Submitter : Dr. Michael Picard **Date:** 10/05/2006

Organization : American Society of Echocardiography

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-454-Attach-1.DOC

Attachment 45

American Society of Echocardiography

Heart and Circulation Ultrasound Specialists

October 5, 2006

Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8018

Re: Proposed CY 2007 Physician Fee Schedule; CMS-1321-P

Dear Dr. McClellan:

The American Society of Echocardiography (ASE) is delighted to have this opportunity to comment on CMS's proposed policies and rates under the Physician Fee Schedule (PFS) for CY 2007, published on August 22, 2006 in the Federal Register (the "Proposed Rule"). The ASE is a professional society consisting of over 11,000 professionals committed to excellence in cardiovascular ultrasound and its application to patient care.

We are aware that many of the major policy and data issues underlying the CY 2007 proposed PFS rates actually were subject to notice and comment earlier this year, in conjunction with a Proposed Notice published in the Federal Register on June 29, 2006 ("June 29 Notice"). ASE submitted comprehensive comments in response to the June 29 Notice, relating to the results of the five year review and to certain changes in the methodology for determining practice expense relative value units. Because these issues contribute significantly to the allowances set forth in the Proposed Rule, we believe that our comments on the June 29 Notice are relevant to CMS's deliberations on the Proposed Rule, and, for that reason, we are incorporating by reference (and attaching for your convenience) our comments on the June 29 Proposed Rule.

One issue that we addressed in our earlier comments may deserve special attention in light of events that occurred after the June 29 Notice comment deadline. Since that time, it has come to our attention that the AMA and some other groups have objected to the budget neutrality adjustment methodology proposed in the June 29 Notice, under which the five year review

changes are to be absorbed exclusively through a 10% reduction in W-RVUs ,while the PE methodology and related changes are to be absorbed exclusively through a reduction in the PE-RVUs. The AMA's position appears to be that the budget neutrality adjustment for the five year review should be made by reducing the conversion factor, while the budget neutrality adjustment attributable to the PE methodology changes should be absorbed exclusively by the PE-RVUs. We understand that the position of these groups is motivated in large part by the fact that, under CMS's proposed budget neutrality methodology, some physicians will not see the full increases that they had anticipated as the result of the five year review changes, especially the increases in evaluation and management (E&M) W-RVUs.

However, we remain concerned about the solution outlined by the AMA in its comment on this issue: The AMA proposes shifting the budget neutrality adjustment resulting from the five year review to the conversion factor, while leaving the budget neutrality adjustment for PE methodology changes to be absorbed exclusively by PE-RVUs. This change clearly would unfairly disadvantage technical component services, including echocardiography technical component services. Since the proposed five year review and PE changes will already result in an overall reduction in the range of 23% for office-based echocardiography services (without counting any conversion factor reduction necessitated by SGR), we strenuously oppose any approach to the budget neutrality adjustment that further disadvantages technical component services.

In the event that CMS shifts the budget neutrality adjustment attributable to the five year review to the conversion factor, the budget neutrality adjustments necessitated by the new PE-RVU methodology (and most certainly the 32% reduction in direct cost allowances) clearly should be shifted to the conversion factor as well. The AMA and other organizations argue that budget neutrality adjustments attributable to PE-RVU methodology changes should be absorbed exclusively by PE-RVUs until certain modifications are made in the equipment utilization and related assumptions and until a multi-specialty survey of indirect costs is completed by the AMA. However, neither changing the equipment-related assumptions nor substituting new indirect cost survey data would affect the 32% direct cost budget neutrality adjustment. There simply is no rational policy reason to treat budget neutrality adjustments made as the result of PE methodology changes differently from those necessitated by the five year review.

While there may be some technical difficulty in determining the amount of the budget neutrality adjustment for indirect PE RVUs, there certainly is no such difficulty in determining the budget neutrality adjustment for direct costs. As CMS has noted, the PEAC has essentially verified all of the direct cost inputs and CMS considers the refined values sufficiently reliable to make substantial methodology changes based on these values. These data represent real costs, and any adjustment made to ensure that these costs "fit" into the direct cost pool represents a real reduction attributable to budgetary constraints. There simply is no convincing rationale for requiring such reductions to be borne exclusively by technical component and other services that are PE-heavy in addition to reductions to the conversion factor necessitated by the five year review.

I. Conversion Factor

One of the major concerns arising from the Proposed Notice is a change in the projection for next year's conversion factor. While prior projections suggested that the conversion factor would decrease by about 4.6% in CY 2007, more recent projections indicate that, unless Congress acts, the conversion factor will decrease by 5.1%.

The issues involved in the calculation of the SGR have been reiterated with some frequency over the past several years, and we are loath to repeat them here. Rather, we incorporate by reference the comments made by the American Medical Association with respect to the SGR calculation, and urge CMS to recalculate the conversion factor in accordance with the methodology recommended by the AMA, which would have the effect of minimizing the projected conversion factor reduction to the extent authorized by current law.

II. Proposed IDTF Changes

The Proposed Rule sets forth a number of new standards for Independent Diagnostic Testing Facilities (IDTFs). These entities provide diagnostic services (including echocardiography) but that are neither physicians' offices nor hospitals. We understand from the preamble of the Proposed Rule that the Office of the Inspector has uncovered a number of serious concerns about the billing practices and quality of some IDTFs.

The ASE is equally concerned about the types of deficiencies identified by the OIG and agrees that additional quality and other standards may be appropriate. However, we urge CMS to utilize existing accreditation standards for echocardiography laboratories adopted by the Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL), rather than establishing completely new federal standards and requiring the Medicare carriers to assure enforcement.

The ASE strongly supports the standards and processes established by the ICAEL, an intersocietal accreditation group sponsored by the American College of Cardiology, the Society of Diagnostic Medical Sonography, and the Society of Pediatric Echocardiography, as well as ASE. The standards are designed to assure the qualifications of interpreting physicians and cardiac sonographers, the quality of the facility and equipment, and the appropriateness of processes for scheduling, performing, interpreting, and reporting the findings of the studies. Separate standards are applied to adult, pediatric, stress, and transesophageal echocardiography. These standards are far more comprehensive than the IDTF standards proposed by CMS.

In fact, compliance with these standards is increasingly required as a condition of Medicare payment, both by Medicare carriers and by private payers. Requiring IDTFs to become accredited would provide far greater assurances of quality than imposing the proposed standards. Moreover, this approach would be far more cost-effective than the proposed

approach, which would require additional funding for Medicare carriers to conduct independent surveys.

In the event that CMS is not willing to substitute an accreditation requirement for the standards set forth in the Proposed Rule, we would suggest that, at a minimum, ICAEL should be accorded "deemed status." Under this approach, IDTFs that are accredited by ICAEL would be deemed to be in compliance with Medicare standards. We would be delighted to work with CMS and with ICAEL to assure that the ICAEL standards are consistent with (albeit more rigorous than) the Medicare requirements.

III. Reassignment and Stark Law Changes

The Proposed Rule includes a number of proposed changes to the regulations implementing the physician self-referral law (the Stark Law regulations) and the reassignment rules for diagnostic services. The potential impact of these changes is difficult to anticipate, but appears to be far-reaching.

A. Reassignment Rule Changes

CMS proposes two changes to the existing reassignment provision and indicates that it is also considering a third set of changes.

1. *Access to Billing Records.*

First, CMS would extend the provision on access to billing records to a group's employees. This may be an issue for group practices that may be reluctant to make billing records available to physician employees (or potentially even to non-physician employees).[1]

2. *Billing for Technical Component Services Performed by Independent Contractors*

Second, CMS is proposing two conditions that must be met for a physician group to bill for an independent contractor's technical component services. First, if the technical component of a diagnostic test is provided by an independent contractor to a physician group, the amount billed to Medicare by the group, less the applicable deductibles and coinsurance, may not exceed (among other things) the independent contractor's charge: The practice may not "mark up" the technical component contractor's charge. In addition, in order to bill for the technical component service, the physician group would be required to perform the interpretation "directly". A physician group could not have separate contracts for both the TC and the PC components with one or more independent contractors.

[1] It is not clear whether the proposal would allow non-physician employees involved in the provision of a TC service to have access to billing records.

It is not clear that the changes proposed by CMS to preclude groups from marking up the TC of services purchased from independent contractors) significantly changes current law. In our view, the current "purchased diagnostic test" rules, properly interpreted, already address this issue. To the extent that those rules need to be clarified to preclude certain laboratories from circumventing them, we would suggest making those changes, rather than modifying the reassignment rules, which have far more sweeping impact.

3. *Billing for Professional Component Services Performed by Independent Contractors*

Third, and more disturbingly, CMS is considering whether it should impose similar restrictions on when a billing entity (like a physician group) can contract and bill for the professional component of a diagnostic test (*e.g.*, interpretations of echocardiographic studies). The conditions CMS are considering parallel the conditions for "purchased interpretations," *including a requirement that the physician or medical group performing the interpretation may not see the patient.* We also understand that CMS is also considering adding a provision that would, in effect, preclude physician groups from marking up professional component services performed by an independent contractor.

Unlike the changes proposed regarding technical component services, these proposed changes would clearly change current law--and change it in a way that may significantly undercut physician groups' flexibility in structuring their legal relationships with their physicians. The provision may have the effect of requiring physician groups to employ physicians who provide PC interpretations on a part-time basis, rather than engaging these physicians as independent contractors. These part-time employment arrangements are frequently disadvantageous from a tax and benefits perspective.

Possible new reassignment rules for PC services are even more disturbing, since the ideas proffered by CMS in the Proposed Rule would generally limit group practices from billing for the interpretative services of independent contractor physicians hired to read diagnostic tests performed for the practice's own patients. Thus, for example, a general cardiology practice retaining an echocardiographer on an independent contractor basis to interpret cardiac images for the group's patients would no longer be able to bill for the PC interpretations if the independent contractor physician also saw the patient. The practical impact of these restrictions may be to ensure that interpretations are provided primarily or exclusively by radiologists, who generally do not see the patient. Thus, this provision has the potential to become a significant barrier inhibiting the integration of diagnostic imaging services into non-radiologists' practices.

Application of an anti-markup rule to contracts for the PC, in addition to being unsupported by the statute, would be fraught with practical difficulty. For example, if the contract was on a fixed price or per hour basis, how would the billing entity determine the true price of the independent contractor's individual PC interpretations in order to apply an anti-markup requirement?

In short, we believe that the proposed changes to the reassignment rules have broad implications that extend far beyond the abusive "pod laboratory" arrangements at which they are aimed. We strongly urge CMS to refrain from finalizing these proposals as drafted, but rather to address these types of abusive arrangements by strengthening and broadening the purchased diagnostic test provisions and limiting even these changes to pathology services. Another approach would be to require direct billing of pathology, as well as other clinical laboratory, services.

B. Stark Law Regulation Changes

Many physician practices rely heavily on the "in-office ancillary services" exception and sometimes on the "physician services" exception to the Stark Law to provide diagnostic imaging services for their Medicare patients. Meeting those exceptions can turn on two definitions which would be affected by the Proposed Rule: (1) what constitutes a "centralized building" for Stark purposes, and (2) who qualifies as a "physician in the group practice" for Stark law purposes. See 42 C.F.R. § 411.351.

New Centralized Building Requirements. Under current law, in order to qualify for the "in-office ancillary service" exception, diagnostic imaging services must be provided either in an office where a group provides services that are not covered by the Stark law (like office visits), or in a "centralized building." CMS proposes to modify the definition of "centralized building" to include a minimum size requirement of 350 square feet (with a complicated exception to waive the limit in certain arrangements involving three or fewer practices in the same location), and to require that the space contain, on a permanent basis, the necessary equipment to perform substantially all (90%) of the designated health services performed in the space.

Both requirements are clearly targeted at "pod labs" which CMS considers abusive, but are drafted in a manner that would apply to any "centralized building," regardless of what designated services are performed there. The proposed changes to the definition of "centralized building" fundamentally attempt to micro-manage the internal workings of group practices. The 350 square foot rule may rule out otherwise legitimate ancillary buildings that simply don't need to be that large. Groups will end up buying or renting more space than they actually need to deliver some services "in-office." The 90% test will require some practices to buy or lease equipment permanently even though they only need it on a temporary or part-time basis, or to abandon those ancillaries that currently rely on mobile equipment. We are confident that abusive "pod lab" arrangements can be eliminated without casting so wide a net.

New Limits on Independent Contractors Engaged by Group Practices. As we understand it, being a physician "in the group" can be important under the Stark Law regulations for various reasons. For example, in order to qualify as in-office ancillary services, diagnostic imaging services must be supervised by a physician who is either a member of a group or "in the group." Under the current rules, a physician who is not a "member" of a group (owner or employee) can be a "physician in the group" during the time he or she is providing services to the group in the

group's "facilities." Often, physicians "in the group" are independent contractors engaged by group practices on a part-time basis to provide specialized services to the group's patients.

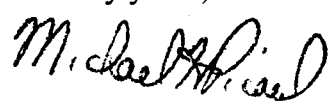
The Proposed Rule would require that, in order to be a physician "in the group" for Stark law purposes, an independent contractor physician would have to comply with the new reassignment rules for TC services. In addition, the proposed language would specifically provide that **PC** services provided by an independent contractor would only qualify as services provided by a physician "in the group" if these services meet the requirements applicable to "purchased interpretations" under applicable Manual instructions (i.e., that the contractor providing the PC must be "independent" of the group ordering the test and may not see the patient and that the group must perform the TC directly).

Fundamentally, this proposal converts what otherwise might be technical violations of the rules on reassignment into violations of the Stark law, with enormous potential penalties. As discussed above, the reassignment rule changes proposed by CMS are overly broad, and have the potential to inhibit substantially the integration of echocardiography and other imaging techniques into physicians' practices, to the detriment of patient care, by precluding treating physicians from performing imaging services. Incorporating these changes into the Stark Law regulations--which are extraordinarily complex and cumbersome already--is far too broad and far-reaching a change for the limited purpose of addressing the far more limited concern about "pod labs."

For these reasons, we urge CMS to refrain from modifying the Stark Law regulations at all, to address the "pod lab" issue by strengthening the "purchased diagnostic test" rules rather than modifying the reassignment regulations, and to limit any changes that are made so that they apply to pathology services but not more broadly. We especially caution that great care should be taken to assure that any changes that are made do not interfere with the ability of group practices to integrate emerging medical imaging technologies into cardiac care.

We appreciate the opportunity to comment on these issues, and look forward to working with you over the coming years to further refine the Physician Fee Schedule allowances for echocardiography services.

Sincerely yours,



Michael H. Picard, M.D.
President
American Society of Echocardiography

American Society of Echocardiography
Heart and Circulation Ultrasound Specialists

August 21, 2006

Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8018

Re: CMS 1512-PN; PRACTICE EXPENSE

Dear Dr. McClellan:

On behalf of the American Society of Echocardiography (ASE), I am delighted to have this opportunity to provide these comments regarding the proposed revisions of the Physician Fee Schedule (PFS) for CY 2007 published on June 29, 2006 in the Federal Register (the "Proposed Notice"). The ASE is a professional society consisting of over 11,000 professionals committed to excellence in cardiovascular ultrasound and its application to patient care.

While ASE very much appreciates the time and effort that CMS has devoted to proposed revisions to the practice expense methodology, we note that these changes will result in extraordinary reductions in Medicare payment for echocardiography services performed in non-hospital settings--reductions averaging 23% by 2010. We are concerned about the impact of so large a reduction on the ability of cardiology practices to maintain high quality echocardiography services in the non-hospital setting, in light of the substantial equipment, non-physician personnel and other costs involved.

Recognizing that there are few if any clear rules for determining and allocating practice expenses among individual services on a system-wide basis, we are organizing our comments and analysis based on CMS's own objectives for the practice expense revisions, as set forth in the Proposed Notice. As stated by CMS, the objectives of the new system are:

- To ensure that the PE portion of the PFS payments reflect, to the greatest extent possible, the relative resources required for each of the services on the PFS.

- To develop a payment system for PE that is understandable and at least somewhat intuitive, so that specialties can better predict the impacts of changes in the PE data.

- To stabilize the PE portion of the PFS payments so that changes in PE-RVUs do not produce large fluctuations in the payment for given procedures from year to year.

Our assessment of whether and to what extent the methodology described in the Proposed Notice achieves these objectives with respect to echocardiography services follows.

I. Ensuring that Payments Reflect Relative Resources

A. Use of ACC Survey Data

As discussed below, we respectfully disagree with CMS's decision to eliminate the Non-Physician Work Pool (NPWP) without first determining a methodology for more equitably allocating indirect costs. However, having made the decision to eliminate the NPWP, CMS appropriately decided to use the ACC supplemental data in its revised methodology. We strongly urge CMS to continue to use the ACC supplemental data to determine cardiology allowances. CMS should use any data resulting from the new AMA multi-specialty survey process only if it meets the same rigorous statistical tests applied to the ACC's supplemental data.

In addition, we urge CMS to make special efforts to ensure that the new AMA survey includes a representative number of cardiology practices that provide technical component services. Even more fundamentally, we advise that the new AMA multi-specialty survey--unlike the SMS survey--include the questions necessary to determine whether or not cardiology respondents provided TC services. Otherwise, neither CMS nor affected groups will have the basis to determine whether or not the results are appropriately representative. Since the ASE is not a constituent society of the AMA, we urge CMS to monitor this issue directly and to keep this consideration in mind before approving the AMA survey instrument or protocol.

B. Indirect Cost Allocation

Without doubt, the single most salient feature of the proposed PE methodology that precludes the final allowances from accurately reflecting relative costs is the use of work relative value units (W-RVUs) to allocate an estimated 40% of all practice expense dollars.[1] Technical component echocardiography services have no W-RVUs and are thus ineligible to receive any of this Medicare payment.

We understand that CMS considers all allocation methodologies for indirect practice expenses to be arbitrary, by definition. However, some allocation methodologies are clearly more arbitrary than others. We understand that physicians who perform services outside of the office setting

[1] Since indirect costs constitute approximately 60% of all practice expenses and approximately two-thirds of indirect costs appear to be allocate on the basis of W-RVUs, approximately 40% of all dollars available to pay providers for their practice expenses are allocated based on W-RVUs.

still incur overhead and other indirect costs to keep their offices open and operational, and that allocating indirect practice expenses on the basis of W-RVUs is intended to account for this. However, it may be more logical to use physician time rather than physician work to allocate indirect practice expenses to these services, since there is no basis for concluding that work intensity (which is reflected in W-RVUs) is related to indirect practice expenses (primarily overhead). Even more fundamentally, to the extent that physician time or work is used as an allocator, its use should be limited to that portion of indirect practice expenses that is reasonably attributable to out-of-office services. Yet, we estimate that approximately two-thirds of all indirect PEs are allocated based on W-RVUs under the current methodology.

In the past, CMS has indicated that because technical component services have very high direct costs, the allocation of some portion of indirect costs on the basis of W-RVUs does not unduly disadvantage technical component services. However, under the proposed methodology, it is our understanding that a budget neutrality/scaling adjustment that reduces direct practice expenses by about 33% is applied before direct costs are used as an allocator. In addition, whatever amount of indirect costs are allocated to a service on the basis of direct costs is again reduced by the (approximate) 65% "indirect adjustment"--an adjustment necessitated in large measure by the use of W-RVUs to allocate indirect costs. Thus, by the end of the process, it is unclear to us whether and to what extent direct costs actually determine indirect cost allocations.

Even more importantly, it is our understanding that CMS is considering modifying direct cost inputs in a way that may substantially reduce direct costs allocated to echocardiography and other technical component services in the future. For example, both CMS and Congress appear to be considering modifying the utilization and interest rate assumptions used to determine equipment costs, which appear to be a major component of the proposed echocardiography rate for in-office services. If CMS does modify the methodology for determining direct costs in a manner that substantially reduces allowances for echocardiography and other technical component payment, the agency cannot continue to rely on the same rationale for failing to correct the indirect cost allocation formula.

For these reasons, we urge CMS to keep the indirect cost allocation methodology open for future changes. We would hope that, during the transition period, CMS will model alternatives to the present system, including alternatives that limit the impact of W-RVUs as an indirect cost allocator. At the very least, we request CMS to commit to re-examine its allocation methodology for indirect costs when and if it changes any of the major assumptions or data used to determine technical component services.

In the interim, we support CMS's proposal to use non-physician staff time as an allocator for services with no physician work. We also suggest that CMS consider modifying the direct and indirect budget neutrality/scaling adjustments in a manner that increases the proportion of indirect practice expenses that are allocated on the basis of direct practice expenses.

II. Developing an Understandable and Intuitive Payment System

We understand that one of CMS's primary priorities in the Proposed Notice is to ensure an understandable and intuitive payment system. Unfortunately, while the "bottom up" treatment of direct costs is more understandable than the "top down" methodology that CMS currently uses, the methodology for determining indirect practice expense allowances remains obtuse. Moreover, as we understand the proposed new PE methodology, the results may vary each year based on annual utilization changes and changes in specialty mix. These elements of the methodology may not only affect the system's transparency but may also affect its overall stability.

We believe that transparency of the system would be improved considerably if CMS simply released the underlying programming to the medical community, along with the Notice of Proposed Rulemaking for each year's PFS update. As it is, those specialties with significant resources are in a position to hire consultants to replicate the CMS methodology, while less affluent specialty and subspecialty groups are not. And because of the time it takes to work out "glitches" in programming, even those specialty societies that are in a position to hire consultants are left with minimal time to put together useful comments. To the extent that CMS truly wants to assure that its system is transparent, we urge the agency to make its programming more fully available to the entire medical community when future proposed rules are published. At a minimum, we hope that CMS will continue to work with the medical community and other affected parties to further improve the transparency of the methodology and the underlying data.

III. Ensuring Stability

We cannot overestimate the importance of stability and predictability of Medicare payment under the PFS, especially for technical component services, which are by definition capital intensive. We applaud CMS for including payment stability among the primary goals of the new system.

For this reason, we strongly support CMS's proposal to provide a four-year transition for practice expense changes, and urge CMS to provide a similar transition period for the five-year review changes described in the Proposed Notice. While five-year review changes are generally incorporated into the PFS without a transition period, the magnitude of the changes proposed for CY 2008 are unprecedented. While these changes will benefit many physicians who provide evaluation and management services and post operative services, the burden will be borne disproportionately by echocardiography and other professional component services that will be adversely affected by the 10% budget neutrality adjustment in W-RVUs. To further assure stability, CMS should phase these changes in over a four-year period, like the PE changes.

In order to further enhance the stability of the methodology, we encourage CMS to model the extent to which the new methodology is sensitive to annual changes in utilization and specialty mix. We are not in a position to assist CMS in this regard since we do not have access to the

underlying programming, but we note that, several years ago, when NPWP allowances were based on one year's utilization, there was an unanticipated drop in allowances. We urge CMS to modify the methodology to the extent necessary to assure that utilization and other year-to-year variations do not result in significant year-to-year fluctuations.

In fact, we urge CMS to consider adopting a review cycle that does not necessitate significant changes on an annual basis, similar to the five-year review cycle for W-RVUs. For example, once the transition to the new system is completed, we would hope that there will be no further modifications of PE allowances until new PE survey data are available. When such new PE survey data do become available, they should be incorporated into the PFS through a multi-year transition.

IV. Other issues--Budget Neutrality

While we recognize that the budget neutrality adjustment methodology set forth in the Proposed Notice is not ideal, we believe that it is the best of the available alternatives under the circumstances. Under the proposed option, W-RVUs will be reduced by 10% to absorb the cost of the five-year review changes, and PE-RVUs will be scaled and adjusted (by an estimated 58%, according to one consultant's report) to maintain budget neutrality on the PE side.

We understand that a number of specialties may object to the 10% reduction in W-RVUs, urging CMS to spread the cost of these changes across the entire fee schedule. This alternative potentially would result in an additional across-the-board reduction of about 5% in either the conversion factor or all RVUs. However, it is our understanding that, under the proposed new PE methodology, direct practice expenses are already reduced by approximately 33% and indirect practice expenses are already reduced by approximately 65% to assure budget neutrality. It clearly would be inequitable to spread the work budget neutrality adjustment across all physician services while requiring the practice expense budget neutrality adjustment to be absorbed exclusively by the PE-RVUs. And making all budget neutrality/scaling adjustments on a fee-schedule-wide basis apparently would result in unacceptable fee-schedule-wide reductions.

We note, however, that if the five-year review changes are incorporated into the PFS over a four-year transition period, as we suggest, the impact of the budget neutrality adjustment on W-RVUs likewise will be moderated, and we urge CMS to consider this alternative.

Finally, to the extent that CMS decides (contrary to our position) that the budget neutrality adjustment resulting from the five-year review should be spread across the entire fee schedule, we urge CMS to eliminate the direct adjustment (step 9) and modify the indirect adjustment (step 22) in a manner that shifts a comparable budget neutrality burden from PE-RVUs to the fee schedule as a whole.

We appreciate the opportunity to comment on this important notice, and look forward to working with CMS over the coming years to refine whatever methodology is adopted.

Sincerely yours,

AMERICAN SOCIETY OF ECHOCARDIOGRAPHY

Michael H. Picard, M.D.
President

Submitter : **Dr. Chung Woo** **Date: 10/05/2006**

Organization : **Vein Clinics of America**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS 1321-P

Policy and Recommendation: Comment
Physician Fee Schedule -Practice Expense
Proposal dated September 21, 2006

I am responding to the CMS proposal of 9/21/06 regarding the proposed changes in the physician fee schedule for 36478 and 36479 Endovenous Laser Ablation - office based.

I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for codes 36478 and 36479 and find several issues of great concern:

One, RVUs have consistently been reduced from 2005 levels to 46.91 in 2006 and down to 40.84 in 2008.

These proposed reductions contrast sharply to the consistent rise in practice expenses. For example, in order to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician use the services of a Registered Vascular Technologist to provide imaging services. These highly skilled technologists are in drastic shortage and therefore are in high demand and as such command extremely high salaries in excess of $70,000 per year plus benefits. It will be impossible to comply with CMS guidelines if the RVUs and subsequent reimbursements continue to drop!

As you know, the 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. Additionally, there are proposed cuts for non-invasive vascular imaging (vascular ultrasound). All these cuts will cripple the ability of physicians to perform this extremely important procedure and ultimately result in a loss of access to care for Medicare beneficiaries.

Two, the proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment.

Three, RVU for codes 36475 and 36476, radiofrequency (RF) vein ablation have been consistently higher that those for laser ablation: in 2006, 51.5 for RF vs 46.91 for laser. Each of these technologies are comparable especially when we look at both the initial capital acquisition cost ($37,900 for laser and $25,000 for RF) and the per patient supply costs ($360 for laser and $750 for radiofrequency for the procedure kits PLUS disposable sterile supplies such as drapes, gowns, anesthetic solution, IV bags and tubing to name just a few). While the per patient supply cost may be slightly higher for 36475 (radiofrequency ablation), the significantly higher acquisition cost for 36478 (laser ablation) raises the overall physician s cost of delivering the service to the same level (possibly even higher).

I would request that the fully implemented, non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5 and that the RVU for 36478 be increased to this same level.

I would be happy to discuss this further with members of your committee.

Respectfully submitted,

Chung Woo, MD

Submitter : Ms. Susan Wysocki **Date:** 10/05/2006

Organization : NPWH- Nurse Practitioners in Women's Health

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-456-Attach-1.DOC

Draft NPWH Letter to CMS re: Proposed Medicare Reimbursement Cuts for PBI

September 26, 2006

Administrator Mark McClellan
Center for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Rule: Physician Fee Schedule (CMS-1321-P); and

Rule: Hospital Outpatient Prospective Payment System (OPPS) (CMS-1506-P)

Dear Administrator McClellan:

It has recently been brought to our attention that the Centers for Medicare and Medicaid Services (CMS), through the Physician Fee Schedule (CMS-1321-P) and Hospital Outpatient Prospective Payment System (OPPS) (CMS-1506-P) rules, has proposed a series of payment cuts which, when taken together, would dramatically reduce Medicare reimbursement for partial breast irradiation (breast brachytherapy) in all the settings in which it is performed, including health care professional offices, freestanding radiation oncology centers, and hospital outpatient departments.

The National Association of Nurse Practitioners in Women's Health (NPWH) is perplexed by the depth of the cuts, which will have the unintended consequence of limiting, rather than expanding, Medicare patients' choice of treatments. In the course of their practice, nurse practitioners see numerous women who have been diagnosed with early-stage breast cancer and are candidates for partial breast irradiation (PBI) following lumpectomy. The American Society of Breast Surgeons and the American Brachytherapy Society have both published guidelines for selecting patients who are appropriate for partial breast irradiation. Partial breast irradiation provides a higher dose of radiation to the area immediately surrounding the lumpectomy cavity, while minimizing radiation exposure to healthy tissue. It also dramatically reduces the course of radiation therapy from 5-6 weeks to 5 days, with corresponding quality of life benefits.

The National Association of Nurse Practitioners in Women's Health knows that CMS shares our commitment to providing high quality health care to women. Breast cancer patients and healthcare providers alike are counting on CMS to honor that commitment by preserving adequate Medicare reimbursement rates

for partial breast irradiation in all delivery sites. Specifically, NPWH urges CMS to refrain from making any reductions to the relative value units (RVUs) for PBI under the physician fee schedule. If changes need to be made, limiting the decrease in practice expense RVUs to no more than 10% would seem to be a reasonable alternative. In the hospital outpatient setting, NPWH believes that CMS should maintain partial breast irradiation in the New Technology APC for another year, in order to allow additional time to collect appropriate cost data. The assignment of PBI to a Clinical APC was clearly in error, since the cost of the medical device is greater than the total proposed reimbursement rate.

The National Association of Nurse Practitioners in Women's Health appreciates the opportunity to comment on CMS' proposed rules, and urges the agency to seriously consider our recommendations and take the necessary steps to preserve Medicare women's access to partial breast irradiation.

Sincerely,

Susan Wysocki, RNC, NP
President/CEO

Cc: Herb Kuhn, Director, Center for Medicare Management, CMS
Helen Pass, MD, President, American Society of Breast Surgeons
Margaret Kirk, CEO, Y-ME National Breast Cancer Organization

Submitter : **Mr. Michael Becker** **Date: 10/05/2006**

Organization : **GE Healthcare**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-457-Attach-1.DOC

GE Healthcare

Michael S. Becker
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October 5, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1312-P

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule

Dear Dr. McClellan:

GE Healthcare (GEHC) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding changes to the Medicare physician fee schedule (MPFS) payment system for calendar year (CY) 2007 (*Federal Register*, Vol. 71, No. 162, August 22, 2006). Our comments focus on a number of issues relating to reimbursement for diagnostic imaging procedures including the following:

- Cumulative Effects of Reimbursement Reforms for Diagnostic Imaging
- Applicability of DRA Cuts to Selected Imaging Procedures
- Multiple Procedure Discount Policy
- Equipment Standards for Independent Diagnostic Testing Facilities (IDTFs)
- Changes in Self-Referral Requirements
- Abdominal Aortic Aneurysm (AAA) Screening Benefit
- Bone Mass Measurement
- Health Care Transparency/Health Information Technology (HIT)

GE Healthcare is a $15 billion unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring, life support systems, disease research, drug discovery and biopharmaceuticals manufacturing technologies. Worldwide, GE Healthcare employs more than

43,000 people committed to serving healthcare professionals and their patients in more than 100 countries.

Our detailed comments follow.

Cumulative Effects of Reimbursement Reforms for Diagnostic Imaging

Recently, there have been a number of legislative and regulatory initiatives that have the potential to greatly impact reimbursement for diagnostic imaging. Beginning in CY 2007, the Deficit Reduction Act (DRA) mandates that reimbursement for imaging procedures paid under the MPFS is capped at the rate paid under the Medicare Hospital Outpatient Prospective Payment System (HOPPS). According to research by the Moran Company, implementation of the DRA caps will result in aggregate Medicare payments for imaging services provided in the physician office setting being materially lower – as much as 16-18% lower – than aggregate payments for similar services provided in the outpatient setting. Moreover, Moran found that, of the procedures affected by the DRA caps, 87% of these procedures would be paid at a rate below the estimated cost of performing the procedure in the physician office setting.[1]

In addition, for CY 2007, MPFS payment rates are scheduled to be reduced across-the-board by 5.1 percent as a result of the Congressionally mandated MPFS update formula.

In June 2006, CMS proposed changes to the practice expense methodology that will result in a high degree of instability in payment levels for imaging procedures over the course of the next four years. When fully implemented as proposed, some imaging procedures may experience decreases in global payment amounts that are in excess of 75%.

Finally, beginning in CY 2006, CMS instituted a reduction in payment for multiple imaging procedures. Referred to as the multiple imaging procedure discount (MPD), Medicare reduces technical component payments for second and subsequent imaging services performed on contiguous body parts in a single session by 25%. Last year, CMS also indicated its intention to increase the level of the MPD to 50% in CY 2007.

These policies, when considered both individually and collectively, introduce varied and potentially harmful disincentives for adoption of important advances in imaging. GEHC understands and supports efforts to maintain health care costs at appropriate levels. We have serious concerns, however, about the cumulative and potentially devastating impact that these disparate actions to contain costs will have on provision of imaging services to Medicare beneficiaries. **We urge CMS to consider the breadth and cumulative effect of these changes on reimbursement levels for diagnostic imaging. We also urge CMS to provide mechanisms that provide for equitable payment levels, enable stability in payment rates, and yield transparency in payment determinations.**

Applicability of DRA Cuts to Selected Imaging Procedures

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[1] The Moran Company, *Assessing the Deficit Reduction Act Limits on Imaging Reimbursement: Cross-Stie Comparisons of Cost and Reimbursement,* August 2006.

As mentioned above, Section 5102 for the Deficit Reduction Act mandates a reduction in the technical component payment for certain imaging services performed in physician offices and clinics to the level of the HOPPS payment. While we understand the provisions specified in the law, we believe that CMS has considerable discretion in defining those imaging services and codes that are reasonably encompassed within the general intent of the statute, and those that should be excluded.

In the proposed rule, CMS discusses the criteria it used to determine suitable codes that are subject to the DRA cap. Among those procedures that CMS proposes to include in the DRA cap are carrier-priced services. Specifically, CMS notes that the agency "included carrier priced services since these services are within the statutory definition of imaging services and are also within the statutory definition of PFS services." In particular, CMS notes the applicability of the DRA caps to carrier-priced technical component payment of PET/CT procedures..

We believe that application of the DRA payment reduction is limited to imaging services that are paid under the Medicare Physician Fee Schedule. Section 5102 of the Act clearly states that imaging cuts apply to "the technical component (including the technical component portion of a global fee) of the service established for a year under the fee schedule." In several cases, which we illustrate below, Medicare payment is not established by the MPFS, but rather rates are set by Medicare regional carriers (i.e., "carrier priced"). Carrier pricing allows local Medicare contractors to account for regional variation in the cost of providing services, as well as provide for payment for new and emerging procedures that are deemed medically necessary.

GEHC recommends that CMS exclude carrier-priced services from the DRA mandated cap. Examples of carrier-priced services include PET and PET/CT imaging services for which no RVUs have been assigned to the technical component of payment under the MPFS. In addition, we recommend that CPT Category III codes (used to report emerging technologies and services) be excluded, as these codes are also typically carrier priced, are not assigned RVUs and are not reimbursed through the Medicare physician fee schedule. Examples of applicable CPT Category III codes include those that were recently established to report coronary CTA procedures (CPT 0144T – 0151T).

In addition, **GEHC requests that CMS clarify that imaging conducted as part of a therapeutic regime is exempt from the DRA mandated cap.** We believe that the DRA text and legislative history do not suggest that Congress intended that the payment cap be extended beyond imaging provided for diagnostic purposes. Further, we believe that it is within CMS's discretion to determine that the cap does not apply to this distinct class of imaging services. Examples of such services include PET/CT scans conducted for therapeutic monitoring purposes, as well as ultrasound or other guidance modalities performed during surgery.

Multiple Procedure Discount Policy

CMS proposes to maintain its policy of multiple procedure discounting at the 25% level in CY 2007. CMS would first apply the discount, then CMS would apply the DRA cap to discounted payment levels for imaging services.

We appreciate the CMS decision to first apply any multiple procedure discount prior to the DRA cap, as this will lessen the impact of DRA payment reductions on providers. More generally,

however, we believe that the multiple procedure discount policy is redundant in light of the impending DRA payment caps and should be discontinued at the time when the DRA cap is implemented in CY 2007.

DRA specifies that payments for imaging services subject to the Medicare physician fee schedule will be capped at the CY 2007 hospital outpatient prospective payment system (HOPPS) payment amount (prior to geographic adjustment). Currently, there is no multiple procedure discount policy for HOPPS. CMS has determined that, at this time, there is insufficient evidence to warrant such a reduction under this payment system. Specifically, in its proposed rule for HOPPS, CMS notes that it does not intend to implement such a policy in CY 2007, stating that the agency's analysis to date support continued deferral of such a policy. Specifically, CMS notes that its analysis does not disprove commenters' assertions that there are efficiencies already reflected in hospital costs and, therefore, in existing HOPPS payment rates.

We believe that application of the multiple procedure discount policy in the MPFS is redundant and excessive in light of the DRA cap. HOPPS rates serve as the basis for the cap, and these rates already factor in the effects and economies of performing multiple imaging procedures during the same session. To apply the MPD policy in the MPFS, and then to apply the cap, would essentially "over-adjust" payment levels to account for economies in multiple procedure imaging. **We urge CMS to remove the MPD policy from the Medicare physician fee schedule and, instead, rely on the DRA cap to accurately account for cost effects of multiple procedure imaging during the same session.**

Equipment Standards for IDTFs

In the rule, CMS proposes to establish fourteen IDTF supplier standards as a condition for obtaining or retaining enrollment as a provider in the Medicare program, effective January 1, 2007. Notably, CMS proposes to implement a standard (Number 11) requiring that an IDTF "must have its testing equipment calibrated according to equipment instructions or in compliance with applicable industry standards." CMS requests public comment on organizations or entities that establish testing specifications for diagnostic equipment.

GEHC currently establishes testing specifications for its imaging equipment. We would welcome the opportunity to work with CMS to establish appropriate requirements for equipment testing and calibration. Accurate equipment calibration and testing, in accordance with scheduled preventive maintenance requirements, is a high priority for GEHC and ensures that imaging equipment is operating safely, accurately and to its fullest capability. **Moreover, GEHC recommends that CMS work with the National Electrical Manufacturers Association (NEMA), of which it is a member, to develop guidelines as needed that reflect the unique aspects of imaging technology and ensure appropriate testing and compliance.** NEMA is the premier, global standards-setting organization for electrical equipment, including imaging equipment.

Changes in Self Referral Requirements

CMS proposes to amend its reassignment regulations with respect to the application of purchased tests and related interpretation. The agency is also proposing to change its definition of "centralized building" for purposes of the physician self-referral in-office ancillary services exception.

GEHC cautions CMS in modifying its definition of centralized building to ensure that mobile radiology services are not unintentionally disrupted. Throughout the country, mobile radiology services provide the optimal method for providing vital imaging services to many Medicare beneficiaries. We urge CMS to preserve this important approach to imaging service delivery in its policies relating to self referral.

AAA Screening Benefit

The DRA establishes ultrasound screening for abdominal aortic aneurysm for Medicare beneficiaries meeting established criteria, effective January 1, 2007. In the proposed rule, CMS includes information and guidance necessary to implement the statutory provisions related to the AAA screening benefit. We believe that the coverage criterion for the benefit, as proposed by CMS, adequately addresses the needs of the Medicare population at greatest risk for AAA. **We commend CMS for establishing the necessary policies and payment assignment to support the availability of this important new benefit.**

Bone Mass Measurement

CMS proposes to revise coverage of bone mass measurement (BMM) tests to reflect advances in technology and changes in medical practice. **GEHC commends CMS for making the necessary revisions to BMM indications and coverage in order to ensure that Medicare beneficiaries are receiving the most appropriate screening services based on optimal practices.**

While we support CMS's coverage policy for BMM, we urge CMS to reconsider the significant proposed reduction in payment for BMM tests. As we noted in our previous comment letter to CMS, we are particularly concerned with respect to the proposed work and practice expense values for bone densitometry studies[2] and we request that CMS revise upward the relative values for this procedure. The CMS proposal to revise the Medicare Physician Fee Schedule (MPFS) work relative value units and practice expense methodology[3] will have major consequences for payment of BMM tests. Specifically, the changes proposed will result in a 71% decrease in reimbursement for central DXA (CPT code 76075) when fully implemented over the next four years. Based on the current CMS proposal, in 2010, the global reimbursement for central DXA procedures will decrease from the current national average of $139.46 to $39.79.

We believe that revisions to the proposed work and practice expense values for DXA procedures is necessary in order to ensure continued availability of this important advance. Early diagnosis and treatment of osteoporosis, made possible with the aid of DXA, is an important measure towards prevention of fracture, its associated medical complications, and related costs of treatment. We will provide additional details on this issue in a separate comment letter to be submitted prior to the conclusion of the comment period.

Health Care Transparency/HIT

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[2] CPT 76075 *Dual energy X-ray absorptiometry (DXA), bone density study, one or more sites; axial skeleton (e.g, hips, pelvis, spine)*

[3] *Federal Register*, Vol. 71, No. 125, June 29, 2006

In the proposed rule, CMS discusses its health care information transparency initiative launched in 2006. Through this effort, CMS plans to expand the quality and price information made available to patients. Through these and other related initiatives, consumers will have information to make thoughtful clinical and economic decisions about their health care.

The success of these efforts will depend, in part, on the accuracy of information and the extent to which it is presented in a clear, accessible and meaningful format that health care stakeholders and consumers can act upon. GEHC supports CMS's emphasis on improving health outcomes, prudently managing health care costs and enhancing beneficiary connectivity to their health care system. **As a leading global health products manufacturer with deep health information systems and quality/process improvement expertise, GEHC is in a unique position to work with CMS to ensure that key services are adequately captured and communicated in a manner that improves beneficiary understanding and use of such data.** We welcome the opportunity to share our experience and expertise with CMS to support advancement of the health care transparency initiative.

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In summary, we urge CMS to carefully consider the specific comments we present herein, as well as the overall cumulative effects of current policies on preserving equitable payment for imaging services. We welcome the opportunity to work constructively with CMS to ensure that quality-enhancing imaging services are available to all Medicare beneficiaries.

Thank you for providing the opportunity to comment on these important issues. Should you have any questions or wish to discuss our comments further, please contact me at (262) 548-2088.

Sincerely,

Michael S. Becker
General Manager, Reimbursement

cc: Amy Bassano

Submitter : **Dr. Stephen Sorenson** **Date: 10/05/2006**

Organization : **Dr. Stephen Sorenson**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am commenting on the September 21, 2006 proposal regarding the changes to be made to the physician fee schedule for 36478 and 36479 (Endovenous Laser Ablation). I feel the practice expense RVUs for codes 36478 and 36479 are being unfairly reduced. My office has noted rising expenses with this important office-based procedure and declining reimbursement. The practice expenses include a registered ultrasound technologist, highly skilled in this particular area of vascular medicine. Laser and laser supplies continue to rise in cost as well. At this rate, myself and others will be unable to offer this minimally invasive and cost-containing treatment for varicose vein disease. It will not be cost effective (or medically advantageous to the patients)to go back to hospital-based surgical strippings. The future of varicose vein disease treatment lies in effective and competent endovenous laser ablation in the office setting.

I am requesting that the non-facility practice expense RVUs for 36475, 36476, 36478 and 36479 at least remain at present levels and ideally be increased. Laser ablation (36478, 36479)has for unknown reasons seen smaller RVUs than radiofrequency (36475, 36476)treatments. The RVUS for laser and radiofrequency need to be equalized . Laser ablation (36478)has proven to have higher costs in initial equipment expenditure and this should be offset by an even higher RVU than radiofrequency treatment.

I respectfuly submit my comments and invite any committee members to contact me in their regards.

Thank you.

Stephen C. Sorenson, M.D.
1101 Perimeter Drive, Suite 620
Schaumburg,IL 60173

(847) 619-5500

ssorenson@veinclinics.net

Submitter : Dr. Captain Gray

Organization : Kansas City Phlebology Group

Category : Physician

Date: 10/05/2006

Issue Areas/Comments

Background

Background

The proposed reduction in reimbursement rates for endovenous laser therapy will unfairly target those practices that provide this service as a viable alternative to surgical ligation and stripping surgery. The reductions in reimbursement will make it hard to cover the overhead expenses involved with this procedure and act as a disincentive to providing the procedure which is less expensive overall than is surgery.

GENERAL

GENERAL

I oppose the proposed reduction in fees for endovenous laser therapy for the reasons stated above.

Submitter :

Date: 10/05/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Physician Fee Schedule -Practice Expense
Proposal dated September 21, 2006

I am responding to the CMS proposal of 9/21/06 regarding the proposed changes in the physician fee schedule for 36478 and 36479 Endovenous Laser Ablation - office based.

I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for codes 36478 and 36479 and I find issues of great concern:

1 RVUs have consistently been reduced from 2005 levels:
a. 2006: 46.91
b. 2007: 43.53
c. 2008: 40.84

While practice expenses have consistently risen, (salaries,utilities, etc.). It has become increasingly difficult to provide these necessary services. In order to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician employ a Registered Vascular Technologist (RVT) to provide imaging services. These highly skilled technologists are in drastic
shortage and therefore are in high demand and as such command extremely high salaries in excess of $70,000 per year plus benefits. It will be impossible to comply with CMS guidelines if the RVUs and subsequent reimbursements continue to drop!

As you know, the 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. Additionally, there are proposed cuts for non-invasive vascular imaging (vascular ultrasound). All these cuts will cripple the ability of physicians to perform this extremely important procedure and ultimately result in a loss of access to care for Medicare beneficiaries.

2. The proposed conversion factor (CF) for 2007 has been reduced from
2006, thus further decreasing reimbursement for endovenous laser treatment.

3. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation:
a. 2006: 51.5
b. 2007: 47.77
c. 2008: 44.52

Each of these technologies are comparable especially when we look at both the initial capital acquisition cost ($37,900 for laser and $25,000 for RF) and the, per patient supply costs ($360 for laser and $750 for radiofrequency for the procedure kits PLUS disposable sterile supplies such as drapes, gowns, Anesthetic solution, IV bags and tubing to name just a few). While the per patient supply cost may be slightly higher for 36475 (radiofrequency ablation), the
significantly higher acquisition cost for 36478 (laser ablation) raises the overall physician s cost of delivering the service to the same level (possibly even higher).

I would request that the fully implemented, non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5 and that the RVU for 36478 be increased to this same level.

I would be happy to discuss this further with members of your committee.

Respectfully submitted,

Keith E. Campbell, M.D.
(865) 671-6578

Submitter : Ms. Susan Wysocki **Date:** 10/05/2006

Organization : NPWH- Nurse Practitioners in Women's Health

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachement

CMS-1321-P-461-Attach-1.DOC

HHSIR
461

October 5, 2006

Administrator Mark McClellan
Center for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Rule: Physician Fee Schedule (CMS-1321-P); and

Rule: Hospital Outpatient Prospective Payment System (OPPS) (CMS-1506-P)

Dear Administrator McClellan:

It has recently been brought to our attention that the Centers for Medicare and Medicaid Services (CMS), through the Physician Fee Schedule (CMS-1321-P) and Hospital Outpatient Prospective Payment System (OPPS) (CMS-1506-P) rules, has proposed a series of payment cuts which, when taken together, would dramatically reduce Medicare reimbursement for partial breast irradiation (breast brachytherapy) in all the settings in which it is performed, including health care professional offices, freestanding radiation oncology centers, and hospital outpatient departments.

The National Association of Nurse Practitioners in Women's Health (NPWH) is perplexed by the depth of the cuts, which will have the unintended consequence of limiting, rather than expanding, Medicare patients' choice of treatments. In the course of their practice, nurse practitioners see numerous women who have been diagnosed with early-stage breast cancer and are candidates for partial breast irradiation (PBI) following lumpectomy. The American Society of Breast Surgeons and the American Brachytherapy Society have both published guidelines for selecting patients who are appropriate for partial breast irradiation. Partial breast irradiation provides a higher dose of radiation to the area immediately surrounding the lumpectomy cavity, while minimizing radiation exposure to healthy tissue. It also dramatically reduces the course of radiation therapy from 5-6 weeks to 5 days, with corresponding quality of life benefits.

The National Association of Nurse Practitioners in Women's Health knows that CMS shares our commitment to providing high quality health care to women. Breast cancer patients and healthcare providers alike are counting on CMS to honor that commitment by preserving adequate Medicare reimbursement rates for partial breast irradiation in all delivery sites. Specifically, NPWH urges CMS to refrain from making any reductions to the relative value units (RVUs) for PBI

under the physician fee schedule. If changes need to be made, limiting the decrease in practice expense RVUs to no more than 10% would seem to be a reasonable alternative. In the hospital outpatient setting, NPWH believes that CMS should maintain partial breast irradiation in the New Technology APC for another year, in order to allow additional time to collect appropriate cost data. The assignment of PBI to a Clinical APC was clearly in error, since the cost of the medical device is greater than the total proposed reimbursement rate.

The National Association of Nurse Practitioners in Women's Health appreciates the opportunity to comment on CMS' proposed rules, and urges the agency to seriously consider our recommendations and take the necessary steps to preserve Medicare women's access to partial breast irradiation.

Sincerely,

Susan Wysocki, RNC, NP
President/CEO

Cc: Herb Kuhn, Director, Center for Medicare Management, CMS
Helen Pass, MD, President, American Society of Breast Surgeons
Margaret Kirk, CEO, Y-ME National Breast Cancer Organization