Submitter : Mr. Adrian Vaagenes **Date:** 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-362-Attach-1.DOC

#362

December 18, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned staff member of an interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder patient access.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Cod 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT Code 72285 (discography interpretation and supervision in cervical spine) or CPT Code 72295 (discography interpretation and supervision in lumbar spine).

I believe that discography should be a separately payable service in the ASC as it is not treated as a surgical procedure eligible for separate payment under the payment system. This payment policy fails to recognize inequality between multiple settings and importance of these being done in an ASC setting.

The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse.

Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Adrian Vaagenes
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Marie Voegele **Date:** 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-363-Attach-1.DOC

#363

December 18, 2007

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Administrator
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Attention: MS-1392-FC
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Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Marie Voegele
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Nancy Wallberg **Date:** 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-364-Attach-1.DOC

#364

December 18, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

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Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Nancy Wallberg
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Claudia Zelaney **Date:** 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-365-Attach-1.DOC

#365

December 18, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

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Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Claudia Zelaney
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Mrs. Becky Shead **Date:** 01/28/2008

Organization : Carrollton Eye Clinic ASC

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

How is the local wage index determined? How is it determined if a facility will fall under the rural category? Our ASC in Carrollton, Georgia is collectively listed under the rural category even though we are in the Metropolitan Statistical Area with Atlanta, Georgia. Also, another city near us (Dalton, GA) with similar population and demographics has its own locality listed in the Atlanta MSA but we do not.

HCPCS codes

HCPCS codes

66984

Submitter : **Ms. Lindsey Kendrick** **Date: 01/28/2008**

Organization : **MAPS Medical Pain Clinics**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-367-Attach-1.DOC

#367

December 18, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

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Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Lindsey Kendrick
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Mrs. Jennifer Kleifgne **Date:** 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-368-Attach-1.DOC

#368

December 18, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

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Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Jennifer Kleifgen
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Laura Kovich **Date:** 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-369-Attach-1.DOC

#369

December 18, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

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Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Laura Kovich
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Mrs. Stephanie Dyson **Date:** 01/28/2008

Organization : RMS Lifeline

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

RMS Lifeline is pleased to have the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments about Ambulatory Surgery Center Payment System Final Rule with eomment. RMS Lifeline provides management services to fifty (50) outpatient vascular access centers across the United States, specifically designed and operated to care for the vascular access needs of End-Stage Renal Disease (ESRD) patients. These access procedures are performed by highly trained interventional nephrologists and vascular surgeons who also treat ESRD patients within their local communities. We are on the leading edge of advances in imaging-guided, minimally-invasive medicine serving patients with unique needs. Patients treated at our managed centers are less likely to be hospitalized or visit the emergency room.

Our main points pertaining to the CY 2008 Final Rule are the following:

" We request that you reconsider bundling of radiological and interventional codes that are critical to the life-saving vascular access procedures;
" CPT code 37205 (Transcath iv stent, precut) should be included on the list of ASC-covered procedures

We look forward to continuing to work with CMS to ensure that Medicare beneficiaries have access to treatment in the appropriate sites of service and sincerely hope that CMS will give consideration to our comments and will incorporate our suggestions in the 2009 Proposed Rule. Please feel free to contact Terry Litchfield at 847-388-2038 if you have any questions regarding these comments.

HCPCS codes

HCPCS codes

1. Bundling of radiological ancillary services and procedural codes

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Patients commonly present on an unscheduled basis to the hospital Emergency Room or hospital outpatient surgery department for thrombectomy/declot procedures. As their condition and surgical procedures are not considered emergent, they are typically regarded as a low priority for operating room time. As such, these patients will wait long periods of time for treatment and, subsequently, may incur substantial additional hospital costs if they are admitted overnight for dialysis treatment CMS recognizes the importance of placement and maintenance of vascular access in dialysis patients and agreed that more vascular access procedures should be performed, generally, and, specifically, more should be performed in the ASC setting. Rather than adopt the codes listed in the Proposed Rule, CMS decided to adopt two new G-codes for arterial angioplasties and venous angioplasties so that vascular access maintenance could be performed in ASCs. Specifically, the Agency stated:

[W]e are committed to the Fistula First end-stage renal disease quality initiative and want to improve access to procedural services for dialysis patients if at all possible.

RMS Lifeline is asking you to continue that commitment as you finalize the ASC rule. We are very concerned about potential beneficiary access issues resulting from CMS proposal to bundle radiological codes and ancillary services codes in the ASC setting. If not implemented correctly, bundling will limit full access to services to ESRD patients for the repair and maintenance of their vascular access. As such, RMS supports the APC Advisory Panel Recommendation to delay bundling until analysis can be performed to determine the impact to patients and the viability of ASC centers providing these services.

Specifically, we would like CMS to re-examine bundling of the ancillary services codes that are crucial to the care of ESRD patients. These codes are:

" Radiological ancillary service codes 75790, 75798, 75710, 75962, 78827, 76937, 75984, 75898, 75820, 77011, and 75902.
" Procedural codes-- 36005, 36010, 36011, 36145, 36215, 36012, 36120, 36216, 36217, and 36245.

RMS Lifeline managed centers have made significant strides in delivering high quality, cost efficient health care to the sickest of our nation s seniors. If CMS wishes to achieve its goals of providing access to quality care, we recommend that particular attention be given to the four radiological codes listed above (75790, 75798, 75710 and 75962), as they are commonly used for vascular access procedures and critical to those living with ESRD. It is this ability to exclusively serve a targeted population that allows Lifeline centers to provide the focused, specialized and comprehensive care management services which ultimately results in savings to the Medicare program.

Medicare GME Affilations

Medicare GME Affilations

RMS Lifeline supports CMS position of being a prudent provider of services and would like to partner with the Agency to ensure negative consequences of bundling do not occur

RMS Lifeline fully supports CMS continued decision in the Final Rule to reimburse all procedures in the ASC setting that do not require an overnight stay or pose a significant safety risk. However, we reaffirm our assertion, based on extensive clinical experience, that CPT code 37205 (Transcath iv stent, precut), should

be removed from the ASC exclusion list in CY 2008. As it pertains to dialysis vascular access repair and maintenance, 37205 does not require an overnight stay or pose a significant safety risk. Over the last year, our interventionalists have increasingly employed stents in the attempt to extend the patency of a fistula or graft longer than angioplasty alone. This trend was set in motion by the FDA s recent change of stent status from off-label to on-label.

We do not believe that CMS should unnecessarily limit physician-patient decision-making authority. While some patients may be too ill to be treated in ASCs, others would benefit from treatment in the less expensive, potentially more convenient and safe ASC setting. Furthermore, if 37205 is excluded from the ASC-approved list, CMS will prevent us from clinically evaluating techniques that we believe could result in a longer useable fistula or graft which would reduce costs and improve patient quality-of-life.

We recognize that 37205 is used by other specialties and may be the driver for why the code was placed on the excluded list. If this is the case, we strongly encourage CMS to consider creating separate code(s) for dialysis vascular access stents similar to the angioplasty G-codes (G-0392 and G-0393) created in 2007. We would welcome the opportunity to work with the Agency to preserve appropriate access to this procedure for dialysis patients.

CMS-1392-FC-370-Attach-1.PDF

#370

Lifeline Inc.

January 28, 2008

Kerry Weems
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-FC – Changes to the Ambulatory Surgical Center Payment System and CY2008 Payment Rates

Dear Administrator Weems:

RMS Lifeline is pleased to have the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments about Ambulatory Surgery Center Payment System Final Rule with comment. RMS Lifeline provides management services to fifty (50) outpatient vascular access centers across the United States, specifically designed and operated to care for the vascular access needs of End-Stage Renal Disease (ESRD) patients. These access procedures are performed by highly trained interventional nephrologists and vascular surgeons who also treat ESRD patients within their local communities. We are on the leading edge of advances in imaging-guided, minimally-invasive medicine serving patients with unique needs. Patients treated at our managed centers are less likely to be hospitalized or visit the emergency room.

Our main points pertaining to the CY 2008 Final Rule are the following:

- We request that you reconsider bundling of radiological and interventional codes that are critical to the life-saving vascular access procedures;
- CPT code 37205 (Transcath iv stent, precut) should be included on the list of ASC-covered procedures

1. ***Bundling of radiological ancillary services and procedural codes***

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Patients commonly present on an unscheduled basis to the hospital Emergency Room or hospital outpatient surgery department for thrombectomy/declot procedures. As their condition and surgical procedures are not considered emergent, they are typically regarded as a low priority for operating room time. As such, these patients will wait long periods of time for treatment and, subsequently, may incur substantial additional hospital costs if they are admitted overnight for dialysis treatment CMS recognizes the importance of placement and maintenance of vascular access in dialysis patients and agreed that more vascular access procedures should be performed, generally, and, specifically, more

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RMS Lifeline is asking you to continue that commitment as you finalize the ASC rule. We are very concerned about potential beneficiary access issues resulting from CMS' proposal to bundle radiological codes and ancillary services codes in the ASC setting. If not implemented correctly, bundling will limit full access to services to ESRD patients for the repair and maintenance of their vascular access. As such, RMS supports the APC Advisory Panel Recommendation to delay bundling until analysis can be performed to determine the impact to patients and the viability of ASC centers providing these services.

Specifically, we would like CMS to re-examine bundling of the ancillary services codes that are crucial to the care of ESRD patients. These codes are:

- Radiological ancillary service codes—75790, 75798, 75710, 75962, 78827, 76937, 75984, 75898, 75820, 77011, and 75902.
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RMS Lifeline managed centers have made significant strides in delivering high quality, cost efficient health care to the sickest of our nation's seniors. If CMS wishes to achieve its goals of providing access to quality care, we recommend that particular attention be given to the four radiological codes listed above (**75790, 75798, 75710 and 75962**), as they are commonly used for vascular access procedures and critical to those living with ESRD. It is this ability to exclusively serve a targeted population that allows Lifeline centers to provide the focused, specialized and comprehensive care management services which ultimately results in savings to the Medicare program.

RMS Lifeline supports CMS' position of being a prudent provider of services and would like to partner with the Agency to ensure negative consequences of bundling do not occur.

2. ***Inclusion of 37205 (Transcath iv stent, precut)***

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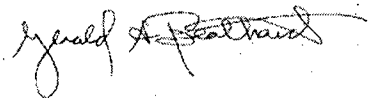
We look forward to continuing to work with CMS to ensure that Medicare beneficiaries have access to treatment in the appropriate sites of service and sincerely hope that CMS will give consideration to our comments and will incorporate our suggestions in the 2009 Proposed Rule. Please feel free to contact Terry Litchfield at 847-388-2038 if you have any questions regarding these comments.

Sincerely,



Gerald Beathard, M.D.
VP, Provider Development
RMS Lifeline, Inc.

Submitter : Dr. Edward Buckley **Date:** 01/28/2008

Organization : American Association for Pediatric Ophthalmology

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-FC-371-Attach-1.DOC

#371

January 28, 2008

Deleted: ¶

Mr. Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1392-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: 42 CFR Parts 410, 411,412, et al. Medicare and Medicaid Programs; Interim and Final Rule. ASC payment for 68816, Probing of nasolacrimal duct, with or without irrigation; with balloon catheter dilation.

Deleted: Rinal

Dear Acting Administrator Weems:

The American Association for Pediatric Ophthalmology and Strabismus (AAPOS), representing over 1200 ophthalmologists who provide medical and surgical eye care for children, is writing to share our comments regarding the proposed ASC payment for CPT 68816. AAPOS members perform probing of the nasolacrimal duct in children with transluminal balloon catheter dilation. These services are most commonly rendered under general anesthesia. This requires the procedure to be performed either in an Ambulatory Surgery Center Operating Room or Hospital Operating Room. This procedure is not performed on children in an office setting.

Deleted: t, with or without irrigation; with transluminal balloon catheter dilation in children under general anesthesia.

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CMS has identified this service in a recent memorandum, "New CY 2008 ASC covered surgical procedures assigned temporary office-based payment indicators on an interim final basis," as most commonly performed in the office, making the facility payment the office rate. Though CMS does not pay for the care of most children, this decision will effectively drive the service out of the ASC and into the Hospital where it will dramatically increase costs of care of children. Furthermore we are not aware of this procedure being commonly performed in the office setting even among adult beneficiaries because of associated discomfort. The hospital payment rate for CPT 68816 is proposed to be $1193.03. Since the procedure is not principally performed in the office, it should be eligible for payment based upon the appropriate percentage of the OPPS rate of $1193.03. AAPOS respectfully requests that this change be made prior to implementation.

Deleted: The ASC payment rate for CPT 68816 of $433.69 is based upon the inclusion of 68816 on a list of "New CY 2008 ASC covered surgical procedures assigned temporary office-based payment indicators on an interim final basis." AAPOS does not believe that 68816 should appear on this list.

Thank you for the opportunity to comment.

Sincerely,

Edward Buckley, M.D.
President

Submitter : Ms. Anna Weinstein **Date:** 01/28/2008

Organization : Florida Medical Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1392-FC-372-Attach-1.PDF

#312

FLORIDA MEDICAL ASSOCIATION, INC.

P.O. Box 10269 • Tallahassee, Florida • 32302 • 123 S. Adams St. • 32301
(850) 224-6496 • (850) 222-8827-FAX • Internet Address: www.fmaonline.org

January 28, 2008

Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Room 455-G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington D.C. 20201

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; and the Amendment of the Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Final Rule (CMS-1385-FC)

Dear Administrator Weems:

The Florida Medical Association ("FMA") is pleased to provide comments to the CY 2008 Medicare Physician Fee Schedule Final Rule. The FMA is a professional association representing more than 16,000 physicians on issues of legislation and regulatory affairs, medical economics, public health and education. The FMA also advocates on behalf of physicians and their patients to promote the public health, to ensure high standards in medical education and ethics, and to enhance the quality and availability of health care.

Based on our members' concerns regarding several provisions in the Final Rule we feel compelled to comment on the following issues:

- Geographic Practice Cost Indices (GPCIs)
- E-Prescribing
- The Sustainable Growth Rate (SGR)

A. GEOGRAPHIC PRACTICE COST INDICES (GPCIs)

The appropriateness and accuracy of the GPCIs in reflecting the actual costs of practice is critically important to ensure adequate reimbursement for Florida physicians, particularly those in rural and underserved localities where reimbursement levels directly affect existing accessibility and physician recruitment and retention difficulties. Physicians in Florida are currently receiving insufficient reimbursement for services because the proxy measurements utilized by CMS do not approximate the true costs of providing medical services in Florida.

We are extremely troubled by the fact that the current geographic adjusters have never been verified by peer-reviewed published research since their institution. Use of valid, reliable measures that directly capture the cost of physician service components is a reasonable, and not impractical, expectation. Furthermore, we believe that the underlying premise for use of proxy measurements – to account for localities' relative physician resource cost differences compared to a national average in a market basket of goods – is not a consistently applicable premise. The FMA strongly recommends that CMS replace these proxy measurements with data generated through nationwide studies that validate and routinely update the actual cost of maintaining a practice.

➢ PHYSICIAN WORK GPCI

The work GPCI is based on a national sample of median hourly earnings of workers in six professional categories: engineers, mathematicians, teachers, social workers, registered nurses, and writers. Physician earnings are not used in the calculation of the work adjuster, because CMS asserts that physicians derive much of their income from Medicare payments, and therefore an index based on physician earnings would be affected by Medicare's geographic adjustments.

Even though the above proxies have been utilized for more than 10 years, they have never been validated. We believe that the earnings of non-physicians are in no way equivalent or related to physician work and earnings, yet these proxies effectively determine the redistribution of Medicare payments across the country.

More fundamentally, we believe the notion of selecting proxies to establish the relative physician resource cost differences among areas compared to the national average in a market basket of goods is fundamentally flawed. One of the basic premises behind the resource based relative value scale as it was originally conceived is that the relative value of physician work should *not* vary across geographic regions. CMS defines physician work as the amount of time, skill, and intensity a physician puts into a patient visit. We contend that there should be no difference in the work of physicians in different locations regardless of where the work occurs. *The FMA urges CMS to replace the current physician work adjuster with an alternative that provides the least variation among payment localities and accurately reflects CMS' definition of physician work.*

➢ PRACTICE EXPENSE GPCI

The FMA calls for CMS to base the components of the practice expense GPCI – *non-physician employee wages, office rent and equipment and supplies* – on valid, direct measurements of these expenses, rather than the inaccurate proxy measurements currently employed.

Non-physician Medicare allowable employee compensation

In the 2008 Final Rule, CMS updated the 2000 Census median hourly earnings of four occupation categories: clerical workers, registered nurses, licensed practical nurses, and medical technicians. While salary data on these four occupational codes are conveniently available nationwide, much has changed in medicine since the four occupational codes were selected well over a decade ago. Average non-physician staff salaries are higher now because of the specialized skills and expertise required. The current proxies do not include or account for the cost employing these highly skilled professionals now considered essential for the

delivery of medical services. These professionals include: nurse practitioners, physician assistants, certified nurse specialists, nurse midwives, certified registered nurse anesthetists, occupational therapists, physical therapists, certified practice managers, attorneys, accountants and billing specialists, information technology professionals, transcriptionists and certified coders. Moreover, previous geographical assumptions regarding wage patterns are inaccurate because today higher wage employees must be recruited from larger employment market areas. Consequently, past wage patterns based on local employment recruitment must also be revised to reflect this change.

We believe that the failure of proxy measurements to reflect the actual cost of providing services has undermined the accuracy of payments for services in different localities nationwide. Small differences between proxy measurements and the real cost of providing services leads to large differences in payment to Medicare providers throughout the country. We urge CMS to work with the FMA and the larger medical community to establish more accurate measures of the employee wage costs.

Rent Component

Because CMS lacks sufficient commercial rent data for all geographic areas, the rent component of the physician practice expense GPCI is based on proxy measurements of residential rental data, specifically the fair market rental data for a two-bedroom Section 8 apartment. In general, the HUD residential proxy for commercial rent adequately captures geographic variation in the price of land. It does *not*, however, reflect the property tax crisis that Florida physicians face and the property insurance crisis that coastal physicians face. In addition, the GPCI formula fails to consider a critical cost in Florida and throughout the Gulf Coast. Physicians who are not employed by a health care system must prepare for a hurricane-based interruption. Our estimates indicate business interruption insurance functions as an additional 4-5.5 percent increase in office rent.

The HUD fair market rents increased from 9.1 percent (rest of Florida) to 27.4 percent (Fort Lauderdale) from 2004 to 2007. We appreciate CMS's acknowledgement that there is a persistent trend toward higher rents across the country. We feel this is especially true in areas at risk for natural disasters, like the vast majority of counties in the state of Florida. Our projections show increases for triple-net commercial leases and owner-occupied practices that range from 21 percent to 42 percent. Thus, the 2008 GPCI will inadequately compensate the vast majority of Florida physicians for rising office rent. Furthermore, the failure of the practice expense GPCI to fully capture higher building insurance payments, increasing property tax levies and the current business interruption insurance has a sizeable impact. In fact, our projections show the true "Rest of Florida" locality practice expense GPCI could be as high as 1.042 rather than the proposed .937.

It is absolutely critical that these extra costs be considered in order to assure there is a sufficient supply of Medicare providers, especially in vulnerable areas. Without a supplemental appropriation for physicians facing the property tax and insurance crisis, we believe the 2008 PE GPCIs will further induce Florida physicians to stop participating in the Medicare program and potentially result in a shortage of quality providers and reduced patient access.

We implore CMS to recognize that the differences in value between residential rental property and professional/commercial space used by physicians are enormous and

must be accommodated in the GPCI calculation to accurately reflect physicians' costs. The FMA urges CMS to work with state medical societies, chambers of commerce and others to identify and evaluate more suitable, accurate measures of commercial/professional medical office rentals instead of the skewed proxy measures in place.

- PAYMENT LOCALITY STRUCTURE

CMS has expressed concern about the potential impact of increased variations in practice costs within payment locality boundaries, and has studied potential alternatives for years. CMS is also concerned about the potential redistributive effects of locality changes, given that by statute; changes must be applied in a budget neutral manner. The FMA shares CMS' concerns about the redistributive effects of locality changes, and does not support taking from one locality to give to another.

However, as demonstrated by the U.S. House of Representative's passage of the Children's Health Assistance and Medicare Protection Act of 2007, members of Congress are willing to dedicate new monies to resolve the GPCI problem in California. Although we understand this would require statutory action, we urge CMS to weigh in with Congress in support of this philosophy, i.e. that forgoing budget neutrality should be extended to any and all necessary country-wide, GPCI improvements.

We applaud the agency's decision not to implement the locality reconfiguration demonstration in California described in the proposed rule. It is premature to consider testing any of the three options for California given the serious inadequacies of the data used to calculate geographic differences in physician work and office practice expense.

B. PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

In the CY 2008 PFS Final Rule, CMS finalized its proposal to eliminate the computer generated fax exemption to the NCPDP SCRIPT Standard for *all* communication of prescription and certain prescription-related information between prescribers and dispensers[1] effective January 1, 2009. CMS' rationale is that since computer-generated faxing retains some of the disadvantages of paper prescribing (for example, the administrative cost of keying the prescription into the pharmacy system and the related potential for data entry errors that may impact patient safety), eliminating the exemption will encourage e-prescribers and dispensers to move as quickly as possible to use of the NCPDP SCRIPT standard with what the agency perceives to be "minimal impact."[2]

While the FMA is supportive of electronic prescribing and other health information technology (HIT), we continue to believe that the January 1, 2009 deadline unrealistic. Recent history has shown that the health industry in general, and providers specifically, have struggled to meet HIT-related compliance dates. The mandate that all covered entities comply with numerous regulations promulgated as a result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Medicare Prescription Drug, Improvement and Modernization Act of 2003, including electronic prescribing standards, has resulted in significant cost and considerable disruption to the health care system, especially for smaller

[1] See §423(b)(1)(i) through (xii) for a description of eliminated transactions
[2] 72 FR 66334

practices. Providers who face significant cuts in Medicare reimbursement each year (twice in 2008) are understandably very troubled by what seems like a government mandate to invest in the expensive technology and the attendant maintenance costs required to fully comply with the SCRIPT standard.

One of the primary impediments to HIT adoption is that in order to comply with most regulations, medical groups are forced to rely on software vendors (i.e. non-covered entities.) In some cases, vendors have refused to upgrade older versions of their products, thus forcing practices to purchase new, and very expensive, software. Many vendors are no longer in business or were acquired by others, resulting in changes to their programs and accordingly, to maintenance contracts.

Currently, a very limited number of prescription programs (e.g. SureScripts) have integrated software that connects newer vendor programs to pharmacies. This has created an interfacing challenge for the large number of diverse electronic medical record programs implemented over the last 15 years. The FMA estimates that only a small portion of the 15-20 percent of physician practices already online have interfaced, computer to computer e-prescribing. Vendors believe that, at best, only 50 percent of practices can be ready by 2009. The Institute of Medicine (IOM) recommended a timeline of 2010.

While we agree that full implementation of the SCRIPT standard will result in an increased level of administrative simplification, the benefits of sending a computer-generated facsimile, even for those that do not utilize the SCRIPT standard, are well documented. Like CMS, we are concerned that if physicians are unable to get their software upgraded to the SCRIPT standard by the January 2009 deadline, they will revert to paper prescriptions. In CMS' own words, this result would be "counterproductive to achieving standardized use of non-fax electronic data interchange for prescribing." Computer-generated facsimiles help eliminate medical errors caused by illegible handwritten prescriptions; allow for faster processing of prescriptions at the pharmacy; and improve record keeping at the individual physician or group practice level and at the pharmacy. Many of these benefits are reduced or lost when paper prescriptions are utilized. Furthermore, the current DEA position on disallowing e-prescribing of controlled substances creates an additional barrier to adoption, and the proposed CMS compliance date of January 2009 will only exacerbate the issue.

The FMA requests that CMS extend the compliance date to January 1, 2010, to give prospective e-prescribers more time to identify and finance compliant products. FMA believes this will compel EMR vendors to develop more affordable eRx upgrades etc. and allow a larger number of physicians to make this transition. Extending the compliance date is a much better solution than penalizing practitioners and potentially adversely impacting patient safety by effectively forcing physicians to revert paper prescriptions.

IMPACT: SUSTAINABLE GROWTH FACTOR, BUDGET NEUTRALITY & RESULTING CUTS IN REIMBURSEMENT

Like the GPCI methodology, the sustainable growth calculation (SGR) methodology continues to be a flawed system for compensating physicians. As we have stated, in order to preserve beneficiary access to care, physicians must receive annual updates that reflect practice expense increases. The FMA strongly recommends that the SGR be repealed and replaced with

an updated system that reflects changing costs of providing the services such as the Medicare Economic Index (MEI).

While we understand that a complete overhaul of the SGR formula is not possible without congressional action, we urge CMS to exercise its authority to make administrative improvements to the Medicare physician payment system. In particular, as outlined above we ask CMS to take steps to re-evaluate the assumed geographic differences in the cost of providing services to assure that payments cover the costs of efficient provision of necessary services by physicians. Consistent with the position of the American Medical Association (AMA), we also request that CMS exercise its authority to remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula.

CONCLUSION

The FMA concurs with CMS that physicians' decisions are the driving force behind the health care their patients receive, and believe that the task of identifying ways to provide better support for utilization decisions is critical to the development of a unified approach for improving quality, avoiding unnecessary costs and reducing overall Medicare program expenditures. We commend CMS for continuing to work with physicians and other organizations to build a consensus around quality and efficiency measures. However, the FMA believes that the current Medicare health care delivery and payment systems are dangerously fragmented and promote perverse incentives that encourage both the under and over provision of care. It is essential that the Medicare program become more patient-centered and properly recognize the sanctity of the patient-physician relationship.

We urge CMS to consider these issues and the resources required to provide quality care by thoughtfully formulating and clearly delineating policies with meaningful quality measures, appropriate incentives and timely reimbursement for demonstrable success. We hope that our comments highlight our sincere interest in working with the agency to ensure care is cost effective, properly reimbursed and readily accessible to Medicare beneficiaries. Should you have any questions on the items addressed in this comment letter, please contact Fred Whitson, FMA Director of Medical Economics, 800-762-0233, fwhitson@medone.org.

Respectfully,

Karl M. Altenburger, M.D., President

cc:
Rick Ensor
Edith Hambrick
Stephanie Monroe
Drew Morgan

Submitter : Dr. Michael Repka **Date:** 01/28/2008

Organization : American Academy of Ophthalmology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

HCPCS codes

HCPCS codes

CPT Code 68816

" Thc Academy requests that CMS remove the interim designation that CPT code 68816 is a physician office provided procedure.

The Academy strongly disagrees and would seriously question the clinical basis by which a determination that code 68816 will be performed more then 50% of the time in the physician office setting. The typical patient for this procedure is a 14-month old infant as indicated in our application to the AMA CPT for this code (see attached.) These patients typically present in the office with one of several diagnosis including 375.55, Obstruction of nasolacrimal duct, neonatal - cxcludes congcnital anomaly of nasolacrimal duct; 375.56, Stenosis of nasolacrimal duct; or 743.65, Acquired congenital anomalies of lacrimal passages absence, agenesis of: lacrimal apparatus, punctum lacrimale, accessory lacrimal canal.

While the infants may first present in the office, the treatment for these conditions in young children or even neonates absolutely requires the use of either the hospital outpatient or ASC setting for surgical repair required for CPT code 68816. There are an estimated 415,000 office visits per year for patients with at least one of the diagnosis codes, according to NAMCS. There are a total of 32,000 hospital discharges per year for these diagnoses, the majority of which are outpatient (sources NHAMCS and HUCP). In addition, a sizeable number of these young patients are treated in the ASC setting.

These infants while not typically Medicare beneficiaries will not be seen in the ASC setting since most other payers will most certainly reiterate this mistaken policy. These children will then be forced to be seen only in the hospital setting as the payment to the facility will not adequately reimburse for the procedure in the ASC.

Keratoprosthesis

" The Academy requests that similar to CMS policy that allows for pass-through status for corneal tissue used in corneal transplantation that the same status should be granted for the corneal Boston Keratoprosthesis (K-pro). The designation of N1 should be removed from CPT code 65770 (Keratoprosthesis) and K-pro should be paid on a pass-through basis at the same rate as for the OPPS.

The Boston Keratoprothesis can be used after standard corneal transplant has failed or when such a transplant would he unlikely to succeed. Thus keratoprosthesis implantation is a procedure designed to help patients whose conditions are the most difficult to treat. The Boston Keratoprosthesis received FDA clearance in 1992. This procedure is not frequently performed with 1200 implantations having been performed through the spring of 2007. However, it is the most commonly used artificial cornea in the United States and in the world.
The K-pro device is also similar to corneal tissue in that it too is produced under the auspices of a non-profit institution, the Massachusetts Eye and Ear Infirmary, a hospital affiliated with Harvard Medical School. These devices, currently developed by Dr. Claus Dohlman and his team at MEEI, are provided on a humanitarian basis at no profit to MEEI.

CMS-1392-FC-373-Attach-1.PDF

#373

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

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1101 Vermont Avenue NW
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Federal Affairs Department

January 27, 2008

Mr. Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Medicare Program; Final Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates.

Dear Acting Administrator Weems:

The American Academy of Ophthalmology is writing to share our comments regarding the CY2008 Final ASC Payment Rule. The Academy is the world's largest association of eye physicians and surgeons—Eye M.D.s—with more than 18,000 members in the U.S.

We appreciate this opportunity to comment on the proposed rule published in the Federal Register on November 27, 2007 which finalizes, among other changes, CY 2008 payment rates for procedures performed in an ambulatory surgery center (ASC).[1] We reiterate our support for the revised ASC payment system, and commend CMS for its efforts in developing the new system.

Eye procedures are one of the most frequently and safely performed procedures in ASCs in this country. In 2003, the Office of the Inspector General reported that Medicare could save more than $1 billion if hospital outpatient (HOPD) and ASC payments were equalized. According to the OIG nearly half of those savings would come from eye procedures (*http://oig.hhs.gov/oei/reports/oei-05-00-00340.pdf*).

A copy of our September 2007 comments on the proposed rule are appended to this letter. The Academy is disappointed that CMS has not found a way to ensure that access to the many newly added procedures for the ASC setting is maintained. As we have indicated previously, there are several ophthalmic devices and prosthetics that because of the four-year transition to the fully implemented OPPS percentage, will not be performed in the high quality lower cost ASC setting.

In addition to our previous concerns, we will focus our final rule comments on one device that should have been included in our earlier comments (keratoprothesis) and then on a new development that only came to light in the final fee schedule regarding the CMS determination that CPT code 68816 (*probing of the nasolacrimal duct, with or without irrigation, with transluminal balloon catheter dilation*) which is new for 2008, is designated to be a procedure that is performed more than 50% of the time in physician

office setting (pg. 66841 TABLE 54.—CY 2008 PAYMENT INDICATORS FOR NEW CY 2008 ASC COVERED SURGICAL PROCEDURES ASSIGNED TEMPORARY OFFICE-BASED PAYMENT INDICATORS ON AN INTERIM FINAL BASIS.)

CPT Code 68816

- **The Academy requests that CMS remove the interim designation that CPT code 68816 is a physician office provided procedure.**

The Academy strongly disagrees and would seriously question the clinical basis by which a determination that code 68816 will be performed more then 50% of the time in the physician office setting. The typical patient for this procedure is a 14-month old infant as indicated in our application to the AMA CPT for this code (see attached.) These patients typically present in the office with one of several diagnosis including 375.55, Obstruction of nasolacrimal duct, neonatal - excludes congenital anomaly of nasolacrimal duct; 375.56, Stenosis of nasolacrimal duct; or 743.65, Acquired congenital anomalies of lacrimal passages absence, agenesis of: lacrimal apparatus, punctum lacrimale, accessory lacrimal canal.

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These infants while not typically Medicare beneficiaries will not be seen in the ASC setting since most other payers will most certainly reiterate this mistaken policy. These children will then be forced to be seen only in the hospital setting as the payment to the facility will not adequately reimburse for the procedure in the ASC.

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The K-pro device is also similar to corneal tissue in that it too is produced under the auspices of a non-profit institution, the Massachusetts Eye and Ear Infirmary, a hospital affiliated with Harvard Medical School. These devices, currently developed by Dr. Claus Dohlman and his team at MEEI, are provided on a humanitarian basis at no profit to MEEI.

Conclusion

We appreciate CMS's significant achievement in developing the new ASC payment system. We believe that CMS has the tools to address the issues discussed above so that opthalmic patient care and surgery for Medicare beneficiaries is uninterrupted during 2008 and beyond. Thank you for your attention to these important matters.

Sincerely,

Michael X. Repka, M.D.
AAO Federal Affairs Secretary

cc: Joan Sanow, CMS

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

September 13, 2007

Mr. Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

VIA ELECTRONIC SUBMISSION

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates.

Dear Acting Administrator Weems:

The American Academy of Ophthalmology is writing to share our comments regarding the CY2008 Proposed Hospital Outpatient Payment System and the related Final ASC Payment Rule. The Academy is the world's largest association of eye physicians and surgeons—Eye M.D.s—with more than 18,000 members in the U.S.

We appreciate this opportunity to comment on the proposed rule published in the Federal Register on August 2, 2007, which proposes, among other changes, CY 2008 payment rates for procedures performed in an ambulatory surgery center (ASC).[2] We reiterate our support for the revised ASC payment system, and commend CMS for its efforts in developing the new system.

Eye procedures are one of the most frequently and safely performed procedures in ASCs in this country. In 2003, the Office of the Inspector General reported that Medicare could save more than $1 billion if hospital outpatient (HOPD) and ASC payments were equalized. According to the OIG nearly half of those savings would come from eye procedures (*http://oig.hhs.gov/oei/reports/oei-05-00-00340.pdf*).

General ASC Comments: List Expansion

The Academy would like to commend CMS for taking into account the comments and recommendations from the ASC community as it moves forward to finalize a new payment system for this care setting. As noted in our proposed rule comments, the Academy applauds the finalization of the new exclusive list that would only eliminate those procedures that are not safe to perform due to patient safety reasons. For ophthalmology this means the addition, of nearly 70 procedures that can now be performed in the ASC. This will expand patient access to the exceptional care in ophthalmic ASCs. We would note that there are additional ocular plastic procedures that meet the patient safety requirements and should be added to the list and we focus on those in another section.

General ASC Comments: Alignment and Budget Neutrality

CMS continued its steps at alignment in its final ASC rule and in the proposed CY2008 OPPS rule. The Academy commends the changes made which demonstrate that alignment of the ASC setting can be more directly tied to the HOPPS. **While the steps taken recognize the linkage, a more equitable and direct linkage to the outpatient setting is necessary in order to continue to expand patient access and the savings to the program by increased use of the ambulatory surgical setting.**

- **We strongly recommend that CMS provide the same annual update mechanism for both settings. Currently, CMS is proposing that ASC updates be based on CPI-U while the HOPD rate is tied to the hospital market basket. Such a disparity is contrary to alignment.** Inflationary costs for facility services, supplies, and medical device costs affect ASCs no differently than they affect hospitals. This part of the proposal will create greater disparity in the reimbursement for services performed in the hospital outpatient and ASC settings without any evidence that hospital costs increase at rates in excess of those of ambulatory surgery centers.

The Academy recognizes that the statutory language in DRA 2005 mandates that the initial calculation of the payment rate for ASCs be budget neutral. However, we strongly disagree with the manner in which such neutrality was applied. In looking at targeted outpatient aggregate expenditures, the Academy urges CMS to consider all Medicare expenditures for outpatient surgical services irrespective of setting, not just those of ASCs. Again this would fit in with CMS's goal to better align these two systems and creates a more transparent methodology for calculating the budget neutrality adjustment.

- **The currently proposed conversion factor derived through a budget neutrality adjustment that pays ASC at a rate that is nearly 35-33% (over a 4 year transition) less then HOPPS is unfair and this differential is not an accurate reflection of the true cost differences of providing care in these two settings.**

- **The Academy remains concerned that the agency underestimated the volume of migration of certain procedures into or out of the ASC that will occur when payments are about 35 percent less for the ASC than the OPPS. By making these incorrect migration estimates CMS has underestimated the payment rate for ASCs at which budget neutrality will be achieved.**

- **At a minimum, ASCs should receive a percent of the HOPD fee schedule that is in the range of 75 percent for all covered procedures as called for in legislation introduced in 2005 and supported by the Academy.**

- **This inequity is especially apparent with the move to eliminate the separate payment for many high cost supplies and devices.** Our comments will discuss specific examples of procedures that are impacted by these bundling requirements. In several cases, there are procedures that are currently being successfully performed in the ASC setting that will now move back to HOPD because their costs will not be covered under the new payment methodology. In another case, current problems already being experienced in the OPD system will be compounded in the new ASC system.

Implantable Devices Under the OPPS

Positive steps were taken by CMS in its efforts to improve the manner in which Medicare plans to pay for device-intensive procedures under the new ASC payment system. However, the Academy has identified a definite problem/oversight in the proposed payment method for procedures that also have associated Level II HCPCS codes and/or associated DMEPOS fee schedule payments today, but do not appear to qualify for the proposed "device-intensive" designation.

With the publication of the final ASC rule and the 2008 proposed OPPS rule an aberration has been created that will result in some implantable devices that are currently paid for in ASCs through the DMEPOS fee schedule to now be considered as bundled into the transitional rate that is being used for phasing in the new ASC payment methodology. For most devices the OPPS rate includes the cost of the device and the bundling is acceptable. However, the Academy has found some instances where, because of the transition, the device cost is inadequately covered until the final rate is achieved in 4 years.

The transition to the new payment rate will occur over 4 years with a blended rate of 75% of the current rate and 25% of the final rate (67%) for the first year, 50%/50% for the second year, 25%/75% the third year and then 100% of full 67% rate in 2011. For some higher cost implantable devices that did not make the list of procedures that are considered device-intensive (the cost of the device is at least 50% of the cost of the service) this will have an extremely negative impact.

- **Ophthalmic Specific Procedure Issues Created By the Proposed OPD and Final ASC Payment Systems**

  1) Proposed CY 2008 ASC Payment for CPT 66180

For ophthalmology, the glaucoma code 66180 commonly known as a placement of a Glaucoma Drainage Implant (e.g., Baerveldt, Molteno, Ahmed shunts) procedure was performed successfully 40 percent of the time in the ASC setting in 2005 (nearly 2750 times out of 7800 done overall). For the sickest glaucoma patients who are facing irreversible vision loss, medical therapy is no longer useful and the standard trabeculectomy procedure typically performed to move fluid out of the eye and relieve pressure may not be an option, or has been tried and failed. For them another procedure, inserting a shunt to relieve the intraocular pressure, is necessary. For some of these high-risk patients there may be other medical reasons, such as anatomic anomalies or scarring, why a shunt would be necessary.

Under the new ASC system the aqueous shunt device and the scleral tissue graft that is used in these cases will no longer be able to be separately billed on the DMEPOS schedule as CMS asserts that the costs of these are included in the payment rate for the OPPS APC. CMS also has not included 66180 on the list of device-intensive procedures.

The total expected payment in the ASC for code 66180 in 2008 is only $940.81. On average, the typical shunt device costs approximately $650 and the pericardium graft tissue that is used to cover the tube shunt is an additional $255 for a total device cost of $905. Previously the ASC facility payment for this service was $717 plus the DME payments for the devices which typically covered their costs in most instances.

2) Proposed CY2008 ASC Payments for Certain Ocular Plastic Implants

Similarly there are at least four oculoplastic procedures that have an implant whose costs will cause a significant shortfall based on the proposed 2008 ASC payment rate. These include: CPT code 65105 (enucleation of eye; with implant, muscles attached to implant); 65140 (insertion of ocular implant secondary; after enucleation, muscles attached to implant); 65155 (reinsertion of ocular implant; with use of foreign material for reinforcement and/or attachment of muscles to implant); and 67912 (correction of lagophthalmos, with implantation of upper eyelid lid load).

Facilities typically use L8610 for both the gold weight used with 67912 and the hydroxyapatite implant used with the other procedures. The price for the gold weight is $200 or $240 depending on the size (platinum weights are may be used with a price of $300 or $400 depending on the size). Following an enucleation, evisceration, or orbital exenteration of a patient's natural eye, the ophthalmologist places an orbital implant in order to prepare for an ocular prosthetic. The plastic implants typically cost $695.

3) Proposed CY 2008 ASC Payment for CPT 65780, amniotic membrane transplant

Addendum B of the Proposed HOPD Rule will assign an "N" status indicator to V2790, the HCPCS Level II code assigned to human amniotic membrane tissue. Accordingly, payment of V2790 is bundled with its related procedure, CPT 65780, amniotic membrane transplant. For the same reasons already discussed, the bundling of V2790 results in a payment rate for CPT 65780 that does not cover the cost of the tissue supplied in the procedure. In order to continue to make this innovative tissue and treatment available, the payment rate must accurately reflect the cost of obtaining, processing and distributing the tissue, as well as performing the procedure.

- **Potential solutions to these payment shortfall problem**

We offer two ways in which CMS can compensate for the payment shortfalls for 66180 and the ocular plastics issues:

1) Pay the fully implemented rate in 2008

CMS has already calculated the fully transitioned ASC payment for 2008. The difference between the actual 2008 payment rate and fully transitioned rate adequately accounts for the

Conclusion

We appreciate CMS's significant achievement in developing the new ASC payment system. We believe that CMS has the tools to address the issues discussed above so that opthalmic patient care and surgery for Medicare beneficiaries is uninterrupted during 2008 and beyond. Thank you for your attention to these important matters.

Sincerely,

Michael X. Repka, M.D.
AAO Federal Affairs Secretary

device. Applying the fully implemented payment to these codes for 2008 would be an administratively simple solution to the problem because CMS has already calculated these values.

2) Include the 2007 device payment in the transition year payment calculation

Another approach to account for the device in the 2008 payment would be to include the current payment for the device in the 2007 payment rate that is used to calculate 75% of the transition payment. Although this payment is generally lower than the fully implemented payment amount suggested in #1 above, it accounts for the device and would allow ophthalmologists to continue to perform these procedure in the ASC during 2008 without suffering a significant financial loss on each case. Alternatively, we ask that CMS create a separate APC for amniotic membrane transplantation procedures for the ocular surface that accurately reflects the cost of amniotic membrane tissue.

Additional Ophthalmic Issues with the revised ASC List

- **Patient Safety Exclusions**

CMS indicates that it is establishing beneficiary safety and the need for an overnight stay as the principal clinical considerations in determining procedures that should be excluded from payment of an ASC facility fee. However if CMS is to exclude procedures in addition to those on the inpatient only list for payment in the ASC, it should fully explain the clinical basis for the exclusion. In addition, as we have supported previously, CMS should develop an advisory group of clinically-trained ASC experts, which will work with CMS staff prior to release of the proposed rule to review and provide clinical safety and procedure data on procedures CMS may initially deem a safety risk.

- **Addition of Oculoplastic Codes to the ASC List**

The specialty of ophthalmology includes oculofacial plastic surgery. This combines orbital and periocular surgery with facial plastic surgery and includes the clinical practice of aesthetic plastic and reconstructive surgery of the face, orbit, eyelid, and lacrimal system. With this unique combination of skills, ophthalmologists perform facial plastic surgery, eyelid surgery, orbital surgery and lacrimal surgery. Outpatient care is the majority site of service for many ocular plastic procedures.

Currently there are several procedures that are not on the revised ASC list that the Academy supports including. CPT codes for the repair of orbital fractures encompassed in 21385 (Open treatment of orbital floor blowout fracture; transantral approach), 21386 (Open treatment of orbital floor blowout fracture; periorbital approach), 21387 (Open treatment of orbital floor blowout fracture; combined approach) are currently not on the list despite the fact that other related procedures such as 21390 (Open treatment of orbital floor blowout fracture; periorbital approach, with alloplastic or other implant), 21406 (Open treatment of fracture of orbit, except blowout; without implant) and 21407 (Open treatment of fracture of orbit, except blowout; with implant) are included. All of the codes that the Academy requests to add

performed at least 40% of the time in the outpatient, ASC or physician setting currently. The physician work involved for 21386 is actually less intensive then code 21390 which was included on the ASC list. The related procedures CPT codes 21385 and 21387 should also be added for consistency with 21386 and 21390.

- **Exclusion of Unlisted Procedures from the ASC Setting**

CMS has indicated that without knowing the specific procedure, it is not possible to evaluate whether the procedure performed would have been excluded from ASC payment due to established safety criteria. In particular, CMS has stated that it would not be able to determine whether the procedure in question involved major blood vessels, major or prolonged invasion of body cavities, or extensive blood loss, or was emergent or life-threatening in nature. The Academy does not see why there would be a safety issue in the ASC, but not in the HOPD or physician office. At a minimum when all of the procedures that fall within the same section of CPT are covered services, then an associated unlisted code should also be eligible for payment in the ASC at the carrier's discretion.

The Academy supports the ASC Coalition's contention that while unlisted surgical CPT codes do not allow reporting of specific procedures, they do allow reporting of the anatomic region of the procedure. This anatomic location can be precisely defined especially for ocular procedures. In some instances, unlisted codes also identify a specific surgical technique or a specific medical condition. Knowing the anatomic location, and occasionally the surgical technique and medical condition for which the procedure is performed, allows evaluation of safety of the entire spectrum of procedures reportable by the unlisted code. By considering the entire range of possible procedures for the particular anatomic location against the safety criteria to be satisfied, a knowledgeable clinician can determine whether there is reason to exclude the unlisted code in question. Asking whether or not any procedure performed on the anatomic structure(s) in question would 1) involve major blood vessels, 2) require major or prolonged invasion of body cavities, 3) result in extensive blood loss, 4) be emergent or life-threatening in nature, 5) require systemic thrombolytic therapy, 6) be included on the inpatient list or 7) require an overnight stay allows a logical and comprehensive assessment of safety risk based on the criteria that CMS has established.

When looked at in this context, nearly all ophthalmic unlisted procedures as well as those for several other specialties would be allowed in the ASC setting. Again, if the agency desires alignment in these two settings, then it should apply uniform safety standards in the ASC and HOPD. The surgeon based on the patients needs should determine the best setting for safely performing the procedure(s) necessary.

Office Based Procedures

In the July 2007 ASC Final Rule, CMS adopted a policy on office-based surgical procedures. The policy provides that the payment for the facility resources associated with office-based procedures will not be greater when provided in ASCs than when provided in physician offices. Thus, payment for office-based surgical procedures performed at an ASC will be capped at the lesser of the Medicare physician fee schedule nonfacility amount, or the ASC rate developed according to the standard methodology of the revised ASC payment system.

The Academy is opposed to this policy because it will force physicians to send a surgical service to the more costly OPD setting that is better suited to an ASC than the office setting due to a particular patient medical issue. This is not only more costly to the Medicare program but also to the beneficiary. The inequity of this policy is exacerbated by the fact that the "lesser of" rule is not applied to payment to hospital outpatient departments. There are no data that the Academy is aware of that shows

that procedures commonly performed in physicians' offices are more likely to migrate to an ASC than to a hospital outpatient department. Therefore, this "lesser of" rule should either be abandoned completely or be made to apply to payments to ASCs and hospital outpatient departments. As the Academy has supported consistently, the site of service should be determined by the surgeon's knowledge of the patient's condition and expertise.

Payment for Corneal Tissue

On behalf of our members that provide corneal transplantation, the Academy very much appreciates the CMS decision to finalize and retain the existing policy to include in the ASC Payment System the payment for corneal tissue on an acquisition cost basis, paid at reasonable cost. This action acknowledges that eye banking is no less variable in this present day as it was in 1998 when CMS acknowledged the role of community-based philanthropy and fund-raising utilized by most eye banks and the variable nature of the costs associated with obtaining this sight saving tissue. Of all the transplant surgery done today, corneal transplants are the most common and the most successful.

However, the Academy believes that Medicare Payment Policy must be consistent for All Tissue Processing for Ocular use under the HOPPS Payment. Currently, there are two HCPCS codes used to report services related to corneal tissue and amniotic membrane transplantation under HOPPS—V2785 (processing, preserving and transporting corneal tissue) and V2790 (amniotic membrane for surgical reconstruction, per procedure). There is a discrepancy in payment policy and status indicators for these two types of tissue which are both used for ocular surface reconstruction procedures. As a result, hospitals are paid separately—in addition to the APC rate—for costs associated with corneal tissue transplantation, but not for costs associated with processing preserved amniotic membrane tissue for ocular surface transplants.

The Academy is concerned that this inequitable payment classification creates a financial disincentive for hospitals to promote the treatment of ocular surface diseases using amniotic membrane tissue, and impedes beneficiary access to this unique ocular reconstructive procedure.

We respectfully request that CMS revise the current HOPPS payment policy for amniotic membrane transplant procedures so that it is consistent with the policy to reimburse hospitals for costs associated with V2785 (processing, preserving and transporting corneal tissue). Or as previously stated, the Academy believes that an appropriate APC should be created for the amniotic membrane transplant.

Comment Period for NTIOL Requests

As previously indicated we generally agree with CMS's new NTIOL notice and comment process that is now aligned with the proposed and final OPPS/ASC annual rules. It should be monitored to ensure that an annual process does not slow or impede the consideration of these new technologies. For consistency with the rule process, the Academy requests that the comment periods also coincide. In the final rule, CMS indicates that the NTIOL process would be a 30-day comment period rather then the 60 days that is allocated for the payment rules.

Submitter : Christopher Holden **Date:** 01/28/2008

Organization : AmSurg Corp.

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-FC-374-Attach-1.PDF

#374

AMSURG

AMERICA'S SINGLE SPECIALTY SURGERY CENTER LEADER

January 28, 2008

VIA E-MAIL

Administrator Kerry Weems
Centers for Medicare and Medicaid Services
Attention: CMS-1392-FC
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-FC - Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates, the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates, the Hospital Inpatient Prospective Payment System and FY 2008 Payment Rates; and Payments for Graduate Medical Education for Affiliated Teaching Hospitals in Certain Emergency Situations Medicare and Medicaid Programs: Hospital Conditions of Participation; Necessary Provider Designations of Critical Access Hospitals

Dear Administrator Weems:

AmSurg is America's single specialty surgery center leader, with 170 centers in 33 states and the District of Columbia. We develop, acquire, own and operate ambulatory surgery centers (ASCs) in partnership with physician practices, and unlike many competing ASC firms, most of our centers focus on procedures related to a single medical specialty such as gastroenterology (GI) (120 centers) or Ophthalmology (37 centers). We believe this specialization makes us the most efficient operator in the industry, and provides us with exceptional insight into the economics associated with common GI and eye procedures. We also maintain a high level of commitment to quality care at our facilities. All AmSurg centers are Medicare certified, and a majority are accredited by JCAHO or the Accreditation Association for Ambulatory Health Care (AAAHC). We are also a member of the ASC Quality Collaborative, which has developed quality measurements accepted and endorsed by the National Quality Forum (NQF). Large insurers contract with AmSurg ASCs as a preferred provider for their enrollees, and surveys indicate our patients are highly satisfied with the level of care they receive.

We appreciate this opportunity to submit comments to CMS regarding the interim and final rule with comment period. As we have noted in the past, we remain concerned the 2008

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severe cuts to reimbursement for lifesaving GI procedures will harm the ability of ASCs to provide these life-saving services to Medicare beneficiaries at a time when many individuals that should receive colorectal cancer screening are still not receiving these critical services. We have highlighted our additional concerns below.

Variability

The new ASC payment system ties ASC rates to the HOPD rate for each surgical procedure. While we have consistently supported aligning ASC and HOPD rates, we are concerned with the significant fluctuation in the HOPD rates on a year-to-year basis. The 2008 HOPD payment rate for highly utilized ophthalmologic procedures differs from the 2007 HOPD payment rate for the same procedure by as little as a 2% reduction or as great as a 50% increase. For example, in 2007, the reimbursement rate for "revision of lower eyelid" (HCPCS code 15820) was $1317.27; in 2008, the reimbursement amount will be $1287.06, a 2% reduction. On the other hand, the 2008 reimbursement amount for "revision of upper eyelid" (HCPCS code 15823) will also be $1287.06; but this represents an increase of almost 50% from the 2007 rate of $862.68. Significant fluctuations exist for GI and orthopedic procedures as well.

Most hospitals perform hundreds of outpatient surgical services. Accordingly, the impact of the fluctuation for any one procedure is typically offset by others. This is not the case for highly-specialized ASCs. The problem is particularly acute for an ASC that is focused on a small set of outpatient procedures, such as GI or ophthalmology. We urge CMS to monitor this issue and the possible impact on the availability of procedures.

Payment Disparity and Access to GI Services

With respect to the particular 2008 rates, we remain concerned that the size of the payment disparity between the ASC and hospital outpatient department (HOPD) payment rates will harm beneficiaries. Two procedures, upper GI endoscopies and diagnostic colonoscopies, represent the top two GI procedures by ASC payment, respectively.[1] However, CMS will pay HOPDs 28.2% and 32.3% more for these two procedures, respectively.[2] ASC costs continue to rise and this payment disparity fosters an unlevel competitive playing field between ASCs and HOPDs.

CMS lists the impact of the revised payment system on ASC procedures with the most Medicare expenditures. Upper GI endoscopy procedures, representing over 25% of the

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[1] Table 64. 72 Fed. Reg. 66,918 (Nov. 27, 2007).

[2] The 2008 ASC payment rate for Upper GI endoscopies (HCPCS code 43249) is $422.52; the HOPD payment rate is $541.59. The 2008 ASC payment rate for diagnostic colonoscopies (HCPCS code 45378) is $426.09; the HOPD payment rate is $541.59.

procedures performed in AmSurg facilities, will see a reduction from the 2007 payment rate of $446 to the 2008 transition year rate of $422.51, a 5.3% reduction.[3] The fully implemented reimbursement amount for these procedures is $352.03, which represents a 21.1% cut.[4] Similarly, diagnostic colonoscopies, representing 64% of AmSurg procedures, will see a reduction from the 2007 payment rate of $446 to the 2008 transition rate of $426.09, a 4.5% reduction.[5] The fully implemented reimbursement amount for these procedures is $366.34, which represents a 17.9% cut.[6]

ASCs specializing in providing colonoscopies will have difficulty modifying their business practices to change the services provided and/or their patient case mix. AmSurg's single specialty ASCs are able to deliver high-quality and efficient care to our patients largely due to the highly-specialized nature of our ASCs and the physician practices associated with them. Introducing the performance of other types of procedures, as CMS indicated would be a possible response to the payment cuts, will significantly reduce the ability to routinize the provision of services. The performance of multiple types of procedures in one ASC introduces the need for varied and expensive equipment, since each type of procedure requires its own type of equipment. Purchasing multiple types of equipment may not be feasible for many ASCs due to the volume and type of patients they see. Also, the physicians that are affiliated with the ASC are not general surgeons, but, rather are practicing gastroenterologists who provide the services that their patient base needs.

Even if an ASC that is currently providing only GI services was able to reduce the number of GI procedures performed and replace those procedures with other higher paying procedures, this behavioral change could significantly reduce the number of Medicare beneficiaries utilizing the colorectal cancer screening benefit. This is a dangerous public health risk as this important preventive benefit is already significantly underutilized. We believe CMS should be looking for ways to improve beneficiary access, not reduce it.

Conclusion

We believe that single-specialty ASCs provide the highest quality setting for Medicare beneficiaries to receive lifesaving surgical procedures like colonoscopies. Our facilities have focused on providing one type of procedure to maximize efficiency, ensure the highest quality care, and provide an environment that Medicare beneficiaries prefer. CMS' payment policies should not encourage GI ASCs to reduce the number of colonoscopies provided to Medicare beneficiaries. We believe that CMS should follow the mandate from Congress to increase access

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[3] Addendum AA. 72 Fed. Reg. 66,975 (Nov. 27, 2007).
[4] Id.
[5] Addendum AA. 72 Fed. Reg. 66,976 (Nov. 27, 2007).
[6] Id.

to colonoscopies and ensure site-neutral competition by paying appropriately for these procedures. By paying less for colonoscopies provided in ASCs, many facilities will be forced to discontinue providing these services, patients will be shifted back to higher-cost settings, and Medicare program spending (including beneficiary copayments) will increase.

We hope CMS will reconsider payment reductions for GI procedures in future rulemakings and instead focus on increasing the utilization of these important procedures through implementation of site-neutral payment policies. We appreciate CMS' consideration of our comments.

Sincerely,

Christopher A. Holden
President and Chief Executive Officer
AmSurg Corp.

Submitter : Dr. Joseph Bailes **Date:** 01/28/2008

Organization : American Society of Clinical Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1392-FC-375-Attach-1.DOC

#375

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

January 28, 2008

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

RE: File code **CMS-1392-FC Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates**

Dear Acting Administrator Weems:

The American Society of Clinical Oncology (ASCO) appreciates the opportunity to submit these comments on the Hospital Outpatient Prospective Payment System (OPPS) final rule for calendar year (CY) 2008 as published in the Federal Register (FR) on November 27, 2007. ASCO is the national organization representing physicians who specialize in the treatment of cancer. ASCO is committed to advancing policies that provide access to high-quality cancer care and as part of this, pays particular attention to the effects Medicare payment systems have at the provider and beneficiary level. ASCO commends CMS for its work to create prospective payment policy and annually update the OPPS, but remains concerned by the practical implications certain final rule decisions (and the interaction of those policy decisions) will have on access to cancer care.

In this letter we limit our final rule comments to three main policy topics of concern, all of which could create potential access problems to important therapies:

1. Setting transitional payment for drugs and pharmacy overhead costs in the hospital outpatient setting at Average Sales Price (ASP) + 5% or lower while continuing to expand the use of packaging;
2. Proceeding with the policy to package all contrast agents and diagnostic radiopharmaceuticals, and CMS's desire to significantly increase the number of separately paid drugs and biologicals that are packaged in the future; and
3. Establishing payments for therapeutic radiopharmaceuticals, and their handling, based on mean unit cost, without resolving issues of charge compression.

As discussed in detail below, ASCO strongly advises CMS to maintain reimbursement for separately paid drugs and biologicals at ASP + 6%. ASCO also disagrees with the CMS decision to package all contrast agents and diagnostic radiopharmaceuticals. We believe that CMS should continue to pay separately for products in these categories with costs above a reasonable threshold. Furthermore, we continue to believe that packaging should never include antineoplastic agents and other products that are part of anticancer chemotherapeutic regimens. ASCO also respectfully requests CMS consider the unique aspects of therapeutic radiopharmaceuticals, revisit its payment policy decisions and establish 2008 payment rates that more appropriately reflect acquisition costs. With these recommendations we seek to assure continued access to important cancer care therapies.

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Payment for Drugs and Pharmacy Overhead Costs in the Hospital Outpatient Setting

CMS's policy to provide a bundled payment for the acquisition costs of separately payable drugs and biologicals and the associated pharmacy overhead costs at a transitional rate of ASP + 5% in 2008, with potentially lower levels in future years is troubling and ill advised. ASCO urges CMS to accept the APC Panel's recommendation to maintain reimbursement for separately payable drugs at ASP + 6%. Moreover, ASCO believes that CMS should maintain reimbursement for separately payable drugs and biologicals at ASP + 6% until the issue of charge compression is sufficiently researched and resolved.

While ASCO understands the CMS decision to use ASP as the basis for reimbursement for separately paid drugs and biologicals, the agency's combined use of ASP with OPPS claims data has created a system that has nothing to do with the "average acquisition cost" that Congress intended be used to pay for separately paid drugs and biologicals. ASCO strongly disagrees with the agency's decision to determine the relative ASP percent using mean costs calculated from the OPPS claims data. If the agency lacks average acquisition cost information, it should use the statutory backup of ASP + 6%, or the average payment under the competitive acquisition program (CAP), where applicable.

Furthermore, providing a packaged payment for drugs and pharmacy overhead costs at the reduced ASP + 5% rate is inadequate to cover the costs incurred by hospitals to acquire and handle drugs. The Medicare Payment Advisory Commission (MedPAC) has found that pharmacies have overhead costs of more than 25% of their direct costs.[1] We do not believe these overhead amounts—particularly for complex chemotherapy products, many of which have special storage and handling requirements—are adequately captured in the CMS reimbursement methodology.

ASCO recognizes that ASP + 5% is a transition policy and is even more concerned by the possibility of additional decreases in the relative ASP percent in future years. As CMS outlines in the rule, the agency has two sources of data to set 2008 payment rates for non-pass through separately paid drugs and biologicals: 1) ASP data from the 4th quarter of 2006, and 2) mean and median costs derived from the CY 2006 hospital claims data. CMS analyzed both data sources to calculate "equivalent average ASP-based payment amounts" and found that using mean unit costs to set the payment rates for drugs and biologicals would be ASP + 3%.

While we appreciate that the agency has decided to use a transition period to keep payment rates at ASP + 5%, ASCO believes that the agency's findings in the final rule represent an unsustainable trend toward lower reimbursement that will threaten patient access to important therapies. ASCO therefore strongly advises CMS to reconsider its reimbursement methodology for separately paid drugs and biologicals.

ASCO believes that the problems caused by the CMS reimbursement methodology may be particularly acute for the higher cost products that are most likely subject to charge compression. Having acknowledged this phenomenon in the OPPS and in the inpatient setting, CMS should pay careful attention to the impact of charge compression on reimbursement for high cost therapies.

CMS must consider the drastic impact its reimbursement policy for drugs and biologicals will have on providers and patients alike, particularly when reimbursement does not cover acquisition costs and when

[1] Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program (June 2005).

additional charges, such as pharmacy overhead costs are increasingly packaged. ASCO believes that reimbursement for drug acquisition cost in the hospital setting should remain at ASP + 6%.

Increased Packaging of Drug and Biological Therapies

ASCO disagrees with the CMS decision to package all contrast agents and diagnostic radiopharmaceuticals. We believe that CMS should continue to pay separately for products in these categories with costs above a reasonable threshold. More importantly, we believe that the agency's stated desire to significantly increase the number of separately paid drugs and biologicals that are packaged in the future is misguided and could cause serious problems for cancer patients.

While we understand that the nature of a prospective payment system dictates packaging many services into payment groups, separate payment for chemotherapy products is an appropriate means to ensure that oncologists have access to the full range of available options in designing chemotherapy treatment. Because of difficulties in tolerating cancer treatments, CMS has stated in the past that Medicare payment rules should not "impede a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician." ASCO believes that this logic holds true for cancer therapies also—and reiterates its comment that chemotherapy products should be separately paid under the OPPS. Given the array of clinical and patient specific parameters involved in treating cancer patients, these drugs would not serve as an appropriate class of products to package under Medicare payment rules.

Cancer chemotherapy treatment is neither ancillary nor supportive, and accordingly the packaging concept should not apply to this class of drugs. The CMS payment methodology for reimbursement of packaged drugs and biologicals, relying on data that can be two years old or more, is particularly ill-designed for the rapidly changing landscape of oncology.

Payment for Therapeutic Radiopharmaceuticals

While ASCO is pleased that CMS will continue to make separate payment for therapeutic radiopharmaceuticals, the society is greatly concerned by CMS's decision to base 2008 payment rates on mean unit costs using 2006 hospital claims data. This policy will be detrimental to monoclonal antibody therapies as it inappropriately separates out components of the FDA-approved treatment regimens and ultimately sets prospective reimbursement at a rate drastically below acquisition costs. Given the unique aspects of these FDA-approved therapeutic regimens, the limited patient populations which they target, and the lack of other therapeutically equivalent products available on the market, ASCO urges CMS to reconsider its decision and make some concessions to more appropriately align reimbursement with cost while also helping to ensure continued access to these novel therapeutic radiopharmaceuticals.

This new classification and methodology is particularly problematic for radioimmunotherapies such as monoclonal antibodies. By using a mean unit cost calculation to set payment for all therapeutic radiopharmaceuticals, even after applying a trimming methodology, expensive items are negatively penalized by averaging and reimbursement is set far below actual acquisition costs. Further, for expensive therapies such as Bexxar®, CMS has segmented integral components of the therapeutic regimen and only provided separate reimbursement for one aspect of the overall protocol.

For example, a dosimetric dose of I-131 Tositumomab is used as part of the Bexxar regimen to assist treating physicians in calculating the subsequent therapeutic dose for the patient. CMS has classified this

dose as a diagnostic radiopharmaceutical. As a result of this "diagnostic" classification, CMS packages the item into payment for the nuclear medicine procedure performed once the I-131 dose is administered. CMS has only categorized the therapeutic dose of I-131 as separately payable and thus does not accurately capture the full breadth of the treatment regimen when calculating mean unit costs. The dosimetric dose of I-131 plays a unique role in the Bexxar therapeutic regime and must be considered when calculating separate payment for these novel radiopharmaceutical therapies.

With either the prior reasonable cost method or the newly implemented policy to reimburse separately payable therapeutic radiopharmaceuticals based on mean unit costs the issue of charge compression is a real and valid concern. The phenomenon of charge compression leads to excessively low reimbursement for very expensive items such as therapeutic radiopharmaceuticals. ASCO encourages CMS to continue to investigate this issue and identify viable solutions to eliminate instances where the CMS cost-finding methodology misestimates the relative costs of medical procedures and items furnished in hospital departments.

Given the complexities associated with the use of claims data to set reimbursement rates for expensive therapeutic radiopharmaceuticals, ASCO appreciates CMS's request for comments on how radiopharmaceutical cost data, such as ASP, could be used in rate setting in the future. ASCO encourages the agency to engage all stakeholders in these discussions. ASCO strongly supports an open and transparent decision making process and requests that, should such data ever be collected and incorporated into the methodology, it be applied and released in a publically available fashion.

Finally, ASCO is concerned that the CMS payment methodology for therapeutic radiopharmaceuticals does not appropriately capture necessary overhead costs despite CMS's belief that hospitals submitted charges representative of their acquisition and associated handling costs based on prior CMS billing guidance. Therapeutic radiopharmaceuticals are further unique as there are compounding costs associated with their preparation. These costs should also be reflected in the prospectively set reimbursement rate. From a practical perspective, hospital billing behavior varies widely and in the instance of therapeutic radiopharmaceuticals, likely does not reflect the full breadth of costs associated with these therapies. This is evidenced in part by the large difference between CMS's calculated mean unit costs and actual acquisition expenses for monoclonal antibody therapies.

Given the importance of these therapies to the beneficiaries that need them, ASCO asks that CMS reconsider its payment decisions for radiopharmaceutical therapies such as Bexxar and establish reimbursement levels that more accurately reflect acquisition costs.

In Conclusion

ASCO remains available to assist CMS on these or other issues that arise during the rule making process. We look forward to continued discussion with CMS and are available to answer any questions the agency might have. Thank you for the opportunity to comment on this final rule.

Sincerely,

Joseph S. Bailes

Joseph S. Bailes, MD
Chair, Government Relations Council

Submitter : Dr. Harvey Neiman **Date:** 01/28/2008

Organization : American College of Radiology

Category : Radiologist

Issue Areas/Comments

GENERAL

GENERAL

Attachments

CMS-1392-FC-376-Attach-1.PDF

#376

ACR™
AMERICAN COLLEGE OF RADIOLOGY

January 28, 2008

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Final Rule

Dear Mr. Weems:

The American College of Radiology (ACR), representing 32,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians and medical physicists, appreciates this opportunity to comment on the final notice "Hospital Outpatient Prospective Payment System (HOPPS)" published in the *Federal Register* on November 27, 2007. The ACR would like to present positions on the following issues: the complex rule by the Centers for Medicare and Medicaid Services (CMS) to package payment for seven categories of supportive ancillary services, composite ambulatory payment classification (APCs), placement of new technologies, and the implications of the Final Rule with respect to the caps on imaging payments imposed by the Deficit Reduction Act (DRA).

Packaging of Drugs and Imaging Services

CMS has finalized its proposal to package seven categories of supportive ancillary services into the primary diagnostic or treatment procedure(s) with which they are performed, but did make some changes in response to public comments. Included in these seven categories are five categories of critical importance to radiology: imaging guidance services, image processing services, imaging supervision and interpretation services, diagnostic radiopharmaceuticals, and contrast media.

The ACR is very disappointed that CMS finalized the packaging of drugs and imaging-related services. The ACR would have liked CMS to implement the packaging proposal in a smaller fashion so that claims data can be collected to determine the impact of packaging. The Final Rule provided insufficient information for stakeholders to assess the reasonableness of the packaging. For example, no information was provided regarding the APCs to which the various ancillary services would be packaged, and no information was provided regarding the impact of packaging by category of ancillary services, only aggregate impacts of the packaging proposal were provided. However, aggregate impacts make it impossible for stakeholders to determine how each service category will be affected.

The comments that follow provide our more detailed assessment of the implications of the packaging on individual categories of ancillary services of concern to the ACR and its members.

1) Guidance Services

CMS has finalized its proposal to bundle HCPCS (Healthcare Common Procedure Coding System) guidance codes, specifically those codes that are reported for supportive guidance services, such as ultrasound, computed tomography (CT), fluoroscopy, and stereotactic navigation services, that aid the performance of an independent procedure including radiation oncology image guidance codes (port films and steroscopic x-ray) for CY 2008. It is the ACR's understanding that CMS is packaging services that are always or commonly performed together. The ACR is opposed to the diagnostic imaging guidance services being bundled because none of the imaging guidance codes is commonly done with any one or only a few surgical or procedural codes, significantly raising the risk that these services will be underpaid if packaged. The ACR requests that CMS make sure the various types of imaging guidance are being billed and costs captured on multiple claims to insure that they are adequately being reimbursed in the hospital setting.

Imaging for radiation oncology procedures is fundamentally different from imaging from radiology procedures. Radiation oncology uses a variety of imaging modalities for a given procedure, which may embrace one of any number of different diseases. The ACR is concerned that bundling imaging and delivery for radiation oncology constitutes a restriction to access of care for Medicare patients that need the specific imaging modality that best targets their diseases. An example shown below shows a case of Intensity Modulated Radiation Therapy (IMRT) with CT-image guidance. The increase in payment for IMRT of $11.00 greatly underestimates the costs of the use of guidance which has always been a separate service for patients. The fears that payment reductions relating to the packaging of CT guidance for verification of tumor size and positioning of the patient will negatively impact future use of this step which is essential in the treatment process.

RADIATION TREATMENT (TX) DELIVERY, IMRT				
Code	**Description**	**SI 2008**	**2007 Payment**	**2008 Payment**
77418	Radiation tx delivery, imrt	S	$336.42	$347.65
77014	Ct scan with therapy guide	N	$94.53	$0
	Total		$430.95	$347.65

*SI = Status Indicators – N= payment is packaged into APC rates; Q= packaged services subject to separate payment; S= significant procedure, not discounted when multiple reduction applies (separate APC payment); T= significant procedure, multiple reduction applies (separate APC payment); V= clinic or emergency department visit (separate APC payment); X= ancillary services (separate APC payment).

The ACR requests that CMS provide data showing how often codes that are finalized for packaging are billed together with other services (and which other services are involved) so that those that comment on the rules can be in a better position to determine the reasonableness of the packaging.

2) Image Processing Services

CMS has finalized its proposal to package image processing services. This package group includes: Doppler echo (93325) into echo transthoracic (93350) and cardio stress (93017), 3-D processing codes (76376, 76377), cine (76125), special x-ray contrast (76350), computer-aided detection (CAD) breast MRI (0159T), and CAD chest (0174T, 0175T). There is concern that most of these services provided to the base service can be done in different sessions and even on different days. CMS suggests in the Final Rule that hospitals may need to hold claims in order to get both codes submitted on the claim and thus all costs captured. The ACR requests CMS make sure the costs of the 3-D processing, computer-aided detection and special x-ray codes in addition to others are being billed and costs captured on multiple claims to ensure that they are adequately being reimbursed in the hospital setting.

The ACR requests that CMS provide data showing how often codes that are finalized for packaging are billed together with other services (and which other services are involved) so that those that comment on the rules can be in a better position to determine the reasonableness of the packaging. The ACR would like CMS to provide data in the Proposed Rule for public comment.

3) Imaging Supervision and Interpretation

There are 33 interventional codes where the status indicator was changed to an "N" and 93 codes that were assigned a "Q" status indicator for 2008. CMS has assigned status indicator "N" to those HCPCS codes that are believed to be always integral to the performance of the primary modality and to package their costs into the costs of the separately paid primary services with which they are billed. CMS has also assigned a status indicator "Q" to those HCPCS codes that are believed to be typically integral to the performance of the primary modality, and to package payment for their costs into the costs of the separately paid primary services with which they are usually billed. In addition, CMS has also assigned to pay those HCPCS codes separately in those cases in which no other separately paid primary service is furnished in the hospital outpatient encounter. As noted earlier, the ACR felt that these changes were too far reaching to be accomplished in a single regulatory cycle.

The following coding scheme represents a complex interventional procedure. During this procedure, the artery x-ray is performed three times for code 75726 on three different mesenteric arteries; celiac artery (CEL), superior mesenteric artery (SMA), inferior mesenteric artery (IMA), and one time for code 75774, common hepatic artery (CHA). However there is no clarity as to whether the hospital will get reimbursed three times in 2008. Under the CMS proposal, codes assigned a "Q" status may occasionally be provided at the same time and at the same hospital with one or more other procedures for which payment is currently packaged under the OPPS, most commonly injection procedures. In these cases, CMS would not treat the imaging supervision and interpretation services as dependent services for purposes of payment.

MESENTERIC ANGIOGRAM				
Code	**Description**	***SI 2008**	**2007 Payment**	**2008 Payment**
75726	Artery x-rays, CEL	Q	$1,279.92	$1,839.41
75726	Artery x-rays, SMA	Q	$1,279.92	$1,839.41
75726	Artery x-rays, IMA	Q	$1,279.92	$1,839.41
75744	Artery x-ray, CHA	N	$584.32	$0
36246	Place catheter in artery	N	$0	$0
36245	Place catheter in artery, SMA	N	$0	$0
36245	Place catheter in artery, IMA	N	$0	$0
	Total		$4,424.08	$5,518.23

We assume that the absence of a procedural code with "T" status allows for the "Q" status codes to be paid in this coding scenario.

The ACR appreciates CMS's refinements to the "Q" status indicators. However, as discussed in more detail in the attached technical appendix, the introduction of the "T-packaged" and "STVX-packaged" concepts increases the complexity of the system, and in order to comment on the packaging logic, the ACR asks CMS to provide more transparency and detail in this area.

In summary, the ACR requests that CMS provide data showing that packaged codes are being billed to ensure that an adequate amount of cost data is being captured in the new packaging methodology. Also, the ACR requests that CMS provide more details about its packaging methodology so that it can be verified and understood how this methodology is being applied before further modifications and expansions are made to it in the future.

4) Diagnostic Radiopharmaceuticals

CMS has finalized its proposal to bundle all HCPCS codes that are radiopharmaceuticals. Radiopharmaceuticals are drugs, and they should be reimbursed separately in the hospital setting to the same extent as other drugs. The ACR supports CMS's mandatory requirement to report all utilization of radiopharmaceuticals on hospital claims. However, the ACR is still concerned that the bundling reimbursement methodology will create an incentive for hospitals to shift away from advanced technologies, which in turn will have negative implications to the quality of patient care as shown in the example below.

Another example of the potential impact of the packaging relates to a nuclear medicine procedure such as a renal scan (kidney imaging with flow) that can be performed with two different radiopharmaceuticals and therefore at two different levels of cost. The ACR is concerned that hospitals will choose to purchase the cheaper radiopharmaceutical when the higher priced one may be more appropriate for the patient's clinical condition.

RENAL SCAN WITH Tc99m GLUCEPTATE				
Code	**Description**	**SI 2008**	**2007 Payment**	**2008 Payment**
78701	Kidney Imaging with Flow	S	$210.28	$323.72
A9550	Tc99m gluceptate	N	$236.53	$0
	Total		$446.81	$323.72
RENAL SCAN WITH Tc99m SUCCIMER				
Code	**Description**	**SI 2008**	**2007 Payment**	**2008 Payment**
78701	Kidney Imaging with Flow	S	$210.28	$323.72
A9551	Tc99m succimer	N	$84.79	$0
	Total		$295.07	$323.72

Therapeutic Radiopharmaceuticals

The ACR appreciates CMS's decision to continue to pay separately for therapeutic radiopharmaceuticals. However, there are some therapeutic radiopharmaceuticals that are under priced. For example, Yttrium-90 (i.e., Zevalin) has an acquisition cost of $24,000 and payment rate of $15,000. Inadequate HOPPS payment rates for products involving monoclonal antibodies could prevent the growth of and access to molecular imaging. Hospitals may choose not to continue to offer the service at a loss, and manufacturers may then choose to no longer produce the products or develop new ones.

The ACR would like to work with CMS further to review data to insure that all radiopharmaceuticals are being paid adequately in the hospital outpatient setting.

5) Contrast Media

The ACR understands CMS's explanation that contrast would be packaged under HOPPS because it would not have met the criteria for separate payment even outside of the new packaging methodology. However, the ACR is concerned that contrast may disappear as a separate billing and cost item.

The ACR recommends that CMS require all claims for "with contrast" studies have at least one contrast code submitted on that claim, similar to what has been implemented for diagnostic radiopharmaceuticals.

Composite APCs

The ACR supports the composite APC methodology for low dose rate prostate brachytherapy (APC 8001, low dose brachytherapy (LDR) prostate brachytherapy composite). APC 8001 would provide one bundled payment for LDR prostate brachytherapy when the hospital bills both CPT codes 55875 and 77778 as component services provided during the same hospital encounters, thereby incorporating more hospital cost data in determining the payment rate.

The ACR would like to explore developing more composite APCs and check their feasibility under the current methodology before making suggestions to CMS. The ACR therefore requests again that CMS provide more details to the public about its methodology so that analysis can be done for future possible recommendations.

Placement for Cardiac CT and Coronary CTA

The ACR appreciates CMS's decision to place cardiac CT and coronary CTA in new APCs with a slight increase in payment.

Placement of New Technologies

The ACR is still concerned with how new technologies are being handled under OPPS. There has not been consistency of: 1) when they are assigned to new technology APCs; 2) how long they remain in new technology APCs; and 3) when they are assigned to regular APCs. An example of inconsistency is computed tomography colonography (CTC). For CY 2008, CMS has reassigned CPT code 0067T (computed tomographic (CT) colonography (i.e., virtual colonoscopy); diagnostic), from APC 0333 (computed tomography without contrast followed by contrast) with a payment rate of $325.64 to APC 0332 (computed tomography without contrast), with a payment rate of $191.78. CTC is a much more extensive procedure than non-contrast abdominal CT (0332), and involves air contrast, as well as multiple body regions and 3D post-processing. The APC Advisory Panel had agreed in 2005 to make the change from 0332 to 0333, but CMS has moved CPT code 0067T back to 0332 after changing it two years ago. The ACR believes that CTC pricing would have been more accurate if the service would have initially been placed in a new technology APC rather than placed in regular APCs where it does not quite match in resource use and costs. The ACR requests that CMS provide further explanation of how it determines which studies belong in new technology APCs versus placement in regular APCs. The ACR requests improvement and consistency in the placement of new technologies and how they are handled under OPPS. These services are the cutting edge advances in medicine that need to be available for future patient care.

Charge Compression

The ACR remains very concerned about the effects of charge compression on the pricing of new and high-cost technologies in hospital charge masters and how this affects the payment of these technologies under the HOPPS. The ACR anxiously awaits the results of additional work on this issue by both CMS and its contractor, RTI, and ***we urge CMS to make available to the public as soon as possible any additional studies done by RTI, preferably well in advance of the publication of any Proposed Rule addressing the charge compression issue.*** The ACR notes that the Final Rule acknowledges a comment suggesting that the standard hospital accounting

methodology for treatment of high capital costs, including the costs of expensive non-movable radiology equipment, results in cost-to-charge ratios (CCRs) for radiology services that understate the true costs of radiology services (due to the fact that these high capital costs are spread over all departments of the hospital on a square footage basis), and indicates that CMS and RTI plan to investigate this matter further. In the Final Rule, CMS also notes that it is developing an all-charges model (that is, inpatient and outpatient charges) to examine possible adjustments to correct charge compression for consideration for the CY 2009 proposed rule. The ACR looks forward to seeing the results of this work.

Implications for DRA-Mandated Caps on Imaging Payments

Policies relating to the packaging of ancillary services and drugs adopted in the Final HOPPS Rule caused some to wonder whether, and how, these changes might affect payments under the Medicare physician fee schedule, especially given the DRA-mandated caps on imaging payments. The ACR appreciates CMS's clarification that such packaging does not directly affect payment policies under the physician fee schedule (for example, with respect to separately billable items and services). Further, the ACR appreciates the steps that CMS took to make clear that DRA-mandated caps on imaging would not apply in the case of individual imaging services that no longer qualify for separate payment under HOPPS (because of the new packaging rules), since it would no longer be possible to compare payments for such services under both the Medicare physician fee schedule and the HOPPS. All of this helps to minimize confusion for radiology practices and payers who must work with the provisions under the Deficit Reduction Act.

Conclusion

Thank you for the opportunity to comment on this Final Rule. The ACR looks forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Sneha Soni at (800) 227-5463, ext. 4576 or via email at ssoni@acr.org.

Respectfully Submitted,

Harvey L. Neiman, MD

Harvey L. Neiman, MD, FACR
Executive Director

cc: Carol Bazell, MD, MPH, CMS
Edith Hambrick, MD, CMS
Tamar Spolter, MHS, CMS
John A. Patti, MD, FACR, Chair, ACR Commission on Economics
Bibb Allen, MD, FACR, Vice-Chair, ACR Commission on Economics
James Rawson, MD, Chair, ACR Economics Committee on HOPPS/APC
Pamela J. Kassing, ACR
Maurine Spillman-Dennis, ACR
Angela J. Choe, ACR
Sneha J. Soni, ACR

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AMERICAN COLLEGE OF
RADIOLOGY

TECHNICAL APPENDIX

Refinements of the "Q" Status Indicator

In the FY 2008 Hospital Outpatient Prospective Payment System (HOPPS) Final Rule, CMS proposed making far greater use of Status Indicator "Q" for conditional packaging.

We applaud CMS's refinements of the conditional status indicator logic – the "Q" status indicator logic – in the OPPS Final Rule versus the Proposed Rule for CY2008. We also appreciate that the descriptions of the new logic are far more complete and inclusive of the different combinations and possibilities of conditional packaging codes.

However, with these additional refinements, and the introduction of the concepts of "T-packaged" and "STVX-packaged" conditional status indicators, the complexity of the system has increased dramatically. In order to most appropriately comment on the conditional packaging logic, and the logic in future years, we strongly encourage CMS to strive for greater transparency by providing additional detail and clarity to make replication possible.

Enhancements to the descriptions of the logic for conditional packaging could include:

- Additional descriptive text;
- Graphical flow charts showing the logic flow; and
- Release of computer code implementing the logic flow

In addition to clearer and more detailed descriptions, we also request additional statistics for the conditional status indicator codes. CMS currently releases – in the HCPCS medians file – statistics on the total frequency of lines present in the data, the number of lines used as "singles," and statistics on the lines used as singles. We request that, in the case of conditional status indicators, there be additional information containing the count of lines that were packaged. This would allow the public to see 1) how many total lines, 2) how many singles, and 3) how many lines were packaged, for all of the HCPCS codes with conditional status indicators.

This additional information will allow outside analysts to more easily replicate the methodology, leading to more specific and relevant comments.

We support CMS's efforts to provide as much detail as possible in order for outside analysts to replicate the methodology and results. We understand from some of our consultants that they are encountering discrepancies on some of the data totals and are in communication with CMS. We look forward to hearing a resolution. If the results will lead to changes in rates, we request that CMS allow a comment period on these new results.

Submitter : Ms. Angela Gilmore **Date:** 01/28/2008

Organization : MAPS Medical Pain Clinic

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-1392-FC-377-Attach-1.DOC

#377

December 18, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned staff member of an interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder patient access.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Cod 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT Code 72285 (discography interpretation and supervision in cervical spine) or CPT Code 72295 (discography interpretation and supervision in lumbar spine).

I believe that discography should be a separately payable service in the A SC as it is not treated as a surgical procedure eligible for separate payment under the payment system. This payment policy fails to recognize inequality between multiple settings and importance of these being done in an ASC setting.

The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse.

Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Angela Gilmore
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : **Ms. Heidi Hackbarth** **Date: 01/28/2008**

Organization : **MAPS Medical Pain Clinics**

Category : **Other Health Care Professional**

Issue Areas/Comments

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Sincerely,

Heidi Hackbarth
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Mr. Reynald Forde **Date:** 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Physician Assistant

Issue Areas/Comments

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Attachment

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Sincerely,

Reynald Forde
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
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55433

Submitter : Ms. Sandy Jex **Date:** 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Other Health Care Professional

Issue Areas/Comments

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CMS-1392-FC-380-Attach-1.DOC

#380

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