

Submitter : Steve Blades
Organization : Cardiovascular Outpatient Center Alliance
Category : Health Care Provider/Association

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-FC-216-Attach-1.DOC

#216.



CARDIOVASCULAR OUTPATIENT CENTER ALLIANCE

206 WELLSRING COURT, BRENTWOOD, TN 37027

PHONE: 615-776-1810

www.cocaheart.org

December 28, 2007

Kerry N. Weems, Administrator (Acting)
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: Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Weems:

On behalf of the members of the Cardiovascular Outpatient Center Alliance (COCA), we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services (CMS) regarding the ***“Cardiac Catheterization Procedures”*** section of the above referenced Final Rule as published in the November 27, 2007 *Federal Register*. We are specifically concerned with the proposed 2008-2010 PE RVU's established for non-facility outpatient cardiac catheterization procedure codes and the significant negative impact on the practices and patients of our members that would result if these RVU changes are implemented.

COCA is a national non-profit organization representing over 60 medical cardiology practices and organizations and more than 1,000 cardiologists that own and operate non-hospital outpatient cardiac catheterization laboratories (OPCLs). As will be described below, the impact of the CMS PE RVU changes would be devastating to cardiovascular OPCLs with the potential to force these facilities to exit the market. As a result, Medicare beneficiaries would be denied access to high quality, convenient cardiovascular services at a reasonable cost. In addition, the overall cost to the Medicare program and the coinsurance obligation for Medicare beneficiaries for these services would increase dramatically if OPCLs are forced to close. COCA has been informed by some of its members with large Medicare patient populations that OPCL closures could occur as early as the first or second quarter of 2008.

CMS Response to COCA's Comments Concerning the July 2, 2007 Proposed Rule

In the November 27, 2007 Federal Register response CMS specifically addressed COCA's comments concerning the PE RVU changes that were detailed in the July 2, 2007 Proposed Rule. Unfortunately, CMS did not accept the specific concerns that COCA raised concerning the flaws in the AMA RUC process when dealing with certain procedures that do not conform to the RUC's defined "standards". The ultimate evidence of the failure of this process in the case of cardiac catheterization procedures is the severe PE RVU reductions that result in draconian reimbursement reductions, which when fully implemented will fall below the cost of providing these services. As COCA pointed out in our previous comments, these cuts are being implemented at the same time that the same procedures performed on the same patients by the same physicians in outpatient hospital settings are receiving a significant increase in APC reimbursement.

While COCA appreciates the need for CMS to rely on the AMA RUC process for their input in setting RVUs for the significant majority of procedure codes, we remain resolute in our position that the 2008 PERC/RUC did not consider all of the data that COCA made available through the process. The RUC's unwavering adherence to a set of "standards" that does not allow for unique procedural settings (i.e. anomalies such as cardiac catheterization procedures) combined with the natural politicization of the process caused by the "specialty-developed PE recommendations" and "multi-specialty scrutiny" (as described on page 66235 of the *Federal Register*) produced an unreasonable outcome.

COCA's Request for Reconsideration

COCA requests that CMS reconsider the 2008 Physician Fee Schedule PE RVUs for cardiac catheterization procedures and either increase them based on the additional data that COCA submitted to CMS on December 17, 2007 or continue carrier-pricing these procedures for 2008 while this data is analyzed for 2009-2010. We base this request on the following unique and compelling reasons:

1) OPCLs are Fundamentally Different than Physician Offices

COCA believes that OPCLs are a true anomaly within the RUC process. This became painfully clear when CMS changed the PE RVU formula to a "bottom up" calculation for 2007. The PERC/RUC definitions and templates are designed to develop PE RVUs for services and procedures performed in physician offices, while OPCLs require much more intensive infrastructure, equipment, staffing, and supplies. The RUC templates and definitions are based on office-based medicine assumptions that automatically eliminate much of the direct and indirect resources (and costs) required to perform invasive cardiac procedures. After spending several months and countless hours working through the 2008 RUC process, COCA experienced this bias first-hand. In the case of OPCLs, there is simply no possibility of the current RUC process being capable of meeting the PE RVU requirements stated in the published 2008 Physician Fee Schedule Final Rule: "Section 4505(d) of the BBA required that, in developing the resource-based PE RVU's, the Secretary must: Use, to the maximum extent possible, generally-accepted cost accounting principles that recognize all staff, equipment, supplies, and expenses, not solely those that can be linked to specific procedures and actual data on equipment utilization."

2) OPCL Staffing Mix

The RUC templates define OPCL staff as a mix of Radiology Technicians (RTs), Registered Nurses (RNs), Cardiovascular Technicians (CV Techs), Licensed Practical Nurses (LPNs), and Medical Assistants (MAs). This staffing model is not practical for an efficient OPCL. The RUC template is based on a hospital staffing model where a variety of staff can be utilized in the cath lab for short periods of time and then rotated elsewhere within the hospital (e.g. MAs as transporters, LPNs in recovery, etc.).

In an OPCL, the staff is dedicated to that facility and cannot be shifted to other areas because the OPCL is a contained unit unlike a hospital or physician office setting. In order to maximize the use of existing staff, OPCLs cross train clinical staff to be able to handle all clinical functions in the cath lab and recovery areas. Naturally, this requires that all clinical staff be able to function at the same level. The most effective and cost-efficient staffing for an OPCL is an RT/RN mix, as it would not be possible to cross train LPNs or MAs for the majority of these functions and CV Techs are unavailable in most parts of the country and/or their functions are limited by state regulations in many states. In addition, most state regulations require an RT's involvement in procedures exposing a patient to ionizing radiation.

3) OPCL Staffing Compensation Differential

One thing that OPCLs and hospital outpatient cath labs have in common is the necessity to pay higher compensation for qualified RTs and RNs. Cath lab personnel are required to have a specific clinical skill set that commands a compensation premium in the medical personnel marketplace.

COCA reviewed data from our various members' OPCLs and determined that RTs and RNs in these clinical positions are commonly paid the same amount in each location. We took a conservative approach to determine the most common salary range and found it to be \$25 - \$30 per hour, without counting overtime, bonuses, or other incentives. Therefore, we believe that a conservative blended rate of \$27.50 per hour should be applied by CMS to the work for OPCL clinical employees in determining reimbursement for cardiac catheterization procedures. This is a substantial differential from the amount currently utilized in CMS' calculations as those amounts are based on physician office clinical personnel who are generally available at a lower compensation level because of a less-specialized skill set. In addition, the need for OPCLs to use RTs and RNs exclusively because of cross training and efficiency significantly changes the personnel mix from that defined by the RUC templates.

Cardiac Catheterization Injection Codes

COCA would also like to address the inconsistencies contained in the 2008 Physician Fee Schedule Final Rule for the injection codes tied to cardiac catheterization procedures:

1) Injection Code PE RVU Changes

The usual injection codes (93543 and 93545) associated with a left heart cath (LHC) were included in the RUC template tied to the procedures discussed above and we believe that it is important to address them in these comments.

In the past these injection codes have been billed by physicians and did not contain TC or -26 modifiers, primarily because they did not include PE RVU values. COCA provided data for the 2008 PERC/RUC process that resulted in PE RVU values being added to these injection codes; however for some reason CMS did not include TC and -26 modifiers in the 2008 Physician Fee Schedule, even though the PE RVU work is performed by OPCL personnel rather than physician office personnel. The need for this to be revised is self-evident if CMS will evaluate the difference between the PE RVUs listed for these codes performed in a facility (hospital) and non-facility (OPCL) as published in the 2008 Physician Fee Schedule Final Rule.

2) -51 modifier: In reviewing the 2008 Physician Fee Schedule Final Rule we noticed an unusual change that removed the -51 modifier exemption from CPT 93543. We are mystified as to why this would occur since this code is almost always performed (>90%) when a LHC is performed (as is 93545 which is still exempt), so we assume that this was an oversight that should be brought to your attention.

Conclusion

COCA believes that CMS has no interest in supporting a flawed process that would drive non-facility cardiac catheterization centers out of business. We base this belief not only on our previous meetings with CMS, but also on the statement CMS made in the July 2, 2007 Proposed Rule when expressing concern with service furnished under arrangement with a hospital because it *"not only costs the Medicare program more, but also costs Medicare beneficiaries more in the form of higher deductibles and coinsurance"* (CMS-1385-P, pages 349-50). This concern about increased Medicare program and beneficiary costs must also apply to other services, which is the point COCA has consistently expressed about non-facility outpatient cardiac catheterization centers for the past two years.

We thank you for the opportunity to describe our concerns about the 2008 Physician Fee Schedule; specifically as it relates to the development of fair and reasonable reimbursement for cardiac catheterization procedures performed in a non-hospital setting.

We sincerely hope that CMS will respond favorably to our requests. If you have any questions, please do not hesitate to contact me at (615) 776-1810.

Sincerely yours,

Steve Blades
President

Submitter : Dr. Jeffrey Apfelbaum
Organization : American Society of Anesthesiologists
Category : Health Care Professional or Association

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-FC-217-Attach-1.PDF

ASA AMERICAN SOCIETY OF ANESTHESIOLOGISTS

Office of Governmental Affairs
1501 M Street, NW, Suite 300
Washington, D.C. 20005
Phone: (202) 289-2222
Fax: (202) 371-0384
mail@ASAwash.org

December 28, 2007

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

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

Dear Mr. Weems:

The American Society of Anesthesiologists (ASA) is pleased to offer comments on the issues discussed in this final rule as published in the November 27, 2007 *Federal Register*.

Anesthesia Coding (Part of 5-Year Review)

We want to thank CMS for implementing the proposed increase to the work component of the anesthesia conversion factor. ASA has long maintained that anesthesia work was undervalued. We are grateful that CMS has acknowledged this problem and taken steps towards rectifying it. This CMS action helps to assure that Medicare beneficiaries will continue to have access to the high quality medical care that anesthesiologists provide.

Additionally, we appreciate CMS's prompt response to ASA's discovery of an error in the payment calculations used to determine the 2008 anesthesia conversion factor. We understand that Part B contractors/carriers were apprised of the situation and received updated information in sufficient time for them to process claims at the correct payment amount on January 1, 2008. We look forward to publication of an official correction notice so that private payers who base their payments on a percentage of the Medicare conversion factor will have access to this important information.

Budget Neutrality Adjustment

ASA urges CMS to reconsider its decision to apply the budget neutrality adjustment to the work relative value units for codes paid under the Resource Based Relative Value System (RBRVS). This approach distorts the RVU scaling, renders the RVU rank-order meaningless, and, as a consequence, devalues work-intensive services. Since the budget neutrality adjustment pertains to payment and not to the RVU rankings, ASA agrees with the RUC that the adjustment should be applied to the conversion factor as a whole.

Establishment of Interim Work Relative Value Units for New and Revised Physician's Current Procedural Terminology (CPT) Codes and New Healthcare Common Procedure Coding System Codes (HCPCS) for 2008 (Includes Table titled "American Medical Association Specialty Relative Value Update Committee and Health Care Professionals Advisory Committee Recommendations and CMS's Decisions for New and Revised 2008 CPT Codes")

In Table 16 of the final rule, CMS indicates that it agrees with the RUC recommendation to assign 2.91 work relative value units to CPT code 93503 - *Insertion and placement of flow directed catheter (eg, Swan-Ganz) for monitoring purposes* - when reported with modifier 26, yet this code has been designated as "carrier priced" in Addenda B and C of the rule. ASA brought this inconsistency to CMS's attention and we are pleased that CMS intends to take prompt corrective action so that claims for this service will be properly paid and processed on and after January 1, 2008.

Annual Work, PE and PLI Updates to the Anesthesia Conversion Factor

Since Medicare's anesthesia payment system does not have procedure-specific work, practice expense and professional liability insurance relative value units, CMS has treated the anesthesia conversion factor as consisting of global shares, representing these three elements. In each annual publication of the Medicare fee schedule, CMS applies updates to these shares which reflect changes such as the new practice expense methodology and the work neutrality update. In this year's proposed and final fee schedule rules, CMS has published a combined update, which blends the updates in the individual shares into a single value. This approach is not transparent, making it exceptionally difficult to confirm that CMS has applied annual updates correctly and consistently with updates to other physician services within the RBRVS. As mentioned previously, an error did occur this year in the anesthesia conversion factor update. ASA also notes that an update error also occurred in 2001. *In order to make the anesthesia update as transparent as the RBRVS update, ASA encourages CMS to individually delineate the updates to the work, PE and PLI shares, in addition to the combined update currently provided.*

ASA appreciates the opportunity to comment on the rule and we look forward to working with CMS on issues of importance to anesthesiology and all of medicine.

Sincerely,



Jeffrey L. Apfelbaum, M.D.
President

Submitter : Dr. Richard Lindstrom
Organization : ASCRS and OOSS
Category : Health Care Professional or Association

Date: 12/28/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1385-FC-218-Attach-1.PDF



AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
OUTPATIENT OPHTHALMIC SURGERY SOCIETY

December 31, 2007

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ATTN: CMS-1385-FC
200 Independence Avenue
Room 445-G
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008

Dear Mr. Weems:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing more than 9,500 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures done annually in the United States.

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association of more than 1,100 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical procedures performed in cost-effective outpatient environments, including ambulatory surgical centers (ASCs).

ASCRS and OOSS appreciate the opportunity to submit comments on the final rule for the 2008 Medicare physician fee schedule.

Sustainable Growth Rate (SGR)

As you are aware, recent congressional action has prevented, for a period of six months, a reduction of 10.1% to the Medicare physician fee schedule conversion factor that was scheduled to begin on January 1, 2008. As a result, physicians will now face a cut of 10.6% on July 1, 2008, if Congress does not intervene.

ASCRS and OOSS are increasingly frustrated with the instability of the current Medicare physician payment system. We have appealed to the agency for many years to make the

necessary adjustments that would reduce the cost of replacing the flawed SGR formula, which produces steep negative updates each year. As you know, the flawed formula is slated to produce steep negative updates of 40% through 2017.

CMS has agreed with the medical community, Congress, and policy experts that the SGR formula is unsustainable. However, the agency has done nothing to address some of the problem areas over which it has control. Some problems have been discussed by ASCRS and OOSS in previous comments, and we again outline them below.

Removal of Physician-Administered Medicare-Covered Drugs Retroactively

We again ask CMS to use its administrative authority to remove drugs from the physician payment pool retroactive to 1996, filling the gap between actual spending and target spending, thereby making it more likely Congress will permanently repeal the SGR.

Here are the facts:

- Physicians do not have control over the cost of drugs and biologics.
- Part B drugs are not procedures, diagnostic tests, or services.
- Part B drugs are only used in conjunction with certain procedures, diagnostic tests, and/or services.

For the past several years, ASCRS and OOSS as well many other medical and specialty societies, members of the Medicare Payment Advisory Commission (MedPAC) and the Practicing Physicians Advisory Committee (PPAC), the Government Accountability Office (GAO), congressional committees with jurisdiction over the Medicare program, and the majority of Congress have identified the cost of physician-administered drugs as a primary factor that drives physician spending above the expenditure target. Collectively and independently, these groups have consistently recommended that CMS use its administrative authority to remove drugs from the definition of physician services back to the base year, 1996.

We continue to believe the agency has the authority to follow through with our requests. CMS is aware that making these adjustments would drastically reduce the cost of replacing the flawed SGR formula with a stable payment system, and there is overwhelming support in favor of making this necessary change. At the very least, we urge CMS to use its authority to remove drugs from the SGR pool, prospectively.

Accurately Accounting for Changes in Law and Regulation

ASCRS and OOSS, again, urge CMS to accurately account for changes in law and regulation when calculating the physician payment update. Specifically, we urge the agency to ensure that national and local coverage decisions and screening benefits (including the services they generate) that have been added to the Medicare program be included in the expenditure target.

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY
6564 UMBER Circle • Arvada, CO 80007 • 866-892-1001 • Facsimile 303-940-7780

We continue to believe that new coverage decisions—national and local—have an impact on utilization. Most notable are coverage decisions that require certain diagnostic tests be performed in conjunction with the procedure(s) being addressed by the coverage decision. Furthermore, we understand that only coverage decisions added to the program by legislation—not by regulation—have been accounted for in the expenditure target. However, we continue to believe that CMS should include all coverage decisions—whether added to the program by statute or by the agency—when calculating the expenditure target.

In previous comments, ASCRS and OOSS used as an example the national coverage determination (NCD) on ocular photodynamic therapy (OPT) with verteporfin (Visudyne) for age-related macular degeneration (ARMD). This NCD, which was implemented in April 2004, expanded coverage for this type of therapy to beneficiaries with certain diagnoses; however, the coverage decision states that the newly expanded coverage is only allowed “provided certain criteria are met.” As a result of the coverage policy created, physicians are required to perform certain diagnostic tests to perform OPT with verteporfin.

Therefore, CMS is directly responsible for volume increases related to certain services and procedures and must adjust the SGR target accordingly.

2008 Physician Quality Reporting Initiative (PQRI)

ASCRS and OOSS continue to be concerned about CMS’ 2008 PQRI. Our major concerns are outlined below:

- Lack of transparency associated with the measure development process
- Numerous proposals to include quality measures that were not created through a “consensus-based development process”
- No clarification on the reporting requirements for the 2008 PQRI and lack of transparency associated with the method for determining successful reporting (validation method)
- No plan to identify gaps in care and prioritize the development of measures.

Lack of transparency associated with the measure development process

We continue to believe there is a lack of transparency when it comes to the measure development process. In addition, we believe that Congress’ intent was to make certain that physician-level quality measures were developed by physicians (through medical specialty societies) and using a consensus-based process. As you know, for a reporting system to be meaningful, quality measures must be evidence-based and developed with the medical specialty societies that have expertise in the area of care in question. In addition, measures should conform to clinical guidelines developed by the various physician specialties.

We are pleased that CMS has included several measures developed through the American Medical Association’s (AMA) Physician Consortium for Performance Improvement (PCPI), but we urge the agency to formally recognize the AMA PCPI as the *sole entity* for

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY
6564 UMBER CIRCLE • ARVADA, CO 80007 • 866-892-1001 • FACSIMILE 303-940-7780

the development of physician-level quality measures. As CMS is aware, the Consortium uses a well-thought-out consensus-based process involving numerous medical specialties (national and state-level), quality improvement organizations, medical specialty boards, government agencies, and public and private payers. This ensures that all health professionals have an opportunity to participate and have a voice at the table when quality measures are being developed. No other entity offers this level of rigor for measure development and, again, this ensures everyone has a voice and is participating in the development of the measures from the ground up.

Numerous proposals to include quality measures that were not developed through a “consensus-based development process”

Not only has CMS included several measures that were not developed through a consensus-based process, it also “leaves the door open” for anyone and everyone to develop and put forward measures for inclusion in CMS’ quality programs. There is no guarantee that any measure developed by a group other than the AMA PCPI will include every health professional who is, or who could potentially be, involved in the development of physician-level quality measures. For example, the quality measures developed by Quality Insights of Pennsylvania and American Podiatric Medical Association did not allow the input of representatives from every medical specialty who could potentially be involved in the care of the patient population for which the measures were developed.

To avoid confusion and prevent the need for reconciliation of measures at the end of the process, CMS should name one entity as the sole developer of quality measures for physicians. We again ask that CMS recognize the AMA PCPI as the sole entity for the development of physician-level quality measures.

No clarification on the reporting requirements for the 2008 PQRI and lack of transparency associated with the method for determining successful reporting (validation method)

We again ask CMS to clarify how the reporting requirements indicated in the 2008 PQRI program apply across the seven categories of proposed measures—including clinical, process, and structural measures—and how successful reporting can be achieved.

In addition, CMS has been advising physicians, for the most part, to continue to their participation in the 2008 PQRI in the same manner they participated in the 2007 PQRI. This is very troublesome for our members because, as you are aware, they are predominantly cataract surgeons and the three cataract measures previously available for use in the 2007 PQRI will not be included in the 2008 PQRI. Our members are concerned about this change and its effect on their ability to participate in this and other Medicare quality programs. We are again asking that CMS clarify the reporting requirements, so those physicians who may choose to continue participating in the 2008 PQRI will understand how to determine the number of measures they should be reporting to qualify for the bonus in this revised program.

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY

6564 Umber Circle • Arvada, CO 80007 • 866-892-1001 • Facsimile 303-940-7780

No plan to identify gaps in care and prioritize the development of measures

CMS has yet to discuss how it plans to identify gaps in care and prioritize the development of measures. This is a major concern for our specialty, in particular our members who provide high-quality cataract surgical care to Medicare beneficiaries.

According to the agency, the goal of the PQRI is to improve the quality of care provided to beneficiaries. If this is indeed the case, we maintain that CMS should focus its efforts on clinical areas that require improvement. That is, CMS should work with the medical community to identify where there are gaps in care and focus on improving those areas first.

As you know, ophthalmology struggled to obtain AQA approval and NQF endorsement for three cataract surgery measures that were included in the 2007 PQRI. Our efforts were unsuccessful because, according to NQF, the measures developed for cataract surgery did not address a significant enough gap in care. With the assistance of the Consortium, ophthalmology recently developed six new measures for cataract surgery and other ophthalmic conditions that are focused on outcomes. These measures were approved by the Consortium and subsequently by the AQA, but have yet to achieve NQF endorsement. We are hopeful that, once presented before the NQF, these rigorously developed, evidence-based outcomes measures will not face the same concerns as their predecessors.

In addition, we believe these six new ophthalmic measures are robust enough for use in the 2008 PQRI. We, along with the rest of the ophthalmic and surgical community, requested that CMS include these and other specialty measures in the 2008 PQRI in accordance with the TRHCA legislation. We were extremely disappointed that CMS choose not to include these measures in the 2008 PQRI, despite its administrative and statutory authority to do so. We firmly believe CMS could have and should have included these measures in the 2008 PQRI, if for no other reason than to achieve its own goal of improving the quality of care provided to its beneficiaries.

The fact that cataract surgery continues to be one of the most successful surgical services provided to Medicare beneficiaries should be considered a positive. Consequently, we continue to have difficulty developing measures for this service that can meet the approval of AQA *and* achieve NQF endorsement. As you can see, our subspecialty represents one example of an area in medicine in which no significant gap in care exists, yet we are put in a position in which we must develop measures to assist our members in being able to participate in CMS' quality programs for the mere sake of reporting.

We maintain that for any reporting system to improve quality, the measures must be meaningful to clinical care and relevant to physicians and other health professionals providing the care. **Measures should not be developed for the sake of developing measures. Reporting should not be done just for the sake of reporting. Instead, CMS should work with the medical community to identify gaps in care and prioritize the development of measures so the agency can achieve its goal of improving the quality of care provided to beneficiaries.**

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY

6564 UMBER Circle • Arvada, CO 80007 • 866-892-1001 • Facsimile 303-940-7780

Other items

We appreciate that CMS has addressed many problems with the 2007 PQRI. These include carriers processing claims improperly or not at all, carriers providing misinformation about the PQRI to its providers, and problems associated with implementing the National Provider Identifier (NPI), which is a key component to participating in the PQRI as it is based on individual physician reporting. However, we are very concerned that changes made to the PQRI for 2008 will, once again, cause a great deal of confusion for our members because carriers are ill prepared to address questions about the changes. We have already received a number of queries from our members related to mis-information provided by the carriers as it relates to the 2008 PQRI. We encourage CMS to make educating individuals who are answering PQRI questions on a day-to-day basis at the carrier level a top priority.

We are also concerned that CMS has not done a thorough analysis of the 2007 PQRI data before moving ahead with a 2008 program. We continue to believe a thorough evaluation of data from the 2007 PQRI is necessary before CMS can reasonably move ahead. Some areas CMS should consider are as follows: the impact of the 2007 PQRI program on patient care because according to the agency, this is its number one priority; data related to physician participation rates to determine whether the program, as established, draws enough participation to outweigh the administrative costs associated with its operation; and finally, the costs physicians have and will continue to incur should they participate in the PQRI.

For all the above-stated reasons, we strongly urge CMS to support provisions included in S. 1519/ H.R. 2749, the Voluntary Medicare Quality Reporting Act. Specifically, we ask CMS to:

- **Name the AMA PCPI as the sole entity for the development of physician-level quality measures**
- **Work with the medical specialty community to identify gaps in care for which quality measures are genuinely needed**
- **Ensure that any Medicare quality program for physicians remains voluntary and non-punitive**
- **Provide positive incentives for those who participate in the PQRI and ensure those incentives are compensated with new funding.**

Budget Neutrality

ASCRS and OOSS urge CMS to reconsider its decision to make budget-neutrality adjustments to the work RVUs and encourage the agency to apply the budget-neutrality adjustments to the 2007 conversion factor.

Last year, CMS finalized a proposal from its 5-year review of work relative value units (RVUs) and 2007 MPFS proposed rules to meet its budget-neutrality requirement by reducing all work RVUs by an estimated 10%. This was against the recommendation of the majority of medical specialty societies, including the AMA. This year, CMS proposes to make a similar adjustment

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY

6564 UMBER CIRCLE • ARVADA, CO 80007 • 866-892-1001 • FACSIMILE 303-940-7780

by reducing work RVUs by an additional 1%. As we explained before, the application of a budget-neutrality work adjuster to the work RVUs is counterintuitive and halts the progress made by specialty societies, the AMA Relative Value System Update Committee (RUC), and CMS, which spent countless hours developing accurate changes to work RVUs. In addition, the application of a budget-neutrality adjuster to the work RVUs goes against CMS' longstanding policy that adjustments to RVUs to maintain budget neutrality are ineffective and cause confusion. It is for this reason CMS has been applying budget-neutrality adjustments, due to changes in the work RVUs, to the physician fee schedule conversion factor since 1998.

In addition, the vast majority of private payers use the Medicare fee schedule in their contracts with physicians, and physicians could be negatively affected if private payers used budget-neutrality-adjusted work RVUs. To maintain two separate work RVU lists, one adjusted for budget neutrality and one not adjusted for budget neutrality, has already generated needless confusion and administrative hassle for most physicians. Let's not create a similar situation this year.

Finally, CMS explained last year that it would implement the work adjuster instead of applying budget-neutrality adjustments to the conversion factor, because it believed it would be more equitable to make the reduction to the portion of the physician payment formula that was directly involved in the 5-year review. This rationale was not plausible, because it assumed all work RVUs were involved in the 5-year review. As you know, only about 6% of the more than 7,500 physician codes were involved in third 5-year review of work RVUs. Under CMS' plan, many codes will be penalized simply because they have work RVUs. Again, it only makes sense to apply budget-neutrality adjustments to the conversion factor, because it is the only monetary factor in the formula.

For the above stated reasons, we again urge CMS to reconsider its decision and apply its budget-neutrality adjustment to the conversion factor rather than the work RVUs.

Coding – Reduction in TC for Imaging Services

ASCRS and OOSS, as well as the AAO and others in ophthalmology, are disappointed that CMS has finalized its decision to apply the Deficit Reduction Act of 2008 (DRA) cap on the technical component (TC) of the MPFS payment amount for imaging services at the Outpatient Prospective Payment System (OPPS) payment amount for several ophthalmic services. As you know, the DRA defines imaging services as "imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography." The ophthalmic services identified by CMS in the proposed rule (CPT 92135, 92235, 92240, 92250, 92285, and 92286) do not meet the DRA definition, which explains why they were not included in the original list of imaging procedures. The ophthalmic codes identified by CMS describe services that use photographic equipment or an angioscope. Clearly, Congress did not intend for any service that uses a camera or microscope, takes photographs, and/or produces negatives to be included in the DRA definition of imaging services. Should CMS actually believe these services are "imaging," it will need to

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY

6564 UMBER Circle • Arvada, CO 80007 • 866-892-1001 • Facsimile 303-940-7780

include many other services that use photographic equipment, microscopes, or any other form of magnification.

We believe subjecting the aforementioned ophthalmic codes to the DRA cap is a deliberate stretch by CMS and goes far beyond the intent of the DRA, as explained by the AAO. Therefore, we strongly oppose the agency's decision and urge CMS to reconsider.

* * * * *

ASCRS and OOSS look forward to working with CMS on the 2008 physician fee schedule and encourage CMS to include the recommendations. Should you have any questions or comments, please contact Emily L. Graham, RHIT, CCS-P, CPC, ASCRS Associate Director of Regulatory Affairs, at 703-591-2220 or egramham@ascrs.org, or Michael A. Romansky, OOSS Legal Counsel, at MRomansky@OOSS.org.

Sincerely,



Richard L. Lindstrom, MD
President, ASCRS



William Fishkind, MD
President, OOSS

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY

6564 UMBER Circle • Arvada, CO 80007 • 866-892-1001 • Facsimile 303-940-7780

Submitter : Dr. John Coster
Organization : Rite Aid Corporation
Category : Drug Industry
Issue Areas/Comments

Date: 12/28/2007

GENERAL

GENERAL

See attachment

CMS-1385-FC-219-Attach-1.DOC



With us, it's personal.

December 31, 2007

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

Subject: CMS-1385-FC: 42 CFR 423.160. Medicare Program; the Amendment of the E- Prescribing Exemption for Computer-Generated Facsimile Transmissions; Final Rule

Dear Sir/Madam:

The Rite Aid Corporation appreciates the opportunity to provide comments on CMS' final rule to amend the e-prescribing exemption for computer-generated facsimile transmissions under 42 CFR 423.160. Rite Aid is one of the nation's largest retail drug chains, operating 5100 pharmacies in 31 states and the District of Columbia.

As we stated in our comments on the proposed regulation, we believe that the final rule will cause prescribers to regress toward using traditional paper and oral prescribing, and away from e-prescribing. This will have negative consequences for both patients and pharmacies. Pharmacies will receive fewer electronic prescriptions, and will have to call prescribers by telephone or send traditional faxes for refill authorizations rather than send electronic requests.

Impact of Rule Greatest on Patients and Pharmacies

We appreciate CMS's recognition in the final regulation that computer-generated faxes will still be needed as a contingency for failures in electronic data exchange (EDI) transmission. This contingency will allow pharmacies to receive prescriptions and submit refill requests to prescribers in a timely manner.

However, the final rule will impose greater workload burdens on pharmacies, despite the fact that pharmacies are doing everything in their power to comply with the NCPDP SCRIPT standard. We believe that any NCPDP SCRIPT enabled sending entity, such as a pharmacy, should be able to send a computer generated fax even if the receiving entity is not capable of receiving an NCPDP SCRIPT message. Many pharmacies send refill requests by computer generated fax to prescribers who do not have e-prescribing technology.

However, the final rule could have the unintended consequence of prohibiting prescription refill request (and new prescription) faxes that are generated by computer programs unrelated to e-prescribing systems, such as word processing systems.

Many prescribers and pharmacies utilize these types of programs as part of a traditional facsimile system. However, the language of the final rule, read literally, would prohibit prescription refill requests (and new prescriptions) from being generated and sent by fax using these types of computer programs. We urge CMS to clarify in the final rule that this is not your intent.

Pharmacies could have to stop submitting electronic refill requests to such prescribers through computer generated faxes, causing them to either have to fax through a stand-alone fax machine or to contact them by telephone, which will result in tremendous slowdowns in pharmacy workflow and consequently, adversely affect patient care.

We estimate that as many as 5 million Rite Aid new and refill prescription requests per year could be affected by this rule making. This would result in significant additional cost to our chain, a disruption in workflow, and could potentially increase medication-related prescription filling errors.

Even if prescribers are NCPDP SCRIPT standard compliant, pharmacies cannot often distinguish between a fax that originated from a fax machine and one that originated electronically. This could result in pharmacies having to refuse prescriptions transmitted by fax. We cannot be in the position of having to confirm the legality of each fax we receive. This would have a tremendous adverse affect on pharmacy workflow, as pharmacists would have to call prescribers by telephone to replace potentially non-compliant faxed prescriptions.

We support CMS' proposal to foster further adoption of true e-prescribing, and we urge CMS to move forward with the final rule, incorporating the recommendations we have provided above. As a summary, we ask that CMS:

- Allow computer generated faxes between pharmacies who engage in e-prescribing and prescribers who do not; and,
- Recognize that pharmacies cannot enforce the rule upon prescribers, and should not be penalized for prescriber non-compliance.

We thank you for the opportunity to provide additional comments on the final rule related to the elimination of the exemption for computer generated faxes. If we can be of any assistance, please contact me at 703-888-0859 or at jcoster@riteaid.com.

Sincerely,

John M. Coster

John M. Coster, Ph.D., R.Ph.

Vice President, Federal Affairs and Public Policy

Submitter : Dr. Joel Cornfield
Organization : Uropartners, LLC
Category : Physician

Date: 12/29/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-FC-220-Attach-1.DOC

December 29, 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 Administrator Weems:

I am a urologist who practices medicine as a member of Uropartners, LLC, a single specialty group practice in the metropolitan Chicago area. Uropartners was formed in the summer of 2005 through the merger of 11 separate urology practices. These practices came together because of a shared belief that patients benefit from the resources and efficiencies of a large, single-specialty group. Today, Uropartners has over 35 urologists treating patients at 20 different office locations. Many of our patients are Medicare beneficiaries. 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

our group practice—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.

After Uropartners was formed, our physician leadership began exploring the possibility of furthering our mission by bringing pathology services in-house. Initially, we were approached by several companies offering us the ability to participate in "condo lab" arrangements. That model did not appeal to Uropartners because we felt it did not give us the control over quality and service that we were seeking. In addition, we believed that this model potentially violated the spirit of the applicable regulations. We ultimately built our own laboratory in a building that is centrally located to our clinics. We invested almost \$700,000 in state-of-the art lab equipment and facilities, hired three board certified pathologists to work exclusively in the lab, and hired a staff of technicians and office personnel that has grown to 10 full-time equivalent employees. Based on the new anti-markup regulations, it will not be possible for our 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 changes proposed in these rules will have a serious impact on the way our urology group practices medicine and will not lead to the best medical practices. These rules will adversely 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 Uropartners to continue to provide pathology services to our patients. Since its opening in 2006, the Uropartners lab has proven to be very beneficial for patient care. Some of the specific benefits our patients have received that are attributable to the Uropartners lab are:

1. Better quality control. The director of our pathology lab is an active participant at all Uropartners' Board of Managers meetings and also serves as the chair of the Clinical Laboratory Quality Assurance Committee which meets regularly and reports to the Board. A laboratory representative also attends all office manager meetings to receive feedback on the quality of care and service. Laboratory information is disseminated via a monthly newsletter, facilitating communication between the pathologists, the urologists, and their respective staffs.

2. Uropartners' urologists controlled the selection of the pathologist. Uropartners conducted an extensive search to find pathologists for our lab who met our standards for competency and responsiveness. The pathologists we hired met, and continue to meet, those standards. Consequently, we have a high degree of confidence and trust in the pathologist making the diagnosis.

3. Our pathologists sub-specialize in urological pathology. Our pathologists only examine urological specimens. As a result, they have an expertise that a general pathologist working for an outside lab is unlikely to have.

4. Pathology reports are more accessible. Because our pathology reports are maintained within our medical records system, our urologists have direct access to those reports.

5. Turnaround time is faster. In large part due to our lab's central location, and due to the fact that the Uropartners lab runs smoothly and efficiently, our patients do not have to wait an unnecessary amount of time to find out whether a biopsy is positive or negative.

6. Our pathologists are more responsive. Our pathologists work exclusively for us and they are directly accountable to us. As a result, we see a level of responsiveness that we did not see with outside labs that we used before establishing the Uropartners lab.

7. Our urologists regularly interact with the pathologists. We are all part of one group, and our urologists and pathologists treat patients in coordination with one another.

8. Patients have the opportunity to visit our lab and review their cases with the diagnosing pathologists. Our lab is easily accessible for patients, and our pathologists welcome the face-to-face interaction with patients.

9. Our urologists have the ability to direct where second opinions are performed. If a Uropartners urologist wants a second opinion from, say, the Mayo Clinic, the opinion is performed at the Mayo Clinic. There are no conflicts with bureaucracy or internal policy, which occasionally occur at commercial labs.

10. Our patients get one bill from one place. When an outside lab is used, the patient often times gets 3 separate bills - one from the urologist, one from the lab, and one from the pathologist. This leads to confusion for the patient. It is also inefficient.

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,

Joel Z. Cornfield, M.D.
Manager
Uropartners, LLC

Submitter : Ms. Camilla Ackerson

Date: 12/29/2007

Organization : Guardian Angel Ambulance Services, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

In regard to the Beneficiary Signature for Ambulance Transport Services, I first feel this would increase the burdon on ambulance services. Second, if this will not be over turned, would an electronic signature from a Hospital on a demographic sheet when the patient is delivered to the hospital be sufficient? This would be for emergency or non-emergency situations. The required information could be included on the hospital sheets. Camilla Ackerson 412 464 1000

Submitter : Dr. Ronald Mann
Organization : Catalina Dermatology
Category : Physician

Date: 12/29/2007

Issue Areas/Comments

GENERAL

GENERAL

To Whom it May Concern: As a fellowship-trained Mohs micrographic surgeon, I am writing with considerable concerns regarding the multiple surgery reduction rule. Removing Mohs from the Multiple Procedure Reduction Rule exemption list is an unwarranted and tragic reversal of 16 years of practice. This determination is bound to negatively impact the quality of care afforded Medicare patients. Medicare patients with multiple tumors will likely encounter delays in treatment. They will also face the inconvenience and increased cost of referral to plastic surgeons for repair. I urge you to consider the plight of Medicare patients. Respectfully, Ronald M. Mann, M.D.

Submitter : Mr. C. Edward Brown
Organization : The Iowa Clinic, P.C.
Category : Other Health Care Professional

Date: 12/29/2007

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached comment on the anti-markup rule

CMS-1385-FC-223-Attach-1.DOC

On behalf of the Iowa Clinic, I would like to offer comments about the new anti-markup rule. I believe that the new rule exceeds CMS' authority under the authorizing statute, and is bad policy. I wish to focus my comments on the requirement that services must be provided in a building where the clinic provides the full range of its services and the implications it has for clinics that might perform lab, imaging or other diagnostic work in a building where there is a limited physician presence. Since many lab or diagnostic tests are performed under general supervision which does not require a physician presence, many tests are performed in buildings where there is no physician presence. Obviously, when the test merits a physician's presence, we have a physician there, but that does not mean that the full range of physician services are provided; the supervising physician is there to supervise the test, not offer every possible service. The new rule inexplicably treats tests performed under general supervision like tests purchased from an outside entity. The new rule also has a perverse negative impact on physician practices that permit physicians to perform reads either at clinic space devoted exclusively to interpretations, space leased in a hospital or at the physician's home. Here are my detailed comments:

1. Under Section 1842(n) of the Social Security Act, commonly called the anti-markup provision, if a physician supervises a test, the anti-mark-up rule does not apply. To the extent the rule imposes additional requirements, it is inconsistent with the statutory language.

As you know, Section 1842(n) of the Social Security Act provides that

If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1861(s)(3) (other than a clinical diagnostic laboratory test) for which the bill or request for payment **does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test**, the amount payable with respect to the test shall be determined as follows:

(A) If the bill or request for payment indicates that the test was performed by a supplier, identifies the supplier, and indicates the amount the supplier charged the billing physician, payment for the test (less the applicable deductible and coinsurance amounts) shall be the actual acquisition costs (net of any discounts) or, if lower, the supplier's reasonable charge (or other applicable limit) for the test.

(B) If the bill or request for payment (i) does not indicate who performed the test, or (ii) indicates that the test was performed by a supplier but does not identify the supplier or include the amount charged by the supplier, no payment shall be made under this part.

The bold language clearly limits applicability of the rule to situations where the test is neither performed nor supervised by the physician or a physician with whom the physician shares a practice. Through your regulatory authority, at 42 C.F.R. 410.32, you created three levels of supervision for diagnostic tests. The definition of general supervision states that "the physician's presence is not required during the performance of the procedure." If a physician (or

someone with whom the physician shares a practice) is providing general supervision to a lab test, imaging, or other diagnostic test done offsite, the anti-markup statute does not apply. To the extent the new rule establishes additional requirements, it is inconsistent with the statute. In particular, the requirement that the physician “provides the full range of services” in the building is inconsistent with the statute. In short, the statute does not permit you to require a physician’s presence unless that presence is necessary to supervise the test.

2. Even if the rule did not exceed the statutory authority, the rule unfairly penalizes organizations that provide diagnostic services in free-standing location.

Many clinics have space designated for diagnostic tests. (In fact, the final rule does not define “space” but some tests, such as MRIs, MUST be performed in special space for safety reasons. One could interpret the rule as requiring physicians to provide services in the room with the MRI, a practical impossibility.) Under the final rule, the organization is treated as if it is purchasing the test from its own employed technician. It is hard to understand what policy is advanced by the rule. Imagine two clinics. Both pay an MRI technician \$75,000 a year, or about \$1500/week, or \$300/day. The technician does about 15 scans a day. The only difference between the two clinics is that one clinic provides the full range of its services in one building, the other has a building designated exclusively for diagnostic services. Under the new rule, the first clinic may bill the full Medicare fee schedule, around \$450. The second clinic may only bill Medicare \$20 for a scan. No policy or logic underlies this dramatic reimbursement distinction. In both cases, the clinic is responsible for the cost of all overhead, including purchasing the equipment, and is responsible for supervising the tests. The services are being provided by employees. There is no reason to characterize the services provided at a centralized location as “purchased.” It is disingenuous to claim that a clinic is purchasing services from its own employees.

The new rule causes the clinic to lose significant money on each test. These are services provided by our employees, under our supervision. There is no reason to characterize these tests as “purchased.” Preventing a clinic from recovering its overhead costs creates an affirmative disincentive to provide care to Medicare patients.

3. The statute only applies to diagnostic tests covered under 1861(s)(3). Interpretations are physician services covered under 1861(s)(1). Therefore, the anti-markup statute does not apply to interpretation.

In recent rulemaking, CMS has gone to some lengths to emphasize that the various items listed under 1861(s) of the social security Act are different benefits. In your September 5th Stark III final rule, CMS stated that if a service was covered by one of the 1861(s) benefits, you will not permit the service to be provided “incident to” a physician’s services. CMS used that rationale to justify its refusal to pay for diagnostic tests as “incident to” a physician’s services.

“Diagnostic tests” are covered under 1861(s)(3), a separate benefit from 1861(s)(1), which covers physician services. The anti-markup statute refers only to “diagnostic tests,” not to “physician services.” CMS’ assertion that perhaps the omission was inadvertent is disingenuous. If Congress had meant to include the term “physician services” in the statute, it was free to do so

over the last 15 years. CMS does not have the authority to disregard the statute and combine 1861(s)(3) and 1861(s)(1), particularly given that CMS' other interpretations have highlighted the distinction between those sections.

4. A clinic should not be deemed to be "purchasing" an interpretation from its own employee simply because the employee is not in the main clinic space.

We certainly understand concern about purchased interpretations. But we do not understand why those concerns would extend to services performed by individuals who are employed exclusively by a clinic. Electronic communication makes it relatively easy for physicians to provide interpretive services offsite, whether at home, at space leased from a hospital or in another location. There is no reason that the clinic should receive lower reimbursement based entirely on the location of physician when s/he performs the exam. The clinic is still incurring all of the overhead costs associated with the scan. (The site of service differential for services provided in the hospital is clearly distinguishable. There the hospital is incurring some of the overhead. For services provided at a physician's home, the clinic is still fully responsible for the full overhead cost.) Limiting the clinic's reimbursement to the amount billed by the physician prevents the clinic from recovering any of its overhead costs, including the costs associated with acquiring the equipment that permits the physician to read at home, the cost of preparing the bills, scheduling the appointment, preparing the report and operating the clinic. In most clinics, overhead costs constitute approximately half of the total clinic revenue. The rule prevents clinics from recovering those costs when interpretations are done at the physician's home, or at space devoted exclusively to providing interpretations. There are many situations where an interpretation performed at a physician's home may be faster. This speed may save lives. It is terrible policy to penalize clinics willing to spend the money to improve patient care.

Submitter : Mr. DAVID ABRAMS
Organization : FAMILY MEDICAL TRANSPORT, LLC
Category : Other Health Care Provider

Date: 12/29/2007

Issue Areas/Comments

GENERAL

GENERAL

The final rule requirement regarding signatures of patients who were unable to sign their name adds such a strain and bureaucratic obstacle on providers so as to harm the Medicare system. When a patient signs up for Medicare, there is a ready made assumption that the patient's intent is for Medicare to pay for health care related charges. The added burden on providers to "track" down a representative (likely in another city) will decrease the liquidity of providers and decrease an ability to focus on services. The burden will also be transferred to POA's and representatives because a signature will be required for EACH PROVIDER caring for the patient. In theory, this idea makes sense for a physician's office, but for an ambulance transport, the representative will have to sign for the ambulance provider, the ER physician, Radiologist, PA, Lab personnel, CT/MRI technicians who perform the test, any physician who admits the patient, etc etc. This is overly burdensome on ALL providers and patients involved to a level of outright ABSURDITY! Patients who are unable to sign should have an implied consent, based on their initial enrollment with Medicare, for providers to be able to invoice on their behalf and receive payments for services rendered. Medicare currently sends EOB's to all patients describing payment to providers, thereby allowing a second opportunity for that consent to be revoked. The burden here is far too great and with little to no benefit to any party involved.

Respectfully submitted,
David Abrams, Esq.
Member-Manager
Family Medical Transport, LLC

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

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

The final rule requirement regarding signatures of patients who were unable to sign their name adds such a strain and bureaucratic obstacle on providers so as to harm the Medicare system. When a patient signs up for Medicare, there is a ready made assumption that the patient's intent is for Medicare to pay for health care related charges. The added burden on providers to "track" down a representative (likely in another city) will decrease the liquidity of providers and decrease an ability to focus on services. The burden will also be transferred to POA's and representatives because a signature will be required for EACH PROVIDER caring for the patient. In theory, this idea makes sense for a physician's office, but for an ambulance transport, the representative will have to sign for the ambulance provider, the ER physician, Radiologist, PA, Lab personnel, CT/MRI technicians who perform the test, any physician who admits the patient, etc etc. This is overly burdensome on ALL providers and patients involved to a level of outright ABSURDITY! Patients who are unable to sign should have an implied consent, based on their initial enrollment with Medicare, for providers to be able to invoice on their behalf and receive payments for services rendered. Medicare currently sends EOB's to all patients describing payment to providers, thereby allowing a second opportunity for that consent to be revoked. The burden here is far too great and with little to no benefit to any party involved.

Respectfully submitted,
David Abrams, Esq.
Member-Manager
Family Medical Transport, LLC

Submitter : Dr. Pamela Woodard
Organization : North American Society for Cardiovascular Imaging
Category : Health Care Professional or Association

Date: 12/29/2007

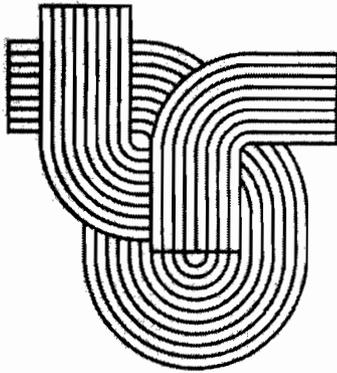
Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1385-FC-225-Attach-1.PDF



NORTH AMERICAN SOCIETY FOR CARDIOVASCULAR IMAGING
(Established 1973)

December 28, 2007

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

President

Pamela K. Woodard, MD

President-Elect

Vincent B. Ho, MD

Secretary-Treasurer

Geoffrey D. Rubin, MD

Immediate Past President

Arthur E. Stillman, MD, Ph D

Board of Directors

Jerome Breen, MD
James P. Earls, MD
Scott D. Flamm, MD
Thomas Gerber, MD
Jill Jacobs, MD
Johan HC Reiber, Ph.D.
Richard White, MD

Past Presidents

Melvin M. Figley, MD
Melvin P. Judkins, MD
M. Paul Capp, MD
Kent Ellis, MD
Erik Carlsson, MD
Larry P. Elliott, MD
Herbert L. Abrams, MD
Murray G. Baron, MD
Harold A. Baltaxe, MD
Richard B. Jaffe, MD
Sven J.K. Paulin, MD
Charles B. Higgins, MD
Kenneth E. Fellows, Jr., MD
Harold T. Dodge, MD
Diana F. Guthaner, MD
Donald P. Harrington, MD
Paul J. Cannon, MD
Ina L. D. Tonkin, MD
Julius H. Grollman, Jr., MD
Curtis E. Green, MD
Lewis Wexler, MD
Lawrence M. Boxt, MD
Martin J. Lipton, MD
Murray G. Baron, MD
André J. Duerinckx, MD-PhD
Paul R. Julsrud, MD
E. Kent Yucel, MD

Executive Director

Teri Saylor

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

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

Dear Mr. Weems:

The North American Society for Cardiovascular Imaging (NASCI), representing over 750 diagnostic radiologists and cardiologists, is pleased to submit comments on the Final Rule "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008" published in the *Federal Register* on November 27, 2007. In this letter, we will specifically address cardiac MRI codes.

Cardiac MRI Codes

As a result of the technological changes in MRI scanning, the CPT® Editorial Panel created eight new cardiac MRI codes and deleted five existing cardiac MRI codes. The new codes are: CPT code 75557, 75558, 75559, 75560, 75561, 75562, 75563, and 75564. The deleted codes are 75552, 75553, 75554, 75555, and 75556. NASCI surveyed the eight new codes and has noted that for the four new cardiac MRI codes that contain "with flow/velocity quantification," CMS stated the following in the final rule.

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

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

1500 Sunday Drive, Suite 102, Raleigh, NC 27607
Phone (919) 861-4533; Fax (919) 787-4916
Web site: www.nasci.org

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

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

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

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

MRA is covered, which do not include determinations of cardiac valve area. Velocity flow mapping has little in common with magnetic resonance angiography except that one type of pulse sequence used for MRA in the past included a phase-contrast MR angiography sequence, in which a phase image was subtracted from one acquired without the velocity encoding gradients in order to obtain an MR angiogram. In fact, even after CMS's comments in the rule regarding the National Coverage policy from 1994, we are still uncertain why 75556 would be included in the group of magnetic resonance angiography codes or MR spectroscopy. Specifically, it is still not clear to us where CMS defines 75556 as magnetic resonance angiography. We have reviewed a number of transmittals for magnetic resonance angiography and magnetic resonance spectroscopy and find that current CMS policy seems to merely instruct the Medicare contractors not to cover 75556 but leaves the reasons for non-coverage ambiguous. The *Carriers Manual* regarding the issue defines the covered indications for MRA, but is silent with respect to specific instruction regarding payment policy for 75556. One contractor's LCD defines the reason for no-coverage as follows: "Other usages of MRA (72159, 72198, 73225) including cardiac MRI for velocity flow mapping (75556) are considered investigational and are not eligible for reimbursement." However, we have been unable to find that specific statement in a CMS transmittal. NASCI, like the ACR, would appreciate clarification and a specific reference in CMS transmittals iterating why flow velocity measurements by MRI for determining cardiac valvular function should be classified as magnetic resonance angiography and why this service should be considered investigational or not reasonable and necessary service.

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

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

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

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

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

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

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

NASCI is particularly disappointed with CMS's decision regarding payment policy for the cardiac MRI codes that include flow velocity determinations because it was our intent, along with the ACR and American College of Cardiology (ACC) to bring forward a set of bundled codes that accurately described the permutations of performing cardiac MRI without having to have a series of component codes where providers would pick and choose the services performed. At the urging of CMS, the CPT Editorial and the RUC, specialty societies have been asked to create codes that describe the entire episode of care rather than a series of component codes or add-on codes in order to eliminate the possibility of duplication of work and practice expense. The ACR and ACC took this advice to heart and created such a set of codes for cardiac MRI. The codes that include velocity determinations are the workhorse examinations for cardiac MRI studies. CMS payment policy puts radiologists and cardiologists in the unanticipated conundrum of choosing between four suboptimal options. Physicians can do the complete examination, code the complete examination and not be reimbursed. Alternatively, the physician can do the complete examination and down-code the examination to the codes that do not include velocity determinations. However, this method violates CPT coding policy, and places providers at risk of Medicare fraud for coding the incorrect examination for the sole purpose of obtaining reimbursement. While either of these alternatives will do what is correct for the patients, both are untenable for the physicians. Unfortunately, CMS payment policy, based on a 1997 assessment that flow velocity determinations by MRI are not reasonable and necessary, now dictates that physicians must perform an incomplete cardiac MRI examination and then refer the patient for additional and/or potentially more invasive studies such as echocardiography, transthoracic echocardiography or cardiac catheterization in order to determine valve area, extent of regurgitation or gradient, or Qp/Qs ratio. NASCI believes this recommendation is flawed because it subjects patients to unnecessary examinations and increases the cost of their cardiac evaluation. Nonetheless, the NASCI will have to provide this recommendation to its members unless CMS reconsiders its payment policy. The final option is to obtain an Advanced Beneficiary Notice from patients undergoing the cardiac MRI examinations that include flow velocity determinations. Certainly, an allowable scenario for physicians under the proposed payment policy. Unfortunately, patients would then have to pay for an entire examination when flow is ordered even though CMS covers all of the other components of the examination when flow is not included. Providers will have to explain to beneficiaries that while CMS will cover a lesser examination, that includes 90% of the cost (based on work RVUs), when flow velocity determinations are not necessary, CMS requires that patients must pay the cost of the entire examination (not just the additional flow velocity component) when determination of valve function is needed. We believe that beneficiaries will have difficulty understanding the nuances of CMS's reimbursement policy and ask the providers to perform only the covered examinations, which will require them to undergo additional and sometimes more invasive testing. We believe that CMS may not have anticipated these outcomes when establishing payment policy for cardiac MRI and are hopeful CMS will reconsider its position.

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

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

Conclusion

Thank you for the opportunity to comment on this Final Rule. NASCI encourages CMS to continue to work with physicians and their professional societies. NASCI looks forward to working with CMS on this important issue. If you have any questions or comments regarding this letter, please contact me at 314-362-9989 or via email at woodardp@wustl.edu.

Respectfully Submitted,

Pamela K. Woodard, MD
President

cc: Vincent Ho, MD
Geoffrey Rubin, MD
Arthur Stillman, MD, PhD
Richard White, MD
Jerome Breen, MD
James P. Earls, MD
Scott D. Flamm, MD
Thomas Gerber, MD
Jill Jacobs, MD
Johan HC Reiber, PhD

Submitter : Ms. deborah daigle

Date: 12/29/2007

Organization : ibc

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

As an insurance case manager who follows up telephonically with patients post hospital and rehabilitation stays, I can personally attest to the medication errors I pick up as a result of ineffective transition of patients across the continuum, misunderstood, unclear written instructions, not including families in the discharge process due to misunderstanding of the HIPPA regulations, and the lack of follow through on orders for the initiation of home services. This results in absolute confusion, disaster and often readmission within one week if not caught in time. I urge you to change the Current Terminology Codes (CPT) 99441, 99442, 99443, 98966, 98967, and 98968 from Status N to Medicare payable and change these codes from an N Status to Medicare payable. Attaching the transition care role to the primary care physician's office is key in my opinion.

Submitter : Rebecca Kelly
Organization : American College of Cardiology
Category : Physician

Date: 12/30/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-FC-227-Attach-1.PDF



Helping Cardiovascular Professionals
Learn. Advance. Heal.

Heart House
2400 N Street, NW
Washington, DC 20037-1153
USA

202.375.6000
800.253.4636
Fax: 202.375.7000
www.acc.org

President
James T. Dove, M.D., F.A.C.C.

President-Elect
W. Douglas Weaver, M.D., F.A.C.C.

Immediate Past President
Steven E. Nissen, M.D., M.A.C.C.

Vice President
Alfred A. Bove, M.D., Ph.D., F.A.C.C.

Secretary
George P. Rodgers, M.D., F.A.C.C.

Treasurer
William A. Zoghbi, M.D., F.A.C.C.

Chair, Board of Governors
George P. Rodgers, M.D., F.A.C.C.

- Trustees*
- Peter Alagona Jr., M.D., F.A.C.C.
 - Elliott M. Antman, M.D., F.A.C.C.
 - Alfred A. Bove, M.D., Ph.D., F.A.C.C.
 - A. John Camm, M.D., F.A.C.C.
 - Richard A. Chazal, M.D., F.A.C.C.
 - Pamela S. Douglas, M.D., M.A.C.C.
 - Paul L. Douglas, M.D., F.A.C.C.
 - James T. Dove, M.D., F.A.C.C.
 - James W. Fasules, M.D., F.A.C.C.
 - Michael D. Freed, M.D., F.A.C.C.
 - Linda D. Gillam, M.D., F.A.C.C.
 - David R. Holmes Jr., M.D., F.A.C.C.
 - Jerry D. Kennett, M.D., F.A.C.C.
 - Michael G. Kienle, M.D., F.A.C.C.
 - Bruce D. Lindsay, M.D., F.A.C.C.
 - Charles R. McKay, M.D., F.A.C.C.
 - Michael J. Mirro, M.D., F.A.C.C.
 - Rick A. Nishimura, M.D., F.A.C.C.
 - Steven E. Nissen, M.D., M.A.C.C.
 - Patrick T. O'Gara, M.D., F.A.C.C.
 - Miguel A. Quinones, M.D., F.A.C.C.
 - George P. Rodgers, M.D., F.A.C.C.
 - Jane E. Schauer, M.D., Ph.D., F.A.C.C.*
 - James E. Udelson, M.D., F.A.C.C.
 - C. Michael Valentine, M.D., F.A.C.C.*
 - W. Douglas Weaver, M.D., F.A.C.C.
 - Kim Allan Williams, M.D., F.A.C.C.
 - Michael J. Wolk, M.D., M.A.C.C.
 - Janet S. Wright, M.D., F.A.C.C.
 - William A. Zoghbi, M.D., F.A.C.C.

*ex officio

Chief Executive Officer
John C. Lewin, M.D.

December 31, 2007

Mr. Kerry Weems
Acting Administrator,
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8018

Dear Mr. Weems:

The American College of Cardiology (ACC) is pleased to offer our comments on Section II (M) of the Final Rule with Comment Period entitled **CMS-1385-FC Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008** (Fee Schedule) published in the *Federal Register* on November 27th, 2007 (72 Fed. Reg., 66221 – 66578).

The ACC is a 34,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The ACC believes that rational, fair physician payment policies are a critical component of adequate access to care. We offer the following comments on Section II (M) [*Physician Self-Referral Provisions*] in support of that goal. In addition, as noted in our previous comments on the proposed Fee Schedule, the College remains eager to assist CMS with any efforts to: further review, revise, or otherwise clarify the anti-markup rule; produce guidance on compliance for affected providers; and develop alternative methods for promoting appropriate use of services to reduce the occurrence of fraud, waste, and abuse in the Medicare program.

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

The College has several significant concerns with the physician self-referral provisions included in the final CY 2008 Medicare Physician Fee Schedule (Fee Schedule). Our reservations arise out of:

1. The anti-markup provision as finalized;
2. The process by which CMS adopted this change; and
3. The agency's intention to adopt additional changes—those first included in the *proposed* Fee Schedule but not adopted in the *final* Fee Schedule—to the physician self-referral provisions through means similar to which it adopted the final anti-markup rule.

ACC Recommendations:

The ACC—

- Respectfully urges CMS not to adopt the changes to the anti-markup rule that were not included in the proposed fee schedule—notably the provision applying the rule to “tests performed outside the office” (See 72 Fed. Reg. 38122 – 38395; July 12, 2007)—without permitting additional public comment first;
- Recommends that CMS reject the process by which it adopted the final modifications to the anti-markup rule—that is, without first permitting additional public comment. Where the additional changes were determined necessary by CMS, we believe the agency should have initiated a separate NPRM for the anti-markup rule divorced from the Fee Schedule. Instead, the process by which CMS adopted this rule change creates the perception among stakeholders that the agency did not find it necessary to seek their input—flying in the face of the CMS' significant efforts to foster collaborative relationships with all interested parties.
- Urges CMS to reconsider its determination to utilize a process, similar to the one used for adopting the changes to the anti-markup rule, by which it intends to adopt future changes to the physician self-referral rules discussed in the *proposed* Fee Schedule but not included in the *final* Fee Schedule (See 72 Fed. Reg. 66306, November 27, 2007)
- Strongly recommends, as an alternative to the process described above—and the potential difficulties it may portend—CMS initiate separate NPRMs for the changes to the physician self-referral rules as introduced in the proposed Fee Schedule but not adopted in the final rule. (ibid.) Using such a process is, we believe, consistent with CMS' previous efforts to seek public input during rulemaking, as opposed to the agency's announced intention to finalize them without providing any additional opportunity for public comment. (id.)
- Encourages CMS—should it choose not to withdraw the changes to the anti-markup rule as recommended by the ACC—to delay application of the revisions to the anti-markup rule for at least one year for purposes of allowing affected

providers to assess their current arrangements and make any changes necessary for compliance.

These recommendations will be discussed in detail below.

The Anti-Markup Rule

As you are aware, in the anti-markup proposal included in the draft Fee Schedule, CMS proposed initially only to prohibit any “markups” on technical and professional components (“TC” and “PC,” respectively) of diagnostic tests in claims submitted to Medicare—if either or both components were purchased outright by the Medicare billing physician. As originally proposed, the ACC took a neutral position, electing not to submit comments either opposing or supporting this position out of respect for both CMS’ concerns regarding certain markup practices targeted by the changes, and some reservations expressed by our membership regarding the implications of the expanded rule.

Setting aside—temporarily, for purposes of discussing the rule’s provisions only—our concerns with the means by which CMS altered its proposed changes to the anti-markup rule from the proposed version to the final version of the Fee Schedule, we wish to draw your attention to the impracticalities that will arise out of implementing the rule as currently finalized. The chief concern of the ACC with the now finalized anti-markup rule is the newly added “site of service” prong for the compliance test to be used by CMS, whereas in the proposed Fee Schedule the agency proposed to limit applicability only to TCs and PCs that were *purchased* by the physician billing Medicare.

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

This revised definition of “office” provided by the rule imposes an unfair burden—via the limitations of the “net charge” requirements—on group practices that otherwise comply with the in-office ancillary services exception to the self-referral rules. Namely, group practices that provide in-office ancillary services to patients (such as diagnostic tests) in a “centralized building” that complies with the physician self-referral rules would no longer be permitted to recover capital costs—by including them as part of a reasonably calculated net charge in claims submitted to Medicare—such as equipment and leasing of space that are incurred in order to provide Medicare beneficiaries greater access to needed services. In other words, CMS plans to require that physician organizations who comply with the self-referral rules take losses on equipment they purchased and spaces they’ve leased (outside of the “office”) for purposes of providing their patients access to needed services. Lastly, the ACC believes the “net charge”

element of the “site of service” test added to the final anti-markup rule is unnecessary since claims submitted by billing physicians to Medicare are already subject to the prohibitions of the Federal False Claims Act.

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

The rule does not distinguish between group or solo practices either, which is unfortunate since these requirements could prove to be more onerous on the latter. For example, under the rule a solo practitioner who reads an x-ray in a rehabilitation facility—not in his office—would be required to generate a charge to him/herself in order to comply with the rule’s requirements. Whereas a group practice may be more capable of absorbing some of these administrative costs due to economies of scale, the smaller (or solo) practice will incur these costs more directly. Ultimately, these administrative costs will be passed along to patients and will contribute, along with other such burdens, to the ongoing inflation of the price of medical care.

The ACC does not understand what benefits, if any, accrue to the Medicare program by imposing this administrative requirement on any providers in these or similar instances.

This “self-charging” consequence could also have a considerably negative—though unintended—impact on private efforts to expand patient access to needed medical services in traditionally underserved areas (i.e. certain rural and urban areas). The unnecessary burden of compliance with the finalized anti-markup rule imposed by CMS could prove to be a significant disincentive for practices (especially solo ones) seeking to open satellite facilities in such underserved areas while maintaining their “primary” office.

Further, the rule does not contemplate the complexity of existing arrangements among physician practices and other providers and payors; it is unclear how the anti-markup provision’s new “office” definition applies to certain types of physician groups. For example, in the case of a surgical practice that focuses on providing substantial services to hospital inpatients, would any non-hospital location provide the “full range” of the practice’s patient care services? Also, with regard to larger, or multi-specialty group practices, could an entire building occupied by such an entity be considered the “office” space where it provides the “full range” of its services? What if the multi-specialty group

practice occupies only a portion of a building? Does ownership vs. leasing of the space become a determining factor? While these issues could be addressed via future guidelines issued by CMS, it will be difficult—if not impossible—to anticipate all of the scenarios affected by this “site of service” requirement without adding another layer of regulatory complexity to a rule that will already prove complicated for providers to comply with. The ACC recommends that CMS, rather than attempt to clarify the application of this portion of the anti-markup rule through additional guidance, instead drop this needlessly complicated provision of the finalized regulation.

If this is the regulatory schema CMS intends to implement, then the ACC cautions that this expansion of the anti-markup rule’s scope to capture the TC and PC of a diagnostic test provided “outside of the office” of the billing entity will prove to be the root cause of considerable disruptions in access to critical diagnostic services of all types by Medicare beneficiaries.

Rulemaking Process – The Anti-Markup Rule

The ACC has serious concerns with the means by which CMS adopted a substantial modification to the anti-markup rule in between its introduction as part of the *proposed* Fee Schedule and its adoption in the *final* Fee Schedule. As discussed in the previous section of this comment letter, the “site of service” prong of the anti-markup rule was published for the first time in the final 2008 Fee Schedule, which unfairly denied stakeholders the opportunity to review the new proposal prior to adoption.

To avoid the prospect of potential legal challenges from different stakeholders on whether CMS’ adoption of this change complied with the negotiated rulemaking process, the ACC again recommends withdrawal of this new “prong” altogether. Otherwise, we believe that—at a minimum—a delay of at least one year in implementation is warranted to allow providers and CMS the opportunity to assess the full impact of these additional changes before they take effect.

Further, independent of the means by which it was adopted, the College believes that application of the anti-markup rule’s “site of service” prong to services provided within a group practice—that is, any “non-purchased” test—exceeds CMS’s statutory authority since the statute itself specifically applies only to purchased diagnostic tests. (See §1842(n) of the Social Security Act) Since members of the same group practice do not “purchase” diagnostic tests from themselves when performed on diagnostic equipment they own as a practice, we fail to see how the interpretation of the statute proffered by CMS in the preamble authorized the agency to extend its application to services provided by physicians in a group practice.

As you are aware, the anti-markup rule—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.” Appropriately, the implementing regulation only bars markups on the technical component of diagnostic tests when they are purchased from an outside supplier. (42 C.F.R. §414.50) Under the new final rule however, and contrary to the statute, CMS expanded the anti-markup rule to apply to services provided within a group practice, as discussed *supra*.

From an implementation standpoint, the ACC believes providers will struggle to understand and make the internal assessments necessary to achieve compliance with the new rule by the January 1, 2008 effective date. In particular, since many will have to develop a new system for “self-charging” required by the rule for physicians providing diagnostic services in off-site locations, we are concerned that the affected providers (of whom we expect will be many) will elect to cease providing diagnostic tests to Medicare patients either temporarily to allow time for compliance, or worse, permanently. As a result, many affected beneficiaries will be forced to travel elsewhere to get the tests they need, which could be highly problematic for patients with limited transportation options.

Again, the ACC urges CMS to either withdraw the “site of service” altogether, or delay implementation of this provision for at least one year in order to evaluate the substantial impact these changes will have on health care providers and, by extension, beneficiaries.

Rulemaking Process – Future Modifications to the Physician Self-Referral Rules

The ACC is similarly concerned with CMS’ announced plans to issue the other physician self-referral proposals discussed in the proposed Fee Schedule as a final rule. We are particularly distressed with CMS’ assessment from the preamble stating: “. . . we are confident that we have sufficient information, both from commenters and our independent research, to finalize revisions to the physician self-referral regulations *without the need for new proposals and additional public comment.*” [Emphasis added.]

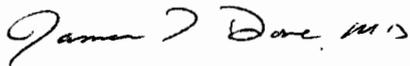
Our dismay stems from the fact that many of the proposed changes to the self-referral rules included in the proposed Fee Schedule were essentially solicitations for public suggestions on how CMS might implement possible changes to address the issues identified. Further, many of the “proposals” themselves offered little substantive detail on how a regulation would operate specifically. CMS, in its own quote provided above, has noted that it has sufficient information from internal research and public comments received to formulate the specifics of their future regulations; unfortunately, the agency has not indicated—in the final Fee Schedule, at least—which comments received from the public it found compelling, or what research findings in particular will inform their forthcoming changes to the rules. In other words, the ACC believes there was little specific content provided on the proposals included in the proposed Fee Schedule that we believe could be reasonably perceived as satisfying the requirement that adequate public notice and comment was provided for prior to adoption as a final rule per the Negotiated Rulemaking Process.

We also believe this approach to rulemaking runs counter to the perception that CMS seeks to work constructively with all stakeholders in the interest of continuing to improve the Medicare program. To avoid potential legal challenges from stakeholders, the College recommends that CMS abandon its stated plan to issue a final rule implementing changes to the Physician Self-Referral rules based on several of the proposals included in the proposed Fee Schedule, and instead initiate a separate NPRM for those changes that do not require individual NPRMs, such as potential modifications to 42 C.F.R. §411.355(b) (the in-office ancillary services exception).

The ACC is sensitive to CMS' concerns regarding fraud, waste, and abuse in the Medicare program, and shares the agency's goal of ensuring appropriate use of medical services. The College is currently following, on its own initiative, another approach to addressing inappropriate or potentially fraudulent utilization of imaging and other procedures, which we invite CMS to consider. Specifically, the ACC continues to strongly advocate among its members, through ongoing educational outreach efforts, the use of ACC guidelines and appropriateness criteria when considering whether to perform/order certain procedures that may be susceptible to overutilization. We again invite CMS to work with the ACC and other medical specialty stakeholder groups to develop alternative means to reducing inappropriate utilization and fraud without also reducing access to, or the promptness and quality of, care provided to beneficiaries.

Once more, the ACC thanks CMS for this opportunity to comment on the 2008 CY Medicare Physician Fee Schedule. The College welcomes any opportunity to assist CMS in general, and if we may be of any help on the Anti-Markup or other Physician Self-Referral provisions in particular, please contact Sergio Santiviago, Senior Specialist – Regulatory Affairs at 202-375-6392 or ssantivi@acc.org with any questions.

Sincerely,



James T. Dove, M.D., F.A.C.C.
President
American College of Cardiology

cc: Jack Lewin, M.D., Chief Executive Officer

Submitter : Dr. James Dove
Organization : American College of Cardiology
Category : Physician

Date: 12/30/2007

Issue Areas/Comments

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

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

See attachment

CMS-1385-FC-228-Attach-1.PDF



Helping Cardiovascular Professionals
Learn. Advance. Heal.

Heart House
2400 N Street, NW
Washington, DC 20037-1153
USA

202.375.6000
800.253.4636
Fax: 202.375.7000
www.acc.org

President
James T. Dove, M.D., F.A.C.C.

President-Elect
W. Douglas Weaver, M.D., F.A.C.C.

Immediate Past President
Steven E. Nissen, M.D., M.A.C.C.

Vice President
Alfred A. Bove, M.D., Ph.D., F.A.C.C.

Secretary
George P. Rodgers, M.D., F.A.C.C.

Treasurer
William A. Zoghbi, M.D., F.A.C.C.

Chair, Board of Governors
George P. Rodgers, M.D., F.A.C.C.

Trustees
Peter Alagona Jr., M.D., F.A.C.C.
Elliott M. Antman, M.D., F.A.C.C.
Alfred A. Bove, M.D., Ph.D., F.A.C.C.
A. John Camm, M.D., F.A.C.C.
Richard A. Chazal, M.D., F.A.C.C.
Pamela S. Douglas, M.D., M.A.C.C.
Paul L. Douglas, M.D., F.A.C.C.
James T. Dove, M.D., F.A.C.C.
James W. Fasules, M.D., F.A.C.C.
Michael D. Freed, M.D., F.A.C.C.
Linda D. Gillam, M.D., F.A.C.C.
David R. Holmes Jr., M.D., F.A.C.C.
Jerry D. Kennett, M.D., F.A.C.C.
Michael G. Kienle, M.D., F.A.C.C.
Bruce D. Lindsay, M.D., F.A.C.C.
Charles R. McKay, M.D., F.A.C.C.
Michael J. Mirro, M.D., F.A.C.C.
Rick A. Nishimura, M.D., F.A.C.C.
Steven E. Nissen, M.D., M.A.C.C.
Patrick T. O'Gara, M.D., F.A.C.C.
Miguel A. Quinones, M.D., F.A.C.C.
George P. Rodgers, M.D., F.A.C.C.
Jane E. Schauer, M.D., Ph.D., F.A.C.C.*
James E. Udelson, M.D., F.A.C.C.
C. Michael Valentine, M.D., F.A.C.C.*
W. Douglas Weaver, M.D., F.A.C.C.
Kim Allan Williams, M.D., F.A.C.C.
Michael J. Wolk, M.D., M.A.C.C.
Janet S. Wright, M.D., F.A.C.C.
William A. Zoghbi, M.D., F.A.C.C.

*ex officio

Chief Executive Officer
John C. Lewin, M.D.

December 31, 2007

Mr. Kerry Weems
Acting Administrator,
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8018

Dear Mr. Weems:

The American College of Cardiology (ACC) is a 34,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC is pleased to offer comments on the final rule with comment period entitled **CMS-1385-FC Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008** published in the *Federal Register* on November 27, 2007. Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair physician payment policies are a critical component of adequate access to care. We offer the following comments in support of that goal.

This letter addresses only practice expense issues and interim relative value units. The College will offer its comments and recommendations related to several other provisions of the Final Rule in a separate letter.

Practice Expense Proposals for 2008

Cardiac Catheterization Procedures

In the Final Rule CMS finalized its proposal to accept the PERC recommendations for 13 cardiac catheterization procedures. The ACC notes that implementation of the revised direct practice expense inputs for these codes has substantially increased the non-facility practice expense RVUs for these services compared to values CMS originally proposed in its June 2006

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

Notice of Proposed Rulemaking. We must also note with concern that, despite this improvement, Medicare payments for these procedures will decline significantly during the remainder of the transition to the new practice expense methodology. The College appreciates CMS's willingness to respond to concerns about the large payment reductions for non-hospital cardiac catheterization facilities.

The ACC is aware of the concerns about the practice expense RVUs for cardiac catheterization procedures that have been raised by the Cardiac Outpatient Center Alliance (COCA). We believe that these concerns involve CMS's practice expense methodology and indirect cost formula. The PERC is highly unlikely to be able to resolve these issues as they fall outside its purview. **The ACC, therefore, recommends that CMS not request that the PERC review this issue again.**

Interim Relative Value Units

Cardiac MRI Codes

The College appreciates the Centers for Medicare and Medicaid Services (CMS) accepting the recommended AMA RUC values for the 8 new CMR CPT codes. However, the College urges CMS to clarify and revise its interpretation and implementation for 4 CPT codes containing the language "with flow/velocity quantification" (CPT 75558, 75560, 75562, and 75564).

The College disagrees with CMS's decision to include a non-covered status indication for the 4 codes "with flow/velocity quantification". We request that CMS provide additional explanation of its determination that blood flow measurement is not "reasonable and necessary" within the meaning of section 1862(a). The quantification for blood flow and velocity is an essential aspect for some Cardiac MRI studies.

In the 2008 MPFS Final Rule, CMS stated:

We have had a national noncoverage determination in place for Magnetic Resonance Imaging (MRI) that provides blood flow measurement since March 1994. Upon review of the new cardiac MRI codes, we recognize that four of the new codes incorporate blood flow measurement, which remains one of the nationally noncovered indications for MRI in the Medicare program. Due to a national non-coverage determination for MRI that provides blood flow measurement, CPT codes 75558, 75560, 75562 and 75564 will not be recognized by the Medicare program and have been assigned a status indicator of "N" (Noncovered) on the Medicare physician fee schedule.

The College urges CMS to change its determination to not cover blood flow measurement. The NCD for MRI was originally effective March 1994 providing limited national coverage, but permitting individual local Medicare contractors to specify additional covered indications. From our research, we have concluded actual language regarding non-coverage of blood flow measurement was inserted into the NCD in 2004 via CMS Change Request 3425 as a clerical/technical edits/clarification without public comment.

The College is very concerned that the nationally covered indications from the NCDs for MRI and MRA deal primarily with the head, neck, central nervous system, spine, masses, and

neoplasms and do not address the importance of using this technology for cardiac conditions. Blood flow measurement is used as an important part for some cardiac MR studies.

The following is a clinical example of a basic cardiac MR examination using morphology, function, and flow/velocity quantification. The CMR is ordered to obtain functional information. Routine clinical indications for cardiac MRI include assessing stenotic and insufficient valves. This requires obtaining velocity and flow measurements. These are often indications for performing a CMR study when an echocardiographic examination is of suboptimal quality.

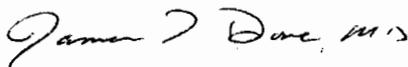
Flow measurements are also obtained routinely in patients with congenital heart disease in order to assess intracardiac shunt ratios to determine the necessity for shunt repair. These patients are often children.

Sequences used to obtain this flow and velocity information are termed "phase contrast" sequences. The information obtained is completely unlike the information obtained from phase contrast MR angiography sequences previously used in lieu of time-of-flight (TOF) imaging to obtain vascular anatomic information without gadolinium-based MR contrast agents. In MR angiography, phase contrast imaging is used solely to provide anatomic information -- no velocity or flow measurements are made. Phase contrast imaging within the heart, conversely, provides purely physiological information.

The College strongly urges CMS to remove the blood flow measurement language from the Nationally Noncovered Indications section from the NCD for MRI, change the status indicator to "A" for CPT codes 75558, 75560, 75562, 75564 and allow its Medicare contractors to determine appropriate covered indications for these 4 "with flow/velocity quantification" codes.

Thank you for the opportunity to comment upon this final rule with comment period. The ACC appreciates CMS' continued willingness to work cooperatively with the physician community to strengthen the Medicare program and improve care for Medicare beneficiaries. Please feel free to contact Denise Garris, ACC's Associate Director of Regulatory Affairs at 202-375-6496 or dgarris@acc.org with any questions.

Sincerely,



James T. Dove, M.D., F.A.C.C.
President
American College of Cardiology

cc: Jack Lewin, M.D., Chief Executive Officer

Submitter : Ms. Cheryl Acres
Organization : Comprehensive Care Management, LLC
Category : Nurse

Date: 12/30/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1385-FC-229-Attach-1.DOC

Comprehensive Care Management, LLC

Your Healthcare Advocates

December 30, 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).

3044 Old Denton Rd., Ste. 111-200, Carrollton, TX 75007-5074
Phone: 972.446.4789 Fax: 972.466.1692
www.txcasemanager.com

Comprehensive Care Management, LLC

Your Healthcare Advocates

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,

Cheryl A. Acres RN, CCM

Signature