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See General Comment below

Provisions of the Proposed Rule

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Submitter : Mr. Matthew Rouff **Date:** 10/10/2006

Organization : United Health Services Hospitals, Inc.

Category : Hospital

Issue Areas/Comments

GENERAL

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See Attachment

Medicare Physician Spending Due to
National Coverage Decisions (NCDs) Should be Reflected in the SGR

When establishing the SGR spending target for physicians' services, CMS, by statute, is required to take into account the impact on spending due to changes in laws and regulations. Changes in national Medicare coverage policy that are adopted by CMS pursuant to a formal or informal rulemaking, such as Program Memorandums or national coverage decisions, constitute a regulatory change. The SGR provision of the law requires that increases in Medicare spending on physicians' services due to changes in "law and regulations" must be taken into account for purposes of the spending target.

When the impact of regulatory changes for purposes of the SGR is not properly taken into account, physicians are forced to finance the cost of new benefits and other program changes through cuts in their payments. Not only is this precluded by the SGR law, it is extremely inequitable and ultimately adversely impacts beneficiary access to important services.

We have previously provided cost estimates for a number of coverage decisions, including drug treatment for macular degeneration, PET scans, lung volume reduction surgery, and insertion of carotid artery stents, that significantly increase Medicare spending. CMS has justified its decision not to include the cost of its own coverage decisions in the SGR based partly on its view that estimating costs or savings associated with specific coverage decisions would be very difficult and any adjustments would likely be small in magnitude. **Yet, CMS already adjusts Medicare Advantage payments to account for NCDs, so the agency clearly is able to estimate their costs and believes that costs are significant enough such that plans should not be held responsible for these coverage expansions. Accordingly, we strongly urge CMS to adjust the SGR to account for increased spending due to NCDs.**

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In establishing the MEI each year, CMS adjusts it downward to account for physicians' productivity in providing patient care. The productivity adjustment to the MEI for 2007 is 1.3%. The AMA believes that a 1.3% productivity adjustment for physicians' services is too high. It is nearly impossible for physicians to increase their productivity in treating patients in light of various new Medicare initiatives, such as the new comprehensive Medicare Part D drug benefit, that impose numerous time and paperwork burdens on physicians. This would tend to slow productivity, not increase it. In comparison, it is unclear why CMS believes that physicians have the ability to achieve higher productivity levels than other providers, none of which have automatic productivity adjustments to their inflation update. **Thus, we urge CMS to work with the physician community to achieve a productivity adjustment that is a more realistic measure of actual increases in physician productivity.**

Further, we reiterate our request that CMS address the broader problem that the MEI only measures changes in the specific types of practice costs that existed in 1973. Factors (or inputs) to the MEI are vastly different now than when the MEI was first developed in the early 1970s, and thus additional inputs may be needed to ensure that the current MEI adequately measures the costs of practicing medicine. For example, physicians must comply with an array of government-imposed regulatory requirements that did not exist in 1973, including those relating to: compliance with rules governing referrals and interactions with other providers; detailed new and modified coverage policies; advanced beneficiary notices; certificates of medical necessity; rules governing Medicare dual eligible patients; limited English proficiency; Medicare audits; the Health Insurance Portability and Accountability Act (HIPAA) and Clinical Laboratory Improvement Act (CLIA); billing errors; quality monitoring and improvement; and patient safety. CMS is also promoting the use of electronic medical records and other new health information technology systems that facilitate physician participation in quality improvement initiatives. To ensure compliance with these requirements, physicians often must take actions that increase their practice costs, including such actions as hiring: additional types of office staff; attorneys for legal and regulatory compliance; and accountants and billing companies to ensure proper billing of claims. These types of inputs are not currently taken into account for purposes of measuring the MEI, and therefore the MEI undervalues actual medical cost increases.

Accordingly, we urge CMS to include in the MEI any additional inputs that are needed to ensure that the MEI adequately measures the costs of practicing medicine.

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The AMA's Practice Expense Review Committee (PERC) reviewed practice expense (PE) inputs for over 2000 existing CPT codes in 2006, and made recommendations to CMS concerning the direct PE inputs (clinical staff, medical supplies, and equipment) for these codes. **We applaud CMS for adopting all of the recommendations from the PERC and appreciate CMS' participation in this important multi-specialty process.**

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DRA PROPOSALS: REDUCTION IN TECHNICAL COMPONENT FOR IMAGING SERVICES

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CMS is proposing to implement Section 5102(b) of the Deficit Reduction Act of 2005 (DRA), which directs that, effective January 1, 2007, payment rates for the technical

component of imaging services furnished in physicians' offices may not exceed the payment rate paid for the same service furnished in a hospital outpatient department. Under this provision, payment cuts would be imposed for numerous imaging procedures, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy services.

While we understand that this is a statutory mandate, the AMA again expresses its opposition to the DRA imaging cuts pursuant to policy adopted by the AMA House of Delegates in June 2006 calling for a repeal or delay of the DRA imaging cuts.

Nevertheless, the AMA is appreciative that, in implementing this DRA provision, CMS proposes to apply the multiple imaging payment reduction prior to the application of the hospital outpatient department payment cap. Thus, if application of the multiple procedure reduction results in a physician office payment amount that is lower than payment for the same procedure in a hospital outpatient department, no additional payment reduction will be made for that service. The AMA agrees with CMS' decision to implement this provision in this manner and prevent further dollars from being permanently removed from the physician services funding pool.

Further, CMS is proposing to continue the multiple imaging procedure payment reduction for 2007 at the current 25% level, rather than the 50% level that CMS had earlier planned to implement. **The AMA agrees with this proposal and applauds CMS' decision not to move forward with the 50% multiple procedure reduction in 2007.**

Budget Neutrality Adjustments Under CMS' "Five-Year Review" Rule

Under CMS' recently proposed "Five-Year Review" rule, CMS announced its plan to revise physician work relative value units (RVUs) that will increase Medicare expenditures for physicians' services by $4 billion. By law, however, CMS must implement these work RVU adjustments on a budget neutral basis. To meet the budget-neutrality requirement, CMS proposes to reduce all work RVUs by an estimated 10 percent. **The AMA submitted comments on the "Five-Year Review" proposed rule and strongly urged CMS to apply the budget neutrality adjuster to the physician fee schedule conversion factor, rather than the work RVUs.** In our comments, we provided CMS with various compelling reasons for doing so, including that applying budget neutrality to the conversion factor rather than the work adjuster is critical in light of the imaging cuts mandated by the DRA and which CMS is proposing to implement under the physician fee schedule proposed rule.

As discussed above, under the DRA, effective January 1, 2007, payment rates for the technical component of imaging services furnished in physicians' offices cannot exceed the payment rate for the same service furnished in a hospital outpatient department. If the budget neutrality adjuster is applied to the work RVUs, payments for all physicians' services with work RVUs would be reduced, but payments for the technical component of imaging services that are slated to be cut under the DRA will not be affected because these services have practice expense RVUs only, not work RVUs. Because the differential in payment

between imaging services furnished in physicians' offices versus a hospital outpatient department would not be narrowed, the DRA cuts will ultimately remove more dollars (about $200 million in 2007, as estimated by the AMA) from the physician payment pool.

If, however, CMS applies the budget neutrality adjuster to the conversion factor, this would reduce payments for all physicians' services equally, including the technical component services, and would narrow the payment differential between imaging services furnished in physicians' offices versus a hospital outpatient department before the DRA provision is applied. Thus, when the DRA cuts are implemented, fewer dollars would be removed from the total Medicare funding for physician services. **Specifically, the AMA estimates that about $200 million dollars in 2007 would be permanently removed from physician services funding if the budget neutrality adjuster is applied to work RVUs instead of the conversion factor.**

VACCINE COVERAGE ISSUES

In establishing a Medicare program to reimburse for outpatient prescription drugs, Congress defined covered Part D drugs to include vaccines that meet certain requirements set forth under the Public Health Service Act. We understand, however, that CMS has decided it will not pay for the physician administration of vaccines covered by Part D. **We urge CMS to reconsider this policy as it undermines the intent of Congress to ensure that Medicare beneficiaries have appropriate access to vaccines that are critical to their health and that may be a matter of life and death.**

Under this policy, for example, physicians could not be paid for the administration of the Herpes Zoster (HZ) vaccine for shingles. Yet, a University of Colorado study of family physicians and general internists found that more than 75% of the physicians surveyed were very likely or somewhat likely to recommend HZ vaccination for their older patients. Respondents cited that the greatest barriers to the provision of the HZ vaccine were coverage and reimbursement, which should not serve as barriers to the administration of the HZ vaccine to Medicare patients. Seniors are extremely vulnerable to HZ as well as long-term pain that is a consequence of HZ. **Physicians should be able to administer the vaccine to their older patients without fear that Medicare claims will be denied. Thus, we urge CMS to ensure payment for the physician administration of Part D-covered vaccines.**

BONE MASS MEASUREMENT TESTS

CMS is proposing several changes to the Medicare coverage policy for bone mass measurement (BMM) tests. In addition, CMS is proposing to identify, through the national coverage determination (NCD) process, additional BMM systems that would be covered for Medicare payment purposes. **We urge that CMS take into account for purposes of calculating the SGR any increases in physician spending that result from any changes to the Medicare BMM coverage policy, including increased spending that results from additional BMM systems that are approved for coverage under the NCD process.**

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

The AMA is concerned about the proposed changes to the exception to the reassignment rules and the physician self-referral rules. **While the commentary in the proposed rule makes clear that these revisions are aimed directly at addressing and eliminating "condo" pathology laboratory arrangements or "pod laboratories" arrangements, as described in Advisory Opinion 04-17, we believe that they could have unintended negative consequences for many common arrangements for diagnostic services.**

Proposed Purchased Diagnostic Test Changes

The proposed rule would amend the current contractual reassignment exception as applied to diagnostic tests to provide that, with certain limited exceptions, if the technical component of a diagnostic test is billed by a physician or medical group under a contractual arrangement with another supplier who performs the service, the billing group must perform the interpretation of the study, and Medicare will limit the payment to the physician or group to the lower of the supplier's net charge to the billing physician or group, the billing physician or group's actual charge, or the Medicare fee schedule amount. Thus, the proposed changes to the reassignment rule would apply the requirements of the purchased diagnostic test rule (PDT Rule) anti-markup provisions to any arrangement in which a physician bills for the technical component of a diagnostic test pursuant to a contractual reassignment relationship. Whether the arrangement truly constitutes the "purchase" of a test from another supplier would be irrelevant.

Application of the anti-markup rule would substantially change the economics of all contractual arrangements involving diagnostic tests. For example, a physician who contracts with another medical practice, a hospital, or an outside company to access the use of diagnostic equipment and personnel on a block-of-time basis could become subject to the purchased diagnostic test anti-markup provisions. Such unintended consequences could cause many physician groups to reconsider arrangements that currently provide convenient and efficient testing to patients, ultimately reducing access to care.

Potential Purchased Interpretation Changes

The proposed rule also notes that CMS is considering further amendments to the rule to incorporate and apply all requirements of the purchased interpretation rule to any contractual arrangement between a billing physician and another physician or medical group to perform professional interpretations of diagnostic tests pursuant to a reassignment. Under these changes, a physician or group would be able to bill for a reassigned professional component of a diagnostic test under the contractual arrangements exception *only* if three conditions are met. First, a physician who is outside of the group performing the billing, and independent of the interpreting physicians must order the test. Second, the physician or group performing the interpretation did not see the patient. And third, the physician or group billing for the interpretation performed the technical component of the test.

These requirements would disrupt a number of well-established, legitimate arrangements throughout the health care industry. For example, it is a common and well-established practice for physicians to enter into independent contract arrangements with physician group practices to provide part-time services at the offices of those physician groups. Such arrangements provide both parties with financial flexibility and can provide access to specialty care, especially in rural or other under-served areas. If CMS were to adopt the aforementioned proposal, independent contractor arrangements such as these would be prohibited because the independently contracting physician would be unable to interpret the test he or she ordered for a patient under his or her care.

In addition, the rule could adversely impact hospital-based groups, such as radiology groups who contract with independent contractors for teleradiology services. It is common for these hospital-based groups to bill Medicare for the professional component services pursuant to a reassignment by the teleradiology group. If CMS imposed this rule change, the hospital-based group would be precluded from billing for the professional component for hospital patients because the hospital-based group would not satisfy the requirement that the group perform and bill for the technical component of the service. Another legitimate arrangement that would be prohibited under the proposed amendment is where a group practice contracts with a physician to furnish only the professional component of diagnostic testing services for its patients and for which the practice bills on a global basis. Such an arrangement would not be permissible under the proposed amendment because the physician ordering the test would be part of the group that bills for the test and interpretation. Thus, independent contractor physicians would effectively be barred from performing the professional interpretation of diagnostic tests that are billed by medical practices.

The AMA believes that amending the reassignment rule as proposed would have a negative effect on patient care, without any corresponding benefit in terms of protecting the Medicare program. Independent contractor arrangements between physicians and physician groups increase access and coordination of care, which ultimately leads to improved patient outcomes and greater health care efficiencies.

Proposed Changes to Stark "Centralized Building" Definition

The proposed rule also seeks to revise the "in-office ancillary services" exception to the prohibition on certain physician self-referrals, or the so-called "Stark law," by changing the definition of what constitutes a "centralized building." Currently, a "centralized building" is defined as all or part of a building, mobile vehicle, van, or trailer that is owned or leased on a full-time basis by the group practice and is used exclusively by that group practice. The proposed rule suggests adding a requirement that in order for a space to qualify as a "centralized building," the space must be at least 350 square feet. And, the space must, on a permanent basis, contain the necessary equipment to perform substantially all—90 percent—of the designated health services that will be performed in the space in any given calendar year. The equipment cannot be temporarily moved into the space from another space in the same building or from outside the same building.

Implementation of the proposed change will likely prove difficult for medical groups that contract with radiologists or other ancillary service providers in other locations to meet the group's patient service needs on a 24/7 basis. Under such arrangements, physicians are able to provide interpretations using Picture Archiving and Communication Systems (PACS) by working in a "centralized building" that is operated by the billing medical group, but located in the remote location. Amendment of the "centralized building" definition would make the economic feasibility of such remote reading arrangements questionable due to the space and equipment requirements. Thus, the AMA suggests that at the very least, radiology, and other imaging services should be excluded.

Finally, CMS is considering a requirement that the group practice must staff the centralized building space with a non-physician employee or independent contractor who performs services exclusively for the group practice in that space no less than 35 hours per week. This requirement would essentially limit use of the centralized building to only those practices that have a significant volume of diagnostic testing or other ancillary services, such that the group could support the existence of a centralized testing site. **The AMA strongly urges CMS not to impose this requirement. Such a costly mandate represents micromanagement of health care delivery and is an unjustified interference and imposition on physician practices.**

PROMOTING EFFECTIVE USE OF HIT

The AMA is optimistic about the prospects that health information technology (HIT) holds for transforming patient care, if properly developed and carefully integrated into the existing health care delivery system. We are encouraged that the Administration recognizes the importance of moving toward an interoperable health information technology infrastructure and understands the crucial role the federal government will play in its viability. We similarly appreciate the agency's recognition that the prediction of considerable savings set forth in a recent RAND study, concerning savings that could result from broad adoption of electronic health records, are based on extrapolation from very limited real-world examples. We agree with CMS that "extreme caution should be used in interpreting" the result of the RAND study.

As CMS and the physician community move toward adoption of HIT, we urge CMS and the Administration to reconsider its view that HIT adoption is a physician's "normal cost of doing business." Under this view, a disproportionate burden would be imposed on physicians, for whom the business case for HIT adoption has yet to be made. A study by Robert H. Miller and others found that initial electronic health record costs were approximately $44,000 per full-time equivalent (FTE) provider, and ongoing costs were about $8,500 annually per FTE provider. (*Health Affairs*, September/October, 2005). While HIT is expected to generate systemwide savings, those who are currently expected to pay for such systems, namely physicians and other practice organizations, will only see 11 percent of that return on investment, while the remaining 89 percent would accrue to those who typically do not share in the cost of the HIT, such as insurers, laboratories, patients, and private and government payers.

Accordingly, the AMA strongly urges CMS and policymakers to consider a direct means for assisting physicians in the adoption of HIT, such as grants, loans, tax credits, and other economic incentives.

Further, despite the complexity and cost of developing a national health information network, physicians are optimistic about the transformative power that adoption of this technology promises for enhanced quality in patient care. Issues regarding the privacy and security of patients' sensitive data, data ownership, liability for data stewardship, funding, and programming issues regarding interoperability standards, however, must be resolved in the near term to allow physicians to integrate efficient, workable, cost-effective HIT systems into their practices.

We appreciate the opportunity to provide our views on the critical foregoing matters and stand ready to work with CMS to achieve a successful solution to each of these issues.

Sincerely,

Michael D. Maves, MD, MBA

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AMA
AMERICAN
MEDICAL
ASSOCIATION

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

October 10, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Administrator McClellan:

The American Medical Association (AMA) appreciates the opportunity to provide our views concerning the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the *Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B*, 71 *Fed. Reg.* 48,982 (August 22, 2006).

MEDICARE PHYSICIAN PAYMENT RATE FOR 2007

CMS estimates in the proposed rule that Medicare payment rates in 2007 for physicians and other health care practitioners whose payment rates are tied to the physician fee schedule will be cut by 5.1%. **The AMA urges CMS to work with Congress to avert this cut and ensure that physician payment updates for 2007 and subsequent years accurately reflect increases in medical practice costs.**

The AMA is grateful for intervention by Congress and the Administration in each of the last four years to forestall steep Medicare physician payment cuts due to the flawed sustainable growth rate (SGR) physician payment formula. Yet, a crisis still looms, and, in fact, is getting worse.

Payments to physicians today are essentially the same as they were five years ago. Due to the SGR, physicians now face drastic Medicare payment cuts totaling almost 40% over the next nine years. Yet, during this same time period, physician practice costs are expected to

increase by about 20%. Further, CMS has underscored the inadequacy of Medicare physician payments in a rule proposed earlier this year relating to the "Five-Year Review of Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology." **Data in that proposed rule indicate that Medicare now covers only two-thirds of the labor, supply, and equipment costs that go into each service.**

According to surveys by the AMA and Medical Group Management Association (MGMA), 45% of physicians and 40% of group practices will be forced to limit the number of new Medicare patients they can accept when the first cut of at least 5% goes into effect January 1, 2007. Medicare beneficiaries and their families understand this concern. In fact, a recent national poll conducted by the AMA shows that the vast majority of Americans, 86%, are concerned that seniors' access to health care will be hurt if impending cuts in Medicare physician payment take effect on January 1, 2007. Further, 82% of current Medicare patients are concerned about the cut's impact on their access to health care. Baby boomers are also very concerned about the impact of the cuts on Medicare patients' access to care. A staggering 93% of baby boomers age 45-54 are concerned about the cut's impact on access to care. In just five years, the first wave of baby boomers will reach age 65, and will turn to Medicare for their health care.

Despite the clear warning signals, however, CMS and the Administration have failed to take a variety of administrative actions, as discussed further below, that could be made without additional legislative authority to ameliorate the problem and pave the way for Congress to adopt a long-term solution.

Only physicians and other health professionals face steep cuts under this flawed payment formula. Other providers have been receiving updates that fully keep pace with their costs (and will continue to do so under current law), including Medicare Advantage plans which are already paid 11% in excess of fee-for-service costs, as indicated in a "Medicare Brief" released by the Medicare Payment Advisory Commission (MedPAC) in June 2006. Physicians and other health care professionals must have payment equity with these other providers. Physicians are the foundation for our nation's health care system, and thus a stable payment environment for their services is critical.

Further, in addition to the 2007 physician cuts due to the flawed SGR, Medicare physician payment policy changes recently announced by CMS will take effect on January 1, 2007. These changes relate to: (i) expiration of the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA) provision that set a floor on geographic practice cost adjusters for the work component of Medicare's physician fee schedule; (ii) changes in both the physician work and practice expense relative values under CMS' recently-proposed five-year review rule; and (iii) payment cuts in imaging services furnished in physicians' offices, as mandated by the Deficit Reduction Act of 2005 (DRA).

These policy changes will have a significant impact on a large number of physicians who could experience combined pay cuts of 10% or more for many physicians' services. In fact,

a recent AMA analysis indicates that if the SGR cut is allowed to take effect in 2007, 13% of physicians will face cuts exceeding 10%, and 32% will see cuts of 6% to 10%. Thus, almost half of physicians will face cuts in addition to the 5.1% across-the-board cut that is scheduled for January 1, 2007.

Time is running out. CMS must take all administrative steps possible to reduce the cost of an SGR solution, work with Congress to avert the 2007 physician pay cut by enacting a positive physician payment update that accurately reflects increases in medical practice costs, as indicated by the Medicare Economic Index (MEI). In addition, over the long-term, CMS must work with Congress to repeal the SGR and replace it with a system that keeps pace with increases in medical practice costs.

ADMINISTRATIVE ACTIONS TO HELP REFORM THE MEDICARE PHYSICIAN PAYMENT FORMULA

We have repeatedly urged CMS to assist Congress in solving the SGR problem and have identified a number of administrative actions that would significantly reduce the cost of repealing the SGR. They are reiterated below.

CMS Should Remove Drugs Retroactively from the SGR

The most significant step that CMS can take to reduce the cost of an SGR solution is to retroactively remove physician-administered drugs from calculations of the SGR. CMS clearly has the authority to make this change, as shown in legal opinions by independent legal counsel, Terry S. Coleman, a former Acting General Counsel of the U.S. Department of Health and Human Services. The AMA has previously provided CMS with these opinions. House and Senate leaders have also expressed this same view to CMS, and have requested that increases in Medicare spending due to physician-administered drugs be removed retroactively from calculations of the SGR.

CMS' authority to remove physician-administered drugs from the SGR, retroactive to 1996, is derived from statute. When CMS calculates actual Medicare spending on "physicians' services," it includes the costs of Medicare-covered prescription drugs administered in physicians' offices. CMS has excluded drugs from "physicians' services" for purposes of administering other Medicare physician payment provisions. Thus, removing drugs from the definition of "physicians' services" for purposes of calculating the SGR is a consistent reading of the Medicare statute. Drugs are not paid under the Medicare physician fee schedule, and it is illogical to include them in calculating the SGR.

Further, if CMS adopts a revised definition of "physicians' services" that excludes drugs, it can revise its SGR calculations going back to 1996 using its revised definition. These revisions would not affect payment updates from previous years, but would only affect payment updates in future years. This recalculation would be similar, for example, to the recalculation of graduate medical education costs in a base year for purposes of setting future payment amounts. That recalculation was approved by the Supreme Court.

It is inequitable to include drug expenditures in calculations of the SGR because drugs continue to grow at a very rapid pace. While the bulk of all physician-administered drugs are used to treat cancer patients, other factors — such as a rise in the number of patients with compromised immune systems and the number of drug-resistant infections in the U.S. — also have contributed to the rapid growth of drug expenditures. This growth has far outpaced that of the physician services that the SGR was intended to include, and Medicare actuaries predict that drug spending growth will continue to significantly outpace spending on physicians' services for years to come. This lopsided growth lowers the SGR target for real physicians' services and significantly increases the odds that Medicare spending on "physicians' services" will exceed the SGR target and thus trigger a payment cut to align payments with the target .

The development of these life-altering drugs has been encouraged by various federal policies including streamlining of the drug approval process and increased funding for the National Institutes of Health. In fact, the National Institutes of Health has made substantial progress toward its goal of wiping out cancer deaths by 2015 and much of that progress is tied to the development and more rapid diffusion of new drugs. The AMA shares and applauds these goals. **It is not equitable or realistic, however, to finance the cost of these drugs through cuts in payments to physicians, and thus these costs should be removed from calculations of the SGR.**

Government-Induced Increases in Spending on
Physicians' Services Should be Accurately Reflected in the SGR Target

As we have previously demonstrated to CMS, the government encourages greater use of physician services through legislative actions and a host of other regulatory decisions. These initiatives clearly are good for patients and, in theory, their impact on physician spending is recognized in the SGR target. In practice, however, many have either been ignored or not accurately reflected when calculating the SGR target. Since the SGR law requires that calculations of Medicare spending on physicians' services cumulates from year to year, erroneous estimates roll over into future years and compound the deficits in spending on physicians' services.

CMS has never provided details of how its estimates of new or expanded physicians' services are calculated, and certain questions remain. Further, CMS reportedly does consider multiple year impacts and the cost of related services, but, as noted by MedPAC, the agency has not provided any itemized descriptions of how the agency determines estimated costs. **We urge CMS to provide the physician community with these itemized descriptions, and accurately reflect in the SGR increased spending due to all government initiatives for purposes of the 2007 physician fee schedule rule.**

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Nevertheless, the AMA is appreciative that, in implementing this DRA provision, CMS proposes to apply the multiple imaging payment reduction prior to the application of the hospital outpatient department payment cap. Thus, if application of the multiple procedure reduction results in a physician office payment amount that is lower than payment for the same procedure in a hospital outpatient department, no additional payment reduction will be made for that service. The AMA agrees with CMS' decision to implement this provision in this manner and prevent further dollars from being permanently removed from the physician services funding pool.

Further, CMS is proposing to continue the multiple imaging procedure payment reduction for 2007 at the current 25% level, rather than the 50% level that CMS had earlier planned to implement. **The AMA agrees with this proposal and applauds CMS' decision not to move forward with the 50% multiple procedure reduction in 2007.**

Budget Neutrality Adjustments Under CMS' "Five-Year Review" Rule

Under CMS' recently proposed "Five-Year Review" rule, CMS announced its plan to revise physician work relative value units (RVUs) that will increase Medicare expenditures for physicians' services by $4 billion. By law, however, CMS must implement these work RVU adjustments on a budget neutral basis. To meet the budget-neutrality requirement, CMS proposes to reduce all work RVUs by an estimated 10 percent. **The AMA submitted comments on the "Five-Year Review" proposed rule and strongly urged CMS to apply the budget neutrality adjuster to the physician fee schedule conversion factor, rather than the work RVUs.** In our comments, we provided CMS with various compelling reasons for doing so, including that applying budget neutrality to the conversion factor rather than the work adjuster is critical in light of the imaging cuts mandated by the DRA and which CMS is proposing to implement under the physician fee schedule proposed rule.

As discussed above, under the DRA, effective January 1, 2007, payment rates for the technical component of imaging services furnished in physicians' offices cannot exceed the payment rate for the same service furnished in a hospital outpatient department. If the budget neutrality adjuster is applied to the work RVUs, payments for all physicians' services with work RVUs would be reduced, but payments for the technical component of imaging services that are slated to be cut under the DRA will not be affected because these services have practice expense RVUs only, not work RVUs. Because the differential in payment

between imaging services furnished in physicians' offices versus a hospital outpatient department would not be narrowed, the DRA cuts will ultimately remove more dollars (about $200 million in 2007, as estimated by the AMA) from the physician payment pool.

If, however, CMS applies the budget neutrality adjuster to the conversion factor, this would reduce payments for all physicians' services equally, including the technical component services, and would narrow the payment differential between imaging services furnished in physicians' offices versus a hospital outpatient department before the DRA provision is applied. Thus, when the DRA cuts are implemented, fewer dollars would be removed from the total Medicare funding for physician services. **Specifically, the AMA estimates that about $200 million dollars in 2007 would be permanently removed from physician services funding if the budget neutrality adjuster is applied to work RVUs instead of the conversion factor.**

VACCINE COVERAGE ISSUES

In establishing a Medicare program to reimburse for outpatient prescription drugs, Congress defined covered Part D drugs to include vaccines that meet certain requirements set forth under the Public Health Service Act. We understand, however, that CMS has decided it will not pay for the physician administration of vaccines covered by Part D. **We urge CMS to reconsider this policy as it undermines the intent of Congress to ensure that Medicare beneficiaries have appropriate access to vaccines that are critical to their health and that may be a matter of life and death.**

Under this policy, for example, physicians could not be paid for the administration of the Herpes Zoster (HZ) vaccine for shingles. Yet, a University of Colorado study of family physicians and general internists found that more than 75% of the physicians surveyed were very likely or somewhat likely to recommend HZ vaccination for their older patients. Respondents cited that the greatest barriers to the provision of the HZ vaccine were coverage and reimbursement, which should not serve as barriers to the administration of the HZ vaccine to Medicare patients. Seniors are extremely vulnerable to HZ as well as long-term pain that is a consequence of HZ. **Physicians should be able to administer the vaccine to their older patients without fear that Medicare claims will be denied. Thus, we urge CMS to ensure payment for the physician administration of Part D-covered vaccines.**

BONE MASS MEASUREMENT TESTS

CMS is proposing several changes to the Medicare coverage policy for bone mass measurement (BMM) tests. In addition, CMS is proposing to identify, through the national coverage determination (NCD) process, additional BMM systems that would be covered for Medicare payment purposes. **We urge that CMS take into account for purposes of calculating the SGR any increases in physician spending that result from any changes to the Medicare BMM coverage policy, including increased spending that results from additional BMM systems that are approved for coverage under the NCD process.**

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

The AMA is concerned about the proposed changes to the exception to the reassignment rules and the physician self-referral rules. **While the commentary in the proposed rule makes clear that these revisions are aimed directly at addressing and eliminating "condo" pathology laboratory arrangements or "pod laboratories" arrangements, as described in Advisory Opinion 04-17, we believe that they could have unintended negative consequences for many common arrangements for diagnostic services.**

Proposed Purchased Diagnostic Test Changes

The proposed rule would amend the current contractual reassignment exception as applied to diagnostic tests to provide that, with certain limited exceptions, if the technical component of a diagnostic test is billed by a physician or medical group under a contractual arrangement with another supplier who performs the service, the billing group must perform the interpretation of the study, and Medicare will limit the payment to the physician or group to the lower of the supplier's net charge to the billing physician or group, the billing physician or group's actual charge, or the Medicare fee schedule amount. Thus, the proposed changes to the reassignment rule would apply the requirements of the purchased diagnostic test rule (PDT Rule) anti-markup provisions to any arrangement in which a physician bills for the technical component of a diagnostic test pursuant to a contractual reassignment relationship. Whether the arrangement truly constitutes the "purchase" of a test from another supplier would be irrelevant.

Application of the anti-markup rule would substantially change the economics of all contractual arrangements involving diagnostic tests. For example, a physician who contracts with another medical practice, a hospital, or an outside company to access the use of diagnostic equipment and personnel on a block-of-time basis could become subject to the purchased diagnostic test anti-markup provisions. Such unintended consequences could cause many physician groups to reconsider arrangements that currently provide convenient and efficient testing to patients, ultimately reducing access to care.

Potential Purchased Interpretation Changes

The proposed rule also notes that CMS is considering further amendments to the rule to incorporate and apply all requirements of the purchased interpretation rule to any contractual arrangement between a billing physician and another physician or medical group to perform professional interpretations of diagnostic tests pursuant to a reassignment. Under these changes, a physician or group would be able to bill for a reassigned professional component of a diagnostic test under the contractual arrangements exception *only* if three conditions are met. First, a physician who is outside of the group performing the billing, and independent of the interpreting physicians must order the test. Second, the physician or group performing the interpretation did not see the patient. And third, the physician or group billing for the interpretation performed the technical component of the test.

These requirements would disrupt a number of well-established, legitimate arrangements throughout the health care industry. For example, it is a common and well-established practice for physicians to enter into independent contract arrangements with physician group practices to provide part-time services at the offices of those physician groups. Such arrangements provide both parties with financial flexibility and can provide access to specialty care, especially in rural or other under-served areas. If CMS were to adopt the aforementioned proposal, independent contractor arrangements such as these would be prohibited because the independently contracting physician would be unable to interpret the test he or she ordered for a patient under his or her care.

In addition, the rule could adversely impact hospital-based groups, such as radiology groups who contract with independent contractors for teleradiology services. It is common for these hospital-based groups to bill Medicare for the professional component services pursuant to a reassignment by the teleradiology group. If CMS imposed this rule change, the hospital-based group would be precluded from billing for the professional component for hospital patients because the hospital-based group would not satisfy the requirement that the group perform and bill for the technical component of the service. Another legitimate arrangement that would be prohibited under the proposed amendment is where a group practice contracts with a physician to furnish only the professional component of diagnostic testing services for its patients and for which the practice bills on a global basis. Such an arrangement would not be permissible under the proposed amendment because the physician ordering the test would be part of the group that bills for the test and interpretation. Thus, independent contractor physicians would effectively be barred from performing the professional interpretation of diagnostic tests that are billed by medical practices.

The AMA believes that amending the reassignment rule as proposed would have a negative effect on patient care, without any corresponding benefit in terms of protecting the Medicare program. Independent contractor arrangements between physicians and physician groups increase access and coordination of care, which ultimately leads to improved patient outcomes and greater health care efficiencies.

Proposed Changes to Stark "Centralized Building" Definition

The proposed rule also seeks to revise the "in-office ancillary services" exception to the prohibition on certain physician self-referrals, or the so-called "Stark law," by changing the definition of what constitutes a "centralized building." Currently, a "centralized building" is defined as all or part of a building, mobile vehicle, van, or trailer that is owned or leased on a full-time basis by the group practice and is used exclusively by that group practice. The proposed rule suggests adding a requirement that in order for a space to qualify as a "centralized building," the space must be at least 350 square feet. And, the space must, on a permanent basis, contain the necessary equipment to perform substantially all—90 percent—of the designated health services that will be performed in the space in any given calendar year. The equipment cannot be temporarily moved into the space from another space in the same building or from outside the same building.

Implementation of the proposed change will likely prove difficult for medical groups that contract with radiologists or other ancillary service providers in other locations to meet the group's patient service needs on a 24/7 basis. Under such arrangements, physicians are able to provide interpretations using Picture Archiving and Communication Systems (PACS) by working in a "centralized building" that is operated by the billing medical group, but located in the remote location. Amendment of the "centralized building" definition would make the economic feasibility of such remote reading arrangements questionable due to the space and equipment requirements. Thus, the AMA suggests that at the very least, radiology, and other imaging services should be excluded.

Finally, CMS is considering a requirement that the group practice must staff the centralized building space with a non-physician employee or independent contractor who performs services exclusively for the group practice in that space no less than 35 hours per week. This requirement would essentially limit use of the centralized building to only those practices that have a significant volume of diagnostic testing or other ancillary services, such that the group could support the existence of a centralized testing site. **The AMA strongly urges CMS not to impose this requirement. Such a costly mandate represents micromanagement of health care delivery and is an unjustified interference and imposition on physician practices.**

PROMOTING EFFECTIVE USE OF HIT

The AMA is optimistic about the prospects that health information technology (HIT) holds for transforming patient care, if properly developed and carefully integrated into the existing health care delivery system. We are encouraged that the Administration recognizes the importance of moving toward an interoperable health information technology infrastructure and understands the crucial role the federal government will play in its viability. We similarly appreciate the agency's recognition that the prediction of considerable savings set forth in a recent RAND study, concerning savings that could result from broad adoption of electronic health records, are based on extrapolation from very limited real-world examples. We agree with CMS that "extreme caution should be used in interpreting" the result of the RAND study.

As CMS and the physician community move toward adoption of HIT, we urge CMS and the Administration to reconsider its view that HIT adoption is a physician's "normal cost of doing business." Under this view, a disproportionate burden would be imposed on physicians, for whom the business case for HIT adoption has yet to be made. A study by Robert H. Miller and others found that initial electronic health record costs were approximately $44,000 per full-time equivalent (FTE) provider, and ongoing costs were about $8,500 annually per FTE provider. (*Health Affairs*, September/October, 2005). While HIT is expected to generate systemwide savings, those who are currently expected to pay for such systems, namely physicians and other practice organizations, will only see 11 percent of that return on investment, while the remaining 89 percent would accrue to those who typically do not share in the cost of the HIT, such as insurers, laboratories, patients, and private and government payers.

Accordingly, the AMA strongly urges CMS and policymakers to consider a direct means for assisting physicians in the adoption of HIT, such as grants, loans, tax credits, and other economic incentives.

Further, despite the complexity and cost of developing a national health information network, physicians are optimistic about the transformative power that adoption of this technology promises for enhanced quality in patient care. Issues regarding the privacy and security of patients' sensitive data, data ownership, liability for data stewardship, funding, and programming issues regarding interoperability standards, however, must be resolved in the near term to allow physicians to integrate efficient, workable, cost-effective HIT systems into their practices.

We appreciate the opportunity to provide our views on the critical foregoing matters and stand ready to work with CMS to achieve a successful solution to each of these issues.

Sincerely,

Michael D. Maves, MD, MBA

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

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

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

Submitter : Dr. Viola Monaghan **Date:** 10/10/2006

Organization : Northeast Surgical Group

Category : Physician

Issue Areas/Comments

Background

Background

The revisions as proposed will have a negative impact on the Medicare population who suffer from venous disease. The reduction of the reimbursement rates will ultimately limit access to physicians who perform these treatments which address venous disease. This is a quality of health and quality of life issue. People who suffer from venous disease have pain and difficulty standing, walking. Many patients can and do develop ulcers which cost thousands of dollars to treat. Current technology for treating venous disease includes laser or radio frequency laser ablation. Without treatment the ulcers will not heal and patients will continue to require far more expensive treatment at wound care facilities or primary care offices only to have the ulcer reopen. Ongoing treatment of the symptoms will not cure the underlying problem and the ultimate costs will be greater than the actual procedure costs to correct this condition.

GENERAL

GENERAL

General Comment

CMS-1321-P
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment Under Part B
Proposal dated August 8, 2006

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation.

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

The costs of running a medical practice including salaries, utilities, malpractice insurance, and medical supplies consistently rise as the reimbursement rates continue to fall. How can we as physicians continue to work in an environment where it has become increasingly difficult to provide these necessary services to patients?

Not only have malpractice insurance rates for physicians risen 30% per but the malpractice rates for Physician Assistants have doubled in the last year. Of course you are painfully aware of the rise in utility bills as the cost of oil rises. The cost of gasoline, which has hovers around $3.00 per gallon, has a dire effect, especially on our practice. In order to address the elderly population in the rural areas of upstate New York, our practice including doctors, nurses and support staff travels to outlaying offices in Syracuse, Vestal and Horseheads, New York every week. How can we continue to help our elderly if we can not pay even our basis expenses?

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,

Viola Monaghan, MD.

Northeast Surgical Group, LLP
8 Brentwood Drive Suite A
Ithaca, NY 14850

Impact

Impact

See Comment

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See Comment

Submitter : **Ms. Vivi Tokatlian** **Date: 10/10/2006**

Organization : **California Hematology Oncology Medical Group**

Category : **Other Health Care Professional**

Issue Areas/Comments

Impact

Impact

-It is advantageous for our Medicare patient's to come in every other week for an Aranesp shot than once a week with a Procrit shot.
-The choices are greater now than they were before when the only drug we could use was Procrit.
-The decision for our physicians to treat patients is based only on the way the drug works, rather than any financial issue.
-Using both Aranesp and Neulasta together is hugely advantageous for our patients, complimenting both the therapeutic and supportive care.
-It would be devastating for our practice if CMS changes the current ASP system. It would decrease the option to choose the best drug for our patients.
-I would like to also note that if we felt Procrit fit our practice better than Aranesp, we could continue to give Neulasta or Neupogen as needed.

Submitter : Ms. Carmen Delgado Votaw **Date:** 10/10/2006

Organization : Alliance for Children and Families, Provident, Inc

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1321-P-762-Attach-1.DOC

762

Alliance for Children and Families
1701 K Street NW, Suite 200
Washington, DC 20006
policy@alliance1.org

Provident, Inc.
2650 Olive Street
St. Louis, MO 63103

October 9, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
P.O. Box 8014
Baltimore, MD 21244-8014

RE: Medicare Physician Fee Schedule, 71 Fed.Reg. 48982 (August 22, 2006)

The Alliance for Children and Families and Provident, Inc., one of its member agencies, are writing to comment on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007, published in the Federal Register on August 22, 2006.

The mission of the Alliance is to strengthen the capacities of North America's nonprofit child and family serving organizations to serve and to advocate for children, families and communities, so that together we may pursue our vision of a healthy society and strong communities for all children and families. The mission of Provident is to strengthen families; to provide youth the opportunity and resources to succeed; and to assist communities to be stable and productive. This is accomplished by providing prevention and treatment services that have the greatest potential for positive impact.

We are writing to oppose the changes to the Relative Value Units (RVUs) and Practice Expense (PE) Methodology that would cause a total 14% fee reduction for clinical social workers by January 1, 2007 when combined with all contemplated adjustments announced in the proposed rule. As advocates for vulnerable children and families across the United States and as a service provider to more than 47,000 individuals in the St. Louis region per year, we are deeply concerned by this proposed action that would deeply affect the ability of clinical social workers to continue to serve Medicare patients. If they cannot be sufficiently reimbursed for the time and services provided to patients, social workers will face a difficult choice between fiscal survival and continuing to serve the Medicare population. This population is particularly in need of quality social workers due to the increased incidence of behavioral health problems, mental illness, and suicide; the potential for abuse or neglect of the elderly, disabled, and vulnerable persons; and the difficult issues that surround long-term care decisions.

The proposed Fee Schedule changes impose greater fee reductions on clinical social workers than on almost any other practice area, with the exception of radiology and anesthesiology. We believe that this reduction is unwarranted and will cause significant harm by effectively reducing the amount of quality social services that will be available to Medicare beneficiaries. We believe that RVUs and PEs should not be increased for only certain practice areas, but that increases should be delayed

until all practice areas can receive appropriate fee increases. In the meantime, some types of providers should not experience a fee reduction that allows for a fee increase for other providers.

We recommend that the Centers for Medicare and Medicaid Services:

- Withdraw the proposed RVU and PE changes that would cause a 14% fee reduction for clinical social workers by January 1, 2007;
- Withdraw the proposed increases to evaluation and management RVUs and PEs until such time as all practice areas can be considered for an appropriate fee increase;
- Select a formula for calculating practice expenses that does not have a negative impact on clinical social workers. The proposed "bottom up" methodology has a disproportionate negative impact on clinical social workers due to their low practice expense as providers.

Thank you for inviting our comments.

Carmen Delgado Votaw
Senior Vice President, Public Policy
Alliance for Children and Families

Kathleen Buescher
President and CEO
Provident, Inc.

Submitter : Dr. Michael Maves **Date:** 10/10/2006

Organization : American Medical Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-763-Attach-1.PDF

CMS-1321-P-763-Attach-2.PDF

763-1

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

October 10, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Administrator McClellan:

The American Medical Association (AMA) appreciates the opportunity to provide our views concerning the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the *Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B*, 71 *Fed. Reg.* 48,982 (August 22, 2006).

MEDICARE PHYSICIAN PAYMENT RATE FOR 2007

CMS estimates in the proposed rule that Medicare payment rates in 2007 for physicians and other health care practitioners whose payment rates are tied to the physician fee schedule will be cut by 5.1%. **The AMA urges CMS to work with Congress to avert this cut and ensure that physician payment updates for 2007 and subsequent years accurately reflect increases in medical practice costs.**

The AMA is grateful for intervention by Congress and the Administration in each of the last four years to forestall steep Medicare physician payment cuts due to the flawed sustainable growth rate (SGR) physician payment formula. Yet, a crisis still looms, and, in fact, is getting worse.

Payments to physicians today are essentially the same as they were five years ago. Due to the SGR, physicians now face drastic Medicare payment cuts totaling almost 40% over the next nine years. Yet, during this same time period, physician practice costs are expected to

increase by about 20%. Further, CMS has underscored the inadequacy of Medicare physician payments in a rule proposed earlier this year relating to the "Five-Year Review of Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology." **Data in that proposed rule indicate that Medicare now covers only two-thirds of the labor, supply, and equipment costs that go into each service.**

According to surveys by the AMA and Medical Group Management Association (MGMA), 45% of physicians and 40% of group practices will be forced to limit the number of new Medicare patients they can accept when the first cut of at least 5% goes into effect January 1, 2007. Medicare beneficiaries and their families understand this concern. In fact, a recent national poll conducted by the AMA shows that the vast majority of Americans, 86%, are concerned that seniors' access to health care will be hurt if impending cuts in Medicare physician payment take effect on January 1, 2007. Further, 82% of current Medicare patients are concerned about the cut's impact on their access to health care. Baby boomers are also very concerned about the impact of the cuts on Medicare patients' access to care. A staggering 93% of baby boomers age 45-54 are concerned about the cut's impact on access to care. In just five years, the first wave of baby boomers will reach age 65, and will turn to Medicare for their health care.

Despite the clear warning signals, however, CMS and the Administration have failed to take a variety of administrative actions, as discussed further below, that could be made without additional legislative authority to ameliorate the problem and pave the way for Congress to adopt a long-term solution.

Only physicians and other health professionals face steep cuts under this flawed payment formula. Other providers have been receiving updates that fully keep pace with their costs (and will continue to do so under current law), including Medicare Advantage plans which are already paid 11% in excess of fee-for-service costs, as indicated in a "Medicare Brief" released by the Medicare Payment Advisory Commission (MedPAC) in June 2006. Physicians and other health care professionals must have payment equity with these other providers. Physicians are the foundation for our nation's health care system, and thus a stable payment environment for their services is critical.

Further, in addition to the 2007 physician cuts due to the flawed SGR, Medicare physician payment policy changes recently announced by CMS will take effect on January 1, 2007. These changes relate to: (i) expiration of the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA) provision that set a floor on geographic practice cost adjusters for the work component of Medicare's physician fee schedule; (ii) changes in both the physician work and practice expense relative values under CMS' recently-proposed five-year review rule; and (iii) payment cuts in imaging services furnished in physicians' offices, as mandated by the Deficit Reduction Act of 2005 (DRA).

These policy changes will have a significant impact on a large number of physicians who could experience combined pay cuts of 10% or more for many physicians' services. In fact,

a recent AMA analysis indicates that if the SGR cut is allowed to take effect in 2007, 13% of physicians will face cuts exceeding 10%, and 32% will see cuts of 6% to 10%. Thus, almost half of physicians will face cuts in addition to the 5.1% across-the-board cut that is scheduled for January 1, 2007.

Time is running out. CMS must take all administrative steps possible to reduce the cost of an SGR solution, work with Congress to avert the 2007 physician pay cut by enacting a positive physician payment update that accurately reflects increases in medical practice costs, as indicated by the Medicare Economic Index (MEI). In addition, over the long-term, CMS must work with Congress to repeal the SGR and replace it with a system that keeps pace with increases in medical practice costs.

ADMINISTRATIVE ACTIONS TO HELP REFORM THE MEDICARE PHYSICIAN PAYMENT FORMULA

We have repeatedly urged CMS to assist Congress in solving the SGR problem and have identified a number of administrative actions that would significantly reduce the cost of repealing the SGR. They are reiterated below.

CMS Should Remove Drugs Retroactively from the SGR

The most significant step that CMS can take to reduce the cost of an SGR solution is to retroactively remove physician-administered drugs from calculations of the SGR. CMS clearly has the authority to make this change, as shown in legal opinions by independent legal counsel, Terry S. Coleman, a former Acting General Counsel of the U.S. Department of Health and Human Services. The AMA has previously provided CMS with these opinions. House and Senate leaders have also expressed this same view to CMS, and have requested that increases in Medicare spending due to physician-administered drugs be removed retroactively from calculations of the SGR.

CMS' authority to remove physician-administered drugs from the SGR, retroactive to 1996, is derived from statute. When CMS calculates actual Medicare spending on "physicians' services," it includes the costs of Medicare-covered prescription drugs administered in physicians' offices. CMS has excluded drugs from "physicians' services" for purposes of administering other Medicare physician payment provisions. Thus, removing drugs from the definition of "physicians' services" for purposes of calculating the SGR is a consistent reading of the Medicare statute. Drugs are not paid under the Medicare physician fee schedule, and it is illogical to include them in calculating the SGR.

Further, if CMS adopts a revised definition of "physicians' services" that excludes drugs, it can revise its SGR calculations going back to 1996 using its revised definition. These revisions would not affect payment updates from previous years, but would only affect payment updates in future years. This recalculation would be similar, for example, to the recalculation of graduate medical education costs in a base year for purposes of setting future payment amounts. That recalculation was approved by the Supreme Court.

It is inequitable to include drug expenditures in calculations of the SGR because drugs continue to grow at a very rapid pace. While the bulk of all physician-administered drugs are used to treat cancer patients, other factors — such as a rise in the number of patients with compromised immune systems and the number of drug-resistant infections in the U.S. — also have contributed to the rapid growth of drug expenditures. This growth has far outpaced that of the physician services that the SGR was intended to include, and Medicare actuaries predict that drug spending growth will continue to significantly outpace spending on physicians' services for years to come. This lopsided growth lowers the SGR target for real physicians' services and significantly increases the odds that Medicare spending on "physicians' services" will exceed the SGR target and thus trigger a payment cut to align payments with the target .

The development of these life-altering drugs has been encouraged by various federal policies including streamlining of the drug approval process and increased funding for the National Institutes of Health. In fact, the National Institutes of Health has made substantial progress toward its goal of wiping out cancer deaths by 2015 and much of that progress is tied to the development and more rapid diffusion of new drugs. The AMA shares and applauds these goals. **It is not equitable or realistic, however, to finance the cost of these drugs through cuts in payments to physicians, and thus these costs should be removed from calculations of the SGR.**

Government-Induced Increases in Spending on
Physicians' Services Should be Accurately Reflected in the SGR Target

As we have previously demonstrated to CMS, the government encourages greater use of physician services through legislative actions and a host of other regulatory decisions. These initiatives clearly are good for patients and, in theory, their impact on physician spending is recognized in the SGR target. In practice, however, many have either been ignored or not accurately reflected when calculating the SGR target. Since the SGR law requires that calculations of Medicare spending on physicians' services cumulates from year to year, erroneous estimates roll over into future years and compound the deficits in spending on physicians' services.

CMS has never provided details of how its estimates of new or expanded physicians' services are calculated, and certain questions remain. Further, CMS reportedly does consider multiple year impacts and the cost of related services, but, as noted by MedPAC, the agency has not provided any itemized descriptions of how the agency determines estimated costs. **We urge CMS to provide the physician community with these itemized descriptions, and accurately reflect in the SGR increased spending due to all government initiatives for purposes of the 2007 physician fee schedule rule.**

Submitter : Ms. Carolyn Klepfer **Date:** 10/10/2006

Organization : Diagnostic and Internal Medicine Associates

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-764-Attach-1.DOC

#764

Diagnostic and Internal Medicine Associates
201 Ridge Street Suite 302
Council Bluffs, IA 51503
Phone: 712.322.5532 Fax: 712.322.4131

Barry L Kricsfeld MD
Alan S Kricsfeld MD
Evelyn E Reher MD
Noel Carosella PAC

October 9, 2006

Re: Document Number 1321-P

To Whom It May Concern:

On behalf of our clinic, I would like to state our concerns over the possible upcoming changes in bone density testing reimbursement rates and reevaluations as proposed by Medicare.

As the x-ray technician for our clinic and one of the trained Bone Mass Measurement techs, I have first-hand knowledge of the involved patient care aspect of this testing process. Intensive skilled human involvement is necessary in the patient interview, evaluation, positioning, quality control and diagnosis of osteoporosis or osteopenia. It is not possible to herd patients through the process without compromising safety or quality.

Several of our patients present to clinic with spine compression fractures. Until the past decade or so, there was little we could do to prevent this condition. However, early detection and treatment has been proven to help reduce the risk of this painful or debilitating condition. Other patients spend weeks, months or the rest of their lives in nursing care facilities due to hip fractures and the secondary life-robbing issues that often come with this ugly scenario of osteoporosis.

In the three years that we have been performing this test in our office, we have seen treatment work in many of the patients diagnosed with and treated for osteoporosis.

Due to the intensive staff time to perform bone scans, we set aside approximately 12% of our operating hours to focus on bone health.

Overall, Medicare carries a large load, so I understand the importance of cutting costs. But from the angle of the doctor's office, a private clinic which is becoming an endangered breed, I have watched Medicare trim reimbursement to the point it often costs money to provide care, while patient cost for private insurance and supplements have climbed with the deductibles and co-pays.

I don't have any answers for this dilemma, but don't see how denying life-saving or life-enhancing testing benefits anyone. A broken hip and subsequent long term care costs Medicare far more than the cost of a yearly test and treatment.

Sincerely,

Carolyn Klepfer

Submitter : Dr. Eric Rhoton **Date:** 10/10/2006

Organization : Mountain Neurological Center, P.A.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1321-P-765-Attach-1.DOC

#765

MOUNTAIN NEUROLOGICAL CENTER, P.A.
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http://www.mtnneuro.com

October 4, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
PO Box 8011
Baltimore, MD 21244-1850

Re: New Technology APCs – Section c. Pages 49553 and 49554

We appreciate the opportunity to submit comments on the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule published August 23, 2006 in the Federal Register Volume 71, No. 183 Part II 42 CFR Parts 410, 414, 416, 419, 421, 485, and 488 [CMS-1506-P; CMS-4125-P] RIN 0938-AO15, pages 49553 and 49544 – New Technology APCs, Section c. Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

New Technology APCs

The Proposed Rule includes changes to the Ambulatory Payment Classifications (APCs) for G0339 (image-guided robotic stereotactic radiosurgery complete or first treatment) and G0340 (image-guided robotic stereotactic radiosurgery fractionated – treatments 2 through 5). Specifically the proposal is to move G0339 from APC 1528 to APC 0067 resulting in a reduction of ($1,190.39) per treatment. It is also proposed to move G0340 from APC 1525 to APC 0066 resulting in a reduction of ($833.32). These proposed revisions would result in a reduction in payment averaging ($2,857.03) per patient (based on the average treatment of three fractions per patient). A reduction of this magnitude for these codes would make it financially prohibitive for institutions to make this technology available to their patients. The proposed reductions were made based on the Center for Medicare and Medicaid Services (CMS) review of the Identifiable Data Set Hospital OPPS file for Calendar Years (CY) 2004 and 2005. We have serious concerns about this review, which we will enumerate in these comments. It is our hope that CMS will modify its proposed changes to payment codes and rates for both staged and single session image-guided robotic stereotactic radiosurgery, effective CY 2007. We request your assistance in setting reasonable Medicare rates for image-guided robotic stereotactic radiosurgery technology.

We want to acknowledge and applaud CMS' efforts over the past several years to continually improve its understanding of image-guided robotic stereotactic radiosurgery and maintain a process that allows for tracking of new technology claims. We would like to take this opportunity to further assist CMS in its efforts to establish appropriate payment rates for this technology and clarify the descriptor related to image-guided robotic stereotactic radiosurgery. To that end, we are supplying a brief overview of the development of the relevant codes and rates.

History of Medicare Coding and Payment for Image-Guided Robotic Stereotactic Radiosurgery (r-SRS)

CY 2002

In the November 30, 2001 Federal Register, CMS acknowledged that, "the APC assignment of (these) G codes and their payment rate was based on the understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session... "[1] Robotic radiosurgery treatment with the CyberKnife is, in fact, just the opposite – predominantly an outpatient staged treatment.

CMS also acknowledged that, "We did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services."[2]

Accordingly, in the November 30, 2001 Federal Register, CMS substantially altered the codes available for stereotactic radiosurgery and modified the then-existing code descriptors. The HCPCS Code used in CY 2001 for reporting stereotactic radiosurgery (for both Gamma Knife® and linear accelerator-based radiosurgery) was HCPCS Code G0173. In the November 30, 2001 Federal Register, CMS announced a modified descriptor for Code G0173 to limit its use to linear accelerator-based stereotactic radiosurgery. However, CMS did not distinguish between gantry-based and image-guided robotic radiosurgery systems because it did not have any data regarding the relative costs of image-guided stereotactic radiosurgery (e.g., the CyberKnife) and non-robotic LINAC-based stereotactic radiosurgery using more conventional technology. CMS assigned HCPCS Code G0173 to New Technology APC 0721 for CY 2002.

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum[3]. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery, fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 2002.

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[1] Federal Register, November 30, 2001, page 59865.
[2] Federal Register, November 30, 2001, page 59866.
[3] CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

CMS acknowledged in its Final Rule, published November 1, 2002, that there are significant fixed costs for all stereotactic radiosurgery, but they did not have enough cost data showing the current APC assignment for G0251 (APC 713) as inappropriate. In response, Georgetown University Hospital submitted cost data for CyberKnife treatment in December 2002. Stanford University Hospital submitted its cost data in January 2003. University of Southern California Keck School of Medicine submitted its cost data in February 2003.

CMS designated G0251 for treatment completed in stages, and priced the treatment using the payment for a single stage treatment (G0173), dividing the payment by 5, and allowing up to five payments. Under the payment methodology, each staged treatment was set at the national rate of $1,125, which did not reflect the consistent use and cost of resources for each treatment.[4] As a result of this initial payment rate calculation methodology, CyberKnife centers continued to be underpaid for treatments 2-5.

CY 2003

CMS agreed to revisit the APC assignments for all stereotactic radiosurgery procedures in 2003 when it had 2002 claims data available. The APC classification for G0173 was based on claims submitted in Calendar Year 2001, before the CyberKnife was used in any substantial way for clinical purposes in the United States. In CY 2001, there was only one HCPCS Code – G0173 – for stereotactic radiosurgery (complete course of treatment in one session), regardless of whether the treatment was provided using a LINAC or cobalt-based system (Gamma Knife®) and regardless of whether the treatment was performed in stages.

CY 2004

For 2004, CMS made certain changes to the HCPCS codes and APCs applicable to robotic stereotactic radiosurgery. CMS recognized new HCPCS codes for robotic stereotactic radiosurgery to distinguish these services from other linear accelerator-based (LINAC-based) SRS services that are substantially less resource-intensive. CMS established HCPCS G0339, which describes image-guided robotic LINAC-based SRS completed in one session (or the first of multiple sessions), and assigned this new code to New Technology APC 1528 -- the same APC used for other forms of SRS. CMS also established HCPCS G0340, which describes the second and any subsequent sessions of r-SRS (up to five sessions), and assigned this new code to New Technology APC 1525, with a rate that was approximately 70% of the rate for the first treatment or session. These decisions were made after a review of the available clinical, cost and other data. **We believe that the decisions that were made were – and are -- correct.**

CY 2005

For CY 2005, no changes were made to G0339 and G0340. In the OPPS final rule (69 FR 65711) CMS stated that ***"any SRS code changes would be premature without cost data to support a code restructuring"***. (CMS-1506-P, page 156).

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[4] Federal Register November 30, 2001, page 59868

CY 2006

At the August, 2005 APC Panel meeting, stereotactic radiosurgery codes including G0339 and G0340 were discussed. The Data Subcommittee reported its analysis of the CY 2004 Identifiable Data Set Hospital OPPS file for all SRS codes. The data reflected significant cost differences among institutions billing the G0339 and G0340 codes, and resulted in the median costs of the procedures being lower than the current APC assignments warranted. The APC Panel's recommendation to CMS was to continue to reimburse G0339 and G0340 at their current APCs because of a lack of adequate and accurate data to assign a permanent APC. At the conclusion of the August, 2005 APC Panel meeting, the Panel recommended to CMS that no changes be made to SRS treatment delivery codes G0173. . . G0339, and G0340 (CMS-1506-P, page 157).

Proposed CY 2007 APC Changes

The Hospital Outpatient Prospective Payment System (OPPS) was intended by Congress to be resource-based, as reflected in hospital cost and charge data. The question is ***whether the APC rates adopted by CMS for a covered service for which there is inadequate and inconsistent claims history appropriately reflect the relative clinical utility and whether the rate established by CMS reflects a reasonable estimate of the resources involved.***

There is no question that image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of LINAC-based SRS. In fact, it was for this reason that ***CMS created separate HCPCS codes to distinguish these two technologies in CY 2004. And yet for CY 2007 CMS proposes to place r-SRS and LINAC-based SRS back into the same APC.***

It is our understanding from the CyberKnife Coalition that CMS is required to have a minimum of two years of claims data before moving a HCPCS code from a new technology to a clinical APC. Like the Coalition, we also believe that CMS does not have meaningful two-year data upon which to base the proposed changes to the APC placement of G0339 and G0340. We support the CyberKnife Coalition's assertions that:

1. The proposed APC classifications and rates are based on claims submitted in Calendar Years 2004 and 2005, before the CyberKnife® (the only true image-guided robotic stereotactic radiosurgery system on the market) was used in any substantial way for clinical purposes in the United States. In the beginning of CY 2004, there were only twelve (12) operational CyberKnife centers in the United States, with eight (8) of these centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

   By the end of CY 2005, there were thirty-five (35) centers operating: fifteen (15) of those centers began operations during that year. Forty-three percent (43%) of all operational CyberKnife centers submitted claims for less than a full calendar year.

Thus, although CMS looked at data from the years 2004 and 2005, they do not have claims data of two years' duration.

2. Further, the CyberKnife Coalition's analysis of the CY 2004 Identifiable Data Set Hospital OPPS file raises serious questions about the reliability of the claims as reported.

   The basis for determining the proposed APC rate for CY 2007 for image-guided robotic stereotactic radiosurgery was a review of claims data for G0339 and G0340. Of the 486 claims analyzed for 2004, 15% of the claims came from centers using the G0339 code which did not have an image-guided robotic stereotactic radiosurgery system. As a result, inclusion of their data in the calculation of the appropriate APC results in a lower median cost. The average cost, as indicated in the Identifiable Data Set Hospital OPPS file for CY 2004 for true image-guided robotic stereotactic centers (CyberKnife) is reported at $6,203.27 per unit. For non-CyberKnife centers, the average cost is $3,479.65. The range in costs and charges is not surprising since the code has been used by centers that do not provide image-guided robotic stereotactic radiosurgery services.

3. In addition, the 2004 Identifiable Data Set Hospital OPPS file does not include data for several of the most productive CyberKnife centers in the country which are also in large urban areas: Georgetown University Hospital had the 2nd highest procedure volume in the United States; Sinai Hospital in Baltimore, 6th highest procedure volume in the United States, and Miami CyberKnife Center with the 7th highest procedure volume in the United States. Other smaller, less urban centers are also not included.

   The total number of claims for both G0339 and G0340 in the CY 2004 Identifiable Data Set Hospital OPPS file is 1,311. The total CY 2004 Medicare claims for Georgetown University Hospital (an institution not included in the Identifiable Data Set Hospital OPPS file) was 282; Miami CyberKnife Center submitted 196 claims to Medicare in CY 2004. ***Georgetown and Miami's claims along with the other centers whose data was not included in the 2004 Identifiable Data Set Hospital OPPS file total, at a minimum, more than thirty-six percent (36%) of the total number of claims that were included in the 2004 Identifiable Data Set Hospital OPPS file for G0339 and G340 together.***

The CY 2004 Identifiable Data Set Hospital OPPS file clearly does not provide a sound basis for modifying the APC classification in light of the relatively low number of appropriate claims, the high number of centers contributing data for less than a full year for both CY 2004 and 2005, the number of claims not included in the Identifiable Data Set Hospital OPPS file that are nonetheless relevant when establishing median cost, and the extraordinary variation in costs caused by a mix of centers utilizing the G0339 and G0340 codes for all types of SRS procedures instead of exclusively for r-SRS procedures.

<u>Historical Precedent – Gamma Knife New Technology Codes</u>

We also note that CMS is proposing to assign the Gamma Knife to a higher APC, while reclassifying image-guided robotic radiosurgery to a lower APC. CMS noted that ***it is a "mature technology [with] stable median costs"*** (CMS-1506-P, p 157). This would be an accurate

reflection of the Gamma Knife, a technology in existence for 30 years with significant and mature data with which to establish an appropriate median cost.

Since the clinical process-of-care, resources utilized and related costs involved in providing intra- and extracranial image-guided robotic stereotactic radiosurgery using CyberKnife are at least as great as, if not greater than, the clinical process-of-care, resources utilized and related costs involved in the provision of intracranial radiosurgery using the Gamma Knife, the APC assignment should reflect a similar reimbursement. Gamma Knife was maintained in temporary APC status for nearly 30 years while data was collected for review and determination of final rate setting. The proposed APC assignment for image-guided robotic radiosurgery for CY 2007 is based on less than two full years of data as well as a small number of claims (a total of 486 single billed claims for G0339 and 940 billed claims for G0340 for CY 2004). The CY 2005 Identifiable Data Set Hospital OPPS file is not yet available to us for purchase and therefore has not been analyzed. However, we expect that these trends will be evident proportionally, and possibly exclude even more centers from the "common working file".

CY 2004 and CY 2005 Data Variability Summary

In 2004, 12 r-SRS centers were operating and 8 new centers started operation that that year. This was the first operational year for 67% of centers who had no established costs on which to set charges.

	# centers operating Jan 1st	New centers treating during year	% of centers in first year
2004 CY 2004	12	8	67%
2005 CY 2005	20	15	43%

Of the 25 centers reported in the 2004 Identifiable Data Set Hospital OPPS file using G0339 / G0340 – only 16 centers or 64% of those listed have dedicated image-guided robotic SRS equipment. The CY 2004 data is a mixture of data from all kinds of stereotactic radiosurgery procedures using various treatment modalities with vastly differing resource requirements. A clearer distinction among SRS codes through continued code descriptor refinement will help facilitate the collection of data for all types of SRS services and the eventual establishment of appropriate permanent rates for each, respectively.

Further, the CY 2004 Identifiable Data Set Hospital OPPS file for code G0339 for example, consists of only 486 claims with cost data ranging from $3,479.65 (non-robotic SRS centers) to $6,203.27 (for image-guided r-SRS centers).

We believe that this analysis establishes that the CY 2004 claims data available for image-guided robotic stereotactic radiosurgery do not currently provide a sound basis for modifying the APC classifications or the proposed CY 2007 payment rates for codes G0339 and G0340.

It was our hope to have received the Coalition's analysis of the CY 2005 Identifiable Data Set Hospital OPPS file, which was to be released at the beginning of September. It was, however, recalled by CMS. We regret that the comment period was not adjusted to allow interested parties to review this important data in the preparation of their comments. As we have indicated, however, we expect the same problems will be evident in the CY 2005 Identifiable Data Set Hospital OPPS file and we urge CMS to review the 2005 data with our comments in mind.

Conclusion

The purpose of new technology HCPCS codes is to allow for collection of a comprehensive, stable data set with which to effect an analysis of the charges and costs associated with the new technology. We understand that two years is the statutory minimum amount of time for which CMS must have data before moving a covered service from a new technology code to a clinical code. In the case of CyberKnife, the minimum is insufficient. An analysis of two years of data is not enough due to the large number of new centers submitting less than a full year of data for 2004 and 2005 and the large number of centers with non-robotic equipment using the image-guided robotic stereotactic radiosurgery codes. Thus, while G0339 and G0340 are a vast improvement over the original SRS codes, they are still unclear and potentially misleading, resulting in a lower median cost as non-robotic SRS procedures are being billed using the image-guided robotic SRS codes. There is clear precedent for maintaining new technology codes well beyond the minimum two years. Gamma Knife, for example, was maintained in temporary new technology codes for the first thirty years of its use.

Image-guided robotic stereotactic radiosurgery is still developing, with the CyberKnife the only dedicated r-SRS system in use at this time. The majority of the centers are new, in full operation for one year or less. ***Thus the 2004 and 2005 Identifiable Data Set Hospital OPPS files result in an analysis of less than two full years of data. The data are not stable and do not accurately capture the resources used in r-SRS as is CMS's charge.*** We join the many stakeholders who urge you to look at external data in making your classification decisions. We have shared with you the analysis the CyberKnife Coalition undertook, which we believe demonstrates the insufficiency of the CY 2004 and 2005 CMS data relative to SRS codes.

Recommendations

▶No changes should be made in the APCs or payment rates for G0339 (APC 1528) and G0340 (APC 1525) for CY 2007.

▶CMS continue to work with CyberKnife centers to establish accurate and adequate reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Sincerely,

Eric L. Rhoton, M.D., F.A.C.S.
Mission Hospitals, Mountain Neurological Center, P.A.
7 Vanderbilt Park Drive, Asheville, NC 28803
828-255-7776 erhoton@mtnneuro.com

Submitter : Dr. John Kelemen **Date:** 10/10/2006

Organization : Island Neurological Associates, P.C.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please see attached

CMS-1321-P-766-Attach-1.DOC

CMS-1321-P-766-Attach-2.TXT

#7660-1

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IRA M. TURNER, M.D., Diplomate American Board of Psychiatry and Neurology (N)
STEPHEN M. NEWMAN, M.D., Diplomate American Board of Psychiatry and Neurology (N)
JOHN KELEMEN, M.D., Diplomate American Board of Psychiatry and Neurology (N)
Diplomate A.B.E.M. (EMG)
BARRY L. MENNA, D.O., Diplomate American Board of Psychiatry and Neurology (N)

Neurology
EEG
Evoked Potentials
NCV/EMG
Headache

October 6, 2006

Mark B. McClellan, MD, PhD.
Administrator, Centers for Medicare & Medicaid Services
US Department of Health and Human Services
Attn: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. McClellan:

I am contacting you regarding the proposed reduction in reimbursement for EMG-guided Botox therapy.

I perform the procedure on patients with spasticity and other types of muscle hyperactivity. Many of these patients are victims of prior stroke, which has rendered them mechanically crippled and disfigured by their affliction. Others have various ailments such as cerebral palsy, subarachnoid hemorrhage and other brain disorders causing motor impairment and disfigurement of upper and lower limbs.

The proper treatment of these conditions is to locate the muscle groups that are responsible for the problem and to inject it with the appropriate doses of botulinum toxin to provide the best possible motor function and posture for the limb in question. This requires precise localization of individual muscles within small spaces. Inaccuracy in this endeavor can lead to inadequate treatment or weakening of the wrong muscles. Searching out and finding the proper location can be quite time consuming. In a single limb, the procedure can take well over 30 – 45 minutes. In upper and lower limb therapy, the procedure can take up to an hour, or longer.

The present fee schedule barely covers expenses. To further reduce this reimbursement forces the treating physician to either reduce the number of muscles treated to sub-optimal or, in some other way, limit the time of treatment if he is to make therapy feasible. Since I, personally, do not feel this is an option, it may simply mean that I may not treat these individuals.

Kindly reconsider your proposed plan for a reduced reimbursement. Inevitably, it will be the patient who will be deprived and suffer.

Very truly yours,

John Kelemen, MD

JK:dsl

#766-2

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BARRY L. MENNA, D.O., Diplomate American Board of Psychiatry and Neurology (N)

Neurology
EEG
Evoked Potentials
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Headache

October 6, 2006

Mark B. McClellan, MD, PhD.
Administrator, Centers for Medicare & Medicaid Services
US Department of Health and Human Services
Attn: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

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Kindly reconsider your proposed plan for a reduced reimbursement. Inevitably, it will be the patient who will be deprived and suffer.

Very truly yours,

John Kelemen, MD

JK:dsl

Submitter : **Dr. Keenan Brown** **Date: 10/10/2006**

Organization : **Mindways Software Inc.**

Category : **Device Industry**

Issue Areas/Comments

Background

Background

BONE MASS MEASUREMENT TESTS--the proposed revision to limit reimbursement for bone mass measurements (BMM) intended for monitoring response or efficacy of an FDA-approved osteoporosis drug therapy to BMMs performed with an axial, dual energy x-ray absorptiometry (DXA) system or other devices approved through the NCD process excludes axial QCT BMMs for this purpose.

Substantial evidence exists indicating quantitative computed tomography (QCT) is non-inferior or even superior to DXA for monitoring osteoporosis treatment efficacy. Despite the prevalence of DXA, QCT is a cost-effective alternative that improves CT equipment utilization and is well suited to small communities lacking monetary resources for DXA. Together these points imply that the proposed revisions addressed here are neither in the best interest of patient care nor the best financial interest of the US healthcare system.

GENERAL

GENERAL

See Attachment

Impact

Impact

BONE MASS MEAUSEMENTS--proposal to limit reimbursement for bone mass measurements (BMMs) for monitoring response or efficacy of an FDA-approved osteoporosis drug therpy to BMMs performed with an axial, dual energy x-ray absoprtiometry (DXA) system is not in the best interest of patient care or the financial interest of the US healthcare system because it excludes use of axial QCT for this purpose..

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Limit of coverage for BMMs for monitoring as defined on page 49060 Vol. 71, No. 162 of the Federal Register published August 22, 2006 should be expanded to include axial QCT in addition to the use of axial DXA measurements as proposed.

CMS-1321-P-767-Attach-1.DOC

#767

BONE MASS MEASUREMENT TESTS

File Code: CMS-1321-P

The following comments are in response to proposed revisions to Medicare payment policy for bone mass measurements published in the Federal Register (Vol. 71, No. 162, pages 49058-49060) in August 2006. In particular the proposed revisions call for limiting reimbursement for bone mass measurements (BMM) intended for monitoring response or efficacy of an FDA-approved osteoporosis drug therapy to BMMs performed with an axial, dual energy x-ray absorptiometry (DXA) system or other devices approved through the NCD process.

Substantial evidence exists indicating quantitative computed tomography (QCT) is non-inferior or even superior to DXA for monitoring osteoporosis treatment efficacy. Despite the prevalence of DXA, QCT is a cost-effective alternative that improves CT equipment utilization and is well suited to small communities lacking monetary resources for DXA. Together these points imply that the proposed revisions addressed here are neither in the best interest of patient care nor the best financial interest of the US healthcare system.

It is reasonable to characterize the various reports of precision for both QCT and DXA as typically falling in the 1% to 2% range. Prior *et al*[1] reported coefficients of variation (CVs) of 0.8% for QCT spine measurements and CVs over 2% for DXA hip measurements in a double-blind drug trial of bone loss in a group of postovariectomy women. Lang *et al* reported a CV for QCT of 1.3%.[12] Early reports of QCT precision in the 3% to 5% range are based upon QCT systems that lack refinements such as simultaneous imaging of a calibration standard with the patient and automated data processing that are available with modern, FDA-marketing approved, clinical QCT devices.

QCT has an advantage over DXA in terms of its ability to distinguish different bone types. The human skeleton, including the spine and hip, consists predominantly of cortical bone. Trabecular bone, which is approximately eight times more metabolically active than cortical bone, is generally observed to change sooner and more rapidly than cortical bone in response to therapeutic interventions or hormone-level changes associated with aging or certain disease states.[2] Whereas QCT can measure changes in more metabolically active trabecular bone independently of cortical bone mineral density, DXA is limited to measuring total mineral mass that is a superposition of cortical and trabecular bone mineral mass.[15]

The combination of good QCT measurement precision and QCT's ability to characterize change in trabecular BMD independently of surrounding cortical bone leads to a greater sensitivity of QCT than DXA for detecting change in trabecular BMD. Documented examples of this include work by Smith *et al* demonstrating a ability of QCT to detect change in trabecular BMD at the spine in 1.54 months relative to 2.66 months for DXA in response to fluoride treatment;[13] Baran *et al* found trabecular bone loss to be 2-3 times greater than integral bone loss measured by DXA;[14] and more recently, Genant *et al* reported that significant changes in BMD were detected with QCT after 2 years of treatment with raloxifene while no significant change in spinal DXA BMD was found.[5]

There are numerous publications documenting the sensitivity of QCT bone mass measurements as a tool for monitoring treatment efficacy. Braillon writes "We conclude that QCT is a precise and accurate method for long-term follow-up of BMD assessment in the population affected by osteoporosis."[3] Rehman *et al* conclude "In postmenopausal women with osteoporosis induced by long-term glucocorticoid treatment who are also receiving HRT, BMD of the lumbar spine as measured by QCT, but not DXA, is an independent predictor of vertebral fractures."[4] Genant *et al* state that "vQCT appears to be a valuable technique for measuring the effects of raloxifene treatment in this population of postmenopausal women with osteoporosis."[5] Yet another example of the efficacy of QCT for treatment monitoring is provided by Bauer *et al* in their report of changes in bone turnover markers and bone density as measured by QCT after one year in a PTH study.[6] They report "each sd increase in the 3-month change of N-propeptide of type I collagen was associated with a 21% greater increase in QCT spine trabecular BMD" and they further state that "greater short-term increases in turnover were even more positively associated with 1-yr increases in BMD" when BMD was measured using QCT as opposed to DXA.

The goal of osteoporosis treatment is fracture risk mitigation, yet as is acknowledged in the proposed revisions published in the Federal Register "assessing the risk of bone disease and fracture remains a challenge" (see Section 2, "Additional Scientific Evidence", page 49059). It is also acknowledged in the Federal Register publication that bone strength is not measured directly by BMD. In fact the FDA stopped accepting BMD as a surrogate for fracture risk in the mid 1990s when clinical fracture trials for alendronate clearly demonstrated that change in BMD as measured by DXA did not adequately explain the observed reduction in fracture risk in the group receiving alendronate.

There are a number of recent publications documenting the inadequacy of using DXA for assessing treatment efficacy with many of the most commonly used (anti-resorptive) drugs approved for treatment of osteoporosis. In 2004 Delmas and Seeman reported "We infer that only a small proportion of risk reduction in vertebral and nonvertebral fractures observed with anti-resorptive drug therapy is explained by the increase in BMD."[7] Cefalu writes in 2006 in the context of DXA bone mass measurements that "BMD increase correlates poorly with fracture risk reduction in clinical trials of osteoporosis therapy conducted in postmenopausal women."[8] Divittorio *et al* also state in a 2006 publication that "clinicians should continue to evaluate drug efficacy for osteoporosis based on the fracture risk reductions from well-designed clinical trials"[9] as opposed to using DXA BMD measurements to assess treatment efficacy.

It is acknowledged in the publications cited above and in numerous others that understanding changes in bone geometry rather than simply change in BMD are important to understanding the impact of osteoporosis treatment. For example Greenspan *et al* say "We conclude that changes in the distribution of bone mass underlying the improvements in density with antiresorptive agents in combination or alone have positive effects on structural strength and stability at the proximal femur."[10] Furthermore Bousson *et al* conclude that "Confirmation of our results in an independent sample would suggest that QCT may better explain failure load variance for cervical fracture than the gold standard DXA-provided BMD."[11]

Much of the work cited in the previous paragraphs was published subsequent to the 2004 Surgeon General report on bone health and osteoporosis, and so would not have been explicitly

addressed by the contributors to the Surgeon General report. In fact, consideration of bone mass measurements is only a small part of the overall report. Much of the emphasis on DXA in this report is probably the result of the prevalence of DXA in the clinical community relative to other bone mass measurement technologies such as QCT. That is reasonable at some level; however, prevalence of DXA is not evidence of the technical superiority of DXA over QCT.

I respectfully disagree with the opinion expressed in the Surgeon General report that monitoring of treatment efficacy should only be performed using DXA. I believe the proposed revisions to Medicare policy on this point should not be adopted. Alternatively I believe that axial QCT should be included with axial DXA in the list of approved methodologies for monitoring osteoporosis treatment efficacy.

The proposed revisions to bone mass measurement coverage policy also include a proposal for using the NCD process to have coverage approved for specific devices for use for treatment monitoring (see Section e "Use of the NCD Process" on page 49060). While I agree with the appropriateness of application of this revision, I do not believe that QCT device manufacturers should have to resort to use of this method to restore coverage of QCT bone mass measurements for assessing osteoporosis treatment efficacy.

While DXA is undeniably the most prevalent bone densitometry technology today, there are many institutions in the US routinely making safe and effective use of QCT both for the detection of individuals at risk of osteoporosis-related fractures and for monitoring the effectiveness of osteoporosis treatment. Many of these institutions are regional hospitals in smaller communities. These hospitals have CT scanners in order to provide quality care to their patients. QCT provides quality bone-mass measurements to their local community and a cost-effective means for improving utilization of their CT scanner. DXA is not financially viable in some of these communities, which would essentially be choosing between not providing bone mass measurements to their patients or resorting to the acquisition and use of a DXA bone densitometer that will be underutilized and that will be a financial burden given the relatively small populations served by these hospitals. The International Society for Clinical Densitometry has reported and supported claims that typical equipment utilization rate for DXA is 15% to 20%. DXA utilization rates probably would be even lower than this in many smaller communities, while QCT improves the CT scanner utilization rate and provides quality bone mass measurements at a fraction of the cost of DXA.

Denying coverage for treatment monitoring via QCT to smaller communities or any other sites served by QCT is neither in the best interest of the patient nor the financial interest of the US healthcare system. Similarly, it makes no sense to temporarily deny coverage to these sites while QCT device manufacturers go through the extensive effort of obtaining approval for coverage via the NCD process—a process that is likely to take 9 to 12 months to complete.

In summary:

- I strongly oppose the published proposal to limit bone mass measurement coverage to DXA when it is used for monitoring response or efficacy of an FDA-approved osteoporosis drug therapy.

- I would support an alternative proposal to limit coverage to either axial DXA or axial QCT for monitoring response or efficacy.
- I would less enthusiastically support delaying implementation of the proposed rule change until at least January 2008 while a more critical review of the scientific basis for the proposed rule change is undertaken in such a way as to include direct input from QCT device manufacturers and users.

Thank you for your consideration of my input. I sincerely hope that CMS rescinds its proposal to limit coverage of bone mass measurements to axial DXA when such measurements are used for monitoring response of efficacy of an FDA-approved osteoporosis drug therapy.

Respectfully yours,

J. Keenan Brown, PhD
Mindways Software Inc.
3001 South Lamar Blvd., Suite 302
Austin, TX 78704

References

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Submitter : **Dr. Joseph Stubbs** **Date: 10/10/2006**

Organization : **American College of Physicians**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

ACP's complete comment letter is attached.

Impact

Impact

DRA Proposals

Imaging Reductions
The rule proposes to continue a 25% reduction in fees for the technical component for certain imaging procedures on contiguous body parts and a decision not to increase the reduction to 50% as proposed in last year s rule. ACP recommends that CMS continue to very closely examine the costs of performing these imaging procedures to insure that physicians are paid properly for their costs as overpaying can lead to overutilization. Also, ACP recommends that CMS continue to study the cost of capital for equipment and the extent to which the equipment is used to insure that the practice expense for equipment is properly reimbursed. ACP provided recommendations to CMS on these issues in its comment letter in response to the proposed rule that the agency published in the June 29, 2006 Federal Register. It is very important that CMS make use of as much information as possible in order to consider payments for expensive imaging studies.

ACP is concerned that the savings generated by these imaging reductions will not be returned to the physician fee schedule. While ACP understands that this is a legislative requirement, ACP urges CMS to encourage legislators that savings made in parts of the physician fee schedule go back to physicians through payments for other fee schedule services.

Abdominal Aortic Aneurysm Screening Coverage
ACP supports the required implementation of the Abdominal Aortic Aneurysm screening benefit for those beneficiaries which meet the risk factors. ACP is concerned, however, that the legislative requirement that the test be referred during the Initial Preventive Physical Examination (IPPE) could result in fewer patients receiving the benefit than would be clinically appropriate. CMS is aware of the low utilization of the IPPE, also known as the Welcome to Medicare exam. ACP believes that one major contributing factor to this low utilization is the low payment rate for the service. ACP has consistently advocated that the payment for IPPE be tied to the established Relative Value Units (RVUs) for the existing preventive medicine codes (99381-99387). If CMS makes the decision to increase these values as ACP has recommended, it will make it more financially viable for physicians to furnish this important preventive benefit and increase utilization of the service. With additional services being tied to the IPPE, it is more important than ever to increase the payment level so that patients may receive the full benefits to which they are entitled.

Elimination of Deductible for Colorectal Screening
ACP supports the required elimination of the deductible required for colorectal screening. The elimination of this deductible will help encourage more beneficiaries to receive this important screening. However, ACP believes that more can be done to raise the rates of colorectal screening among Medicare beneficiaries. Patients often require extensive counseling in order to consent to receive screening endoscopies and this counseling service is not paid for at all by Medicare. If physicians are reimbursed for the important work that they do in coordinating these important preventive health services, they will be more likely to spend the time to encourage patients to receive these services.

ACP urges CMS to continue its support for preventive health benefits by recognizing the important contribution of physicians, often primary care physicians, in coordinating and referring for many of these preventive screenings. Those physicians need to be reimbursed for these services.

We appreciate the opportunity to review and comment on the proposed rule. If you have any questions about this letter, please contact Brian Whitman, Senior Analyst for Regulatory and Insurer Affairs at (202) 261-4544 or bwhitman@acponline.org

CMS-1321-P-768-Attach-1.DOC

#768

October 9, 2006

Mark McClellan, MD, PhD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
PO Box 8014
Baltimore MD 21244-8014

Attention: CMS-1321-P

Dear Dr. McClellan:

The American College of Physicians (ACP), representing more than 120,000 physicians specializing in internal medicine and medical students is pleased to have the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B.*

DRA Proposals

Imaging Reductions
The rule proposes to continue a 25% reduction in fees for the technical component for certain imaging procedures on contiguous body parts and a decision not to increase the reduction to 50% as proposed in last year's rule. ACP recommends that CMS continue to very closely examine the costs of performing these imaging procedures to insure that physicians are paid properly for their costs as overpaying can lead to overutilization. Also, ACP recommends that CMS continue to study the cost of capital for equipment and the extent to which the equipment is used to insure that the practice expense for equipment is properly reimbursed. ACP provided recommendations to CMS on these issues in its comment letter in response to the proposed rule that the agency published in the June 29, 2006 *Federal Register*. It is very important that CMS make use of as much information as possible in order to consider payments for expensive imaging studies.

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known as the "Welcome to Medicare" exam. ACP believes that one major contributing factor to this low utilization is the low payment rate for the service. ACP has consistently advocated that the payment for IPPE be tied to the established Relative Value Units (RVUs) for the existing preventive medicine codes (99381-99387). If CMS makes the decision to increase these values as ACP has recommended, it will make it more financially viable for physicians to furnish this important preventive benefit and increase utilization of the service. With additional services being tied to the IPPE, it is more important than ever to increase the payment level so that patients may receive the full benefits to which they are entitled.

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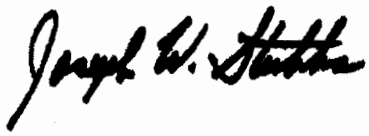
ACP urges CMS to continue its support for preventive health benefits by recognizing the important contribution of physicians, often primary care physicians, in coordinating and referring for many of these preventive screenings. Those physicians need to be reimbursed for these services.

We appreciate the opportunity to review and comment on the proposed rule. If you have any questions about this letter, please contact Brian Whitman, Senior Analyst for Regulatory and Insurer Affairs at (202) 261-4544 or bwhitman@acponline.org

Sincerely,



Joseph W. Stubbs, MD
Chairman, Medical Service Committee
American College of Physicians

Submitter : Dr. Brett Coldiron **Date:** 10/10/2006

Organization : American Academy of Dermatology Assn

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-769-Attach-1.DOC

#769

American Academy of Dermatology Association

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October 10, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1321-P**

Dear Administrator McClellan:

On behalf of the 15,000 members of the American Academy of Dermatology Association (AADA), I appreciate the opportunity to submit written comments regarding the 2007 Medicare Physician Fee Schedule. As advocates for dermatologists and their patients, the AADA believes that an adequate physician fee schedule ensures fairness and continued beneficiary access to quality, specialty health care services.

Unfortunately, flaws in the Sustainable Growth Rate (SGR) formula will lead to sharp cuts in Medicare physician payments beginning January 1, 2007 unless Congress takes action this year to avert a -5.1 percent reduction. If not addressed this year, physicians will have experienced five years of inadequate payments that have not begun to keep up with inflation as measured by the medical economic index (MEI). Further, according to the 2006 Medicare Trustees Report, if the SGR formula is not fixed, physicians will receive negative updates of approximately five percent each year from 2007 until 2015. These reductions may prompt a number of physicians to reconsider their participation in the Medicare program, to limit services to Medicare beneficiaries, or to restrict the number of new Medicare patients they are able to accommodate in their practice.

Changes in the Medicare Economic Index (MEI)
The Academy is concerned with the additional 0.5 percent reduction of the 2007 physician fee schedule update from -4.6 percent to -5.1 percent, announced earlier this year. The increase in the cut was caused by a downward revision of the MEI. This reduction was not proposed or even discussed in the proposed rule for implementing the 2007 fee schedule. Based on the impact table in the proposed rule that shows $75 billion of allowed charges under the physician fee schedule, a -0.5 percent reduction in the update will result in a $375 million cut in physician payments in 2007. We believe that CMS is in violation of the spirit if not the letter of the Administrative Procedures Act (APA) which requires publication in the Federal Register of most rules and a period for public comment.

Further, the reduced MEI was based on the use of a new measure of productivity by the Bureau of Labor Statistics (BLS) and lower projections of inflation. Few details were provided and comments on the changes were not requested. If able to comment, we would have questioned the use of data that shows increased productivity in a year when the productivity of most physician practices has been reduced significantly by the need to counsel Medicare beneficiaries about the new prescription drug benefit and the availability of preventive services. We therefore urge CMS to

delay any changes in the MEI pending publication in the Federal Register of the proposed changes and the solicitation of public comments.

Dermatology Specific Issue - Reassignment and Physician Self-Referral

We recognize the need to discourage business arrangements that carry significant risk of fraud, waste, and abuse—through kickbacks, fee-splitting and mark-ups, generation of unnecessary pathology lab tests, inappropriate referrals, and other dubious practices. We are concerned that the proposed rule changes contemplated by CMS regarding reassignment and physician self-referral relating to pathology laboratory services may not only prevent dermatologists from practicing their specialty, but may well cause unnecessary confusion. Indeed, this may adversely impact the role of dermatopathology in providing dermatologists with correct, accurate and timely diagnoses and thus threatens to compromise patient safety and quality of care.

The Academy strongly encourages CMS to consider the negative implications such revisions would have by preventing patients from access to care and restricting dermatologists—the physician specialists treating the majority of melanoma patients—to have timely and accurate interpretation of patients' skin biopsies, from exercising their choice of dermatopathologists.

All dermatologists have training and experience in dermatopathology. Indeed, dermatopathology is an integral part of a dermatologist's professional training. Dermatologists receive intensive training in dermatology, which includes dermatopathology and dermatologic surgery. With this background and knowledge, dermatologists are singularly qualified to diagnose and treat the wide variety of dermatologic conditions as well as benign and malignant skin tumors. Dermatologists perform many specialized diagnostic procedures and often purchase the technical component (slide preparation) in order to be able to perform their own in-house diagnostic interpretation and pathology report.

The Academy is concerned that the proposed rule can be misinterpreted and misapplied so as to prevent a dermatologist from being able to read their own slides. As many dermatologist choose to interpret their own dermatopathology, the Academy supports the right of dermatologist to be able to continue to perform their own dermatopathology interpretation, including having the ability to purchase the technical component, in accordance with current Medicare regulations, from an outside lab vendor in order to provide their own in-house professional diagnosis and render cost-effective quality patient care.

We wish to remind CMS that the expertise of dermatopathologists is relatively cost effective because as the foremost experts in reading and interpreting skin biopsy specimens, dermatopathologists are able to detect and properly diagnose skin biopsies the first time around. Moreover, the consultative communication that goes on between dermatologists and their trusted dermatopathologists is essential; without communication or trained eyes, the skin's subtle signs may confuse and mislead. Misdiagnosis leads not only to deficient care by forcing patients to undergo unnecessary procedures, but also increases the cost of care and the risk of a liability lawsuit. Conversely, an early and correct diagnosis allows a problem to be treated before it becomes more severe—and thus more costly to treat.

We consider dermatopathologic interpretation of biopsies an integral part of a dermatologist's ability to serve their patients. Many dermatologists prefer to refer skin biopsy specimens to specialized dermatopathology labs directed and staffed by dermatologists and/or pathologists with expertise in dermatopathology and immunopathology. Pathologists employed with national reference labs often lack this high level of training and expertise to accurately interpret skin biopsies. Accurate interpretation of skin biopsies requires an ability to recognize and record the details of the specimen, and to synthesize these findings with the clinical data available. Failure to

interpret skin biopsies, can mislead the clinician and interfere with appropriate medical or surgical therapy, potentially harming the patient.

The Academy wishes to remind CMS that any final rule changes, designed to prevent markups of assigned pathology lab services, need to be simple, straightforward, and uncomplicated so as to lighten the regulatory burden, minimize the margin of error, and contain costs. To that end, we wish to emphasize the following points:

1. Dermatologists should have the opportunity and the right to interpret their own specimens and be reimbursed by a professional component for their professional services. The CMS regulations regarding "purchased diagnostic test" state that if the tissue is prepared by an outside lab, either the lab should bill Medicare directly for the technical service, or the dermatologist can submit the bill to Medicare for the ***lesser of either*** the net lab charge, actual physician billing charge, or the Medicare fee schedule amount. These regulations have been in place since 1992. We believe that the preceding scenario offers straightforward guidance to allow a physician to follow the basic premise ***when performing a medical service and being reimbursed for that service, nothing more, nothing less.***
2. The same anti-markup provision should apply to contractual arrangements whereby "condo or pod labs" reassign their payment rights to physician group practices to "indirectly" bill for technical and/or professional laboratory services. Therefore, we believe that CMS's proposal to amend 42CFR 424.80 (prohibiting markups of the technical component of the diagnostic service when reassigned in a contract exception arrangement) would suffice.
3. We also agree with the second provision that requires the billing entity (physician or group practice) to perform the test interpretation themselves in order to bill the TC along with the professional component. The physician performing the interpretation should be the only entity billing for this professional service. The Academy supports the current trend of larger dermatology groups or perhaps busy one- to two-person dermatology practices hiring their own pathologist as a member in the practice to interpret specimens at that same practice when the billing is in accord with the "purchased diagnostic test" regulation and is not marked up in the sense that there would be a big discrepancy between what a practice bills and what they pay the pathologist plus his/her expenses.
4. As for redefining "centralized building" criteria by adding a 350 sq ft. minimum requirement, we don't believe that such technical revisions are necessary since they appear to provide little or no disincentive to discourage abusive pod lab practices arrangements and wouldn't necessarily curtail of markups. Such technical requirements may risk inviting more creative responses by those willing to circumvent such narrow criteria. We believe that the best patient care is given when the dermatopathologists are focused on managing the lab and being responsible for various regulations in their lab, rather than running around and dividing their attention among different "pod" lab practices for purposes of marking up assigned technical pathology services. In these situations, utilization increases, there is indirectly a violation of the regulation regarding a markup of a "purchased diagnostic test", and a huge number of resources are expended trying to interpret and/or police these regulations. Therefore, we believe that by removing the financial incentives for markups and eliminating the opportunity of profit for increased self-referrals, CMS can effectively addresses the reimbursement issue without the need to monitor space and technician requirements.
5. We recommend a back to basics approach where many years ago Medicare said that one could not markup a "purchased diagnostic test". Whether it is the technical component or the professional component, if there is ***no mark up allowed***, there would be no problem. Indeed, such a clear and uncomplicated guideline would allow dermatologists to read their own slides and be reimbursed appropriately for this service and dermatopathologists, who have full-service labs, to be reimbursed fairly and appropriately for their services and not be in jeopardy of participating in a fee splitting and markup arrangements.

The Academy supports the principles of freedom of choice of consultants, and access to physicians of all specialties, direct access to dermatopathologists and/or dermatologists of their choice for interpreting skin cancers and other serious skin conditions. Medicare patients can be assured improved quality of care if their physicians have access to expert opinion from specialists trained in the evaluation of skin biopsy specimen. By working together, we believe we can help ensure patient safety and quality of care.

Dermatology Specific Issue - Payment for Splint and Cast Supplies
We appreciate that CMS has indicated that it intends to reimburse separately via HCPCS Q codes for splint and casting supplies. We agree that costs for these should be extracted from the practice expense direct inputs for those code ranges listed within the proposed rule. However, as supplies for CPT 29580 - Unna boot applications have been specifically excluded in the past and now is included within the listed code ranges, we would appreciate it if Unna boot supplies are specifically included in the list of supplies that will now be separately billable using HCPCS Q code(s).

Budget Neutrality
The proposed notice requires budget neutrality adjustments to physician work relative value units only as a result of changes from the five-year review process and other payment policy revisions. Application of the budget neutrality adjustment to the conversion factor would impact all physician services, whereas the application of the budget neutrality adjustment to the work RVUs would impact only those services that have physician work RVUs. Thus, we strongly urge CMS to implement any budget neutrality adjustments to the conversion factor.

Practice Expense
The Academy appreciates the CMS proposal to incorporate our practice expense supplemental survey data into the 2007 fee schedule. The Academy dedicated considerable staff and physician volunteer time and significant financial resources to submitting supplemental survey data, as provided by the Balanced Budget Refinement Act of 1999 (BBRA) and requested by CMS. Incorporating this data into the CY2007 fee schedule will increase the accuracy in determining the PE RVUs for the services our members provide, as well as improving the overall accuracy of the practice expense component of the fee schedule. Again, we appreciate CMS at last including the supplemental survey data into the proposed rule and request that the data be implemented in the final rule.

As you know, the AMA is sponsoring a multi-specialty supplemental study of practice expense costs. The AADA has already agreed to participate in and contribute to this additional practice expense survey. However, we are deeply concerned that the design and structure of the new survey in fact focus on practice expense costs – as originally communicated to the physician community – and also be in compliance with all of the criteria established for the specialty specific practice expense supplemental surveys accepted by CMS. Additionally, for consistency's sake, the new multi-specialty practice expense survey results must be held to the same standard relating to the level of precision as the supplemental surveys already accepted by CMS.

Telehealth Services

The AADA appreciates CMS extending the opportunity to submit requests for added telehealth services to the Medicare program. Besides increasing access for patients, telemedicine can also reduce overall costs. Dermatology patients who participate in telemedicine would otherwise likely receive treatment for their skin conditions from a non-dermatologist physician, the accuracy of the diagnoses rendered via telemedicine can be higher and diseases can be treated effectively and at earlier stages than they would be if a patient waited until complications made a long trip to see a dermatologist imperative. Patients who are spared a long trip also benefit economically from such

an arrangement because they do not bear the cost of missing work or traveling. Telemedicine moves information – not the patient.

While making treatment more effective for patients, telemedicine also helps to make optimal use of the short supply of dermatologists. While it will never replace the face to face patient visit, the Academy considers telemedicine a viable method of treatment and one important component of an overall plan to improve patient access to dermatology.

Currently, Medicare reimburses telemedicine for rural patients (defined as patients who live in non-metropolitan statistical areas) if it takes place in a live interactive ("two way") mode. The patient and physician communicate in real time but from different locations using video conferencing technology. Medicare reimbursement currently does not exist for store and forward consultations, which take place when patient pictures and information are forwarded by a referring physician to a dermatologist, who evaluates them and responds with a diagnosis and treatment plan. The AADA and the American Telemedicine Association have reviewed the effectiveness of live interactive telemedicine visits compared with store and forward and found both to be clinically equivalent to traditional face to face patient encounters. Store and forward is more convenient for both the patient and the two physicians, allowing for asynchronous communication that simplifies the amount of coordination required. Therefore, the AADA believes that dermatologic office visits conducted via live interactive or store and forward telemedicine should be covered under the Medicare program.

Thank you for the opportunity to comment on this proposed notice. For further information, please contact Jayna Bonfini at jbonfini@aad.org or 202-842-3555 or Norma Border at nborder@aad.org or 847-330-0230.

Sincerely,

Brett M. Coldiron MD

Brett Coldiron, MD, FAAD
Chairman, Health Care Financing Committee

Cc: Stephen P. Stone, MD, FAAD, President
Diane R. Baker, MD, FAAD, President-Elect
David M. Pariser, MD, FAAD, Secretary-Treasurer
Ronald A. Henrichs, CAE, Executive Director and CEO
Daniel Siegel, MD, FAAD, AADA RUC Representative
Michael Bigby, MD, FAAD, AADA RUC Representative
Bruce Deitchman, MD, FAAD, AADA RUC Representative
John Zitelli, MD, FAAD, Chair, AADA CPT Committee
John D. Barnes, Deputy Executive Director, AADA
Judy Magel, PhD, Senior Director, Practice, Science & Research
Laura Saul Edwards, Director, Federal Affairs
Cyndi Del Boccio, Director, Executive Office
Jayna Bonfini, Assistant Director, Federal Affairs
Norma Border, Senior Manager, Coding and Reimbursement
Sandra Peters, Senior Manager, Workforce, Insurance & Practice Issues
William Brady, Manager, Practice Management
Vernell St. John, Senior Coding and Reimbursement Specialist
Peggy Eiden, Coding & Reimbursement Specialist

Submitter : **Dr. Richard Bohannon** **Date: 10/10/2006**

Organization : **Dr. Richard Bohannon**

Category : **Physician**

Issue Areas/Comments

Background

Background

Provisions of the Proposed Rule: This is in regard to ASP issues.
Paramount in the ability of practicing oncologists to provide state of the art care to cancer patients involves the critical issue of hematopoietic support. Most clinically useful chemotherapeutic agents have toxic, suppressive action on the blood that results in a temporary drop of granulocytes, as well as red cells. The drop of granulocytes can be life threatening. Cancer itself may lead to anemia, either as a result of blood loss or the cytokine suppressuve action of tumors. Added to the injury to the bone marrow from chemotherapy, most cancer patients need red cell bone marrow stimulation with erythropoietic factor from the outset.
Chemotherapy is difficult for patients to tolerate. Anything that clinicians can do to mitigate the hardship of chemotherapy makes patient care more acceptable. The over-riding consideration of clinicians is: What can we do to ease the discomfort and difficulty to patients getting cancer treatment? Surely, the ability to coordinate hematological support measures, ie, Neulasta and Aranesp, to chemotherapy regimens make chemotherapy more tolerable for patients and at the same time reduces cost and inconvenience for patients.
The Amgen program gives the flexibility and incentives to make patient care more manageable and less costly.
As currently operational, I find ASP+6% fair and not subject to abuse. I believe ASP should continue withour further change.

Impact

Impact

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Submitter : Dr. Thomas Wu **Date:** 10/10/2006

Organization : Sacramento Radiology Medical Group

Category : Physician

Issue Areas/Comments

Background

Background

Impact
Making these revisions as proposed will impact negatively on the Medicare populations access to quality health care. The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments.

GENERAL

GENERAL

CMS-1321-P
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment Under Part B
Proposal dated August 8, 2006

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation.

I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for CPT codes 36478 and 36479 and find several 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 consistently rise, (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 employee 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. Given the limited number of these procedures that the average physician performs per year it is 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,

Thomas Wu, MD
Sacramento, CA
cutr2000@hotmail.com

Impact

Impact

See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment Below

Submitter : Dr. Orin Guidry **Date:** 10/10/2006

Organization : American Society of Anesthesiologists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-772-Attach-1.DOC

#772

AMERICAN SOCIETY
OF ANESTHESIOLOGISTS

Office of Governmental Affairs
1101 Vermont Avenue, N.W.
Suite 606
Washington, DC 20005
(202) 289-2222
FAX (202) 371-0384
mail@ASAwash.org

October 10, 2006

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1321-P
Mail Stop C4-25-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: **CMS File Code CMS-1321-P**
Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Ms. Norwalk:

The American Society of Anesthesiologists (ASA), on behalf of its 41,000 members, appreciates the opportunity to comment on several of the issues addressed in the proposed rule published in the August 22, 2006 Federal Register.

BACKGROUND – Anesthesiology Teaching Rule

ASA is most concerned that CMS mentions anesthesiology teaching services only in passing. Since 1994, CMS has unfairly penalized anesthesiology teaching programs. If a teaching anesthesiologist works with two residents on cases that overlap – even for a minute – CMS cuts payments by 50% per case. In contrast, surgeons can oversee two overlapping teaching cases without payment reduction and primary care physicians, under certain circumstances, can oversee even more cases.

This misguided policy costs academic anesthesiology programs an average of $400,000 each year, and some programs lose more than $1 million annually. Thirty-one out of 161 anesthesiology teaching programs (20%) have closed since the CMS instituted the anesthesiology teaching rule, and several other programs are currently at risk of being shuttered.

Prompt Federal action is needed to change the Medicare anesthesiology teaching rule to allow full payment for up to two concurrent teaching cases, achieving parity with the teaching surgeons. Without prompt action, additional residency programs will close, teaching anesthesiologists will leave academia, important clinical and basic science research initiatives to improve the safety and quality of perioperative care will end, and training sufficient numbers of anesthesiologists to care for the "baby-boomer" retirees will not happen. The fact that this ongoing problem received essentially no attention in the 2007 Fee Schedule proposed rule leads us to believe that CMS has underestimated the scope of the problem and the adverse effects it will have on patient care and safety, now and in the near future.

Impact of Proposed Rule

Table 7 of the Proposed Rule shows that Anesthesiology is slated to see a ***7% decrease*** in Medicare payments resulting from the Work and Practice Expense changes announced in the June 29, 2006 Proposed Rule: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology; Notice. When these changes are combined with the anticipated -5.1% SGR update for CY 2007, the specialty may expect a ***12% decrease***. We would point out that these reductions are in addition to the teaching rule penalty and the unresolved Five-Year Review of anesthesia work. The ASA has previously commented to CMS on the elements that are creating this critical threat to the future of our specialty and restates them here:

- The undervaluation of physician work in the anesthesia fee schedule to physician work in the RBRVS must be corrected. While this was studied in the first two Five-Year Reviews, it remains an open question in the third. Since the second Five-Year Review produced only a 1.6 percent conversion factor increase, ASA has recently presented a methodology to finally fix this problem and awaits CMS's reaction to this proposal. We urge the Agency to promptly complete its review and pursue a solution with ASA.

- The E/M update affects all anesthesia services but CMS only applied the update to a small subset of anesthesia codes. During the 2000 Five Year Review, the RUC established that evaluation and management work is present in every anesthesia service studied, just as it is in the surgical global packages. ASA understands that CMS applied an E/M update only to the 19 anesthesia codes studied in the 2000 review. This dramatically understates the correction necessary for a fair and equitable update. An E/M update must be applied to the entire spectrum of anesthesia codes.

- Work RVU changes from the recently concluded third Five-Year Review were of the magnitude to trigger a budget neutrality adjustment. ASA disagrees with CMS's proposal to account for this with an adjustment to the work RVUs assigned to each service. We urge the Agency to use an adjustment to the conversion factor as the method for applying a budget neutrality correction.

- Proposed changes to the Practice Expense methodology as outlined in the June 29, 2006 proposed rule will have another disproportionately harmful impact on Anesthesiology, accounting for about a 4% decrease in payments. Much of this impact is due to the fact CMS will use recent supplemental survey data for some specialties while using outdated data for others in calculating indirect PE RVUs, maintaining budget neutrality. Many of the increased costs found in the supplemental surveys are common to all specialties; therefore, use of the supplemental surveys will create large new distortions in practice expense payments at the time that CMS is trying to improve transparency and accuracy. As you know, the AMA, in collaboration with over 46 medical specialty/health professions and CMS, is prepared to conduct a new and comprehensive expense survey. We request that CMS provide financial support for the survey, above and beyond the AMA's and other medical societies' committed dollars. We also urge CMS to delay integration of the supplemental surveys until this new data is available for fairly calculating indirect practice expenses.

- While the ASA recognizes that CMS must currently employ the sustainable growth rate formula in calculating the annual fee schedule update, we encourage the Agency to continue to advocate to Congress for a replacement of this flawed system. The projected SGR updates for 2007 and subsequent years of -5% per annum will be devastating for all of medicine, and even more so for anesthesiology which faces the other payment challenges just outlined.

Other Provisions

We commend the Agency for accepting the PERC/RUC recommendations for the clinical staff direct practice expense inputs for CPT® codes 00100-01999. We are also pleased to see that the Agency will continue to list programmers in the equipment inputs for codes 62367-62368 and 95970-97979.

Some codes in the Physician Fee Schedule were originally valued only for performance in a facility setting. The non-facility practice expense values for these codes are listed as "NA." In the proposed rule, CMS has clarified that when a carrier determines that it will pay for these services in a non-facility setting, it will use the facility PE RVU values to determine physician payment. ASA considers this to be a good interim measure, but requests further clarification on the topic. Because a number of services commonly performed by anesthesiologists only carry facility pricing and the ASA has received comments from its membership that these services are being performed in the office setting, we request that CMS provide the time-table or process to follow to bring these codes (64416, 64446, 64447, 64448, 64449) forward for valuation in the non-facility setting.

Thank you very much for your consideration of our comments. If you have any questions, please contact Norman A. Cohen, M.D. at (503) 299-9906 or Karin Bierstein, JD, MPH at (202) 289-2222.

Sincerely,

Orin F. Guidry, M.D.
President
American Society of Anesthesiologists

Submitter : Mr. Roger Schulte **Date:** 10/10/2006

Organization : Image Analysis, Inc.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1321-P-773-Attach-1.DOC

#773

October 9, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
7500 Security Boulevard
Baltimore, MD 21244-8015

RE: BONE MASS MEASUREMENTS
Federal Register, Vol. 71, No.162/August 22, 2006

"**Summary**: This proposed rule would additionally contain provisions of the Deficit Reduction Act of 2005 as well as make other proposed changes to Medicare Part B payment policy"

Dear Ladies/Gentlemen,

We believe that the proposal to require use of central DXA technology for all follow up bone mass measurements will result in an unnecessary increase in cost and a delay in follow up diagnosis by the minimum of 23 months required by the current rules. Implementation of this proposal will undeservedly harm our business, our customers, and the patient, particularly those in small towns. The Medicare reimbursement for QCT and DXA are essentially the same and there is virtually no cost issue to allow both central bone mass measurement technologies to continue under current rules. This proposal with a primary goal supporting the Deficit Reduction Act of 2005 will actually result in an additional and unnecessary testing and cost for every patient studied by QCT and followed in the manner described. Additionally, this follow up DXA scan will not be a follow up at all – it will only be a baseline DXA test – and the real follow up exam will be 23 months or more in the future by current rule. It is more cost effective to leave current rules in effect than to make the changes proposed for patient follow up testing.

QCT is in wide general use in hospitals and imaging centers and has been the mainstay technology used for bone density measurements in radiology departments located in smaller communities throughout the United States. QCT has been relied upon for both testing for osteoporosis and assessment of drug therapies for years in this segment of medical services. In most of these towns, purchase of a central DXA system is not an economic alternative. To insist that follow up studies be done on DXA is a disservice to the medical institutions and patients of these communities as well as to other institutions that choose to use QCT based on the unique diagnostic advantages of QCT over DXA.

Image Analysis, Inc.
1380 Burkesville Street Columbia, KY 42728 USA Phone 270/384-6400 Fax 270/384-6405

- Patients will have to bear the cost and inconvenience of having to travel to another location for follow up studies.
- The Medicare cost is virtually the same if the follow up is done by QCT or DXA
- There is good evidence that QCT is more likely to accurately diagnose low bone density – particularly in the elderly population
- Many scientific, peer reviewed, studies confirm that assessment of drug therapies is more readily detected by comparisons of trabecular bone by QCT than by integral projection methods used by DXA
- Most importantly, using DXA as a follow up to QCT will not be meaningful because each modality measures different tissues and uses different techniques (Volumetric versus areal-projection).

The proposal to relegate all follow up testing in bone density measurement by DXA amounts to a virtual endorsement by CMA to create an exclusive franchise to DXA in assessment of bone density therapy response measurement when there is ample published scientific evidence that DXA may be a poorer choice in this role than is QCT. Input from medical researchers and scientists who are not DXA users and who understand the physics of these devices is missing. It would be a disservice to current patients being followed by QCT and/or the many future patients who can better be studied with this highly reliable technique.

Sincerely,

Roger Schulte
Vice President Sales and Marketing
Image Analysis, Inc.
1380 Burkesville Street
Columbia, KY 42728

Submitter : **Dr. Rayda Hernandez Guasch** **Date: 10/10/2006**

Organization : **Sociedad Radiologica de Puerto Rico**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See two attachments 1) Letter submitted by the Radiological Society of Puerto Rico and 2) Report prepared by two consultant economists on the cost of living indexes for Puerto Rico.

Impact

Impact

GPCI Provisions

Provisions of the Proposed Rule

Provisions of the Proposed Rule

GPCI calculations as they affect providers in Puerto Rico.

CMS-1321-P-774-Attach-1.DOC

CMS-1321-P-774-Attach-2.DOC

CMS-1321-P-774-Attach-3.DOC

#774-1

October 9, 2006

BY HAND DELIVERY
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 21244-1850

Re: Federal Register Vol. 71, No. 162/August 22, 2006/Proposed Rules GPCI Provisions

Dear Sir or Madam:

The Puerto Rico Radiological Society appreciates the opportunity to comment upon certain aspects of the above-referenced proposed rule which directly impact reimbursement for radiological services furnished to Medicare beneficiaries residing in Puerto Rico. Our comments are largely based on the attached report prepared by two economists specific to cost of living calculations in Puerto Rico. We believe that the proposed adjustments to the GPCI's for Puerto Rico are not aligned with the economic reality of the cost of delivering quality and timely care to Medicare beneficiaries. Therefore, the Radiological Society, in conjunction with the Puerto Rico College of Physicians and Surgeons, commissioned the referenced study, focusing on work and practice expense GPCI components.

We believe that the both the Work and Practice Expense components of the GPCI calculations should be revised for Puerto Rico-based services, as follows:

1. **Adjustments to the Practice Component of the GPCI for Puerto Rico**

We suggest that the suggested practice component for the GPCI be revised and updated due to the following operational cost increases: mandated nurse salaries, increased transportation costs into Puerto Rico, and the recent increases in utilities cost (water and electricity).

a) Nurse Wage Cost:

Law Number 27, enacted on July 20, 2005, regulates nurse salaries in both the public and private sectors, excepting locations that only employ one nurse. The law has a three year phase-in period, commencing in October 2006. Prior to the mandated wage increases, the median nurse salary in Puerto Rico was approximately half of that in the U.S. After adjusting for the mandated increases, the wage index increases from .5 to .593. The vast majority of nurses in Puerto Rico qualify for the mandated increase, because of educational and work experience. The employee wage index represents 39.1% of the practice cost GPCI, therefore the practice cost GPCI should increase by .036. The current practice cost index for Puerto Rico is .699, and with the proposed adjustment, it should increase to .735. Minimum wage increases tend to have an inflationary effect upon other practice expense costs such as payroll taxes and salaries paid to other office personnel.

b) Utilities Cost:

The costs for both basic utilities in Puerto Rico, water and electricity, have risen dramatically over the last several years.

The Puerto Rico Water Authority, faced with crippling deficits, raised its rates anywhere from 166% percent to 387%. As an example, the base residential charge increased from $8 to $32, or a 300 percent increase, effective July 1, 2006. Given that the increases are of recent implementation, the rent index used for purposes of the Practice Expense GPCI calculation does not reflect this increase. The 2005 reported rent index for Puerto Rico is 0.631, or an 8.3% reduction from the previous reported index of 0.688. No index is reported in the draft regulation for 2006. Based on Census data, water costs represent 5% of gross rent, prior to the rate increase. Rent index represents 27.6% of the Practice Expense GPCI; therefore, the GPCI should be adjusted to reflect the increase. The corresponding increase would be 0.026 (rent index * [1 +(rent index)(% gross rent affected)(% cost increase).

Electricity rates in Puerto Rico are significantly higher than the rates in the U.S. In 2003, the average kilowatt hour in Puerto Rico cost 12.61 cents, while the same kilowatt hour in the U.S. cost 7.42 cents. In 2005, the increase in the power rates for Puerto Rico was 24% while in the US that same increase averaged out to 12%. Therefore, the corresponding GPCI for Puerto Rico should reflect that differential in rates. Using 2000 US Census data, electricity costs account for 10.6% of the median gross rent paid for a two bedroom apartment. Applying the 12% increase to 10.6% of the rent index yields an increase of 0.008. Given that 27.6% of the Practice Expense GPCI is comprised by the rent index, the corresponding increase in the component due to electricity rate cost differentials would be 0.002.

c) Transportation Costs into Puerto Rico:

All the equipment and supplies that are used for furnishing radiological services in Puerto Rico have to be imported, be that by air or maritime cargo. Transportation costs into Puerto Rico are estimated to be approximately 15% higher than in the Continental U.S. Therefore, we recommend that there be an adjustment to the portion of the Practice Expense GPCI in the amount of 0.002, to account for transportation costs. Approximately 4.4% of the total import costs are because of transportation costs.[1] Equipment and supplies cost account for 33.3% of the Practice Expense Index. The transportation cost portion corresponds to 1.5% of the total cost ((.333*.044)*100). Increasing this portion by the 15% add-on for increased transportation costs to Puerto Rico yields a 1.7% share ((0.015*1.15)*100). Hence, the adjustment increased transportation costs would be 0.002 (0.017-0.015).

2. Adjustments to the Work Component of the GPCI for Puerto Rico

Puerto Rico is one of the geographic areas that are directly affected by the proposed elimination of the work floor of 1.000, further decreasing physician reimbursement in addition to the proposed overall negative adjustments. The proposed work GAF for Puerto Rico in CY 2006 is 0.0905 and for CY 2007 is 0.883. Upon adjustment for the median wage for nurses following the legislatively mandated raises, the component should reflect an increase to 0.924 for both years.

Summary:

Total Adjustments suggested for the GPCI Components in Puerto Rico:

Practice Expense GPCI
Proposed PE GPCI 0.699

Adjustments	
Nurse Wages	0.034
Transportation Cost	0.002
Water Cost	0.026
Electricity Cost	0.002
Adjusted PE GPCI for PR	**0.763**

Work GPCI	
Proposed Work GPCI	0.906
Nurse Wage Adjustment	0.018
Adjusted Work GPCI for PR	**0.924**

We also recognize that there are differences in the cost of malpractice insurance, but at this moment we do not have data that is sufficiently well developed in order to make an appropriate comparison. To that end, we would like the opportunity to, at a later time, submit data for consideration in the revision of the malpractice insurance component, since the current index appears not to reflect the market conditions in Puerto Rico. Medical malpractice insurance coverage in Puerto Rico is mandatory; however, the coverage limits available for purchase are considerably lower than the coverage available in most markets in the US.

In summary, we believe that the proposed negative updates for Puerto Rico, including the elimination of the 1.000 wage index floor, should be suspended for Calendar Year 2007 and that the totality of the impact of any negative updates be thoroughly considered before implementation. We recognize that the amount of real data is scarce and perhaps not as well-developed as necessary in order to present a thorough picture of the cost of running a radiological practice in Puerto Rico. However, we would like to engage in a discussion with CMS staff regarding the availability and accuracy of data, provide additional information, and answer any questions or concerns regarding the comments and suggestions contained in this letter. I am available at 787 269 2250 or by email at rhg2003@prtc.net.

Sincerely,

Rayda Hernández Guasch, M.D.
President
Radiological Society of Puerto Rico

RHG/hgg

Enclosure

Cc: James Kerr, Regional Administrator, Region II
Delia Lasanta, Director, Puerto Rico/USVI District Office
Hon. Luis Fortuño, Resident Commissioner
Eduardo Bhatia, Esq., Director, Puerto Rico Federal Affairs Administration

#774-2

RECOMMENDATIONS FOR ADJUSTMENTS TO THE GEOGRAPHICAL PRACTICE COST INDEXES FOR PUERTO RICO, FOLLOWING THE PROPOSED RULE PUBLISHED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) IN THE FEDERAL REGISTER, AUGUST 22, 2005

Presented to
Colegio de Médicos y Cirujanos de Puerto Rico

By

Alicia Rodríguez Castro, M.A. Economics
Eileen V. Segarra Alméstica, Ph.D, Economics

October 3, 2006
San Juan, Puerto Rico

I. Adjusting for the effect of legislated changes in the minimum wages for nurses

The **Practice** and **Work** component of the GPCI's for Puerto Rico need to be adjusted by the recent legislated increases in wages and salaries for nurses in the Island. Act No.27 of July 20, 2005, regulates Puerto Rico Nursing Professionals Minimum Wages in the private sector, with the exception of establishments with only one nurse employed, and establishes a system of administrative fines to discourage its violation. The legislated Minimum Wages, which should be adopted fully in a period not less than three years, are:

Licensed Practical Nurse (LPN)	$1,500 monthly ($8.67 hourly)
Registered Nurse (RN)	
Associate Degree	$2,000 monthly ($11.56 hourly)
College Degree (no experience)	$2,350 monthly ($13.58 hourly)
College Degree (Experience)	$2,500 monthly ($14.45 hourly)

Since the Census data used for the calculation of the current GPCI corresponds to the 2000 Census, the effect of the legislation is not reflected in the data. The new legislation affects the calculation of two components of the GPCI, the **Work** and the **Practice** costs components.

We estimated the Work GPCI for Puerto Rico and the Employee Wage Index for the Practical Cost GPCI using the 2000 Census PUMS for Puerto Rico and the Integrated Public Use Microdata for the US, provided by the Minnesota Population Center at the University of Minnesota.

A. Adjustment to the Practice Cost GPCI

The Employee Wages Index used in the calculation of the **Practice** costs GPCI includes the wages for licensed practical nurses and register nurses. We began estimating the wage index for Puerto Rico following the methodology described in "Updating the Geographic Practice Cost Index: The Practice Expense GPCI. Final Report," Health Economics Research, Inc. May 1994 (NTIS PB94161098). Our calculations are shown in **Table 1**

Table 1

	Median Hourly Wage ($)	
Occupation	**US**	**PR**
Clerical	11.34	7.12
Registered Nurses	20.30	8.65
Licensed Practical Nurses	12.98	6.25
Health Technicians	15.39	6.59
Weighted Average	14.56	7.31
Ratio (PR/US)		0.50

Quarter GPCI	0.909

In order to estimate the adjustment, we substituted the median wage for registered nurses and pharmacists by the weighted average of the median wage reported for pharmacist in the PUMS and the minimum wage calculated for all registered nurses, as explained in the previous section. The weights correspond to the percentage of workers in each of the two occupational categories. The new estimated median wage for the group is $13.15. As shown in **Table 4**, the Quarter Work GPCI increases to 0.923, after the adjustment.

Table 4

	Adjusted Medium Hourly Wage	
Occupation Category	**US**	**PR**
Engineers, Surveyors and Architects	25.00	19.23
Natural Scientists and Mathematicians	20.83	14.42
Social Scientists, Social Workers and Lawyers	21.13	13.46
Teachers, Counselors and Librarians	20.83	9.09
Register Nurses and Pharmacists	17.31	**13.15**
Writers, Artists and Editors	15.07	10.90
Weighted average[3]	20.07	13.94
Ratio		0.69
Quarter GPCI		**0.923**

II. Adjusment for transportation costs.

The calculation of the Practice Expenses GPCI assumes that equipment and supplies costs are the same across all geographical areas. Nevertheless, Health Economic Research, Inc. estimated that transportation costs in Puerto Rico are 15 percent higher than in the Continental US.[4]

To estimate the percentage of equipment and supplies costs that corresponds to transportation, we divided the total value of imports for Puerto Rico by the sum freights on imports and marine insurance on imports (obtained from Puerto Rico Planning Board, "Balance of Payment 2005"). The percentage was estimated from 1996 to 2005. The average transportation cost accounts for 4.4 percent of import cost, during the 1996 – 2005 period.

The information was used to calculate a transportation cost adjustment for Puerto Rico. According to the 2003 Federal Register, equipment and supplies accounts for 33.3 percent of the Practice Expense Index. Under the assumption that 4.4 percent of that cost belongs to transportation, we estimated that transportation costs correspond to 1.5 percent of the Practice GPCI ((.333

[3] The weights were taken from "Updating the Geographic Practice Cost Index: The Physician Work GPCI" Health Economics Research, Inc., Walthen MA, May 1994, Table 3.1 page 9.

[4] "Updating the Geographic Practice Cost Index: The Practice Expense GPCI. Final Report and Appendices to Final Report" Health Economics Research, Inc. Waltham, MA, May 1994, pp. III-2-7.

*.044)*100). If we increase this amount by 15 percent the resulting transportation cost share for Puerto Rico is 1.7 percent ((0.015*1.15)*100). This implies that the transportation cost included in the Practice Expense GPCI should increase by 0.002 (0.017-0.015).

III. Adjustment for a new scheme for water utility costs.

Operational expenses for the Puerto Rico Water Authority (PRWA) increased by 273% between 1986 and 2005, while revenues only increased by 38% during the same period. As a result, in fiscal year 2005-2006, the PRWA confronted a $400 millions deficit, which prompted the Authority to implement a dramatic increase in water prices. The estimated increase in residential water cost range from a minimum of 166 percent to a maximum of 387 percent. The lowest water charge increased from $8 to $32, a 300 percent increase; which is representative of the increase for most households.

The rise in water prices represents a large increase in Puerto Rico's utility costs relative to the US. Due to the timing, it is not reflected in the rent index currently used for the calculation of the Practice Expense GPCI. The rent index reported for Puerto Rico for 2005 is 0.631, which represents an 8.3 percent reduction from the previous index of 0.688. The Federal Register update notice for the 2006 GPCI's does not report a new rent index.

Based on 2000 Census PUMS data for Puerto Rico, we estimated the median gross rent for a two bedroom apartment to be $284, while median monthly water cost for two bedrooms apartments was $14.17. This implies that monthly water costs represent 5 percent of gross rent. Therefore, the 300 percent increase in water costs should be applied to 5 percent of the rent index. Accordingly, the rent index should increase from 0.631 to 0.726. This number was estimated as follows:

Rent index *[1 + (rent index)(% of gross rent affected)(% increase in cost)]

= 0.631 * [1 + (0.631)(0.05)(3)] = 0.726

Since the rent index represents 27.6 percent of the Practice Expense GPCI, the increase in the PE GPCI component should be equal to the increase in the rent index multiplied by 0.276. The resulting increase in the Practice Expense GPCI component is:

0.276* [0.726 – 0.631] = 0.026

II. Adjustment for larger increases in electricity cost

Electricity costs are significantly higher in Puerto Rico than in the US. The Centre for the New Economy reports "On average, the Puerto Rican average customer paid 12.61 cents per kWh in 2003, which equals 169.9 percent of the average rate of 7.42 cents per kWh paid by the average customer in the United States".[1] In addition, electricity costs have increased more rapidly in Puerto Rico than in the US. As a result, delays in the updating of the GPCI data are more critical for Puerto Rico. For this reason, we propose an adjustment to the rental index to account for larger increases in electricity cost.

In order to take into consideration differences in energy cost between Puerto Rico and the United States, we obtained the historical data (2000 – 2006) for the average electricity cost for residential consumers for both locations. Since the FMR were adjusted in 2005, we estimated the rate of change in the residential retail prices of electricity (average revenue per kWh). Data for the United States was obtained from the Energy Information Administration official publications 2006. Data for Puerto Rico was provided by PREPA (Puerto Rico Electric Power Authority, October 2006). The increase between 2005 and 2006, was 24 percent for Puerto Rico and 12 percent for the US.

Table 5

Average Cost per kWh (¢/kWh)		
Fiscal Year	**Puerto Rico**	**US**
1999-00	9.92	8.24
2000-01	11.76	8.63
2001-02	10.50	8.46
2002-03	11.92	8.70
2003-04	12.24	8.97
2004-05	14.34	9.08
2005-06	17.72	10.15
Percentage Change	**24%**	**12%**

We adjusted the rent index to account for the 12 percent difference in the increase in electricity costs. According to 2000 Census PUMS data for Puerto Rico, median monthly electricity cost for two bedrooms apartments was $30, which represent 10.6 percent of the median gross rent. This implies that the 12 percent adjustment should apply to 10.6 percent of the rent index. The rent index should be increased by:

(rent index)(% affected by the increase)(% Increase in cost)
=0.631*0.106*0.12= 0.008

[1] "Reestructuring the Puerto Rican Electricity Sector", Sergio M Marxuach, Center for the New Economy, August 22, 2005.

Since the rent index represents 27.6 percent of the Practice Expense GPCI, the increased in the PE GPCI component should be equal to the increase in the rent index multiplied by 0.276. The resulting increase in the Practice Expense GPCI component is:

0.276* [0.008] = 0.002

III. Total Adjustments suggested for the GPCI Components:

Work GPCI	
Proposed Work GPCI	0.906
Nurse Wages Adjustment	0.018
Our suggested Work GPCI for PR	**0.924**
Practice Expense GPCI	
Proposed PE GPCI	0.699
Adjustments	
Nurse Wages	0.034
Transportation Cost	0.002
Water Cost	0.026
Electricity Cost	0.002
Our suggested PE GPCI for PR	**0.763**

IV. Additional Comments

There are other critiques that given the time limitation to meet the deadline and the difficulty in obtaining the data, we have not been able to quantify. Nevertheless, they should be mentioned and take into consideration in future reviews to the Puerto Rican GPCI's.

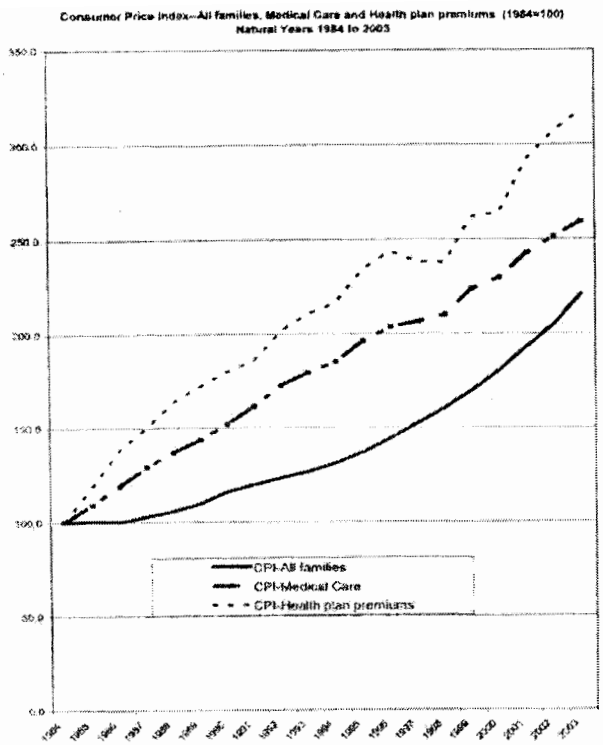
First, we have not been able to obtain comparable insurances rate for Puerto Rico and the US to evaluated how adequate is the malpractice GPCI component for Puerto Rico. There are two issues that should be addressed. Although it is mandatory, the insurance coverage in Puerto Rico is more limited (from $100,000 to $300,000) than the 1 million to 3 million coverage offered in the US. Therefore any comparison between Puerto Rico and the US should be

adjusted and such adjustment should be carefully evaluated. In addition, the growth rate of premiums in Puerto Rico should be compared to those of the US.

Second, The composition of professions that are taken into consideration to calculate the Work GPCI should be reevaluated. Professionals such as teachers and nurses earn a lot less that doctors, and this is especially true in Puerto Rico.

Another concerned is whether or not the Fair Market Rents adequately incorporates the difference in electricity cost between Puerto Rico and the US. In fact, medium monthly electricity cost reported in the PUMS is much lower for Puerto Rico than for the US, even though the average unit rate in Puerto Rico is 70 percent higher than the US average rate.

Finally, price inflation has been higher in Puerto Rico (a double digit rate of inflation for the overall economy) than in the US. Therefore, the fact that most GPCI components are not regularly updated, have a negative impact on Puerto Rico's GPCI components. The following graph presents the historical trend for the 1984-2003 period of the Consumer Price Indexes for All Families, Medical Care and for the Health Plan premiums in Puerto Rico. It can be observed that medical care CPI has been continuously increasing at a higher rate than de overall CPI. Thus, we can state that costs for the medical profession have been increasing at a higher rate than other components of the economy, leading us to recommend a revision of the GPCI's that incorporates inflation differentials between Puerto Rico and the United States.



Presentation of Marissel Velázquez-Vicente, MD
President of Colegio de Médicos Cirujanos de P.R. and Ramón Vidal Fandiño
To The Puerto Rico State Senate Health Commission
Regarding R de S 1327
September 6, 2006

As suggested by the General Accounting Office,[2] with the data from the American Community Survey the GPCI estimations can be updated more often. In fact, from 2005 on the Community Survey is also available for Puerto Rico.

[2] "Medicare Physician Fees: Geographic Adjustment Indices are Valid in Design, but Data and Meteds Need Refinement", General Accounting Office, Report to Congressional Committees, GAO-05-119, March 2005

Submitter : **Ms. Jean Ewing** **Date: 10/10/2006**

Organization : **St. Louis P.E.T. Centers**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

We are an independent testing facility that provides nuclear medicine services including P.E.T./C.T. scanning. It is our feeling that we provide an excellent, cost-effective service to our patients and physicians. Our facility is able to provide same day or next day service with a 24 hour or less report turnaround time. The facility has convenient access with free parking, and we provide a ride service free of charge for patients who live a long distance away or are uncomfortable driving in city traffic.

The cuts proposed in the deficit reduction act are excessive. It is quite likely that many IDTF's such as ours will be unable to continue in business. Furthermore, the DRA will be denying many patients access to a service, PET/CT, which has been shown time and again to reduce morbidity and mortality in cancer patients. PET/CT imaging has actually reduced the total cost of cancer therapy by enabling physician to identify distant metastases, monitor response to therapy, and assess for recurrences without ordering additional studies. In short, PET/CT is a one-stop shop for cancer imaging.

To deny or restrict patients' access to this modality would be almost criminal. Just ask any cancer patient how this modality has helped them. Look at the statistics which demonstrate the effectiveness of this modality in increasing life expectancy and life quality.

As an IDTF, we feel that we can better provide a high quality, cost-effective service than many hospitals. The reason is that we have a lower overhead, and we can more effectively manage our costs. The DRA will not only cause many IDTF'S to close, but, the ones that remain open, will have difficulty upgrading to better, more efficient technology.

Finally, the DRA, in an effort to reduce costs, will, in effect, cause costs to rise by reducing access to a cost effective imaging modality that increases diagnostic and treatment accuracy in cancer patients. Limiting the types of facilities that provide PET/CT to primarily hospitals will also increase costs. Hospitals are notoriously inefficient, and they are completely unaware of what their actual costs are. Therefore, their charges tend to be quite exhorbitant.

As an IDTF, we will continue to try to provide high quality healthcare in the most cost-effective manner possible. It is our hope that you, at CMS, will share our vision.

Thank-you,

Submitter : Dr. Richard Kyle **Date:** 10/10/2006

Organization : American Academy of Orthopaedic Surgeons

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1321-P-776-Attach-1.DOC

#776

American Academy of Orthopaedic Surgeons® | AAOS | American Association of Orthopaedic Surgeons®

6300 North River Road Rosemont, Illinois 60018-4262
Phone 847/823-7186, 800/346-2267 Fax 847/823-8125 Internet www.aaos.org

October 10, 2006

Mark B. McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue
Room 445-G
Washington, DC 20201

Re: Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B – CMS-1321-P

Dear Administrator McClellan:

The American Association of Orthopaedic Surgeons (AAOS) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) *Proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B, Fed. Reg.* CMS-1321-P (August 21, 2006). The AAOS' comments address proposed changes to payments for splint and cast supplies, multiple procedure reduction for diagnostic imaging, the methodology for calculating practice expense relative value units, and the conversion factor.

PAYMENT OF SPLINT AND CAST SUPPLIES

The AAOS appreciates the willingness of CMS to provide fair reimbursement for medically indicated casting and strapping supplies. We recognize and appreciate the fact that CMS has been willing to work with our society to develop appropriate supply inputs. If CMS would like to continue the use of Q-codes, we feel this is reasonable. Separate billing for casting and strapping supplies is consistent with CPT guidelines and private carrier practices, and would avoid confusion with private carrier payment practices.

If CMS chooses to implement this new proposal for casting and strapping supplies, we would like CMS to confirm that all appropriate CPT codes may be billed with an appropriate Q-code. The AAOS notes the Q codes listed in the proposed rule should be applicable to the following series of CPT codes: 23500 – 23680, 24500 – 24685, 25500 – 25695, 26600 – 26785, 27500 – 27566, 27750 – 27848, 28400 – 28675, and 29000 – 29750. It appears the new proposal has omitted codes 23500 – 23680. The AAOS would like CMS to review its final list of CPT codes that may be billed with Q codes to ensure it includes all fracture care, casting, and strapping codes.

The AAOS would also like CMS to affirm that the proposed rule does not affect existing Medicare policy which permits separate reporting and billing of the appropriate cast application

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(29000 - 29750), and supply codes for replacement (subsequent) casts applied for fracture care during the global period.

DEFICIT REDUCTION ACT (DRA) RELATED PROPOSALS

The AAOS believes that applying the multiple image payment imposes an unfair burden on physicians who provide imaging services that patients and payers continue to require. However, given the existence of this policy, the AAOS agrees with CMS' decision to maintain this 25% reduction rather than the 50% reduction proposed in the 2006 Physician Fee Schedule. We feel the policy of making full payment for the technical component (practice expense RVU) for the highest priced procedure, and paying at 25 percent of the technical component for each additional procedure when multiple diagnostic images involving "contiguous body parts within a family of codes" are obtained incorrectly assumes that imaging services are provided in the same method as surgical procedures. While there might be some overlap in terms of clinical labor when obtaining multiple images, the percentage of greater efficiency and economy-of-scale is not equal to the payment reductions.

In addition, the AAOS believes it is inappropriate to combine the 25% multiple procedure reduction with the Outpatient Payment Policy System (OPPS) payment caps as proposed by CMS. The payment rates under the physician fee schedule have been developed under the RBRVS system and CMS' current proposal to cap diagnostic imaging payments with a different methodology is inconsistent with the rest of the physician fee schedule methodology.

CHANGES TO PRACTICE EXPENSE METHODOLOGY

The AAOS appreciates the opportunity to work with CMS in the refinement of practice expense inputs for musculoskeletal codes through the Practice Expense Advisory Committee (PEAC). Although most of the physician fee schedule has gone through the PEAC refinement process, the AAOS believes it is important for the medical community to continue to be involved in the development and refinement of practice expense relative value units used for the Medicare fee schedule.

EQUIPMENT SUPPLY COST INPUTS

The AAOS thanks CMS for its request for input from AAOS on the pricing of practice expense inputs for the Micro Air Burr (Table 1, Page 47). Micro Air is an equipment manufacturing company. Similar pieces of equipment are manufactured by other companies. A similar piece of equipment is already in the CMS supply database, listed as "drill system, surgical, small-micro". Stryker Inc lists the price for this item as $8,979 (please see attached word document which is a copy of the Stryker price list). We suggest that Micro Air Burr be replaced with the Stryker "drill system, surgical, small-micro". If CMS should have any additional questions please feel free to contact AAOS for further review.

American Academy of Orthopaedic Surgeons®

AAOS American Association of Orthopaedic Surgeons®

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SUSTAINABLE GROWTH RATE

The AAOS believes the projected 5.1 percent reduction in the 2006 conversion factor is inappropriate. The costs associated with practicing medicine, such as increases in liability premiums, rising cost of medical equipment, and other factors, continue to increase. The decrease in the conversion factor completely fails to recognize these actual increases in medical costs. The AAOS reiterates its concerns with the Sustainable Growth Rate (SGR) formula used to calculate the conversion factor. In particular, CMS' failure to remove drugs from the SGR pool will continue to have an adverse impact on physicians. The AAOS believes continued cuts in Medicare reimbursement to physicians will lead to access problems for Medicare beneficiaries.

The AAOS appreciates the opportunity to comment on these important issues effecting Medicare beneficiaries and the physician community. The AAOS believes it is important for CMS to consider comments from medical specialty societies because these organizations provide CMS with valuable advice on how to improve the Medicare physician fee schedule. Thank you and please follow up with AAOS staff for continued support and with any questions.

Sincerely,

Richard F. Kyle

Richard F. Kyle, MD
President
American Association of Orthopaedic Surgeons

Submitter : **Dr. Neil Finkler** **Date: 10/10/2006**

Organization : **Florida Hospital Cancer Institute**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

INDEPENDENT LAB BILLING - Also attached

Oncotech has recently informed me that CMS is re-interpreting an existing policy which would have a harmful effect on Oncotech, Inc and the patients they serve. This re-interpretation would require Oncotech to bill their services to a hospital as part of the Medicare Part A program instead, of as an outpatient service,directly to Medicare Part B. As a result, their Extreme Drug Resistance EDR Assay would fall under the current DRG's and hospitals would be responsible for the cost of the Assay and would not be reimbursed for the payment to Oncotech.

In case you aren't familiar with Oncotech, they provide a very effective drug resistance assay. Their EDR Assay identifies patients who are resistant to a chemotherapy drug and therefore would be highly unlikely (<1% as reported in published literature) to respond to specific drugs in a clinical setting. I use this test to assist me in the management of my cancer patients. By utilizing the EDR Assay, both the patient and Medicare are spared the hardship and expense of ineffective chemotherapy. As I mentioned above, their EDR Assay is currently eligible for Medicare Part B reimbursement as a physician provided laboratory test which is performed out of the hospital, however this new interpretation would force their services into Part A. The consequence is a result of the EDR Assay laboratory procedures requiring living tumor tissue which must be collected at the time of the patient's surgery (obtained during the patient's hospital stay): linking the services to the Part A program.

The company does not believe the new interpretation was not directed specifically at Oncotec or similar laboratories but the labs are being affected as an unintended consequence. Patients and physicians may be unduly denied the ability to utilize Oncotech's valuable cancer treatment tool because Oncotech's services will be unfairly classified as a Medicare Part A procedure. I respectfully request a review of the reinterpretation of this federal regulation which directly affects Oncotech's EDR Assay procedure.

CMS-1321-P-777-Attach-1.PDF

#777

FLORIDA HOSPITAL
Cancer Institute

Neil J. Finkler, MD, FACOG, FACS
Robert W. Holloway, MD, FACOG, FACS
B. Hannah Ortiz, MD
Gynecologic Oncology

2501 N. Orange Ave., Suite 689
Orlando, Florida 32804
407/303-2422 • 800/531-0087
Fax 407/305-7435

October 10, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

Oncotech, Inc. has recently informed me that CMS is re-interpreting an existing policy which would have a harmful effect on Oncotech, Inc. and the patient's they serve. This re-interpretation would require Oncotech to bill their services to a hospital as part of the Medicare Part A program, instead of as an outpatient service, directly to Medicare Part B. As a result, their Extreme Drug Resistance EDR Assay would fall under current DRG's and Hospitals would be responsible for the cost of the Assay and would not be reimbursed for the payment to Oncotech.

In case you aren't familiar with Oncotech, they provide a very effective drug resistance assay. Their EDR Assay identifies patients who are resistant to a chemotherapy drug and therefore would be highly unlikely (<1% as reported in published literature) to respond to specific drugs in a clinical setting. I use this test to assist me in the management of my cancer patients. By utilizing the EDR Assay, both the patient and Medicare are spared the hardship and expense of ineffective chemotherapy. As I mentioned above, their EDR Assay is currently eligible for Medicare Part B reimbursement as a physician provided laboratory test which is performed out of the hospital, however this new interpretation would force their services into Part A. The consequence is a result of the EDR Assay laboratory procedures requiring living tumor tissue which must be collected at the time of the patient's surgery (obtained during the patients' hospital stay); linking our services to the Part A program.

The company does not believe the new interpretation was not directed specifically at Oncotech or similar laboratories but the labs are being affected as an unintended consequence. Patients and physicians may be unduly denied the ability to utilize Oncotech's valuable cancer treatment tool because Oncotech's services will be unfairly classified as a Medicare Part A procedure. I respectfully request a review of the

reinterpretation of this federal regulation which directly affects Oncotech's HDR Assay procedure.

Sincerely,

Neil J. Finkler, M.D.
Co-Director
Gynecologic Oncology
Florida Hospital Cancer Institute

Submitter : **Miss. Millicent Gorham** **Date: 10/10/2006**

Organization : **Natinal Black Nurses Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-778-Attach-1.DOC

CMS-1321-P-778-Attach-2.DOC

#778-1

October 10, 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:

On behalf of the National Black Nurses Association (NBNA), I am writing to request that CMS refrain from instituting severe reimbursement cuts for breast brachytherapy (also known as partial breast irradiation (PBI)). NBNA is concerned that the cuts proposed in the Medicare Physician Fee Schedule and OPPS proposed rules would deny a greater number of African American women access to this important, patient-friendly, proven breast cancer treatment.

The National Black Nurses Association represents approximately 150,000 African American nurses, and has 76 chartered chapters nationwide. Our mission is to improve the health status of all people, particularly African Americans and other minority consumers.

Breast cancer is the most common cancer among African American women, and the second most common cause of death, surpassed only by lung cancer. African American women experience a greater delay between the time of breast cancer diagnosis and treatment than white women. In addition, poor or minority women tend to get less than optimal therapy for breast cancer, including surgery, chemotherapy, or radiation. Taken together, these factors contribute to African American women having death rates twice as high for all stages of breast cancer diagnosis compared to white women. Prevention, early detection, and access to the broadest range of breast cancer treatment options are critical for African American women.

Given our interest in this issue, we were distressed to realize that despite the availability and proven effectiveness of breast conservation therapy - a lumpectomy followed by radiation - fewer than 40% of eligible patients choose this treatment. This underutilization is likely due in no small part to the difficulties women, particularly low-income, minority women, have in complying with a 5-6 week radiation treatment course. A recent GAO report confirmed that "lengthy travel distances may especially pose an access barrier for medically underserved women."

Fortunately, with partial breast irradiation, the course of radiation treatment is reduced to 5 days. This increases the likelihood that eligible women will be able to take advantage of breast conservation therapy.

It is our understanding that under the proposed rules, Medicare reimbursement for partial breast irradiation would decrease by more than 50% by 2010, whereas payment for whole breast radiation would increase by over 60% in the same time period. These proposed Medicare cuts threaten to hinder African American women's access to partial breast irradiation post lumpectomy, while encouraging whole breast radiation and/or mastectomies, even if those treatments are not the preferred option of the patient and her health care provider.

The National Black Nurses Association urges CMS to reconsider the proposed reimbursement cuts to partial breast irradiation, and not force patients and health care providers to make critical treatment decisions based upon reimbursement considerations. Thank you in advance for your consideration of our views.

Sincerely,

Millicent Gorham

Millicent Gorham
Executive Director

Cc: U.S. Representative Donna Christian Christensen, Chair, Congressional Black Caucus Health Braintrust
Leslie Norwalk, Deputy Administrator, CMS

Herb Kuhn, Director, Center for Medicare Management, CMS
Albert Morris, Jr., M.D., President, National Medical Association
Eleanor Hinton Hoyt, Interim CEO, Black Women's Health Imperative

Millicent Gorham, MBA
Executive Director
National Black Nurses Association
8630 Fenton Street, Suite 330
Silver Spring, MD 20910

#778-2

October 10, 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)

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The National Black Nurses Association urges CMS to reconsider the proposed reimbursement cuts to partial breast irradiation, and not force patients and health care providers to make critical treatment decisions based upon reimbursement considerations. Thank you in advance for your consideration of our views.

Sincerely,

Millicent Gorham

Millicent Gorham
Executive Director

Cc: U.S. Representative Donna Christian Christensen, Chair, Congressional Black Caucus Health Braintrust
Leslie Norwalk, Deputy Administrator, CMS

Herb Kuhn, Director, Center for Medicare Management, CMS
Albert Morris, Jr., M.D., President, National Medical Association
Eleanor Hinton Hoyt, Interim CEO, Black Women's Health Imperative

Millicent Gorham, MBA
Executive Director
National Black Nurses Association
8630 Fenton Street, Suite 330
Silver Spring, MD 20910

Submitter : Dr. Thomas Wieters **Date:** 10/10/2006

Organization : The Vein Center

Category : Physician

Issue Areas/Comments

Background

Background

Making these revisions as proposed will impact negatively on the Medicare poplulations' access to quality healthcare. The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments.

GENERAL

GENERAL

CMS-1321-P
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment Under Part B
Proposal dated August 8, 2006

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT codes 36478 and 36479, Endovenous Laser Ablation.

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

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

While practice expenses consistently rise (salaries, utilities, supplies, etc.) it has become increasingly difficult to provide these medically necessary services for Medicare beneficiaries. 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. There is a drastic shortage of these highly qualified technologists, and therefore they are in high demand and, as such, command an extremely high salary in excess of $70,000 per year, plus benefits. Given the limited number of technologists available, and the procedures that the average physician performs each year, it is impossible to comply with CMS guidelines if the RVUs and subsequent reimbursement continue to drop.

As you are aware, 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). The continuation of these fee schedule cuts will cripple the ability of physicians to perform these extremely important procedures and ultimately result in the loss of access of care for Medicare beneficiaries.

2. The proposed converstion 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 slightly higher than those for laser ablation:
    a. 2006: 51.50
    b. 2007: 47.77
    c. 2008: 44.52

All of the above-mentioned technologies are comparable, especially when you consider the initial capital acquisition costs ($37,900 for laser and $25,000 for radiofrequency) and the per patient supply costs ($360.00 for laser and $750.00 for radiofrequency for the procedure kits, plus the additional costs of disposable sterile supplies such as gowns, drapes, anesthetic solutions, IV bags, tubing, and the like). While the per patient supply costs may be just slightly higher for 36475 (radiofrequency ablation), the higher acquisition costs for 36468 (laser ablation) raises the overall physician's cost of delivering the service to the same level.

I would request that the fully implemented, non-facility practice expense RVU be significantly increased for 36475 and that the RVU for 36478 be increased accordingly.

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

Respectfully submitted,

Thomas R. Wieters, M.D.
Charleston, South Carolina
trwietersmd@aol.com

Impact

Impact

see general comment below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

see general comment below

Submitter : **Dr. Michael Sulkin** **Date: 10/10/2006**

Organization : **Horizon Surgical Group**

Category : **Physician**

Issue Areas/Comments

Background

Background

The proposed reductions in reimbursement for CPT codes 36475 and 36476, radiofrequency vein ablation as well as codes 36478 and 36479, laser vein ablation will negatively impact Medicare beneficiaries' quality of health care and access to treatments that can maintain their mobility and independence.

GENERAL

GENERAL

This response is pertinent to the proposal of CMS on 8/8/2006 to lower reimbursement for CPT codes 36475 and 36476, radiofrequency vein ablation as well as codes 36478 and 36479, endovenous laser abltion. I reviewed the proposal in detail and am dismayed that Mediare beneficiaries will be restricted from access to these eritically important interventions if the proposed reductions are implemented.

I am a vascular surgeon with 35 years experience treating patients with venous disorders. My practice, Horizon Surgical Group, is composed of 5 vascular surgeons. We see Medicare beneficiaries with vein disorders every day. Vein stripping, ligation and division and other surgical interventions were only partially beneficial in treating these painful, life limiting conditions. Many patients declined invasive treatment, leading to venous ulcers and immobility. The ability of vascular specialists to intervene in a meaningful minimally invasive manner is now greatly enhanced with the introduction of these procedures. This does, however, come with a cost. The capital equipment to provide these services ranges between $25,000 to $35,000. Supplies for each procedure ranges from $350 to $750. But the clinical results are outstanding. I have treated patient from ages 14 to 95 with excellent outcomes. To have to restrict my utilization of these procedures is most disturbing.

Please reconsider these reductions. I am available to discuss this with the members of your committee.

Thank you for your consideration.

Michael D. Sulkin, M.D., F.A.C.S.
Horizon Surgical Group
9715 Medical Center Drive
Suite 105
Rockville, Maryland 20850
msulkin@horizonsurgicalgroup.com

Impact

Impact

Please see General Comments

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Please see General Comments

Submitter : **Dr. Robert Holloway** **Date: 10/10/2006**

Organization : **Florida Hospital Cancer Institute**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

INDEPENDENT LAB BILLING - Also attached

Oncotech has recently informed me that CMS is re-interpreting an existing policy which would have a harmful effect on Oncotech, Inc and the patients they serve. This re-interpretation would require Oncotech to bill their services to a hospital as part of the Medicare Part A program instead, of as an outpatient service,directly to Medicare Part B. As a result, their Extreme Drug Resistance EDR Assay would fall under the current DRG's and hospitals would be responsible for the cost of the Assay and would not be reimbursed for the payment to Oncotech.

In case you aren't familiar with Oncotech, they provide a very effective drug resistance assay. Their EDR Assay identifies patients who are resistant to a chemotherapy drug and therefore would be highly unlikely (<1% as reported in published literature) to respond to specific drugs in a clinical setting. I use this test to assist me in the management of my cancer patients. By utilizing the EDR Assay, both the patient and Medicare are spared the hardship and expense of ineffective chemotherapy. As I mentioned above, their EDR Assay is currently eligible for Medicare Part B reimbursement as a physician provided laboratory test which is performed out of the hospital, however this new interpretation would force their services into Part A. The consequence is a result of the EDR Assay laboratory procedures requiring living tumor tissue which must be collected at the time of the patient's surgery (obtained during the patient's hospital stay): linking the services to the Part A program.

The company does not believe the new interpretation was not directed specifically at Oncotec or similar laboratories but the labs are being affected as an unintended consequence. Patients and physicians may be unduly denied the ability to utilize Oncotech's valuable cancer treatment tool because Oncotech's services will be unfairly classified as a Medicare Part A procedure. I respectfully request a review of the reinterpretation of this federal regulation which directly affects Oncotech's EDR Assay procedure.

CMS-1321-P-781-Attach-1.PDF

FLORIDA HOSPITAL
Cancer Institute

Neal J. Finkler, MD, FACOG, FACS
Robert W. Holloway, MD, FACOG, FACS
B. Hannah Ortiz, MD
Gynecologic Oncologists

2501 N. Orange Ave. Suite 630
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Fax 407/303-2436

October 10, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan

Oncotech, Inc. has recently informed me that CMS is re-interpreting an existing policy which would have a harmful effect on Oncotech, Inc. and the patient's they serve. This re-interpretation would require Oncotech to bill their services to a hospital as part of the Medicare Part A program, instead of as an outpatient service, directly to Medicare Part B. As a result, their Extreme Drug Resistance EDR Assay would fall under current DRG's and Hospitals would be responsible for the cost of the Assay and would not be reimbursed for the payment to Oncotech.

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The company does not believe the new interpretation was not directed specifically at Oncotech or similar laboratories but the labs are being affected as an unintended consequence. Patients and physicians may be unduly denied the ability to utilize Oncotech's valuable cancer treatment tool because Oncotech's services will be unfairly classified as a Medicare Part A procedure. I respectfully request a review of the

reinterpretation of this federal regulation which directly affects Oncotech's EDR Assay procedure.

Sincerely,

Robert W Holloway, MD
Co-Director
Gynecologic Oncology
Florida Hospital Cancer Institute

Submitter : **Dr. Hannah Ortiz** **Date: 10/10/2006**

Organization : **Florida Hospital Cancer Institute**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

INDEPENDENT LAB BILLING - Also attached

Oncotech has recently informed me that CMS is re-interpreting an existing policy which would have a harmful effect on Oncotech, Inc and the patients they serve. This re-interpretation would require Oncotech to bill their services to a hospital as part of the Medicare Part A program instead, of as an outpatient service,directly to Medicare Part B. As a result, their Extreme Drug Resistance EDR Assay would fall under the current DRG's and hospitals would be responsible for the cost of the Assay and would not be reimbursed for the payment to Oncotech.

In case you aren't familiar with Oncotech, they provide a very effective drug resistance assay. Their EDR Assay identifies patients who are resistant to a chemotherapy drug and therefore would be highly unlikely (<1% as reported in published literature) to respond to speeific drugs in a clinical setting. I use this test to assist me in the management of my cancer patients. By utilizing the EDR Assay, both the patient and Medicare are spared the hardship and expense of ineffective chemotherapy. As I mentioned above, their EDR Assay is currently eligible for Medicare Part B reimbursement as a physician provided laboratory test which is performed out of the hospital, however this new interpretation would force their services into Part A. The consequence is a result of the EDR Assay laboratory procedures requiring living tumor tissue which must be collected at the time of the patient's surgery (obtained during the patient's hospital stay): linking the services to the Part A program.

The company does not believe the new interpretation was not directed specifically at Oncotec or similar laboratories but the labs are being affected as an unintended consequence. Patients and physieians may be unduly denied the ability to utilize Oncotech's valuable cancer treatment tool because Oncotech's services will be unfairly classified as a Medicare Part A procedure. I respectfully request a review of the reinterpretation of this federal regulation which directly affects Oncotech's EDR Assay procedure.

CMS-1321-P-782-Attach-1.PDF

#782

FLORIDA HOSPITAL
Cancer Institute

Neil J. Fiekler, MD, FACOG, FACS
Robert W. Holloway, MD, FACOG, FACS
B. Hannah Ortiz, MD
Gynecologic Oncology

2501 N. Orange Ave. Suite 622
Orlando, Florida 32804
407.303.7622 • 800.551.0887
Fax 407.303.7630

October 10, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan,

Oncotech, Inc. has recently informed me that CMS is re-interpreting an existing policy which would have a harmful effect on Oncotech, Inc. and the patient's they serve. This re-interpretation would require Oncotech to bill their services to a hospital as part of the Medicare Part A program, instead of as an outpatient service, directly to Medicare Part B. As a result, their Extreme Drug Resistance EDR Assay would fall under current DRG's and Hospitals would be responsible for the cost of the Assay and would not be reimbursed for the payment to Oncotech.

In case you aren't familiar with Oncotech, they provide a very effective drug resistance assay. Their EDR Assay identifies patients who are resistant to a chemotherapy drug and therefore would be highly unlikely (< 1% as reported in published literature) to respond to specific drugs in a clinical setting. I use this test to assist me in the management of my cancer patients. By utilizing the EDR Assay, both the patient and Medicare are spared the hardship and expense of ineffective chemotherapy. As I mentioned above, their EDR Assay is currently eligible for Medicare Part B reimbursement as a physician provided laboratory test which is performed out of the hospital, however this new interpretation would force their services into Part A. The consequence is a result of the EDR Assay laboratory procedures requiring living tumor tissue which must be collected at the time of the patient's surgery (obtained during the patients' hospital stay); linking our services to the Part A program.

The company does not believe the new interpretation was not directed specifically at Oncotech or similar laboratories but the labs are being affected as an unintended consequence. Patients and physicians may be unduly denied the ability to utilize Oncotech's valuable cancer treatment tool because Oncotech's services will be unfairly classified as a Medicare Part A procedure. I respectfully request a review of the

#784-1

ABNS

American Board of Nursing Specialties

October 10, 2006

TO: Centers for Medicare and Medicaid Services
Department of Health and Human Services

FR: American Board of Nursing Specialties (ABNS)

RE: File Code CMS – 1321-P – Public Comment

On behalf of the American Board of Nursing Specialties (ABNS) and its Board of Directors, I appreciate the opportunity to respond to your request for public comment on criteria or standards that CMS could use to determine whether an organization is an appropriate national certifying body for advanced practice nurses. The American Board of Nursing Specialties (ABNS) is a membership organization comprised of 28 specialty nursing certifying organizations that represent over 400,000 certified nurses committed to the delivery of quality nursing care to patients. Most importantly, within the nursing community ABNS is a well recognized accrediting agency for national specialty nursing certification programs at both the RN and APRN levels.

ABNS is an organization committed to the delivery of quality nursing care to patients. Incorporated in 1991 to create uniformity in nursing certification and to increase public awareness of the value of certification, ABNS serves as an advocate for consumer protection by establishing and maintaining standards for professional specialty nursing certification. We believe that specialty nursing certification is a means to ensuring such quality and our commitment is made clear in our vision that *Specialty nursing certification is THE standard by which the public recognizes quality nursing care.*

In order to receive accreditation by ABNS, a specialty nursing certification program must demonstrate compliance with 18 rigorous standards. A complete listing of the accreditation standards can be found on the ABNS web site (**www.nursingcertification.org**). I have also attached a brief summary of each standard.

Because of the rigorous nature of its accreditation standards and the depth of its program review to determine if an organization should be granted accreditation, ABNS urges CMS to use ABNS accreditation of advanced practice nursing certification programs as a criteria for determining that an organization is an appropriate national certifying body for advanced practice nurses.

If I can provide further information about ABNS and its accreditation function, do not hesitate to contact me.

Sincerely,

Bonnie Niebuhr

Bonnie Niebuhr, MS, RN, CAE
Chief Executive Officer

Cc: Board of Directors

610 Thornhill Lane • Aurora, OH 44202
Phone: 330-995-9172 • Fax: 330-995-9743 • E-mail: ABNSCEO@aol.com
www.nursingcertification.org

#784-2

ABNS

American Board of Nursing Specialties

October 10, 2006

TO: Centers for Medicare and Medicaid Services
Department of Health and Human Services

FR: American Board of Nursing Specialties (ABNS)

RE: File Code CMS – 1321-P – Public Comment

On behalf of the American Board of Nursing Specialties (ABNS) and its Board of Directors, I appreciate the opportunity to respond to your request for public comment on criteria or standards that CMS could use to determine whether an organization is an appropriate national certifying body for advanced practice nurses. The American Board of Nursing Specialties (ABNS) is a membership organization comprised of 28 specialty nursing certifying organizations that represent over 400,000 certified nurses committed to the delivery of quality nursing care to patients. Most importantly, within the nursing community ABNS is a well recognized accrediting agency for national specialty nursing certification programs at both the RN and APRN levels.

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If I can provide further information about ABNS and its accreditation function, do not hesitate to contact me.

Sincerely,

Bonnie Niebuhr

Bonnie Niebuhr, MS, RN, CAE
Chief Executive Officer

Cc: Board of Directors

610 Thornhill Lane • Aurora, OH 44202
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www.nursingcertification.org

ABNS

American Board of Nursing Specialties

Promoting Excellence in Nursing Certification

Accreditation Standards

The ABNS Accreditation Council is the only accrediting body specifically for nursing certification programs. Both ABNS members and non-members are eligible for accreditation. Nursing certification organizations may attain accreditation by demonstrating compliance with the eighteen standards established by the ABNS Accreditation Council.

ABNS is an approved accrediting agency for the National Council of State Boards of Nursing's Advanced Practice Registered Nurses (APRN) Certification Review Program.

Standard 1 **Definition and Scope of Nursing Specialty**

The certification examination program is based on a distinct and well-defined field of nursing practice that subscribes to the overall purpose and functions of nursing. The nursing specialty is distinct from other nursing specialties and is national in scope. There is an identified need for the specialty and nurses who devote most of their practice to the specialty.

Standard 2 **Research Based Body of Knowledge**

A tested body of research/data-based knowledge related to the nursing specialty exists. Mechanisms are established for the support, review, and dissemination of research in the specialty. Activities within the specialty contribute to the advancement of nursing science within the specialty.

Standard 3 **Organizational Autonomy**

The certifying organization is an entity with organizational autonomy. However, a collaborative relationship exists between the certifying organization and a national or international nursing specialty association that supports the nursing specialty and the standards for specialty practice.

Standard 4 **Non Discrimination**

The certifying organization does not discriminate among candidates as to age, gender, race, religion, ethnic origin, disability, marital status, or sexual orientation.

Standard 5 **Public Representation**

The certifying organization (certifying governing body) includes at least one public member with voting rights.

Standard 6 **Eligibility Criteria for Test Candidates**

The eligibility criteria for basic specialty certification include:

- RN licensure
- Educational and experiential qualifications as determined by the individual specialty certifying organization.

The eligibility criteria for advanced practice nursing certification include:

- RN licensure
- A minimum of a graduate degree in nursing or the appropriate equivalent, including content in the specified area of specialty practice

Standard 7 **Validity**

The certifying organization has conducted validation studies to assure that inferences made on the basis of test scores are appropriate and justified.

Standard 8 **Test Development**

Certification examinations are constructed and evaluated using methods that are psychometrically sound and fair to all candidates

Standard 9 **Reliability**

The certifying organization assures that test scores, including subscores, are sufficiently reliable for their intended uses.

Standard 10 **Test Administration**

The certification examination(s) are administered in a manner that minimizes construct-irrelevant variance

Standard 11 **Test Security**

Procedures are in place to maximize the security of all certification examination materials.

Standard 12 **Passing Scores**

Passing scores for the certification examination(s) are set in a manner that is fair to all candidates, using methods that are psychometrically sound.

Standard 13 **Continued Competency**

The certifying organization has a recertification program in place that requires certificants to maintain current knowledge and to periodically document the knowledge necessary to maintain competence in the specialty.

Standard 14 **Communications**

The certifying organization provides information that clearly describes the certification process to candidates and other stakeholders.

Standard 15 **Confidentiality**

The certifying organization assures that confidential information about candidates and certificants is protected

Standard 16 **Appeals**

The certifying organization has an appeal process in place for candidates/certificants who have been denied access to an examination or renewal of certification or who have had certification revoked.

Standard 17 **Misrepresentation and Non-Compliance**

The certifying organization has a mechanism in place to respond to instances of misrepresentation and non-compliance with eligibility criteria or certifying organization's rules; this mechanism includes reporting cases of misrepresentation to appropriate authorities.

Standard 18 **Quality Improvement**

The certifying organization shall have an internal audit and review system in place including provision for continuous corrective and preventive actions for quality improvement.

Submitter : Dr. Eric Hohenwalter **Date:** 10/10/2006

Organization : Dr. Eric Hohenwalter

Category : Physician

Issue Areas/Comments

Background

Background

Making these revisions as proposed will impact negatively on the Medicare populations access to quality health care. The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments.

GENERAL

GENERAL

CMS-1321-P
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment Under Part B
Proposal dated August 8, 2006

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation.

I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for CPT codes 36478 and 36479 and find several 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 consistently rise, (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 employee 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. Given the limited number of these procedures that the average physician performs per year it is 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.

Impact

Impact

See general comment.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See general comment.

Submitter : Dr. YOUNG LEE **Date:** 10/10/2006

Organization : CHESAPEAKE ONCOLOGY

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I AM OPPOSING TO ASP CHANGES THAT PROPOSES TO HAVE AMGEN AND ORTHO-BIOTECH SHARE A J-CODE. CURRENTLY, AMGEN PROVIDES SEVERAL EXCELLENT SUPPORTIVE CARE PRODUCTS FOR OUR CANCER PATIENTS, AND I AM USING ITS PRODUCTS BASED ON THEIR EFFICACY AND NOT BECAUSE OF DISCOUNT CONTRACTS. ORTHO-BIOTECH ONLY HAS PROCRIT WHICH IS ONLY GOOD FOR ANEMIA, PROCRIT DOES NOTHING FOR LOW IMMUNE SYSTEM PRODUCED BY CHEMOTHERAPY AND I WOULD STILL NEED TO USE AMGEN'S NEUPOGEN AND NEULASTA.

FURTHERMORE, ARANEST IS A LONG-ACTING ERYTHROPOIETIN AND ALLOWS ME TO GIVE INJECTIONS EVERY 3 WEEK PERIOD, TOGETHER WITH EACH CYCLE OF CHEMOTHERAPY, WHEREAS PROCRIT HAS TO BE ADMINISTERED EVERY WEEK WHICH CREATES PROBLEMS WITH MULTIPLE VISITS TO DOCTORS' OFFICES FOR USUALLY SICK CANCER PATIENTS WHO HAVE TO RELY ON THEIR FAMILY AND FRIENDS TO COME FOR ALL THEIR MEDICAL APPOINTMENTS. THEREFORE AGAIN MY PREFERENCE FOR AMGEN PRODUCT IS BASED ON PATIENT COMFORT AND CONVENIENCE RATHER THAN THE DISCOUNT CONTRACTS. ALSO, DO KEEP IN MIND THAT ARANESP IS ONLY COVERED IN CERTAIN CLINICAL SITUATIONS, AND THAT PROCRIT HAS MUCH BROADER INDICATION AND WE STILL USE IT WHEN IT IS APPROPRIATE. THANK YOU FOR YOUR ATTENTION.

Impact

Impact

MY COMMENTS DEAL WITH ASP ISSUES.

Submitter : Mr. James Freymiller **Date:** 10/10/2006

Organization : Atlantic CardioLink

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-787-Attach-1.PDF

#787

October 10, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: Proposed Rule; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (Federal Register, August 22, 2006)

Dear Dr. McClellan:

On behalf of Atlantic CardioLink, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

Under the proposed rule CMS states that the payment for cardiac catheterization related procedures (e.g. CPT code 93510 TC, 93553 TC and 93555 TC) will be established by the Medicare carriers. The change in the payment method appears only in Addendum B, and CMS provides no explanation or justification in the body of the proposed rule for this change. We object to this approach because it is inconsistent with the overall policy of basing Medicare payment rates for physician services on a national fee schedule methodology. We are also concerned that if carrier pricing were to be implemented, the carriers would look to the values in the June 29, 2006 Notice that addressed the changes to the methodology for the development of practice expense (PE) relative value units (RVUs). Therefore, we request that CMS give serious consideration to addressing the flaws in the proposed changes to the bottom up "PE" methodology for procedures where the technical component (TC) can be billed separately. We know that

developing an adequate solution will take time and, therefore, request that CMS set the 2007 relative value units for the three codes listed based on the 2006 values.

We urge CMS to use the current relative value units as the basis for determining reimbursement for these procedures rather than relying on the Medicare carriers to price these services. By doing so, CMS will be able to set a reimbursement rate that fairly reflects the costs of performing these procedures. This recommendation is supported by actual data from outpatient centers. COCA sponsored a study to estimate the costs of performing a cardiac catheterization (CPT Code 93510 TC) in an outpatient center. The study results demonstrated that the 2006 Part B physician fee schedule payment approximates the average cost of providing these services. As a result, we do not believe that a new pricing methodology is necessary.

The current relative value units result in a payment rate that is in relative parity with the payment amount hospitals receive under the hospital outpatient prospective payment system. In fact, the 2006 physician fee schedule payments for the three CPT codes included in the Ambulatory Procedure Classification ("APC") for cardiac catheterizations are 93 percent of the relevant APC rate.

In our response to CMS' Proposed Changes to the Practice Expense Methodology (Federal Register, June 29, 2006) we outlined our concerns with the proposed changes to the PE Methodology, i.e., use of a bottom-up methodology and the elimination of the non-physician work pool. The proposed payment rates resulting from the use of the practice expense RVUs for the left heart catheterization procedure alone (CPT code 93510 TC) reduce payment levels in 2007 by 16 percent, and by 2010 make overall reductions of 53 percent. The flaws in the methodology, particularly as they relate to the cardiac catheterization procedure codes were described in general in a comment letter dated in an August 22, 2006 comment letter submitted by COCA.

Cardiac catheterizations that are billed through the Medicare physician fee schedule are performed primarily in cardiology groups and freestanding centers which are grouped into a diverse group of diagnostic testing facilities known as IDTFs.

We believe that the development of unique standards for each type of diagnostic testing facilities will facilitate the development of a consistent Medicare policy for outpatient cardiac catheterization services. The standards will provide a solution to the issue that cardiac catheterization labs faced when the national coverage determination for outpatient catheterizations was rescinded because of the change of scope in the CMS contracts with the Peer Review Organizations in January 2006.

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS's observation that these types of IDTFs are different, we believe that cardiac catheterization centers are unique and that their cost structure and quality standards are similar regardless of whether they are performed in a

cardiology practice or an independent outpatient center. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average profile of all IDTFs. We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers because the data can be used to estimate the impact that each standard has on practice expenses. The cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

In summary, we have grave concerns about the use of carrier-based pricing for procedures that are offered nationwide and historically have been paid according to the physician fee schedule methodology. The carrier based pricing approach is more often used for new services where there is insufficient data on which to determine a national rate. We have previously described our concerns with the proposed 2007 PE RVUs for the cardiac catheterization-related procedures, and, therefore, request that the 2006 rates be frozen so that payments reflect the costs of performing the procedure in the outpatient setting and are on par with the APC rate for a comparable family of cardiac catheterization-related procedures. In addition, we also note that carrier-based pricing has the potential to create disparities in beneficiary co-payment liability.

We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-related procedures and the development of standards for centers that perform these procedures on an outpatient basis.

Sincerely,

James D. Freymiller, RCIS
Director, Atlantic CardioLink, LLC

Submitter : **Ms. Judy Mink** **Date: 10/10/2006**

Organization : **Robinson Memorial Hospital**

Category : **Other Technician**

Issue Areas/Comments

Background

Background

I am concerned about the projected 39% reduction of the Medicare payments for Computer Aided Detection (CAD) when used with mammography (CPT 76082 and 76083) by the year 2010. CAD systems for mammography are important diagnostic tools which can increase breast cancer detection rates, especially in early stages. The use of CAD requires the purchase and maintenance of medical equipment which is operated by certified mammography technologists. The process of digitizing images for CAD is time and labor-intensive. There is no rationale to reduce a valuable service by 39% because of modifications of payment calculations. I am deeply concerned that the combined effect of all the proposed changes in reimbursement along with an anticipated reduction of the conversion factor of 5.1% will make it economically impossible for me and my colleagues to continue to provide mammography with CAD analysis to our Medicare patients. Please consider withdrawing the proposed reduction, or at a minimum, delay the implementation of this new practice expense methodology, especially in light of the other payment reductions planned for other imaging procedures. Thank you for your consideration.

Submitter : **Mr. James Giger** **Date: 10/10/2006**

Organization : **Systematic Management Systems**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-789-Attach-1.DOC

#789

Reference File Code CMS-1321-P
Section (N) Public Consultation for Medicare Payment for
New Outpatient Clinical Diagnostic Laboratory Tests
Subsection (3) Other Laboratory Tests
Provision (b) Blood Glucose Monitoring in SNFs

BACKGROUND

As identified by the House, Ways and Means Committee Report and finalized by the Conference Committee Report (copies attached) Section 4554 of the Balanced Budget Act of 1997 (BBA-1997) the Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests (Committee) was formed to develop National Policies for the Medicare Part B Clinical Laboratory Tests Benefit.

Congress' statutorily mandated establishment of the Negotiated Rulemaking Committee, in essence, preempted the field of payment and coverage for the Medicare Part B laboratory benefits. The Committee's National Coverage Determinations and Administrative Policies became binding on the Secretary (HHS) in accordance with Section 4554(b) of the BBA-1997 no later than January 1, 1999.

As published in the Federal Register on November 23, 2001 pursuant to Section 4554(b) of the BBA-1997 and subject to a Final Agreement of the Committee dated August 31, 1999 (copy attached), 23 national policies were developed by the Negotiating Committee. These national policies were designed to promote uniformity and integrity through universal simplified administrative requirements to be followed for all laboratory covered services without any differentiation/distinction as to where the services were provided. (See attached synopsis of Committee's key applicable Final Administrative Policies for Clinical Diagnostic Laboratory Tests)

One of the Negotiated Rulemaking Committee's 23 National Policies (commonly referred to as a National Coverage Determination or NCD) addressed Blood Glucose Testing. This often utilized laboratory service is universally accepted as needed to be performed (up to several times a day) for a Medicare Part B beneficiary who is afflicted with **diabetes** or similar illness/medical condition. (Copy of the final NCD for Blood Glucose Testing is attached)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)
AUGUST 22, 2006 PUBLICATION OF PROPOSED RULE
BLOOD GLUCOSE MONITORING IN SNFs

CMS states that the purpose of its publication contained in the Federal Register dated August 22, 2006 is to take an opportunity to restate its long standing policy on coverage of blood glucose monitoring services and proposes to codify physician certification requirements for blood glucose monitoring in SNFs.

Prior to the issuance of Program Memorandums AB-00-099 (August 24, 2000) and AB-00-108 (December 1, 2000) CMS published that it had no national policy for blood glucose testing (monitoring). The issuance of these two instructions were the initial publications issued by CMS to its Medicare contractors.

The above instructions were issued despite CMS' (HHS) confirmed concurrence with the proposed rule provision published by the Committee (Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests) in the Federal Register dated March 10, 2000. The Committee's unanimous agreement precluded any participant from taking any action to inhibit the proposed regulation as final and published by the Department of Health and Human Services (HHS) through the Health Care Financing Administration (currently known as CMS).

In PM AB-00-108, CMS, addressing laboratory services, restates Section 1862(a)(1)(A) of the Social Security Act requirement that the service needs to be reasonable for the diagnosis and treatment of an illness in order to be covered by Medicare. CMS cites 42 CFR 410.32 and 411.15 for the proposition that the physician must order the test/service and use the result in the management of the beneficiary's specific medical problem. However, CMS went further to include the following additional requirement: **"Implicitly, the laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care; this includes the physician order for another laboratory service."** Clearly by their own terms, CMS confesses that the statute or regulations do not require such criteria in order for a SNF to perform a treating physician ordered subsequent laboratory test.

We are submitting the comment below as part of our objection to the proposed rule by CMS which is based on previous publications that are in conflict with or unsupported under the Congressionally binding Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests' NCD and Administrative Policies.

COMMENT

In the proposed rule section, which is identified and entitled *Blood Glucose Monitoring in SNFs*, it strictly applies to the physician service(s) payment for the treating physician's ongoing services in monitoring the blood glucose test results for a diabetic Medicare Part B beneficiary. This rule, therefore, directly relates to the global payment made to the treating physician for each physician visit and not to the testing done by the SNF pursuant to the physician order as even a standing order satisfies the requirement(s) of Section 1862(a)(1) of the Social Security Act.

The blood glucose laboratory testing service performed by the SNF is subject to the Blood Glucose NCD and Administrative (payment) Policies and therefore, this proposed rule cannot have any affect on the Medicare payment for blood glucose testing.

If this regulation is meant to apply to the blood glucose testing services, such rule is prohibited by the Congressionally mandated provision of Section 4554(b) of the Balanced Budget Act of 1997.

Submitted by:
James J. Giger

October 10, 2006

Submitter : **Mrs. Connie Woodburn** **Date: 10/10/2006**

Organization : **Cardinal Health**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-790-Attach-1.PDF

#790

Cardinal Health
7000 Cardinal Place
Columbus, OH 43017
614.757.5000 tel

www.cardinal.com

CardinalHealth

October 10, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Office of the Administrator
Centers for Medicare and Medicaid
Department of Health and Human Services
Attn: CMS-1321-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: CMS-1321-P (ASP Issues)

Dear Dr. McClellan:

On behalf of Cardinal Health, I would like to take this opportunity to provide our comments on the Proposed Rule CMS-1321-P, "*Revisions to Payment Policies under the Physician Fee Schedule for Calendar year 2007 and Other Changes to Payment under Part B" (the "Proposed Rule").* This rule was published in the *Federal Register* on August 22, 2006.

Cardinal Health is a member of the Healthcare Distribution Management Association ("HDMA"), and we have worked closely with HDMA on their written comments to the Centers for Medicare and Medicaid Services ("CMS") on the Proposed Rule. Cardinal Health fully endorses the HDMA comments, and hereby incorporates the HDMA comments into our comments for the record.

Cardinal Health is a leading provider of products and services to the healthcare industry. As one of the largest national pharmaceutical distributors in the country, Cardinal Health delivers over 1.4 million products per day and make over 50,000 daily deliveries to over 40,000 different customer sites. We have been at the forefront of the move to a fee for service distribution model with manufacturers and have spent a considerable amount of time and effort developing a customized, appropriate framework for determining the fees paid by manufacturers for those services. Cardinal Health strongly believes in the value that wholesalers provide to the healthcare industry by serving as an efficient and necessary link in the supply chain to safely get the right drugs to the right place at the right time.

Cardinal Health will limit our comments to the portion of the Proposed Rule that addresses ASP reporting issues.

Bona Fide Service Fees

The Proposed Rule would codify the definition of *bona fide* service fee at 42 C.F.R. 414.802, defining such fees as "fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug." The Proposed Rule also would stipulate at 42 C.F.R. 414.804(a)(2)(ii) that manufacturers may not treat *bona fide* service fees as price concessions when they calculate ASP.

Wholesalers deliver significant value to the pharmaceutical supply chain through the logistics, administrative and financial services they provide to manufacturers. For example, with respect to logistics, wholesalers: maintain working inventories of product, monitor and control multiple levels of controlled substances, manage returns and recalls and ensure immediate product availability. Some of the financial and administrative services rendered by wholesalers include: collecting accounts receivable, managing the credit risks, administering contract and chargeback functions on behalf of the manufacturers, and handling significant customer service inquiries concerning products sold. In addition, wholesalers provide valuable inventory, sales and other data to manufacturers which help manufacturers improve their visibility to actual usage of their product by the end user customers and assist manufacturers in more efficient timing of product production. Ultimately, and most importantly, wholesalers work to ensure that Americans have the medications they need when they need them.

Over the last three years, the wholesaler business model has transformed into a fee for service model. In an attempt to provide transparency and visibility to the services rendered by wholesalers, wholesalers have begun charging manufacturers a negotiated fee for the specific services provided to each manufacturer. While there are similarities in some services provided to multiple manufacturers, the overall volume, product mix, specific products, and services desired by the manufacturer are the defining characteristics of the individual services agreement between the wholesaler and a given manufacturer.

Cardinal Health commends CMS for its decision to codify the definition of *bona fide* service fees and the instruction not to deduct those fees when ASP is calculated. We appreciate that CMS has published a Frequently Asked Question regarding service fees, recognizing that these fees would not ultimately affect the price realized by the manufacturer. In spite of the guidance in the FAQ, we have been told by some manufacturers that they are not following this guidance, and we are concerned that this will result in inconsistencies in the manner in which the manufacturers treat *bona fide* service fees when calculating ASP. Excluding *bona fide* service fees from the ASP

calculation will help ensure that physicians do not receive an artificially reduced reimbursement for the pharmaceuticals they administer in their offices.

Equivalent Treatment of Wholesalers and Third-Party Logistics Companies

Cardinal Health strongly endorses CMS's decision to structure the definition of *bona fide* services in a way that treats entities which perform the same services on behalf of manufacturers consistently for the purposes of ASP calculations. Some manufacturers have expressed concern about accounting for the logistical pick, pack and ship services provided by wholesalers without further clarification as to the appropriateness of treating the fees paid for those services as fees for *bona fide* services for purposes of the ASP calculation. One stated reason is that service fees are accounted for differently for financial accounting purposes than for reimbursement purposes. Specifically, manufacturers have expressed the opinion that Generally Accepted Accounting Principles ("GAAP") mandate treating service fees as reductions to revenue when the fees are paid to a wholesaler that takes title to products, as all wholesalers have historically done. Manufacturers are concerned that failure to treat these service fees as a price concession for ASP purposes would create an unacceptable disconnect between the ASP reporting and financial reporting. A number of manufacturers have indicated that they will, therefore, treat service fees as a price concession under ASP in order to maintain continuity with their treatment under GAPP.

This issue is exacerbated by the fact that accounting principles appear to permit fees to be treated as an expense on the income statement (as opposed to a reduction of revenue) when a third party logistics company ("3PL") (as opposed to a wholesaler) is retained to distribute drugs without taking title to the products. We do not believe that there is any rational basis for treating service fees paid to 3PL differently than those paid to a wholesaler for the same *bona fide* service. Deducting service fees paid to wholesalers from the reimbursement paid to providers would result in an unfair or inappropriately lower reimbursement for the provider, given the fact that the service fees are paid to the wholesaler and not the provider. Furthermore, basic economic principles would dictate that manufacturers would want to ensure that the providers who are dispensing their products to patients receive the most favorable reimbursement allowed by law. The failure to do so would place the manufacturer's products at a disadvantage vis-à-vis other products that are in the same therapeutic class but may have a higher reimbursement level. This could discourage providers from utilizing those products with inadequate reimbursement, and as a result, some manufacturers may choose to contract with a 3PL for distribution services rather than use traditional wholesalers to avoid having to deduct the distribution fees from ASP.

There is already precedent for establishing separate treatment for accounting and price reporting rules in government reimbursement principles. Specifically, manufacturer rebate agreements prohibit manufacturers from deducting rebates when AMP is determined. However, the IRS has ruled that Medicaid rebates should be treated as reductions to revenue. Similarly, we believe it is appropriate to calculate ASP without deducting the service fees, even if such fees are treated as a reduction to revenue under

GAAP. To clarify this issue, we urge CMS to expressly confirm in the preamble to the final ASP rule that pick, pack and ship are *bona fide* wholesaler services.

For these reasons, Cardinal Health endorses the portion of the definition of *bona fide* service fee that makes it clear that the determination of whether a given fee paid by a manufacturer qualifies as a *bona fide* service fee under the Proposed Rule does not turn on "whether or not the entity takes title to the drug,". This will level the playing field between entities performing similar services on behalf of the manufacturer, while providing a reimbursement metric that more closely represents the amount paid by the provider for the pharmaceutical.

Definition of Fair Market Value

CMS has asked for input on how manufacturers should determine whether service fee payments represent fair market value ("FMV") for the services rendered. Cardinal Health believes that it is not necessary to precisely define what constitutes FMV in the wholesaler service fee context. The pharmaceutical supply chain is a very well established market with very sophisticated participants. There are multiple national and regional wholesalers, as well as a large number of 3PLs that can service the industry. The distribution service agreements between manufacturers and service providers are negotiated at arms' length between knowledgeable parties, acting to protect their best interests in a very competitive marketplace. In addition, the manufacturers can individually evaluate the cost of distributing their pharmaceuticals directly to the provider. Therefore, we believe that it would be inappropriate to define or restrict how this is done, and we respectfully encourage CMS to consider that there are several mechanisms used to ascertain the FMV for pharmaceutical distribution services when considering the extent to which such mechanisms need to be defined in the final rule.

There have also been questions raised regarding FMV in the context of how the payment for service fees is made to the wholesaler. Currently, under a number of distribution services agreements, the service fees are paid as a percentage of the pharmaceutical volume that the manufacturer distributes through the wholesaler. Many of the cost drivers for wholesalers, including, but not limited to, facility insurance, transportation insurance, security, damage risk and the cost of capital, are based on the value of the pharmaceuticals that the wholesaler distributes. For the majority of the services rendered by a wholesaler, a percentage-based fee model most accurately reflects costs incurred by the wholesaler in rendering the services. Prohibiting this type of model would considerably complicate the system and may result in fees that are not FMV. We assert that, as long as the service fees are for *bona fide* services that are actually performed on behalf of the manufacturer, paid at FMV and negotiated at arms' length between well-educated parties, CMS should not limit the financial arrangement to one specific methodology, but rather allow that decision to be left to the negotiating parties.

We feel strongly about the importance of permitting all forms of FMV payment methodologies, including one that consolidates a variety of services into a single percentage amount. Therefore, we encourage CMS to substitute the words "supply

chain" for the word "itemized" in the proposed definition of *bona fide* service fees. We are concerned that the word "itemized" could be construed as requiring the parties to outline specific fees for each specific service in the distribution agreement.

Providing a Specific List of Wholesaler Services

The pharmaceutical supply chain is constantly changing and evolving in order to meet the needs of the manufacturers, the wholesalers and the provider customers. With the increased criminal activity in counterfeiting, the introduction of new drugs requiring special handling or services, and more innovative technology to increase efficiencies and protect supply chain integrity, it is very difficult to create a list of all of the possible services that a manufacturer may require from a wholesaler. In just the last five years, the industry has changed considerably, and we believe that it will continue to evolve rapidly in the future.

Cardinal Health believes that inserting a comprehensive list of services into the final rule would not only be difficult, but would also limit the innovative services that will evolve over the next few years. Further, as noted above, the specific services that we render under our distribution services agreements vary widely from manufacturer to manufacturer based on their products, the handling they require, the customers that use the product, etc. We believe that a list may unintentionally limit the number of services we can provide and inadvertently increase costs across the supply chain. Therefore, we would prefer that CMS not publish a specific list in the final rule. However, if CMS decides that a list is needed, we would refer you to Exhibit 1 of the HDMA comments and urge the Agency to preface the definition in the preamble of the final rule, or in such other guidance as the Agency deems appropriate, with an introductory statement emphasizing that the list is illustrative and intended to be dynamic and flexible. CMS should then also provide manufacturers and wholesalers with information about how to recommend updates to the list and establish a mechanism for publishing these updates periodically.

No Pass-Through Requirement

The proposed definition of *bona fide* service fees also requires that the service fees "are not passed on in whole or in part to a client or customer of an entity". It is our understanding that many manufacturers are concerned about this phrase, and Cardinal Health respectfully requests that CMS consider clarifying this provision. Specifically, we believe that the regulation should affirmatively state that FMV service fees paid to pharmaceutical wholesalers for distribution services are not to be deducted when ASP is calculated, so long as there is no implicit or explicit agreement between the manufacturer and wholesaler that the fees will be passed on in whole or in part to the wholesaler's customers. This clarification would recognize what we believe is the original intent of the CMS guidance. This additional guidance would allow wholesalers to make independent pricing decisions to their end use customers to meet competitive market conditions without putting manufacturers in the untenable position of trying to regulate wholesalers' interactions with their customers.

Prompt Pay Discounts

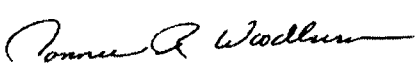
Cardinal Health appreciates CMS's willingness to hear additional comments on the regulations at 42 C.F.R. 414.800 *et seq.* governing manufacturer reporting of ASP. We specifically would like to address the issue of prompt pay discounts to wholesalers.

ASP is the reimbursement metric for Medicare Part B pharmaceuticals. It is intended to be representative of the drug prices available in the market to physicians and other providers who bill drugs to Part B. CMS has instructed manufacturers to deduct customary prompt pay discounts when calculating ASP. These prompt pay discounts are paid by manufacturers to wholesalers, and they represent the time value of money, not a price concession on the cost of the product. In general, a wholesaler's payment terms are negotiated in an arms' length transaction, and the prompt pay discount is paid when wholesalers make timely payments to the manufacturers for the drugs that they purchase. Providing a prompt pay discount is a common practice that is widely accepted across many industries, and they are not price concessions.

When enacting the Deficit Reduction Act, Congress recognized that prompt pay discounts were a financial transaction representing the time value of money. In order to better match drug reimbursement to the pricing available to retail pharmacies in the marketplace, Congress made a critical change to the Average Manufacturers Price ("AMP") calculation by deleting the instruction requiring manufacturers to deduct customary prompt pay discounts when the manufacturers calculate AMP. We encourage CMS to reevaluate the treatment of prompt pay discounts paid to wholesalers under ASP and follow the policy outlined by Congress for AMP. The prompt pay discounts paid in both situations are exactly the same, and both ASP and AMP are designed to reflect prices paid by the provider. Therefore, we believe that the treatment of prompt pay discounts should be the same in both circumstances.

Thank you for giving us this opportunity to provide our comments on the Proposed Rule, and to endorse the comments submitted by the HDMA. We hope these comments are constructive in your deliberations to develop an ASP calculation that represents an equitable and reasonable approach to reimbursement for the products we distribute.

Sincerely,



Connie R. Woodburn
Senior Vice President, Professional & Government Relations
Cardinal Health

Submitter : Ms. Alice Smith **Date:** 10/10/2006

Organization : EPOCH Senior Living

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Mr. James Giger **Date:** 10/10/2006

Organization : Systematic Management Systems

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-792-Attach-1.DOC

#792

Reference File Code CMS-1321-P
Section (N) Public Consultation for Medicare Payment for
New Outpatient Clinical Diagnostic Laboratory Tests
Subsection (3) Other Laboratory Tests
Provision (b) Blood Glucose Monitoring in SNFs

BACKGROUND

As identified by the House, Ways and Means Committee Report and finalized by the Conference Committee Report (copies attached) Section 4554 of the Balanced Budget Act of 1997 (BBA-1997) the Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests (Committee) was formed to develop National Policies for the Medicare Part B Clinical Laboratory Tests Benefit.

Congress' statutorily mandated establishment of the Negotiated Rulemaking Committee, in essence, preempted the field of payment and coverage for the Medicare Part B laboratory benefits. The Committee's National Coverage Determinations and Administrative Policies became binding on the Secretary (HHS) in accordance with Section 4554(b) of the BBA-1997 no later than January 1, 1999.

As published in the Federal Register on November 23, 2001 pursuant to Section 4554(b) of the BBA-1997 and subject to a Final Agreement of the Committee dated August 31, 1999 (copy attached), 23 national policies were developed by the Negotiating Committee. These national policies were designed to promote uniformity and integrity through universal simplified administrative requirements to be followed for all laboratory covered services without any differentiation/distinction as to where the services were provided. (See attached synopsis of Committee's key applicable Final Administrative Policies for Clinical Diagnostic Laboratory Tests)

One of the Negotiated Rulemaking Committee's 23 National Policies (commonly referred to as a National Coverage Determination or NCD) addressed Blood Glucose Testing. This often utilized laboratory service is universally accepted as needed to be performed (up to several times a day) for a Medicare Part B beneficiary who is afflicted with **diabetes** or similar illness/medical condition. (Copy of the final NCD for Blood Glucose Testing is attached)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)
AUGUST 22, 2006 PUBLICATION OF PROPOSED RULE
BLOOD GLUCOSE MONITORING IN SNFs

CMS states that the purpose of its publication contained in the Federal Register dated August 22, 2006 is to take an opportunity to restate its long standing policy on coverage of blood glucose monitoring services and proposes to codify physician certification requirements for blood glucose monitoring in SNFs.

Prior to the issuance of Program Memorandums AB-00-099 (August 24, 2000) and AB-00-108 (December 1, 2000) CMS published that it had no national policy for blood glucose testing (monitoring). The issuance of these two instructions were the initial publications issued by CMS to its Medicare contractors.

The above instructions were issued despite CMS' (HHS) confirmed concurrence with the proposed rule provision published by the Committee (Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests) in the Federal Register dated March 10, 2000. The Committee's unanimous agreement precluded any participant from taking any action to inhibit the proposed regulation as final and published by the Department of Health and Human Services (HHS) through the Health Care Financing Administration (currently known as CMS).

In PM AB-00-108, CMS, addressing laboratory services, restates Section 1862(a)(1)(A) of the Social Security Act requirement that the service needs to be reasonable for the diagnosis and treatment of an illness in order to be covered by Medicare. CMS cites 42 CFR 410.32 and 411.15 for the proposition that the physician must order the test/service and use the result in the management of the beneficiary's specific medical problem. However, CMS went further to include the following additional requirement: **"Implicitly, the laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care; this includes the physician order for another laboratory service."** Clearly by their own terms, CMS confesses that the statute or regulations do not require such criteria in order for a SNF to perform a treating physician ordered subsequent laboratory test.

We are submitting the comment below as part of our objection to the proposed rule by CMS which is based on previous publications that are in conflict with or unsupported under the Congressionally binding Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests' NCD and Administrative Policies.

COMMENT

Pursuant to the proposed rule section which is identified and entitled *Blood Glucose Monitoring in SNFs*, the apparent main purpose of this rule reflects a direct attempt to evade the payment of blood glucose tests ordered by and used by the treating physician in the management of a Medicare Part B resident who is afflicted with diabetes. The order for specifically scheduled multiple (repetitive) testing issued by the treating physician based on his knowledge of the patient's overall medical condition is not a standing order. Several physicians representing the entire SNF industry nationwide have clearly explained this to CMS in a written communication dated April 5, 2001.

CMS has published in December, 2000 (program memorandum) its acknowledgment that blood glucose testing several times a day is common in order to maintain tight control of glucose levels in order to prevent both debilitating and life threatening conditions for a confirmed diabetic (i.e. both reasonable and necessary).

Further, CMS has clearly demonstrated its own misunderstanding of what constitutes a "standing order" versus an order for planned and scheduled repetitive/multiple tests. This clear misuse of the phrase standing order has been mistakenly applied by Medicare contractors.

In diabetes management "standing order prescriptions" are non-patient specific and are designed to control situations where abrupt unplanned conditions arise. Multiple repetitive testing on the other hand is a planned schedule of testing to be performed as determined by the treating physician in his overall management of a patient, including the monitoring of the blood glucose test results performed by SNF personnel and his subsequent changes in the treatment of the patient.

Additionally, the CMS proposal that a standing order (where they occur) is not sufficient to order multiple tests or a series of tests directly conflicts with both the superior authority of and as contained in the HHS Compliance Program specifications, the applicable CLIA regulations and the Congressionally mandated Negotiated Rulemaking Committee's statutory Administrative Policies.

Submitted by:
James J. Giger

October 10, 2006