.

Manufacturer-report ASP data are reliable, comprehensive and timely. Using ASP plus 6-percent is a reasonable estimate of average hospital acquisition cost for botulinum toxin type A, and we support CMS' decision to use these data for OPSS payment determinations. Use of this payment standard, consistent with payment in the physician office setting, will avoid financial incentives for selecting site of service that have existed over the past several years when payment rates for botulinum toxin type A fell below actual acquisition costs first in the hospital setting and later in the physician office setting. Use of this payment standard will also provide greater predictability—avoiding annual changes in the methodology for payment of drugs and biologicals, like botulinum toxin type A.

Therefore, we strongly endorse CMS' proposal to use ASP plus 6-percent as the basis for average hospital acquisition cost of separately payable drugs and biologicals under OPSS.

⁴ MMA § 621(a)(1) (Soc. Sec. Act § 1833(t)(14)(A)(iii)).

⁵ Soc. Sec. Act § 1833(t)(14)(B)(i).

⁶ APC 0902 has the descriptor: "Botulinum toxin a, per unit."

⁷ 70 Fed. Reg. 42674,42725 (Jul. 25, 2005).

⁸ Allergan is the sole manufacturer of FDA-approved botulinum toxin type A in the U.S.

⁹ 68 Fed. Reg. 63398,63447 (Nov. 7, 2003).

2. CMS Should Update Payment Rates for Separately Paid Drugs and Biologicals on a Quarterly Basis Consistent with Quarterly Reports of ASP Data from Manufacturers.

We were pleased to see that CMS is proposing to update payment rates for separately payable drugs and biologicals on a quarterly basis consistent with updates in manufacturer-reported ASP data. The ASP reported by manufacturers represent as near to real-time costs as any data source CMS uses for rate setting. Even with quarterly updates, however, there is a 4 to 6 month lag between the time prices are adjusted in the marketplace and the time these are reflected in Medicare payment rates. Less frequent updates would put a greater burden on hospitals when prices are increasing and would result in unnecessary Medicare payments when prices are decreasing. Updating the OPPS payment rates for separately payable drugs and biologicals would keep the OPPS payments on par with those made under Part B in the physician office setting. This will help avoid financial incentives for selection of site of service.

3. CMS Should Move Forward with Development of a Method for Determining Pharmacy Handling Costs for Drugs and Biologicals. Pending Development of a New Method for Determining These Costs, CMS Should Implement an Appropriate Adjustment to the ASP-based Payments to Reflect These Significant Costs.

In the MMA, Congress mandated the Medicare Payment Advisory Commission (MedPAC) to study pharmacy service and handling costs hospitals incur related to drugs and biologicals and to prepare a report to CMS with MedPAC's findings and recommendations on making adjustments to payments for drugs and biologicals to reflect these costs.¹⁰ MedPAC issued its report in June 2005 and found that pharmacy handling, labor and supplies—i.e., costs other than drug acquisition costs—comprise 25-percent to 33-percent of total pharmacy costs. Based on these findings, MedPAC made the following recommendations:

“6A The Secretary should establish separate, budget-neutral payments to cover the costs that hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals

6B The Secretary should:

- define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs;*
- instruct hospitals to submit charges for those APCs; and*
- base payment rates for the handling fee APCs on submitted charges, reduced to costs.”¹¹*

We agree that pharmacy handling, labor and supply costs are significant and should be reimbursed under OPPS. These costs are over and above drug acquisition costs reflected by ASP plus 6-percent. Therefore, we support CMS' recognition of these costs and its determination to pay appropriately for these costs.

We also agree that it is important to capture accurate data on pharmacy handling costs in order to establish equitable payment rates and that specific codes to report these services may be the best way to identify these costs. At the same time, we understand the concerns raised at the August meeting of the APC Panel, where the APC Panel recommended that CMS delay implementation of the proposed new

¹⁰ MMA § 621(a)(1) (Soc. Sec. Act 1833(t)(14)(E)).

¹¹ MedPAC. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. In: Report to the Congress: Issues in a Modernized Medicare Program. June 2005.

“C” codes to report pharmacy handling. More time is needed to allow interested stakeholders to provide comments to CMS on the proposal, for CMS to refine the proposal based upon these comments and—most importantly—for CMS to provide hospitals clear instructions on the use of these new codes and for hospitals to implement systems to assure appropriate and accurate reporting of these services.

The importance of providing clear guidance to hospitals on appropriate reporting of these new codes cannot be underestimated. For example, from our review of the proposed codes and descriptors, it would appear that the appropriate code to report handling of botulinum toxin type A would be CYYYY “Specialty IV or Agents requiring special handling in order to preserve their therapeutic value . . .”¹² Unopened vials of botulinum toxin type A must be stored refrigerated (2° to 8° C). The neurotoxin must be diluted carefully, must be kept refrigerated after dilution and must be used within 4 hours following dilution. At the same time, because it is also an injection/sterile preparation, which is drawn up for administration, some hospital coders may question whether code CXXXX is the appropriate code to report pharmacy handling for this neurotoxin.¹³ Clear instructions are needed to assure accurate and consistent reporting of these new codes.

Therefore, we would recommend that CMS make an appropriate adjustment to payment for drugs and biologicals to reflect pharmacy handling and supply costs pending development of new codes to report these services and the establishment of appropriate payment rates to reflect these costs. We also encourage CMS to take the time to reflect carefully on comments received from interested stakeholders before implementing new codes and request that CMS provide clear instructions to hospitals about the appropriate use of these codes before implementation.

4. CMS Should Assign New CPT Procedure Codes for Chemodenervation of Eccrine Glands and for Electromyography Guidance to Established Clinical APCs that Are Clinically and Economically Coherent with the New Codes.

a. New codes to report chemodenervation of eccrine glands for treatment of patients with severe focal hyperhidrosis should be assigned to APC 0204 “Level I Nerve Injections.”

The administration of most drugs and biologicals is reported using one of the injection/infusion codes (e.g., the codes for intravenous injection or for intramuscular injection). With botulinum toxin type A, however, administration of the neurotoxin comprises a specific type of procedure called chemodenervation. The most common codes used to report chemodenervation procedures are: 64612, 64613 and 64614.¹⁴ These codes are assigned to APC 0204 “Level I Nerve Injections.”

¹² The full descriptor for code CYYY is:

- Specialty IV or Agents requiring special handling in order to preserve their therapeutic value or Cytotoxic Agents, oral (chemotherapeutic, teratogenic, or toxic) requiring PPE.
- Cytotoxic Agents (chemotherapeutic, teratogenic, or toxic) in all formulations except oral requiring personal protective equipment (PPE).

¹³ The full descriptor for code CXXX includes: Injection/Sterile Preparation (draw up a drug for administration).

¹⁴ The descriptors of these codes are: **64612**—Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (eg, for blepharospasm, hemifacial spasm); **64613**—Chemodenervation of muscle(s); cervical spinal muscle(s) (eg, for spasmodic torticollis); **64614**—Chemodenervation of muscle(s); extremity(s) and/or trunk muscle(s) (eg, for dystonia, cerebral palsy, multiple sclerosis). Other codes are used to report administration of botulinum toxin type A at other body sites, such as 67345 “Chemodenervation of extraocular muscle” (used for the treatment of strabismus); code 43201 “Esophagoscopy, rigid or flexible: with directed submucosal injection(s), any substance” has been used to report chemodenervation of lower esophageal sphincter muscles by injection of botulinum toxin through endoscopic visualization in the treatment of patients with achalasia.

Mark McClellan, M.D., Ph.D.
September 16, 2005
Page 6 of 6

We are aware that the American Medical Association's CPT Editorial Panel has approved at least 2 new chemodenervation codes, to be implemented January 2006, to report chemodenervation of eccrine glands for the treatment of patients with severe focal hyperhidrosis. These codes will be included in the 6468x series.

The new chemodenervation of eccrine gland codes are clinically and economically coherent with the chemodenervation of muscle codes currently assigned to APC 0204. Therefore, we would recommend that CMS also assign the new chemodenervation of eccrine gland codes to APC 0204. Chemodenervation procedures are appropriately grouped among nerve injection procedures, and APC 0204 represents the lowest resource level of the nerve injection codes. As these are new codes for 2006, we understand why CMS did not identify these codes or propose APC assignments for them in the NPRM. Nevertheless, because CMS will assign APCs to these codes in the Final Rule, we thought it appropriate to provide our recommendations to you.

b. New codes to report needle EMG or electrical stimulation as guidance for chemodenervation procedures should be assigned to APCs that are clinically and economically appropriate. It would appear either APC 0215 "Level I Nerve and Muscle Tests" or APC 0218 "Level II Nerve and Muscle Tests" would be clinically and economically coherent with these new codes.

In addition to the new chemodenervation codes for eccrine glands, we are also aware that the CPT Editorial Panel has approved 2 new codes to report needle EMG or electrical stimulation as guidance for chemodenervation procedures. These procedures are performed at the discretion of the physician when s/he considers it necessary to identify the appropriate target muscle(s) for treatment with botulinum toxin type A. The guidance procedures are not required nor used in all cases when chemodenervation is performed. These new codes will be included in the 95858x and 95859x series.

The new codes replace current reporting of EMG guidance for chemodenervation under code 95870 "Needle electromyography; limited study of muscles in one extremity or non-limb(axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters," which is assigned to APC 0215 "Level I Nerve and Muscle Tests." The new codes were created to allow more specific reporting of the needle EMG and electrical stimulation procedures for chemotherapy guidance. We would defer to the hospital and professional societies for specific recommendations regarding which clinical APCs these procedures appear to fit best. We would identify APC 0215 or APC 0218 ("Level II Nerve and Muscle Tests," the APC to which most single needle EMG codes are assigned) as the most appropriate APCs comprising clinically and economically coherent procedures.

* * * *

We appreciate having the opportunity to comment on the NPRM and hope CMS will consider these recommendations in preparing the Final Rule for implementation in 2006. If you have any questions about our comments, please contact Jim Hayes, Director, Reimbursement Strategy and Healthcare Policy, Neuroscience Division at 714-246-6401 or by e-mail at hayes_jim@allergan.com. Thank you.

Sincerely yours,

/s/ Jim Hayes

Director, Reimbursement Strategy and Healthcare Policy
Neuroscience Division
Allergan Inc.

Submitter : Mr. Roger Sarao
Organization : New Jersey Hospital Association
Category : Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment (Word document titled "NJHA 2006 OPPS NPRM Technical Comments.doc").

CMS-1501-P-583-Attach-1.DOC



September 16, 2005

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

Ref: [CMS-1501-P] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2006 Payment Rates (70 *Federal Register* 42673), July 25, 2005.

Dear Dr. McClellan:

On behalf of our 112 member hospitals, health care systems and other health care organizations, the New Jersey Hospital Association (NJHA) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule establishing new policies and payment rates for the hospital outpatient prospective payment system (OPPS) for calendar year 2006.

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 2006 than in 2005. These changes make it extremely difficult for hospitals to plan and budget from year to year. Among these "broken" APCs, several evaluation and management (E/M) services APCs – especially clinic visits – continue to experience declines in payment rates. We would expect that four years after the start of the OPPS, the payment rates and associated payment-to-cost ratios would be much more stable.

In addition to this instability, the entire OPPS 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, skyrocketing liability premiums, the rising cost of drugs and technologies, aging facilities, expensive regulatory mandates and more.

The proposed rule contains a number of significant policy changes, including changes to payments for handling costs hospitals incur for separately paid drugs, increases in the threshold for the outlier policy, and reduced payments for multiple imaging procedures. We address these areas briefly in this cover letter and in more detail in the attachment.

PHARMACY OVERHEAD AND DRUG HANDLING PAYMENT RATE ADJUSTMENT

The proposed rule adjusts the APC rates for separately payable drugs to take into account pharmacy overhead and drug handling costs. Since CMS does not have separate hospital charge data on these pharmacy costs, the agency proposes in 2006 to pay 2 percent of the average sales price (ASP) for these products. To set payment rates in the future, CMS proposes three distinct temporary healthcare common procedure coding system (HCPCS) codes (C-codes) and corresponding APCs to differentiate by level of overhead costs for drugs and biologicals. Hospitals would be instructed to charge the appropriate pharmacy overhead C-code when they provide separately payable drugs.

The NJHA believes that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We are concerned, however, that the ASP+2 percent adjustment for drug handling is not adequate for certain drugs that have very high handling costs due to special equipment or procedures related to the drug's toxicity, or special compounding or preparation requirements. **CMS should freeze payments at 2005 levels for those drugs whose payments would decline significantly from the 2005 rates, particularly for those drugs that may have especially complex and costly handling requirements.** We also have serious operational concerns about the requirement that hospitals establish separate charges for pharmacy overhead using the three proposed C-codes. Most importantly, Medicare providers must have uniform charges for all payers (see *70 Federal Register* 42693), but payers other than Medicare do not use the C-codes. If implemented, this policy would seem to be inconsistent with the requirement stated in the *Federal Register* that "Medicare providers are required to maintain uniform charges for all payers" because providers would now be obligated to maintain different charge structures for drugs – one for Medicare that does not include handling costs and one for other payers that does.

For this and many other reasons outlined in our detailed comments, the NJHA **opposes CMS' proposal to require hospitals to establish separate charges for pharmacy overhead for separately payable drugs using the three proposed C-codes.** Instead, we recommend that CMS work with stakeholder groups to collect further data and develop simpler solutions.

OUTLIER POLICY

The NJHA also continues to be concerned about the outlier policy. The proposed rule would decrease the set-aside for outlier payments from 2 to 1 percent and increase the dollar threshold for receiving outlier payments by \$400, to \$1,575. We are concerned about whether the proposed threshold is too high and request clarification on how it was determined. In addition, as in previous years, the proposed rule does not include data on the actual outlier payments made in 2005 and prior years. **The NJHA strongly recommends that CMS publish in the final rule data on actual outlier payments made in 2004 and prior years, and that actual outlier payments for 2005 and later years be reported as soon as possible.**

REDUCED PAYMENT FOR MULTIPLE IMAGING PROCEDURES

CMS proposes reducing payment when multiple imaging services are provided on the same day, with full payment for the costliest imaging service and a 50 percent reduction in payment for additional procedures from the same "family" of procedures performed in the same session. The proposed rule outlines 11 "families" of imaging procedures by imaging modality and by

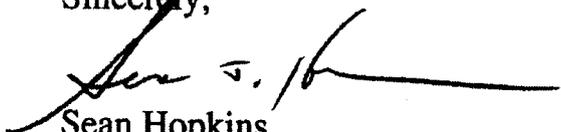
contiguous body area. In developing this policy, CMS did not examine hospital cost data, but relied on Medicare physician fee schedule practice expense data. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the right level of efficiencies obtained by hospitals, if they even exist.

The NJHA opposes moving forward with this policy without a better justification and more substantial, hospital-based data to support the policy. We would note that the APC advisory panel came to the same conclusion. We also are concerned with the lack of implementation detail provided in the proposed rule, such as defining “the same session.” Finally, we would like clarification on how CMS would ensure that this change is budget neutral. The proposed rule provides no detail on how the impact of the multiple imaging procedures discount was calculated or how the budget neutrality factor was adjusted.

The attached detailed comments on the proposed changes expand on the points raised above and also on several other important parts of the rule.

The NJHA appreciates the opportunity to comment. If you have questions please feel free to contact me at 609-275-4022, or shopkins@njha.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Sean S. Hopkins", with a long horizontal flourish extending to the right.

Sean Hopkins
Senior Vice President

Attachment



Detailed Comments on the Proposed Rule for the 2006 Outpatient Prospective Payment System

APC RELATIVE WEIGHTS

Current law requires that the Centers for Medicare & Medicaid Services (CMS) review and revise the relative payment weights for ambulatory payment classifications (APC) at least annually. The New Jersey Hospital Association (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 prospective payment system (OPPS), payment rates for specific APCs have fluctuated dramatically. For 2006, the proposed rates continue to show significant volatility for several reasons.

First, in the proposed rule, CMS uses the most recent claims data for outpatient services to set 2006 weights or rates, using approximately 49 million whole claims for hospital outpatient department services furnished during calendar year 2004 to create 81 million single records. **The NJHA continues to support the use of the most recent claims and cost report data to set the 2006 payment weights and rates.**

Second, CMS continues its efforts to include more claims data in the calculation of the APC payment rates, especially those "multiple procedure claims" that contain charges for more than one service or procedure. CMS is proposing to expand the number of Healthcare Common Procedure Coding System (HCPCS) codes it bypasses on a claim – from 383 in 2005 to 404 in 2006 – so that "pseudo" single-procedure claims are created. This list of bypassed codes was developed using an empirical approach established in 2005 and described in the rule. CMS also proposes to continue using "date of service matching" – in which charges are attributed to separately payable HCPCS codes based on the code's date of service – as a tool for creation of "pseudo" single claims. **In general, the NJHA continues to support the use of multi-procedure claims, as we believe that these data improve hospital cost estimates. The NJHA 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. We also continue to support the use of "date of service matching" in developing the 2006 outpatient rates.**

The NJHA is concerned, however, that while the proposed rule provides a detailed description of the methodology used to calculate the APC weights, it does not provide adequate information for hospitals to evaluate the impact of each of the proposed policy changes independently or in combination. Questions such as, "What would the weights be without the changes?" and "How much of the volatility in the weights is due to the changes?" cannot be answered due to this lack of data. **The NJHA requests that CMS provide a public use file that shows the impact of**

each individual proposed change in methodology so that health care providers can review the file to determine how the changes would affect their own operations, and provide a basis for submitting thoughtful comments to CMS.

In addition, although we understand the empirical criteria used to determine the additional codes to add to the bypass list, we find it puzzling that the bypass list includes only some office visit and consultation services codes. For instance, the list includes HCPCS codes 99213 and 99214, but not 99211, 99212, and 99215. One could speculate that this might be explained, in part, by the continuing lack of consistency across hospitals in the use of the evaluation and management (E/M) codes due to the absence of uniform guidelines for hospital coding of E/M services. **The NJHA seeks clarification regarding why only some of the office visit and consultation service E/M codes are included in the bypass list.**

Proposed Changes to Packaged Services: The NJHA commends CMS and the APC Panel's Packaging Subcommittee for initiating a process 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. When hospitals provide services described by these "N" status codes alone, there is no way to be reimbursed for the costs of providing these services. **We strongly encourage CMS to continue to work with the APC Panel's Packaging Subcommittee to further review "N" status codes and identify those that should be paid separately.**

PARTIAL HOSPITALIZATION

The NJHA is concerned that the proposed 15 percent reduction in the per diem payment rate for partial hospitalization services could dramatically harm the financial viability of partial hospitalization services in hospitals and health care systems, and could endanger Medicare beneficiary access to them. These services already are quite vulnerable, with many programs in recent years closing or limiting the number of patients they can accept.

We share CMS's concern about volatility of the community mental health center (CMHC) data and support the agency's intent to monitor CMHC costs and charges for these services, and work with CMHCs to improve their cost reporting so that payments can be calculated based on better empirical data.

Although the NJHA recognizes that CMS made the proposal to avoid at a later time an even more significant reduction in the payment rate for these services, we do not believe that hospitals offering partial hospitalization services should be penalized for the instability in data reporting that stems from CMHC-based services. Instead, the NJHA recommends that in the final rule for 2006, CMS freeze payment rates for partial hospitalization services at the 2005 levels. 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.

CONVERSION FACTOR

The NJHA assumes that CMS again will follow the practice it has used in previous years of utilizing the same market basket update published in the inpatient PPS final rule for the purposes of the outpatient PPS. In the inpatient final rule for FY 2006, CMS responded to an American Hospital Association (AHA) request – which NJHA supported – and changed the market basket estimation methodology to provide a better estimate of hospitals' cost increases. We assume that this change also will be part of the final outpatient rule.

OUTLIER PAYMENTS

Outlier payments are additional payments to the APC amount to mitigate hospitals' losses when treating high-cost cases. For 2006, CMS proposes reducing the outlier pool to 1 percent of total outpatient PPS payments. Further, CMS says that the fixed-dollar threshold should be increased by \$400, to \$1,575, to ensure that estimated 2006 outlier payments would equal 1 percent of total outpatient PPS payments. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment rate and at least \$1,575 more than the APC rate.

While the NJHA supports the continued need for an outlier policy in all prospective payment systems, including the outpatient PPS, we are concerned that CMS has set the thresholds for outliers in this rule too high. The NJHA seeks further clarification from CMS regarding how the agency determined that a \$400 increase in the fixed-dollar threshold was appropriate and how the \$1,575 fixed-dollar threshold was calculated.

In addition, for the past four years, CMS set aside 2 percent of total estimated outpatient PPS payments to fund outlier payments to hospitals. For 2006, CMS is proposing to set aside only 1 percent for outliers. However, CMS does not publicly release in the *Federal Register* or on the CMS Web site data about how much of the outlier set-aside was actually spent in prior years. With the significant changes to outlier policies proposed for 2006, the NJHA is concerned that Medicare may not actually spend the outlier target set-aside.

The NJHA strongly recommends that in the final rule CMS publish data on actual outlier payments made in 2004 and prior years, that actual outlier payments for 2005 be reported as soon as CMS is able to obtain complete data, and that CMS continue to report this data into the future. If CMS is able to obtain this information on the inpatient side and publicly report it, it should be similarly obtained and reported on the outpatient side. Interested parties should not have to purchase costly databases in order to determine whether these thresholds are being set at the right level. Even if CMS believes that it does not have a statutory mandate to return unspent outlier pool funds to the outpatient PPS system, we believe that CMS has a duty to make appropriate estimates, and we are concerned that CMS cannot set the outlier threshold at an appropriate level if it does not know the actual outlier spending.

In issuing a public accounting of total outlier payments for 2005, CMS will need to take into consideration the implications of an error that occurred in identifying services that qualified for outlier payments. CMS incorrectly set the outlier threshold too high in the 2005 fiscal intermediary system, which resulted in underpayment for outliers. Providers were requested to

identify and re-bill those claims that should have received outlier payments. These additional outlier payments should be considered in its calculation of actual outlier expenditures for 2005.

NEW TECHNOLOGY

The NJHA supports CMS's proposal to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA's) CPT Editorial Panel before CMS accepts a New Technology APC application for review.

The proliferation of G-codes and C-codes and their potentially overlapping descriptions with CPT codes is confusing and burdensome for hospital coders. This confusion often has resulted in incorrect coding and unreliable data available for rate setting. Requiring that an application for a new CPT code be submitted at the time of a New Technology APC application will minimize the need for expedited issuance of temporary G- or C-codes. HCPCS level II G- and C-codes generally are not accepted by payers other than Medicare, thus requiring hospitals to have two different codes to report the same procedure, depending on the payer. This new process will reduce the duplication of codes so that it will start the process correctly via CPT, rather than with a New Technology assignment and no way to report the procedure. While we understand that circumstances may exist when a G- or C-code still will be required, having a CPT code available for new technology will simplify the billing and coding process for hospitals because one set of codes (i.e., CPT) will be used as much as possible for all payers.

Device manufacturers may not be planning ahead and applying for CPT codes for a variety of reasons, including fear of application denial. In any event, the CPT process involves a more rigorous process than level II HCPCS codes and includes the opportunity for input from the physician specialty societies. Without support from the physician specialties that would embrace the new technology, it is doubtful that the new technology will achieve acceptance from the medical community. Input from the physician community also ensures that the code descriptor selected for new technology procedures will be as close as possible to the terminology that physicians will use to document these services. This in turn will reduce the confusion in determining proper code selection.

HYPERBARIC OXYGEN

The NJHA supports CMS's decision to no longer use the respiratory therapy cost-to-charge ratio (CCR) for purposes of calculating the median cost for hyperbaric oxygen therapy (HBOT), and instead use the hospital's overall CCR. Since some hospitals, though, currently report HBOT costs on a separate line on their cost report, the NJHA would recommend that in 2006, CMS should calculate the median rate for HBOT using the HBOT CCR for hospitals that report separately. If hospitals do not separately report HBOT, then the overall hospital CCR would be used. In order to develop rates that are more accurate for HBOT in the future, CMS should encourage hospitals to report the HBOT costs on a separate HBOT line on their cost report. This should not be administratively difficult for hospitals because HBOT revenues already are captured in a specific separate revenue code, and would involve only a change in where costs for HBOT are reported on the cost report.

NON-PASS-THROUGHS

The MMA requires that in 2006, payment for specified covered outpatient drugs be equal to the average acquisition cost for the drug, subject to any adjustment for overhead costs. In the proposed rule, CMS evaluates three alternatives for setting 2006 payment rates for these drugs: (1) average and median purchase price data for drugs purchased from July 1, 2003 to June 30, 2004, derived from a General Accountability Office survey of 1,157 hospitals; (2) the average sales price (ASP) data from the fourth quarter of 2004; and (3) mean and median costs derived from the 2004 hospital claims data. After considering the merits and weaknesses of each approach, CMS proposes to pay ASP+6 percent for separately payable drugs and biologicals in 2006.

In general, the NJHA supports this proposal and agrees that paying for drugs at ASP+6 percent appears to be the best available estimate of average acquisition cost. This also has the additional benefit of providing for consistent payment rates across the hospital outpatient PPS and the physician fee schedule payment systems. Finally, given the inflation in drug prices over time, we believe that the ability to update ASP rates on a quarterly basis also is a key advantage of this proposal. However, the proposal to pay at ASP+6 percent will result in significant reductions in payments for some separately payable drugs and biologicals.

Therefore, the NJHA supports the APC Panel's recommendation that CMS carefully track the drug codes to be paid at ASP+6 percent, with a particular focus on drugs with rates that would fall significantly in 2006. We are concerned that steep drops in payments for certain drugs and biologicals could have implications on manufacturer production levels of these drugs and hurt patient access to some drug therapies. If CMS obtains evidence that access to certain drug therapies would be threatened due to payment rate decreases, then it should consider freezing payments or otherwise limiting decline in payments for these products.

Pharmacy overhead and drug handling adjustment: In the proposed rule, CMS took into consideration the Medicare Payment Advisory Commission (MedPAC) recommendations on how to adjust the APC rates for separately payable drugs to account for pharmacy overhead and drug handling costs. To address this, CMS proposes to establish three distinct HCPCS C-codes and corresponding APCs for drug handling categories. This will differentiate overhead costs for drugs and biologicals and instruct hospitals to charge the appropriate pharmacy C-code for overhead costs associated with the administration of each separately payable drug and biological based on the code description that best reflects the service the hospital provides in preparing to administer the product. Since CMS does not have separate hospital charge data on pharmacy overhead, the agency proposes for 2006 to pay for these costs based on 2 percent of the ASP. This would result in overall drug payments, including the drug itself and the associated handling payment, of ASP+8 percent, which CMS states is equivalent, on average, to the mean cost for drugs derived from hospital claims data.

The NJHA agrees with the MedPAC finding that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We are concerned, however, that the ASP+2 percent adjustment for drug handling is not adequate for certain drugs that have very high handling costs due to special

equipment or procedures related to the drug's toxicity, or special compounding or preparation requirements. As noted above, we recommend that CMS consider freezing payments in 2006 for those drugs whose payments would decline significantly from the 2005 rates, particularly for drugs that may have especially complex and costly handling requirements. In the future, CMS should work with hospital and pharmacy stakeholders to establish differential add-on payments for drug handling costs for a wide variety of drug handling categories.

The NJHA strongly opposes CMS' proposal requiring hospitals to establish separate charges for pharmacy overhead for separately payable drugs and biologicals, and utilize the three proposed C-codes for charging these overhead costs. This would be extremely burdensome and difficult for hospitals to implement.

There are many complex issues and administratively burdensome aspects to adopting CMS' proposal for charging for drug handling through the use of these new C-codes. The most important is that, if implemented, this policy would seem to be inconsistent with the requirement that Medicare providers maintain uniform charges for all payers (see *70 Federal Register* 42693). Given this, it is impossible to charge Medicare a rate that does not reflect handling costs, and charge other payers for the same drug a higher rate that does reflect handling costs. This simply could not be done. Even assuming that hospitals could provide differential charges, other concerns remain:

- Hospitals would have to evaluate the normal mark-up formula for all pharmacy items and deduct the handling costs for some, but not all, of these drugs and biologicals. That is, hospitals would have to identify and strip out the handling charges for separately payable drugs under Medicare while the drug handling charges for packaged drugs would remain incorporated within the overall charge for the drug. This would be an extremely complex and time-consuming process.
- For each separately payable drug, hospitals would need to assign the handling charge to one of CMS's proposed new drug handling C-codes. These C-codes are only recognized by and acceptable to Medicare, but not to other payers. Hospitals therefore would have to modify their billing systems to separate out the drug handling from the drug charge for Medicare claims, but bill them as a single line item for other payers. Setting aside the concern raised above about violating the Medicare requirement for uniform charges, this also introduces another level of complexity and burden.
- Confusion exists about how the drug handling C-codes would apply when a hospital pharmacy mixes multiple doses of a drug for a patient. Would the hospital report a single C-code for handling costs in this case or multiple C-codes? Confusion around how to charge could result in incorrect data, which would make it difficult to establish appropriate future payment rates for these services.
- Drug pricing is generated through a pharmacy charging system often located outside the hospital's normal charging system, and may not be able to accommodate CMS' proposed C-codes.
- Many hospitals use the same charge master for inpatient and outpatient services. If the handling charge must be separated out of the drug charge for the outpatient setting, it is unclear how CMS will expect providers to report drug charges in the inpatient setting versus the outpatient setting.

The NJHA also is aware that the APC Panel, based on testimony provided by a number of organizations representing drug manufacturers and others, has proposed that CMS expand the application of its proposed drug handling coding and payment methodology to drugs that are packaged into other APCs. **The NJHA opposes this expansion of the drug handling C-coding proposal to packaged drugs. This would exponentially increase the coding and administrative burden on hospitals due to the sheer number of drugs that would require special charging practices for Medicare purposes.** In addition, hospitals generally do not provide detailed billing for drugs that are not separately paid, meaning that hospitals do not separately assign HCPCS C-codes or J-codes for these drugs. More importantly, not all drugs have C-codes or J-codes. Creating new codes for all drugs would be a significant burden. It would therefore be extremely difficult for hospitals to bill the right drug handling C-code for packaged drugs. Further, many hospitals that have adopted a paperless billing system also use an imaging system to generate a bill for a patient. Given the large volume of drugs used in hospital outpatient departments, expanding the drug handling coding requirements to all these drugs, regardless of their packaging status, would dramatically increase hospital administrative costs associated with this already misguided proposal.

The NJHA recommends that CMS *not* implement the proposed drug handling C-codes in 2006. Instead, we recommend that CMS work with stakeholder groups to collect additional data, and develop alternative and simpler solutions for ensuring that hospitals are appropriately paid for their pharmacy overhead and drug handling costs. Such an approach should incorporate the payments for drug handling directly into the payment rate for the drug itself, rather than requiring separate coding systems.

If CMS decides to implement this burdensome drug handling C-codes policy, then NJHA suggests that CMS provide a grace period of no less than 6 months after implementation of the 2006 outpatient PPS (June 1, 2006) so that hospitals can create the new charging system, make system changes and educate pharmacy staff, hospital finance staff, and coders on the required use of the drug handling "C" codes.

DRUG ADMINISTRATION

The NJHA continues to support CMS' proposal to use CPT codes to bill for drug administration services provided in the hospital outpatient department. Using CPT codes simplifies the administrative burden for the coding of drug administration since hospitals can use the same codes for Medicare and non-Medicare payers. We understand that under the proposed methodology, payment for services within the same APC would be collapsed by the outpatient code editor (OCE) into a single per-visit APC payment – just as it currently does – until 2005 claims data become available, when CMS will provide further refinement and recognize resources associated with drug administrations that last several hours.

Because of the significant changes expected with the new 2006 CPT codes for drug administration, hospitals will need instruction and clarification on the application of these new codes. For example, clarification will be needed regarding the following:

- How the code application may be similar or different for the hospital outpatient department as compared to the physician setting – especially for non-oncology providers of infusion and injection services, since they often cross departments.
- Definitions of what constitutes an “initial” vs. subsequent infusion vs. concurrent infusion.
- Definition of “hydration” and how it is different from a hydration that is given for therapeutic reasons. In other words, a therapeutic infusion can be hydration.
- How should infusions or titrations be reported? Many times they are established with a documented start time and administered via pump. As such, many infusions are maintained by equipment function rather than manual intervention. In these cases, a nurse may be aware of the start time of an infusion and may document it. It is unlikely, though, that the stop time will be documented.

E/M SERVICES

Since the implementation of the outpatient PPS, hospitals have coded clinic and emergency department (ED) visits using the same CPT code as physicians. CMS has recognized that existing E/M codes correspond to different levels of physician effort but do not adequately describe non-physician resources. Although hospitals were anticipating that CMS would propose a national, uniform E/M coding system in 2003, the agency chose not to do so. As a result, in 2003 the AHA and the American Health Information Management Association convened an independent panel of experts to develop a set of coding guidelines for CMS.

Specifically, the panel recommended that CMS should:

1. Make payment for emergency department and clinic visits based on four levels of care.
2. Create HCPCS codes to describe these levels of care as follows:
 - Gxxx1 - Level 1 Emergency Visit
 - Gxxx2 - Level 2 Emergency Visit
 - Gxxx3 - Level 3 Emergency Visit
 - Gxxx4 - Critical Care provided in the Emergency Department
 - Gxxx5 - Level 1 Clinic Visit
 - Gxxx6 - Level 2 Clinic Visit
 - Gxxx7 - Level 3 Clinic Visit
 - Gxxx8 - Critical Care provided in the Clinic
3. Replace all the HCPCS currently in APCs 600, 601, 602, 610, 611, 612 and 620 with GXXX1 through GXXX8.
4. Crosswalk payments from GXXX1 to APC 610, GXXX2 to APC 611, etc.

In the 2004 and 2005 OPSS rules, CMS stated it would consider national coding guidelines recommended by the panel, and planned to post for public comment the proposed guidelines on the outpatient PPS Web site. CMS also proposed to implement new E/M codes only when it could also implement guidelines for their use. This guidance would be issued after ample opportunity for public comment, systems change and provider education.

The NJHA is disappointed that the 2006 proposed rule fails to include national guidelines for facility E/M reporting. While we applaud CMS as the agency continues to develop and test

the new codes, hospitals still are without a standard methodology for reporting E/M services. This lack of uniformity not only puts hospitals at compliance risk for multiple interpretations of the level of service that should be coded and billed, but also affects CMS' ability to gather consistent, meaningful data on services provided in the emergency department and hospital clinics. This is especially important because CMS uses the mid-level clinic visit (APC 601) as the anchor for establishing the relative weights within the outpatient PPS, and, due to a lack of national coding guidelines, there is no agreement on what a mid-level clinic visit encompasses. We believe that the E/M coding recommendations made by the independent panel will adequately meet hospitals' needs.

BLOOD AND BLOOD PRODUCTS

CMS proposes to continue making separate payments for blood and blood products through individual APCs for each product. The agency also proposes to establish payment rates for blood and blood products based on their 2004 claims data, utilizing an actual or simulated hospital blood-specific cost-to-charge ratio to convert charges to costs for blood and blood products. For blood and blood products whose 2006 simulated medians would experience a decrease of more than 10 percent in comparison to their 2005 payment medians, CMS is proposing to limit the decrease in medians to 10 percent.

While this approach results in modest payment increases for many blood and blood product APCs, the payment rate for leukocyte-reduced red blood cells (APC 0954), the most commonly transfused blood product, and rates for certain other blood and blood product APCs will continue to decline under this methodology. According to data from the American Association of Blood Banks, the proposed rate for several of these blood products is significantly below hospitals' actual acquisition costs, most notably for leukocyte-reduced red blood cells. With the introduction of additional blood safety measures, it is likely that the cost of these products will continue to increase, making the proposed Medicare payment rate even more inadequate.

To ensure continued beneficiary access to all blood and blood products, the NJHA recommends that CMS set 2006 rates at *the greater of*: the simulated medians calculated using the 2004 claims data; or the 2005 APC payment medians for these products.

The NJHA also commends CMS for issuing in March 2005 comprehensive and clear billing guidelines for blood and blood products, addressing issues such as the blood deductible and differences between donor and non-donor states. This document was well received by hospitals, and it should help clear up much of the confusion regarding the correct way to code and bill for blood and blood products.

OBSERVATION SERVICES

Currently, Medicare provides a separate observation care payment for patients with congestive heart failure (CHF), chest pain and asthma. To reduce the administrative burden on hospitals attempting to differentiate between packaged and separately payable observation services, CMS proposes to discontinue current HCPCS codes for observation services (G0244, G0263, and G0264) and instead create two new HCPCS codes to be used by hospitals to report all

observation services: GXXXX (Hospital observation services, per hour) and GYYYY (Direct admission of patient for hospital observation care). CMS would shift determination of whether observation services are separately payable under APC 0339 from the hospital billing department to the outpatient PPS claims processing logic contained in the Outpatient Code Editor (OCE) system.

The NJHA supports the concept of allowing the OCE logic to determine whether services are separately payable. This will result in a simpler and less burdensome process for ensuring payment for covered outpatient observation services. The existing G codes for observation services, with their long, complex descriptors that encompass all variables required for claim processing into a single code, create a significant administrative burden for hospital coders and billers. We are pleased that CMS has found a method to reduce the burden by simplifying the G codes required for observation services and making changes to the OCE logic.

However, we believe that the OCE logic could be used even more efficiently to make the HCPCS code GYYYY unnecessary. If the hospital bills the GXXXX code and the claim *does not* include a 45X (emergency department) or 516 (urgent care center) revenue code, then OCE logic should determine that this was a direct admission to observation care. If the hospital bills the GXXXX code with a 45X or 516 revenue code, then it is clear that the patient came in through the ED or urgent care center. Once such logic is programmed into the OCE, it would be up to the system to determine whether the observation is a result of a direct admission, and pay accordingly.

Further, the NJHA seeks clarification on the reference to inpatient status on page 42743 in the proposed rule that states “That is, hospitals would bill GXXXX when observation services are provided to any patient admitted to ‘observation status,’ regardless of the patient’s status as an *inpatient* [emphasis added] or outpatient.” We are concerned about this statement because if a patient is admitted as an inpatient, the hospital would not report HCPCS codes, but instead would be using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes since ICD-9-CM is the Health Insurance Portability and Accountability Act code set standard for reporting procedures for hospital inpatient reporting.

INPATIENT PROCEDURES

CMS proposes to remove 25 codes from the “inpatient only” list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and then assigns them to clinically appropriate APCs.

The NJHA continues to urge CMS to eliminate the “inpatient only” list. Physicians, not hospitals, determine where procedures can be performed safely, as well as whether a patient’s condition warrants an inpatient admission. If a physician determines that a service can be safely performed in an outpatient setting, then under current rules the hospital is penalized if that procedure happens to be on the “inpatient only” list.

If the “inpatient only” list is not eliminated for 2006, CMS should 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.

ANCILLARY OUTPATIENT SERVICES

In the proposed rule, CMS expresses concern about the increase in the volume of hospital claims that are billed with the –CA modifier from 2003-2004, growing from 18 to 300 claims over that one year. This modifier was initially used in 2003 to address situations where a procedure on the “inpatient only” list must be performed to resuscitate or stabilize a patient in a hospital outpatient department with an emergency, life-threatening condition and the patient dies before being admitted as an inpatient. In addition, CMS states that a clinical review of the claims reported using this modifier support their concerns regarding the increased modifier volume and hospitals’ possible incorrect use of the modifier for services that do not meet the payment conditions CMS established.

The NJHA agrees that the –CA modifier should be used only in rare circumstances. It is unclear why CMS has seen such a substantial increase in the use of the –CA modifier. It could be that hospitals are using the modifier incorrectly, or that, because it is a relatively new modifier, hospitals were only recently aware of it. In addition, there may be circumstances to explain why few of the claims also include a clinic or emergency department visit on the same date of service as the procedure appended with a –CA modifier. For example, a Medicare beneficiary arrives for a scheduled procedure and, due to complications, the physician finds it necessary to provide a service that they had not otherwise intended to perform in an outpatient setting, and the patient dies prior to admission.

The NJHA believes that the –CA modifier policy supports an important function for hospitals and should be preserved. However, it appears that hospitals would benefit from additional education on the appropriate use of the –CA modifier. In collaboration with CMS, the AHA will provide further education to hospitals through its Coding Clinic publication. In addition, we support CMS’ continuing to closely monitor hospital use of this modifier.

MULTIPLE DIAGNOSTIC IMAGING PROCEDURES

CMS proposes reducing payment when multiple imaging services are provided on the same day. In accordance with a MedPAC recommendation, CMS proposes to make full payment for the highest paid imaging service and pay 50 percent of the APC payment rate for every additional procedure within the same “family” of procedures performed in the same session. The proposed rule outlines 11 “families” of imaging procedures by imaging modality and by contiguous body area.

The NJHA opposes implementation of this policy without better justification and more substantial, supporting hospital-based data. In developing this policy, CMS did not examine

hospital cost data. Rather, the agency relied on Medicare physician fee schedule practice expense data to determine the level of the discount. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the right level of efficiencies, if they exist.

Furthermore, CMS uses different methods to set payments in physician offices and hospital outpatient departments. The physician fee schedules are based on expert opinion of the resources required to perform different services while the outpatient rates are set based on hospital cost data. Hospitals conduct imaging procedures in unique circumstances not found in physician offices, such as in EDs and urgent care circumstances. **We urge CMS to conduct analyses using hospital data before implementing this policy.**

In addition, hospital cost data already may reflect efficiencies gained when multiple images are performed, leading to lower cost estimates across all procedures. CMS determines the median cost for outpatient services by multiplying the charges on the claim by the appropriate hospital department's cost-to-charge ratio (CCR). And while costs may be lower when multiple imaging studies are performed during the same session, most hospitals do not reduce their charges when more than one imaging service is performed in the same encounter. The hospital's CCR would therefore be lower than it should be because the denominator (charges) is higher than it otherwise would be if the hospital had charged less for the subsequent imaging studies. This results in a cost determination at the individual service level that is too low for single imaging studies, and too high for subsequent imaging studies. Because hospitals do both single and multiple imaging studies, the overall payments may be appropriate as they currently are calculated. **However, CMS's proposal to discount payments for subsequent imaging studies performed during the same encounter would underpay for both single procedures and for the highest rate APC when multiple imaging procedures are performed and reduce payment for other imaging services provided.**

We are also concerned with how this policy will be implemented and the lack of detail provided in the proposed rule, such as defining "the same session." During a suite of tests or an emergency stay, a patient may have an imaging procedure done in the morning, followed by medical review or other tests that indicate the need for a procedure from the same "family" later in the day. In this case, the tests would not be performed at the same time, or perhaps even in the same part of the hospital, and would be incorrectly subject to the discount. The APC advisory panel rejected the use of modifier 59 (separate procedure) for this purpose as too burdensome because it would require hospitals to track patients through the course of a day.

Finally, the proposed rule states that this policy will be budget neutral. However, no detail is provided on how the impact of the multiple imaging procedures discount was estimated or how the budget neutrality factor was adjusted to account for this. What share of imaging procedures did CMS estimate to be multiple imaging procedures? How were they defined? Will CMS analyze the data later to see if the estimates were correct?

In conclusion, the NJHA agrees with the APC advisory panel recommendation that this policy should not be implemented without additional analysis and better substantiation.

INTERRUPTED PROCEDURES

CMS proposed to decrease payment from 100 percent to 50 percent for interrupted procedures coded with modifiers 52 (discontinued procedure, no anesthesia provided) or 74 (procedure discontinued after administration of anesthesia). However, no analysis was conducted to support the reduction.

These modifiers cannot be used for elective cancellations; therefore, the procedures generally have been interrupted for clinical reasons. In the event that a procedure is interrupted because a patient is having medical problems, costs actually may increase, not decrease, as the clinical team addresses the patient's needs. Detailed claims analysis is needed to determine whether these additional costs could be covered through additional billed services or not. In any event, many of the hospital's costs already will have been incurred. For example, the operating room will have been occupied during the start of the procedure and must still be prepared for the next patient. Similarly, sterile supplies will have been opened and either will be disposed or be reprocessed at additional cost.

Before CMS reduces payments for procedures billed using these modifiers, evidence must support both the need for and the level of those reductions.

PHYSICIAN OVERSIGHT OF NONPHYSICIAN PRACTITIONERS

The NJHA supports CMS's proposal to defer to state law regarding the need for physicians to review and sign the medical records for outpatients cared for by nonphysician practitioners in critical access hospitals (CAHs). However, we also recommend that CMS extend the application of this policy to physician review of inpatient records for patients cared for by nonphysician practitioners. If state law permits these practitioners to practice independently, CMS should not require physician oversight in either the outpatient or inpatient setting. We agree that state laws providing independent practice authority generate sufficient control and oversight of these nonphysician practitioners, and we do not believe that nonphysician practitioners reduce quality of care.

The NJHA also supports the additional flexibility CMS adds under this proposed policy for those states that do not allow for independent practice of nonphysician practitioners – in particular permitting the facility to establish policy regarding the sample size of outpatient records to be reviewed and signed, consistent with current standards of practice.