

Submitter : Michael Hansen

Date: 12/27/2007

Organization : EMS Advisory Council & IL Fire Chiefs Assn

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

"See attachment"

CMS-1385-FC-192-Attach-1.PDF

CMS-1385-FC-192-Attach-2.PDF



**State of Illinois
Emergency Medical Service Advisory Council**



December 27, 2007

Kerry N. Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1541-P
Box 8012
Baltimore, Maryland 21244-8012

Re: CMS-1385-FC; Medicare Program; re: Beneficiary Signature for Ambulance Transport Services

Dear Mr. Weems:

I am writing to you on behalf of the 27,500 EMS providers in the State of Illinois that serve a population of a little more than 12 million residents. As the Chairman of the Illinois Fire Chief's Association's EMS Committee and the Illinois EMS Advisory Council, our groups provide guidance and direction to the Illinois Department of Public Health and the Illinois Fire Chiefs Association on matters concerning EMS and trauma issues. After reviewing the Federal Register dated November 27, 2008 we have some significant issues with the signature requirements under 42 C.F.R.

My comments relate specifically to the section of the Final Rule entitled "Beneficiary Signature for Ambulance Transport Service". We currently have great difficulty obtaining the patient's signature when the patient is having an emergency, is in physical distress, is unconscious, has a diminished mental capacity, or suffers from some other condition that makes getting a signature impossible at the time of transport.

While the new exception for emergency ambulance transports, listed in 42 C.F.R. §424.36(b)(6), provides a little more flexibility, it will not resolve the problem in most cases. Further, we face problems with getting the patient's signature for non-emergencies as well. For our non-emergency transports, the patient is frequently suffering from a chronic or terminal condition—in fact, this may be the very reason they need an ambulance—that makes it extremely difficult to get the patient's signature, not only at the time of transport, but also after the fact. **Therefore, we ask that you expand this new exception to include both emergency and non-emergency transports.**

The Final Rule also laid out CMS' interpretation of 42 C.F.R. §424.36(b)(5). This is an exception to the patient signature requirement, which permits the entity furnishing services to the patient, in some instances, to sign on the patient's behalf. According to CMS, this exception applies only to institutional ambulance providers who bill Medicare Part A. This is a new interpretation, as the ambulance industry has relied upon previous guidance from both CMS and

its Medicare contractors that indicated that this provision applied to both providers and suppliers, e.g. Section 20.1.2 of Chapter 10 of the Medicare Benefit Policy Manual. It is extremely unfair to impose a stricter requirement on ambulance suppliers than institutional ambulance services. **Therefore, we ask that you go back to your prior interpretation and make 42 C.F.R. §424.36(b)(5) applicable to both providers and suppliers.**

The Final Rule also changed 42 C.F.R. §424.36(b)(5) to require that the entity use “reasonable efforts” to obtain the signature of the patient or another authorized person before the entity could sign on the patient’s behalf. In the response to comments, you also made clear that these reasonable efforts would extend over a reasonable period of time. For Medicare, ambulance coverage is always based on the patient’s condition at the time of transport. As a result, the industry has always understood the patient signature requirement to be based on the time of transport, i.e., that a claim could be submitted to Medicare as long as we documented that the patient was unable to sign and that no one was able to sign for the patient at the time of transport. This view is supported by guidance issued by Medicare contractors. To require us to now chase the patient’s signature for some “reasonable period” after the transport will dramatically increase the administrative costs associated with billing for Medicare patients, at a time when Medicare already pays us less than our costs. **Therefore, we ask that, for ambulance services, “reasonable efforts” under 42 C.F.R. §424.36(b)(5) mean reasonable efforts taken at the time of transport.**

In the Final Rule, you also stated that the purpose of the patient’s signature was to prove that the service being billed was actually provided to the patient. We have always believed that the purpose of the patient’s signature was to effect the assignment of Medicare benefits, and to authorize us to release the patient’s medical records to CMS and its contractors to determine whether payment was warranted. Thus, proving that the transport was completed is a new purpose for the signature requirement.

While we understand CMS’ desire to verify that transports were actually provided before payment is made, we believe there are more effective means of verifying that the transport was completed. Nearly all covered ambulance transports will be to or from a medical facility. These facilities must keep records as to how the patient arrived or was discharged. Thus, in the event it becomes necessary to prove an ambulance transport was provided, CMS could request the records of the medical facility. Also, since the overwhelming majority of claims are submitted electronically, the patient is not signing the actual claim form anyway. Instead, they are signing a separate piece of paper.

We are grateful that you recognize the need for relief from the patient signature requirement in certain instances. **However, to provide meaningful relief, we would ask you to eliminate the patient signature requirement entirely for ambulance services submitted using electronic claims.**

Finally, to comply with all these changes we will need to retrain all of our crew members, billing staff and other personnel. We will also need to develop new forms and educate the medical facilities we work with (both on the new exception for emergency and on the new interpretation for non-emergencies). In addition to being very costly, this training will take time. The January

1, 2008 effective date will not give us nearly enough time to retrain all of our personnel to comply with the new requirement. **For this reason, we urge you to delay implementation for a few months, in order to give ambulance services like ours the time to make these needed changes.**

Thank you for your consideration of these comments.

Sincerely,

Mike Hansen

Chief Mike Hansen, Chairman
State Emergency Medical Services Advisory Council
Illinois Fire Chiefs Association's EMS Committee

Submitter : Mr. Chuck Latimer

Date: 12/27/2007

Organization : Tennessee Ambulance Service Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

I wish to ask you to examine your changes to the signature requirements for ambulance services until a better financial study can be made on changing these requirements. Many times during emergent ambulance trips, it is next to impossible to obtain a lifetime signature from a patient due to their critical condition. Many of these patients also do not have family members near to sign this form for them. The hospitals in which we transport these patients to are mostly uncooperative. Representatives such as nurses, do not feel comfortable signing for a patients release of benefits, etc. We ask that you put this ruling on hold until the financial impact can be further examined. As you know in 2007, the Government Accountability Office determined that Medicare reimbursed ambulance services an average of 6% lower than cost, and up to 17% below cost in rural areas. Many ambulance services in Tennessee operate emergency ALS and BLS. This ruling will especially effect these particular ambulance services who are the stand alone provider for all emergency medical services in a particular geographic region, usually within a county.

Submitter : Mrs. Danna Page
Organization : City of Longview Fire/EMS
Category : Health Care Provider/Association

Date: 12/27/2007

Issue Areas/Comments

GENERAL

GENERAL

We believe that CMS should withdraw this regulation until the impact of any change from the current regulations can be fully evaluated. We encourage CMS to review the many questions that have arisen since publication of the final regulations before re-publishing any changes to the current signature regulations.

Submitter : Dr. Michael Maves
Organization : American Medical Association
Category : Health Care Professional or Association

Date: 12/27/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-FC-195-Attach-1.DOC



Michael D. Maves, MD, MBA, Executive Vice President, CEO

December 28, 2007

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

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Final Rule with Comment Period; CMS—1385—FC

Dear Administrator Weems:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to reiterate our request that CMS provide the utmost flexibility for the inclusion of physician quality measures in the 2008 Physician Quality Reporting Initiative (PQRI). CMS' strict interpretation of regulatory and administrative deadlines has barred inclusion in the 2008 PQRI of a number of important measures developed in 2007, and this will deny many physicians an opportunity to participate in the PQRI until 2009.

The urgency of this request is furthered by Congressional action this week to continue funding the PQRI through 2008. To ensure that physicians receive the greatest benefit from the PQRI we urge CMS to include all measures that would allow physicians the opportunity to participate in 2008 and benefit from the program.

Unlike hospitals, which are fairly homogeneous in terms of the services provided, the reality of physician care makes a one-size fits all approach impossible. CMS recognized this diversity by including 74 quality measures in the original 2007 PQRI, far greater than the 10 measures in Medicare's first hospital reporting program. Even so, many physicians still cannot participate in PQRI due to a lack of measures that are applicable to the patients and conditions they treat.

Section 101 of the Tax Relief and Health Care Act (TRHCA) requires that PQRI quality measures "shall be measures that have been adopted or endorsed by a consensus organization (such as the National Quality Forum or AQA), that include measures that have been submitted by a physician specialty, and that the Secretary identifies as having used a consensus-based process for developing such measures." A number of quality measures

developed in 2007 met this criteria, but were not included in the July 12, 2007, PQRI proposed rule because they did not meet various internal CMS-imposed administrative deadlines.

Although we urged in comments to the proposed physician fee schedule rule that CMS exercise flexibility and include these additional measures in the final rule, CMS has declined to do so. We continue to urge CMS to include these measures in the PQRI for 2008. CMS stated in the final rule that the public would not have a "true opportunity" to comment if these additional measures were included in the final rule. We disagree. Medical specialty societies that would be impacted by inclusion of these additional measures in the 2008 PQRI commented on the proposed rule and urged their inclusion. These specialties were also integrally involved in the development of the measures relevant to their specialty. Thus, there is a fully rational basis for including these measures in the 2008 PQRI.

Further, in subsequent oral communications, CMS stated that it did not have the CPT II codes that are needed to report data on each quality measure, and thus it could not administratively implement these additional measures for 2008. We note that the appropriate CPT II codes for these additional measures are available for CMS' use, and we further urge that flexibility be the keystone in establishing the quality measures for use in the 2008 PQRI. A somewhat delayed implementation of the CPT II codes for these quality measures should not be a complete bar to their use in 2008.

We strongly urge CMS to include all measures in the 2008 PQRI that meet statutory consensus development and endorsement/adoption requirements prior to the November 15, 2007 deadline set forth in TRHCA. Flexibility in this regard is critical, and it is incumbent on CMS to do everything in its power to see that all eligible measures are included in the 2008 program.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA

Submitter : Mr. Robert Blaser
Organization : Renal Physicians Association
Category : Health Care Professional or Association

Date: 12/27/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

#196

FILE:///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

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 : Michael Kerner
Organization : Kuhl Hose Company
Category : Health Care Professional or Association

Date: 12/27/2007

Issue Areas/Comments

**Refinement of RVUs for CY 2008
and Response to Public Comments
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

My name is Michael Kerner, President of Kuhl Hose Company. Kuhl Hose is an all-volunteer fire department, located in Greene Township, a rural portion of Erie County, Pennsylvania. Kuhl Hose is concerned about several of the proposed changes in 42CFR 424.36, .37 and .40. First, the period of time given to us to become compliant is unreasonably short. Our billing partner, law firm, and we were just able to all review and discuss the proposed changes today, five days before the regulations are scheduled to take effect. This does not give us any reasonable time to meet with or train our all-volunteer staff as to the new procedures to be followed as a result of the regulations. Secondly, the "Authorized Signers" section, which details individuals who can sign for a Beneficiary in the event that the Beneficiary is unwilling or unable to sign, presumes that we, as a Supplier, are in a position to obtain said signature, and that we are going to be able to determine that someone signing is indeed Authorized as indicated under the new rule. These requirements presume that the Beneficiary is unable to sign, which generally means they are unconscious. When we responds to such scenes, the family members are normally not in a good mindset to sign paperwork, then demonstrate that they are Authorized to do so. More importantly, we believe that the Rule should have more consideration for crews, who are generally busy performing life-sustaining or life-saving interventions at these kinds of scenes. Distracting them from those duties for the purpose of seeking out, calming down, and verifying that a signer is Authorized is, in our opinion, a great waste of resources in a time of great need for our undivided attention. The most reasonable course of action is therefore to delay transport, as our only other alternative is to, after transporting "Priority 1" to wait for a potentially indefinite period of time for an Authorized signer to arrive at the Hospital. Thirdly, the new Rule removes our ability to, after making a good faith effort to obtain a signature, invoke the so-called "Exception 5", which, for an all-volunteer service, was a considerable time saver. We think the elimination of this exception is both unreasonable and onerous on agencies that are the sole lifeline to emergency care in rural areas such as ours, with staff that, at best, answer a few calls a week, and now must not only remember the various treatment protocols, but also must make extra sure to read and follow a complex series of rules in which they are not well versed BEFORE transporting. Lastly, we believe that the "catch all" "three types of documentation" option should also be reconsidered. The statement from Medicare that "We continue to believe that in many, if not most, cases the ambulance transport personnel will have no difficulty in securing a signature from personnel at the hospital..." is, in our opinion, naive. To begin with, "...many, if not most..." does not feed the bulldog. Medicare's reimbursements to our services are already laughably low. Placing the onus on small operators such as Kuhl Hose Company to fight a big hospital to obtain a signature when no requirement that such a signature be provided is unreasonable. At least in our area, the ER's and Trauma Centers are always busting-at-the-seams busy, personnel overworked, lines long, triage packed, and extra paperwork unwelcome. Obtaining registration paperwork is frequently a long process. One facility we transport to does not provide us with anything other than an ID sticker that they place on their own internal paperwork. We believe that the comment period should be extended and that the rules should be reconsidered in light of the impact they will have on small departments such as ours. While we applaud Medicare's efforts to reduce fraud, we believe that other means can be employed to achieve the same goal.

Submitter : Dr. Gale Oleson

Date: 12/27/2007

Organization : Dr. Gale Oleson

Category : Physician

Issue Areas/Comments

**Refinement of RVUs for CY 2008
and Response to Public Comments
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

Re: CMS 1385-FC: 2008 Medicare Fee Schedule

Coding Multiple Procedure Payment Reduction for Mohs Surgery

I have several concerns about applying a 50% reduction to Mohs Micrographic Surgery.

1. Application of a 50 % reduction to the Mohs Surgery Codes will also impact any reconstruction that occurs after the Mohs tumor extirpation is complete. In all instances, the reconstruction is a separate operative session from the Mohs surgery. Even when the reconstruction occurs on the same day as the Mohs surgery, it is never at the same operative session. As the pathology portion of the Mohs surgery is a long process, any reconstruction occurs long after the Mohs resection. When a reconstructive effort occurs, the patient must return to the procedure room, be re-positioned, re-prepped, re-draped, and re-anesthetized. Separate instrumentation and supplies are utilized for the reconstruction. The fact that the patient had a Mohs resection earlier in the day does not decrease the amount of work involved in the reconstruction. The Mohs procedure does not decrease the pre-service work of the reconstruction as the nature of the reconstruction cannot be known prior to the completion of the Mohs resection.

2. In instances where the primary Mohs code (17311 or 17313) is reduced, the associated add on codes (17312 or 17314) will be more highly valued than the primary codes. As the value of the add on codes has already been determined to reflect the fact that less work is involved in the add on code, it appears inconsistent to value the primary code below the add on code. In no other family of codes in the integumentary system does this phenomenon exist, this making the reduction of the Mohs codes a true anomaly.

3. The application of a 50 % reduction is not appropriate given the amount of intraservice work in the Mohs codes. In Mohs surgery, at least 80% of the total work is repeated when a second Mohs procedure is performed. Moreover, there is no efficiency gained in the pathology portion of the code when more than one procedure is performed. Therefore, reducing the value of this code by 50% would significantly undervalue the code.

In light of the concerns raised above, I am requesting that CMS reconsider their plan to remove Mohs surgery from the MPRR exemption list permanently or delay implementation until a refinement in the reduction can be established that will alleviate the inconsistencies that a 50% reduction will generate.

4. I have never seen the RBRVS justification of the 50% reduction on surgeries at unrelated sites. I would request now, under the Freedom of Information Act, that I either be sent this data to Gale B. Oleson MD

510 Mock Avenue
Blue Springs, MO 64014

Or present me with a web address where I can access the data in its entirety.

Respectfully,

Gale B. Oleson MD

Submitter : Dr. Thomas Moody
Organization : Urology Centers of Alabama PC
Category : Physician

Date: 12/27/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-FC-199-Attach-1.DOC

Thomas Moody, M.D.
President
Urology Centers of Alabama, PC
3485 Independence Drive
Homewood, Al 35209

(205) 930-0920

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-FC
P.O. Box 8020
Baltimore, MD 21244-8020

December 27, 2007

Dear Administrator Weems:

I am an Urologist practicing at Urology Centers of Alabama, a medical group with 15 Urologists and other specialists in Birmingham, Alabama. Approximately 40% of the patients we treat are Medicare patients. I am writing on behalf of all of the Urologists in our group to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007.

Based on the Stark regulations, we developed an UroPathology laboratory service to comply with the regulations. We spent in excess of \$175,000 just to set up this laboratory and we incur substantial expenses each month for staff, supplies, equipment and rental of space to provide this service. To improve the quality of pathology services available to our patients, we contracted with an UroPathologist who manages our specialized pathology laboratory. Our UroPathologist has unique expertise in the analysis of urological specimens and samples, especially prostate biopsies, to determine if a patient has urologic cancer.

Prostate Cancer is the number one diagnosis that brings patients to our group. We are a Prostate Cancer Specialty Center that offers all treatment modalities for this disease. Alabama received an F last year for our poor record on prostate cancer screening. This year our group has worked very hard through the state legislature and by offering free prostate cancer screenings all over the state to raise prostate cancer awareness in Alabama. As a result we have been able to

improve the Alabama rating to a C. Proper screening and accurate diagnosis of prostate cancer is needed in Alabama.

Medicare has now published a rule that will make it impossible for our practice to maintain our relationship with our UroPathologist. This rule was issued when there is absolutely no evidence that shows this specialty pathology service results in inappropriate usage or overutilization to support this action. In fact, under our arrangement, we have greatly improved our detection of treatable prostate cancer and have been able to reduce the overall number of biopsies because of the accuracy and skill of the UroPathologist we work with. This action by Medicare will make it harder for Urologists to identify prostate and other cancers at the earlier, treatable stage. This new Medicare rule will promote poor quality medical care without any basis for implementation. This new rule was placed in effect entirely based on the CMS decision making process despite significant opposition. Prior to this rule we were operating under the Stark rules set up based on Congressional intent rather than one promulgated by just CMS.

The rule quite simply requires the pathologist provide their services in the same physical office rather than off site at a Centralized Office Building as provided for under the Stark legislation. It is the UroPathologist's expertise in urologic cancer that is important – not where he or she happens to be physically sitting when they look at slides under a microscope and make the diagnosis.

Also when the anti-markup rule is applicable, we are required to calculate a "net charge". CMS has given little guidance with respect to calculating the "net charge" when a service is provided by the employed technologists and physicians of a practice where those individuals are not compensated based on a per test basis. In addition, the CMS rules requires the "net charge" to be calculated without regard to any overhead, including the cost of equipment or leased space. Based on the new anti-markup regulations, it will not be possible for our practice to offer these services to Medicare patients without operating at a loss. As a result, when these services are no longer available, patients will lose access to quality services.

If this rule is not stopped, Medicare's costs will actually increase as quality declines and more repeat studies have to be performed. These pathology studies are essential and will have to be performed by someone. The only questions will be who performs them and how qualified are they to do the work. If we are no longer able to work with the UroPathologist of our choice, we will certainly see a decline in the quality of pathology available to our patients.

While we do have pathologists in the Birmingham area to which we can refer these specimens, they are generalists who might see 100 – 250 prostate specimens per year. In contrast our UroPathologist will see several thousand prostate and other urologic specimens per year. Furthermore he practices in the

same location with four other UroPathologists and has them available for immediate consultation on all specimens where the diagnosis is not clear cut.

I urge you to support high quality cancer detection. The sweeping changes to the anti-markup rules go far beyond what is necessary to protect the Medicare program from fraud and abuse. I respectfully request that CMS reconsider its position in light of the potentially devastating impact on the quality of care for Medicare beneficiaries and delay the implementation of the rule until CMS has had time to understand the full impact of these rules.

Thank you. Please feel free to contact me if you have any questions.

Sincerely,

Thomas Moody, M.D.
President
Urology Centers of Alabama, PC

Submitter : Dr. Charles Mick
Organization : North American Spine Society
Category : Health Care Professional or Association

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-FC-200-Attach-1.RTF

From: Dawn Brennaman
Sent: Thursday, December 27, 2007 4:25 PM
To: Kim Kuman
Subject: 2008 Fee Schedule comments

Attachments: NASS comment to CMS 2008 fee schedule.doc
Kim,

Please submit attached letter.

Thank you,

Dawn

R. Dawn Brennaman, MPA
Director, Health Policy and Reimbursement
North American Spine Society
7075 Veterans Boulevard
Burr Ridge, Illinois 60527
630/230-3681

Submitter : Mr. Scott Parsley
Organization : Keller Fire-Rescue
Category : Local Government

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

Please be advised that it is our opinion that the proposed signature rule would create a hardship and burden on law abiding ambulance providers and that we would instead desire that CMS consider exercising enforcement of the current rule on those who fail to comply.

Submitter : diane millman
Organization : American Society of Echocardiography
Category : Physician

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-FC-202-Attach-1.DOC

December 31, 2007

Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1385-FC

Dear Administrator Weems:

This comment is submitted on behalf of the American Society of Echocardiography (ASE), a professional organization representing over 12,000 physicians and sonographers dedicated to excellence in cardiovascular ultrasound. The purpose of this letter is to object to the expansion of rules that are currently applicable to "purchased diagnostic tests" to echocardiography and other diagnostic services performed by group practices. The expansion of these rules to diagnostic services performed by group practices was announced for the first time in the final rule implementing the Physician Fee Schedule (PFS) for CY 2008.

While CMS has not yet finalized the modifications of the Stark Law regulations that were set forth in the proposed 2008 PFS notice, it did substantially expand the scope of the purchased diagnostic test rule. The purchased diagnostic test rule currently precludes practices from "marking up" technical component services of diagnostic tests purchased from outside suppliers--like mobile services. The proposed 2008 PFS notice indicated CMS's intention to extend this rule to professional component services, but did not indicate that this rule would be applied to services provided directly by group practices, with no outside supplier involved.

However, the final CY 2008 PFS rule includes an expansion of the purchased diagnostic test rule, so that, after January 1, 2008, this rule will apply to all diagnostic tests that are provided directly by a group practice at a location other than the one where the group provides the "full range" of its patient care services. For example, under the expanded regulation, after January 1, 2008, a cardiology practice (or any other entity) that provides echocardiography services in a location where it does not provide the "full range" of its other services, would be precluded from "marking up" the echocardiography services.

At this stage, it is unclear to us (and to many others) what this new rule means. For example, if echocardiography services are provided across the hall or in the basement of the same building where a group provides other patient care services, does the anti-mark-up rule apply? What about services in a building across the street? How about large group practices, such as the Mayo Clinic, which does not have a single office that provides the "full range" of all of its patient care services, but rather provides services throughout a large campus?

Nor is it clear what it really means for a group practice to "mark up" its own services. The preamble to the new anti-mark-up rule suggests that, in order to comply with the regulation, a cardiology group would have to generate an internal "charge" that is, in effect, a charge from the group to itself for the off-site diagnostic tests. Statements in the preamble further suggest that the cost of overhead and equipment would have to be excluded from this internal charge, and the cardiology practice would be paid the lower of the internal charge or the PFS amount. Thus, for example, if a cardiologist specializing in echocardiography is a member of a group practice, and

he or she interprets an echocardiogram at an area hospital, the group must generate a charge from itself to itself that reflects the pro-rata share of the echocardiographer's salary that is attributable to that particular interpretation. The group could be paid no more than the lesser of the PFS amount or the internal charge for the interpretation. As this example makes clear, this expansion of the purchased diagnostic test rule appears to be intended to ensure that practices get paid so little for their diagnostic tests--and to make their provision so cumbersome-- that the group simply ceases providing the services involved.

We do not believe that any public purpose is served by extending the purchased diagnostic test rule to group practices' provision of diagnostic services to their own patients. To the extent that the expansion discourages the provision of diagnostic services in locations other than a group's primary office, it inhibits expeditious access to important diagnostic services in remote areas and in hospital outpatient facilities. To the extent that it requires groups to relocate their diagnostic testing facilities, it results in wasteful expenditure of increasingly scarce resources. And to the extent that it dissuades group practices from continuing to provide diagnostic services to their patients, it assures the performance of these services in higher cost hospital settings. In addition, it is entirely unclear to us what abuse is involved in a group's decision to provide a diagnostic test in a location other than its primary office.

We can only conclude that CMS chose to expand the purchased diagnostic test rule because it believes that "self-referral" is a primary cause of the increased utilization of diagnostic services in the Medicare patient population. If this is CMS's assumption, however, we respectfully suggest that it be re-examined: In fact, the diagnostic services that have been growing most rapidly—MRI, CT, and PET—are performed (and billed) virtually exclusively by radiologists and not by referring physicians' practices. The data shows that, in the case of echocardiography, almost 70% of tests are referred by non-cardiologists who have no financial interest in the performance or interpretation of the tests.

Finally, we believe that the extension of the "purchased diagnostic test" rule to professional component services and its expansion to services provided by bona fide group practices is illegal. The governing statute (at 42 U.S.C. Section 1842(n)) does not authorize application of the purchased diagnostic test rule to services "performed" by a physician—and all professional component services are performed by a physician. Nor does the governing statute authorize application of the rule to services supervised by the billing physician or by a physician with whom the billing physician "shares a practice." A physician who is a member of a group practice that meets the Stark Law definitions does not suddenly cease "sharing a practice" with other group practice members when he or she leaves the office (if any) where the practice provides the "full range" of patient care services to its patients. Insofar as the new rule extends the purchased diagnostic test rules to services "performed" by physicians (professional component services), it is clearly inconsistent with the statute. And to the extent that the new purchased diagnostic test rule applies to services that are supervised by physicians with whom the referring physician "shares a practice" just because the services are provided off-site, the new rule exceeds the scope of the agency's authority under the governing statute.

In addition, since the expansion of the purchased diagnostic test rules to services provided directly by group practices was not included in the proposed 2008 PFS rule and is not a natural outgrowth of that proposed rule, it is procedurally invalid under the provisions of the Administrative Procedures Act. The APA clearly requires that the public have the opportunity to comment on changes of this magnitude.

Under these circumstances, we respectfully request that CMS rescind the rule expanding the purchased diagnostic test rule, or at the very least delay its implementation pending resolution of these issues.

Sincerely yours,

Thomas Ryan
President
American Society of Echocardiography

Submitter : Mr. Robert Sorg
Organization : St. Marys Area Ambulance Service
Category : Other Health Care Professional

Date: 12/28/2007

Issue Areas/Comments

**Refinement of RVUs for CY 2008
and Response to Public Comments
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

I am writing to you on behalf of St. Marys Area Ambulance Service. Our ambulance service provides both emergency and non emergency ambulance services to the residents of the City of St. Marys which is located in Elk County Pennsylvania. The population of the area that we serve is approximately 13,900.

My comments relate specifically to the section of the Final Rule entitled Beneficiary Signature for Ambulance Transport Service. We currently have great difficulty obtaining the patient's signature when the patient is having an emergency, is in physical distress, is unconscious, has a diminished mental capacity, or suffers from some other condition that makes getting a signature impossible at the time of transport.

For our non-emergency transports, the patient is frequently suffering from a chronic or terminal condition in fact, this may be the very reason they need an ambulance that makes it extremely difficult to get the patient's signature, not only at the time of transport, but also after the fact.

The Final Rule also laid out CMS interpretation of 42 C.F.R. 424.36(b)(5). This is an exception to the patient signature requirement, which permits the entity furnishing services to the patient, in some instances, to sign on the patient's behalf. According to CMS, this exception applies only to institutional ambulance providers who bill Medicare Part A. This is a new interpretation, as the ambulance industry has relied upon previous guidance from both CMS and its Medicare contractors that indicated that this provision applied to both providers and suppliers, e.g. Section 20.1.2 of Chapter 10 of the Medicare Benefit Policy Manual. It is extremely unfair to impose a stricter requirement on ambulance suppliers than institutional ambulance services. Therefore, we ask that you go back to your prior interpretation and make 42 C.F.R. 424.36(b)(5) applicable to both providers and suppliers.

The Final Rule also changed 42 C.F.R. 424.36(b)(5) to require that the entity use reasonable efforts to obtain the signature of the patient or another authorized person before the entity could sign on the patient's behalf. In the response to comments, you also made clear that these reasonable efforts would extend over a reasonable period of time. To require us to now chase the patient's signature for some reasonable period after the transport will dramatically increase the administrative costs associated with billing for Medicare patients, at a time when Medicare already pays us less than our costs. Therefore, we ask that, for ambulance services, reasonable efforts under 42 C.F.R. 424.36(b)(5) mean reasonable efforts taken at the time of transport.

While we understand CMS desire to verify that transports were actually provided before payment is made, we believe there are more effective means of verifying that the transport was completed. Nearly all covered ambulance transports will be to or from a medical facility. These facilities must keep records as to how the patient arrived or was discharged. Thus, in the event it becomes necessary to prove an ambulance transport was provided, CMS could request the records of the medical facility. Also, since the overwhelming majority of claims are submitted electronically, the patient is not signing the actual claim form anyway. Instead, they are signing a separate piece of paper.

We are grateful that you recognize the need for relief from the patient signature requirement in certain instances. However, to provide meaningful relief, we would ask you to eliminate the patient signature requirement entirely for ambulance services submitted using electronic claims.

Finally, to comply with all these changes we will need to retrain all of our crew members, billing staff and other personnel. We will also need to develop new forms and educate the medical facilities we work with (both on the new exception for emergency and on the new interpretation.

Submitter : Dr. Harvey Neiman

Date: 12/28/2007

Organization : American College of Radiology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-FC-204-Attach-1.PDF



December 28, 2007

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

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: CMS-1385-FC Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008

Dear Mr. Weems:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, is pleased to submit comments on the Final Rule "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008" published in the *Federal Register* on November 27, 2007. We will address budget neutrality; resource-based practice expense relative value units (RVUs); cardiac MRI codes; independent diagnostic testing facility requirements; physician quality reporting initiative; and changes to reassignment and physician self-referral rules relating to diagnostic tests [Anti-Markup Provisions].

Budget Neutrality

The ACR disagrees with, and remains concerned with the impact of the Centers for Medicare & Medicaid Services (CMS) decision to apply the budget neutrality adjustment required for the 5-Year Review to the physician work RVUs. The vast majority of professional societies whose members treat Medicare beneficiaries recommended that the budget neutrality adjustment be made to the conversion factor and not to the physician work values. Budget neutrality adjustments required by changes in work RVUs typically have been applied to the conversion factor, consistent with the long-standing recommendations of the Relative Value Update Committee (RUC).

The ACR believes that historical consistency with previous adjustments to the conversion factor is a necessary and appropriate policy decision that would result in the most equitable application of budget neutrality adjustments.

Furthermore, CMS should be cognizant that maintaining the stability of the work RVUs is essential, since Medicare's RVUs are used by many other payers. They are often the basis of

physician compensation and productivity analyses. Merely publishing unadjusted work values in Addendum B does not change the fact that CMS finalized to scale the work values as a result of the 5-Year Review. While we understand it is not the intention of the Agency, by scaling the RVUs it gives the appearance, to outside observers, that the physician work of the services unaffected by the 5-Year Review has decreased as a result of the 5-Year Review.

The ACR strongly recommends that CMS reconsider its current policy and apply the budget neutrality adjustment to the conversion factor. In addition, the ACR reiterates its recommendation that CMS use the unadjusted work RVUs in the calculation of indirect practice expense.

Resource Based Practice Expense Relative Value Units

Interest Rate and Equipment Usage Percentage

The ACR agrees with and appreciates CMS's decision to make no change in the equipment utilization and interest rate in the practice expense methodology until there are further data to justify the changes. We are pleased to offer our resources to assist CMS in obtaining accurate data relative to those factors.

Practice Expense Per Physician Hour

The ACR agrees with and appreciates CMS's decision to increase the radiology practice expense per physician hour based on the correct weighting of the ACR supplemental survey data collected on practice expense.

Cardiac MRI Codes

As a result of the technological changes in MRI scanning, the CPT® Editorial Panel created eight new cardiac MRI codes and deleted five existing cardiac MRI codes. The new codes are: CPT code 75557, 75558, 75559, 75560, 75561, 75562, 75563 and 75564. The deleted codes are 75552, 75553, 75554, 75555 and 75556. The ACR, with the American College of Cardiology (ACC) surveyed the eight new codes and CMS accepted the RUC recommendation. However, for the four new cardiac MRI codes that contain "with flow/velocity quantification," CMS stated the following in the Final Rule.

"...four of the new codes incorporate blood flow measurement, which remains one of the nationally non-covered indications for MRI in the Medicare program. Due to a national non-coverage determination for MRI that provides blood flow measurement, CPT codes 75558, 75560, 75562 and 75564 will not be recognized by the Medicare program..."

These four codes were assigned status indicator of "N" (Non-covered) in Addendum B of the Final Rule.

The ACR is very disappointed with CMS's decision not to cover these four new cardiac MRI codes. The ACR realizes that 75556 (*Cardiac magnetic resonance imaging for velocity flow mapping*) has been a non-covered service for many years; however, there has been considerable confusion regarding the reasons for CMS's decision not to cover this examination. Flow quantification and velocity assessment is a requisite to any functional cardiac MRI examination when determination of valve function is necessary. It is necessary to determine the extent of valvular insufficiency and stenosis. Moreover, flow quantification is critical in some congenital cardiac MRI examinations to determine the severity of intracardiac shunting (Qp/Qs ratio). These flow measurements are used in much the same way as Doppler measurements are used in echocardiography. The temporal resolution of this methodology is good, and the information obtained is accurate.

The information obtained via flow quantification cardiac MRI is functional, and although the morphology of valves can be inferred by this functional information, the examination is not used to create an anatomic image and, as such, is not similar to magnetic resonance angiography or MR spectroscopy. In a transmittal from 2004 where CMS defines national coverage policy for MR spectroscopy, we did find a statement regarding non-coverage of flow determinations stating "the CMS has determined that blood flow measurement, imaging of cortical bone and calcifications, and procedures involving spatial resolution of bone and calcifications, are not considered reasonable and necessary indications within the meaning of section 1862(a)(1)(A) of the Social Security Act, and are therefore non-covered" which apparently reiterates CMS policy from 1997; however, CMS does not reference 75556 directly in that transmittal, and it is not clear to providers or contractors that this statement is the sole reason for non-coverage of 75556. In fact, we can find no statements in any CMS transmittal where CMS discusses the reasons why velocity measurements for cardiac imaging are "investigational" or not "reasonable and necessary." Had these been the sole reasons for CMS's non-coverage of 75556, the ACR and other medical societies would have been more forceful in their opposition to non-coverage of 75556. However, it was assumed that non-payment for 75556 was based on bundling 75556 with the other cardiac MRI codes.

Even though 75556 was listed in CPT and valued by the RUC as a stand-alone code, in clinical practice, 75556 was seldom (if ever) performed as a stand-alone service. Since 75556 was almost always an add-on code to other cardiac MRI examinations, medical specialty societies, including the ACR, assumed a major part of CMS's decision to not cover 75556 stemmed from the fact that many of the resources required to provide this service would be included in the base code (75552, 75553 or most commonly 75554). The ACR and other medical specialty societies have for years assumed that the primary reason for non-coverage of 75556 was based on the rationale that CMS believed that valvular function determinations were included with the base cardiac MRI examination, not that velocity determinations were investigational or not reasonable and necessary.

The Medicare contractors have further added to the ambiguity in language from a number of Local Coverage Determinations (LCDs). Many Medicare contractors have lumped 75556 into MR angiography services and have denied payment for 75556 based on the fact that CMS has national coverage policy that iterates the specific indications for which MRA is covered, which

do not include determinations of cardiac valve area. Velocity flow mapping has little in common with magnetic resonance angiography except that one type of pulse sequence used for MRA in the past included a phase-contrast MR angiography sequence, in which a phase image was subtracted from one acquired without the velocity encoding gradients in order to obtain an MR angiogram. In fact, even after CMS's comments in the rule regarding the National Coverage policy from 1994, we are still uncertain why 75556 would be included in the group of magnetic resonance angiography codes or MR spectroscopy. Specifically, it is still not clear to us where CMS defines 75556 as magnetic resonance angiography. We have reviewed a number of transmittals for magnetic resonance angiography and magnetic resonance spectroscopy and find that current CMS policy seems to merely instruct the Medicare contractors not to cover 75556 but leaves the reasons for non-coverage ambiguous. The *Carriers Manual* regarding the issue defines the covered indications for MRA, but is silent with respect to specific instruction regarding payment policy for 75556. One contractor's LCD defines the reason for non-coverage as follows: "Other usages of MRA (72159, 72198, 73225) including cardiac MRI for velocity flow mapping (75556) are considered investigational and are not eligible for reimbursement." However, we have been unable to find that specific statement in a CMS transmittal. The ACR would appreciate clarification and a specific reference in CMS transmittals iterating why flow velocity measurements by MRI for determining cardiac valvular function should be classified as magnetic resonance angiography and why this service should be considered investigational or not reasonable and necessary service.

The ACR strongly believes any existing National Coverage Determination for magnetic resonance angiography is not applicable to flow and velocity measurements. The argument that these measurements remain investigational is irrational based on current literature and clinical acceptance. Studies published as early as 1995 have demonstrated the accuracy of MR determinations of valve disease^{1,2,3,4} and Qp/Qs ratios^{5,6} compared with both invasive and other non-invasive methods. Functional evaluation of the cardiac valves with MRI in most instances is equal in accuracy to echocardiography, and to require that Medicare beneficiaries undergo an additional and potentially more invasive examination (e.g., echocardiography or catheterization) following cardiac MRI to assess valvular stenosis or regurgitation based purely upon payment policy is irrational and, ultimately, not cost effective.

¹ Caruthers SD, Lin SJ, Brown P, et al. Practical Value of Cardiac Magnetic Resonance Imaging for Clinical Quantification of Aortic Valve Stenosis: Comparison with Echocardiography. *Circulation* 2003; 108:2236-43.

² Hundley WG, Li HF, Willard JE, et al. Magnetic Resonance Imaging Assessment of the Severity of Mitral Regurgitation. Comparison with Invasive Techniques. *Circulation* 1995; 92:1151-8.

³ Kizilbash AM, Hundley WG, Willet DL, Franco F Peshock RM, Grayburn PA. Comparison of Quantitative Doppler with Magnetic Resonance Imaging for Assessment of the Severity of Mitral Regurgitation. *Am J Cardiol* 1998; 81: 792-795.

⁴ Kon MW, Myerson SG, Moat NE, Pennell DJ. Quantification of Regurgitant Fraction in Mitral Regurgitation by Cardiovascular Magnetic Resonance: Comparison of Techniques. *J Heart Valve Dis* 2004; 13:600-607

⁵ Hundley WG, Li HF, Lang RA, et al. Assessment of Left-to-right Intracardiac Shunting by Velocity-encoded, Phase-difference Magnetic Resonance Imaging. A Comparison with Oximetric and Indicator Dilution Techniques. *Circulation* 1995; 91:2955-60.

⁶ Weber OM, Higgins CB. MR Evaluation of Cardiovascular Physiology in Congenital Heart Disease: Flow and Function. *J Cardiovasc Magn Reson* 2006; 8:607-17.

The ACR is particularly disappointed with CMS's decision regarding payment policy for the cardiac MRI codes that include flow velocity determinations because it was our intent to bring forward a set of bundled codes that accurately described the permutations of performing cardiac MRI without having to have a series of component codes where providers would pick and choose the services performed. At the urging of CMS, the CPT Editorial Panel and the RUC, specialty societies have been asked to create codes that describe the entire episode of care rather than a series of component codes or add-on codes in order to eliminate the possibility of duplication of work and practice expense. The ACR and ACC took this advice to heart and created such a set of codes for cardiac MRI. The codes that include velocity determinations are the workhorse examinations for cardiac MRI studies. CMS payment policy puts radiologists in the unanticipated conundrum of choosing between four suboptimal options. Physicians can do the complete examination, code the complete examination and not be reimbursed. Alternatively, the physician can do the complete examination and down-code the examination to the codes that do not include velocity determinations. However, this method violates CPT coding policy, and places providers at risk of Medicare fraud for coding the incorrect examination for the sole purpose of obtaining reimbursement. While either of these alternatives will do what is correct for the patients, both are untenable for the physicians. Unfortunately, CMS payment policy, based on a 1997 assessment that flow velocity determinations by MRI are not reasonable and necessary, now dictates that physicians must perform an incomplete cardiac MRI examination and then refer the patient for additional and/or potentially more invasive studies such as echocardiography, transthoracic echocardiography or cardiac catheterization in order to determine valve area, extent of regurgitation or gradient, or Qp/Qs ratio.

The ACR believes this recommendation is flawed because it subjects patients to unnecessary examinations and increases the cost of their cardiac evaluation. Nonetheless, the ACR will have to provide this recommendation to its members unless CMS reconsiders its payment policy. The final option is to obtain an Advanced Beneficiary Notice from patients undergoing the cardiac MRI examinations that include flow velocity determinations. Certainly, an allowable scenario for physicians under the proposed payment policy. Unfortunately, patients would then have to pay for an entire examination when flow is ordered even though CMS covers all of the other components of the examination when flow is not included. Providers will have to explain to beneficiaries that while CMS will cover a lesser examination, that includes 90 percent of the cost (based on work RVUs), when flow velocity determinations are not necessary, CMS requires that patients must pay the cost of the entire examination (not just the additional flow velocity component) when determination of valve function is needed. We believe that beneficiaries will have difficulty understanding the nuances of CMS's reimbursement policy and ask the providers to perform only the covered examinations, which will require them to undergo additional and sometimes more invasive testing. We believe that CMS may not have anticipated these outcomes when establishing payment policy for cardiac MRI and are hopeful CMS will reconsider its position.

Because current payment policy is based on a 1997 analysis of flow measurements that may not have even included an assessment of the accuracy of such measurements for cardiac valvular function, the ACR believes CMS can change its decision regarding coverage of 75558, 75560, 75562 and 75564 without opening a new National Coverage Assessment (NCA) and value these

services at the RUC recommended values. Alternatively, if CMS believes that a new NCA is required before coverage policy can be changed, the ACR recommends that these four codes be valued at the RUC recommended values for 75557, 75559, 75561 and 75563 while the NCA is pending. This latter recommendation, would in effect, continue current payment policy whereby physicians are frequently providing velocity determinations and valvular assessment for their patients but are not being reimbursed. Any other decision by CMS will be detrimental to beneficiaries and ultimately more costly for the Medicare program. The ACR looks forward to working with CMS on this important issue.

Independent Diagnostic Testing Facility (IDTF) Issues

New IDTF Standards: § 410.33(g) (15)

The ACR supports CMS's decision to implement its proposal prohibiting the sharing of space or equipment by an IDTF with any other Medicare-enrolled provider or entity. We also agree with and appreciate the exclusion of radiologist ownership or investment interest from this prohibition. We firmly believe that patient care will benefit because of physicians' inability to enter into "lease" or similar purchased test arrangements with imaging centers primarily to allow physicians to profit from their own referrals.

Physician Quality Reporting Initiative (PQRI)

Selection of Measures for 2008

The Final Rule states that measures not identified in the MPFS proposed rule but recommended for inclusion via the comment period cannot be included in the 2008 list because there was not opportunity for public comment within the rulemaking process. The ACR is extremely disappointed that the eight new AQA approved radiology measures will not be included in the 2008 PQRI.

An enormous amount of effort was expended in developing and obtaining approval of these measures that, if implemented, would likely improve quality of care and also afford many more physicians the opportunity to participate in the PQRI program. We understand the constraints imposed on CMS by the statute and we appreciate the acknowledgement of these additional measures in the Final Rule. We also appreciate the stated commitment to keep these measures available for consideration in identifying measure sets for future years' PQRI. We ask that the eight new AQA approved radiology measures be a priority for adoption at the earliest possible time.

Registry Based Reporting for 2008 PQRI

The Final Rule states that medical registry reporting of PQRI measures will be tested in 2008 using two options (identified in Proposed Rule as Options 2 and 3). The ACR supports Option 3, in which a registry will calculate and submit reporting and performance rates for various measures to CMS.

Physician Self-Referral Provisions

In-Office Ancillary Services Exception

The ACR strongly believes that changes to the Stark in-office ancillary services exception are necessary. We are pleased that CMS has indicated its intent to address revisions to this exception through a future notice of proposed rulemaking. The ACR strongly encourages CMS to propose those revisions in CY 2008 and is willing to assist CMS by providing new data to support the need for such timely revision.

We reiterate the recommendations made in our comments on the proposed rule because we regard changes to the in-office ancillary services exception as fundamental to protecting against program or patient abuse.

The ACR recommends that certain medical services should not qualify for the in-office ancillary services exemption. Services that should not qualify, and should never be defined as “ancillary,” are CT, CTA, MRI, MRA, PET, PET/CT and radiation therapy.

The ACR also recommends that CMS place restrictions on any service provided under the in-office ancillary services exemption to require that the exempted ancillary service must be provided within one hour of the time of the office visit.

In response to the questions of whether and how to change the definitions of “same building” and “centralized building” the ACR believes that, if convenience and timeliness of diagnosis are the rationale for the in-office ancillary services exception, CMS should require that a “centralized building” be within five miles of the building where the physician or medical group furnishes medical services. We would support this definition only if CMS adopted the ACR recommendations for time restriction and deletion of certain medical services from those qualifying for the in-office medical exemption.

The ACR recommends that non-specialist physicians should not be able to use the in-office ancillary services exemption to refer patients for specialized services involving the use of equipment owned, leased, or controlled through a joint venture by the referring physician unless the equipment provides the simple and truly “ancillary” services that Congress originally intended in this exception.

Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests [Anti-Markup Provisions]

The ACR strongly supports the CMS decision to extend the anti-markup rule to both the technical component and the professional component of diagnostic tests. The ACR is pleased that CMS has refined the definition of the “office of the billing physician” to more accurately identify those situations in which use of a “centralized building” could potentially result in abusive practices. The ACR believes that the anti-markup rule properly restricts financial influence on patient care decisions and will help to curb inappropriate utilization and strengthen

Medicare program integrity.

Other Self-Referral Provisions

The ACR is pleased to learn that CMS has sufficient information, both from the commenters and its independent research, to finalize revisions to the physician self-referral regulations without the need for new proposals and additional public comment. We urge CMS to publish its Final Rule implementing these proposals early in CY 2008.

Conclusion

Thank you for the opportunity to comment on this Final Rule. The ACR encourages CMS to continue to work with physicians and their professional societies. The ACR looks forward to a continuing dialogue with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter or any other issues on radiology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at achoe@acr.org.

Respectfully Submitted,

Harvey L. Neiman, MD

Harvey L. Neiman, MD, FACR
Executive Director

cc: Ken Simon, MD, CMS
Pamela West, CMS
Rick Ensor, CMS
Ken Marsalek, CMS
John A. Patti, MD, FACR, Chair, ACR Commission on Economics
Bibb Allen, Jr., MD, FACR, Vice-Chair, ACR Commission on Economics
Pamela J. Kassing, ACR
Maurine Spillman-Dennis, ACR
Angela J. Choe, ACR

Submitter : diane millman
Organization : American Society of Echocardiography
Category : Physician

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-FC-205-Attach-1.DOC

CMS-1385-FC-205-Attach-2.DOC

This comment is submitted on behalf of the American Society of Echocardiography (ASE), which represents over 12,000 physicians and sonographers dedicated to excellence in cardiovascular ultrasound. The ASE objects to the expansion of the rule prohibiting the mark up of diagnostic tests provided by outside suppliers (the "Purchased Test Rule" or "the Rule") to diagnostic tests provided directly by a group practice at a location other than one where the group provides the "full range" of its patient care services.

It is unclear to us (and to many others) what qualifies as a location "other than one where the group provides the full range of its patient care services" ("off-site tests"). Nor is it clear what it really means for a group practice to "mark up" its own services.

However, it appears that the Rule requires that a group generate an internal "charge"—a charge from itself and to itself-- for off-site tests, and that the cost of overhead and equipment must be excluded from this internal charge. The group is paid the lower of the internal charge or the PFS amount.

Thus, if a cardiologist is a group practice member, and s/he interprets an echo at an area hospital, the group must generate a charge from itself to itself that reflects the pro-rata share of the cardiologist's salary that is attributable to that particular interpretation. The group is paid no more than the lesser of the PFS amount or the internal charge for the interpretation. Thus the expansion of the Rule is apparently intended to ensure that practices get paid so little for their diagnostic tests--and to make their provision so cumbersome-- that the group simply ceases providing the services involved.

We do not see what public purpose is served by extending the Purchased Test Rule to diagnostic services provided by groups to their own patients: It is entirely unclear to us what abuse is involved in a group's decision to provide a diagnostic test in a location other than its primary office. To the extent that the expansion discourages the provision of diagnostic services in locations other than a group's primary office, it inhibits expeditious access to important diagnostic services in remote areas and in hospital outpatient facilities. To the extent that it requires groups to relocate their diagnostic testing facilities, it results in wasteful expenditure of increasingly scarce resources. And to the extent that it dissuades group practices from continuing to provide diagnostic services to their patients, it assures the performance of these services in higher cost hospital settings.

We can only conclude that CMS chose to expand the Purchased Test Rule because it believes that "self-referral" is a primary cause of the increased utilization of diagnostic services in the Medicare patient population. If this is CMS's assumption, however, we respectfully suggest that it be re-examined: In fact, the diagnostic services that have been growing most rapidly—MRI, CT, and PET—are performed (and billed) virtually exclusively by radiologists and not by referring physicians' practices. The data shows that, in the case of echocardiography, almost 70% of tests are referred by non-cardiologists who have no financial interest in the performance or interpretation of the tests.

Finally, both the extension of the Purchased Test Rule to professional component services and its extension to services provided by bona fide group practices are illegal. The governing statute (at 42 U.S.C. Section 1842(n)) does not authorize application of the Rule to services "performed" by a physician—and all professional component services are performed by a physician. Nor does the governing statute authorize application of the rule to services supervised by the billing physician or by a physician with whom the billing physician "shares a practice." A physician who is a member of a group practice that meets the Stark Law definitions does not suddenly cease

“sharing a practice” with other group practice members when he or she leaves the office (if any) where the practice provides the “full range” of patient care services to its patients. Thus the Purchase Test Rule is inconsistent with the statute in both respects.

In addition, since the Purchased Test Rule’s expansion to group practices was not included in the proposed 2008 PFS rule, it is procedurally invalid under the provisions of the Administrative Procedures Act, which requires that the public have the opportunity to comment on changes of this magnitude.

For these reasons, we urge CMS to rescind the Purchased Test Rule expansion, or at least delay its implementation pending resolution of these issues.

Submitter : Mr. Wesley Rippy
Organization : City of Hurst Fire Department
Category : Local Government

Date: 12/28/2007

Issue Areas/Comments

**Refinement of RVUs for CY 2008
and Response to Public Comments
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

The "Final Signature Rule" is a burden and hardship on law abiding provider. It would detract from the continuum of patient care, which we feel is our primary and most important call to duty. We ask that you consider exercising the current rule on those who fail to comply.

Submitter : Dr. Harvey Neiman
Organization : American College of Radiology
Category : Health Care Professional or Association

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-FC-207-Attach-1.PDF



December 28, 2007

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

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: CMS-1385-FC Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008

Dear Mr. Weems:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, is pleased to submit comments on the Final Rule "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008" published in the *Federal Register* on November 27, 2007. We will address budget neutrality; resource-based practice expense relative value units (RVUs); cardiac MRI codes; independent diagnostic testing facility requirements; physician quality reporting initiative; and changes to reassignment and physician self-referral rules relating to diagnostic tests [Anti-Markup Provisions].

Budget Neutrality

The ACR disagrees with, and remains concerned with the impact of the Centers for Medicare & Medicaid Services (CMS) decision to apply the budget neutrality adjustment required for the 5-Year Review to the physician work RVUs. The vast majority of professional societies whose members treat Medicare beneficiaries recommended that the budget neutrality adjustment be made to the conversion factor and not to the physician work values. Budget neutrality adjustments required by changes in work RVUs typically have been applied to the conversion factor, consistent with the long-standing recommendations of the Relative Value Update Committee (RUC).

The ACR believes that historical consistency with previous adjustments to the conversion factor is a necessary and appropriate policy decision that would result in the most equitable application of budget neutrality adjustments.

Furthermore, CMS should be cognizant that maintaining the stability of the work RVUs is essential, since Medicare's RVUs are used by many other payers. They are often the basis of

physician compensation and productivity analyses. Merely publishing unadjusted work values in Addendum B does not change the fact that CMS finalized to scale the work values as a result of the 5-Year Review. While we understand it is not the intention of the Agency, by scaling the RVUs it gives the appearance, to outside observers, that the physician work of the services unaffected by the 5-Year Review has decreased as a result of the 5-Year Review.

The ACR strongly recommends that CMS reconsider its current policy and apply the budget neutrality adjustment to the conversion factor. In addition, the ACR reiterates its recommendation that CMS use the unadjusted work RVUs in the calculation of indirect practice expense.

Resource Based Practice Expense Relative Value Units

Interest Rate and Equipment Usage Percentage

The ACR agrees with and appreciates CMS's decision to make no change in the equipment utilization and interest rate in the practice expense methodology until there are further data to justify the changes. We are pleased to offer our resources to assist CMS in obtaining accurate data relative to those factors.

Practice Expense Per Physician Hour

The ACR agrees with and appreciates CMS's decision to increase the radiology practice expense per physician hour based on the correct weighting of the ACR supplemental survey data collected on practice expense.

Cardiac MRI Codes

As a result of the technological changes in MRI scanning, the CPT® Editorial Panel created eight new cardiac MRI codes and deleted five existing cardiac MRI codes. The new codes are: CPT code 75557, 75558, 75559, 75560, 75561, 75562, 75563 and 75564. The deleted codes are 75552, 75553, 75554, 75555 and 75556. The ACR, with the American College of Cardiology (ACC) surveyed the eight new codes and CMS accepted the RUC recommendation. However, for the four new cardiac MRI codes that contain "with flow/velocity quantification," CMS stated the following in the Final Rule.

"...four of the new codes incorporate blood flow measurement, which remains one of the nationally non-covered indications for MRI in the Medicare program. Due to a national non-coverage determination for MRI that provides blood flow measurement, CPT codes 75558, 75560, 75562 and 75564 will not be recognized by the Medicare program..."

These four codes were assigned status indicator of "N" (Non-covered) in Addendum B of the Final Rule.

The ACR is very disappointed with CMS's decision not to cover these four new cardiac MRI codes. The ACR realizes that 75556 (*Cardiac magnetic resonance imaging for velocity flow mapping*) has been a non-covered service for many years; however, there has been considerable confusion regarding the reasons for CMS's decision not to cover this examination. Flow quantification and velocity assessment is a requisite to any functional cardiac MRI examination when determination of valve function is necessary. It is necessary to determine the extent of valvular insufficiency and stenosis. Moreover, flow quantification is critical in some congenital cardiac MRI examinations to determine the severity of intracardiac shunting (Qp/Qs ratio). These flow measurements are used in much the same way as Doppler measurements are used in echocardiography. The temporal resolution of this methodology is good, and the information obtained is accurate.

The information obtained via flow quantification cardiac MRI is functional, and although the morphology of valves can be inferred by this functional information, the examination is not used to create an anatomic image and, as such, is not similar to magnetic resonance angiography or MR spectroscopy. In a transmittal from 2004 where CMS defines national coverage policy for MR spectroscopy, we did find a statement regarding non-coverage of flow determinations stating "the CMS has determined that blood flow measurement, imaging of cortical bone and calcifications, and procedures involving spatial resolution of bone and calcifications, are not considered reasonable and necessary indications within the meaning of section 1862(a)(1)(A) of the Social Security Act, and are therefore non-covered" which apparently reiterates CMS policy from 1997; however, CMS does not reference 75556 directly in that transmittal, and it is not clear to providers or contractors that this statement is the sole reason for non-coverage of 75556. In fact, we can find no statements in any CMS transmittal where CMS discusses the reasons why velocity measurements for cardiac imaging are "investigational" or not "reasonable and necessary." Had these been the sole reasons for CMS's non-coverage of 75556, the ACR and other medical societies would have been more forceful in their opposition to non-coverage of 75556. However, it was assumed that non-payment for 75556 was based on bundling 75556 with the other cardiac MRI codes.

Even though 75556 was listed in CPT and valued by the RUC as a stand-alone code, in clinical practice, 75556 was seldom (if ever) performed as a stand-alone service. Since 75556 was almost always an add-on code to other cardiac MRI examinations, medical specialty societies, including the ACR, assumed a major part of CMS's decision to not cover 75556 stemmed from the fact that many of the resources required to provide this service would be included in the base code (75552, 75553 or most commonly 75554). The ACR and other medical specialty societies have for years assumed that the primary reason for non-coverage of 75556 was based on the rationale that CMS believed that valvular function determinations were included with the base cardiac MRI examination, not that velocity determinations were investigational or not reasonable and necessary.

The Medicare contractors have further added to the ambiguity in language from a number of Local Coverage Determinations (LCDs). Many Medicare contractors have lumped 75556 into MR angiography services and have denied payment for 75556 based on the fact that CMS has national coverage policy that iterates the specific indications for which MRA is covered, which

do not include determinations of cardiac valve area. Velocity flow mapping has little in common with magnetic resonance angiography except that one type of pulse sequence used for MRA in the past included a phase-contrast MR angiography sequence, in which a phase image was subtracted from one acquired without the velocity encoding gradients in order to obtain an MR angiogram. In fact, even after CMS's comments in the rule regarding the National Coverage policy from 1994, we are still uncertain why 75556 would be included in the group of magnetic resonance angiography codes or MR spectroscopy. Specifically, it is still not clear to us where CMS defines 75556 as magnetic resonance angiography. We have reviewed a number of transmittals for magnetic resonance angiography and magnetic resonance spectroscopy and find that current CMS policy seems to merely instruct the Medicare contractors not to cover 75556 but leaves the reasons for non-coverage ambiguous. The *Carriers Manual* regarding the issue defines the covered indications for MRA, but is silent with respect to specific instruction regarding payment policy for 75556. One contractor's LCD defines the reason for non-coverage as follows: "Other usages of MRA (72159, 72198, 73225) including cardiac MRI for velocity flow mapping (75556) are considered investigational and are not eligible for reimbursement." However, we have been unable to find that specific statement in a CMS transmittal. The ACR would appreciate clarification and a specific reference in CMS transmittals iterating why flow velocity measurements by MRI for determining cardiac valvular function should be classified as magnetic resonance angiography and why this service should be considered investigational or not reasonable and necessary service.

The ACR strongly believes any existing National Coverage Determination for magnetic resonance angiography is not applicable to flow and velocity measurements. The argument that these measurements remain investigational is irrational based on current literature and clinical acceptance. Studies published as early as 1995 have demonstrated the accuracy of MR determinations of valve disease^{1,2,3,4} and Qp/Qs ratios^{5,6} compared with both invasive and other non-invasive methods. Functional evaluation of the cardiac valves with MRI in most instances is equal in accuracy to echocardiography, and to require that Medicare beneficiaries undergo an additional and potentially more invasive examination (e.g., echocardiography or catheterization) following cardiac MRI to assess valvular stenosis or regurgitation based purely upon payment policy is irrational and, ultimately, not cost effective.

¹ Caruthers SD, Lin SJ, Brown P, et al. Practical Value of Cardiac Magnetic Resonance Imaging for Clinical Quantification of Aortic Valve Stenosis: Comparison with Echocardiography. *Circulation* 2003; 108:2236-43.

² Hundley WG, Li HF, Willard JE, et al. Magnetic Resonance Imaging Assessment of the Severity of Mitral Regurgitation. Comparison with Invasive Techniques. *Circulation* 1995; 92:1151-8.

³ Kizilbash AM, Hundley WG, Willet DL, Franco F Peshock RM, Grayburn PA. Comparison of Quantitative Doppler with Magnetic Resonance Imaging for Assessment of the Severity of Mitral Regurgitation. *Am J Cardiol* 1998; 81: 792-795.

⁴ Kon MW, Myerson SG, Moat NE, Pennell DJ. Quantification of Regurgitant Fraction in Mitral Regurgitation by Cardiovascular Magnetic Resonance: Comparison of Techniques. *J Heart Valve Dis* 2004; 13:600-607

⁵ Hundley WG, Li HF, Lang RA, et al. Assessment of Left-to-right Intracardiac Shunting by Velocity-encoded, Phase-difference Magnetic Resonance Imaging. A Comparison with Oximetric and Indicator Dilution Techniques. *Circulation* 1995; 91:2955-60.

⁶ Weber OM, Higgins CB. MR Evaluation of Cardiovascular Physiology in Congenital Heart Disease: Flow and Function. *J Cardiovasc Magn Reson* 2006; 8:607-17.

The ACR is particularly disappointed with CMS's decision regarding payment policy for the cardiac MRI codes that include flow velocity determinations because it was our intent to bring forward a set of bundled codes that accurately described the permutations of performing cardiac MRI without having to have a series of component codes where providers would pick and choose the services performed. At the urging of CMS, the CPT Editorial Panel and the RUC, specialty societies have been asked to create codes that describe the entire episode of care rather than a series of component codes or add-on codes in order to eliminate the possibility of duplication of work and practice expense. The ACR and ACC took this advice to heart and created such a set of codes for cardiac MRI. The codes that include velocity determinations are the workhorse examinations for cardiac MRI studies. CMS payment policy puts radiologists in the unanticipated conundrum of choosing between four suboptimal options. Physicians can do the complete examination, code the complete examination and not be reimbursed. Alternatively, the physician can do the complete examination and down-code the examination to the codes that do not include velocity determinations. However, this method violates CPT coding policy, and places providers at risk of Medicare fraud for coding the incorrect examination for the sole purpose of obtaining reimbursement. While either of these alternatives will do what is correct for the patients, both are untenable for the physicians. Unfortunately, CMS payment policy, based on a 1997 assessment that flow velocity determinations by MRI are not reasonable and necessary, now dictates that physicians must perform an incomplete cardiac MRI examination and then refer the patient for additional and/or potentially more invasive studies such as echocardiography, transthoracic echocardiography or cardiac catheterization in order to determine valve area, extent of regurgitation or gradient, or Qp/Qs ratio.

The ACR believes this recommendation is flawed because it subjects patients to unnecessary examinations and increases the cost of their cardiac evaluation. Nonetheless, the ACR will have to provide this recommendation to its members unless CMS reconsiders its payment policy. The final option is to obtain an Advanced Beneficiary Notice from patients undergoing the cardiac MRI examinations that include flow velocity determinations. Certainly, an allowable scenario for physicians under the proposed payment policy. Unfortunately, patients would then have to pay for an entire examination when flow is ordered even though CMS covers all of the other components of the examination when flow is not included. Providers will have to explain to beneficiaries that while CMS will cover a lesser examination, that includes 90 percent of the cost (based on work RVUs), when flow velocity determinations are not necessary, CMS requires that patients must pay the cost of the entire examination (not just the additional flow velocity component) when determination of valve function is needed. We believe that beneficiaries will have difficulty understanding the nuances of CMS's reimbursement policy and ask the providers to perform only the covered examinations, which will require them to undergo additional and sometimes more invasive testing. We believe that CMS may not have anticipated these outcomes when establishing payment policy for cardiac MRI and are hopeful CMS will reconsider its position.

Because current payment policy is based on a 1997 analysis of flow measurements that may not have even included an assessment of the accuracy of such measurements for cardiac valvular function, the ACR believes CMS can change its decision regarding coverage of 75558, 75560, 75562 and 75564 without opening a new National Coverage Assessment (NCA) and value these

services at the RUC recommended values. Alternatively, if CMS believes that a new NCA is required before coverage policy can be changed, the ACR recommends that these four codes be valued at the RUC recommended values for 75557, 75559, 75561 and 75563 while the NCA is pending. This latter recommendation, would in effect, continue current payment policy whereby physicians are frequently providing velocity determinations and valvular assessment for their patients but are not being reimbursed. Any other decision by CMS will be detrimental to beneficiaries and ultimately more costly for the Medicare program. The ACR looks forward to working with CMS on this important issue.

Independent Diagnostic Testing Facility (IDTF) Issues

New IDTF Standards: § 410.33(g) (15)

The ACR supports CMS's decision to implement its proposal prohibiting the sharing of space or equipment by an IDTF with any other Medicare-enrolled provider or entity. We also agree with and appreciate the exclusion of radiologist ownership or investment interest from this prohibition. We firmly believe that patient care will benefit because of physicians' inability to enter into "lease" or similar purchased test arrangements with imaging centers primarily to allow physicians to profit from their own referrals.

Physician Quality Reporting Initiative (PQRI)

Selection of Measures for 2008

The Final Rule states that measures not identified in the MPFS proposed rule but recommended for inclusion via the comment period cannot be included in the 2008 list because there was not opportunity for public comment within the rulemaking process. The ACR is extremely disappointed that the eight new AQA approved radiology measures will not be included in the 2008 PQRI.

An enormous amount of effort was expended in developing and obtaining approval of these measures that, if implemented, would likely improve quality of care and also afford many more physicians the opportunity to participate in the PQRI program. We understand the constraints imposed on CMS by the statute and we appreciate the acknowledgement of these additional measures in the Final Rule. We also appreciate the stated commitment to keep these measures available for consideration in identifying measure sets for future years' PQRI. We ask that the eight new AQA approved radiology measures be a priority for adoption at the earliest possible time.

Registry Based Reporting for 2008 PQRI

The Final Rule states that medical registry reporting of PQRI measures will be tested in 2008 using two options (identified in Proposed Rule as Options 2 and 3). The ACR supports Option 3, in which a registry will calculate and submit reporting and performance rates for various measures to CMS.

Physician Self-Referral Provisions

In-Office Ancillary Services Exception

The ACR strongly believes that changes to the Stark in-office ancillary services exception are necessary. We are pleased that CMS has indicated its intent to address revisions to this exception through a future notice of proposed rulemaking. The ACR strongly encourages CMS to propose those revisions in CY 2008 and is willing to assist CMS by providing new data to support the need for such timely revision.

We reiterate the recommendations made in our comments on the proposed rule because we regard changes to the in-office ancillary services exception as fundamental to protecting against program or patient abuse.

The ACR recommends that certain medical services should not qualify for the in-office ancillary services exemption. Services that should not qualify, and should never be defined as “ancillary,” are CT, CTA, MRI, MRA, PET, PET/CT and radiation therapy.

The ACR also recommends that CMS place restrictions on any service provided under the in-office ancillary services exemption to require that the exempted ancillary service must be provided within one hour of the time of the office visit.

In response to the questions of whether and how to change the definitions of “same building” and “centralized building” the ACR believes that, if convenience and timeliness of diagnosis are the rationale for the in-office ancillary services exception, CMS should require that a “centralized building” be within five miles of the building where the physician or medical group furnishes medical services. We would support this definition only if CMS adopted the ACR recommendations for time restriction and deletion of certain medical services from those qualifying for the in-office medical exemption.

The ACR recommends that non-specialist physicians should not be able to use the in-office ancillary services exemption to refer patients for specialized services involving the use of equipment owned, leased, or controlled through a joint venture by the referring physician unless the equipment provides the simple and truly “ancillary” services that Congress originally intended in this exception.

Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests [Anti-Markup Provisions]

The ACR strongly supports the CMS decision to extend the anti-markup rule to both the technical component and the professional component of diagnostic tests. The ACR is pleased that CMS has refined the definition of the “office of the billing physician” to more accurately identify those situations in which use of a “centralized building” could potentially result in abusive practices. The ACR believes that the anti-markup rule properly restricts financial influence on patient care decisions and will help to curb inappropriate utilization and strengthen

Medicare program integrity.

Other Self-Referral Provisions

The ACR is pleased to learn that CMS has sufficient information, both from the commenters and its independent research, to finalize revisions to the physician self-referral regulations without the need for new proposals and additional public comment. We urge CMS to publish its Final Rule implementing these proposals early in CY 2008.

Conclusion

Thank you for the opportunity to comment on this Final Rule. The ACR encourages CMS to continue to work with physicians and their professional societies. The ACR looks forward to a continuing dialogue with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter or any other issues on radiology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at achoe@acr.org.

Respectfully Submitted,



Harvey L. Neiman, MD, FACR
Executive Director

cc: Ken Simon, MD, CMS
Pamela West, CMS
Rick Ensor, CMS
Ken Marsalek, CMS
John A. Patti, MD, FACR, Chair, ACR Commission on Economics
Bibb Allen, Jr., MD, FACR, Vice-Chair, ACR Commission on Economics
Pamela J. Kassing, ACR
Maurine Spillman-Dennis, ACR
Angela J. Choe, ACR

Submitter : Mr. Jonathan Linkous
Organization : American Telemedicine Association
Category : Health Care Professional or Association

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-FC-208-Attach-1.DOC

American Telemedicine Association
2007 Request to CMS for CPT Code Additions for Telehealth
CMS-1385-FC

Contact Information:

Name: Jonathan D. Linkous, Executive Director
Address: American Telemedicine Association
1100 Connecticut Avenue, NW, Suite 540
Washington, DC 20036
Phone: 202.223.3333
Fax: 202.223.2787
Email: jlinkous@americantelemed.org

The American Telemedicine Association (ATA) requests that two CPT codes be added to the approved list of CPT codes used for telehealth services for 2009. This request is being submitted prior to December 31, 2007, for consideration in the 2008 physician fee schedule process.

This request for additions to the list of approved Medicare telehealth services is submitted in accordance with the CMS published regulation "CMS-1385-FC - Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions" as appearing on the CMS website <http://www.cms.hhs.gov/eRulemaking/>.

Since 2001, CMS has increased the number of telehealth services that can be reimbursed under Medicare. These decisions were largely, though not entirely, as a result of petitions submitted to CMS each year using the process set forth by the agency.

Diabetes Outpatient Self-Management Training Services (DSM)
(Individual Session – G0108 and Group Session – G0109)

ATA, on behalf of its membership and the patients that are served, requests that CMS add Diabetes Self-Management Training G0108 and G0109 to the list of telehealth approved CPT codes, based on the following:

- 1) Evidence exists that diabetes self-management training improves clinical outcomes for persons with diabetes in:
 - a. Reducing HbA1c levels;
 - b. Improving blood pressure;
 - c. Reducing incidence of microvascular complications of diabetes;
 - d. Improves motivation to comply with treatment regimens;
 - e. Provides group peer support as an incentive to change behaviors;

- 2) Evidence exists that group education sessions provide valuable clinical and educational support to the diabetic person;
- 3) Evidence exists that certified diabetes programs have been approved by CMS as the evidence-based practice necessary to support the diabetic person and to achieve the best possible clinical outcomes;
- 4) Evidence exists that diabetes self-management provided via telehealth is equal to or slightly better than providing services in person based on the clinical outcomes of HbA1c levels;
- 5) Evidence exists that diabetes self-management provided via telehealth is vastly superior to no self-management training on HbA1c levels, blood pressure, compliance with treatment plans and overall quality of life for persons with diabetes.

Basis for CMS Determination of Adding These Codes

In reviewing requests for new CPT codes to be added to the list of telehealth services, CMS uses two categorical assumptions in its consideration: is the service similar to office and other outpatient visits, consultations, and office psychiatry services; or is it not? When CMS deems that the request is similar to currently existing telehealth CPT codes, the request is approved. When CMS determines that the request is not similar to currently approved codes, the request is required to be supported by scientific, peer-reviewed clinical trial data that supports the elements that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to in person (CMS uses the term face-to-face) care. The intent is to determine whether the use of a telecommunications system to deliver the service produces similar diagnostic findings or therapeutic interventions as compared with the face-to-face “hands on” delivery of the same service (Fed Reg/Vol 70(151), Aug 8, 2005, p. 45786).

Process of Care for Remote Diabetes Training

In the case of Diabetes Outpatient Self-Management Training (G0108, G0109), a diagnosis is not made as a part of the diabetes self-management training process. The diagnosis is made as a result of an extensive primary care evaluation which is done in person, with laboratory and other diagnostic supportive evidence indicating any one of a group of metabolic disorders characterized by high blood sugar levels caused by a defect in insulin secretion, action, or both (www.medicinenet.com, accessed 21-11-2007). The patient is managed in person or through a combination of in person and telemedically-based care. The care is typically managed by the primary care provider, but in some cases the care is managed in conjunction with an endocrinologist.

Once the patient is referred to diabetes management staff, the patient has already been diagnosed and an intervention plan is identified and documented. This includes decisions as to whether the patient will be on an anti-glycemic or insulin, how often HbA1c levels should be drawn. In the intervention plan, nutritional issues are identified and documented and the patient’s treatment plan is outlined and documented. The diagnosis is not changed during diabetes self-management education, as the purpose of diabetes

self-management training is not to make a diagnosis or to provide therapeutic interventions. The purpose of the service is to provide education.

Therefore, the criteria for analysis of Category 2 services cannot be applied to the decision taxonomy used by CMS for this request to add G0108 and G0109 to the approved list of telehealth CPT codes. Rather, we request that CMS use the same process applied in 2004 when Medical Nutrition Therapy and Dialysis codes were added to the telehealth list. At that time, CMS looked at the merits in the form of clinical outcomes of providing service and evidence-based practice (the most current strategy for determining appropriate care) in determining if the codes should be added. Additionally, CMS added medical nutritional therapists and other nutrition professionals to the list of approved practitioners without legislative mandates. We request that CMS use the same process for evaluating the CPT code submission in 2007 for Diabetes Management codes G0108 and G0109.

ATA believes that the actual analysis of whether or not Diabetes Self-Management codes G0108 and G0109 should be added to the current list of telehealth CPT codes must be based on the analysis of the evidence that providing diabetes self-management training by registered nurses has a direct effect on reducing HbA1c levels and improves outcomes for patients (i.e. limits the development of micro vascular complications of diabetes), and not on the comparison of providing services in person versus via telehealth.

Importance of Diabetes Self-Management

Diabetes self-management is an interactive, collaborative, ongoing process involving the person with diabetes and the educator(s). The process includes:

1. assessment of the individual's specific education needs;
2. identification of the individual's specific diabetes self-management goals;
3. education and behavioral intervention directed toward helping the individual achieve identified self-management goals; and
4. evaluation of the individual's attainment of identified self-management goals (Mensing et. al. *Diabetes Care*, 23(5), May 2006, p. 685).

No part of diabetes self-management involves making a diagnosis or providing therapeutic intervention. The process goals are only assessment and education.

Diabetes self-management education is the cornerstone of care for all individuals with diabetes who want to achieve successful health related outcomes (Mensing et. al. p. 682). The American Diabetes Association has set national standards for diabetes self-management and programs using those standards must go through a rigorous process of certification in order to maintain a certified diabetes program. The standards are reviewed on an ongoing basis to reflect advances in scientific knowledge and health care.

CMS itself recognizes the importance of diabetes self-management. The Medicare website indicates, "Medicare approves certain diabetes self-management training services

to help beneficiaries successfully manage their disease. A beneficiary can receive diabetes self-management training services if he or she is at risk for complications from diabetes, has been recently diagnosed with diabetes, or has diabetes and is now eligible for Medicare” (www.com.hhs.com/DiabetesSelfManagement accessed 12-11-2007). In addition, Medicare states that “Medicare covers services to help people with diabetes manage their condition so they can prevent or reduce the severity of diabetes-related complications” (www.com.hhs.com/DiabetesSelfManagement accessed 12-11-2007). Section 4105 of the Balanced Budget Act of 1997 permits Medicare coverage of diabetes outpatient self-management training services when these services are furnished by a certified provider who meets certain quality standards.

The goal of medical care for people with diabetes is to optimize glycemic control and minimize complications. The Diabetes Control and Complications Trial demonstrated that treatment that maintains blood glucose levels near normal in type 1 diabetes delays the onset and reduces the progression of micro vascular complications (American Diabetes Association Position Statement, 2007. *Diabetes Care*, 30:S86-S87). To achieve optimal glucose control, the person with diabetes must be able to access health care providers who have expertise in the field of diabetes. Treatment plans must also include self-management training (p. S86).

The goal in management of diabetes is the achievement of near-normoglycemia, which can delay the onset or progression of diabetes-related complications, improve quality of life and reduce the economic burden associated with diabetes (Shojania et al. *JAMA*, 2006. July; 296(4):427-40). Despite the fact that clinical guidelines are widely disseminated, glycemic control continues to be sub-optimal (Change et al. 23007. *Dis Management Health Outcomes*, 15(6): 377-382). Factors that have contributed to the poor outcomes include insufficient physician time and adherence to recommended diabetes practice guidelines, the lack of adequate information systems, and the burden of daily management of diabetes that is placed on patients (p. 378). Diabetes care management programs have been the answer to the problem and have been implemented and supported by private and government payers as the method to improve quality of care to diabetes patients. Registered nurses are integral to the success of diabetes management programs (Knight et al. *Am J Managed Care* 2005 Apr;11(4):242-50).

Diabetes requires complicated treatment and self-discipline on the part of the patient. Education is essential to its management (Siminerio, *Diabetes Spectrum* 19:76-78, 2006). Diabetes complications are some of the most serious of all chronic conditions and many are the result of behaviors of the patient. The education process and certification for diabetes education was started in the early 1970s by Dr Donnell Etzweiler. Traditionally, clinical outcomes had been measured in terms of changes in HbA1c levels and knowledge base. Behavior change is also now an appropriate outcome for measuring the effectiveness of diabetes education. Over 90 percent of patients with diabetes receive their care from primary care providers (Janes, GR, *Diabetes in America*, 2nd Ed., 1995, p. 541-552, NIH publ. 95-1468). Therefore, effective implementation of diabetes education programs in primary care settings requires innovative ways of spreading the resources of certified diabetes educators in the vast primary care setting. Telehealth is an appropriate

tool to do so. CMS has already approved medical nutrition therapists for telehealth, which is an education based service which does not make a diagnosis or provide therapeutic interventions, and thus sets a comparative value (similar service in the existing list of approved telehealth codes) for Diabetes Self-Management. Medical Nutrition Therapy and Diabetes Self-Management provide exactly the same service; both are designed to provide education in the primary care setting and to facilitate behavior modification on the part of the patient.

In a study conducted by Bloomgarden et. al., (1987) 749 insulin treated patients of the Mount Sinai Medical Center Diabetes Clinic were enrolled in a controlled trial of diabetic patient education (Bloomgarden et. al. *Diabetes Care*, Vol 10, Issue 3, 263-272). Patients were assigned to an education group (165) or to a control group (180)(no education). Cognitive scores increased from 5.3 (+/- 1.6) to 5.8 (+/- 1.6) in the education group but there was no change in the control group. HbA1c levels fell from 6.8 (+/- 2.0) to 6.3 (+/- 2.0) and from 6.6 (+/- 2.0) to 6.3 (+/- 2.0) in the control group, and insignificant difference (P=.1995). The fasting blood glucose decreased from 223 (+/- 94) to 179 (+/- 73)mg/dl in the education group and 199 (+/- 81) to 185 (+/- 76) mg/dl in the control group.

Results of Related Studies

A systematic review and methodological critique of the literature done by Warsi et. al. (2004) provided insight into self-management programs and the efficacy of patient self-management education for chronic disease (Warsi A et. al, *Arch of Int Med*, Vol 164, Aug 9.23, p. 1641-1649). Seventy-one trials of self-management education were included in the analysis. In the study, diabetic patients involved with self-management education programs demonstrated reductions in HbA1c levels, and improvements in systolic blood pressure. Another study conducted at Johns Hopkins University by Gary et. al., (2003), indicated that educational and behavioral modification programs in type 2 diabetes produced modest improvements in glycemic control and weight (Gary et al. *The Diabetes Educator*, Vol 29, No 3, 488-501, 2003).

Specific to telemedicine, Izquierdo and his colleagues (2003) conducted a study to determine whether diabetes education can be provided as effectively through telemedicine technology as through in person encounters with diabetes nurse and nutrition educators (*Diabetes Care*, Vol 26(4), April, P. 1002-1007). A total of 56 patients with diabetes were randomized to receive diabetes education via telemedicine or in person (control group). The groups were compared using measures of HbA1c and questionnaires to assess patient satisfaction and psychosocial functioning as related to diabetes. Outcome measures were obtained at baseline, immediately after completion of the education program, and at three months after the third educational visit. Results indicated that patient satisfaction was high in the telemedicine group, Problem Areas in Diabetes scale scores improved significantly with diabetes education immediately after education and three month after education, and the attainment of behavior-change goals did not differ between groups. With diabetes education HbA1c improved from 8.6 (+/- 1.8%) at baseline to 7.8 (+/-1.5%) immediately after education and 7.8 (+/- 1.8%) three

months after the third educational visit, with similar changes observed in the telemedicine and in person group. The conclusion of the study supported diabetes education via telemedicine and in person care as equally effective in improving glycemic control, and both methods were well accepted by patients. Reduced diabetes-related stress was observed in both groups (p. 1002).

Dimmick et. al. (2003) conducted a study of patients receiving care over a telemedicine network that linked three hospitals and an FQHC with six sites, a dental clinic, and patient homes. Outcomes from the disease management programs conducted over telemedicine for the diabetes group showed that the diabetes disease management program increased the number of diabetics who brought their blood sugar under control (Dimmick et. al. *Telemed Journal and e-Health*, 9(1): 13-23).

Group Sessions for Diabetic Self-Management

One component of diabetes self-management training is group visits. Group visits are a practical method of delivering extensive group education as well as some medical care (Jaber R. 2007. *DOC News*, Vol 4 (2): p. 3). Diabetes is one of the top ten chronic conditions that has been effectively treated with group visits (Scott et. al. 2004. *J Am Geriatric Soc*, 52: 1463-1470). Trento (2002, *Diabetology*, 45: 1231-1239) indicates that diabetes HbA1c and retinopathy improves in patients who have been seen in group visits compared with a group receiving usual care. The Kaiser Permanente (Group Health Cooperative) have used group visits very successfully for years in the HMO setting as well as the non-HMO setting, such as private practices. Jaber R, Braksmajer A, Trilling J. 2006. *Fam Pract Manag* 13: 37-40). Group visits are an ideal format to provide patients with comprehensive care. Group visits allow the necessary time to deliver quality care with personalized education that empowers patients to acquire disease specific and general wellness skills in a supportive and supervised environment. In addition, the group visit format provides modeling reinforcement by other patients as well as the power of the group dynamic in supporting patient goals to improve self-care (Jabar 2007, p. 4).

The Need to Improve Participation in Diabetes Self-Management

What is important to understand is the need to improve access and motivation for diabetics who participate in educational programs. Gucciardi et. al (2007) examined 536 charts for first time visits of diabetics to the Diabetic Education Centre in Toronto, Canada (Gucciardi et. al. *Journ of Evaluation in Clinical Practice*, 13(6): 913-919). The purpose of the review was to examine utilization patterns of diabetes self-management training and identify patient factors associated with attrition from the services. Almost 50 percent of new patients withdrew prematurely from recommended Diabetes Self-Management services over the one-year period, and only 24.8 percent attended group education. What is imperative is that we as health care providers and government payers come up with innovative ways to help diabetics complete education programs that are proven to positively impact clinical outcomes. Telemedicine makes it easy for diabetics

to receive the education needed and for diabetes management staff to partner with primary care providers, exponentially improving outcomes even more.

Conclusion

There is clearly a link between reducing complications of diabetes in persons who receive diabetes self-management training, and there is clearly support for providing services via interactive telehealth. With the shortage of registered nurses, and the growing shortage of diabetes educators, a clear choice emerges in terms of adding Diabetes Self-Management codes G0108 and G0109 to the list of approved telehealth codes. ATA requests that Diabetes Self-Management G0108 and G0109 be added to the list of approved telehealth codes.

There are both significant economic costs and tremendous human suffering when diabetes is not properly managed. It is particularly difficult to provide necessary diabetes self-management training services in rural areas. Telehealth is a tool that can provide these services to beneficiaries who would otherwise not have access to them. Approval of these codes will reduce costs to Medicare by keeping diabetes patients healthy. Approval of these codes will also improve the quality of life for these beneficiaries.

Submitted December 28, 2007

Submitter : Ms. Marjorie Ingelsby
Organization : Naval Branch Health Clinic, Key West Florida
Category : Federal Government

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

**Refinement of RVUs for CY 2008
and Response to Public Comments
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

December 28, 2007

Centers for Medicare & Medicaid Services
Baltimore, Maryland

Re: Docket: CMS-1385-FC - Revisions to Payment Policies Under the Physician Fee Schedule: Medicare Interim Final Rule Physician Fee Schedule 2008 related to codes 99441, 99442, 99443, 98966, 98967, 98968

Dear Sir:

I appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) interim final rule regarding revisions to payment policies under the proposed 2008 Medicare Physician Fee Schedule Docket CMS-1385-FC.

Case/care management is a collaborative process of assessment, planning, facilitation and advocacy for options and services to meet an individual's healthcare needs through communication and available resources (CMSA, 2002). As an essential part of the healthcare team, case managers routinely work directly with patients in support of medical management assessments, objectives, services, and health care coordination. The processes of health adherence assessment, education, and adherence monitoring are well within the scope of case/care management practice.

Professional case/care managers perform these responsibilities as a core function of their jobs. As licensed professionals, nurses, social workers case/care managers use proven techniques (e.g., evidenced-based practice guidelines, health literacy assessment, readiness to change tool) in working with patients, caregivers, and fellow healthcare professionals toward measurable improvement in health status.

Case/care managers work collaboratively with physicians and pharmacists in coordinating and providing assessments and management services through individualized care planning and care coordination in collaboration with beneficiaries, care givers and families. In support of those interventions and services, we ask for reconsideration of the interim payment rule on CPT codes: 99441, 99442, 99443, 98966, 98967 & 98968 from an N status to payable codes by Medicare. These codes represent assessment and management services to beneficiaries such as:

- " Transition of care
- " Medication reconciliation
- " Health literacy assessment, medication knowledge, readiness to change
- " Motivational interviewing
- " Patient education
- " Medical Home coordination

Failure to provide appropriate incentives and funding for these codes affects the alignment of care coordination quality between providers, especially at the various levels for transitions of care within settings, between settings, and between health states. Poor transitions of care may result in poor outcomes such as incorrect treatments, medication errors, delay in diagnosis and treatment, readmissions, patient complaints, increased health care costs).

I believe that by requesting funding support for these six codes, providers will more readily integrate case/care managers in support of the care management concepts such as the Medicare Medical Home Demonstration (MMHD), pay for performance programs, and various collaborative care models which CMS and other regulatory agencies are discussing.

I urge CMS to adopt a payable ruling structure for these much needed codes to ensure consistency, accountability, and improved quality of care for beneficiaries. I thank you for your consideration of these comments on this Interim Final Rule.

Sincerely,

Marjorie Ingelsby, RN, CPHQ, CCM
Case Manager
Naval Branch Health Clinic
1300 Douglas Circle

Key West, Florida 33040

cptcms07

Submitter : Matthew Twetten

Date: 12/28/2007

Organization : American Association of Orthopaedic Surgeons

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-FC-210-Attach-1.PDF

AAOSAMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONSAMERICAN ASSOCIATION OF
ORTHOPAEDIC SURGEONS6300 North River Road
Rosemont, Illinois 60018P. 847.823.7186
F. 847.823.8125

www.aaos.org

BOARD OF DIRECTORS

PRESIDENT

James H. Beatty, MD
Memphis, Tennessee

FIRST VICE PRESIDENT

E. Anthony Rankin, MD
Washington, DC

SECOND VICE PRESIDENT

Joseph D. Zuckerman, MD
New York, New York

TREASURER

William L. Healy, MD
Burlington, Massachusetts

PAST PRESIDENT

Richard F. Kyle, MD
Minneapolis, Minnesota

CHAIR

BOARD OF COUNCILORS
Matthew S. Shapiro, MD
Eugene, Oregon

CHAIR-ELECT

BOARD OF COUNCILORS
John T. Gill, MD
Dallas, Texas

SECRETARY

BOARD OF COUNCILORS
Thomas S. Barber, MD
Oakland, California

CHAIR

BOARD OF SPECIALTY
SOCIETIES
Joseph C. McCarthy, MD
Boston, Massachusetts

CHAIR-ELECT

BOARD OF SPECIALTY
SOCIETIES
James P. Tasto, MD
San Diego, California

SECRETARY

BOARD OF SPECIALTY
SOCIETIES
William J. Rohb, III, MD
Evanston, Illinois

LAY MEMBER

George Zachary Wilhoit, MS, MBA
South Hackensack, New Jersey

MEMBERS-AT-LARGE

Kevin J. Bozic, MD, MBA
San Francisco, CaliforniaChristopher D. Harner, MD
Pittsburgh, PennsylvaniaNorman Otsuka, MD
Los Angeles, CaliforniaKen Yamaguchi, MD
Saint Louis, MissouriKen Yamaguchi, MD
Saint Louis, MissouriKen Yamaguchi, MD
Saint Louis, Missouri

CHIEF EXECUTIVE OFFICER

(Ex-Officio)
Karen L. Hackett, FACHE, CAE
Rosemont, IllinoisSeventy-Fifth Annual Meeting
March 5-9, 2008
San Francisco, California

December 28, 2007

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850Subject: CMS-1385-FC Medicare Program; Revisions to Payment Policies
Under the Physician Fee Schedule, and Other Part B Payment Policies
for Calendar Year 2008

Dear Mr. Weems:

The American Academy of Orthopaedic Surgeons (AAOS) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) *Final Rule* on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year 2008, published in the November 1, 2007 *Federal Register*. We will be commenting on the non-facility practice expense pricing for diagnostic arthroscopy procedures, the anti-markup provision, and the interim new and revised work relative values for new and revised physician CPT codes related to orthopaedic surgery.

DIAGNOSTIC ARTHROSCOPY NON-FACILITY PRACTICE EXPENSE INPUTS

In the Final Rule, CMS stated its desire for further clarification on a request by a group of providers to assign non-facility practice expense (PE) RVUs for 5 diagnostic arthroscopy CPT codes (29805, 29830, 29840, 29870, and 29900). In our comments to CMS on the 2008 Proposed Rule we stated that at that time the AAOS did not support the assignment of non-facility practice expense RVUs these diagnostic arthroscopy CPT codes and we wish to reiterate our support for maintaining non-facility practice expense settings for these codes.

The AAOS has carefully considered the pros and cons of this issue and continues to believe it would be a mistake to assign non-facility PE RVUs to these procedures. Clinically, it is important that diagnostic arthroscopy be performed in a setting where, if complications arise during the procedure(s), physicians have more clinical options to deal with them. If one of these procedures is done in an office setting and a surgically treatable lesion is found, the patient would need to be moved to a facility, prepared again for surgery, and then undergo a second procedure, most of which could have been avoided if the diagnostic procedure had been done in the facility in the first place.

In addition, the AAOS believes patients will face other significant risks because untrained practitioners may begin to perform these procedures in the non-facility setting. The facility setting only allows credentialed practitioners to perform these procedures. In the non-facility setting, there is no method to ensure providers have adequate training. The performance of these procedures by undertrained providers could have adverse effects on patient safety and could lead to increased hospitalization for the complications that could arise when the arthroscopy is done improperly.

In addition, utilization data then and now does not support non-facility PE RVUs. According to MedPAR data for 2005, none of the procedures were performed in an office setting more than 5% of the time for Medicare patients. We believe the reason these are rarely performed in the office setting is because most providers recognize the facility setting is the safest and most appropriate place to perform diagnostic arthroscopy.

ANTI-MARKUP PROVISIONS

1. Introduction

The AAOS urges CMS to reconsider the implementation of the revisions to the anti-markup provision and to corresponding provisions in the reassignment rules. The AAOS believes that the new provision will have negative results, not only for the physician practices that will be affected but, more importantly, for patients who will ultimately face access and quality of care issues.

2. Utilization of Imaging Services

CMS raises concerns about overutilization based on the growth of imaging services. It appears that CMS is attributing this increase, in large part, to the trend away from hospital-based imaging services to in-office imaging services. The AAOS suggests that, instead, CMS should focus on the increase in clinically-superior, convenient, and efficient patient care. While there may be an increase in utilization, this does not necessarily mean that imaging services are being incorrectly utilized. It is just as logical to attribute the increase in utilization to the increased availability of imaging technology.

Not only may the increase in utilization of imaging services be attributed to the increase in availability, but CMS fails to acknowledge various other factors that contribute to this trend. First, and of paramount importance, there has been a migration from the use of invasive to non-invasive diagnostic tools. This is because physicians have been relying more on imaging services in an effort to avoid exploratory surgeries, detect diseases and complications earlier, and prevent unnecessary hospitalizations. There have also been significant changes in Medicare population demographics and shifts in the site of service.

As more specialists offer in-office diagnostic imaging tests, patients are less likely to receive these services in the hospital setting. In addition, this trend may also be explained by the improvement in the *quality* of imaging services. Physician specialists who offer in-office diagnostic imaging services have the expertise, educational background and the experience to perform and interpret imaging that could have a significant impact on clinical decision making.

When imaging is available in a physician's office, the imaging can be obtained, interpreted, and used in patient care decisions all in a single visit. This is a significant convenience to patients, whose compliance tends to drop off if more than one visit must be scheduled. Ultimately, when imaging results are available immediately, it is more likely that there will be more time to positively impact patient care.

The AAOS, along with the rest of the health care community, were taken completely by surprise by the revisions to the anti-markup provision. The revisions in the final rule are a significant departure from the revisions that CMS proposed last July. The AAOS believes that the new anti-markup provision will vitiate many of the physician self-referral rules currently relied upon by vast numbers of orthopaedic practices throughout the nation. For this reason, countless physician practices that currently offer imaging services will have to re-structure their practices or simply cease to offer imaging services. This would be an unfortunate result because imaging services provided by specialists, such as orthopaedists, have enhanced patient care.

3. Changes to Anti-markup Provision

In the 2008 Proposed Rule, CMS stated its intention to "clarify" the anti-markup rule so that the anti-markup provision on the professional portion of a purchased diagnostic test would match the anti-markup provision already imposed on the technical component of such tests. Much of the Proposed Rule focused on whether the person performing either the technical or professional component of a test was a full-time employee of the group practice, rather than a part-time employee or an independent contractor. The Final Rule eliminates this distinction and simply imposes an anti-markup provision on the technical or professional component of diagnostic tests that are ordered by a billing physician or other supplier (or a related party) if the technical or professional component is purchased from an "outside supplier" *or if it is performed at a site other than the office of the billing physician or other supplier.*

Unfortunately, the Final Rule creates a completely different billing standard than what CMS had proposed. The Final Rule applies the anti-markup provision simply based on *where the test is furnished*, rather than focusing on whether the test was or was not purchased. Under the Final Rule, to avoid the anti-markup provisions, a test would have to be furnished "in the office of the billing physician or other supplier," (*ie*, the "space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally."). For many physician practices, diagnostic tests are not purchased. They are actually provided by the group. The Final Rule fails to recognize that Congress did not intend to apply an anti-markup provision to services that are *provided* rather than *purchased*. In fact, the statute specifically declines to apply the anti-markup provision when the test is performed by a physician in the practice. In addition, the new anti-markup provisions would apply to the professional component as well as the technical component of diagnostic tests. Again, this runs contrary to Congressional intent.

4. CMS Statutory Authority

There is no support in the statute, or in the legislative history that Congress intended to apply the anti-markup provision to the professional component of diagnostic tests, or to tests that are clearly not purchased. The statute states that if a physician (or another physician with whom the physician “shares a practice”) bills for a test without indicating on the claim that he or she personally performed (or supervised the performance of) the test (that is, if the claim indicates that a test was performed by a supplier), then the amount payable on that claim is limited to the lower of (1) the actual acquisition cost or (2) “the supplier’s reasonable charge.” If the claim fails to identify who performed the test, or, for a test performed by a supplier, the claim does not include the amount charged by a supplier, then no payment may be made. 42 USC 1395u(n)(1).

The statute does not refer to “technical” and “professional” components of diagnostic tests, because, in using the term “test” Congress intended only to subject the technical component to the anti-markup rule and *not* the interpretation or personally-performed tests. The House Conference Report addressing the anti-markup provision supports this view:

The conference agreement would eliminate the physician mark-up for services obtained from outside suppliers....The mark-up is eliminated as follows: If a physician bills a global fee for a service (i.e., a fee for technical and professional components combined), the carrier limits the global fee to the sum of (i) the reasonable charge for associate professional services plus (ii) the lower of the reasonable charge for the technical component of the test or the actual acquisition cost (net of any discount). If a physician bills separately for a technical and professional component, then separate limits apply. Carriers would gap-fill any professional component fees for which they did not have established allowances. (H.R. Rep. No. 100-495, at 605-606 (1987))

Hence, the new anti-markup provision is not based on statutory provisions and, we believe, is contrary to Congressional intent. The AAOS submits that the final anti-markup provision is unsupported by statute and its implementation violates the federal Administrative Procedure Act (APA). CMS itself recognizes the statute does not establish an anti-markup provision for the professional component of diagnostic tests; however, CMS appears to be dismissing the statutory omission as “inadvertent.” (See 72 Fed. Reg. 66315 (November 27, 2007)).

CMS failed to give proper notice to the healthcare community by finalizing a rule that was significantly different than the proposed rule. Under the APA, agencies must include in their notice of proposed rulemaking “either the terms or substance of the proposed rule or a description of the subjects and issues involved.” 5 U.S.C. § 553(b)(3). In addition, they must give “interested persons an opportunity to participate in the rulemaking through submission of written data, views, or other arguments.” 5 U.S.C. § 553(c). Further, “[w]hile an agency may promulgate final rules that differ from the proposed rule, a final rule is a ‘logical outgrowth’ of a proposed rule only if interested parties ‘should have anticipated that the change was possible, and thus reasonably should have filed their comments during the notice-and-comment period.’” *Int’l Union, United Mine Workers of Amer. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005).

The Proposed Rule was based on the differentiation of full-time employees, part-time employees, and independent contractors. (72 Fed. Reg. 38122, 38225 (July 12, 2007)). The Final Rule, however,

creates a very different standard-one that is based on where the test is furnished. In addition, the Final Rule creates new criteria which are inconsistent with the Stark rules promulgated by CMS. The Stark rules address overutilization and contain an exception for in-office ancillary services. This exception, which was subject to no less than two rulemakings, determines under what circumstances ancillary services, including diagnostic tests, could be provided by physicians. Without notice by CMS, stakeholders could never have expected that the anti-markup rule would be based on a location test.

5. Net Change Payment Methodology

Under the final anti-markup provision CMS limits the payment for a diagnostic test (both the technical and the professional components) that is either purchased from an outside supplier or performed at a site other than the office of the billing physician or other supplier to the lower of:

- (i) the performing supplier's *net charge* to the billing physician or other supplier,
- (ii) the billing physician or other supplier's actual charge, or
- (iii) the fee schedule amount for the test that would be allowed if the performing supplier billed directly.

72 Fed. Reg. 66401 (November 27, 2007).

The provision further restricts payment by requiring that the "net charge" be calculated "without regard to any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing physician or other supplier." Id.

By only permitting physicians to be reimbursed for a portion of their costs, the AAOS believes CMS is, in effect, changing the payment methodology for diagnostic tests. Rather than making payment on a fee schedule basis, CMS is now creating a net charge system that is intended to reimburse physicians below cost, with the ultimate goal of eradicating the provision of diagnostic services by physician groups under "same building" or "centralized building" arrangements. The Medicare payment system makes allowances for overhead. In fact, the amount of the technical component, which is established in the Medicare fee schedule, contains an intricate calculation for practice expenses (PE) that deliberately includes equipment and overhead costs. This PE calculation is itself subject to notice and comment as part of the physician fee schedule regulations. The AAOS believes that CMS should not have altered the payment methodology for diagnostic tests without a statutory basis, without a reasoned decision-making process, and without adequate notice.

As drafted, the new anti-markup provision will adversely affect physician arrangements that were structured from their inception to meet the Stark requirements for the in-office ancillary services exception. These practices will not be reimbursed for equipment, facility, overhead, or any other related expenses for providing imaging or other diagnostic procedures to its patients. In effect, these practices will be forced to lose money when providing these services to Medicare beneficiaries.

The AAOS urges CMS to reconsider the implementation of this provision not just because of the negative impact it will have on physician practices but, first and foremost, because of the detrimental impact it will have on patient care.

ESTABLISHMENT OF INTERIM WORK RELATIVE VALUES FOR NEW AND REVISED PHYSICIAN CURRENT PROCEDURAL TERMINOLOGY (CPT) CODES AND NEW HEALTHCARE COMMON PROCEDURE CODING SYSTEM CODES (HCPCS) FOR 2008

A. 26 New and Revised CPT Code Work RVU Packages

The AAOS and the RUC recommended RVU settings for 23 new orthopaedic CPT codes for 2008 and we appreciate CMS' acceptance of those recommendations. The AAOS also commends CMS for accepting our recommendations regarding 3 new RVU packages for 3 established CPT codes (20660, 20690 and 20692) that were removed from the Modifier -51 list at our recommendation and resurveyed and revalued by the RUC.

B. 62 Revised Open Fracture Care Code Packages

1. Introduction

The AAOS also commends CMS for accepting the RUC recommended RVU settings for 62 revised open treatment of fracture code packages that were re-surveyed and re-valued through the Medicare 5-Year Review.

However, the AAOS believes that CMS made an error in its approach to maintaining budget neutrality for the RVU changes to these codes. Instead of (correctly) maintaining budget neutrality through the budget neutrality work adjuster, with no change to the work values themselves for these 62 services and procedures, CMS (incorrectly) changed the RVUs for these codes. This is a radical departure from the established method for maintaining budget neutrality for codes in the 5-Year Review process.

As a result of this action CMS has created significant rank order anomalies throughout the musculoskeletal section of the relative value scale. These rank order anomalies exist not only between and among the 62 codes but between and among the other 300-plus fracture treatment codes thus affecting all musculoskeletal codes.

The AAOS finds CMS' action especially difficult to understand because the total fiscal impact of the RUC recommended changes amounts to slightly more than \$7 million. This impact could easily be absorbed through the budget neutrality work adjuster with very little change in the adjuster.

Throughout the process to review these codes CMS seemed to agree they were part of the 5-Year Review. There was no indication at any point that CMS did not believe these codes were being reviewed under any other process. But the way in which CMS has applied budget neutrality to these codes indicates to us that the agency somehow decided the codes were not part of the 5-Year Review.

2. Why These Codes Were Part of the 5-Year Review:

The 62 codes were included in the original AAOS 5-Year Review comment to CMS. Our rationale for including these codes in the 5-Year Review was the existence of compelling evidence that the previous valuations assigned in 1992 and 1993 were incorrect. We addressed several aspects of the 5-Year Review compelling evidence standards, most significantly, the substantial changes in the technology used by the providers of these services which, in turn, affected the amount of work involved in these procedures. However, the work RVUs had never previously been adjusted to account for these technological changes.

We also feel that incorrect assumptions about the work involved in these procedures were made in the 1992 and 1993 valuation processes because of the imprecise wording of the CPT Code descriptors at that time, which stated, “ open treatment of ___; with or without internal or external fixation, when performed”.¹

In addition, the last valuation process only included general orthopaedists. Generalists rarely perform these procedures. The most common providers of open fracture care treatment are orthopaedic sub-specialists in trauma, hand, shoulder, knee and foot/ankle, as well as podiatrists. None of these provider groups were involved in the original valuations.

The RUC reviewed the 62 codes listed below in Table 1 in February and April 2007 and the RUC agreed that most of the codes met 5-Year Review compelling evidence standards. For those codes that did not meet compelling evidence standards, the RUC recommended no change in work RVUs.

TABLE 1

CPT	DESCRIPTOR	2007 FINAL RVU	RUC REC RVU	2008 FINAL RVU	07 TO 08 RVU CHANGE
23515	Open treatment of clavicular fracture, includes internal fixation, when performed	7.47	11.00	9.53	2.06
23585	Open treatment of scapular fracture (body, glenoid or acromion) includes internal fixation	9.15	16.25	14.07	4.92
23615	Open treatment of proximal humeral (surgical or anatomical neck) fracture, includes internal fixation, when performed, includes repair of tuberosity(s), when performed;	10.93	14.00	12.12	1.19

¹ Application of External Fixation has always been an adjunctive procedure to the open fracture treatment, coded with a separate 090-day global CPT code. This coding practice is long established and referred to in the CPT Guide with a note for fracture treatment stating, “for application of external fixation in addition to internal fixation, use 20690 and the appropriate internal fixation code)

CPT	DESCRIPTOR	2007 FINAL RVU	RUC REC RVU	2008 FINAL RVU	07 TO 08 RVU CHANGE
23616	Open treatment of proximal humeral (surgical or anatomical neck) fracture, includes internal fixation, when performed, includes repair of tuberosity(s) , when performed; with proximal humeral prosthetic replacement	21.68	21.00	18.19	(3.49)
23670	Open treatment of shoulder dislocation, with fracture of greater humeral tuberosity, includes internal fixation, when performed	8.02	14.00	12.12	4.10
23680	Open treatment of shoulder dislocation, with surgical or anatomical neck fracture, includes internal fixation, when performed	10.30	15.00	12.99	2.69
24545	Open treatment of humeral supracondylar or transcondylar fracture, includes internal fixation, when performed; without intercondylar extension	10.88	15.00	12.99	2.11
24546	Open treatment of humeral supracondylar or transcondylar fracture, includes internal fixation, when performed; with intercondylar extension	15.99	17.00	14.73	(1.26)
24575	Open treatment of humeral epicondylar fracture, medial or lateral, includes internal fixation, when performed	11.02	11.00	9.53	(1.49)
24579	Open treatment of humeral condylar fracture, medial or lateral, includes internal fixation, when performed	11.96	13.00	11.26	(0.70)
24635	Open treatment of Monteggia type of fracture dislocation at elbow (fracture proximal end of ulna with dislocation of radial head), includes internal fixation, when performed	13.56	10.00	8.64	(4.92)
24685	Open treatment of ulnar fracture proximal end (olecranon process), includes internal fixation, when performed	8.92	9.50	8.21	(0.71)

CPT	DESCRIPTOR	2007 FINAL RVU	RUC REC RVU	2008 FINAL RVU	07 TO 08 RVU CHANGE
25515	Open treatment of radial shaft fracture, includes internal fixation, when performed	9.37	10.00	8.64	(0.73)
25525	Open treatment of radial shaft fracture, with internal fixation, when performed, and closed treatment of dislocation of distal radioulnar joint (Galeazzi fracture/dislocation), with percutaneous skeletal fixation, when performed	12.69	12.00	10.37	(2.32)
25545	Open treatment of ulnar shaft fracture, includes internal fixation, when performed	9.09	9.00	7.78	(1.31)
25574	Open treatment of radial AND ulnar shaft fractures, with internal fixation, when performed; of radius OR ulna	7.47	10.00	8.64	1.17
25575	Open treatment of radial AND ulnar shaft fractures, with internal fixation, when performed; of radius AND ulna	12.02	14.00	12.10	0.08
25628	Open treatment of carpal scaphoid (navicular) fracture, includes internal fixation, when performed	9.50	11.00	9.51	0.01
26615	Open treatment of metacarpal fracture, single, includes internal fixation, when performed, each bone	5.38	8.00	6.91	1.53
26650	Percutaneous skeletal fixation of carpometacarpal fracture dislocation, thumb (Bennett fracture), with manipulation	5.80	6.00	5.19	(0.61)
26665	Open treatment of carpometacarpal fracture dislocation, thumb (Bennett fracture), includes internal fixation, when performed	7.72	9.00	7.78	0.06
26685	Open treatment of carpometacarpal dislocation, other than thumb; includes internal fixation, when performed, each joint	7.09	8.00	6.91	(0.18)
26715	Open treatment of metacarpophalangeal dislocation, single, includes internal fixation, when performed	5.79	7.95	6.87	1.08

CPT	DESCRIPTOR	2007 FINAL RVU	RUC REC RVU	2008 FINAL RVU	07 TO 08 RVU CHANGE
26735	Open treatment of phalangeal shaft fracture, proximal or middle phalanx, finger or thumb, includes internal fixation, when performed, each	6.03	8.40	7.26	1.23
26746	Open treatment of articular fracture, involving metacarpophalangeal or interphalangeal joint, includes internal fixation, when performed, each	5.86	11.10	9.59	3.73
26765	Open treatment of distal phalangeal fracture, finger or thumb, includes internal fixation, when performed, each	4.21	6.60	5.70	1.49
27248	Open treatment of greater trochanteric fracture, includes internal fixation, when performed	10.80	16.00	10.64	(0.16)
27511	Open treatment of femoral supracondylar or transcondylar fracture without intercondylar extension, includes internal fixation, when performed	13.94	20.96	14.97	1.03
27513	Open treatment of femoral supracondylar or transcondylar fracture with intercondylar extension, includes internal fixation, when performed	19.45	23.04	19.11	(0.34)
27514	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	19.09	19.09	14.46	(4.63)
27519	Open treatment of distal femoral epiphyseal separation, includes internal fixation, when performed	15.80	15.80	13.11	(2.69)
27535	Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	11.80	16.00	13.27	1.47
27540	Open treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, includes internal fixation, when performed	13.45	13.45	11.16	(2.29)
27556	Open treatment of knee dislocation, with internal fixation, when performed; without primary ligamentous repair or augmentation/reconstruction	14.95	15.50	12.86	(2.09)

CPT	DESC	2007 FINAL RVU	RUC REC RVU	2008 FINAL RVU	07 TO 08 RVU CHANGE
27557	Open treatment of knee dislocation, with internal fixation, when performed; with primary ligamentous repair	17.31	19.00	15.76	(1.55)
27558	Open treatment of knee dislocation, with internal fixation, when performed; with primary ligamentous repair, with augmentation/reconstruction	18.01	22.00	18.25	0.24
27766	Open treatment of medial malleolus fracture, includes internal fixation, when performed	8.73	8.50	7.73	(1.00)
27784	Open treatment of proximal fibula or shaft fracture, includes internal fixation, when performed	7.41	10.45	9.51	2.10
27792	Open treatment of distal fibular fracture (lateral malleolus), includes internal fixation, when performed	7.91	10.50	9.55	1.64
27814	Open treatment of bimalleolar ankle fracture, includes internal fixation, when performed	11.10	11.50	10.46	(0.64)
27822	Open treatment of trimalleolar ankle fracture, with internal fixation, when performed, medial and/or lateral malleolus; without fixation of posterior lip	12.12	12.12	11.03	(1.09)
27823	Open treatment of trimalleolar ankle fracture, with internal fixation, when performed, medial and/or lateral malleolus; with fixation of posterior lip	14.26	14.26	12.98	(1.28)
27826	Open treatment of fracture of weight bearing articular surface/portion of distal tibia (eg, pilon or tibial plafond), with internal fixation, when performed; of fibula only				
27827	Open treatment of fracture of weight bearing articular surface/portion of distal tibia (eg, pilon or tibial plafond), with internal fixation, when performed; of tibia only	15.75	16.00	14.56	(1.19)

CPT	DESC	2007 FINAL RVU	RUC REC RVU	2008 FINAL RVU	07 TO 08 RVU CHANGE
27828	Open treatment of fracture of weight bearing articular surface/portion of distal tibia (eg, pilon or tibial plafond), with internal fixation, when performed; of both tibia and fibula	18.19	20.00	18.20	0.01
27829	Open treatment of distal tibiofibular joint (syndesmosis) disruption, includes internal fixation, when performed	5.68	9.50	8.64	2.96
27832	Open treatment of proximal tibiofibular joint dislocation, includes internal fixation, when performed, or with excision of proximal fibula	6.87	11.00	10.01	3.14
28420	Open treatment of calcaneal fracture, includes internal fixation, when performed; with primary iliac or other autogenous bone graft (includes obtaining graft)	17.07	19.00	17.29	0.22
28445	Open treatment of talus fracture, includes internal fixation, when performed	17.07	17.07	15.53	(1.54)
28465	Open treatment of tarsal bone fracture (except talus and calcaneus), includes internal fixation, when performed, each	7.13	9.50	8.64	1.51
28485	Open treatment of metatarsal fracture, includes internal fixation, when performed, each	5.77	8.00	7.28	1.51
28505	Open treatment of fracture great toe, phalanx or phalanges, includes internal fixation, when performed	3.86	8.00	7.28	3.42
28525	Open treatment of fracture, phalanx or phalanges, other than great toe, includes internal fixation, when performed, each	3.37	6.00	5.46	2.09
28555	Open treatment of tarsal bone dislocation, includes internal fixation, when performed	6.42	10.43	9.49	3.07
28585	Open treatment of talotarsal joint dislocation, includes internal fixation, when performed	8.17	12.00	10.92	2.75
28615	Open treatment of tarsometatarsal joint dislocation, includes internal fixation, when performed	8.96	11.50	10.46	1.50

CPT	DESC	2007 FINAL RVU	RUC REC RVU	2008 FINAL RVU	07 TO 08 RVU CHANGE
28645	Open treatment of metatarsophalangeal joint dislocation, includes internal fixation, when performed	4.27	8.00	7.28	3.01
28675	Open treatment of interphalangeal joint dislocation, includes internal fixation, when performed	2.97	6.00	5.46	2.49

3. Chronology of 5-Year Review of These 62 Codes:

A. January 2005- AAOS Comment Letter to CMS Regarding 2005 Five-Year Review

In its January 2005 comments on the 2005 Physician Fee Schedule Final Rule, the AAOS petitioned CMS to include these codes in the 2005 5-Year Review. At that time, the AAOS stated there was reason to believe these codes were misvalued and indicated we would present compelling evidence to the RUC at its April 2005 meeting when specialties were required to address compelling evidence as part of the Level of Interest (LOI) process for the 5-Year Review. CMS then forwarded these codes to the RUC for the 5-Year Review.

B. March 2005- AAOS Level of Interest Letter to RUC

The AAOS submitted a letter to the RUC, dated March 24, 2005, stating its intention to survey these codes for the 5-Year Review. But in order to conduct valid RUC surveys with clear vignettes to help surveyees properly estimate the time and intensity involved in providing these procedures, and for RUC reviewers to clearly understand the work that was being reviewed, we recommended the RUC send the entire set of codes to the CPT Editorial Panel to improve the CPT code descriptors. The RUC agreed.

C. July 2005-AAOS Code Change Proposal to CPT

In July 2005, the AAOS submitted a proposal to the CPT Editorial Panel for the fracture treatment codes. In the Code Change Proposal, the AAOS clearly indicated the codes were considered as 5-Year Review codes and no one involved with the review (including CMS) stated at any point there was a reason to not consider the codes as 5-Year Review codes.

In October 2006, the CPT Editorial Panel agreed to change the descriptors to say, "Open treatment of ____, includes internal fixation when performed" instead of the previous wording "Open treatment of ____, with or without internal or external fixation." At that point, the AAOS and other interested specialty societies were satisfied they could now conduct valid RUC surveys under the 5-Year Review. The Editorial Panel then sent the revised codes back to the RUC for review of physician work.

D. November 2006-AAOS and Other Specialty Societies Survey the Open Fracture Care Codes:

In November 2006, the AAOS, the American Society of Surgery for the Hand (ASSH), the Orthopaedic Trauma Association (OTA), the American Orthopaedic Foot and Ankle Society (AOFAS) and the American Podiatric Medical Association (APMA) began to conduct full 5-Year Review RUC surveys for all 62 codes. The survey results were presented over two RUC meetings - February 2007 and April 2007.

E. February and April 2007- RUC Review of the Open Treatment of Fracture Codes

The AAOS, ASSH, AOFAS, OTA, and APMA appeared before the entire RUC to present the survey data and the compelling evidence for re-valuing this set of codes. Before addressing the work values the RUC required the presenters to show 5-Year Review compelling evidence for reviewing the codes. The presenting societies' compelling evidence arguments were outlined in a letter submitted to the RUC on January 19, 2006.

The entire RUC reviewed the letter at the February and April meetings. The letter made clear there were several reasons why these codes merited re-valuation under the 5-Year Review.

The primary reason was changes in technology that made the performance of open fracture treatment with internal fixation more complex than it had been in the early 1990's. Surgical treatment using open anatomical reduction and internal fixation has become more complex because of the introduction of new imaging methods, such as CT which allow for better detection of fracture pathology and provides the basis for new surgical strategies. There are also new internal fixation devices and surgical techniques which require more work. Beginning in the mid-1990s, new plates, screws and intramedullary fixation systems were developed for fracture repair, with most becoming available in the late 1990s and early 2000s. As an example of the complexity of the decision process in current practice, the 1990's have given the surgeon numerous options for bone fixation. The options for a bone fixation device currently include Kirschner wires, wire, staples, screws, as well as newer alternatives such as headless bone screws, T-screws, absorbable pins, locking screws, captured screws, cannulated screws, and a myriad of plates (locking, variable angle locking, anatomic, periarticular, etc.). The goal of all these devices remains constant: to achieve stable approximation of bone fragments to facilitate healing. The various devices afford rigid fixation along with compression of the osseous fragments. This allows early range of motion and preservation of surrounding joint function, as well as primary bone healing. Selection of the most advantageous form of fixation is dependent on many factors and takes considerable time in the pre-evaluation of a patient. These include the type, complexity, location of fracture treated, bone density, patient's body mass, associated soft tissue injury(ies), patient's level of activity, expectations, and the desire for interfragmental compression. All of this has resulted in more work.

The standards of care (fracture reduction, limb alignment, etc.) have also been elevated by literature that shows fracture displacements and poor alignments lead to poorer results. This requires significantly more work as each fracture fragment mandates a more exacting fracture reduction especially for periarticular and intraarticular fractures. The newer plates are generally longer, and have many screws insertion options than those from 10-15 years ago. The trajectory for each screw is now frequently planned preoperatively based on two and three dimensional

computerized tomography images and this must be verified during the procedure with intraoperative real-time fluoroscopy. All of these technologies generate more physician work.

Additionally, women over 50 are a fast growing segment of our population. A huge percentage of these patients are osteoporotic, making fracture fixation and maintenance of fixation far more difficult than in the past. The new plates are more complex to use when the underlying bone is of much poorer quality.

In addition to these technology changes, and as noted above, it appears that the last valuation process for these procedures involved only general orthopaedic surgeons in its study. While general orthopaedic surgeons can and occasionally do perform open treatment of fractures, the most common providers are trauma, hand and foot specialists.

The RUC took these various compelling evidence standards seriously enough to refuse to consider the survey results for three fixation codes, 27822, 27823 and 28445 that had been surveyed and re-valued by the RUC in the 2000 5-Year Review.² The RUC specifically stated it believed, “the work involved in providing these (three) services has not substantially changed since the RUC last reviewed them in 2000.”

The RUC then carefully reviewed the survey results for the 62 open fracture care codes and agreed to a very specific rank ordering that accurately captured the work involved in these procedures. In order to arrive at proper rank ordering, the RUC often chose 25th percentile survey values for its recommendations and in several cases, it developed recommendations with lower work values than those in existence at the time.

F. March 13, 2007-Conference Call with CMS

The five presenting societies, AMA RUC staff, RUC members, and Medicare Carrier Medical Directors, convened a conference call with CMS officials to again review the recommended value changes. The purpose of the call was to clarify to CMS that the RUC recommended values accurately captured the work involved in providing open fracture treatment. At the conclusion of this call, it appeared there was a clear understanding on the part of all those involved regarding the accuracy and integrity of this 5-Year Review process.

3. Impact of How CMS Applied Budget Neutrality to the Open Fracture Care Codes

The impact of the changes CMS made to the 62 open fracture care codes re-valued by the RUC will profoundly disrupt the relative value scale. Instead of a value system that correctly ranks all open fracture care codes in proper relation with other fracture care codes, as well as other musculoskeletal care codes there are now several glaring and harmful rank order anomalies.

² These three codes, because they were RUC surveyed, are the only 3 open fracture treatment codes that have typical patient vignettes and work descriptors. These can be found in the RUC database. These three vignettes and work descriptors make clear that when the RUC had the opportunity to consider open fracture treatment work values, they did not consider external fixation as part of the value.

First, there are now large rank order anomalies within the series of open fracture care codes. The anomalies also expand into the entire set of 370 fracture care codes, including closed, percutaneous, and other types of fracture care codes. Once the impact is expanded across orthopaedics and related surgical procedures, nearly 2000 more codes are affected.

A. Rank Order Anomalies Within Open Fracture Care Codes

Table 2 below illustrates a sample of the rank order anomalies within the open fracture care codes. The AAOS and the RUC deliberately ranked these 62 codes so as to accurately capture the differentiation in work between and among these codes. However, the CMS adjustments created a number of rank order anomalies just within the open fracture care codes, 13 of which (20%) involve rank order anomalies where a code value has been moved lower in the rank order than the RUC recommended values would have placed them. The rank order anomalies are particularly prevalent toward the top end of the RVU values, with CPT code 27511, for instance, now having the ninth highest work RVU instead of correctly having the third highest work RVU.

TABLE 2

	2007	RUC	2008	2008	RUC	2008
CPT	RVW	REC	RVW	IWPUT	RANK ORDER	RANK ORDER
27513	19.45	23.04	19.11	0.056	1	1
27558	18.01	22.00	18.25	0.056	2	2
27828	18.19	20.00	18.20	0.055	5	3
23616	21.68	21.00	18.19	0.078	3	4
28420	17.07	19.00	17.29	0.048	7	5
28415	17.54	17.54	15.96	0.05	9	6
27557	17.31	19.00	15.76	0.05	8	7
28445	17.07	17.07	15.53	0.046	10	8
27511	13.94	20.96	14.97	0.029	4	9
24546	15.99	17.00	14.73	0.038	11	10
27827	15.75	16.00	14.56	0.039	13	11
27514	19.09	19.09	14.46	0.023	6	12
23585	9.15	16.25	14.07	0.048	12	13
27535	11.80	16.00	13.27	0.039	14	14
27519	15.80	15.80	13.11	0.039	16	15
23680	10.30	15.00	12.99	0.051	18	16
24545	10.88	15.00	12.99	0.051	19	17
27823	14.26	14.26	12.98	0.051	21	18
25526	13.43	15.00	12.96	0.05	20	19
27556	14.95	15.50	12.86	0.04	17	20
23615	10.93	14.00	12.12	0.059	22	21
23670	8.02	14.00	12.12	0.053	23	22
25575	12.02	14.00	12.10	0.054	24	23
24579	11.96	13.00	11.26	0.043	26	24

27540	13.45	13.45	11.16	0.03	25	25
27822	12.12	12.12	11.03	0.035	27	26
27826	8.97	12.00	10.92	0.048	28	27
28585	8.17	12.00	10.92	0.046	29	28
27248	10.80	16.00	10.64	-0.008	15	29
27814	11.10	11.50	10.46	0.043	32	30
28615	8.96	11.50	10.46	0.034	33	31
23630	7.47	12.00	10.39	0.047	30	32
25525	12.69	12.00	10.37	0.047	31	33
27832	6.87	11.00	10.01	0.046	35	34
26746	5.86	11.10	9.59	0.04	34	35
27792	7.91	10.50	9.55	0.051	39	36
23515	7.47	11.00	9.53	0.046	36	37
24575	11.02	11.00	9.53	0.036	37	38
25628	9.50	11.00	9.51	0.048	38	39

The table above illustrates the impact of the CMS budget neutrality adjustments and how dramatically these adjustments have adversely affected the relative valuations of the 62 open fracture care codes. Column 5 shows the IWP/UT for each of the 62 codes. IWP/UT is an accepted RUC methodology for evaluating work RVUs and, in this case, IWP/UT serves to highlight the rank order anomalies for these codes. .060 is generally considered a reasonable surgical IWP/UT. None of the 62 codes has an IWP/UT at or above .060. Most surgical codes do not, and should not have an IWP/UT below .050, yet 2/3's (46 codes) of the 62 codes are below .050 and several are below .030 which is even lower than Evaluation and Management codes. CPT Code 27248 - *Open treatment of greater trochanteric fracture, includes internal fixation, when performed-now* has a negative IWP/UT. CPT Code 27514 - *Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed-now* has an IWP/UT of .023 and CPT Code 27511 - *Open treatment of femoral supracondylar or transcondylar fracture without intercondylar extension, includes internal fixation, when performed-* has an IWP/UT of .029. If the values for these codes are not corrected, they can never be used as comparison codes in future surveys.

B. Rank Order Anomalies Within All Fracture Treatment Codes

Rank order anomalies are not limited to these 62 codes as Table 3 below illustrates. This is a very small sample of the rank order anomalies within the larger set of all fracture care codes.³

As this table illustrates, the budget neutrality adjustments have completely disrupted the proper rank ordering of these procedures based on the relative work involved. For instance, CPT Code 27558- *Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair, with augmentation/reconstruction*-instead of being correctly ranked to be nearly the same work value as CPT Code 22318- *Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; without grafting*- at 22.00 is now incorrectly virtually

³ For a complete list of all fracture care CPT codes and the rank order anomalies within them, please see Appendix A.

identical to CPT Code 21336 -*Open treatment of nasal septal fracture, with or without stabilization*-at 18.25.

TABLE 3

	2007	RUC	2008	RUC REC	2008 REC
CPT	RVU	RVU	RVU	RANK ORDER	RANK ORDER
21436	30.01	30.01	30.01	1	1
27228	29.13	29.13	29.13	2	2
21433	26.13	26.13	26.13	3	3
27227	25.21	25.21	25.21	4	4
22319	25.15	25.15	25.15	5	5
27259	23.03	23.03	23.03	7	6
22318	22.54	22.54	22.54	8	7
21344	21.36	21.36	21.36	10	8
62010	21.30	21.30	21.30	11	9
27245	21.09	21.09	21.09	12	10
27218	20.93	20.93	20.93	14	11
22326	20.64	20.64	20.64	15	12
22327	20.52	20.52	20.52	16	13
31584	20.35	20.35	20.35	17	14
21435	20.02	20.02	20.02	18	15
22325	19.62	19.62	19.62	20	16
27506	19.42	19.42	19.42	21	17
27513	19.45	23.04	19.11	6	18
27254	18.80	18.80	18.80	23	19
27269		18.75	18.75	24	20
21366	18.44	18.44	18.44	25	21
27558	18.01	22.00	18.25	9	22
27828	18.19	20.00	18.20	19	23
23816	21.88	21.00	18.19	13	24
62005	17.53	17.53	17.53	26	25
27236	17.43	17.43	17.43	27	26
21348	17.36	17.36	17.36	28	27
28420	17.07	19.00	17.29	22	28
21470	17.24	17.24	17.24	29	29
27536	17.19	17.19	17.19	30	30
27244	17.08	17.08	17.08	31	31
21365	16.52	16.52	16.52	32	32
27258	16.04	16.04	16.04	33	33
27181	15.98	15.98	15.98	34	34

C. Rank Order Anomalies Within All Surgical Treatment Codes

Table 4 expands the rank order anomaly illustration even further by looking at CPT codes for other surgical procedures. Here again, the anomalies between the open fracture treatment codes and other surgical codes is apparent. For instance, CPT Code 27513- *Open treatment of femoral supracondylar or transcondylar fracture with intercondylar extension, includes internal fixation, when performed*-which the RUC concluded it involved exactly the same work as CPT Code 27447- *Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty.)* Now, 27513 is valued at 19.11 which is very similar to the work value for CPT Code 37215 - *Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection*. The RUC valued 28415-*Open treatment of calcaneal fracture, includes internal fixation, when performed*- at 17.54 in order for it to be very similar to the work value of 27236 - *Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement*. Instead it now as a work value of 15.96 that is nearly the same as CPT Code 65750 - *Keratoplasty (corneal transplant); penetrating (in aphakia)*. These are just a few examples of the several rank order anomalies that Table 4 illustrates.

TABLE 4⁴

	2007	RUC	2008	RUC REC	2008 REC
CPT	RVU	RVU	RVU	RANK ORDER	RANK ORDER
27487	26.91	26.91	26.91	1	1
44204	26.29	26.29	26.29	2	2
63051	25.38	25.38	25.38	3	3
27447	23.04	23.04	23.04	4	4
23472	22.47	22.47	22.47	6	5
50546	21.69	21.69	21.69	8	6
28705	20.12	20.12	20.12	10	7
37215	19.58	19.58	19.58	12	8
27513	19.45	23.04	19.11	5	9
27558	18.01	22.00	18.25	7	10
27828	18.19	20.00	18.2	11	11
23616	21.68	21.00	18.19	9	12
27236	17.43	17.43	17.43	16	13
27709	17.32	17.32	17.32	17	14
28420	17.07	19.00	17.29	13	15
58150	17.21	17.21	17.21	18	16
65750	16.6	16.6	16.6	19	17
28415	17.54	17.54	15.96	15	18
27557	17.31	19.00	15.76	14	19
29827	15.44	15.44	15.44	20	20

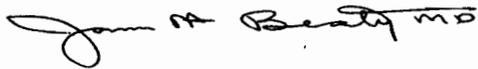
⁴ The work RVUs listed in Table 4 are all taken from the Multi-Specialty Points of Comparison (MPC) list and were included on the Reference Service list (RSL) for the Open Fracture Treatment codes.

4. Conclusion

The examples shown in the tables above illustrate how unbalanced the entire relative value scale is as a result of the budget neutrality adjustments applied by CMS to the 62 open treatment fracture care codes. Clearly there are dozens of other examples of significant rank order anomalies. We have to believe CMS did not intend to create these rank order anomalies. Rather they are the result of a technical error, one that can be easily remedied and reversed with a technical correction.

The AAOS appreciates the opportunity to comment on these important policy issues that affect our patients and our profession. We look forward to continuing our work together on behalf of Medicare beneficiaries and our nation's healthcare delivery systems.

Sincerely,



James H. Beaty, MD
President
American Association of Orthopaedic Surgeons

cc: M. Bradford Henley, MD, Chair, AAOS Coding, Coverage and Reimbursement Committee
Karen Hackett, FACHE, CAE, AAOS Chief Executive Officer
Robert Haralson, MD, MBA, AAOS Medical Director
Robert Fine, JD, CAE, Director, AAOS Health Policy & Governance Initiatives
Matthew Twetten, MA, AAOS Senior Policy Analyst

APPENDIX A-RANK ORDER ANOMALIES IN ALL FRACTURE CARE CODES

		PERIOD	OPT	RVA	RVA	RVA
1	1	90	21436	30.01	30.01	30.01
2	2	90	27228	29.13	29.13	29.13
3	3	90	21433	26.13	26.13	26.13
4	4	90	27227	25.21	25.21	25.21
5	5	90	22319	25.15	25.15	25.15
6	7	90	27259	23.03	23.03	23.03
7	8	90	22318	22.54	22.54	22.54
8	10	90	21344	21.36	21.36	21.36
9	11	90	62010	21.30	21.30	21.30
10	12	90	27245	21.09	21.09	21.09
11	15	90	27218	20.93	20.93	20.93
12	16	90	22326	20.64	20.64	20.64
13	17	90	22327	20.52	20.52	20.52
14	18	90	31584	20.35	20.35	20.35
15	19	90	21435	20.02	20.02	20.02
16	21	90	22325	19.62	19.62	19.62
17	22	90	27506	19.42	19.42	19.42
18	6	90	27513	19.45	23.04	19.11
19	26	90	27254	18.80	18.80	18.80
20	27	90	27269		18.75	18.75
21	28	90	21366	18.44	18.44	18.44
22	9	90	27558	18.01	22.00	18.25
23	20	90	27828	18.19	20.00	18.20
24	13	90	23616	21.68	21.00	18.19
25	30	90	62005	17.53	17.53	17.53
26	31	90	27236	17.43	17.43	17.43
27	32	90	21348	17.36	17.36	17.36
28	25	90	28420	17.07	19.00	17.29
29	33	90	21470	17.24	17.24	17.24
30	34	90	27536	17.19	17.19	17.19
31	35	90	27244	17.08	17.08	17.08
32	38	90	21365	16.52	16.52	16.52
33	40	90	27258	16.04	16.04	16.04
34	44	90	27181	15.98	15.98	15.98
35	29	90	28415	17.54	17.54	15.96
36	45	90	27177	15.94	15.94	15.94
37	24	90	27557	17.31	19.00	15.76
38	47	90	27216	15.73	15.73	15.73
39	48	90	24587	15.65	15.65	15.65
40	49	90	24586	15.64	15.64	15.64
41	36	90	28445	17.07	17.07	15.53

42	51	90	27226	15.45	15.45	15.45
43	14	90	27511	13.94	20.96	14.97
44	37	90	24546	15.99	17.00	14.73
45	55	90	27217	14.65	14.65	14.65
46	56	90	21395	14.62	14.62	14.62
47	41	90	27827	15.75	16.00	14.56
48	23	90	27514	19.09	19.09	14.46
49	57	90	27507	14.39	14.39	14.39
50	58	90	27759	14.31	14.31	14.31
51	60	90	25609	14.12	14.12	14.12
52	61	90	29856	14.12	14.12	14.12
53	62	90	21343	14.11	14.11	14.11
54	39	90	23585	9.15	16.25	14.07
55	66	90	27222	13.97	13.97	13.97
56	67	90	27179	13.83	13.83	13.83
57	68	90	62000	13.83	13.83	13.83
58	69	90	27240	13.66	13.66	13.66
59	70	90	27253	13.46	13.46	13.46
60	72	90	21347	13.37	13.37	13.37
61	42	90	27535	11.80	16.00	13.27
62	46	90	27519	15.80	15.80	13.11
63	73	90	29851	13.08	13.08	13.08
64	53	90	24545	10.88	15.00	12.99
65	54	90	23680	10.30	15.00	12.99
66	59	90	27823	14.26	14.26	12.98
67	52	90	25526	13.43	15.00	12.96
68	75	90	21465	12.88	12.88	12.88
69	76	90	27235	12.88	12.88	12.88
70	50	90	27556	14.95	15.50	12.86
71	77	90	27176	12.78	12.78	12.78
72	78	90	27178	12.78	12.78	12.78
73	79	90	21490	12.71	12.71	12.71
74	80	90	21408	12.67	12.67	12.67
75	81	90	27566	12.59	12.59	12.59
76	82	90	27758	12.40	12.40	12.40
77	64	90	23615	10.93	14.00	12.12
78	65	90	23670	8.02	14.00	12.12
79	63	90	25575	12.02	14.00	12.10
80	84	90	24516	12.07	12.07	12.07
81	89	90	24515	11.97	11.97	11.97
82	90	90	27232	11.66	11.66	11.66
83	91	90	27848	11.56	11.56	11.56
84	94	90	21340	11.33	11.33	11.33
85	95	90	21346	11.29	11.29	11.29
86	74	90	24579	11.96	13.00	11.26
87	96	90	27502	11.24	11.24	11.24
88	71	90	27540	13.45	13.45	11.16
89	97	90	27503	11.13	11.13	11.13

90	99	90	21390	11.07	11.07	11.07
91	83	90	27822	12.12	12.12	11.03
92	86	90	27826	8.97	12.00	10.92
93	87	90	28585	8.17	12.00	10.92
94	104	90	27252	10.92	10.92	10.92
95	105	90	25608	10.86	10.86	10.86
96	106	90	21462	10.77	10.77	10.77
97	107	90	21423	10.71	10.71	10.71
98	43	90	27248	10.80	16.00	10.64
99	108	90	29855	10.60	10.60	10.60
100	92	90	27814	11.10	11.50	10.46
101	93	90	28615	8.96	11.50	10.46
102	110	90	27215	10.45	10.45	10.45
103	88	90	23630	7.47	12.00	10.39
104	85	90	25525	12.69	12.00	10.37
105	113	90	27524	10.25	10.25	10.25
106	114	90	27846	10.16	10.16	10.16
107	115	90	27194	10.08	10.08	10.08
108	116	90	29892	10.07	10.07	10.07
109	103	90	27832	6.67	11.00	10.01
110	118	90	21387	10.00	10.00	10.00
111	121	90	27769		10.00	10.00
112	122	90	25685	9.97	9.97	9.97
113	123	90	22315	9.91	9.91	9.91
114	124	90	24582	9.89	9.89	9.89
115	125	90	24666	9.74	9.74	9.74
116	126	90	24615	9.72	9.72	9.72
117	127	90	27510	9.68	9.68	9.68
118	128	90	24538	9.63	9.63	9.63
119	98	90	26746	5.86	11.10	9.59
120	109	90	27792	7.91	10.50	9.55
121	100	90	24575	11.02	11.00	9.53
122	102	90	23515	7.47	11.00	9.53
123	101	90	25628	9.50	11.00	9.51
124	111	90	27784	7.41	10.45	9.51
125	130	90	28465	7.13	9.50	9.50
126	112	90	28555	6.42	10.43	9.49
127	132	90	21385	9.46	9.46	9.46
128	133	90	21386	9.46	9.46	9.46
129	134	90	25607	9.35	9.35	9.35
130	135	90	27175	9.29	9.29	9.29
131	136	10	22523	9.21	9.21	9.21
132	137	10	22520	9.17	9.17	9.17
133	138	90	21461	9.07	9.07	9.07
134	141	90	27517	8.98	8.98	8.98
135	142	90	21335	8.91	8.91	8.91
136	143	90	21407	8.91	8.91	8.91
137	144	90	21345	8.87	8.87	8.87

138	145	90	24566	8.86	8.86	8.86
139	146	10	22524	8.81	8.81	8.81
140	147	90	21432	8.76	8.76	8.76
141	148	90	23552	8.70	8.70	8.70
142	117	90	24635	13.56	10.00	8.64
143	119	90	25515	9.37	10.00	8.64
144	120	90	25574	7.47	10.00	8.64
145	131	90	27829	5.68	9.50	8.64
146	149	90	21422	8.62	8.62	8.62
147	150	10	22521	8.60	8.60	8.60
148	152	90	25695	8.40	8.40	8.40
149	154	90	21339	8.39	8.39	8.39
150	155	90	24665	8.22	8.22	8.22
151	129	90	24685	8.92	9.50	8.21
152	156	90	29850	8.18	8.18	8.18
153	157	90	25676	8.17	8.17	8.17
154	158	90	25606	8.10	8.10	8.10
155	159	90	23532	8.08	8.08	8.08
156	160	90	26686	8.06	8.06	8.06
157	161	90	27552	8.04	8.04	8.04
158	162	90	27509	8.02	8.02	8.02
159	164	90	28485	5.77	8.00	8.00
160	168	90	25670	7.98	7.98	7.98
161	170	90	25652	7.92	7.92	7.92
162	139	90	25545	9.09	9.00	7.78
163	140	90	26665	7.72	9.00	7.78
164	171	90	21431	7.74	7.74	7.74
165	151	90	27766	8.73	8.50	7.73
166	172	90	27266	7.67	7.67	7.67
167	173	90	21825	7.65	7.65	7.65
168	174	90	23660	7.55	7.55	7.55
169	175	90	23550	7.48	7.48	7.48
170	177	90	27532	7.43	7.43	7.43
171	178	90	23530	7.37	7.37	7.37
172	179	90	27756	7.33	7.33	7.33
173	180	90	21406	7.31	7.31	7.31
174	181	90	25645	7.31	7.31	7.31
175	166	90	28645	4.27	8.00	7.28
176	167	90	28505	3.86	8.00	7.28
177	153	90	26735	6.03	8.40	7.26
178	182	90	27202	7.25	7.25	7.25
179	183	90	27250	7.21	7.21	7.21
180	184	90	21454	7.17	7.17	7.17
181	185	90	29847	7.13	7.13	7.13
182	186	90	24620	7.07	7.07	7.07
183	187	90	21360	7.03	7.03	7.03
184	188	90	25605	7.02	7.02	7.02
185	189	90	27268		7.00	7.00

186	190	90	24535	6.96	6.96	6.96
187	191	90	21810	6.92	6.92	6.92
188	163	90	26685	7.09	8.00	6.91
189	165	90	26615	5.38	8.00	6.91
190	169	90	26715	5.79	7.95	6.87
191	192	90	21338	6.76	6.76	6.76
192	193	90	27220	6.72	6.72	6.72
193	194	90	27825	6.60	6.60	6.60
194	196	90	21336	6.56	6.56	6.56
195	197	90	21495	6.55	6.55	6.55
196	176	90	26785	4.25	7.45	6.44
197	198	90	28406	6.44	6.44	6.44
198	199	90	21453	6.40	6.40	6.40
199	200	90	25520	6.35	6.35	6.35
200	201	90	27501	6.34	6.34	6.34
201	202	90	27842	6.34	6.34	6.34
202	203	90	25671	6.32	6.32	6.32
203	204	90	27500	6.21	6.21	6.21
204	205	90	27752	6.15	6.15	6.15
205	206	90	23675	6.13	6.13	6.13
206	207	90	25680	6.08	6.08	6.08
207	208	90	27508	6.08	6.08	6.08
208	209	90	21445	6.04	6.04	6.04
209	213	90	27193	5.98	5.98	5.98
210	214	90	24577	5.87	5.87	5.87
211	215	90	27562	5.86	5.86	5.86
212	216	90	27550	5.84	5.84	5.84
213	217	90	21421	5.80	5.80	5.80
214	218	90	25565	5.71	5.71	5.71
215	195	90	26765	4.21	6.60	5.70
216	219	90	27230	5.69	5.69	5.69
217	220	90	21330	5.68	5.68	5.68
218	221	90	25651	5.68	5.68	5.68
219	222	90	24565	5.64	5.64	5.64
220	223	90	27238	5.64	5.64	5.64
221	224	90	26676	5.60	5.60	5.60
222	225	90	25690	5.58	5.58	5.58
223	226	90	27818	5.57	5.57	5.57
224	211	90	28525	3.37	6.00	5.46
225	212	90	28675	2.97	6.00	5.46
226	227	90	21451	5.46	5.46	5.46
227	228	90	27516	5.45	5.45	5.45
228	229	90	26608	5.43	5.43	5.43
229	230	90	26607	5.40	5.40	5.40
230	231	90	27267		5.38	5.38
231	232	10	27257	5.35	5.35	5.35
232	233	90	27762	5.33	5.33	5.33
233	234	90	25505	5.30	5.30	5.30

234	235	90	26727	5.30	5.30	5.30
235	236	90	24505	5.25	5.25	5.25
236	237	90	25535	5.22	5.22	5.22
237	238	90	27810	5.20	5.20	5.20
238	210	90	26650	5.80	6.00	5.19
239	239	90	26706	5.19	5.19	5.19
240	240	90	27265	5.12	5.12	5.12
241	241	90	27768		5.00	5.00
242	242	90	28606	4.97	4.97	4.97
243	243	90	27538	4.95	4.95	4.95
244	244	90	23605	4.94	4.94	4.94
245	245	90	26776	4.87	4.87	4.87
246	246	90	25660	4.84	4.84	4.84
247	247	90	24675	4.79	4.79	4.79
248	248	90	28436	4.78	4.78	4.78
249	249	90	25675	4.75	4.75	4.75
250	250	90	27246	4.75	4.75	4.75
251	251	90	26675	4.71	4.71	4.71
252	252	10	21356	4.70	4.70	4.70
253	253	90	27840	4.65	4.65	4.65
254	254	90	23655	4.64	4.64	4.64
255	255	90	28405	4.63	4.63	4.63
256	256	90	25624	4.62	4.62	4.62
257	257	90	27831	4.62	4.62	4.62
258	258	ZZZ	22328	4.60	4.60	4.60
259	259	90	21485	4.58	4.58	4.58
260	260	90	23665	4.54	4.54	4.54
261	261	90	27788	4.52	4.52	4.52
262	262	90	24655	4.48	4.48	4.48
263	263	90	28576	4.48	4.48	4.48
264	264	ZZZ	22525	4.47	4.47	4.47
265	265	90	25635	4.47	4.47	4.47
266	266	90	26645	4.47	4.47	4.47
267	267	90	27781	4.47	4.47	4.47
268	268	90	26756	4.46	4.46	4.46
269	269	10	21355	4.32	4.32	4.32
270	270	ZZZ	22522	4.30	4.30	4.30
271	271	90	26705	4.26	4.26	4.26
272	272	10	27256	4.25	4.25	4.25
273	273	90	23575	4.12	4.12	4.12
274	274	90	21325	4.07	4.07	4.07
275	275	90	26432	4.07	4.07	4.07
276	276	90	26641	4.01	4.01	4.01
277	277	90	23625	3.99	3.99	3.99
278	278	90	27530	3.97	3.97	3.97
279	279	90	26742	3.90	3.90	3.90
280	280	90	27560	3.88	3.88	3.88
281	281	90	27830	3.85	3.85	3.85

282	282	0	31630	3.81	3.81	3.81
283	283	90	26775	3.78	3.78	3.78
284	284	90	23505	3.74	3.74	3.74
285	285	90	26670	3.74	3.74	3.74
286	286	90	26700	3.74	3.74	3.74
287	287	90	22310	3.69	3.69	3.69
288	288	90	23525	3.67	3.67	3.67
289	289	90	21401	3.57	3.57	3.57
290	290	90	24530	3.57	3.57	3.57
291	291	90	21450	3.55	3.55	3.55
292	292	90	28476	3.46	3.46	3.46
293	293	90	28435	3.45	3.45	3.45
294	294	90	23650	3.44	3.44	3.44
295	295	90	26725	3.39	3.39	3.39
296	296	90	28575	3.38	3.38	3.38
297	297	90	23545	3.32	3.32	3.32
298	298	90	24500	3.29	3.29	3.29
299	299	90	21440	3.28	3.28	3.28
300	300	90	28546	3.28	3.28	3.28
301	301	90	21337	3.26	3.26	3.26
302	302	90	27750	3.26	3.26	3.26
303	303	90	27824	3.20	3.20	3.20
304	304	90	26755	3.15	3.15	3.15
305	305	90	28455	3.15	3.15	3.15
306	306	90	25650	3.12	3.12	3.12
307	307	90	27760	3.09	3.09	3.09
308	308	90	26770	3.07	3.07	3.07
309	309	90	23600	3.00	3.00	3.00
310	310	90	28475	2.97	2.97	2.97
311	311	90	27816	2.96	2.96	2.96
312	312	90	24576	2.94	2.94	2.94
313	313	90	25630	2.94	2.94	2.94
314	314	90	27520	2.93	2.93	2.93
315	315	90	26605	2.92	2.92	2.92
316	316	90	27786	2.91	2.91	2.91
317	317	90	27808	2.91	2.91	2.91
318	318	90	24560	2.87	2.87	2.87
319	319	90	21805	2.80	2.80	2.80
320	320	90	28605	2.78	2.78	2.78
321	321	10	28636	2.77	2.77	2.77
322	322	90	28456	2.75	2.75	2.75
323	323	90	27780	2.72	2.72	2.72
324	324	90	25600	2.69	2.69	2.69
325	325	90	25622	2.68	2.68	2.68
326	326	10	28666	2.66	2.66	2.66
327	327	90	24670	2.60	2.60	2.60
328	328	90	25500	2.51	2.51	2.51
329	329	90	28531	2.51	2.51	2.51

330	330	90	28545	2.51	2.51	2.51
331	331	90	25560	2.50	2.50	2.50
332	332	90	27767		2.50	2.50
333	333	90	26600	2.48	2.48	2.48
334	334	90	23620	2.46	2.46	2.46
335	335	90	28496	2.39	2.39	2.39
336	336	90	21452	2.29	2.29	2.29
337	337	90	23540	2.28	2.28	2.28
338	338	90	23570	2.28	2.28	2.28
339	339	90	24650	2.22	2.22	2.22
340	340	90	28400	2.22	2.22	2.22
341	341	90	23520	2.21	2.21	2.21
342	342	90	25530	2.15	2.15	2.15
343	343	90	28430	2.14	2.14	2.14
344	344	90	23500	2.13	2.13	2.13
345	345	90	28540	2.10	2.10	2.10
346	346	90	22305	2.08	2.08	2.08
347	347	90	26740	1.99	1.99	1.99
348	348	90	28470	1.99	1.99	1.99
349	349	90	28450	1.95	1.95	1.95
350	350	90	28600	1.94	1.94	1.94
351	351	10	28665	1.94	1.94	1.94
352	352	10	28635	1.93	1.93	1.93
353	353	90	27200	1.87	1.87	1.87
354	354	10	21320	1.86	1.86	1.86
355	355	10	21315	1.78	1.78	1.78
356	356	90	26750	1.74	1.74	1.74
357	357	10	28630	1.72	1.72	1.72
358	358	90	26720	1.70	1.70	1.70
359	359	90	28570	1.70	1.70	1.70
360	360	90	28495	1.62	1.62	1.62
361	361	90	28515	1.50	1.50	1.50
362	362	90	21400	1.44	1.44	1.44
363	363	90	21820	1.31	1.31	1.31
364	364	10	28660	1.25	1.25	1.25
365	365	10	24640	1.22	1.22	1.22
366	366	90	28490	1.12	1.12	1.12
367	367	90	28510	1.12	1.12	1.12
368	368	90	28530	1.08	1.08	1.08
369	369	90	21800	0.98	0.98	0.98
370	370	0	21480	0.61	0.61	0.61
371	371	0	21310	0.58	0.58	0.58

Submitter : Jodi Cotner
Organization : Jodi Cotner
Category : Nurse

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

In an attempt to collect data the may very well be unavailable due to patient condition, once again Emergency Care Providers and Hospitals may be required to absorb even more costs. Patients who are unconscious and have no identification and no family or friend available, are unable to provide information. Hopefully at some point after the patient is delivered to the hospital this information may become available, but it may only happen after diligent searching that may take hours or days, or may never become available. Sometimes people are not identified until after taken to the medical examiner.

This refinement puts an unfair burden on Emergency Healthcare Providers and should not be instituted.

Thank you for the opportunity to comment

**Refinement of RVUs for CY 2008
and Response to Public Comments
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

In an attempt to collect data the may very well be unavailable due to patient condition, once again Emergency Care Providers and Hospitals may be required to absorb even more costs. Patients who are unconscious and have no identification and no family or friend available, are unable to provide information. Hopefully at some point after the patient is delivered to the hospital this information may become available, but it may only happen after diligent searching that may take hours or days, or may never become available. Sometimes people are not identified until after taken to the medical examiner.

This refinement puts an unfair burden on Emergency Healthcare Providers and should not be instituted.

Thank you for the opportunity to comment

Submitter : Mrs. June Babineau
Organization : Naval Branch Health Clinic Key West, FL
Category : Federal Government

Date: 12/28/2007

Issue Areas/Comments

**Refinement of RVUs for CY 2008
and Response to Public Comments
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

December 28, 2007

Centers for Medicare & Medicaid Services
Baltimore, Maryland

Re: Docket: CMS-1385-FC - Revisions to Payment Policies Under the Physician Fee Schedule: Medicare Interim Final Rule Physician Fee Schedule 2008 related to codes 99441, 99442, 99443, 98966, 98967, 98968

Dear Sir:

I appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) interim final rule regarding revisions to payment policies under the proposed 2008 Medicare Physician Fee Schedule Docket CMS-1385-FC.

Case/care management is a collaborative process of assessment, planning, facilitation and advocacy for options and services to meet an individual's healthcare needs through communication and available resources (CMSA, 2002). As an essential part of the healthcare team, case managers routinely work directly with patients in support of medical management assessments, objectives, services, and health care coordination. The processes of health adherence assessment, education, and adherence monitoring are well within the scope of case/care management practice.

Professional case/care managers perform these responsibilities as a core function of their jobs. As licensed professionals, nurses, social workers case/care managers use proven techniques (e.g., evidenced-based practice guidelines, health literacy assessment, readiness to change tool) in working with patients, caregivers, and fellow healthcare professionals toward measurable improvement in health status.

Case/care managers work collaboratively with physicians and pharmacists in coordinating and providing assessments and management services through individualized care planning and care coordination in collaboration with beneficiaries, care givers and families. In support of those interventions and services, we ask for reconsideration of the interim payment rule on CPT codes: 99441, 99442, 99443, 98966, 98967 & 98968 from an N status to payable codes by Medicare. These codes represent assessment and management services to beneficiaries such as:

- " Transition of care
- " Medication reconciliation
- " Health literacy assessment, medication knowledge, readiness to change
- " Motivational interviewing
- " Patient education
- " Medical Home coordination

Failure to provide appropriate incentives and funding for these codes affects the alignment of care coordination quality between providers, especially at the various levels for transitions of care within settings, between settings, and between health states. Poor transitions of care may result in poor outcomes such as incorrect treatments, medication errors, delay in diagnosis and treatment, readmissions, patient complaints, increased health care costs).

I believe that by requesting funding support for these six codes, providers will more readily integrate case/care managers in support of the care management concepts such as the Medicare Medical Home Demonstration (MMHD), pay for performance programs, and various collaborative care models which CMS and other regulatory agencies are discussing.

I urge CMS to adopt a payable ruling structure for these much needed codes to ensure consistency, accountability, and improved quality of care for beneficiaries. I thank you for your consideration of these comments on this Interim Final Rule.

Sincerely,

June Babineau LCSW, C-ASWCM,
Case Manager
Naval Branch Health Clinic
1300 Douglas Circle
Key West, Florida 33040

Submitter : Ms. Deitzah Woll
Organization : Concerned Pathologists
Category : Health Care Professional or Association

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

Comments to Physician Self-Referral Provisions. Please see attachments.

CMS-1385-FC-213-Attach-1.DOC

CMS-1385-FC-213-Attach-2.DOC



SIDLEY AUSTIN LLP
ONE SOUTH DEARBORN
CHICAGO, IL 60603
(312) 853 7000
(312) 853 7036 FAX

BEIJING
BRUSSELS
CHICAGO
DALLAS
FRANKFURT
GENEVA
HONG KONG
LONDON

LOS ANGELES
NEW YORK
SAN FRANCISCO
SHANGHAI
SINGAPORE
SYDNEY
TOKYO
WASHINGTON, D.C.

dwooll@sidley.com
(312) 853-3456

FOUNDED 1866

December 28, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-FC
7500 Security Boulevard
Baltimore, MD 21244-8018

Re: CMS-1385-FC - Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions.

Dear CMS:

Concerned Pathologists appreciate this opportunity to comment on the Final Rule (CMS-1385-FC) published in the Nov. 27, 2007 Federal Register (72 Fed. Reg. 66222). On behalf of Concerned Pathologists, please accept the following comments regarding physician self-referral issues.

Sincerely,

Deitzah A. Woll

CMS-1385-FC

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL RULES

Concerned Pathologists submit these comments in response to the Physician Self-Referral rules and related comments portion of the final 2008 physician fee schedule rules adopted by the Centers for Medicare & Medicaid Services ("CMS").¹ We commend CMS for addressing the problems associated with various arrangements which provide ordering physicians an opportunity to profit from various pathology services. However, we urge CMS to monitor carefully developments in response to the anti-markup provisions. We agree that the concept of prohibitions on mark-ups has the potential of reducing abusive self-referral arrangements.

However, in our experience, CMS's new rules prohibiting mark-ups of lab tests not performed in the billing physician's office are unlikely to be effective in curbing abuses. Rather, we have already seen restructuring of the very abusive arrangements that are implicated by the new rule. Practices composed primarily of urologists, gastroenterologists or dermatologists that had set up abusive arrangements permitting them to profit from self-referrals have simply moved the site of their anatomic pathology labs. Labs previously located in a centralized building have now been moved to an "in-office" lab at a site used by the practice for physician services. The practices now require the independent contractor pathologist to read out the cases (at least the Medicare cases) at the practice's "in-office" lab. CMS's changes have not prevented practices intent on profiting from their referrals from doing so. Practices now just contract with an independent pathologist not otherwise connected with the practice to read out cases at the "in-office" lab, permitting mark-ups and profits to the referring physicians while still technically complying with CMS's rules.

We strongly urge CMS to consider broader rules to address arrangements which are the functional equivalent of the structures that are implicated by the anti-mark-up rules. CMS properly should prohibit all arrangements which provide financial incentives to referring physicians and thus violate at least the spirit of the Stark Act's prohibitions against physician self-referral. Below, we provide our comments on CMS's proposed rules, and we propose changes that we believe CMS should adopt to address the physician self-referral problem.

Comments on CMS's Anti-Markup Rule

CMS recognized that it would need to "monitor the effectiveness of our site-of-service approach in addressing our concerns regarding overutilization."² CMS acknowledged:

If arrangements that currently are taking place at a site other than the office of the billing physician or other supplier simply migrate to the "office of the billing physician or other

¹ 72 Fed. Reg. 66222 (November 27, 2007).

² 72 Fed. Reg. at 66317.

supplier” in order to escape the application of the anti-markup provisions, we may revisit the idea of imposing an anti-markup provision for services performed by a technician or physician who works for more than a certain number of physician practices.³

In fact, the ink was scarcely dry on the new regulations before practices intent on profiting from their referrals of pathology specimens simply re-structured. In point of fact, it is not that difficult to set up a histology/pathology lab in a relatively small space almost anywhere. Practices that had utilized a centralized building where no other physician services were performed have simply moved the operation to a building where the practice provides other physician services. While it is more burdensome on the pathologist to require all cases to be read out in the billing physician’s office, the practices have simply required the pathologist to do so. With these changes, the practices are able to continue profiting from the anatomic pathology cases they generate and refer.

CMS has recognized “that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic tests and then to realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization of services and result in higher costs to the Medicare program.”⁴ Yet, CMS’s current rules do not go far enough towards prohibiting referring physicians from profiting from their ordering of pathology services. The amendments do not prohibit referring physicians from establishing restructured relationships with pathologists which achieve the same objectives.

Regardless of where pathology services are performed and how contractual relationships between referring physicians and pathologists are characterized, the regulations should seek to remove the profit incentive from referring physicians. As long as referring physicians can directly profit from pathologists’ Medicare services, referring physicians will have a financial incentive to overutilize services payable by the federal government.

Concerned Pathologists’ Proposal

Amendments to Reassignment Provisions

In the past, CMS has suggested that one way of addressing the financial self-interest concerns is to ensure that the referring physician, or the physician ordering the test, be financially independent of the physician or medical group performing the interpretation.⁵ We recognize that the anti-markup provisions are an attempt to address the need for financial independence. Unfortunately, merely requiring that anatomic pathology tests provided by an independent contractor pathologist be performed in the same space

³ *Id.*

⁴ 71 Fed. Reg. 48981, 49054 (Aug. 22, 2006).

⁵ 71 Fed. Reg. at 49056.

where a practice sees patients does nothing to ensure that the test is performed by an entity that is financially independent from the referring physician.

We recognize that true multi-specialty group practices should be permitted to perform anatomic pathology services for patients of the group practice. It is critical, however, that the privilege of performing and billing for anatomic pathology services be limited to group practices that place pathologists on an equal footing with other members of the group practice. In general, that means that a practice should not be able to mark-up the services of a part-time pathologist who maintains a separate practice and is not integrated into a practice in the same way as other specialists included in the group practice, regardless of where the pathology services are performed.

We propose applying the anti-markup prohibition to all pathology arrangements except where the pathologist is a full-time employee or shareholder in the group practice. In circumstances where a pathologist is only providing services part-time in the group practice and also maintains a separate practice, the referring physician should not be able to mark-up charges from the amount paid to the pathologist for the services.

Amendments to 42 C.F.R. § 411.352

In addition to the reassignment regulations, the Stark regulations should also be tightened up to preclude the “pro-forma” group practices that are thinly veiled disguises to financial relationships providing a financial benefit to referring physicians. In order to do so, we propose a new prong to the definition of “group practice”, § 411.352(j), which ensures that referring physicians within a group practice cannot profit from reassigned Medicare payments for pathology services performed by members of, or physicians in, the group practice. Note, we propose limiting the application of the rule to those specialties that have been the most prominently identified as involved in pod labs and other similar financial arrangements providing them with a financial incentive for their referrals of pathology specimens.

- (j) *Special rule for allocating profits derived from pathology services.* Notwithstanding § 411.352(i), in a group practice composed of (1) Gastroenterologists, Urologists and/or Dermatologists who comprise at least seventy-five percent of the physicians in the group and (2) one or more Pathologists in the group who provide pathology services for the other members of the group practice, all of the revenues derived from pathology services shall be used exclusively to pay for the direct costs of the pathology services and compensation of the physicians performing or supervising pathology services, except that pathology may be asked to make a contribution to the overhead of the practice that does not exceed, as a percentage of net revenues, the percentage contribution to overhead made from revenues of the other specialties.

The intent of the foregoing language is to prohibit, as part of the regulatory requirements for a qualifying group practice, the referring specialties from profiting from the pathology services to which those physicians refer. Referring physicians should not be able to avoid a prohibition on profiting from referrals through the creation of a “pro forma” group practice that is the functional equivalent of the pod lab.

Conclusion

We appreciate this opportunity to comment on CMS's proposed rules. While we commend CMS for taking a strong first step towards the elimination of pod labs, we respectfully request that CMS expand the scope of its rulemaking and address the more fundamental problem of contractual arrangements that allow referring physicians to profit from the Medicare services performed by pathologists.

Submitter :

Date: 12/28/2007

Organization :

Category : Nurse

Issue Areas/Comments

**Refinement of RVUs for CY 2008
and Response to Public Comments
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

The proposed changes would require transport crews to spend additional out of service time attempting to obtain documentation above and beyond the current rule as well as BURDENING ill or injured patients, distressed family members and taking emergency department staff away from their role as care providers to satisfy compliance with this rule.

If this rule change is implemented it will still need CMS oversight and auditing for compliance and enforcement, no less than what the current rule requires.

Instead of implementing this rule it would be PREFERRED that CMS exercise greater enforcement of the current rule on those who are not in compliance instead of shifting the burden back onto those who do comply.

Submitter : Mrs. Liz Herring
Organization : Tarrant County Emer. Med. Services Organization
Category : Other Health Care Provider

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

The proposed changes regarding increasing the requirements for signatures to document patients transported by ambulance would increase the cost of providing ambulance service by requiring ambulance crews to spend additional time out of service at hospitals while attempting to obtain documentation above necessary to satisfy compliance with this rule.

If this rule change is implemented it will still need CMS oversight and auditing for compliance and enforcement, no less than what the current rule requires. Instead of implementing this rule CMS should exercise greater enforcement of the current rule on those who are not in compliance instead of further burdening those who do comply.