Submitter : Mr. Carl McClellan **Date:** 12/21/2007

Organization : Winchester Fire & Rescue Department

Category : Local Government

Issue Areas/Comments

GENERAL

GENERAL

I can understand the rule being necessary for non-emergent Ambulance transport providers. However, for 911 services such as ours, I find the new rule detrimental to patient care. With the new rule our providers must now have to worry more about making sure they obtain an appropriate signature prior to loading the patient and transporting them to a hospital. So, thanks for not thinking about what is in the best interest (immediate treatment) of our Citizens when they have a medical emergency. Thanks also for punishing all emergency 911 service agencies and providers by making their jobs more difficult because you would rather make your job easier in detecting fraudulent practices. As an American Citizen I appreciate your lack of concern for what is in the best interest of a sick or injured patient.

Submitter : Mr. Christopher Dick **Date:** 12/21/2007

Organization : Western Eagle County Ambulance District

Category : Local Government

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS

The new regulations including new signature requirements for ambulance providers will impose substantial burden on all ambulance providers, whether public, private or non-profit. We feel the new signature requirements should not be required and the rule should be revised.

The new signature guidelines are not clear as they have been written and they seem to place substantial burden on EMS field providers to do their job and help with the billing process for Medicare patients. We are quite confused by the new rules and are not even clear on which patients fall under this rule. We also feel CMS is being shortsighted in the implementation of this rule as they have not even provided instructions to their Medicare contractors as to how the regulations should be applied.

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.

Thank you in advance for reviewing my comments.

Sincerely,

Christopher Dick, Deputy Chief
Western Eagle County Ambulance District, Eagle, CO

Submitter : **Robert Latimer** **Date: 12/21/2007**

Organization : **Northern Dutchess Paramedics**

Category : **Other Health Care Professional**

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

In the provision of ambulance service patient contact times are brief, morbidity is often high, and recurrent utilization is frequent, it is difficult to obtain signatures, or alternatives under the current mandate. To place more, and in the case of ambulance service redundent obligations on providers is to in essence compromise care. MMS needs to streamline reocrd keeping, not increase the already burdensome requirements.

Submitter : **Dean Bollendorf** **Date: 12/21/2007**

Organization : **Em-Star Ambulance Service**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

The final rule requiring new signature requirements for ambulance providers will create a new operational burden and increase our costs to provide services at a time when ambulance providers are struggling to survive - the recent GAO report indicates ambulance providers are paid on average 6% less than the cost to provide the service.

Thank you.

Submitter : **Dr. Rick Kellerman** **Date: 12/21/2007**

Organization : **American Academy of Family Physicians**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-FC-158-Attach-1.DOC

#158

AMERICAN ACADEMY OF FAMILY PHYSICIANS

STRONG MEDICINE FOR AMERICA

December 19, 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 21244-1850

Dear Mr. Weems:

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents nearly 94,000 physicians and medical students nationwide. Specifically, I am writing to offer our comments on the final rule regarding revisions to payment policies under the Medicare physician fee schedule and other Part B payment policies for 2008 as well as the amendment of the e-prescribing exemption for computer-generated facsimile transmissions. CMS published the final rule in the *Federal Register* on November 27, 2007, and invited comments on the interim relative value units (RVUs) for selected codes identified in Addendum C of the rule. Before commenting on those codes, we will offer our comments on a few other issues addressed in the final rule.

Budget Neutrality/Five-Year Review Work Adjuster

Do Not Use the Work Adjuster. We were deeply disappointed to read in the final rule CMS's announcement that the Five-Year Review Work Adjuster will increase from -10.10% to -11.94%. The AAFP strongly urges CMS to eliminate this work adjuster and return to the budget neutrality approach that it used from 1998 to 2006, when it implemented all work neutrality adjustments by adjusting the Medicare conversion factor.

As we noted in our comments on the proposed rule, applying budget neutrality to the work RVUs to offset the improvements in E/M and other services is bad policy and a step backward. It is an ongoing distortion to the relativity of services in the Medicare physician fee schedule, and as we feared, private payers have copied this distortion in setting their own fee schedules. We strongly urge CMS to abandon the work adjuster and instead apply any necessary budget neutrality adjustments to the conversion factor.

TRHCA – Section 101(d): Physician Assistance and Quality Initiative (PAQI) Fund

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11400 Tomahawk Creek Parkway • Leawood, KS 66211-2672 • 800 274 2237 • 913 906 6000 • Fax 913 906 6075 • fp@aafp.org

Use PAQI to offset negative conversion factor. We were equally disappointed to learn that CMS finalized its proposal to use the entire $1.35 billion PAQI fund to make bonus payments during 2009 for physician reporting of quality measures during 2008 rather than offset some of the negative 10.1% update forecast for the 2008 conversion factor.

As stated in our comments on the proposed rule, we oppose CMS's use of the entire PAQI fund to pay Physician Quality Reporting Initiative bonuses. Instead, we support the use of the PAQI to offset any negative Medicare conversion factor update in 2008. We find it hard to understand CMS's refusal to do anything to attempt to offset the negative update forecast for the conversion factor. Congress is poised to provide a 0.5% update for the first six months of 2008, which will delay but not prevent the negative 10.1% update referenced in the final rule. We can appreciate CMS's desire to pay for quality care, *but family physicians will be hard pressed to provide any care to Medicare patients* if Medicare proceeds to reduce its payments by 10.1% in 2008, with additional cuts in the years to follow.

Physician Self-Referral Provisions

Do not implement any of proposed anti-markup provisions in current form. We were pleased to read that, with one exception, CMS elected not to finalize any of the proposals related to the physician self-referral issue in this final rule. As noted in our comments on the proposed rule, we had concerns about some of the changes in the proposed rule and thought that those changes would make it even more difficult for physicians to participate in legitimate business ventures without the fear of inadvertent violations. We appreciate that CMS followed the advice of the AAFP and others not to implement the proposed changes until the full potential impact on both physicians and their Medicare patients can be determined.

Regrettably, CMS did elect to finalize, for implementation effective January 1, 2008, its proposal regarding the anti-markup provision of the technical and professional components of diagnostic tests. The anti-markup rule, which is based on Section 1842(n) of the Social Security Act, precludes physician practices from "marking up" certain diagnostic tests. The statute specifically excludes diagnostic tests that are performed personally by, or supervised by, the billing physician or another physician "with whom [the billing physician or entity] shares a practice." Accordingly, the implementing regulation, 42 C.F.R. § 414.50, currently limits application of the anti-markup rule to the technical component of diagnostic tests purchased from an outside supplier.

The proposed rule stated CMS's intent to tighten and clarify the anti-markup rule as it applies to technical component services and extend it to the professional component of diagnostic tests. It did not propose extending it to diagnostic services provided within a physician group.

Under the final rule, however, CMS expanded the anti-markup rule to apply to services provided within a group practice. Specifically, CMS expanded the anti-markup rule to apply to both the professional component and the technical component of a diagnostic test provided "outside of the office" of the billing entity. Notably, when the billing entity is a "physician organization" [i.e., a "group practice" for the purposes of the federal restriction on physician self-referral], the "office of the billing physician or other supplier" is defined narrowly as "space in which the physician organization provides *substantially the full range of patient care services* that the physician organization provides generally." [Emphasis added.]

Where a diagnostic test is provided in a place other than the location (if any) where a physician group provides substantially the "full range" of its patient care services, the group will be required to include a "per procedure" charge on the Medicare claim for the test, as if the group were purchasing the test from an outside supplier rather than providing it directly. The practice will then be paid the lesser of the physician fee schedule amount or the internally generated "charge." If no "charge" is reported on the claim, the practice will not be paid, and the group may be subject to significant sanctions.

Significantly, while there is no definite guidance on how to calculate a "per procedure" charge for services performed by an employee technician or physician, the preamble of the rule suggests that the employee's salary should be the sole factor used in determining the charge. In other words, physicians and medical groups may not be paid for equipment, facility, overhead or any other expenses for providing diagnostic procedures that they are legally entitled to provide under the federal physician-self referral regulations.

Strict application of this expanded anti-markup rule could lead to nonsensical results. For example, under the rule, a sole practitioner who reads an x-ray in a rehabilitation facility would be required to generate a charge to himself.

In some situations, it is unclear whether there will be <u>any</u> location where the group provides the "full range" of its patient care services, and ironically, the larger a group practice is, the less likely that it will have any space where it provides the "full range" of its services. For example, consider a large multi-specialty clinic whose services are located throughout a medical complex. There may be <u>no</u> office where the "full range" of services is provided: Hence the anti-markup prohibition may apply regardless of where the diagnostic test is provided.

We believe that the application of the anti-markup rule to services provided within a bona fide group practice far exceeds CMS's statutory authority; the statute specifically precludes application of the rule to services provided by physicians who "share a practice." Moreover, the expansion of the rule to services provided within group practices was never subject to notice and

comment rule making, and is implicitly inconsistent with the federal self-referral regulations, which explicitly authorize group practices to provide these services.

In addition, the rule is ambiguous on its face; clearly, providers will struggle to understand the impact of this rule and to comply by the January 1, 2008, effective date. Some will incur needless expense to move equipment and modify facilities. Many others will be unable to comply with the new site of service test, and will either have to develop a new system for charging themselves for diagnostic services provided in an off-site location, or cease providing diagnostic tests to Medicare patients, forcing them to travel elsewhere to get the tests they need.

For all of these reasons, we urge CMS to delay implementation of this provision in order to evaluate the substantial impact these changes will have on physicians and other health care providers.

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Do not require NCPDP SCRIPT in computer-generated faxes at this time. In the proposed rule, CMS proposed to eliminate the exemption for computer-generated faxes from the e-prescribing standards. Currently, entities that transmit prescriptions or prescription-related information by means of computer-generated faxes are exempt from the requirement to use the adopted National Council for Prescription Drug Programs' (NCPDP) SCRIPT standard.

In the final rule, CMS amended its proposal. Effective January 1, 2009, electronic transmission of prescriptions or prescription-related information by means of computer-generated facsimile is only permitted in instances of temporary/transient transmission failure and communications problems that would preclude the use of the NCPDP SCRIPT Standard.

As noted in our comments on the proposed rule, the Academy is very supportive of standards based e-prescribing and of the NCPDP SCRIPT standard for that purpose. However, the issue remains that there are forces outside the control of physicians that limits their ability to do true e-prescribing. Specifically, e-prescribing technology has not been perfected by its developers, and recurrent failures are noted in the available e-prescribing systems. Further, the receiving parties (i.e., pharmacies) have not fully integrated this technology, and in many rural areas, it is simply not possible to e-prescribe to the pharmacy since they do not have the capability to receive despite the physician's implementation of the system. For these reasons, many of the physicians faxing prescriptions now will move back to paper instead of moving forward to true e-prescribing as a result of this provision, which is exactly opposite of CMS's intent.

We believe that one of the core tenets of the Medicare Modernization Act is to improve the quality, safety, and efficiency of care delivery. By effectively removing this exemption for computer-generated facsimile transmission in all but the limited circumstances of temporary/transient transmission failure and communications problems that would preclude the use of the NCPDP SCRIPT Standard, CMS will cause quality, safety, and efficiency to suffer as physicians are forced to revert back to paper-based prescriptions. To truly move e-prescribing forward, CMS should initiate an incentive for all stakeholders, not restrict the electronic transmission of prescriptions from physicians.

Anticoagulation Management

Anticoagulation management should not be bundled. The Academy strongly disagrees with the CMS decision to continue to consider anticoagulation management codes (99363 and 99364) to be bundled into the work of E/M codes. We are especially frustrated by CMS's position since the initial impetus for the creation of these codes was the statement by CMS that these services were not managed as well as they should be and that the existing coding structure failed to provide incentives to optimize care. During the creation of the code, the Current Procedural Terminology (CPT) editorial panel and the RUC were very careful to create protections in the code that would prevent work from anticoagulation management being included in selecting the level of E/M codes.

CMS's rationale for its position, as offered in the final rule, said:

> We generally do not pay separately for disease-specific management services. We believe the services represented by CPT codes 99363 and 99364 are inherent in the services captured by the existing E/M codes. We will continue to recognize codes 99363 and 99364 as bundled services and continue to pay for E/M services as appropriate.

These CPT codes are recognition of the important work of managing serious disease, and the CMS decision to not pay separately for this service could have a devastating impact. Anticoagulation management is of paramount importance in light of the increasing prevalence of cardiovascular and related diseases as the leading cause of death. As therapy is improved, many patients are identified to have a need for anticoagulation, and anticoagulation therapy is one with a potential for life-threatening outcomes if not properly managed. The burden is placed upon the primary care physician in the community where the patient resides to assist with compliance. Yet, thanks in part to policies such as CMS's, payment for anticoagulation management remains non-existent to inadequate, thus increasing the risk for non-compliance if physicians can no longer tolerate the financial loss.

The Academy strongly encourages CMS to reverse its position that these services are bundled and instead change their status to a separately payable, covered service. Anticoagulation management services are an important responsibility, and CMS should recognize the extensive work involved by paying separately for this service.

Interim RVUs (Addendum C)

Cover electronic visits. In the final rule, CMS published the RUC recommendations for several new non face-to-face services, including the new codes for telephone E/M services (99441-99443) and the new code for an online E/M service (99444). However, we were disappointed to see that CMS chose to not cover the codes describing these services because the services are not face-to-face and because the code descriptors include language that recognizes the provision of services to parties other than the beneficiary and for whom Medicare does not provide coverage (e.g., patient's guardian). Because these codes were designed to also apply to pediatricians, it is critical for a parent initiated phone call to be included. We believe that these concerns could be specifically addressed with the CPT Editorial Panel, and we urge CMS to reconsider the coverage status for these services.

We appreciate this opportunity to comment on matters related to the Medicare Fee Schedule. As always, the American Academy of Family Physicians looks forward to working with CMS in its continued efforts to ensure access to appropriate physician services.

Sincerely,

Rick Kellerman MD

Rick Kellerman, M.D.
Board Chair

Submitter : Mr. Wayne Briscoe **Date:** 12/21/2007

Organization : Frankfort Fire and EMS

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

As an Administator of a Fire based EMS service, I wish to inform you of the negative impact this final ruling will cause. I wish that you would reconsider this rule untill until the impact of any change
from the current regulations can be fully evaluated and the many questions that have arisen since publication of the final regulations before re-publishing any changes to the current signature regulations. Signatures are getting very difficult to obtain as when we arrive at ED they are swept to X-ray, CT or other testing sites within the hospital making it impossible to obtain signatures. With this final rule, you are sending the notion that a patients signature is more important than receiving good quality of care. What happens when there are no famliy members, patients unable to read/write, are we as public health providers expected to write off the patients bill. How is it that you obtain an unresponsive patients signature. I wish that all parties involved in this rediculous final rule, please revisit the issue, as this is going to affect over all patient care, as providers will be more worried about obtaining signatures than providing quality patient care.

Submitter : **Kraig Kinney** **Date: 12/21/2007**

Organization : **Putnam County Operation LIfe**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

Putnam County Operation Life is a non-profit organization that has served as the county 911 ambulance provider since 1974. We provide convalescent transports for all six (6) county Extended Care Facilities. There are no other ambulance services or a wheelchair van service available in this county. To be frank, with Medicare and Medicaid reimbursement rates, we do the convalescent transports as a public service and not based upon financial incentive. We comply with billing requirements and use a Billing Form that includes the required Assignment of Benefits signatures. When a patient is unable to sign currently and a family member is unavailable, our crew will sign an additional line noting that the patient is unable to sign and a reason. We also verify the patient status on the Physician Certification Statement (PCS) to see if it corresponds with the crew's assessment.

Our primary concern is that the new signature rule/contemporaneous statement creates the need for additional signatures when a patient is unable to sign. These signatures require a staff member of a facility to sign indicating the patient is unable to sign. In our area, we have found ECF staff and hospital staff very hesitant to give signatures for any paperwork. The staffs are very busy and they also question why. We have NO enforcement authority or any mechanism to force signatures. We are totally reliant upon the third paties to cooperate when they receive nothing in return. Even when the form clearly states that the signature does not financially obligate the person signing, facility staff remain very concerned to sign when they see that it is a billing. This does not account for the fact that facilities are very busy and so are their staff. Waiting for signatures from staff will be a burden in a busy system but will also be a burden to our ambulances which need to return to service as quickly as possible.

We also belicve there is confusion over the lifetime signatures if the new changes are approved as proposed. Are these provisions still effective? It is our belief that the lifetime signature is still valid for the Assignment of Benefits. Does the lifetime signature apply to the new signature rule? That would alleviate some of the burden of the new rule.

To close, for a rural ambulance provider (or supplier in CMS terminology)that is doing emergency responses and non-emergency responses in the absence of alternative transport such as wheelchair transport, these proposed rule changes are just too much of a burden. If we encounter too much difficulty in the complying with the new rules, we will be forced to focus on emergency transports which could leave the elderly in the county without a viable option for non-emergency transport. This would be a sad and tragic outcome.

Submitter : **Brian Whitman** **Date: 12/21/2007**

Organization : **American College of Physicians**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-FC-161-Attach-1.DOC

#161

December 21, 2007

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-FC
PO Box 8020
7500 Security Boulevard
Baltimore MD 21244-8020

Attention: CMS-1385-FC

Dear Mr. Weems:

The American College of Physicians (ACP), representing more than 124,000 physicians specializing in internal medicine and medical students, is pleased to offer comments on the Center for Medicare and Medicaid Services (CMS) final rule with comment period *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions [CMS 1385-FC]* published in the *Federal Register* on November 27, 2007. As the specialty that provides more care to Medicare beneficiaries than any other, internal medicine is particularly affected by the final rule.

Resource-Based Practice Expense (PE) Relative Value Units
ACP continues to urge CMS to change the utilization assumption for equipment. ACP does not believe that the current 50% assumption of the equipment utilization rate accurately reflects the rate of usage in most cases. CMS has acknowledged that the current assumption is arbitrary and not based on a review of data. CMS also notes in this final rule that many stakeholders have weighed in on this issue, so CMS should have a good understanding of the potential issues of associated with revaluation that would occur as a result of an use assumption change. ACP urges CMS to issue a proposal to change utilization assumptions based on available data in the proposed rule for the 2009 Medicare physician fee schedule scheduled to be published in July of 2008. Specifically, ACP urges CMS to establish equipment mutually exclusive equipment categories each of which has an assigned percentage utilization rate and to ensure that any "savings" that result from these changes are put back into the physician payment pool of dollars to be redistributed through payments to all other services.

Physician Self-Referral Issues

ACP appreciates the CMS decision to further consider the impact of the self-referral proposals that were included in the proposed rule and the decision not to finalize them at this time. These rules can have a significant impact on physicians and must be carefully

considered before implementation. ACP urges CMS to continue to consider potential access issues that may result from further reductions on available exceptions.

ACP is concerned that CMS significantly expanded the proposal to prohibit the marking-up of diagnostic tests. While CMS had proposed an expansion of the anti-markup rule to the technical component of services purchased from an outside supplier, the final rule appears to apply these requirements to services provided within a group practice, but in separate buildings. ACP urges CMS to clarify if this anti-markup rule is intended to apply to employees of physician groups that are unable to bill Medicare for their services. ACP believes that this rule is still very confusing and requests that CMS delay implementation.

E-prescribing Standards; Computer-Generated Facsimile Exemption

ACP is disappointed with the CMS decision to finalize its rule that will eliminate the computer-generated facsimile exemption to e-prescribing standards starting in 2009. As ACP stated in its comments on the proposed rule, the elimination of this exemption is more likely to result in physicians reverting to the use of paper-based prescriptions, which will only make it more difficult to move to electronic prescribing in the future.

Division B of the Tax Relief and Health Care Act of 2006 – Medicare Improvements and Extension Act of 2006 (Pub. L. 109-432) (MIEA-TRCHA)

ACP appreciates the CMS decision to finalize its proposal to require Physician Quality Reporting Initiative (PQRI) measures to be either be endorsed by the National Quality Forum (NQF) or adopted by the AQA. ACP continues to recommend a prominent and expansive role for the AQA so that it can continue to provide valuable contributions in this area.

ACP supports the inclusion of structural measures in the PQRI program and recommends that CMS consult with NQF and AQA to define structural measures for future use so that they are developed with the same level of consideration and physician input as other measures used in the PQRI program.

Interim Relative Value Units

Home/Domiciliary/Nursing Facility Visits
ACP appreciates the CMS decision to incorporate the recommendations of a refinement panel and increase the work values for a number of home and domiciliary visit codes. These codes represent important services to some of the sickest Medicare beneficiaries and it is important that the work of the physicians who provide these services is accurately reflected in the relative value units. ACP also appreciates the CMS decision to finalize increased values for nursing home services as proposed.

Anticoagulation Management

ACP is disappointed by the CMS decisions to continue to consider codes 99363 and 99364 for anticoagulation management to be bundled into existing evaluation and management service codes. Addressing CMS concern that warfarin therapy is not managed as well as it could be in the Medicare population was a key factor in the ACP decision to propose the creation of these codes. The CMS decision to consider these services bundled into existing E/M services makes it very difficult for physicians to financially justify offering this important service to a needy population. CMS must recognize the true impact of chronic disease on the spending of the Medicare program, in which 80% of the patients, and begin to consider more innovative solutions to paying for the services provided to these patients.

Interim Relative Value Units for New and Revised Physician's Current Procedural Terminology

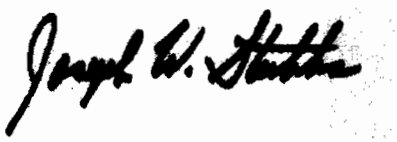
Non Face to Face Services
ACP disagrees with the CMS decision to consider the provision of E/M services by phone and through online mechanisms (99441-99444) to be considered non-covered services. CMS indicates that it is not paying for these services because they are not provided on a face-to-face basis with the patient. ACP is not aware of any statutory exclusion from benefits of non-face-to-face services and notes that Medicare pays for other services that are not provided on a face-to-face basis, such as care plan oversight services for beneficiaries receiving home health care and care from a hospice. ACP understands that most phone calls that are provided by physicians would not be reported using these codes, but it is unclear why CMS would provide a barrier that would prevent patients from seeking care in the most efficient form of care from their physicians—as a phone or e-mail service would be most efficient in some circumstances. The codes were carefully defined to ensure appropriate clinical use and to make clear the circumstances in which they can be billed. ACP is educating its members regarding how to use these codes. Further, these, as with other physician services, would need to be appropriately documented, which would allow audits to prevent fraud and abuse.

If CMS continues to consider these services to be non-covered, ACP urges CMS to release guidance to physicians on how they may be able to charge beneficiaries for these non-covered services so that they are in compliance with all applicable Medicare requirements.

Reporting of Alcohol and/or Substance Abuse Assessment and Intervention Services
ACP appreciates the CMS effort to provide coverage for substance abuse assessment and intervention services, but finds it unfortunate that physicians will be required to report Medicare-only G codes in order to report this service. Medicare should endeavor to pay for CPT codes when at all possible in order to make the coding system as simple as possible for physicians and others. Requiring separate codes for Medicare and other payers is likely to lead to mistakes and denials on a more frequent basis than if a uniform coding set was used.

ACP appreciates the opportunity to comment on this final rule. If you have questions or would like to discuss these issues further, please contact Brian Whitman, Senior Analyst, Regulatory and Insurer Affairs at (202) 261-4544 or bwhitman@acponline.org

Sincerely,



Joseph W. Stubbs, MD, FACP
Chair, Medical Service Committee

#162

CMS-

Because the referenced comment number does not pertain to the subject matter for CMS- , it is not included in the electronic public comments for this regulatory document.

Submitter : **Ms. Lisle Soukup Poulsen** **Date: 12/21/2007**

Organization : **American Society for Dermatologic Surgery**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-FC-163-Attach-1.DOC

CMS-1385-FC-163-Attach-2.DOC

#163

ASDS
American Society for Dermatologic Surgery

December 21, 2007

The Honorable 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 21244-1850

Re: CMS 1385-P: 2008 Medicare Fee Schedule
Coding – Multiple Procedure Reduction Rule for Mohs Surgery

Dear Acting Administrator Weems:

As President of the American Society for Dermatologic Surgery (ASDS), a medical specialty organization representing over 5000 dermatologic surgeons, including the vast majority of those performing Mohs micrographic surgery, I would like to thank you for the opportunity to comment on the change in the exempt status of Mohs surgery codes 17311 and 17313 from the Multiple Procedure Reduction Rule (MPRR).

We are concerned that the proposed rule, which is a significant reversal of CMS' own longstanding exemption of the Mohs codes from the MPRR, represents a misunderstanding of the separate and unique nature of Mohs surgery relative to other procedures on the same day. This inappropriate application of the MPRR will have a negative impact on Medicare beneficiaries' access to timely care, with a potential increase in risk and cost.

Back in 1991, CMS determined that the Mohs codes were indeed separate and distinct procedures, for which an exemption from the Multiple Procedure Reduction Rule was appropriate. CMS stated at that time that Mohs surgeries "are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures...They will be paid separately with no multiple surgery reductions." We believe this determination by CMS was correct, and note that the exemption has been maintained ever since.

At the request of CMS in the 2006 five-year review of the Mohs codes, we worked with AMA CPT/AMA RUC to develop two new base codes, 17311 and 17313, to reflect Mohs surgery on different anatomic sites. The new codes differed only in the specification of anatomic site. Although new codes were created, there were and have been no changes in the "technical elements of the procedure" that should alter CMS' original determination that exemption was appropriate. The AMA CPT/AMA RUC review of the new codes and descriptors did not change the characteristics that qualified the new 17311 and 17313

codes for inclusion on the modifier -51 exemption list. While the old Mohs surgery code was deleted with the adoption of the new codes, the nature of the procedure has not changed, nor should the exempt status of the new codes change.

The basis for CMS's original exemption related to an examination of the procedure itself. Mohs surgical excision of a skin cancer includes meticulous excision of the tumor and complete histopathologic examination of the margins. The excision of tumors is completed in stages, such that each stage must be completed in entirety prior to subsequent stages or repair. Each stage consists of

5550 Meadowbrook Drive, Suite 120 Rolling Meadows, IL 60008 Tel. 847-956-0900 Fax. 847-956-0999 www.asds.net

rooming the patient, discussing, positioning, anesthetizing, prepping, draping, excising, dressing, mapping, inking, processing, and interpreting the histopathology; stages are repeated until tumor margins are clear.

Treatment of multiple tumors at the same time requires each component be completed for each tumor. The patient waits during the processing and interpretation portions of the procedure. Repair procedures following Mohs tumor excision require that all the same steps be undertaken again (except the tissue processing and interpretation), usually with new instrumentation and often in different rooms. As such, each Mohs tumor excision is performed in a completely separate operative session from every other tumor excision and from any repair procedure. There is minimal overlap in work from one stage to the next, from excision to repair, or between Mohs excision of two separate tumors at the same time.

Mohs surgery includes both surgical and pathological components; the inherent requirements for both account for the minimal overlap between Mohs excision of two separate tumors at the same time and between Mohs excision and a subsequent repair. Because of these dual components of surgery and pathology, 80% of the work of Mohs code 17311 is intra-service work (78% for 17313), with little pre- or post-service work. Such valuation was examined and approved by the RUC. The large amount of intra-service work, in addition to the fact that the Mohs tumor excisions are performed at separate operative sessions from repairs, differentiate the Mohs codes from other surgical codes. Because of the large pathology component of the Mohs codes, which must be completed in its entirety for each tumor independently and before contemplating repair, the "efficiencies" referred to in the rule are not realized for Mohs surgery, even for treatment of two tumors on the same date. It is inappropriate to subject these codes to the MPRR for efficiencies which don't exist.

Additionally, approximately half the physician work of the Mohs codes represents work related to histopathology. As with all pathology codes, work of interpreting one block or specimen is completely independent of interpretation of other specimens; as such, exemption of pathology codes is appropriate, and they traditionally have not been subject to multiple surgery reduction. Application of the MPRR to the Mohs codes is incongruous with the appropriate exemption of other pathology codes.

In determining characteristics of codes appropriate for exemption from the MPRR, the AMA CPT/AMA RUC Modifier -51 Workgroup identified various criteria. In addition to CMS longstanding exemption and the large amount of intra-service work referred to above, which meet two of the criteria, Mohs surgery codes are used both as adjunct codes

and as stand-alone codes. Although usually used as adjunct codes with separate repair codes, in 10-30% of cases, depending on the surgeon, wounds created by Mohs excision
are allowed to heal by second intention, with no repair procedure performed. This is particularly true for defects in concave areas such as the alar crease, medial canthus, and conchal bowl, in addition to sites off the face and less noticeable areas, such as the posterior pinna. Such adjunct and stand-alone use meets a third criterion for exemption.

We are concerned that the application of the MPRR to the Mohs codes will decrease Medicare beneficiaries' access to timely care and potentially increase complications and costs. In approximately 10% of cases, more than one Mohs excision is performed on the same date. This is most likely for patients with multiple tumors, who tend to be older patients and those patients at high risk due to immunosuppression from organ transplantation, chemotherapy, medication, etc. These are also the patients at greatest risk for metastasis from squamous cell carcinoma and subsequent morbidity and mortality. Application of the MPRR will delay treatment for these high-risk patients and increase the risk of subsequent complications.

Application of the MPRR to the Mohs codes may also affect repair patterns, with potential increases in cost. Reduced reimbursement for the lower-valued code, whether Mohs tumor excision or the associated repair, will make it less cost-effective for surgeons to excise and reconstruct cancers on the same day. This will likely result in an increase in referral by Mohs surgeons to other surgeons for reconstruction. Such referrals would most often be to plastic surgeons, facial plastic surgeons, or oculoplastic surgeons, most of whom operate in the hospital or in ambulatory surgery centers, where the cost of reconstruction is greater than that of the Mohs surgeon practicing in less expensive facilities. The increased cost of repair will offset potential cost savings of the MPRR.

ASDS
American Society for
Dermatologic Surgery

There are many reasons for the increase in utilization of the Mohs codes, including an increasing number of skin cancers, which currently affect over one million Americans and are projected to affect one in five Americans in their lifetimes. At the same time, there is an increasing number of surgeons trained in the Mohs technique utilizing the codes. While application of the Multiple Procedure Reduction Rule could appear to be a cost-savings measure and tempting to apply to Mohs surgery, it is inappropriate by previous CMS decision and current RUC policy, as I have detailed previously. Mohs surgery is a separate and distinct procedure from other procedures performed on the same day and for which no significant gain in efficiencies exists when performed with other procedures.

We do not believe that CMS has been forthcoming with appropriate justification for its decision to remove the Mohs surgery codes from the MPPR exemption list. We hope that CMS will make public the correspondence between CMS, the CPT Editorial Panel and the RUC to both better understand the justification for the code removal and to be assured that this decision was made using appropriate process.

Application of the reduction will negatively impact care and unnecessarily put patients at risk without generating significant cost savings. We urge CMS to permanently restore the exemption from the Multiple Procedure Reduction Rule to the Mohs codes 17311 and 17313.

Thank you again for the opportunity to comment on an issue that is critically important to our members and the skin cancer patients we serve. Should you require additional information, please do not hesitate to contact Lisle Poulsen, ASDS Advocacy and Socioeconomic Affairs Manager, at lpoulsen@asds.net or (847) 956-9126.

Sincerely,

Darrell S. Rigel, MD
President

cc: Robert A. Weiss, MD, President-Elect
Alastair Carruthers, FRCPC, Immediate Past President
Jeffrey Dover, MD, Vice President
David Goldberg, MD, JD, Secretary
Christopher J. Arpey, MD, Treasury
Katherine J. Svedman, Executive Director
Lisle Poulsen, Advocacy and Socioeconomic Affairs Manager

Submitter : **Dr. John Lin** **Date: 12/21/2007**

Organization : **Sunrise Urology, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-FC-164-Attach-1.PDF

To whom it may concern:

I am a urologist who practices in solo practice who treats a large number of Medicare patients for enlarged prostate, abnormal prostate lab results, prostate cancer, among other issues. I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

The final rule imposes an anti-markup provision on the technical and professional components 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*. This is a wholly different test than what was proposed. Rather than focusing on whether the test was purchased or not, the new rule applies the anti-markup provision simply based on ***where the test is furnished***. Under the final version of the rule, to avoid the anti-markup provisions, a test would have to be furnished "in the office of the billing physician or other supplier," *i.e.*, the "space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally."

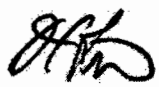
When the anti-markup rule applies to a diagnostic test, the amount of payment is affected by requiring that a "net charge" be calculated. CMS has given little guidance with respect to calculating the "net charge" when a service is provided by the employed technologists and physicians of a practice where those individuals are not compensated based on a per test basis. In addition, the CMS rules require that the "net charge" be calculated without regard to any overhead, including the cost of equipment or leased space.

Finally, the new rule prohibits full payment for physician arrangements that were structured to meet the Stark requirements of the in-office ancillary services exception with respect to the provisions concerning "same" and "centralized" buildings (locations which are specifically identified within the Stark statute itself). As a result, thousands of physician practices, including my own, — after relying upon CMS guidance with respect to the physician self-referral laws and regulations — will not be reimbursed for equipment, facility, overhead, or any other related expenses for providing imaging or other diagnostic procedures to its patients.

The changes proposed in these rules will have a serious impact on the way I practice medicine and will **not** lead to the best medical practices. ***These rules will impact the quality of, and access to, diagnostic tests for Medicare beneficiaries***. The proposed changes to the anti-markup rule will make it difficult, if not impossible for me to provide the best care for these patients. As the person who has examined the patient and who has clinical background on the patient, it behooves anyone to have the urologist intimately involved in the care of the patient.

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 for your consideration,



John C. Lin, M.D.
Sunrise Urology, PC
Gilbert, AZ 85234
480 507-9600

Submitter : Jeff Michel, RN, MS, CPUR **Date:** 12/21/2007

Organization : Jeff Michel, RN, MS, CPUR

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

December 21, 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., 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. Thank you for your consideration of these comments on this Interim Final Rule.

Sincerely,

Jeff Michel, RN, MS, CPUR

Submitter : **Dr. Todd Goldblum** **Date: 12/21/2007**

Organization : **Dr. Todd Goldblum**

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

Hello,
A new code for balloon dacryoplasty (68816) will take effect on Jan 1, 2008. Please understand that the bulk of these surgeries are on children and will NOT be done in an office setting. As such, general anesthesia in a hospital setting is required. Please consider the inherent risks and physician time for general anesthesia when assigning physician payment. Thank you.
Todd Goldblum, MD
303 Mulberry St. NE
Albuquerque, NM 87106

Submitter : Mr. Michael Nasitka **Date:** 12/21/2007

Organization : Mr. Michael Nasitka

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document

CMS-1385-FC-167-Attach-1.DOC

#167

21 December 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 myself, an Nationally Registered Emergency Medical Technician- Paramedic, currently licensing and practicing in Alaska. Currently, I conduct mostly emergency transports, but, have in the past, done a significant number of routine (non-emergency transports).

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 Nasitka
Firefighter/ Paramedic

Submitter : Dr. James Gigantelli **Date:** 12/22/2007

Organization : University of Nebraska Medical Center

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

Dear Sir/Madam:

I wish to comment on the newly created Category I CPT code 68816 (balloon dilation of the nasal lacrimal duct) and the flawed rationale used by CMS to construct its proposed physician and facility payment schedules for this procedure. Balloon dacrocystoplasty (DCP) is normally performed on children with congenital nasolacrimal duct obstruction and selected adults with acquired incomplete nasolacrimal duct obstruction. The balloon dilation is normally accompanied by the intraoperative placement of lacrimal outflow stents. This procedure requires deep intravenous sedation with regional infiltrative anesthesia for most adults or general anesthesia for children and some adults. The procedure is typically performed in the ambulatory surgical center (ASC) and not in the office setting. The technical steps of DCP with stent placement require an operative time greater than that spent for nasolacrimal duct probing with stent placement (CPT code 68815). It is therefore counterintuitive that the proposed work RVU s for 68816 are less than those prescribed to 68815.

As noted above, the majority of DCP are performed in an ASC or hospital outpatient operating room setting. Thus, CMS is flawed in assigning this new code to those procedures that are performed predominately in non-facility settings. CPT 68816 should be reassigned and placed amongst those procedures that get reimbursed at a fixed percentage (65% in 2008) of the OPPS payment. The proposed interim ASC payment for 68816 ($433.69) will not cover the ASC s fixed costs for performing DCP; the wholesale cost of the balloon catheter itself is $306.

If left uncorrected, the current payment schedule will harm patients. Some physicians may abandon DCP for less efficacious procedures. Others may no longer accept patients requiring DCP to their practice. From a practical prospective, most physicians will be pressured to schedule DCP-requiring patients into the hospital outpatient O.R. setting, thus costing both the patient and CMS unnecessary additional dollars.

Thank you for allowing me to offer my comments regarding the proposed fee schedules for balloon dilation of the nasolacrimal duct. I would be happy to provide a CMS representative with additional comments should it be necessary. I may be reached via my secretary, Patricia Yount at 402-559-4276.

Yours Sincerely,

James W. Gigantelli, M.D., F.A.C.S.
Professor of Ophthalmology and Otolaryngology
Director, Ophthalmic Plastic Surgery Service

Submitter : Dr. Ira Klimberg **Date:** 12/22/2007

Organization : Urology Center of Florida

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-FC-169-Attach-1.DOC

#169

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

Dear Administrator Weems:

I am a urologist who practices in a large multi-physician Urology Group Practice in Florida. I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

The final rule imposes an anti-markup provision on the technical and professional components 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*. This is a wholly different test than what was proposed. Rather than focusing on whether the test was purchased or not, the new rule applies the anti-markup provision simply based on *where the test is furnished.* Under the final version of the rule, to avoid the anti-markup provisions, a test would have to be furnished "in the office of the billing physician or other supplier," *i.e.*, the "space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally."

When the anti-markup rule applies to a diagnostic test, the amount of payment is affected by requiring that a "net charge" be calculated. 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 require that the "net charge" be calculated without regard to any overhead, including the cost of equipment or leased space.

Finally, the new rule prohibits full payment for physician arrangements that were structured to meet the Stark requirements of the in-office ancillary services exception with respect to the provisions concerning "same" and "centralized" buildings (locations which are specifically identified within the Stark statute itself). As a result, thousands of physician practices, including my own —after relying upon CMS guidance with respect to the physician self-referral laws and regulations—will not be reimbursed for equipment, facility, overhead, or any other related expenses for providing imaging or other diagnostic procedures to its patients.

The changes proposed in these rules will have a serious impact on the way my Urology group practices medicine and will not lead to the best medical practices. These rules will impact the quality of, and access to, diagnostic tests for Medicare beneficiaries. The proposed changes to

the anti-markup rule will make it difficult, if not impossible for me to provide many of the services that are group was constructed and designed to provide for our patients.

Our group provides diagnostic imaging services at all or our locations, however we have our CT Scans performed at one centralized location. This facility provides CT services to all of our patients, however this site DOES NOT provide the full range of services that our group provides. In addition we have a centralized histo-pathology and clinical Laboratory location, that is separate from any of our direct patient care locations. Although all testing is performed by employees of our practice, and supervised by group physicians, this arrangement, specifically designed and contstructed to be fully compliant with all regulatory issues, will no longer be viable if the new rules are enacted. The only issue is the location of where the services are provided, despite the fact that they continue to be delivered by the same staff, under the auspices of our group practice.

The development of these separate radiology and Laboratory services was in direct response to short comings with the delivery of care in our community. On-site imaging, and the ambulatory surgery center, allow our patients to get imaging immediately prior, or at the time of surgery without the need for delay or transport. This leads to more efficient and integrated delivery of care. Pathology services were developed in response to local shortcomings in the quality of pathology services. Our specialized Uro-Pathologists provide superb timely care. This is evidenced by the fact that many urologic specimens were NOT processed here in town, but had to be sent to distant reference laboratories, causing a needless delay, and increasing the anxiety and stress level among our patients as they waited for the results of the out of town pathology analysis to return.

Designed, constructed, and implemented with the appropriate equipment, staffing, health care professionals, and facilities to be full compliant our practice invested approximately $400,000 in diagnostic imaging as well as $300,00 in laboratory to provide quality services to my patients. Based on the new anti-markup regulations, it will not be possible for my practice to offer these services without operating at a loss. As a result, when these services are no longer available, patients will lose access to quality services.

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 for your consideration,

Ira W. Klimberg MD

Submitter : **Dr. Sam Duncan** **Date: 12/22/2007**

Organization : **Ritzville DrugComapny**

Category : **Pharmacist**

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

Reqiring e-prescribing and elimanating our current pharmacy to doctor fax requcst for refills and not allowing our doctors fax from the computers to ours is a finacial burdens to both businesses. Driven soley in pharmacy case by 1 oranganizaton that has tried for years to get independents to pay them a transmission fee for each and every precription thatwe recieve from a doctors office. This is patently unfair to the government require us to "purchasse " this product. The systems we have now should continue to be exempt. Paper faxes and electronic faxes have not prsented a problem and are still free for us. Medicares invention of Part D written by the insurance and PBM lobbists have bancrupted over a thousand pharmacies in the US in the last two years. we can not sustain another expense to pay for e-scripts and faxes. The governmentwould need to provide us the interace for free for this to be a viable option for the independtents. A third-party vendor ought not be allowed to profit from a govement mandated service, this whole issure came about because the e-prescibing company could not sell us all their product. Our exemtion should stay intact and the issure dropped.

Submitter : **Ms. Debbie Garza** **Date: 12/22/2007**

Organization : **Walgreen Co.**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-FC-171-Attach-1.DOC

#171

Government and Community Relations Department

December 22, 2007

Submitted Via eRulemaking

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

Re: CMS-1385-FC—Final Rule with Comment Period: Amendment of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

Dear Sir or Madam :

Walgreen Co. ("Walgreens") is writing to comment on the above-referenced matter concerning the amendment, and eventual elimination, of the e-prescribing exemption for computer-generated facsimile transmissions. We submitted comments earlier this year when this rule was initially proposed. We appreciate CMS's clarification that computer-generated facsimiles may be used in the event of system outages that would preclude the use of the NCPDP SCRIPT Standard. However, we remain concerned that the final rule could cause severe workflow disruptions for prescribers and pharmacies under certain circumstances that could lead to unnecessary patient delays in receiving needed prescriptions.

Walgreens is the nation's leading community pharmacy, with more than 6,100 pharmacies in 49 states and the Commonwealth of Puerto Rico. We employ more than 200,000 people, including more than 20,000 pharmacists, and we fill in excess of 580 million prescriptions each year.

Walgreens is a proud member of the National Association of Chain Drug Stores and we join that organization's detailed comments submitted on this topic. As a founding member of SureScripts, we also join their comments. We are writing separately to amplify our concerns about two aspects of the final rule and to quantify the significant disruption to patient care and additional costs that the final rule will cause.

Computer-Generated Facsimiles Must Be Available for Refill Authorization Requests

We note initially that Walgreens is a strong proponent of electronic prescribing. We recognize the clear benefits that e-prescribing brings to patients, prescribers and payers, and have adopted e-prescribing in all of our pharmacies. Indeed, when both a prescriber and a pharmacy are capable of communicating with the NCPDP SCRIPT Standard, we believe that they should do so (absent an applicable exemption).

However, it is simply a fact that many prescribers have been slow to adopt true, complete e-prescribing capabilities (systems capable of both sending new electronic prescriptions **and** receiving electronic refill requests) utilizing the NCPDP SCRIPT Standard. Under such circumstances, when the prescriber is not enabled to receive electronic refill requests, a computer-generated facsimile is frequently the most efficient and effective way to communicate with such prescribers concerning refill authorization requests.

We are concerned that, read literally, the final rule would require an NCPDP SCRIPT enabled pharmacy to cease using computer-generated facsimiles for refill requests even if the physician is not enabled to accept e-prescribing messages. We do not believe that this is in the best interests of patients nor the health care delivery system. If computer-generated facsimiles are prohibited, then pharmacies will be forced to communicate with physicians that are not enabled for e-prescribing using stand-alone fax machines or by telephone, resulting in significant slowdowns in pharmacy workflow and subsequent delays for patients.

As a result, we ask CMS explicitly to clarify that pharmacies are permitted to transmit computer-generated facsimile refill requests to prescribers.

Pharmacies Should Not be Penalized for Prescriber Non-Compliance

It is impossible for a pharmacy to differentiate between a facsimile that originated from a stand-alone fax machine and one that was computer-generated. As a result, if pharmacies are held responsible for ensuring prescriber compliance with the provision prohibiting computer-generated facsimiles, pharmacies will have no option but to refuse all prescription facsimile transmission from prescribers. This, in turn, would force pharmacies to telephone prescribers in order prophylactically to obtain valid telephonic prescriptions for all facsimile prescriptions to avoid accepting an improper computer-generated facsimile. This would add significant delay to prescription processing and would negatively impact patient care. Thus, we urge CMS to clarify that pharmacies will not be subject to any recoupment of claims that were filled with a good faith belief that the prescription complied with the rule concerning the elimination of the computer-generated facsimile exemption and to specifically advise all applicable enforcement agencies that the fulfillment of a prescription transmitted in a non-compliant manner may not be deemed to be a violation of federal or state false claims statutes.

Workflow and Fiscal Impact

While the practical differences between sending a computer-generated facsimile to a prescriber requesting a refill authorization and contacting such prescriber by telephone or traditional facsimile machine may seem insignificant, in reality such differences are substantial. If computer-generated facsimiles were eliminated, pharmacies would be forced substantially to alter their workflows and to incur considerable additional, incremental expenses.

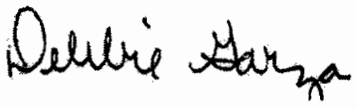
With respect to workflow, if computer-generated facsimiles were prohibited, Walgreens would radically have to alter its workflow concerning refill authorizations. Presently, if a refill authorization is required from a prescriber (and the prescriber is not enabled for true e-prescribing), a computer-generated facsimile is automatically sent to the prescriber. If the prescriber authorizes refills for the prescription, he or she faxes the document back and our pharmacy staff enters the information into our prescription system. In the absence of computer-generated facsimiles, Walgreens would be forced to incur significant upfront costs because of the need to modify our computer system to prevent computer-generated facsimiles from being sent and to train our staff on new procedures. In addition, traditional manual fax machines (that allow outgoing fax capabilities) would have to be purchased in order to accommodate any facsimile communications with prescribers concerning refills authorizations (presently, our store fax machines allow only incoming faxes and do not allow outbound fax transmissions).

Moreover, and more substantially, in addition to the upfront system and training costs associated with the elimination of computer-generated facsimiles, each refill request undertaken thereafter will be more time-consuming and, as a result, more disruptive to patient care and more costly. Without the availability of computer-generated facsimiles, our staff would have to initiate a request for a refill authorization by telephoning the presciber's office. Often, multiple phone calls will be necessary, because the prescriber may not be available at the time our staff initially calls.

Our internal studies indicate that a refill authorization request undertaken by telephone takes 1.43 minutes longer to complete than one initiated by computer-generated facsimile. As we initiate an estimated 123 million computer-generated facsimile refill requests each year, the elimination of computer-generated facsimiles would result in 9.2 lost hours of pharmacy staff time per store per week that is currently available for patient care. On an annual basis, the additional staff time necessitated by the elimination of computer-generated facsimiles would require Walgreens to incur $88 million in additional costs, based on a blended payroll rate between pharmacists and pharmacy technicians. This suggests, extrapolating Walgreens additional costs across the entire community pharmacy industry based on market share, additional industry-wide costs of at least $520 million based on the elimination of computer-generated facsimiles.

We appreciate the opportunity to comment on this important matter.

Very truly yours,



Debbie Garza, R.Ph.
Vice President, Government and Community Relations
202-624-3172
debbie.garza@walgreens.com

Submitter : **Mrs. Sharon Geiger** **Date: 12/23/2007**

Organization : **Mrs. Sharon Geiger**

Category : **Individual**

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-P: 2008 Medicare Fee Schedule
Coding Multiple Procedure Payment Reduction for Mohs Surgery

As a Medicare beneficiary, I am writing to express my disappointment that Mohs Micrographic Surgery will be subject to the multiple surgery reduction rule.

Effective January1, 2008, CMS will remove Mohs surgery from a list of procedures exempt from the Multiple Procedure Reduction Rule. I am personally familiar with Mohs Micrographic Surgery and the valuable role it plays in the treatment of some skin cancers. Mohs surgery is an outpatient surgical procedure and is considered the gold standard treatment for skin cancer. The office where Mohs is performed has a lab onsite, and the patient waits while the doctor analyzes the tissue excised to determine if the cancer has been removed. If not, the Mohs surgeon returns to the patient as many times as necessary to completely remove the cancer. Once removed, most patients have a surgical repair of the wound to provide the best possible outcome.

My surgeon has explained to me the rational of the multiple surgery reduction rule. Even as a layperson, it is obvious to me that the application of this rule to Mohs Micrographic Surgery is not justifiable. Each Mohs surgery and reconstruction is a separate and distinct procedure. There is little efficiency gained when 2 or more procedures are performed on the same day. I believe that this is a mis-application of the principle behind the multiple surgery reduction rule.

As you can imagine, the change concerns me a great deal. I would ask that you reconsider this ruling and reinstate Mohs Surgery to the reduction exempt list.

Sincerely,

Sharon Geiger
LaGrange, KY

Submitter : Mrs. Shelby Moody **Date:** 12/23/2007

Organization : Mrs. Shelby Moody

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Coding Multiple Procedure Payment Reduction for Mohs Surgery

I am concerned that Mohs Micrographic Surgery will be subject to the multiple surgery reduction rule.

I am personally familiar with Mohs Micrographic Surgery and the valuable role it plays in the treatment of some skin cancers. I understand the multiple stage nature of this procedure and the amount of work needed to treat each cancer when more that one cancer is present.

My surgeon has told me about the multiple surgery reduction rule and I understand the concept. As a CPA, I am comfortable with concepts of how much work is involved in a process. It is apparent to me that the concept of the multiple surgery reduction should not apply to Mohs Surgery. Why should the payment be so drastically reduced, when the amount of work involved in doing a second procedure with Mohs Surgery is nearly doubled? Each Mohs surgery and reconstruction stands alone. I don t see much efficiency being gained when a second procedure is performed.

I would ask that you study this issue further and reconsider this ruling.

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

Coding Multiple Procedure Payment Reduction for Mohs Surgery

I am concerned that Mohs Micrographic Surgery will be subject to the multiple surgery reduction rule.

I am personally familiar with Mohs Micrographic Surgery and the valuable role it plays in the treatment of some skin cancers. I understand the multiple stage nature of this procedure and the amount of work needed to treat each cancer when more that one cancer is present.

My surgeon has told me about the multiple surgery reduction rule and I understand the concept. As a CPA, I am comfortable with concepts of how much work is involved in a process. It is apparent to me that the concept of the multiple surgery reduction should not apply to Mohs Surgery. Why should the payment be so drastically reduced, when the amount of work involved in doing a second procedure with Mohs Surgery is nearly doubled? Each Mohs surgery and reconstruction stands alone. I don t see much efficiency being gained when a second procedure is performed.

I would ask that you study this issue further and reconsider this ruling.

Submitter : Mr. Russel Hiller III **Date:** 12/23/2007

Organization : Mr. Russel Hiller III

Category : Individual

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

As a Medicare beneficiary and skin cancer patient, I am concerned that Mohs Micrographic Surgery will be subject to the multiple surgery reduction rule.

I am personally familiar with Mohs Micrographic Surgery and the valuable role it plays in the treatment of some skin cancers.

My surgeon has explained to me the rational of the multiple surgery reduction rule. I am not involved in the medical field, but even as a real estate broker, it is clear that the application of this rule to Mohs Micrographic Surgery does not make sense. Each Mohs surgery and reconstruction is a separate operation. There is little efficiency gained when 2 or more surgeries are performed on the same day. I believe that this is a mis-application of the multiple surgery reduction rule.

As you can imagine, given the negative impact this will have on the treatment of skin cancer, this change concerns me a great deal. I would ask that you reconsider this ruling.

Sincerely,

Rusty Hiller
Albuquerque, NM

Submitter : Ms. Anne Zepeda **Date:** 12/24/2007

Organization : Palm Valley EMS

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

see attachment

#175

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

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

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

Submitter : Mr. John Fekety **Date:** 12/24/2007

Organization : Mr. John Fekety

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

It has been well documented that the fees paid by Medicare to ambulance services barely, if at all, even cover the operational costs for the transportation of patients. The revisions to the "signature rule will place an onerous burden on ambulance services that will create more of a financial hardship and contribute to the decline of qualified providers and services for all patients in need of emergency medical services transport.

Although the emergency exception does recognize that obtaining a signature is not always possible, as someone who has been involved in EMS for over 17 years, I can attest that in many instances the non-emergency patients are less able to provide a signature as the result of long standing debilitating conditions that make transport via ambulance with a professional crew necessary. With the ever increasing populations of patients in long term care facilities who have dementia, Alzheimer s or other psychiatric and/or neurological impairments, requiring ambulance providers to chase down signatures will add further costs to already financially strapped services.

By increasing the financial burdens to ambulance services the ultimate victims will be the recipients of Medicare services. Each year more ambulance services close their doors as the result of the widening gap between expenses and health care reimbursements. As the result there are less ambulances and qualified providers which will result in delays in both emergent and especially non-emergent transportation services. In some emergency cases this will also mean that rather than having advanced life support care provided by paramedics, patients will be only able to receive basic life support from emergency medical technicians because there are not enough ALS vehicles available to cover an area. As the result the patients will not be able to receive medications and treatments that could not only lessen the patients' symptoms during transport and upon arrival at the hospital, but could also result in shortened in-patient hospitalization.

At the very least, the revisions should not be implemented until a further study can be completed that will truly reflect the impact the revisions will have on the medical transport industry both as a whole, as well as in areas where ambulance service is already in crisis.

Submitter : **Date: 12/24/2007**

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Signatures from busy ER staff members are almost impossible to obtain in multiple sections or forms. Statements will be even more rare. This rule punishes healthcare workers and EMS personnel. We are again using more resources and time to receive less payment. Rural EMS cannot withstand more cutbacks.

Submitter : **Mr. Heath Goldstein** **Date: 12/25/2007**

Organization : **Mr. Heath Goldstein**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

I am a Pennsylvania Certified Emergency Medical Technician. I currently volunteer for four (4) Fire Companies, all of whom have Basic Life Support Ambulance Services. In one of the Companies, I am currently in charge of Billing, and making sure that our providers, have their charts completed and documented to the standards and requirements.

This regulation I very much oppose, and it will put a burdon in the field to our EMT's. Our number one (1) priority from the time of dispatch, till Patient is brought to a ER Facility (Besides our Safety) is Patient Care. There are times where is does make it difficult to obtain signatures from beneficiaries, or a representative on behalf of Patient. Hospital Staff are extrememly busy, and and this extra burdon on our EMT's can and will make more difficult to obtain documentation from a facility Staff. As volunteers we do enjoy what we do, but we should not be put with any extra burdon than what we have to deal with to obtain extra documentation and paperwork. I beleive that communications from dispatchers, when we are enroute and arrive at a facility which are on (or should be on) recorded frequencies, would and should be enough proof that a beneficiary was transported to that facility. There has to be other options that CMS can come up with as an alternative for this documentation. This also adds extra burdon on paperwork, for which everyone is trying to cut down on. With today's technology, there has to be someother options that CMS should be able to come up with.

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

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

Submitter : Dr. erci smith **Date:** 12/26/2007

Organization : summit urology specialists

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

Dear Administrator Weems-I am a urologist in Bloomington, Indiana with a large Medicare population. Our group provides basically the only coverage for a 6 county rural area. The proposed anti-markup provision is inappropriate in my view, as it will adversely impact our ability to continue to provide pathology services to our patients. We provide pathology services in strict accordance with Stark guidelines, but in the proposals the rules are changed with regard to anti-markup provisions and "centralized" office buildings. We would not be able to provide timely pathology results to our patients, nor would we have quality control over these tests, if the new rules are implemented. It is frustrating to us to spend time and legal fees to set up quality medical services for our patients based on regulations that are now once again being revised. Thank you fro your consideration.

Eric Smith MD

Submitter : **Dr. Deborah Bash** **Date: 12/26/2007**

Organization : **American Society of Plastic Surgeons**

Category : **Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see Attachment

CMS-1385-FC-180-Attach-1.DOC

#180

AMERICAN SOCIETY OF PLASTIC SURGEONS®

Executive Office
444 East Algonquin Road
Arlington Heights, IL 60005-4664
847-228-9900
Fax: 847-228-9131
www.plasticsurgery.org

November, 2007

Herb Kuhn
Deputy Acting Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3887-P
P.O. Box 8017
Baltimore, MD 21244-8017

Submitted Electronically

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for CY 2008; Final Rule (CMS-1385-FC)

Dear Mr. Kuhn:

The American Society of Plastic Surgeons (ASPS) is the largest association of plastic surgeons in the world, representing surgeons certified by the American Board of Plastic Surgery. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, and cancer. ASPS promotes the highest quality patient care, professional, and ethical standards and supports education, research and public service activities of plastic surgeons.

ASPS offers the following comments on the Center for Medicare and Medicaid Services (CMS) final rule for "2008 Physician Fee Schedule Final Rule" (CMS-1385-FC) that was published in the Tuesday, November 27, 2007 *Federal Register*. As requested in the proposed rule, the relevant "issue identifier" that precedes the section we are commenting on is used as a sub-heading to assist the Agency in reviewing these comments.

The American Society of Plastic Surgeons (ASPS) would like to thank the Centers for Medicare and Medicaid Services (CMS) for recognizing

Sincerely,

Submitter : **Date: 12/26/2007**

Organization :

Category : **Local Government**

Issue Areas/Comments

GENERAL

GENERAL

The proposed revision could place unreasonable restrictions on the emergency ambulance service providers. The requirement to obtain a signature from either the patient or the receiving facility at the time of service is not always medically feasable and therefore highly unreasonable. Most ambulance service providers must be available at the very moment in which they arrive at the hospital and, therefore, makes it nearly impossible to ensure that, each and every time, a signature is obtained at the time of service. In many instances, the patient is not medically capable of signing and the emergency room staff may also not have anyone available to sign any document before the ambulance must leave for another emergency.

This revision should not be made as it is certain to cause a reduction in the availability of ambulance service to patients and this will will ultimately cost us lives.

#182

CMS-

Because the referenced comment number does not pertain to the subject matter for CMS- , it is not included in the electronic public comments for this regulatory document.

Submitter : **Cinda James** **Date: 12/26/2007**

Organization : **Clark County Ambulance District**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

Our concern is with the requirement for patient signatures for ambulance transports. Our crews see patient's at the time of a crisis or emergency in their lives. Many are not capable, either mentally or physically, to understand any consent form or signature form concerning payment by Medicare. Payment of their bill is their least concern in an emergency. It is also of least concern to the crew who is giving emergency care and transport. The crews see first hand that the second you start to talk about signatures for payment, the patient looses confidence in their intent...it looks like we are only concerned about getting paid and not the treatment of the patient. And then, unlike doctor's offices, hospitals or other various health professionals, we do not see the patient again once they are delivered to an ER so there is no further chance to talk calmly when the patient is improved. I think the requirement for signatures should, at best, be completely deleted or at least put on hold until the many questions are addressed.

Submitter : Dr. John Franz **Date:** 12/26/2007

Organization : Stept and Arnheim Urologic Associates

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

As a 65 year old urologist in a group practice with three offices, seven physicians, three physician assistants/nurse practitioners I am unable to recruit partners and successors because of the continuing economic pressures. These revisions will only add to those pressures and frustrations. In an attempt to control costs the CMS is guaranteeing that future urologists in our area will be employees of large systems who can use their monopoly power to increase fees and capture the profits of the studies their physicians order. We have already been told by the chief executive of the UPMC Hospital and health care system that we were fools for not exerting monopoly power and capturing the market. He now does so. He is the largest employer of urologists in our area. his hospitals have significantly higher reimbursement for services than to competing and independent hospitals in our metropolitan area. Sometimes his premium is 30%. Hospitals in other areas of Pennsylvania are also offering salaries that independent practitioners can not match. A friend in State College is loosing his youngest partner to another state and will not be able to recruit a replacement for the departing partner or for himself as he completes his own process of retirement. We have become worth more to the hospitals and the health insurers than we are to ourselves. We do not have their monopoly power to deal with the insurers or the competing specialties would would like to restrict our offering of services that we do better. We are trying to provide prostate biopsy pathology services from one of the premier urologie pathologists in the country in an coordinated and integrated process in our practice. Often we ask or our local pathologists volunteer to send out biopsies to such authorities. We would like to eliminate such uncertainties and delays. The new revisions will block such improvements. They will fossilize the rapidly changing structures of medical practice into rigid monopolies. Unfortunately virtually everything and physician does with any patient is a potential conflict of interest. It is for that reason that we take the Hippocratic Oath and treasure it. The hospital and insurance company administrators take no such oath. We try to shun, within the limitations of our legal system, those physicians who do no honor their oath.

Submitter : Mr. Mark Weber **Date:** 12/26/2007

Organization : ND EMS Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see Attachment

CMS-1385-FC-185-Attach-1.PDF

#185

December 26, 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 North Dakota EMS Association. Our association represents approximately 1,900 EMS providers and 143 ground ambulance services in North Dakota

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,

Mark Weber, President

North Dakota EMS Association

Submitter : Dr. keith whitmer **Date:** 12/26/2007

Organization : gainesville dermatology

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

I strongly oppose the multiple reduction rule for Mohs Micrographic Surgery. This is a staged procedure requiring the patient to return to the waiting room between stages and before closure of the defect. Full surgery setup is necessary for each stage and closure so there is not a decrease in time required for each stage or closure. Unfortunately, this may decrease the likelihood that a patient will receive multiple Mohs surgeries on the same day or increase the possibility that a patient may return to the clinic the following day for closure. This would be inconvenient for the patient and physician and decrease efficiency. Please reconsider the exemption for Mohs surgery with the multiple surgery reduction rule.

Thank you for you time.

Submitter : **Mr. Dean Lampe** **Date: 12/26/2007**

Organization : **F-M Ambulance Service**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

Please See Attached pdf Document

CMS-1385-FC-187-Attach-1.PDF

#187

F-M Ambulance Service
2215 South 18th Street
Fargo, ND 58103

December 26, 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 F-M Ambulance Service. Our service responds to approximately 12,000 calls annually in the Fargo/Moorhead areas of North Dakota and Minnesota. Much of our response area includes rural regions of these states.

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,

Dean Lampe, Executive Director

F-M Ambulance Service

Submitter : **Mrs. Barbara Heilskov** **Date: 12/26/2007**

Organization : **CMSA**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

December 26, 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., 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,
Barb Heilskov
Hampton, IA

Submitter : Ms. Mary Kay Gilbert **Date:** 12/26/2007

Organization : ING Reinsurance

Category : Nurse

Issue Areas/Comments

GENERAL

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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: 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

Submitter : Ms. Doris Imperati **Date:** 12/26/2007

Organization : Ms. Doris Imperati

Category : Nurse

Issue Areas/Comments

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Sincerely,
Doris Imperati, BSN, MHSA, CCM

Submitter : **Dr. Bradley Kovach** **Date: 12/26/2007**

Organization : **Florida Coastal Dermatology Associates**

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.

This proposal represents a dramatic reversal of sixteen years of the Centers for Medicare and Medicaid Services'(CMS) own determination that the Mohs codes are and should be exempt from the MPRR. I believe this proposal will negatively impact Medicare beneficiaries access to timely and quality care. In addition, application of this proposal will not likely generate significant cost savings and may paradoxically increase costs of providing care to these patients.

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.

Respectfully,

Bradley T. Kovach, M.D.