

Submitter : Ms. Lisa Finley
Organization : MAPS
Category : Nurse Practitioner

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-340-Attach-1.DOC

#340

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 CMS's 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 Code 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,

Lisa Finley
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter :

Date: 01/28/2008

Organization : American Society of Nuclear Cardiology

Category : Health Care Professional or Association

Issue Areas/Comments

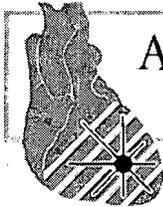
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See Attachment

CMS-1392-FC-341-Attach-1.PDF

#341



AMERICAN SOCIETY OF
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January 28, 2008

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

Kerry Weems
Acting Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1392-P
7500 Security Boulevard
Baltimore, MD 21244

ATTN: FILE CODE CMS-1392-FC

Re: Medicare Program; Changes to Payment Policy under the Hospital
Outpatient Prospective Payment System for Year 2008; Final Rule

Dear Mr. Weems:

The American Society of Nuclear Cardiology (ASNC) is pleased to provide comments on the final rule for Medicare payments under the Hospital Outpatient Prospective Payment System for calendar year 2008, published in the Federal Register on November 27, 2007 by the Centers for Medicare & Medicaid Services (CMS).

ASNC is a greater than 5,000 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

As mentioned in our September 14, 2007 comments on the 2008 proposed HOPPS rule, ASNC remains extremely concerned with the significant changes now finalized by CMS for the 2008 HOPPS.

In particular, ASNC is troubled by the agency's decision to bundle all diagnostic radiopharmaceuticals within the clinical APCs for nuclear medicine procedures; package certain nuclear cardiology add-on procedures into APC 377; and

relegate the Cardiac Computed Tomography (CT) codes to APCs that clearly undervalue this new technology service.

Packaging Diagnostic Radiopharmaceuticals

ASNC is extremely disappointed that CMS continues to classify radiopharmaceuticals as "supplies" rather than drugs. Radiopharmaceuticals are unique drugs that are integral to every nuclear medicine procedure. Radiopharmaceuticals are regulated as drugs by both the FDA and NRC, and the Medicare HOPPS statute consistently recognizes all radiopharmaceuticals – diagnostic and therapeutic – as "specified covered outpatient drugs." Thus, ASNC reiterates that bundling radiopharmaceuticals in with the procedure APC based on the categorization of the agency that they are, in fact, supplies is unjustified.

ANSC remains concerned that bundling diagnostic radiopharmaceuticals brings with it significant policy and data problems. For example, there are radiopharmaceuticals with very different clinical and cost features that CMS intends to pay under the same APC – resulting in overpayment for some products and underpayment for others. Many radiopharmaceuticals can be used with a variety of acquisition CPT codes and many acquisition CPT codes can use a variety of radiopharmaceuticals. In addition, bundling radiopharmaceuticals creates perhaps perverse financial incentives for hospitals and physicians that could block the selection of radiopharmaceuticals based on the patient's clinical needs.

While ASNC was pleased to learn that Congress included a provision in the Medicare, Medicaid and SCHIP extension Act of 2007 to continue to pay for therapeutic radiopharmaceuticals at the cost to charge ratio (CCR), ASNC is sorry that policymakers chose not to include diagnostic radiopharmaceuticals in the legislation. By continuing payment for therapeutic radiopharmaceuticals at the CCR, Congress has helped to ensure that these radiopharmaceuticals are available to all Medicare patients and paid for appropriately. And, while we acknowledge that there are greater differences in cost between therapeutic and diagnostic radiopharmaceuticals, underpayment of certain diagnostic radiopharmaceuticals carry with it the same problems Congress sought to address on the therapeutic side.

As CMS and Congress work to address concerns with therapeutic radiopharmaceutical pricing, we hope that both the agency and the legislators will not forget diagnostic radiopharmaceuticals in developing a system that appropriately captures all costs associated with these unique drugs.

OPPS Packaged Services

ASNC is disappointed that CMS finalized its decision to proceed with seven new categories of codes that are "bundled" or "dependant items" of the primary procedure called the "independent service." In particular, we are troubled by the agency's move to package certain nuclear cardiology add-on procedures into APC 377.

These seven categories and the two "composite" categories are wide sweeping bundling changes that warrant a comprehensive and transparent review. At a minimum, CMS should establish OCE edits that would require hospitals to include all CPT codes for all bundled services or dependent items utilized as part of these bundled categories. ASNC believes that the actual cost of these services will be lost because hospitals will not report the charges on the claim unless CMS mandates and enforces their reporting.

Such a policy would parallel what CMS is doing for radiopharmaceuticals, where the agency stressed the importance of having hospitals report the costs of radiopharmaceuticals on the same claim with the nuclear medicine service so that CMS "can have confidence that the payment for the nuclear medicine procedure reflects the cost of the radiopharmaceutical as well as the nuclear medicine service." Therefore, CMS should also recognize the importance of capturing the cost of each of the bundled services that it has packaged into these new APCs.

Cardiac Computed Tomography and Computed Tomography Angiography

ASNC applauds and thanks CMS for recognizing the unique clinical homogeneity of cardiac CT with its own series of APCs.

However, ASNC is disappointed that CMS finalized such low payment rates for the CCTA APCs (\$100.88 for APC 0282; and \$299.39 for APC 0383), and we fear that CMS did not consider the exam in the context of packaging of the contrast materials. These materials serve unique necessary purposes (for diagnosis) and are chosen clinically on patient need just as drugs for therapeutics. Further, ASNC believes that CMS has based its payment rates of this new technology on limited hospital charge data that is inadequate and flawed.

CCTA is a rapidly developing technology with established clinical competency and appropriateness criteria. CCTA is a far safer and more cost effective test for the exclusion of coronary artery disease, having a very high negative predictive value in multiple comparison studies with invasive catheterization. By dramatically reducing reimbursement for this procedure, ASNC fears that CMS has inadvertently encouraged the use of far more costly, expensive and invasive diagnostic procedures for Medicare beneficiaries.

Again, ASNC appreciates the opportunity to provide comments regarding these important issues. Should you have any questions, please feel free to contact Emily Gardner, ASNC Director of Health Policy, at 301-215-7575 or via email at egardner@asnc.org. Thank you.

Sincerely,

A handwritten signature in cursive script that reads "William A. Van Decker".

William A. Van Decker, MD
President

Submitter :

Date: 01/28/2008

Organization : American Society of Nuclear Cardiology

Category : Health Care Professional or Association

Issue Areas/Comments

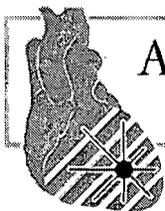
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See Attachment

CMS-1392-FC-342-Attach-1.PDF

342



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January 28, 2008

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

Kerry Weems
Acting Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1392-P
7500 Security Boulevard
Baltimore, MD 21244

ATTN: FILE CODE CMS-1385-FC

Re: Medicare Program; Revisions to Payment Policy under the Physician Fee Schedule for Calendar and other Part B payment Policies for Year 2008; Final Rule

Dear Mr. Weems:

The American Society of Nuclear Cardiology (ASNC) is pleased to provide comments on the final rule for Medicare payments in the Physician Fee Schedule for calendar year 2008, published in the Federal Register on November 27, 2007 by the Centers for Medicare & Medicaid Services (CMS).

As you know, ASNC is a greater than 5,000 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

Medicare Physician Payment Rate for 2008

While ASNC and the rest of the physician community are pleased that Congress stepped in to temporarily halt the 10.1 percent reduction in the conversion factor for 2008 and provide a short-term positive update, we are extremely disappointed that both Congress and CMS have not been able to provide a long-term solution to the severely flawed Sustainable Growth Rate (SGR) formula.

During this year, ASNC hopes that CMS will use its administrative authority to make policy changes to: reduce the productivity adjustment to the Medicare Economic Index so that it will be more in line with those productivity rates recommended for other Medicare providers; remove Part B drug costs from all of the agency's SGR calculations, retroactive to the 1996 SGR base year; and exclude services affected by national coverage determinations from its SGR calculations for a period of least two years to better understand the actual experience with these services as a basis for adding their spending to the SGR in third year of coverage.

While Congress has provided a "six-month stay" for the 10.1 percent payment cut, CMS must understand that if no corrective action is taken by July 1st, nuclear cardiologists will experience profound payment reductions stemming from the conversion factor, phase-in of new practice expense values and continuing effects of the recent Five Year Review of work values. These payment cuts will surely impact physicians' ability to adopt information technology and quality initiatives, as well as to continue accepting new Medicare patients as they prepare for the influx of baby boomers.

Resource Based Practice Expense Relative Value Units

*Equipment Usage Percentage Assumptions – Equipment Utilization Data
& Equipment Interest Rate Assumptions – Cost of Capital Assumptions*

ASNC again applauds CMS for not changing the equipment utilization assumption of 50 percent or the 11 percent equipment interest rate assumption. Like CMS, ASNC agrees that creating disincentives for the use of equipment by arbitrarily increasing the equipment usage percentage is bad policy. As the agency continues to investigate this issue, ASNC remains committed to working with CMS where possible. Similarly, ASNC agrees with CMS's belief that 11 percent continues to be an appropriate assumption for interest rates.

Physician Self-Referral Rules Relating to Diagnostic Tests

ASNC remains extremely troubled over the process, which CMS utilized in attempting to implement new self-referral provisions. We believe CMS should issue a separate proposed rule with public comment, specific to the self-referral changes that the agency first included in the proposed rule but failed to include in the MPFS final rule. ASNC believes that such a process is consistent with CMS' previous efforts to seek public input during rulemaking, as opposed to the agency's announced intention to finalize them without providing any additional opportunity for public comment.

Anti-Markup Provisions

While ASNC is pleased that CMS has delayed implementation of many aspects of the anti-markup provisions, we would like to advise the agency regarding many of the

impracticalities that will arise in 2009, should the agency fail to make any changes to its anti-markup policy that it outlined in the final rule. ASNC's primary concern stems from the newly added "site of service" hurdle that CMS would employ for compliance. Under the proposed rule, it was understood that the agency sought to limit applicability only to TCs and PCs that were purchased by the physician billing Medicare.

As we understand the final anti-markup rule, where a billing entity is a "physician organization" (i.e., a "group practice"), any portion of a diagnostic test not conducted in the "office of the billing physician or other supplier" is subject to the anti-markup rule. Further, the final rule also narrowly defines the office as "space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally."

This revised definition of "office" provided by the rule imposes an unfair burden—via the limitations of the "net charge" requirements—on group practices that otherwise comply with the in-office ancillary services exception to the self-referral rules. Namely, group practices that provide in-office ancillary services to patients (such as diagnostic tests) in a "centralized building" that complies with the physician self-referral rules would no longer be permitted to recover capital costs—by including them as part of a reasonably calculated net charge in claims submitted to Medicare—such as equipment and leasing of space that are incurred in order to provide Medicare beneficiaries greater access to needed services.

In other words, CMS plans to require that physician organizations, which comply with the self-referral rules, take losses on equipment they purchased and spaces they've leased (outside of the "office") for purposes of providing their patients access to needed services. Lastly, ASNC believes the "net charge" element of the "site of service" test added to the final anti-markup rule is unnecessary since claims submitted by billing physicians to Medicare are already subject to the prohibitions of the Federal False Claims Act.

One impractical and wasteful administrative consequence emerging out of the finalized anti-markup rule will be the obligation of physician organizations to generate "self-charges" on Medicare claims submitted in situations where a diagnostic test is provided by the group practice in a place other than the location where the physician group provides "substantially the full range of its patient care services." To comply with the rule, the group will be required to include a "per procedure" charge on the Medicare claim for the test, as if the group were purchasing the test from an outside supplier rather than by providing it directly. The physician organization will then be paid the lesser of the fee schedule amount or the internally generated "charge." Further, any failure to report a "charge" on the claim invites risk of incurring significant sanctions, in addition to being denied payment by Medicare.

ASNC does not understand what benefits, if any, accrue to the Medicare program by imposing this administrative requirement on any providers in these or similar instances. Ultimately, these administrative costs will be passed along to patients and will contribute, along with other such burdens, to the ongoing inflation of the price of medical care. ASNC is hopeful that CMS will use the next 12 months to address these issues.

Again, ASNC appreciates the opportunity to provide comments regarding these important issues. Should you have any questions, please feel free to contact Emily Gardner, ASNC Director of Health Policy, at 301-215-7575 or via email at egardner@asnc.org. Thank you.

Sincerely,

A handwritten signature in cursive script that reads "William A. Van Decker".

William A. Van Decker, MD
President

Submitter : Ms. Denise Merlino
Organization : Society of Nuclear Medicine
Category : Health Care Provider/Association

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1392-FC-343-Attach-1.PDF

#343

SNM

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

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

January 27, 2008

ATTN: FILE CODE CMS-1392-FC

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates; Final Rule

Dear Mr. Weems:

We are writing in response to the 2008 Hospital Outpatient Prospective Payment System (HOPPS) Rule, Federal Register Vol. 72, No. 227, November 27, 2007. The Society of Nuclear Medicine (SNM) representing more than 16,000 physicians, scientists, pharmacists and nuclear medicine technologists appreciates the opportunity to provide comments to assist the Centers for Medicare and Medicaid Services (CMS) in further refining the HOPPS. We will address the following topics in our comments including, OPSS packaged services, modifications to the 2008 methodology in rate setting for nuclear medicine APCs, transparency, the new 2008 OCE edits for nuclear medicine claims and refinements of APC placements for nuclear medicine procedures.

OPSS Packaged Services

Diagnostic Radiopharmaceuticals Bundled

The SNM is very concerned that CMS bundled all diagnostic radiopharmaceuticals in 2008. We have supported various aspects of bundling, including a dollar threshold and consideration of radiopharmaceutical APC categories in 2003. However, we do not believe that the hospital data accurately reflects the true acquisition cost for these drugs. We spent significant time and money conducting a radiopharmaceutical acquisition cost survey, which was dismissed during the last APC panel meeting by CMS, stating "at all cost, we try not to use external data." The SNM Survey showed a wide disparity, consistent with "charge compression" of higher cost diagnostic and therapeutic radiopharmaceutical when compared to the CMS claims data. The discrepancy between CMS mean radiopharmaceutical cost data and the SNM Survey data were, in many cases, so great that it supports a serious challenge to the validity of bundling all diagnostic radiopharmaceuticals at this time. Especially since the SNM Survey did NOT include the added costs associated with general hospital handling and waste management, which should have been present in the hospital CCR data.



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Radiopharmaceuticals are a major cost component of many nuclear medicine procedures, often exceeding the cost of the imaging or therapeutic procedure itself. Table I is an analysis of radiopharmaceutical and procedure costs for procedures in the Levels I -III Tumor/Infection Imaging procedures in APCs 0406, 0408, and 0414. Please note that mean radiopharmaceutical hospital reported costs vary from 20 -74% of the total *bundled* costs in those APCs; that is, the cost of the radiopharmaceutical often exceeded the cost of the procedure. CMS states that radiopharmaceuticals are supplies used for nuclear medicine imaging. As we have stated before, they are drugs. Any one radiopharmaceutical may be used for more than one imaging procedure; further, any one procedure may be performed by one of several radiopharmaceuticals depending on its clinical indication.

There is a marked disparity in the hospital cost data for the same radiopharmaceuticals from one APC to the next. Note in Table II, a comparison of median and mean radiopharmaceutical cost data, that the median hospital costs for A9508 range from \$102 to \$764 in the three Tumor Imaging APCs for the same adrenal tumor imaging agent and same dose. Similarly note that the commonly used RP drug A9500 cost varies more than 2X from APC 0404 to 0414. As another example note in Tables I and II that A9544 median cost ranged from \$18.80 to \$1,015., whereas the SNM Survey mean cost data was \$2,447. There is no explanation for this other than faulty hospital reporting data.

The SNM disagrees with any assumption that mean or median national hospital CCR radiopharmaceutical cost bundled into procedure APCs is either appropriate or adequate for an individual hospital reimbursement. Specific hospital/patient mix dictates the choice of radiopharmaceutical for each nuclear medicine procedure, as well as the relative incidence of each procedure within an APC. This is well illustrated by analysis of Tables I and II. Several of the radiopharmaceuticals cost two to five times the actual bundled total payment for APCs 0408 (\$981), 0406 (\$323) and 0414 (\$536.15). Individual hospitals are impacted by the bundled inclusion of radiopharmaceutical cost into those APCs.

We remain concerned about the potential negative impact that bundling without accurate cost data may have on development of new and more specific biological radiopharmaceuticals. We remain committed to find an alternate option for CMS to implement in CY 2009, that is analogous to the ASP for other drugs and biologicals. To that end, we will continue our efforts to work with industry and nuclear pharmacies to develop a *Nuclear Pharmacy Calculated Invoiced Price (Averaged) (CIP)* weighted by volume and vetted by the industry stakeholders. We believe there is a better methodology for acquiring accurate cost data for all radiopharmaceuticals that could be obtained through a standardized formula for collecting radiopharmaceutical average invoice data.

We strongly encourage CMS to consider alternate methods to ascertain actual hospital radiopharmaceutical acquisition costs, and to not simply dismiss the use of external data. As a reminder, CMS does use external data for drugs (ASP plus 5%) in their rate setting. At this time, the SNM requests that CMS utilize average sales/invoice price data when it is provided



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by manufacturers and/or nuclear pharmacies, and to continue to work with the SNM and the industry to facilitate prospective payment for radiopharmaceuticals based on such data.

Therapeutic Radiopharmaceuticals

CMS finalized the policy to use CMS claims data to set rates for therapeutic radiopharmaceuticals over the \$60.00 threshold. We agree with the threshold. Consistent with our comments about the diagnostic radiopharmaceuticals, we believe that ALL radiopharmaceuticals should be paid using the same methodology.

In summary, we believe that the continuation of separate payment for all radiopharmaceuticals (following the same criteria as other drugs and biologics) is critical to enable hospitals to account for the complex combinations of radiopharmaceuticals used with nuclear medicine procedures.

The SNM recommends that the CMS work with stakeholders to develop a standardized format for CY 2009 and accept radiopharmaceutical external data defined by the nuclear pharmacies and/or manufacturers in a standardized format, instead of claims data reduced by department or hospital specific CCR. If no external data were available, we would support the CMS using its hospital claims data (for established radiopharmaceuticals) alone to set CY 2009 payment rates for radiopharmaceuticals, but separately from the procedures in which they are used.

While CMS contends and is correct that detailed, complex CMS hospital claims data is made available to the public, the CMS should also recognize that without significant cost and expertise in the ability to analyze the complicated claims data, the public release in its current form is useless to the general public and hospitals.

New Methodology for Rate Setting for Nuclear Medicine Procedures in CY 2008

In this final rule for CY 2008, CMS implemented a new rate setting methodology by which CMS selected only claims where a radiopharmaceutical was billed on the same claim. Claims without a radiopharmaceutical were eliminated from rate setting. We are surprised that CMS implemented a policy that significantly modifies the methodology for rate setting for all nuclear medicine procedures without the benefit of all stakeholder input. We believe CMS implemented this based on limited data provided by one commenter and showing only one APC group example. Without conducting a detailed analysis, it appears to us that a minor number of nuclear medicine APCs groups benefited from this rate setting methodology change while the majority of codes resulted in lower rates. For example, hospitals received, per CMS, in general, a 3.8% increase for all procedures. However, there was only a 1% increase in the bone scan imaging rates for 2008, yet that rate includes the cost of the RP.



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This change in methodology resulted in limiting the number of claims used in the rate setting process; we disagree in principle with this particular methodology change that limits the number of claims, without ample analysis and stakeholder input.

Combining major policy changes complicates any attempt to determine the impact from an individual single CMS policy change. We believe this new policy would have been better implemented if finalized for CY 2010 rate setting following the implementation of the OCE edits. This would ensure hospitals were afforded a clear and transparent system and had the appropriate time to fully understand the implications of their claims submitted in the new methodology. **CMS should not implement new methodologies for payment policies in a final rule that are not at a minimum vetted through the comment period by all stakeholders. Also, when CMS proposes significant payment policy changes, CMS should make any significant payment policy changes transparent to the general public**

Bypass list CPT 93017

In this final rule for CY 2008, CMS added CPT 93017 to the bypass list. The SNM agrees with this addition as it allows more claims into the rate setting process.

New 2008 OCE Edits Requiring Hospitals to Bill Radiopharmaceuticals

We applaud CMS for implementing the new OCE edit requiring hospital claims to have at least one radiopharmaceutical on the same claim as a nuclear medicine procedure beginning in 2008. The SNM and other stakeholders have over the years requested such an edit and we fully agree and commend CMS for implementing this requirement for hospitals. The SNM will use its web site and educational seminars to alert hospitals to this new CY 2008 requirement.

Refinement APC Placements

Sentinel Node, Adrenal Imaging Placement & Single versus Multiple Imaging, Intra-arterial Therapy

The SNM appreciates that the procedures CPT 38792 Sentinel Node Injection and CPT 78075 Adrenal Nuclear Imaging were placed into more suitable APC categories based on resource differences.

We remained concerned that CMS did not agree that CPT 78070 Parathyroid Imaging should be placed into Level III Tumor Imaging APC 0408 along with the other multi-day, multi-imaging, SPECT tumor procedures such as CPT 78804 and CPT 78803.

SNM

Advancing Molecular Imaging and Therapy

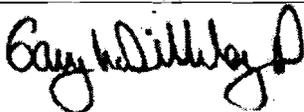
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We recommend that CPT 79445 Intra-arterial Radiotherapy be placed in APC 0413, rather than in APC0407. The resources required for that procedure are decidedly more comparable to the other therapy procedures in the Level II Therapy APC that currently includes intracavitary, intra-articular, and radiolabeled monoclonal therapies.

The SNM is perplexed by the placement into the same APC of some nuclear medicine imaging procedures that have marked differences in resource requirements. For example, single phase with a multiple phase imaging procedure. We have addressed this in the past, as well as our concern that the CMS has adopted a policy of bundling the costs of an add-on procedures into its base procedure. The SNM remains disappointed that CMS ignores what we believe are *clinical* and *resource* differences for a variety of nuclear medicine CPT codes. We understand CMS is basing decisions on the hospital claims data; however we caution that reliance on that hospital derived cost data without consideration of clinical and other external information may be contrary to the intent that APCs are clinically homogeneous.

The SNM appreciates the opportunity to comment on this HOPPS 2008 Final Rule to the CMS. The SNM will contact CMS prior to the winter APC panel meeting to share any preliminary standardized invoice methodology and data, when it is available, we welcome your input into the methodology. As always, the SNM is ready to discuss any of its comments or meet with CMS on the above issues. Please contact the Society of Nuclear Medicine coding and reimbursement advisor, Denise A. Merlino at dmerlino@snm.org, or at 781-435-1124.

Respectfully Submitted,



Gary Dillehay, M.D., FACR, FACNP
Chairman, Coding & Reimbursement Committee

Kenneth McKusick, M.D., FACR, FACNP
SNM Member, CPT Advisory Committee

cc:

Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
Don Thompson, CMS
Carol Bazell, MD, CMS
Chris Ritter, CMS
Joan Sanow, CMS
SNM Coding & Reimbursement Committee
Nuclear Medicine APC Task Force

Table I

APC	Definition	2008 Payment	Total Cost Per Claim				Cost for Tumor Scan Only				Cost for Diagnostic Radiopharmaceutical Only				Percent of Diagnostic Radiopharmaceutical Cost			
Diagnostic Radiopharm	Definition	Single /Pseudo Single Claims	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim
APC 406 408 414 - Analysis by Diagnostic Radiopharmaceutical																		
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Note 1: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.																		
Note 2: This analysis uses the CMS single/multiple logic, but does not include any trimming of cost values.																		
APC	Definition	2008 Payment	Total Cost Per Claim				Cost for Tumor Scan Only				Cost for Diagnostic Radiopharmaceutical Only				Percent of Diagnostic Radiopharmaceutical Cost			
APC 0406	Level II Tumor/Infection Imaging	\$ 322.81	Total Cost Per Claim				Cost for Tumor Scan Only				Cost for Diagnostic Radiopharmaceutical Only				Percent of Diagnostic Radiopharmaceutical Cost			
Diagnostic Radiopharm	Definition	Single /Pseudo Single Claims	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim
A4641	Diagnostic imaging agent	186	631.46	86.69	3,482.38	504.24	298.96	60.30	1,682.68	233.87	150.82	3.98	3,031.60	72.10	23.4%	1.7%	88.6%	19.2%
A9500	Tc-99m sestambi. up to 40 mCi	565	338.46	51.19	3,092.93	257.81	228.50	28.21	788.02	161.52	84.78	19.66	2,514.73	61.04	26.5%	3.8%	95.0%	27.2%
A9507	In-111 capromab pendetide, up to 10 mCi	12	1,571.92	507.67	3,256.58	1,317.73	372.47	149.76	602.92	365.02	1,182.43	357.91	3,039.82	718.98	71.2%	49.7%	93.3%	77.8%
A9508	Iodine I-131 iobenguane sulfate, per 0.5 mCi	53	532.60	147.24	1,910.18	284.01	189.44	32.23	425.53	182.06	337.68	37.15	1,471.61	101.95	47.8%	11.6%	97.0%	35.9%
A9521	Technetium Tc-99m exametazine, up to 25 mCi	27	523.73	406.87	1,550.35	408.52	178.38	93.80	434.60	165.00	325.04	241.87	978.21	241.87	62.0%	47.6%	79.6%	59.4%
A9528	I-131 sodium iodide capsule(s) per mCi	1,572	501.46	53.09	6,164.50	369.28	288.33	50.64	1,380.92	245.13	93.73	1.32	6,045.58	58.21	20.1%	0.6%	98.1%	16.1%
A9544	I-131 tositumomab, dx, per dose	13	426.40	284.51	833.49	286.80	208.95	153.45	311.65	221.43	187.86	18.80	680.04	18.80	30.3%	5.4%	81.6%	6.6%
A9556	Ga-67 gallium citrate, per mCi	163	342.26	91.14	1,375.19	288.04	204.29	57.91	1,218.38	169.73	115.23	4.20	751.71	87.66	33.9%	1.8%	79.6%	30.2%
A9565	In-111 pentetreotide, per mCi	145	1,261.58	115.41	4,755.37	946.31	253.04	42.74	2,233.18	180.50	1,000.42	45.30	4,607.83	765.69	74.3%	23.8%	96.9%	79.2%
APC	Definition	2008 Payment	Total Cost Per Claim				Cost for Tumor Scan Only				Cost for Diagnostic Radiopharmaceutical Only				Percent of Diagnostic Radiopharmaceutical Cost			
0408	Level III Tumor/Infection Imaging	\$ 981.10	Total Cost Per Claim				Cost for Tumor Scan Only				Cost for Diagnostic Radiopharmaceutical Only				Percent of Diagnostic Radiopharmaceutical Cost			
Diagnostic Radiopharm	Definition	Single /Pseudo Single Claims	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim
A4641	Diagnostic imaging agent	99	1,302.34	103.36	8,023.57	1,085.74	352.02	60.65	1,158.61	298.34	836.90	15.36	2,156.46	754.23	60.6%	0.6%	91.4%	67.8%
A9500	Tc-99m sestambi. up to 40 mCi	193	479.20	148.24	1,455.92	410.97	314.42	99.93	818.02	247.61	112.49	25.00	350.58	93.93	24.5%	4.1%	44.4%	24.8%
A9507	In-111 capromab pendetide, up to 10 mCi	501	1,467.68	377.43	10,270.48	1,210.42	356.28	90.92	2,304.08	281.38	1,049.98	217.81	7,771.50	888.35	70.9%	19.3%	97.9%	74.2%
A9508	Iodine I-131 iobenguane sulfate, per 0.5 mCi	105	1,338.45	49.20	5,452.58	1,158.38	407.42	15.06	1,778.09	394.85	926.30	34.14	3,674.49	763.58	66.9%	38.1%	95.9%	67.8%
A9528	I-131 sodium iodide capsule(s) per mCi	22	587.45	177.16	1,455.96	562.60	470.04	99.70	1,366.70	427.07	110.26	26.06	191.20	81.39	25.1%	3.2%	43.7%	29.8%
A9542	In-111 ibritumomab, dx, up to 5 mCi	150	3,354.55	309.97	28,165.30	2,129.75	489.72	43.00	2,726.62	382.01	1,865.07	151.82	26,336.69	1,362.18	65.5%	6.8%	94.9%	73.0%
A9544	I-131 tositumomab, dx, per dose	46	1,896.19	960.92	6,059.95	1,513.25	411.55	75.76	1,023.16	380.50	1,264.85	459.24	2,497.88	1,015.35	68.9%	26.2%	91.1%	68.0%
A9547	In-111 oxyquinoline, dx, per 0.5 mCi	18	560.94	354.20	1,117.69	518.56	264.13	136.75	644.28	221.87	260.34	34.08	541.33	220.43	46.1%	6.8%	67.5%	49.5%
A9556	Ga-67 gallium citrate, per mCi	187	547.98	128.68	2,223.11	443.44	383.88	99.07	1,962.28	313.85	120.54	4.76	1,602.20	82.14	21.7%	1.2%	72.1%	16.8%
A9565	In-111 pentetreotide, per mCi	938	2,044.69	148.06	16,309.12	1,196.44	612.35	54.82	3,874.95	345.17	1,398.38	1.17	14,715.00	829.18	85.0%	0.5%	98.3%	66.8%
APC	Definition	2008 Payment	Total Cost Per Claim				Cost for Tumor Scan Only				Cost for Diagnostic Radiopharmaceutical Only				Percent of Diagnostic Radiopharmaceutical Cost			
0414	Level II Tumor/Infection Imaging	\$ 536.15	Total Cost Per Claim				Cost for Tumor Scan Only				Cost for Diagnostic Radiopharmaceutical Only				Percent of Diagnostic Radiopharmaceutical Cost			
Diagnostic Radiopharm	Definition	Single /Pseudo Single Claims	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim
A4641	Diagnostic imaging agent	691	733.21	145.10	3,627.52	637.80	291.16	48.93	1,753.00	224.05	405.81	6.84	3,319.30	329.84	53.3%	1.4%	91.9%	56.9%
A9500	Tc-99m sestambi. up to 40 mCi	19	356.28	140.06	606.44	332.37	208.21	58.24	585.00	169.31	127.52	5.08	352.31	103.55	38.9%	2.8%	71.7%	34.3%
A9507	In-111 capromab pendetide, up to 10 mCi	156	1,358.62	309.71	3,599.77	1,233.65	283.59	72.09	1,025.19	266.17	1,010.65	36.91	2,778.92	852.54	70.8%	7.5%	91.4%	74.8%
A9508	Iodine I-131 iobenguane sulfate, per 0.5 mCi	97	1,262.12	284.47	7,368.64	877.12	307.35	102.21	757.61	269.01	940.60	38.85	6,804.97	573.22	63.9%	6.0%	94.3%	70.8%
A9521	Technetium Tc-99m exametazine, up to 25 mCi	3,499	663.79	93.85	11,795.14	553.03	254.48	20.96	2,009.76	212.45	373.79	8.10	11,592.63	284.21	54.7%	4.1%	98.3%	55.9%
A9528	I-131 sodium iodide capsule(s) per mCi	23	393.44	206.33	705.45	392.57	255.86	107.02	394.67	212.45	117.83	26.06	598.43	104.86	27.9%	6.3%	84.8%	29.3%
A9542	In-111 ibritumomab, dx, up to 5 mCi	106	2,303.86	259.92	11,330.49	1,533.46	274.59	52.14	1,059.93	245.62	1,282.75	151.00	8,263.01	1,243.03	67.3%	9.8%	95.0%	73.4%
A9547	In-111 oxyquinoline, dx, per 0.5 mCi	2,704	670.80	102.54	6,362.30	564.48	275.06	7.66	2,577.26	232.10	355.53	2.41	5,438.72	276.35	52.8%	1.6%	97.0%	53.4%
A9556	Ga-67 gallium citrate, per mCi	1,354	399.60	66.78	6,624.03	332.33	264.51	43.42	1,209.27	220.18	87.66	1.51	2,734.17	67.81	24.3%	0.4%	89.7%	22.5%
A9565	In-111 pentetreotide, per mCi	600	1,401.61	62.74	13,071.21	1,048.47	326.08	23.87	1,315.26	286.55	1,044.38	24.00	12,798.47	673.80	65.7%	6.1%	97.9%	70.4%

Table II RP Costs Derived from Hospital CCR in Tumor/Inflammation Imaging APCs Compared to Total RP Cost Data (Web), and to SNM Survey of 2006 Costs

Radiopharmaceutical	Median RP Only Cost (Cleverly RP Breakout)			Median Web	Mean Web	Mean 2007 SNM
	0406	0408	0414	CMS 2006	CMS 2006 per unit/ per units per day	Survey w/ 2006 Data per unit/ per units per day
A4641 Dx, RP, NOS	\$72.88	\$766.22	\$330.92	\$37.97	\$70.28/\$85.03	Depends on RP
A9500 Tc-99m sestamibi, up to 40 mCi	\$61.04	\$94.04	\$121.74	\$68.07	\$83.48/\$135.83	\$81.05/\$132.11
A9507 In-111 capromab pendetide, up to 10 mCi	\$766.38	\$957.20	\$766.07	\$748.29	\$925.28/same	\$2,135.84/same
A9508 Iodine I-131 iobenguane sulfate, per 0.5 mCi	\$101.95	\$763.58	\$627.89	\$321.98	\$453.74/\$697.70	\$1,799.93/\$2,771.89
A9521 Technetium Tc-99m exametazine, up to 25 mCi	\$241.87		\$284.21	\$268.39	\$333.14/same	\$465.58/same
A9528 I-131 sodium iodide capsule(s) per mCi	\$58.21	\$81.39	\$104.86	\$11.07	\$21.65/\$100.65	\$56.38/\$262.17
A9544 I-131 tositumomab, dx, per dose	\$18.80	\$1015.35		\$1,209.34	\$1,472.49/same	\$2,447.22/same
A9556 Ga-67 gallium citrate, per mCi	\$87.66	\$81.83	\$67.81	\$12.46	\$19.76/\$93.53	\$51.52/\$243.69
A9565 In-111 pentetrotide, per mCi	\$765.69	\$828.96	\$659.04	\$178.52	\$296.72/\$1054.40	\$1,139.16/\$4,044.02
A9542 In-111 ibritumomab, dx, up to 5 mCi		1344.00	\$1243.03	\$1,240.81	\$1,609.00/\$1,626.92	\$2598.03/same
A9547 In-111 oxyquinoline, dx, per 0.5 mCi		\$203.59	\$276.35	\$259.38	\$313.16/\$331.55	\$988.84/same

The wide variation in RP cost from one APC to another likely represents the difference in providers reporting procedures in each of the APCs, and is evidence of the inaccuracy of hospital derived cost data for these products. Note the large disparity of median costs by APC of A9544 and A9500, for example.

Submitter : Ms. Deb Fisher
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-344-Attach-1.DOC

#344

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 CMS's 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 Code 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,

Deb Fisher
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Mary Jane Gook
Organization : MAPS Medical Pain Clinic
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

· CMS-1392-FC-345-Attach-1.DOC

#345

December 18, 2007

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

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

Sincerely,

Deb Fisher
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Georgann Gillund
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachments

CMS-1392-FC-346-Attach-1.DOC

#346

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,

Georgann Gillund
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Angela Greene
Organization : MAPS Medical Pain Clinics
Category : Nurse Practitioner

Date: 01/28/2008

Issue Areas/Comments :

GENERAL

GENERAL

attachment

CMS-1392-FC-347-Attach-1.DOC

#347

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,

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

Submitter : Ms. Joy Gripentrog
Organization : MAPS Medical Pain Climics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-348-Attach-1.DOC

#348

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,

Joy Gripenrog
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Mr. Eric Zimmerman
Organization : McDermott Will & Emery
Category : Ambulatory Surgical Center

Date: 01/28/2008

Issue Areas/Comments

HCPCS codes

HCPCS codes

See Attachment

CMS-1392-FC-349-Attach-1.PDF

#349



Surgical Care Affiliates

January 28, 2008

VIA HAND DELIVERY

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human 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

Dear Acting Administrator Weems:

On behalf of Surgical Care Affiliates, please accept the following comments regarding this rule, which, among other items, sets forth payment classifications for HCPCS codes for ambulatory surgical centers (ASCs). 72 Fed. Reg. at 66579 (November 27, 2007). We appreciate the work that has gone into establishing the payment classifications on a code-by-code basis.

With interests in 131 ASCs in 33 states, Surgical Care Affiliates is one of the largest operators of ASCs in the United States. ASCs offer outpatient surgery in a convenient, safe environment characterized by superior patient care.

I. ASC Payment Indicators for HCPCS Codes with Comment Indicator "NI"

While we generally support the ASC payment indicators CMS has designated for HCPCS codes assigned a comment indicator of "NI", we believe the payment indicator assignments for certain of the HCPCS codes under comment should be reconsidered. In particular, we draw your attention to the following procedures:

HCPCS Code 21073: The newly created CPT code 21073, Manipulation of temporomandibular joint(s), therapeutic, requiring an anesthesia service (i.e., general or

monitored anesthesia care), has been assigned a payment indicator of P3. This assignment assumes that this procedure meets the criteria CMS has set forth for designating services as office based, namely that Medicare physician claims data show the service is rendered more than 50 percent of the time in the physician office setting (see 72 FR beginning at 42509). In this case, we do not believe the criteria CMS established have been met, as there is no existing claims data that would allow the agency to determine the service has been rendered more than 50 percent of the time in the physician office setting. Moreover, this new code is not analogous, or essentially equivalent, to a previously existing code. As a result, there is no existing data that may be used as a proxy for demonstrating site of service patterns (as might be true in cases in which the AMA deletes a given code and replaces it with another code which has an identical descriptor for purposes of improving the organization of the CPT manual). Particularly because the office-based designation is a permanent one, we believe the agency bears a burden of proof in categorizing any service as office-based under its new policies.

Further, CPT code 21073, by definition, may only be reported when anesthesia services such as general anesthesia and monitored anesthesia care have been necessary to perform the therapeutic manipulation. We believe it is unlikely that physician offices, which do not commonly provide these anesthesia services, will be the primary site of this service.

We also note that other similar surgical services that include a requirement for anesthesia have all been assigned a payment indicator of either A2 or G2. These include the following: CPT code 23700, Manipulation under anesthesia, shoulder joint, including application of fixation apparatus; CPT code 24300, Manipulation, elbow, under anesthesia; CPT code 25259, Manipulation, wrist, under anesthesia; CPT code 26340, Manipulation, finger joint, under anesthesia, each joint; CPT code 27275, Manipulation, hip joint, requiring general anesthesia; and CPT code 27570, Manipulation of knee joint under general anesthesia.

For the above reasons, CMS should reconsider the interim assignment of a P3 payment indicator to CPT code 21073. We believe a payment indicator of G2 is the appropriate assignment.

HCPCS Code 68816: The newly created CPT code 68816, Probing of nasolacrimal duct, with or without irrigation; with transluminal balloon catheter dilation, has also been assigned a payment indicator of P3. While this is a newly created CPT code, the American Medical Association (AMA) has indicated that it is most closely related to existing CPT code 68815. Specifically, the AMA stated, in their publication *CPT Changes 2008: An Insider's View*, "The code previously used to identify this procedure, code 68815, Probing of nasolacrimal duct, with or without irrigation; requiring general anesthesia, was inadequate."

We have reviewed the CMS data file for 2006 showing the numbers of allowed services for the hospital outpatient, ambulatory surgical center and physician office setting for CPT code 68815 and found that 68815 was not performed 50 percent or more of the time in the physician office setting.

In light of this information, we believe that the payment indicator for code 68816 should be changed to G2.

II. Newly Created HCPCS Code Not Included for ASC Coverage in 2008

The newly created CPT code 52649, Prostate laser enucleation is covered under the OPSS for 2008, but was not included for ASC coverage in Addendum AA. This procedure, commonly referred to as holmium laser enucleation of the prostate (or HoLEP), is similar to CPT code 52647, Laser surgery of prostate and CPT code 52648, Laser surgery of prostate. Both codes 52647 and 52648 were covered under the original ASC payment system and remain included for coverage under the revised ASC payment system. A study of HoLEP by Aho et al (see J Urol. 2005 Jul;174(1):210-4.) describes a mean hospital time of 13.7 hours, which could readily be accommodated in the ASC setting under current CMS policies. An additional HoLEP study by Kuo et al (see World J Surg Oncol. 2003 Jun 6;1(1):6.) confirms that the procedure may be performed as either an outpatient or overnight procedure depending on patient preference.

Based on this information, we request CMS add CPT code 52649 to the listed of covered surgical procedures in Addendum AA for 2008.

III. Additional Comments Regarding the Revised ASC Payment System

While we support many of the policies CMS has implemented in its revision of the ASC payment system, ASCs still face certain significant barriers to providing a full range of surgical services to Medicare beneficiaries. These obstacles not only limit access to selected services, but also limit the savings that might otherwise have accrued to both the Medicare program and its beneficiaries. In particular, we draw your attention to the following issues:

ASC payment for covered surgical services involving devices and biologicals: Many ASCs are interested in offering covered surgical services involving devices and biologicals to Medicare beneficiaries, but are finding that the revised payment policies result in reimbursement that is not sufficient to cover costs. This is true both for services for which reimbursement is determined according to the standard ASC methodology and also for services for which reimbursement is determined according to the adjusted methodology for device-intensive procedures.

For example, the reimbursement for CPT 57288, Repair bladder defect, is calculated according to the standard ASC methodology. The national payment amount for 2008 is \$979.81. The cost of the sling is \$1095.00 (Johnson & Johnson, Gynecare TVT Secur®), which exceeds the 2008 reimbursement established for the procedure and the implant. Moving immediately to the fully implemented payment amount may allow this procedure to become economically feasible for ASCs now, rather than years from now.

An additional example of a device-dependent procedure with reimbursement insufficient to cover costs is CPT code 63685, Insert/redo spinal neurostimulator pulse generator. Despite having been designated as a device-intensive procedure under the revised ASC payment system, and therefore having had special allowance made for device cost as estimated by CMS, the 2008 national reimbursement amount of \$13,727.20 is inadequate. The pulse generator alone has an invoice cost of \$14,760 (Advanced Bionics Corporation, Precision Implantable Pulse Generator).

Even when this procedure is fully transitioned in 2011 with an estimated national reimbursement amount of \$14,524.72, the reimbursement will not cover the cost of the pulse generator alone. We believe the policy CMS has established for device-intensive procedures should be modified in a manner that takes into account the differences between hospital and ASC device costs.

In order to allow access to these services in the ASC setting, CMS should consider modifying its current policies. Options would include: 1) allowing full payment to ASCs for the device portion of any device dependent APC, regardless of the percentage the device represents in relation to the total APC reimbursement; 2) moving to a fully implemented payment amount for procedures previously covered under the ASC benefit that require implanted devices or biologicals; and 3) allowing reimbursement for implanted biologicals on a reasonable cost basis or invoice amount, as is currently the case for corneal tissue. As stated previously, establishing policies that allow adequate reimbursement rates for ASCs ultimately results in savings both to the Medicare program and its beneficiaries as compared to the generally more costly HOPD setting.

ASC conversion factor: As we have stated in previous comments, we believe the estimated 15% migration of services from the physician office to the ASC is significantly overstated. Our facilities have little interest in using their specialized physical plant, personnel, and equipment to perform minor procedures on a routine basis for reimbursement that is below cost, and physicians have no reason to move cases from the office to the ASC setting unless it is medically necessary to do so. Using more reasonable migration assumptions would result in a more appropriate ASC conversion factor. We continue to encourage CMS to revisit its migration assumptions and evaluate their accuracy when data becomes available.

Coverage policies for ASCs: We remain very concerned by the definition of overnight stay CMS has adopted. From a clinical standpoint, it would be much more appropriate to define a length of stay. Further, the use of midnight as the equivalent of overnight is not only counter to previous CMS statements on this matter, which defined an overnight stay as a stay of less than 24 hours in duration, but also at odds with numerous state regulations. We also remain concerned about the exclusion of unlisted surgical procedure codes from ASC payment under the revised ASC payment system. This policy, in addition to being incongruent with the approach CMS takes to reimbursement of unlisted codes under OPSS, is unnecessarily restrictive.

Surgical services packaged into radiologic services: With the implementation of the expanded packaging policies under OPSS, even more procedures safely performed in the ASC setting have been packaged with services outside the CPT surgical range (CPT 10000-69999). Procedures that had been (or would otherwise be) eligible for payment in the ASC are now newly ineligible because of a change in OPSS packaging policy, not because there has been a determination that the procedure is unsafe in the ASC.

Specifically, current policy creates barriers to performing selected services that meet CMS's definition of ASC surgical services (CPTs 10000-69999). Procedures such as arthrography, diskography and epidurography have both a surgical injection component and a radiographic component. In CPT, the injection portion of the service is described by a code in

the surgical range (in the case of diskography, 62290 or 62291), while the radiographic portion of the service is described by a code in the radiology range (in the case of diskography, 72285 and 72295). Under OPSS, the injection portion of the procedure is packaged into the radiographic portion of the procedure. As a result, only CPT codes 72285 and 72295 are payable.

Although CMS has adopted policies that will allow ASCs to bill for selected radiology services as ancillary services when provided integral to the surgical service under the revised ASC payment system, the codes for radiology services that package a surgical service have not been designated as separately payable. CMS has stated that it sees no rationale for offering separate payment for the surgical portion of these services. However, the surgical service is a necessary precedent to the radiologic service in these cases and the radiologic service cannot be properly performed in absence of the surgical injection procedure. Therefore, we request that the agency outline an alternative approach for ASC providers who wish to offer these surgical services to Medicare beneficiaries. One of the predominant trends in today's clinical practice is the integration of multiple disciplines and modalities to streamline patient care. These integrated care processes enhance efficiency and quality. However, payment policies that view these services in separates silos can disrupt these interrelationships and limit beneficiary access to efficiently integrated services, particularly in the ASC setting.

ASC wage index: We have reviewed both the proposed and final rules for the revised ASC payment system (CMS-1517-F and CMS-1392-P) and have not found reference to excluding the occupational mix adjustment from the ASC wage index. It was our understanding that CMS intended to "apply to ASC payments under the revised ASC payment system the IPPS pre-reclassification wage index values associated with the June 2003 OMB geographic localities, as recognized under the IPPS and OPSS, in order to adjust national ASC payment rates for geographic wage differences under the revised payment system" (see CMS-1517-F, p 42547 of the August 2, 2007, Federal Register). Removing the occupational mix adjustment from the ASC wage index re-introduces variation in the geographic adjustment completely unrelated to the ASC industry. We request CMS describe its rationale for having two different geographic adjustment factors for providers in the same market in future rulemaking.

ASC adjustment for inflation: ASC adjustments for inflation should be made using the hospital market basket rather than the CPI-U. The CPI-U is a measure of consumer inflation and its inputs do not reflect the items and services that ASCs must purchase in order to provide care for their patients. On the other hand, the hospital market basket is based on expense categories that are shared by both hospitals and ASCs. Given that CMS is not bound by statute to use the CPI-U to adjust ASC payments for inflation, the agency should adopt the hospital market basket for ASC updates, recognizing the similar resource requirements and inflationary pressures facing ASCs and HOPDs.

Kerry Weems, Acting Administrator
January 28, 2008
Page 6 of 6

Thank you for considering these comments. We appreciate the opportunity to share our views on the payment indicator designations and other issues pertinent to the revised ASC payment system.

Sincerely,

A handwritten signature in cursive script that reads "Joe Clark".

Joe Clark
Executive Vice President and Chief Operating Officer
Surgical Care Affiliates
P.O. Box 382497
Birmingham, AL 35243

Submitter : Ms. Nikki Gruber
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-350-Attach-1.DOC

#350

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).

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

Sincerely,

Nikki Gruber
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Mr. Brian Hicks
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

#351

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

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

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

Submitter : Ms. Becky Higgins
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

#352

file:///T:/ELECTRONIC%20COMMENTS/ELECTRONIC%20COMMENTS/E-Comments/Active%20Files/Missing%20file1.txt

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

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

Submitter : Ms. Robin Janette
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

#353

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

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

Submitter : Ms. Roni Hopkins
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-354-Attach-1.DOC

354

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:

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

Sincerely,

Roni Hopkins
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

#356

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,

Heather Keenan
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Mrs. Pat Tomshine
Organization : MAPS Medical Pain Clinics
Category : Nurse Practitioner

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-357-Attach-1.DOC

#357

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,

Pat Tomshine
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Jackie Torma
Organization : MAPS Medical Pain Clinic
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-358-Attach-1.DOC

358

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,

Jackie Torma
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Lisa Torma

Date: 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-359-Attach-1.DOC

#359

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,

Lisa Torma
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Angela Gilmore
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-1392-FC-360-Attach-1.DOC

#360

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,

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

Submitter : Ms. Anne Trujillo
Organization : MAPS Medical Pain Clinics
Category : Nurse Practitioner

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-361-Attach-1.DOC

#361

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 CMS's 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,

Anne Trujillo
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