ASTRO
American Society for Therapeutic Radiology and Oncology

December 17, 2007

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

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008 (CMS 1385-FC)

Dear Mr. Weems:

The American Society for Therapeutic Radiology and Oncology (ASTRO)[1] appreciates the opportunity to provide written comments on the "Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" published in the *Federal Register* as a final rule with comment on November 27, 2007. Our comments focus on issues related to: (1) The CY 2008 update and the Sustainable Growth Rate (SGR); (2) the Physician Quality Reporting Initiative (PQRI); (3) the Physician Assistance and Quality Improvement Fund; (4) physician self-referral and the in-office ancillary services exception; and, (5) RUC recommendations and interim work RVUs for new CPT codes.

I. The CY 2008 Update and the Sustainable Growth Rate (SGR) (72 Fed. Reg. 66373)

In the CY 2008 proposed rule, CMS estimated the fee schedule update factor for 2008 would be reduced by 9.9 percent. In our comments on this estimate (and in many previous comments), we described the flaws in the SGR formula. Consistent with the position of the American Medical Association (AMA), we identified several steps that should be taken that would significantly reduce the costs associated with a permanent legislative fix to the Sustainable Growth Rate (SGR) formula. Most importantly, we recommended that CMS remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996.

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[1] ASTRO is the largest radiation oncology society in the world, with more than 9,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing healthcare environment.

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In the final rule, CMS rejected our recommendations and announced that the conversion factor for 2008 would be reduced by 10.1 percent from $37.8975 to $34.0682. If these cuts begin on January 1, 2008, average physician payment rates will be less in 2008 than they were in 1995, despite substantial practice cost inflation. These reductions are not cuts in the rate of increase, but are actual cuts in the amount paid for each service. Physicians simply cannot absorb these severe payment cuts and, unless CMS or Congress acts, physicians will be forced to reevaluate their relationship with Medicare and will be forced to avoid, discontinue or limit the provision of services to Medicare patients.

In the final rule, CMS indicated that many of the comments they received suggesting administrative changes were statutorily difficult, and according to their current estimates, would not provide relief from the projected negative updates for the next several years. While the administrative changes may be statutorily difficult, they are not impossible. Also, even if the changes did not provide immediate relief, the cost of fixing the problems associated with the SGR and update formulas would be reduced, making it easier for a legislative fix. We again recommend that CMS remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996.

II. Physician Quality Reporting Initiative (PQRI) (72 Fed. Reg. 66336)

ASTRO strongly supports increasing attention on quality measurement to help physicians evaluate areas in their practice where improvements to patient care can be made. We were extremely disappointed by CMS' decision not to include the full oncology measure set in the 2008 Physician Quality Reporting Initiative program which includes measures to evaluate and provide a plan of care for patients experiencing pain. We recommend the adoption of these measures at the earliest possible date. We also continue to urge CMS to recognize the American Medical Association's Physician Consortium for Performance Improvement (AMA-PCPI) as the only entity for the development of physician-level quality measures. We look forward to working with CMS as it continues to refine this program.

III. Physician Assistance and Quality Improvement (PAQI) Fund (72 Fed. Reg. 66357)

Section 101(d) of Division B of the Tax Relief and Health Care Act of 2006 - Medicare Improvements and Extension Act of 2006 (Pub. L. 109 432) (MIEA-TRHCA) requires that the Secretary establish a Physician Assistance and Quality Improvement Fund to be available for physician payment and quality improvement. The statute appropriates $1.35 billion for this purpose in 2008. In the CY 2008 proposed rule, CMS proposed to use these funds to extend for another year the Physician Quality Reporting Initiative (PQRI) on the same basis as has been in place for the last 6 months of 2007. Funds from the PAQI Fund would be used to pay bonuses to physicians (in 2009) who satisfy the 2008 reporting performance standards.

In our comments on this proposal, ASTRO urged CMS to use the $1.35 billion available in the Physician Assistance and Quality Improvement Fund to buy down the deleterious effects of the proposed 9.9% payment cuts (now 10.1%) scheduled to take effect January 1, 2008. We expressed our belief that the CMS proposal was counter to the intent of Congress and the recommendation of the Medicare Payment Advisory Commission. In the final rule, CMS announced its decision to finalize its proposal.

We remain opposed to this decision. We continue to believe that CMS should overcome the "legal and operational" problems associated with applying the funds to the negative update, as the dire situation posed by the harmful cuts surely prevails over the potential obstacles. For example, CMS could explore applying the $1.35 billion to past years' SGR debt. This would reduce the slated cuts to the 2008 conversion factor. We believe it is more appropriate for CMS to use the funds to buy down the pending negative update than it is to use the funds to pay for a future quality reporting program whose value has not been studied, let alone demonstrated. While we prefer to use the PAQI fund to help address the update problem, radiation oncologists and our physician colleagues are committed to providing the highest level of quality care regardless of any financial incentive and we support continuation of the PQRI program with physician participation on a voluntary basis.

IV. Physician Self-Referral Provisions: In-Office Ancillary Services Exception (72 Fed. Reg. 66372)

In the CY 2008 Physician Fee Schedule (PFS) proposed rule, CMS proposed several revisions to the physician self-referral regulations. CMS received approximately 1,100 pieces of correspondence in response to these proposals and announced in the final rule that they would not finalize any of the proposals (except for the proposal for anti-markup provisions for diagnostic tests) in this rule (the CY 2008 PFS final rule). CMS also announced its intention to finalize revisions to the physician self-referral regulations at a later time "without the need for new proposals and additional public comments."

In the CY 2008 PFS proposed rule, CMS also solicited comments regarding potential changes to or limitations on the use of the in-office ancillary services exception specified in § 411.355(b) of the regulations. ASTRO is pleased with CMS' recognition and interest in revisiting the extent to which the in-office ancillary services exception ("IOAE") has come to be misapplied in practice well beyond Congress' original intent. As we articulated in our comments on the proposed rule, ASTRO believes the protection of radiation therapy services under the IOAE has led to the proliferation of business arrangements where profits have become exalted over patient care. Further, the key health care policy concerns which the Stark Law was initially intended to address – medical decisions being made based on financial interest, higher costs, increases in unnecessary services, and less patient choice – are in fact being disserved. As such, ASTRO believes radiation therapy services should be exempt, or carved out of, those designated health services which qualify for coverage under the IOAE. A copy of our previously submitted comments on this issue is attached at the end of the letter for easy reference. We look forward to working with CMS as it considers revisions in this area (Attachment A).

V. RUC Recommendations and Interim Work RVUs for New CPT Codes

1. Interim Relative Value Units (72 Fed. Reg. 66360)

For CY 2008, CMS received work RVU recommendations for 169 new and revised CPT codes from the RUC and seven recommendations from the Health Care Professional Advisory Committee (HCPAC). Included with these recommendations were three codes of importance to radiation oncology. The RUC recommendations and the CMS decisions for these codes are shown in the table below:

Code	Descriptor	RUC Recommendation	CMS Decision	2008 Work RVUs
20555	Place ndl musc/tis for rt	6.00	Agree	6.00
41019	Place needles h&n for rt	8.84	Agree	8.84
55920	Place needles pelvic for rt	8.31	Agree	8.31

ASTRO supports the RUC recommendations and we appreciate the CMS decision to accept those recommendations. The RVUs, which will be interim in 2008, should be made final for the CY 2009 fee schedule.

Conclusion

Thank you for the opportunity to comment on this final rule. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Marsha Kaufman, MSW, ASTRO Assistant Director of Health Policy at (703) 839-7300.

Respectfully,

Laura Thevenot

Laura Thevenot
Chief Executive Officer

cc: Ken Simon, M.D.
Edith Hambrick, M.D.
Rick Ensor
Ken Marsalek
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Attachment

Attachment A: ASTRO Comments on the In-Office Ancillary Services Exception[2]

ASTRO is particularly pleased with CMS' recognition of the extent to which the in-office ancillary services exception ("IOAE") has come to be misapplied in practice well beyond Congress' original intent. ASTRO's membership has for some time raised concerns specifically with respect to the relationship of the IOAE to radiation therapy services.

While, as CMS notes, previous commenters have warned CMS that the exception has always been "susceptible to abuse," the recent liberalization of the "centralized building" and other IOAE qualifying criteria have encouraged physicians and physician groups to use the exception to cover services in no way "ancillary" to the physician service which initially brought the patient in for care. Based on the IOAE, physician business models have evolved – often with the involvement of for-profit operators/owners – that have permitted certain physicians to benefit not only from the in-group "ancillary" revenues from the specialized services they are able to capture, but also to seek to capture profits from all services they can bring into their group practice with the force of their referral power. Some are also drawn into the use of highly specialized equipment these physicians are able to "lease" to themselves. The result is that these arrangements can and do lead to distortions in the healthcare marketplace that result in over-utilization and over-referral, higher costs, the potential for lower quality and inappropriate care, a reduction in patient choice, and a pernicious and unhealthy narrowing of the healthcare marketplace. Radiation therapy services present perhaps the most disturbing example of how the IOAE has truly become "the exception that has swallowed the rule" and in so doing eviscerated the Stark Law's original intent.

ASTRO is therefore grateful at this time for CMS' recent recognition of the potential problems that have arisen in this area. We were especially pleased to see that CMS appears to share at least some of ASTRO's concerns in this regard. While these concerns already appear well-placed and warrant immediate corrective action, ASTRO understands that at this juncture CMS does not propose changes in the IOAE itself. Instead, CMS has asked for input on whether *inter alia* a) certain designated health services ("DHS") ought not to qualify for coverage under the IOAE, and b) certain non-specialists should be able to use the exception to refer patients for specialized services provided by specialists and involving the use of equipment owned by the non-specialists. As providers of the specialized service of radiation oncology, ASTRO's members are pleased to respond to these inquiries.

In response to CMS' inquiries, ASTRO's position is as follows:

1. "Radiation therapy services" are not "ancillary services" (i.e., services that are subordinate or auxiliary), and therefore should not be included in the group of DHS which qualify for coverage under the "in-office ancillary services" exception. The inclusion of radiation therapy services on the list of DHS qualifying for IOAE protection is inconsistent with the original intent of the law and with the policy goals intended to be furthered thereby.

2. Permitting physicians without significant training in radiation oncology to refer patients for radiation therapy services, from which the non-radiation specialists will benefit financially, has and will result in abusive arrangements. ASTRO has mounting concerns that these arrangements

[2] Originally submitted on August 20, 2007 as comments on the CY 2008 Physician fee Schedule Proposed Rule (CMS-1385-P)

will lead to increased utilization, questionable quality and inappropriate care, increased costs, reduction in patient choice and access, and will also impact negatively on the healthcare marketplace.

3. "Radiation therapy services" should therefore be excepted from, or carved out of, those DHS which qualify for coverage under the IOAE.

The In-Office Ancillary Services Exception Should Apply Only to Those Services That Are Subsidiary to the Primary Physician Service the Patient is Seeking. Radiation Therapy is Not Such an "Ancillary" Service.

The legislative history leading up to the establishment of the statutory IOAE is very clear. Only two types of services were originally intended by Congress to be covered by the exception, that is, services that *supplement* or are *subsidiary* to the service that brought the patient to the physician's door originally. As Congressman Stark himself testified in 1989:

> *The exception would most commonly apply* ***to in-office lab tests or x-rays.*** *The exception reflects a judgment that there is often a clear need for* ***quick turn-around time on crucial tests.***[3] (Emphasis added.)

Years later, in drafting its own Stark I regulations, CMS itself commented upon and endorsed Congress' purpose in establishing the in-office ancillary exception:

> *First, Congress clearly was concerned with regulating physicians' ordering of DHS, even in the context of their own practices; otherwise, a detailed exception would not have been necessary. Second, the Congress intended to protect* ***some*** *in-office ancillary* ***services provided they were truly ancillary to the medical services being provided by the physician or group.***[4] (Emphasis added.)

Thus, not only the literal language of the exception itself, but the statute's underlying Congressional intent, as well as CMS' own commentary, reflect a clear understanding and expectation that only a limited scope of services would qualify for IOAE coverage. Services intended to be covered were only those *integral* to the *medical service* for which the patient was *then seeking* treatment, and those that needed to be performed in a timely manner to ensure a "quick turnaround" so that the physician can properly and thoroughly perform his or her core medical service on that patient.

"Radiation therapy services" do not qualify on any of these grounds. These services should never have been included as an "ancillary service" for which the exception applied. Instead, radiation therapy services occupy a distinct, clearly distinguishable "next step" from any other physician's treatment and care of cancer patients. These services are neither "ancillary" to the diagnostic and/or general medical services performed by any other physician, nor is their provision essential to the comprehensiveness or quality of the patient care provided by any other physician during a patient visit. As such, radiation therapy services stand in sharp distinction to diagnostic imaging services such as x-ray, MRI, CAT scan

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[3] 135 Cong. Rec. H240-01 at 6 (Feb. 9, 1989).
[4] 66 Fed. Reg. 856, 881 (Jan. 4, 2001).

or laboratory test, which all may inform and guide the physician's clinical care at the time a patient is being treated.

In contrast, the decision for a patient to receive radiation therapy treatments is usually made after a series of physician consultations. For example, a patient who has symptoms associated with prostate cancer is referred to a urologist by a primary care physician. The prostate cancer diagnosis is confirmed by the urologist and the pathology report. The patient is then referred by the urologist to consult with other specialists such as a radiation oncologist (who is expert with radiation therapy) and a medical oncologist (who is expert with chemotherapy agents). Depending on the stage and histology of the cancer and the patient's general medical condition, each specialist examines the patient, reviews the patient's diagnostic studies, discusses the case with the patient and his family and finally makes recommendations as to the treatment he/she believes to be the most appropriate for that specific patient. Potential treatment options include prostatectomy, brachytherapy, external beam radiation, chemotherapy, some combination of the aforementioned treatments, or watchful waiting. Radiation therapy, surgery and chemotherapy are all primary cancer therapies and none of them are "ancillary."

Thus, in "referring" a patient for radiation therapy services, the treating physician is concluding simply that the patient's condition requires the clinical expertise and input of another physician before another altogether distinct treatment modality is next applied. The "referring" physician is specifically acknowledging that the patient's clinical needs require the evaluation, care and treatment of a radiation oncologist. The "referral" is thus from one physician to another – not to an "ancillary service." Once referred, based entirely on the knowledge and experience of the radiation oncologist – the only specialist who has completed a four-year residency in the specialty and who can truly determine whether radiation therapy is appropriate, and if so, its nature and extent – the patient then may embark upon a wholly unique course of sophisticated treatments, planned and supervised by specialists expert in the sophisticated techniques of radiation therapy.

In short, radiation therapy services occupy a distinct service level on the cancer treatment continuum. The provision of these services result from the "referral" from one physician to another physician – not to an "ancillary service." Sweeping "radiation therapy services" into the IOAE's "ancillary" coverage is wholly inconsistent with Congress', CMS' and Rep. Stark's intentions in the original crafting of this exception.

The IOAE Protection of Radiation Therapy Services Has Led to Abuses and Hampered the Achievement of Laudable Health Policy Goals.

Had the IOAE remained appropriately focused on truly "ancillary" services, physician group practices would be able to utilize the exception only to assure the availability of those services essential to treating patients in a high quality, comprehensive fashion within the context of a primary care setting. However, the evolving elasticity of the IOAE has enhanced the ability of some physicians to gather under their group practices services (and revenues) from a wholly separate and distinct treatment setting, thereby creating the establishment of financially integrated, but service distinct practice environments.

More specifically, the attractiveness of folding radiation therapy services into a group practice's core business through use of the IOAE has not gone unnoticed by financially aggressive physicians or certain for-profit companies. These companies have established lucrative business models – and attracted

physician participants to these models – based on dropping turnkey radiation therapy services into these groups, permitting the sharing of the revenues from the "captured" radiation therapy revenues and the equipment leases related thereto. The following example of how ASTRO has seen this model work in practice – time and time again – will serve as a basis for setting forth ASTRO's legal and policy concerns with this method of exploitation of the IOAE:

- A for-profit company will target the premier urology group since they are the gatekeepers to referral and treatment for patients with prostate cancer in a community and offer to provide a "turnkey radiation oncology service." The proposal will focus on using their market power as the gatekeeper to bring into the urology group practice radiation therapy services for patients with prostate cancer.

- The for-profit "pitch" will emphasize the increase in revenues the urology group will attain by capturing these referrals within the group's business structure. The pitch may also include an opportunity for the physicians to joint venture in an equipment leasing company which will lease the radiation therapy equipment "to" the group.

- The company will recruit a radiation oncologist – usually from an existing radiation oncology center – to provide the radiation therapy services for the urology group. The radiation oncologist will not be offered ownership in the business, but will be paid via a services contract only.

- The radiation therapy services will typically be set up in a location separate from the urology practice (a "centralized building"). The radiation oncologist and his/her technical staff will function separate and apart from the group on a day-to-day basis. There is little or no integration of the physicians, staff, locations or services.

- The urology group benefits from the revenue flowing from its referrals and, if available, the equipment lease. The for-profit company may share in those revenues directly and/or through its share of the equipment leasing fees, as well as through a management fee.

This business model – increasing in prevalence at a rapid rate – presents the sort of potentially abusive relationships CMS is rightfully concerned about, and which the IOAE has spawned. The model poses the following hindrances to achieving laudable health policy goals:

Patient Choice

By setting up a business model that holds the radiation oncologist captive to the referral, cancer patients are denied the independent judgment and choice they need and deserve in making life and death decisions. Further, the patient does not understand how the referring physician's deriving a financial benefit from the referral potentially impacts the involved physician's judgment and recommendations.

Quality of Care

The quality of care may suffer because the model focuses on only a single cancer specialty and a single treatment modality. The only radiation therapy services of interest to a urology group practice will be those focused on the treatment of prostate cancer. In the model described, only one type of radiation

therapy service – Intensity Modulated Radiation Therapy ("IMRT") – is typically offered for prostate cancer patients because of its reimbursement. Thus, while a typical comprehensive radiation treatment center may offer its prostate patients alternative radiation therapy treatment options, i.e. low or high dose brachytherapy, radionuclide therapy, etc., this business model results in the urologist overwhelmingly recommending IMRT for his or her patients.

Not only does this business model pose the risk of restricting the type of radiation therapy a patient might be offered, there is the added risk that alternative prostate cancer treatment options aside from radiation might not be fully explored with these patients. For example, it is often the case with prostate cancer that "watchful waiting" prior to any proactive treatment might be the most prudent course of treatment. With the substantial financial return that a urology group can realize on IMRT treatments, however, the risk is not insignificant that a urologist's clinical judgment would be skewed by financial considerations toward recommending IMRT – the most costly form of radiation therapy – over other potentially appropriate alternatives.

Quality of care may also suffer as radiation therapy service components are pulled piecemeal from more comprehensive settings into smaller, one dimensional treatment settings. Providing radiation therapy on a group-by-group basis can create a number of smaller, less utilized, therapy services, and threaten the ongoing existence of more comprehensive, highly utilized centers with the capacity to offer additional supportive services such as social work, nutritional services, etc.

Access to Services

Access to care issues are also exacerbated by this model when its overall effect on the healthcare marketplace is considered. In a recent situation illustrating this point, a well-regarded radiation oncology group in the state of New York has fallen victim to sophisticated efforts to take advantage of the IOAE to capture radiation therapy revenues. A radiation oncology group operates a radiation oncology center a half a block from a community hospital which has no radiation therapy capabilities and that has depended on this center for those services. The radiation oncology center offered state-of-the-art and capital intensive equipment. The group offers a full range of curative and palliative radiation therapy treatments for patients with a variety of cancer types (i.e., breast, prostate, colon, etc.).

The practice is the sole provider of radiation oncology services for referrals from the local hospital. This practice historically received approximately 35% of its referrals – prostate cancer referrals – from the urologists in town. These prostate cancer referrals were critical to the ongoing viability of the radiation oncology practice and to its ability to continue to provide the full spectrum of therapy services described above with state-of-the-art technology.

A urology group recently approached the radiation oncologists to advise that they would cease referring prostate patients and instead the oncologists should "sell the practice" to the urologists. Given the high percentage of the oncologists' patient base that came from the urologists' referrals, the radiation oncologists recognized that failure to acquiesce in the sale would likely result in the collapse of their practice, to their detriment and that of the community.

Such was the market power of the urology group that the radiation oncologists were compelled to sell. The radiation oncology services will become those of the urology practice, for whom one of the group's

oncologists will now work. The New York community in question now faces the conversion of this radiation oncology center and the loss of readily accessible radiation therapy services for all the non-prostate cancer patients normally served at the center. Moreover, the prostate cancer patient population in this community is now left with one single resource for cancer treatment services – the urology group – and with an overwhelming preference for a single therapy treatment approach – IMRT.

ASTRO has received a growing number of reports of similar tactics undertaken by large urology practices around the country. In each case non-radiation oncologists seek to control specialized clinicians and specialized equipment so they can capture the revenues from the specialized services they had previously referred to independent groups. In each case, if successful, reductions in quality, patient choice and access are likely to occur, and costs will rise.

Continuity of Care Issues

ASTRO anticipates that those who have benefited financially from the ability of urology groups and other physician groups to control radiation therapy services and their revenues within their groups, through use of the IOAE, will assert that "continuity of care" or "comprehensiveness of care" is furthered in such a model. These assertions are belied in practice by the lack of integration which occurs when turnkey radiation oncology services are "dropped in" to the existing group practice. The radiation therapy service is typically provided in a separate "centralized" building separate from the group's core practice; the radiation oncologist(s) is typically on contract with the group, but is not a partner or owner of the group; technical staff report to the radiation oncologist, not the group's other physicians.

The notion that "continuity of care" is the driving force in the creation of the financially lucrative business models created when radiation therapy services are dropped into a urology group practice is also belied by the marketing material produced by one national for-profit purveyor of this approach. Quoting from that company's own website, the following "Frequently Asked Questions" and their responses are telling:

> ***Why should we integrate radiation oncology into our practice?***
>
> In light of decreasing LHRH and rising overhead, urologists need to seriously begin considering new revenue sources, and there is no better revenue source available to urologists than IMRT. In fact, the opportunity cost associated with IMRT is very high.

Every month that a group with the necessary critical mass delays in developing a center is potentially a loss of over $500,000 of gross revenues PER month.

> ***What is the breakeven point for an IMRT center?***
>
> The breakeven point would be 4 new patients per month. This would approximately yield each of the 14 physicians an annual return of $8,600. However, the more typical rate of new patients per physician is between 1 and 2 new patients per month. With a new patient rate of 1 per physician, the projected annual return per physician is approximately $255,000 per physician. At an average rate of 1.5 new patients per month, the projected annual return per physician is over $425,000. These projections are based on current prevailing Medicare reimbursement.

Continuity of care has taken the proverbial backseat to the real driving force behind this model. Instead, economic gain is the answer to the question "why integrate," *not* quality or continuity of care.

It is indeed ironic, given the Stark Law's core purpose that the IOAE now actually serves as a catalyst for revenue-producing schemes heretofore unheard of. Today, under the current regulatory framework, there are truly no serious barriers to physicians and physician groups enjoying fully the benefits of their DHS referral revenues. Clever physicians and their business and legal advisors no longer see the Stark Law as a serious regulatory problem to overcome, but as a simple IOAE-based puzzle to solve, the solution of which can lead to precisely the "referral based on financial incentive" behavior the Stark Law was intended to eliminate.

ASTRO appreciates the opportunity to comment on the current state of the IOAE and how it should be changed. Simply put, the exception has grown far beyond the original intent of Congress and CMS itself, that is, as a safe harbor to protect those services closely and directly related to the underlying purpose of the patient visit – lab tests, x-rays, etc. Radiation therapy neither was nor is that sort of "ancillary" service. ASTRO strongly believes that the law should no longer allow for the establishment of business models which are based upon rewarding physicians solely for the referral of a patient.

Based on our analysis of the exception's original intent, ASTRO is convinced that "radiation therapy services" should be explicitly excluded from the list of designated health services for which the in-office ancillary services exception may apply.

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MOHS MICROGRAPHIC SURGERY
CUTANEOUS ONCOLOGY
SKIN SURGERY

December 17, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-FC
Mail Stop C4-26-05
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Re: CMS 1385-FC: 2008 Medicare Fee Schedule
Coding – Multiple Procedure Payment Reduction for Mohs Surgery

As a Mohs surgeon I am deeply concerned about the proposed rule to remove Mohs surgery from the Multiple Procedure Reduction Rule (MPRR) exemption list. This proposal represents a dramatic reversal of sixteen years of the Centers for Medicare and Medicaid Services' (CMS) own determination that the Mohs codes are and should be exempt from the MPRR. I believe this proposal will negatively impact Medicare beneficiaries' access to timely and quality care. In addition, application of this proposal will not likely generate significant cost savings and may paradoxically increase costs of providing care to these patients.

I have three main areas of concern with applying a 50% reduction to Mohs Micrographic Surgery.

1. In instances where the primary Mohs code (17311 or 17313) is reduced, the associated add on codes (17312 or 17314) will be more highly valued than the primary codes. As the value of the add on codes has already been determined to reflect the fact that less work is involved in the add on code, it appears inconsistent to value the primary code below the add on code. In no other family of codes in the integumentary system does this phenomenon exist, this making the reduction of the Mohs codes a true anomaly.
2. The application of a 50 % reduction is not appropriate given the amount of intraservice work in the Mohs codes. In my practice, at least 80% of the total work is repeated when a second Mohs procedure is performed. Therefore, reducing the value of this code by 50% would significantly undervalue the code when utilized a second time.
3. The application of a 50% reduction to either the Mohs surgery code or an associated reconstruction code will drive the value of the code below the cost of providing the service, thus limiting my ability to effectively care for Medicare patients.

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

Respectfully,

Brent R. Moody, MD, FACP, FAAD

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:LLOW AMERICAN COLLEGE OF MOHS SURGERY

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December 20, 2007

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

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

Dear Mr. Weems:

The American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) *Final Rule* on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year 2008, published in the November 27, 2007 *Federal Register*.

RUC's Recommendations to Correct Misvaluations within the RBRVS

As you are aware, the Medicare Payment Advisory Commission (MedPAC) and others have recently criticized the perceived misvaluation within the Resource-Based Relative Value Scale (RBRVS), particularly for services driven by technology. The RUC, which is sometimes unfairly assigned blame for inaccuracies within the RBRVS, has submitted several key recommendations to CMS to improve this payment system. These recommendations were fully detailed in the RUC's comment letter to CMS' *Proposed Rule*, published in the July 12, 2007, *Federal Register*. We believe that CMS has failed to seriously consider these recommendations to date. We are encouraged that more recent public statements by CMS indicate a willingness to consider the pending RUC recommendations in future rulemaking. We urge you to do so and will continue to develop data and rationale to support this effort. For nearly two decades the RUC, comprised of physicians and health care professional volunteers, has dedicated itself to the improvement of the RBRVS. We hope that we share a mutual goal to ensure that the RBRVS payment system is fair and accurate in its relativity. We must work together to make certain these improvements are appropriately considered and implemented.

A summary of the pending RUC recommendations are as follows:

- *Equipment Usage Percentage Assumptions* - The RUC has consistently recommended that the existing 50% standard utilization rate for all equipment is not an accurate measure. CMS should consider using a higher rate for all equipment, providing an opportunity to specialty societies to provide data to support lower utilization rates, if appropriate, based on clinical or geographic considerations. An increase in the utilization rate should redistribute practice expense relative values to all services within the RBRVS.

- *Equipment Interest Rate Assumptions* – The RUC's principal objection is that CMS had not reviewed the interest rate assumptions since the inception of resource-based practice expenses in 1997. The prime rate fluctuated between 4% and 9.5% in the past ten years. In addition, CMS has never provided a clear explanation of the exact method of determining the interest rates, although it appears that the Small Business Association's maximum rates have been utilized. Commenters have suggested that prime plus two percent would be appropriate. CMS merely stated that prime plus two is currently 11.5% (9.5% +2%) and compares well to the current CMS assignment of 11%, without explaining the method the agency originally used to determine the interest rate. The RUC also noted inconsistencies in the assumptions for loan cost related to equipment costs and useful life of equipment. CMS did not address the RUC comments on either of these two issues. We encourage you to review our August 27, 2007, letter again as you consider interest rate computations in future rulemaking.

- *Pricing of High Cost Disposable Medical Supplies* – The RUC has repeatedly recommended that high cost disposable medical supplies (priced at or above $200) should either be reported separately with HCPCS II codes or individually identified within the payment bundle and then re-priced on an annual basis. CMS reaction to the RUC's recommendation is particularly disappointing. CMS states that it will not review pricing as "any annual repricing of these supplies [disposable medical supplies at or above $200] would place undue burden on specific physician groups."

  The RUC believes this claim is unjustifiable. After a careful analysis of the medical supplies that are priced at or above $200, the RUC determined that there are a total of 53 supply items that fall into this category. Attached is a spreadsheet that lists these 53 items, their prices, the procedure codes with which they are utilized and the top specialty that performs these procedures. After reviewing this list, it became evident that the task of reviewing and potentially re-pricing these items on an annual basis would not place an undue burden on the specialty societies as 1) the current CMS requirement to provide the cost of a supply is to provide the agency with a single invoice and 2) the specialties with the largest number of supplies on this list were diagnostic radiology (thirteen items) and urology (nine items). As such, we do not believe that it would be an undue burden placed

on these societies and the other specialty societies enumerated on this list to provide one invoice for each of their supply items on this list to CMS on an annual basis.

Further, the maintenance of this policy has other detrimental effects. In the *Final Rule*, CMS disagreed with the RUC recommendation and a clinical research study that 1 stent is utilized in transcatheter placement of stent(s) (CPT codes 37205). CMS concluded to amend the practice expense database to reflect 1.5 stents for 37205, a compromise between the RUC's recommendation, clinical research studies and other information provided by commenters that suggested 2 stents would be appropriate. The stents used in these services are currently priced at $1,645, as indicated on the aforementioned list. By not updating these costly supplies on an annual basis, not only will the supply item be potentially over-valued over time, but the supply cost will be overstated each time a single stent is used. The RUC considered this scenario when it recommended that CMS develop separate HCPCS Level II supply coding for these very high cost medical supplies. CMS has made clear, both in the *Final Rule* and in separate communications, that it will not develop separate coding. At a minimum CMS must make sure the pricing for these supplies is accurate and updated on an annual basis.

The refusal to update these supplies on an annual basis could result in distorted relative valuation for these services compared to other physician services. We believe that this action by CMS perfectly illustrates the situation that the RUC is unfortunately enduring. While the RUC has clearly put forward a significant recommendation to address and prevent potential misvaluations in the RBRVS, CMS has decided to ignore the RUC recommendation for specialty society convenience.

- *Professional Liability Insurance (PLI) RVUs* - In the July *Proposed Rule*, CMS indicated that "we would like to better understand how, and if, technicians employed by facilities purchase PLI and how their professional liability is insured. In addition, we are soliciting comments on what types of PLI are carried by facilities that perform technical services."

  In the *Final Rule,* CMS indicates that the agency will not make any changes to the technical component PLI relative values as no data are available. We are not aware that CMS received any evidence that separate professional liability insurance is typically purchased for technicians. In absence of any submitted evidence, and in receipt of a recommendation from the RUC that these policies are not typical, we are perplexed that CMS did not accept the RUC recommendation to eliminate the PLI relative values for the technical component and redistribute these PLI relative values across all physician services. This recommendation from the RUC received a unanimous vote.

CMS was required to publish resource-based PLI relative values in 2000, however the technical component PLI valuation remains charged based. It has distorted relativity in the PLI component for eight years and it is time that CMS take this component of the RBRVS seriously. Although, it is less than 5% of payment for most services, it is a significant cost for some specialties and it is CMS' responsibility to ensure that the relativity reflects these higher premiums relative to other groups with lower premiums. The example provided in our August letter illustrates the problem. It is intuitive that the PLI costs for an obstetrician performing an amniocentesis is higher than the technician's risk in an MRI of the upper extremity. Yet, CMS PLI relative values are higher for the technician.

- *Budget Neutrality/Five-Year Review Work Adjustor* - In this *Final Rule*, CMS announced that the Five-Year Review Work Adjuster will increase from -10.10% to -11.94%. The RUC strongly urges CMS to eliminate this work adjuster. Applying budget neutrality to the work RVUs to offset the improvements in E/M and other services is a step backward, and we strongly urge CMS to instead apply any necessary adjustments to the conversion factor. The RUC also recommends that CMS use unadjusted work relative values as the allocator of indirect practice expenses.

Physician Practice Information Survey Data

CMS currently utilizes practice expense data and physician hours from the 1995-1999 AMA Socioeconomic Monitoring System (SMS) survey to calculate a "practice expense per hour" estimation for each specialty. At several meetings, the RUC has recognized that these data are outdated and that there is a significant need for new survey data. On March 24, 2006, a multi-specialty sign-on letter (signed by more than 70 organizations) was sent to CMS with the following recommendation:

We are all in agreement, however, that moving forward, it is imperative that a multi-specialty practice expense survey be conducted to collect recent, reliable, consistent practice expense data for all specialties and health care professionals. We urge CMS to work with the AMA and other physician and health professions organizations to achieve this goal.

The RUC appreciates that CMS has expressed support of this survey process. CMS indicated in the *Final Rule*, that "we look forward to analyzing the results of the AMA data collection efforts for possible inclusion in the resource-based practice expense methodology in future rulemaking cycles." We understand that the survey will be conducted throughout 2007 and 2008 to collect data for the 2010 Medicare Physician Payment Schedule.

Five-Year Review of Practice Expense Inputs

During the 2005 Five-Year Review process, practice expense inputs were not reviewed as it was considered that the refinement process for the costs had just been completed. Since that time, the RUC has discussed with CMS staff the timing of the next review of practice expense inputs. From these discussions, the RUC assumes that this process will be initiated in the 2009 *Final Rule* along with the initiation of the Five-Year Review Process, culminating in implementation on January 1, 2012. However, we are not confident in this assumption. In this *Final Rule*, CMS responds to several commenters seeking increases in their practice expense relative values by referring them to their specialty and the RUC. We require clarification from CMS. Is it the intention of CMS to initiate a rolling review of practice expense inputs? If this is the case, what is the mechanism to identify the codes for review?

We are also concerned that CMS has included statements in the *Final Rule* that attribute decisions to the RUC that the RUC has not made. For example, CMS discussed a comment that the RUC has failed to consider crash carts to be a direct cost, without clarifying that this was not a RUC action, but rather a decision made by CMS when the practice expense methodology was developed. We also want to clarify that at no time has the RUC attested to whether a service may or may not be safely performed in a physician's office. We want to make abundantly clear to those individuals who have reviewed your comments for transcather placement of stent(s) and arthoscopic procedures that the RUC defers to the specialty society for that determination. We mention these two items to clarify the RUC's role. The RUC process utilizes the methodology and rules developed by CMS and has no role in determining the safety or effectiveness of any medical service.

New and Revised Process: CPT 2008

CMS reviewed and accepted all of the RUC recommendations. The RUC sincerely appreciates the confidence that CMS has displayed in our process of developing work relative value recommendations. We also acknowledge the valuable contribution of your staff in attending and observing our meetings.

Non Face-to-Face Services:

Although, we appreciate your decision to publish the RUC recommendations for several new non face-to-face services in the *Final Rule*, we are disappointed that CMS chose to either bundle or not cover several new CPT codes describing these services. These team conferences, phone calls, and on-line communications were specifically created by CPT and valued by the RUC to exclude any duplication of pre- or post-service time from other physician services. CMS also mentions that the agency will not cover services that include conversations with parents or guardians as they are not the Medicare beneficiary. These codes were designed to also apply to pediatricians, and therefore it is critical for a parent initiated phone call to be included.

We believe that these concerns could be specifically addressed with the CPT Editorial Panel. We urge CMS to reconsider the coverage status for these services.

Fracture Treatment Procedures

As part of the 2005 Five Year Review process, the American Academy of Orthopaedic Surgery (AAOS) commented that the compelling evidence rationale for examining the work RVU for the fracture treatment codes is that there is evidence that incorrect assumptions were made in the valuation of these codes due to lack of clarity of the CPT descriptor. In particular, the CPT descriptor stated "with or without internal or external fixation." However, it is unclear whether the previous valuation for the code included the situation when internal and external fixation is applied to a fracture site. Therefore, the RUC recommended that these codes be referred to the CPT Editorial Panel first for clarification, prior to reviewing evidence of misvaluation.

At the October 2006 CPT Editorial Panel Meeting, the AAOS recommended to the CPT Editorial Panel that the identified fracture treatment codes in the musculoskeletal section of CPT, that includes the nomenclature "internal or external" fixation should be clarified to state that external fixation should be an adjunctive procedure to these procedures. The CPT Editorial Panel agreed with the specialty that these codes needed to be clarified and removed reference to external fixation from 64 CPT codes. These 64 codes were divided into four categories based on convenience of review: Shoulder/Elbow, Elbow/Hand, Hip/Knee and Foot/Ankle. At the February 2007 RUC Meeting, three of these categories were discussed: Shoulder/Elbow, Elbow/Hand and Foot/Ankle. The Hip/Knee codes were discussed at the April 2007 RUC Meeting.

Between 150 and 450 individuals participated in each of the surveys. These respondents included general orthopaedic surgeons, shoulder and elbow surgeons, orthopaedic trauma surgeons, hip and knee surgeons, podiatrists and general hand surgeons. After the results from all of these groups were tabulated, a consensus committee of physicians representing the American Academy of Orthopaedic Surgeons, American Shoulder and Elbow Surgeons, American Society for Surgery of the Hand, Arthroscopy Association of North America, American Association of Hip and Knee Surgeons, American Podiatric Medical Association and Orthopaedic Trauma Association met to discuss the survey data for the revised fracture treatment codes.

The RUC reviewed the specialties' presentation of the 25th percentile of the survey median for most services. The RUC made several modifications to the recommendations to ensure appropriate rank order and compared these services to multiple reference service codes, including many on the Multi-Specialty Points of Comparison (MPC) list. The issue was deliberated over the course of multiple meetings and hours to ensure not only appropriate intra-service work per unit of time (IWPUT), but appropriate pre- and post-service time and visit allocation. The RUC was confident that its review of these procedures was thorough and

comprehensive. To ensure that the written rationales were complete and appropriate, AMA RUC staff convened a conference call with RUC members and CMS staff prior to the formal submission in May.

In the *Final Rule*, CMS commented that "although we agree with the relationships, the increases in work RVUs re-establish the relativity of the services in these families and in doing so created budget neutrality issues. In order to retain budget neutrality within these families of codes, the work RVUs associated with each code had to be adjusted." The RUC believes that the internal/external fixation codes should not be subject to budget neutrality. The RUC carefully considered whether budget neutrality guidelines should be applied to these recommendations as the RUC operates with the initial presumption that the current values assigned to codes under review are correct. This presumption can be challenged by a society presenting a compelling argument that the existing values are no longer appropriate for the codes in question. The argument for a change in value must be substantial and meet the RUC's compelling evidence standards.

The RUC reviewed the compelling evidence offered by the specialties for these procedures. The specialty societies explained that the CPT descriptors originally contained the phrase "with or without internal or external fixation," leaving it is difficult to determine what the original Harvard survey data actually represented. Furthermore, an Abt study was performed in 1992 for RUC consideration. This study produced percentage relationships to key reference codes, but not surveyed time and visit data. Some of these recommendations were accepted by the RUC and CMS and others were adjusted up or down, but no changes were made to the Harvard time and visit data, if available. Therefore, the specialty society believes that there is little, if any, relationship between the Harvard database time and visit information and the current work RVUs. The specialty societies stated that there was a significant change in the technology for how these procedures are performed. The surgical treatments use open anatomical reduction, and internal fixation has been made more complex with the introduction of new imaging methods such as computed tomography which allows better detection of the fracture pathology and provides the basis for new surgical strategies. There are also new internal fixation devices that require more work.

Further, the patient population has changed, as women over 50 are a fast growing segment of the population. A huge percentage of these patients are osteoporatic – making fracture fixation and maintenance of fixation far more difficult. Also, for several of the identified procedures, the provider of the services has changed and was not a part of the original Harvard studies such as the American Society for Surgery of the Hand. The RUC also reviewed CPT code 20690 *Application of a uniplane (pins or wires in one plane), unilateral, external fixation system* and 20692 *Application of a multiplane (pins or wires in more than one plane), unilateral, external fixation system (eg, Ilizarov, Monticelli type)*. It is the RUC's understanding that the utilization for these two procedures will not change with this coding

change made by the CPT Editorial Panel. Therefore, given the ample amount of compelling evidence offered by the specialty societies, the RUC disagrees with CMS' determination to apply work neutrality to these services and requests that the RUC recommended relative values for these services be implemented.

However, if CMS does not implement the RUC recommended relative values for these services, the RUC requests that the budget neutrality impacts be implemented across a family of codes (i.e. the entire fracture family of codes), not across the arbitrary groupings (i.e. shoulder/elbow), that were created during their valuation process. The method employed by CMS distorted the relativity of the fracture codes.

Specialty Society Request

PE Input Correction for 43760 Change of gastrostomy tube

The RUC in coordination with the American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE) noted an error in Table 4, *Practice Expense Supply Item Additions for CY 2008,* in the *Final Rule.* The RUC practice expense recommendation for CPT code 43760 *Change of gastrostomy tube,* included 1 low profile gastronomy replacement button and 1 stoma measuring device. As these items were new supplies, the specialty society provided an invoice and product information from the manufacturer. This information detailed that the MIC-KEY Low-Profile Gastrostomy Tube Kit included the following components: MIC-KEY low-profile device, feeding extension set, bolus extension set, one 6 ML syringe (to fill balloon), one 35 ml syringe (to check placement) and four gauze pads. The retail price of this kit was $210. The stoma measuring device had a retail price of $8.82. CMS assigned a unit price of $5 for the MIC-KEY Low-Profile Gastrostomy Tube Kit and $10 for the stoma measuring device.

Furthermore, the specialties recognized that there was some duplicative items listed in the RUC recommendations forwarded to CMS as many of these items are included in the MIC-KEY kit. Items to be removed include: the drainage catheter, one syringe, and four gauze pads. In addition, the specialty wishes to clarify the low profile replacement button is equivalent to the MIC-KEY low profile device which is part of the MIC-KEY kit and therefore recommends that the low profile replacement button also be removed as it is part of the MIC-KEY kit. The RUC is supportive of these modification made by the AGA and ASGE and refers CMS to their letter for further information. Attached to this letter is the modified RUC practice expense recommendation for 43760, and the invoice and product information for these supplies. The RUC requests that CMS correct the pricing error by reviewing the invoices for these two supply items and incorporate the requested modifications.

Please note, however, that the RUC does not endorse any particular supply price. Cost estimates for medical supplies and equipment not listed on "CMS's Labor, Supply, and Equipment List for the Year 2007" are based on provided source(s) as noted, such as manufacturer's catalogue prices, and may not reflect the wholesale prices, quantity or cash discounts, prices for used equipment or any other factors which may alter the cost estimates.

The RUC appreciates the opportunity to offer these comments to CMS. We look forward to the work ahead to further improve the RBRVS.

Sincerely,

William L. Rich, III, MD, FACS

cc: RUC participants
Attachments

Medical Supplies Used in the Non-Facility Setting Priced at or Greater than $200

Supply Description	Price	Procedure Codes with Supply	Top Specialty for CPT Code
tray, RTS applicator (MammoSite)	2,550.00	19296	GENERAL SURGERY
array kit, GenoSensor	2,121.00	88386	INDEPENDENT LABORATORY
probe, radiofrequency, 3 array (StarBurstSDE)	1,995.00	20982	DIAGNOSTIC RADIOLOGY
		50592	DIAGNOSTIC RADIOLOGY
		32998	No Data Available
catheter, CVA, system, tunneled w-port, dual (LifeSite)	1,750.00	36566	GENERAL SURGERY
stent, vascular, deployment system, Cordis SMART	1,645.00	37205	DIAGNOSTIC RADIOLOGY
		37206	DIAGNOSTIC RADIOLOGY
probe, cryoablation (Visica ICE 30 or 40)	1,589.00	19105	No Data Available
kit, gene, MLL fusion	1,395.00	88385	INDEPENDENT LABORATORY
catheter, intradiscal (spineCATH)	1,380.00	22526	No Data Available
		22527	No Data Available
plasma LDL adsorption column (Liposorber)	1,300.00	36516	INTERNAL MEDICINE
probe, endometrial cryoablation (Her Option)	1,250.00	58356	OBSTETRICS/GYNECOLOGY
kit, hysteroscopic tubal implant for sterilization	1,245.00	58565	OBSTETRICS/GYNECOLOGY
probe, cryoablation, renal	1,175.00	50593	UROLOGY
plasma antibody adsorption column (Prosorba)	1,150.00	36515	RHEUMATOLOGY
kit, transurethral microwave thermotherapy	1,149.00	53850	UROLOGY
hysteroscope, ablation device	1,146.00	58563	OBSTETRICS/GYNECOLOGY
kit, transurethral needle ablation (TUNA)	1,050.00	53852	UROLOGY
kit, photopheresis procedure	858.00	36522	HEMATOLOGY/ONCOLOGY
laser tip, diffuser fiber	850.00	52647	UROLOGY
		52648	UROLOGY
tray, scoop, fast track system	750.00	31730	OTOLARYNGOLOGY
catheter, balloon, thermal ablation (Thermachoice)	727.00	58353	OBSTETRICS/GYNECOLOGY
catheter, RF endovenous occlusion	725.00	36475	GENERAL SURGERY
plate, surgical, reconstruction, left, 5 x 16 hole	719.00	21127	ORAL SURGERY (DENTISTS ONLY)
		21215	ORAL SURGERY (DENTISTS ONLY)
		21125	No Data Available
kit, vertebroplasty (LP2, CDO)	696.00	22520	DIAGNOSTIC RADIOLOGY
		22521	DIAGNOSTIC RADIOLOGY
kit, transurethral water-induced thermotherapy	650.00	53853	UROLOGY
kit, PICC with subcut port	586.00	36585	DIAGNOSTIC RADIOLOGY
		36571	GENERAL SURGERY
		36570	No Data Available
fiducial screws (set of 4 uou)	558.00	77011	DIAGNOSTIC RADIOLOGY
		77301	RADIATION ONCOLOGY
kit, endovascular laser treatment	519.00	36478	GENERAL SURGERY
kit, CVA catheter, tunneled, with subcut port	495.00	36561	DIAGNOSTIC RADIOLOGY
		36582	DIAGNOSTIC RADIOLOGY
		36563	GENERAL SURGERY
		36583	VASCULAR SURGERY
		36560	No Data Available
kit, for percutaneous thrombolytic device (Trerotola)	487.50	37188	CRITICAL CARE (INTENSIVISTS)
		37184	DIAGNOSTIC RADIOLOGY
		37186	DIAGNOSTIC RADIOLOGY
		37187	INTERVENTIONAL RADIOLOGY
		36870	NEPHROLOGY
electrode, grid	475.00	95829	GENERAL PRACTICE
kit, priming, random	463.00	88385	INDEPENDENT LABORATORY
		88386	INDEPENDENT LABORATORY
kit, capsule endoscopy w-application supplies (M2A)	450.00	91110	GASTROENTEROLOGY
kit, capsule, ESO, endoscopy w-application supplies (ESO)	450.00	91111	No Data Available
catheter, balloon, low profile PTA	431.50	35471	CARDIOLOGY
		35474	CARDIOLOGY

Medical Supplies Used in the Non-Facility Setting Priced at or Greater than $200

Supply Description	Price	Procedure Codes with Supply	Top Specialty for CPT Code
		35470	DIAGNOSTIC RADIOLOGY
plate, surgical, rigid comminuted fracture	389.00	21461	ORAL SURGERY (DENTISTS ONLY)
		21462	ORAL SURGERY (DENTISTS ONLY)
catheter, CVA, tunneled, dual (Tesio)	355.00	36565	DIAGNOSTIC RADIOLOGY
catheter, microcatheter (selective 3rd order)	337.88	36217	CARDIOLOGY
		36247	CARDIOLOGY
		37210	No Data Available
kit, pleural catheter insertion	329.00	32550	PULMONARY DISEASE
collagen, dermal implant (2.5ml uou) (Contigen)	317.00	52330	UROLOGY
kit, CVA catheter, tunneled, without port-pump	308.00	36558	NEPHROLOGY
		36581	NEPHROLOGY
		36557	No Data Available
catheter, balloon, lacrimal	306.00	68816	No Data Available
kit, percutaneous neuro test stimulation	305.00	63610	ANESTHESIOLOGY
		64561	UROLOGY
laser tip (single use)	290.00	30117	OTOLARYNGOLOGY
		52214	UROLOGY
		52224	UROLOGY
		52317	UROLOGY
kit, loop snare (Microvena)	275.00	36595	DIAGNOSTIC RADIOLOGY
		37203	DIAGNOSTIC RADIOLOGY
agent, embolic, 2 ml uou	258.00	37210	No Data Available
catheter, balloon, PTA	243.50	35472	DIAGNOSTIC RADIOLOGY
		35473	DIAGNOSTIC RADIOLOGY
		35475	NEPHROLOGY
		35476	NEPHROLOGY
		G0392	No Data Available
		G0393	No Data Available
stent, ureteral, w-guidewire, 3cm flexible tip	235.00	52332	UROLOGY
plate, surgical, mini-compression, 4 hole	226.00	21208	ORAL SURGERY (DENTISTS ONLY)
suture device for vessel closure (Perclose A-T)	225.00	35471	CARDIOLOGY
		35474	CARDIOLOGY
		37188	CRITICAL CARE (INTENSIVISTS)
		35470	DIAGNOSTIC RADIOLOGY
		35472	DIAGNOSTIC RADIOLOGY
		35473	DIAGNOSTIC RADIOLOGY
		37184	DIAGNOSTIC RADIOLOGY
		37205	DIAGNOSTIC RADIOLOGY
		37187	INTERVENTIONAL RADIOLOGY
		35475	NEPHROLOGY
		G0392	No Data Available
sensor, pH capsule (Bravo)	225.00	91035	GASTROENTEROLOGY
eyelid weight implant, gold	217.50	67912	OPHTHALMOLOGY
catheter, balloon, esophageal or rectal (graded distention test)	217.00	91120	COLORECTAL SURGERY
		91040	PHYSICIANS ASSISTANT
Mammotome probe	200.00	19103	DIAGNOSTIC RADIOLOGY

	A	B	C	D	E
1				43760	
2	**American Gastroenterological Association American Society for Gastrointestinal Endoscopy**			**Code Descriptor Change of Gastrostomy Tube**	
3	**LOCATION**	**CMS Code**	**Staff Type**	**Non Facility**	**Facility**
4	**GLOBAL PERIOD**				
5	**TOTAL CLINICAL LABOR TIME**	L037B	RN/LPN/MTA	**31.0**	**3.0**
6	**TOTAL PRE-SERV CLINICAL LABOR TIME**	L037B	RN/LPN/MTA	**0.0**	**3.0**
7	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**	L037B	RN/LPN/MTA	**28.0**	**0.0**
8	**TOTAL POST-SERV CLINICAL LABOR TIME**	L037B	RN/LPN/MTA	**3.0**	**0.0**
9					
10	**Start: Following visit when decision for surgery or procedure made**				
11	Complete pre-service diagnostic & referral forms	L037B	RN/LPN/MTA		
12	Coordinate pre-surgery services	L037B	RN/LPN/MTA		
13	Schedule space and equipment in facility	L037B	RN/LPN/MTA		3
14	Provide pre-service education/obtain consent	L037B	RN/LPN/MTA		
15	Follow-up phone calls & prescriptions	L037B	RN/LPN/MTA		
16	Other Clinical Activity (please specify)				
17	**End:When patient enters office/facility for surgery/procedure**				
18					
19	**Start: When patient enters office/facility for surgery/procedure**				
20	**Pre-service services**				
21	Review charts				
22	Greet patient and provide gowning	L037B	RN/LPN/MTA	3	
23	Obtain vital signs	L037B	RN/LPN/MTA	3	
24	Provide pre-service education/obtain consent	L037B	RN/LPN/MTA	5	
25	Prepare room, equipment, supplies	L037B	RN/LPN/MTA	2	
26	Setup scope (non facility setting only)				
27	Prepare and position patient/ monitor patient/ set up IV	L037B	RN/LPN/MTA	2	
28	Sedate/apply anesthesia				
29	**Intra-service**				
30	Assist physician in performing procedure	L037B	RN/LPN/MTA	7	
31	**Post-Service**				
32	Monitor pt. following service/check tubes, monitors, drains	L037B	RN/LPN/MTA		
33	Clean room/equipment by physician staff	L037B	RN/LPN/MTA	3	
34	Clean Scope				
35	Clean Surgical Instrument Package				
36	Complete diagnostic forms, lab & X-ray requisitions				
37	Review/read X-ray, lab, and pathology reports				
38	Check dressings & wound/ home care instructions /coordinat	L037B	RN/LPN/MTA	3	
39	Discharge day management 99238 –12 minutes	99239 –15 minutes			
40	Other Clinical Activity (please specify)				
41	**End: Patient leaves office**				
42					
43	**Start: Patient leaves office/facility**				
44	Conduct phone calls/call in prescriptions	L037B	RN/LPN/MTA	3	
45	*List Number and Level of Office Visits*				
46	99211 16 minutes		16		
47	99212 27 minutes		27		
48	99213 36 minutes		36		
49	99214 53 minutes		53		
50	99215 63 minutes		63		
51	*Total Office Visit Time*			**0**	**0**
53	**End: with last office visit before end of global period**				
54					
55	pack, minimum multi-specialty visit	SA048	item	1	
56	gown, surgical, sterile	SB028	item	2	
57	gloves, sterile	SB024	item	2	
58	mask, surgical, with face shield	SB034	item	2	
59	cap, surgical	SB001	item	2	
60	shoe covers, surgical	SB039	item	2	
61	drape, sterile, fenestrated 16in x 29in	SB011	item	1	
62	drape-towel, sterile 18inx26in	SB019	item	2	
63	kit, suture removal	SA031	item	1	
64	tray, shave prep	SA067	item	1	
65	underpad 2ftx3ft (Chux)	SB044	item	1	
66	povidone soln (Betadine)	SJ041	cc	60	
67	applicator, sponge-tipped	SG009	item	4	
68	lidocaine 1%-2% inj (Xylocaine)	SH047	cc	10	
69	syringe w-needle, OSHA compliant (SafetyGlide)	SC058	item	2	
70	3 way stop cock (for irrigation)	SC049	item	1	
71	syringe 60ml (for irrigation)	SC056	item	1	
72	sodium chloride 0.9% irrigation (500-1000ml uou)	SH069	item	1	
73	closed flush system, angiography	SC010	item	1	
74	sodium chloride 0.9% flush syringe	SH065	item	2	
75	guidewire	SD088	item	1	
76	gauze, sterile 4in x 4in	SG055	item	2	
77	tape, surgical paper 1in (Micropore)	SG079	item	12	
78	stoma measuring device	See invoice	item	1	
79	MIC-KEY Kit- includes 1- MIC-KEY Low-Profile Device, 1- Feeding Extension Set, 1- Bolus Extension Set,1- 6 ml syringe, 1- 35 ml syringe and 4-gauze pads	See invoice	kit	1	
80					

AMA Specialty Society Recommendation

	A	B	C	D	E
1				43760	
2	**American Gastroenterological Association American Society for Gastrointestinal Endoscopy**			**Code Descriptor Change of Gastrostomy Tube**	
3	**LOCATION**	**CMS Code**	**Staff Type**	**Non Facility**	**Facility**
81	Exam table	EF03	100%	10	

>>> "Joel Brill" <joel.brill@verizon.net> 3/26/2007 2:22:38 PM >>>
Model numbers and pricing for low-profile gastrostomy tube (43760)

From: Vermeulen, David
Sent: Monday, March 26, 2007 7:35 AM
To: 'joelbrill@verizon.net'
Subject: MIC-KEY Info

Dr. Brill,
Per our discussion, under CPT 43760, using our MIC-KEY Low-Profile Gastrostomy Tube, a physician would need the following:

1. MIC-KEY "Kit" which includes the following components:
   - MIC-KEY Low-Profile Device
   - Feeding Extension Set
   - Bolus Extension Set
   - One 6 ML syringe (to fill balloon)
   - One 35 ml syringe (to check placement)
   - Four Gauze Pads
2. MIC-KEY Stoma Measuring Device

Our retail prices on these products are:

- MIC-KEY "Kit": $210.00 each
- Stoma Measuring Device: $8.82 each

I have attached the following for your information:

- MIC-KEY Brochure
- MIC-KEY Care Guide

Should have any questions or require additional information, please give me a call.

David Vermeulen
Sr. Customer Marketing Manager
Kimberly-Clark Health Care
Phone: 770-587-8036

INTRODUCTION TO TUBE FEEDING

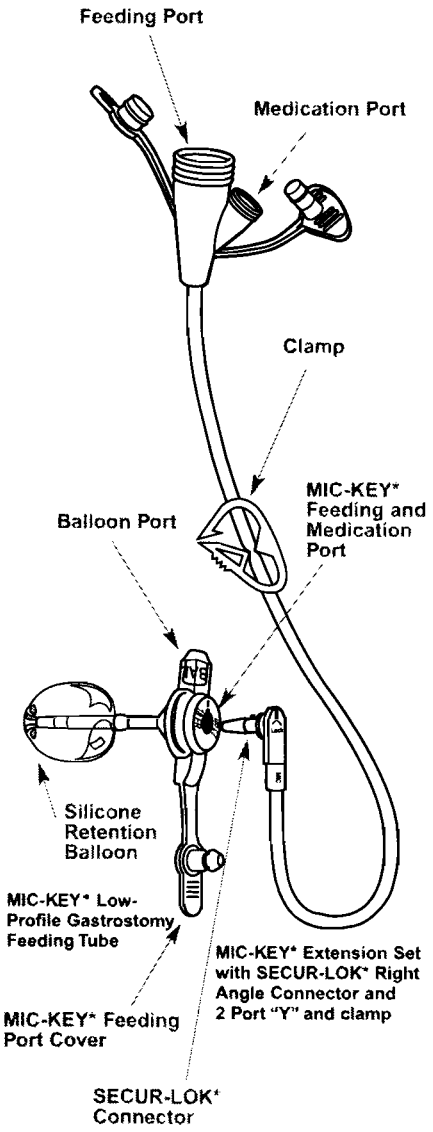
Good nutrition maintains health, growth and healing. Many different medical problems are treated by gastrostomies when the person cannot eat or eat enough to meet nutritional requirements. A gastrostomy delivers nourishment and liquid through a tube into the stomach. Formula suitable for tube feeding may be commercially prepared or may be blenderized table food prescribed by the specialist.

Adequate nutrition depends on the right type and amount of formula. Your specialist has prescribed your feeding schedule, formula, and amount of water.

ABOUT THE MIC-KEY*

A MIC-KEY* Low Profile feeding tube (MIC-KEY*) has been inserted into your stomach through the abdominal wall. There is an inflatable balloon at one end and an external base at the other. This tube allows the intake of food and water that your body requires.

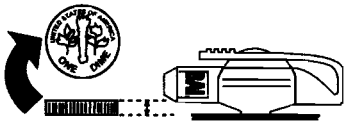
Your specialist has measured you to ensure that you have the right size MIC-KEY* feeding tube. You also received care and maintenance instructions. This pamphlet will help you remember the instructions. You received instructions about your diet and medication. Follow the instructions closely and never put any other diet or medication through your tube.



MIC-KEY* CARE GUIDE

THE EXTERNAL BASE

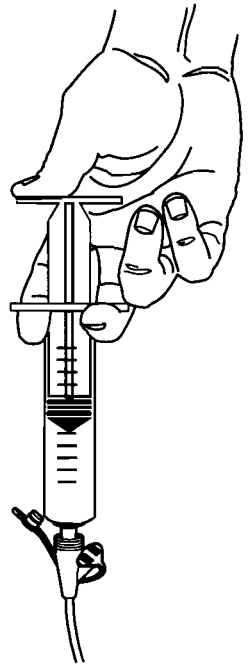
The external base holds the tube in place yet allows air circulation to the skin around and underneath it. The bottom of the base should rest just above the skin surface. A good fit is considered one-eighth inch (3 mm) above the skin, or approximately the thickness of a dime.



THE MIC-KEY* FEEDING PORT

Nourishment and liquids are delivered through the gastrostomy tube and into the stomach through the feeding and medication port. When nourishment or liquids are not being administered, the feeding port is capped off with the attached feeding port cover.

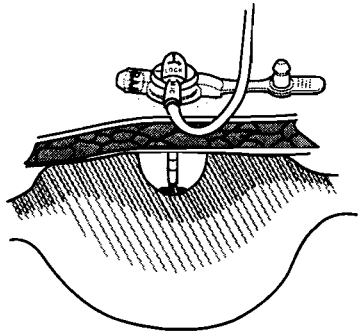
An anti-reflux valve is located inside and toward the top of the feeding port. This helps prevent stomach contents from leaking out of the tube. The use of the extension set will open or unlock the valve. The extension set is used for feeding and venting (also called decompression or burping).



It is important to keep the feeding port and anti-reflux valve clean. Dried formula may lodge inside the recess and hold the valve open. The best preventative measure is to flush thoroughly with enough water to clear all formula and to use cotton tipped applicators and water. Be sure that residual formula is not left to pool and dry inside the valve opening.

THE SILICONE RETENTION BALLOON

Your feeding tube has a balloon inside the stomach that has been inflated to hold the tube in place. Your specialist filled it with water when the tube was inserted. Check the balloon volume once a week.



THE BALLOON VALVE

The balloon, which holds the tube in place, is inflated and deflated by inserting a luer slip syringe into the balloon valve. It should only be used when checking the balloon volume or replacing the MIC-KEY*. It is important to never attempt to feed through the balloon valve. It is also important to keep this valve clean. The recess in the valve can trap foreign material and it must be clean to function properly.

ACCESSORIES

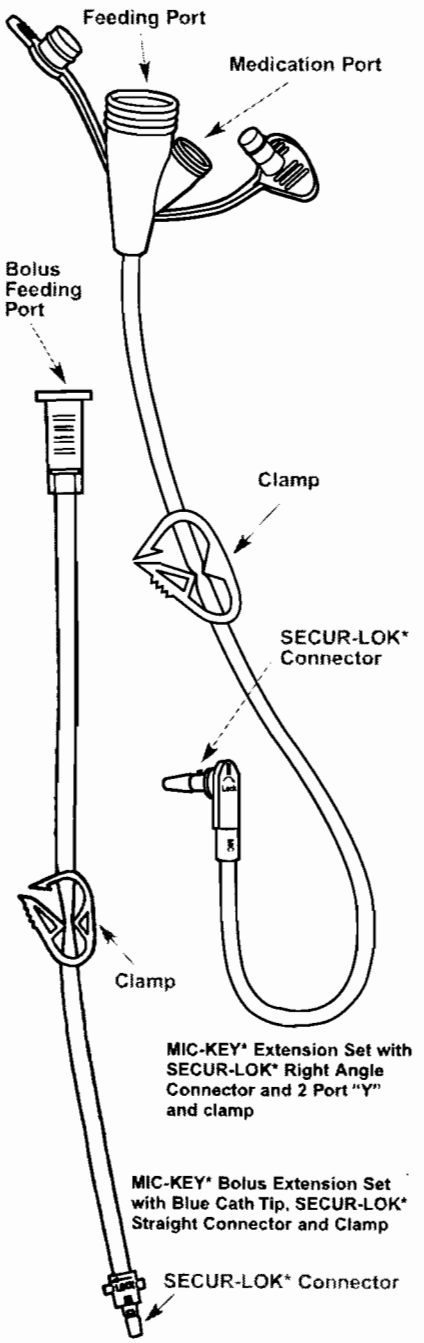
THE MIC-KEY* EXTENSION SET

Your MIC-KEY* kit contains an extension set. Use this extension set for continuous feeding with a formula pump. To attach the extension set, align the black line on the extension set with black line on the feeding port. Insert the "nose" of the Secur-Lok* connector into the feeding port and rotate it one quarter turn clockwise. Open the extension set feeding port and attach the feeding bag connector to the extension set with a firm push and twist. The extension set "swivels" with movement and allows you to change position during feeding.

Wash the extension set after every feeding with warm soapy water and rinse it thoroughly. Prompt flushing and rinsing prevents the formula from drying and building up. Extension sets are disposable and should be replaced every few weeks.

THE MIC-KEY* BOLUS EXTENSION SET

Your MIC-KEY* feeding tube kit also contains a MIC-KEY* bolus extension set. Some people receive several feedings during the day. Use the bolus extension set to feed with a catheter tip syringe or feeding bag. It normally takes twenty to forty minutes to bolus feed. This method resembles a normal feeding pattern.



MIC-KEY* Extension Set with SECUR-LOK* Right Angle Connector and 2 Port "Y" and clamp

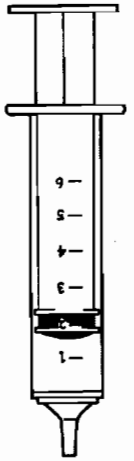
MIC-KEY* Bolus Extension Set with Blue Cath Tip, SECUR-LOK* Straight Connector and Clamp

MIC-KEY* CARE GUIDE

THE SYRINGES

A 6ml luer slip syringe is included with your feeding tube kit. Use it to inflate and deflate the retention balloon when periodically checking its volume and when you replace the MIC-KEY* feeding tube.

Your MIC-KEY* feeding tube kit also includes a 35 ml catheter tip syringe. It should be used when priming and flushing the extension sets, and when checking for proper placement of the MIC-KEY* feeding tube.



CARE AND USE

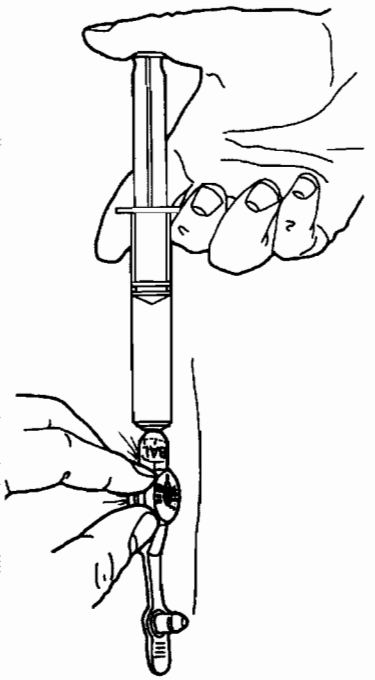
Clean the MIC-KEY* feeding tube daily. Care is simple and easy. Just keep the tube and the skin around the tube (stoma) clean and dry.

The following supplies will make your work easier:

- soap and water
- cotton-tip applicators
- tissues
- luer slip syringe

The balloon holds your feeding tube in place. Check the volume of water in the balloon at least once a week. To do this, attach the luer slip syringe to the balloon port and withdraw all the water while leaving the feeding tube in place. If there is less fluid than the amount originally prescribed, replace it with the prescribed amount. Distilled or sterile water is a good choice for the replacement fluid once the stoma site has healed. (Never fill the balloon with air. Air will rapidly migrate out of the balloon and the MIC-KEY* feeding tube will not stay in place).

Rotate the MIC-KEY* feeding tube in a full circle when you perform daily tube care. This will prevent the tube or balloon from adhering to the skin.



MAINTENANCE OF THE MIC-KEY* LOW-PROFILE GASTROSTOMY FEEDING TUBE

ALWAYS WASH YOUR HANDS WITH WARM SOAPY WATER BEFORE TOUCHING YOUR TUBE.

Develop a habit of inspecting the skin around the tube (stoma) after feeding. Make sure the skin is clean and dry. Observe the stoma for a few minutes checking for gastric leakage. If you use a dressing, change it when it becomes wet or soiled. Never allow a wet dressing to remain in contact with the skin. Note: The MIC-KEY* feeding tube does not require a dressing. gently clean the skin around the stoma. Rotate the MIC-KEY* feeding tube and clean again. Use cotton-tip applicators or a soft cloth, using soap and warm water. If you think soap is irritating the skin, try cleansing with water alone or try another soap.

Clean the feeding port with a cotton tip applicator or soft cloth to remove oil or food. If you receive a continuous feeding, flush the tube and the extension set tubing at least three times daily.

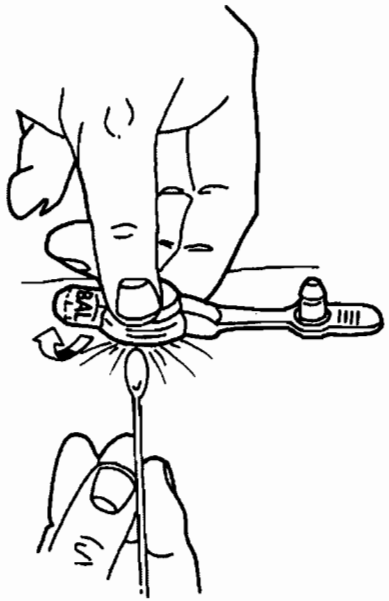
AVOID PUNCTURING OR TEARING ANY PART OF THE MIC-KEY* LOW-PROFILE GASTROSTOMY FEEDING TUBE.

FEEDING THROUGH THE MIC-KEY*

PROPER PLACEMENT

Before feeding, check the tube to be sure that it is not clogged or displaced outside the stomach. To do this, connect the extension set to the MIC-KEY* feeding tube and attach a Monoject catheter tip syringe with 10 ml's of water to the extension set feeding port. Pull back on the plunger. When you see stomach contents in the tube, flush the MIC-KEY* feeding tube with water. Stomach contents are normally yellow or clear unless there is food in the stomach. If you feel resistance as you inject the water, pull back stomach contents again, then try to re-inject the water. Check for leaking around the stoma.

Another method is to draw 5 to 10 ml's of air into a syringe. Place a stethoscope on the



MIC-KEY* CARE GUIDE

left side of the abdomen just above the waist. Inject the air into the extension set feeding port and listen for the stomach to "growl". Try again if you do not hear it. If you still do not hear it, do not proceed to feed. Contact the specialist and report the problem.

RESIDUAL

Another advantage of the MIC-KEY* feeding tube is the ability to measure stomach residual without a decompression tube. Residual is the amount of gastric fluid and formula left in the stomach four hours after feeding. The stomach may not always empty completely. The amount of residual varies and may depend upon your activity or position. Check for residual if the formula backs up in the extension tubing or if you feel nauseated. Generally, replace the residual back into the stomach. It contains important electrolytes and nutrients. Check the residual again in 30 minutes and resume the feeding if the amount is less than you obtained at the first check.

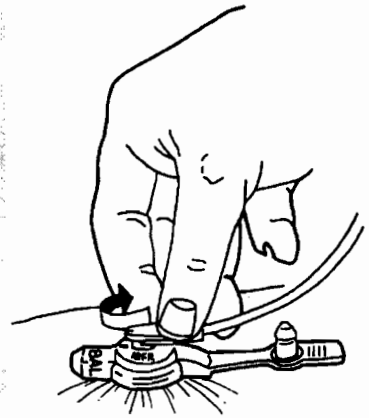
DECOMPRESSION OR VENTING

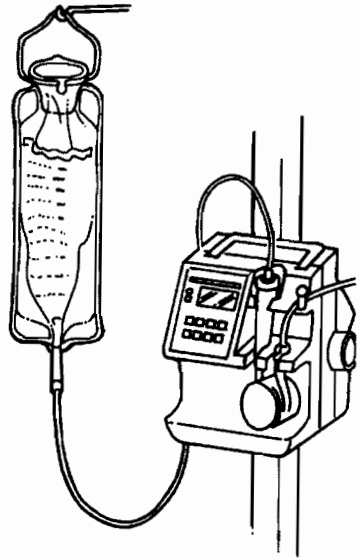
Your specialist may instruct you to decompress (release air or food from the stomach) before or after feedings. To decompress the stomach, attach the extension set or bolus extension set to the MIC-KEY* feeding tube. Drain into a collecting cup or bag.

CONTINUOUS FEEDING

The specialist will recommend the type of formula best for you.

1. Clean the tops of formula cans and shake well. (If using powdered formula, it should be prepared fresh every day. Refer to the information section of this booklet for the prescribed amount. Label each formula batch with the date and time you prepared it.)
2. Wash hands with soap and water and dry thoroughly.
3. Fill the feeding administration bag with formula.
4. Connect the feeding administration bag tubing to the MIC-KEY* extension set feeding port.
5. Purge air from the tubing by allowing formula to run through the tubing. When formula has reached the extension set SECUR-LOK* Connector, clamp the tubing.
6. Remove the feeding port cover. Insert the extension set into the feeding port by matching the black lines on the extension set and feeding port. Lock the extension set into place by turning the connector CLOCKWISE until you feel a slight resistance (approximately three-quarters turn). DO NOT turn the connector past the stop point.
7. Connect the feeding administration bag tubing to the pump. Set the pump rate according to the manufacturer's instructions. Unclamp the tubing and begin feeding.
8. When the feeding is nearly finished, add the prescribed amount of water to the feeding bag.
9. After the formula and water have been administered, disconnect the feeding administration bag tubing from the extension set. Flush the extension set with 10–20 ml's of warm water or until the tubing is clear.
10. Disconnect the extension set from the MIC-KEY* feeding tube by rotating it COUNTER-CLOCKWISE until the black line on the feeding port lines up with the black line on the extension set. Gently detach the extension set and cap the MIC-KEY* feeding tube securely with the attached feeding port cover.
11. Wash the extension set and feeding bag in warm soapy water immediately after each use. Rinse thoroughly and air dry.

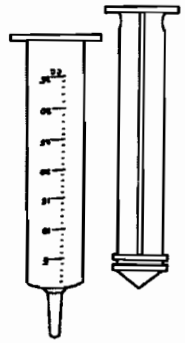




MIC-KEY* CARE GUIDE

BOLUS FEEDING

1. Attach a water filled catheter tip syringe to the MIC-KEY*bolus extension set. Prime the extension set by filling it with water.
2. Attach the bolus extension set to the feeding port by matching the black lines on the extension set and feeding port. Insert the bolus extension set locking adapter into the feeding port and rotate it CLOCKWISE until you feel a slight resistance (approximately three-quarters turn). DO NOT turn the connector past the stop point.
3. Clamp the extension set.
4. Disconnect the syringe and remove the syringe plunger. Reattach the syringe.
5. Slowly pour the formula into the syringe and unclamp the tubing. Keep the syringe filled to prevent air from entering the stomach. Adjust the flow rate by raising or lowering the syringe. The feeding should finish in 20 to 40 minutes.
6. When the syringe is nearly empty, add the prescribed amount of water to the syringe.
7. After the formula and water have been administered, clamp the tube and fill the syringe with 10–20 ml of warm water. Reinsert the syringe plunger and unclamp the tube. Flush the bolus extension set until the tubing is clear. Proceed to Step 12.
8. To bolus feed with a ("Gravity Drip") bag, fill the bag with the desired amount of formula and evacuate the air from the bag's tubing. Attach the bolus extension set to the feeding administration bag tubing , prime it and clamp the tubing. Attach the bolus extension set to the feeding port and open the clamp. Adjust the flow by opening or closing the clamp on the bag's tubing.
9. When the feeding is nearly finished, administer the prescribed amount of water by adding it to the feeding administration bag.
10. After the formula and water have been administered, disconnect the bolus extension set from the feeding administration bag tubing.
11. Flush the bolus extension set tubing with 10–20 ml's of warm water or until the tubing is clear.
12. Disconnect the bolus extension set and wash in warm soapy water until the tubing is clear.



MEDICATIONS

Give medications in liquid form. Thick medication can plug the feeding port and is easier to give when diluted with water.

When a medication is only available in tablets or capsules, check with the pharmacist first to make sure it can be crushed and mixed with water.

Do not mix medication with formula unless directed by your specialist.

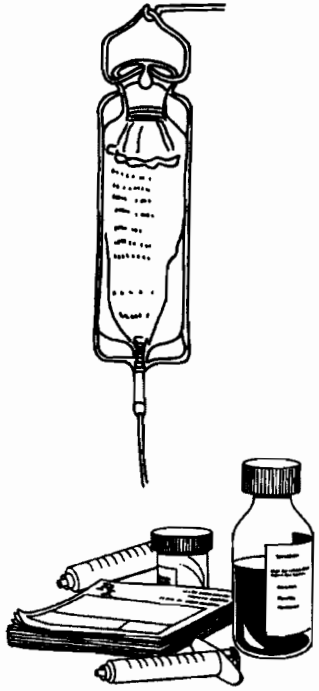
Small amounts of medication can be diluted with water in a luer slip syringe and injected directly into feeding port. This method eliminates the need for extension tubing. Flush with at least 10 ml's of water after giving the medication.

REPLACING THE MIC-KEY* FEEDING TUBE

The specialist will decide when to replace the MIC-KEY* feeding tube. Look for the change date on the information page in this handbook. You may change the tube yourself if the specialist trains you to do so.

To replace a MIC-KEY* feeding tube:

1. Remove the new MIC-KEY*feeding tube from the package. Fill the balloon with 5ml sterile or distilled water.
2. Remove the syringe and observe the balloon. It should be symmetrical. Check for leaks. Remove the water from the balloon.
3. Attach the luer slip syringe to the balloon valve of the MIC-KEY* feeding tube that is in the patient's stomach. Pull back on the plunger until all of the water is out of the balloon.
4. Gently remove the MIC-KEY* feeding tube from the patient's stomach. It may help to use a little water soluble lubricant as you are removing it.
5. Lubricate the tip of the replacement MIC-KEY* feeding tube with a water soluble agent. DO NOT USE OIL OR PETROLEUM JELLY.
6. Gently guide the new tube into the stoma. Insert the tube all the way until the MIC-KEY* feeding tube is flat against the skin.

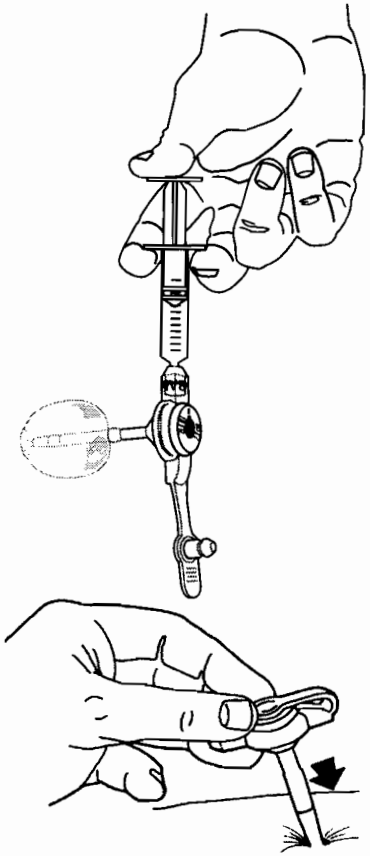


MIC-KEY* CARE GUIDE

7. Hold the tube in place and fill the balloon with 5 ml (3-5 ml for 12 French sizes) distilled or sterile water. Do not use air.

NEVER FILL THE BALLOON WITH MORE THAN 10 ML (5 ML FOR 12 FRENCH SIZES) OF FLUID.

8. Position the balloon against the stomach wall by pulling the MIC-KEY* feeding tube up and away very gently until it stops.
9. Wipe away fluid or lubricant from the tube and stoma.
10. Check the tube for correct placement. Insert an extension set into the feeding port and...
    (a) Listen for air
    (b) Aspirate residual stomach contents



CHILDREN'S CORNER

Children are special and they have special needs. If you are caring for a child with a gastrostomy, the following points may help.

CHILDREN HAVE SMALL STOMACHS

Infants develop the capacity to hold large feedings in their stomachs as they grow. Feedings usually begin with frequent small amounts of formula. Bolus feedings take 20 to 40 minutes. A gravity flow system or a pump regulates a slow steady flow and leaves you free to do other things. Be patient, and slowly increase the amount of formula given during the feeding.

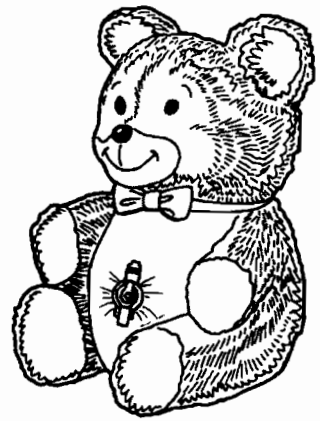
If the child's stomach is full, formula may leak around the stoma. The child may also act colicky and vomit, or burp up formula. Ask your specialist if decompression or venting is appropriate for this child.

CHILDREN ARE GROWING

Children with gastrostomies have the same basic growth and developmental needs as other children.

HOW MUCH WATER?

When our bodies need water we feel thirsty and we drink more. Gastrostomy patients are the same. If the weather is warm or the child has a fever, additional water may prevent dehydration. Ask your specialists for guidelines.



LEARNING ABOUT FOOD

Although your child receives nourishment through a tube, group participation at the table during meals is important. It gives the child an opportunity to experience food. Encourage your child to touch and taste, just like everyone else, even if it makes a mess around the high chair.

MOUTH

The mouth is a very sensitive part of the baby's body. Even if the child cannot suck and swallow well enough to eat, the sucking reflex is there. Sucking seems to comfort babies. Experiment with a pacifier. Use it to stimulate your child's lips, gums, and tongue during feedings. As the baby grows, provide other opportunities to chew or suck.

Talk with your specialist about oral stimulation and ways to promote normal development.

NORMAL ACTIVITY

It is important for babies to roll over on their stomachs. They learn to push up and crawl this way. The MIC-KEY* feeding tube low profile design may make it easier for this activity to occur.

PROBLEM SOLVING

STOMACH CONTENTS LEAK OUT AROUND THE TUBE

First, check stomach residual. The stomach may be too full or contain gas. If the stomach contains too much residual more than a few times, the patient may be getting too much formula at one time. If you are using an intermittent (bolus) feeding, consider switching to continuous. If using a continuous feeding, try decreasing the flow rate. Assure that the balloon inside the stomach is filled by gently pulling on the tube and checking for resistance. Check the Gastrostomy Information Section for the prescribed balloon fill volume. Test the balloon by attaching a luer slip syringe to the inflation valve. Withdraw the fluid from the balloon and note the volume in the syringe. If the amount is less than prescribed, refill the balloon with the prescribed amount of water, wait 10 to 20 minutes and repeat the procedure. If the prescribed volume of water

is still in the balloon, try increasing the volume by 2 ml at a time until the leak stops. The maximum fill volume is 10 ml's (5 ml for 12 French sizes). Do not exceed this.

CAUTION: USE CARE WHILE FILLING OR REMOVING WATER FROM THE BALLOON. THE MIC-KEY* FEEDING TUBE MAY EASILY BE PULLED OUT.

IF THE FEEDING TUBE BECOMES DISCONNECTED

Stop the pump. Estimate the amount of formula lost. Thoroughly wipe the tube connections with soap and water or alcohol. They must be free from oil or formula build up. Clean inside the extension set feeding port with a cotton-tipped applicator and alcohol. Irrigate the tube with warm water. Dry the connections and firmly reconnect the tubes with a quarter turn. Resume the feeding, replacing the estimated volume lost during the disconnection.

BALLOON LEAKS OR RUPTURES

Always keep a replacement MIC-KEY* feeding tube or conventional gastrostomy tube at home. Silicone balloons generally last several months, but the life span of the balloon varies according to several factors. These factors may include medication, volume of water used to fill the balloon, gastric pH, and tube care.

TUBE BLOCKAGE

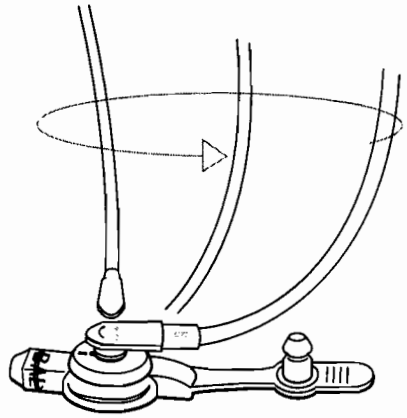
To prevent tube blockage, flush the tube with 10–20 ml warm water. If your specialist has instructed otherwise, follow your specialists instructions.

1. Before and after each feeding.
2. Before and after giving medications.
3. Every 3 to 4 hours if the patient is receiving continuous feedings.
4. After checking for stomach content residuals.

Do not mix medication with formula. Medication should be in liquid form when possible. If not, crush finely and make sure it is well dispersed in water. Give multiple medications one at a time and rinse the tube with warm water before and after. Flush the tube with 5 ml water between each medication.

BALLOON WILL NOT DEFLATE

If you cannot extract water from the balloon



with the syringe, ensure the recess in the balloon valve is clean. Occassionally the recess will trap spills of formula or other material as a result of normal daily living. Be sure the valve is not frozen closed by food. Clean inside the recess, then firmly seat the syringe into the valve, push and twist one quarter turn. Try pulling back on the plunger again. If the balloon will not deflate, use the end of a large paper clip to depress the valve and release the water. BE SURE YOU HAVE A REPLACEMENT TUBE TO INSERT INTO STOMA.

STOMA AND SKIN PROBLEMS

Bleeding stoma. Notify your specialist.

IF THE STOMA BLEEDS, (MORE THAN A SMALL AMOUNT) OR IF IT LOOKS LIKE BLOOD IS MIXED WITH STOMACH CONTENTS, CALL YOUR SPECIALIST IMMEDIATELY.

Redness or soreness around the skin and stoma may be the result of gastric leakage. Clean and dry the area frequently. Be sure to rotate the MIC-KEY* feeding tube in a full circle during daily tube care.

CALL THE SPECIALIST IF:

1. The stoma is persistently red and sore.
2. The red area is larger than 2.5 cm in diameter.
3. The stoma emits an odor.
4. The skin surrounding the stoma is swollen.
5. There is pus around the stoma.
6. The patient has a fever.

GRANULATION TISSUE

Granulation tissue is the result of the body trying to repair the surgical incision. The tissue may proliferate and require treatment. If it bleeds or a large amount of tissue builds up, contact your specialist.

SPECIAL CHILDREN'S PROBLEMS

IF A CHILD VOMITS

When vomiting occurs, it is possible to inhale formula and stomach contents into the lungs. Aspiration is the medical term for this and it can lead to serious medical problems.

MIC-KEY* CARE GUIDE

If a child develops difficulty breathing during or immediately after a feeding, STOP THE FEEDING AT ONCE, DRAIN (DECOMPRESS) THE STOMACH AND CALL THE SPECIALIST.

If the child feels nauseated, wait one to two hours before feeding and then resume the feeding slowly. The same is true for vomiting. Wait and feed at a slower rate.

IF NAUSEA OR VOMITING PERSIST, CALL THE SPECIALIST.

NOTE: Some children have gastroesophageal reflux. Food routinely flows backward up the esophagus. Correct feeding position is VERY IMPORTANT for these children. Place them in an upright position or at least a 30-degree angle before feeding. Notify your specialist if your child vomits after feeding.

SMALLER TUBES

The tubes used in children may have a smaller diameter than those used in adults. Smaller tubes clog more easily but require less water to flush out. Infants usually receive a 10 to 15 ml flush.

DIARRHEA

Two reasons for diarrhea are rapid formula administration or spoiled formula. Try giving the formula at a slower rate and refrigerate leftover formula.

MIX NEW FORMULA FOR EACH FEEDING AND NEVER KEEP MIXED FORMULA LONGER THAN 24 HOURS.

Changes in formula, medications or feeding routines can also cause diarrhea.

IF DIARRHEA PERSISTS FOR MORE THAN THREE DAYS, CALL YOUR SPECIALIST.

CONSTIPATION

Certain types of formulas cause constipation in sensitive individuals. Inactivity, change in formula, medication, or change in the feeding routine can also cause constipation.

MIC-KEY* CARE GUIDE

GLOSSARY OF TERMS

ASPIRATION: Accidently inhaling liquid into the windpipe and/or lungs.

BOLUS FEEDING: Large amounts of formula delivered through the tube.

CONSTIPATION: Bowel movements (stools) sometimes painful, and difficult to pass.

CONTINUOUS FEEDING: Small amounts of formula constantly throughout the day (or night) without interruption.

DIARRHEA: Frequent, loose, watery bowel movements.

ESOPHAGUS: The passage in the throat through which food passes from the mouth into the stomach.

FEEDING PUMP: A small machine, plug-in or battery powered, that automatically controls the amount of formula being delivered through the feeding tube.

FEEDING SET: Tubing that connects the feeding container to the feeding tube.

FEEDING TUBE: Tube through which formula flows into the stomach or intestine. Gastrostomy or jejunostomy tube.

G-TUBE: Gastrostomy tube. A tube that passes through the skin into the stomach. Also called feeding tube.

GASTROESOPHAGEAL REFLUX: Backing up of formula or gastric juice from the stomach into the esophagus.

GASTROINTESTINAL DECOMPRESSION: The removal of gas or fluid from the stomach. (also called "venting").

GASTROSTOMY: A surgical opening (stoma) through the skin into the stomach.

GRANULATION TISSUE: Fleshy projections formed on the surface of the stoma that will later form fibrous scar tissue.

GRAVITY DRIP: Formula flows into the stomach by gravity.

INTERMITTENT FEEDING: Feeding smaller amounts of formula frequently during the day or night. Intermittent feeding supplements night-time continous feeding.

NUTRIENTS: Food or any substance that nourishes the body - protein, carbohydrate, fat, vitamins, minerals, and water.

STOMA: Surgical opening through which a feeding tube can enter the body.

STOMACH RESIDUAL: Contents of the last feeding remaining in the stomach just before the next feeding is to be given.

SYMMETRICAL: Correspondence in shape, size, and relative position of parts on opposite sides.

CONTENTS

MIC-KEY* CARE GUIDE

GASTROSTOMY INFORMATION

NAME _____ PHONE _____

SPECIALIST _____ PHONE _____

PLACEMENT DATE _____ TYPE _____

TUBE REPLACEMENT DATES _____

TUBE SPECIFICATIONS:

FRENCH SIZE _____ LENGTH IN CENTIMETERS _____

BALLOON VOLUME _____ LOT NUMBER _____

FORMULA PREPARATION:

TYPE OF FORMULA _____ AMOUNT OF FORMULA _____

FEEDING TIMES _____ _____ _____ _____ _____

AMOUNT OF EACH FEEDING _____ AMOUNT OF WATER _____

PUMP SETTING OR FLOW RATE ____ ADDITIONAL INGREDIENTS ____

BLENDERIZED TABLE FOOD: FOLLOW THE DOCTOR'S INSTRUCTIONS

FLUSH WITH _____ ml WATER BEFORE AND AFTER EVERY FEEDING

MIX WELL AND REFRIGERATE. FOLLOW SPECIALIST'S INSTRUCTIONS

IF YOU HAVE ANY QUESTIONS ABOUT YOUR MIC GASTROSTOMY TUBE, YOU MAY CALL BALLARD MEDICAL PRODUCTS TOLL FREE AT 1-800-528-5591

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- Directions for use
- Care guide pamphlets
- Animated care instructions

Patients:
www.mic-key.com
- Patient success stories
- Links to relevant journal articles
- "Be the Expert" forum articles
- Directions for use
- Care guide pamphlets
- Animated care instructions

Manufactured by Ballard Medical Products, Draper, Utah 84020 USA
Distributed in the U.S. by Kimberly-Clark Global Sales, Inc. Roswell, GA. 30076 USA
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Kimberly-Clark*

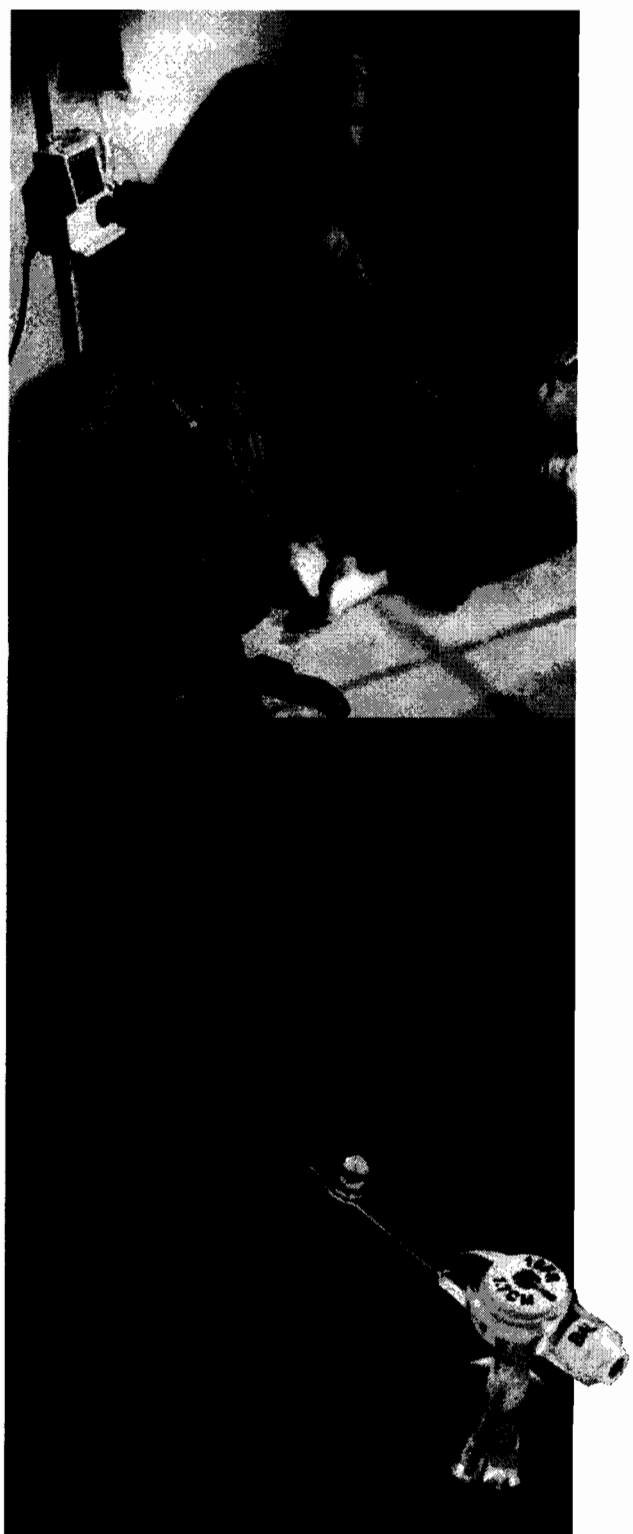
MIC-KEY*

LOW-PROFILE GASTROSTOMY FEEDING TUBE

YOUR GUIDE TO PROPER CARE

Visit our websites:
Clinicians - www.kchealthcare.com/mic-key.com
Patients - www.mic-key.com

KIMBERLY-CLARK* MIC-KEY*
Low-Profile Gastrostomy Feeding Tube



Helping your patient face the use of a gastrostomy tube, possibly for a lifetime, can be a challenge. That's why the KIMBERLY-CLARK* MIC-KEY* Low-Profile Gastrostomy Feeding Tube is designed to provide a little peace of mind for both of you.

The KIMBERLY-CLARK MIC-KEY Feeding Tube is available in 79 sizes for a comfortable, proper fit that minimizes the chance of leakage. The MIC-KEY feeding tube does not require the use of an obturator, so the tube does not need to be distorted for insertion. The slim design allows more air to circulate around the stoma and makes it easy to care for.

For active patients, the MIC-KEY feeding tube is less cumbersome than conventional gastrostomy tubes, and its low-profile design makes it unobtrusive and easier to conceal.

Tube Features Include:

- Medical Grade Silicone Construction
- Low-Profile Design
- Tapered Distal Tip
- Silicone Internal Retention Balloon
- Distal Tip Recessed at Recommended Fill Volume
- Proximal Anti-Reflux Valve
- SECUR-LOK* Extension Set Connector Mechanism
- Radiopaque Stripe
- Wide Variety of Extension Sets Available

The KIMBERLY-CLARK* MIC-KEY* Low-Profile Gastrostomy Feeding Tube is just one of the clinical solutions that you can depend on to meet the demands of your fast-paced world.

Whether your needs involve preventing healthcare-associated infections, surgical and digestive solutions or pain management, with Kimberly-Clark you'll always have one less worry.

Kimberly-Clark

*Trusted Clinical Solutions**

KIMBERLY-CLARK* MIC-KEY* feeding tubes provide a worry-free solution to enteral feeding

12 French

STOCK #	STOMA LENGTH
0120-12-0.8	0.8 cm
0120-12-1.0	1.0 cm
0120-12-1.2	1.2 cm
0120-12-1.5	1.5 cm
0120-12-1.7	1.7 cm
0120-12-2.0	2.0 cm
0120-12-2.3	2.3 cm
0120-12-2.5	2.5 cm
0120-12-2.7	2.7 cm
0120-12-3.0	3.0 cm
0120-12-3.5	3.5 cm
0120-12-4.0	4.0 cm

14 French

STOCK #	STOMA LENGTH
0120-14-0.8	0.8 cm
0120-14-1.0	1.0 cm
0120-14-1.2	1.2 cm
0120-14-1.5	1.5 cm
0120-14-1.7	1.7 cm
0120-14-2.0	2.0 cm
0120-14-2.3	2.3 cm
0120-14-2.5	2.5 cm
0120-14-2.7	2.7 cm
0120-14-3.0	3.0 cm
0120-14-3.5	3.5 cm
0120-14-4.0	4.0 cm
0120-14-4.5	4.5 cm
0120-14-5.0	5.0 cm

16 French

STOCK #	STOMA LENGTH
0120-16-0.8	0.8 cm
0120-16-1.0	1.0 cm
0120-16-1.2	1.2 cm
0120-16-1.5	1.5 cm
0120-16-1.7	1.7 cm
0120-16-2.0	2.0 cm
0120-16-2.3	2.3 cm
0120-16-2.5	2.5 cm
0120-16-2.7	2.7 cm
0120-16-3.0	3.0 cm
0120-16-3.5	3.5 cm
0120-16-4.0	4.0 cm
0120-16-4.5	4.5 cm
0120-16-5.0	5.0 cm

18 French

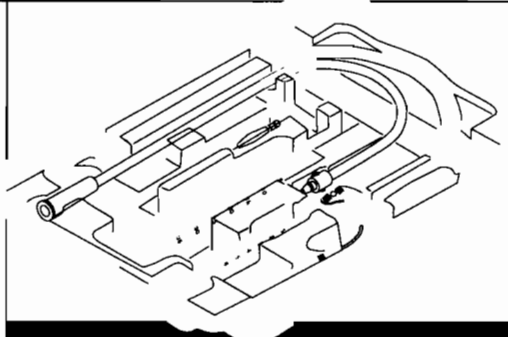
STOCK #	STOMA LENGTH
0120-18-0.8	0.8 cm
0120-18-1.0	1.0 cm
0120-18-1.2	1.2 cm
0120-18-1.5	1.5 cm
0120-18-1.7	1.7 cm
0120-18-2.0	2.0 cm
0120-18-2.3	2.3 cm
0120-18-2.5	2.5 cm
0120-18-2.7	2.7 cm
0120-18-3.0	3.0 cm
0120-18-3.5	3.5 cm
0120-18-4.0	4.0 cm
0120-18-4.5	4.5 cm
0120-18-5.0	5.0 cm

20 French

STOCK #	STOMA LENGTH
0120-20-0.8	0.8 cm
0120-20-1.0	1.0 cm
0120-20-1.2	1.2 cm
0120-20-1.5	1.5 cm
0120-20-1.7	1.7 cm
0120-20-2.0	2.0 cm
0120-20-2.3	2.3 cm
0120-20-2.5	2.5 cm
0120-20-2.7	2.7 cm
0120-20-3.0	3.0 cm
0120-20-3.5	3.5 cm
0120-20-4.0	4.0 cm
0120-20-4.5	4.5 cm
0120-20-5.0	5.0 cm

24 French

STOCK #	STOMA LENGTH
0120-24-1.5	1.5 cm
0120-24-1.7	1.7 cm
0120-24-2.0	2.0 cm
0120-24-2.3	2.3 cm
0120-24-2.5	2.5 cm
0120-24-2.7	2.7 cm
0120-24-3.0	3.0 cm
0120-24-3.5	3.5 cm
0120-24-4.0	4.0 cm
0120-24-4.5	4.5 cm
0120-24-5.0	5.0 cm



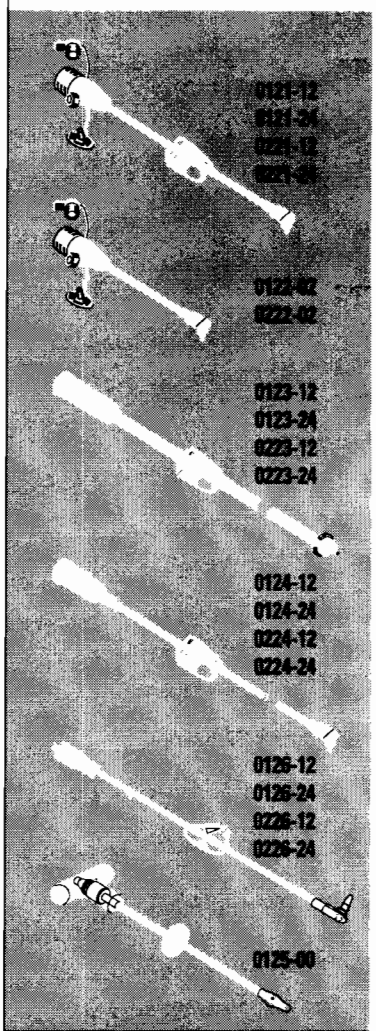
Kit Includes†:

- 1- MIC-KEY* Low-Profile Feeding Tube
- 1- MIC-KEY* Extension Set with SECUR-LOK* Right Angle Connector and 2 Port "Y" and Clamp – 12" Length (for continuous feeding)
- 1- MIC-KEY* Bolus Extension Set with Cath Tip, SECUR-LOK* Straight Connector and Clamp – 12" Length (for bolus feeding)
- 1- 6ml Syringe
- 1- 35ml Catheter Tip Syringe
- 4- Gauze Pads

Accessories

To complement the KIMBERLY-CLARK* MIC-KEY* Low-Profile Feeding Tube, a variety of feeding accessories and lengths are available for the continuous or bolus delivery of nutrients and medications. Each features the SECUR-LOK* connection mechanism to minimize feeding set disconnects. In addition, each set allows for complete range of motion by allowing the Extension Set to rotate within the MIC-KEY* feeding port during movement.

STANDARD[11] STOCK #	DEHP-FREE FORMULATION STOCK #	LENGTH	DESCRIPTION	EACH
0221-12	0121-12	12"	MIC-KEY* Extension Set with SECUR-LOK* Right Angle Connector and 2 Port "Y" and Clamp	5
0221-24	0121-24	24"	MIC-KEY Extension Set with SECUR-LOK Right Angle Connector and 2 Port "Y" and Clamp	5
0222-02	0122-02	2"	MIC-KEY* Medication Set with SECUR-LOK* Right Angle Connector and 2 Port "Y"	5
0223-12	0123-12	12"	MIC-KEY* Bolus Extension Set with Cath Tip, SECUR-LOK Straight Connector and Clamp	5
0223-24	0123-24	24"	MIC-KEY Bolus Extension Set with Cath Tip, SECUR-LOK Straight Connector and Clamp	5
0224-12	0124-12	12"	MIC-KEY* Bolus Extension Set with Cath Tip, SECUR-LOK* Right Angle Connector and Clamp	5
0224-24	0124-24	24"	MIC-KEY Bolus Extension Set with Cath Tip, SECUR-LOK Right Angle Connector and Clamp	5
0226-12	0126-12	12"	MIC-KEY* Threaded Extension Set with SECUR-LOK* Right Angle Connector and Clamp (for International sale only)	5
0226-24	0126-24	24"	MIC-KEY Threaded Extension Set with SECUR-LOK Right Angle Connector and Clamp (for International sale only)	5
	0125-00		MIC-KEY* Stoma Measuring Device	10



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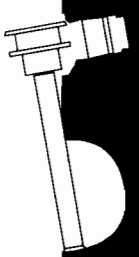
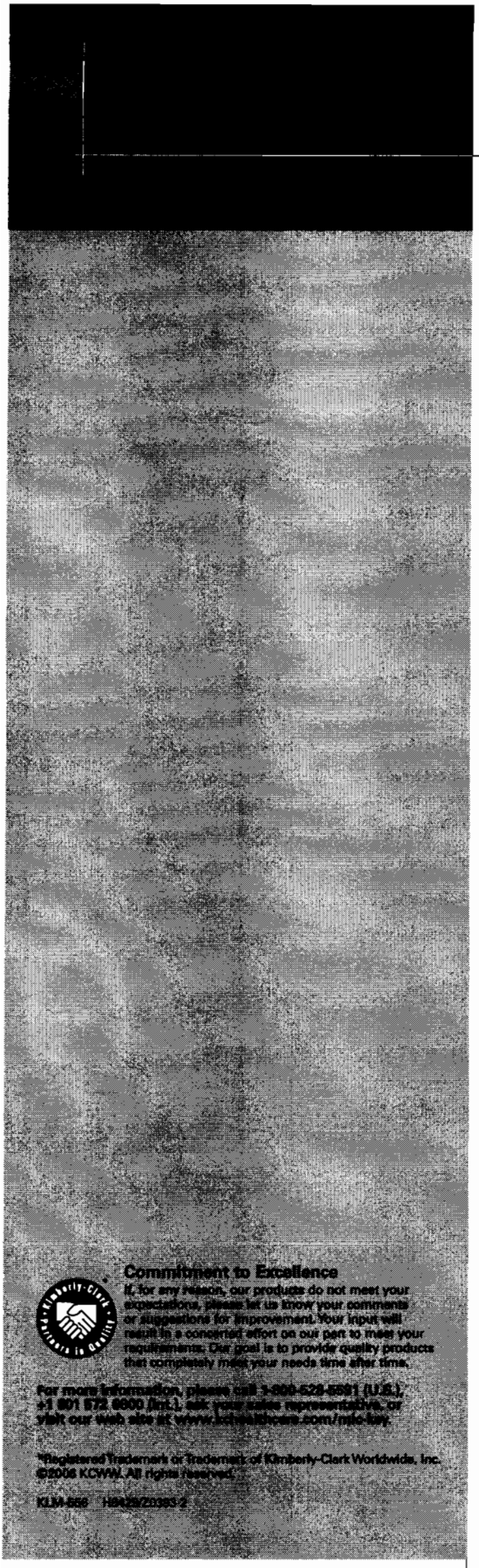


† All KIMBERLY-CLARK* MIC-KEY* Low-Profile Gastrostomy Feeding Tube Kits include OEHP-Free Formulation extension sets

†† Standard formulation contains DEHP. For further information about DEHP, please visit our website at www.kchealthcare.com/DEHP

KIMBERLY-CLARK* MIC-KEY*
Low-Profile Gastrostomy Feeding Tube



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KLM-666 H0426/20060-2

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AstraZeneca

December 27, 2007

By Courier

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

Re: CMS-1385-FC – CAP Issues/Prefilled Syringes and Drug Compendia

Dear Mr. Weems:

AstraZeneca (encompassing AstraZeneca Pharmaceuticals LP and AstraZeneca LP ("AstraZeneca")) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services ("CMS") final rule with comment period on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 and Other Part B Payment Policies (the "Final Rule With Comment Period"). AstraZeneca is a leading global healthcare company dedicated to the research and development of new medicines in therapeutic areas including cardiovascular, gastrointestinal, oncology, respiratory, and neuroscience. AstraZeneca is committed to the discovery of drugs that will allow patients to lead longer, healthier and more productive lives. We conduct and support scientifically robust research that improves the delivery of effective, high-quality care to patients.

In that regard, we appreciate the opportunity to present additional comments on the following two issues:

- CMS should maintain its current policy prohibiting competitive acquisition program ("CAP") vendors from repackaging CAP drugs.

- To ensure patient access to life-improving therapies, it is imperative that CMS approve at least one additional compendium as soon as possible.

I. CAP Issues: AstraZeneca requests that CMS maintain its current prohibition against CAP vendors repackaging CAP drugs.

CMS should maintain its current policy that prohibits CAP vendors from repackaging CAP drugs. In the July 12, 2007 Medicare physician fee schedule proposed rule, CMS solicited comments as to whether it would be feasible for an approved CAP vendor(s) to supply prefilled syringes to all physicians who participate in the CAP. This approach would be in lieu of the current requirement that physicians obtain CAP drugs that are provided in prefilled syringes from an entity other than a CAP vendor.

AstraZeneca Pharmaceuticals LP
Federal Government Affairs
701 Pennsylvania Avenue NW Suite 500 Washington DC 20004

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Fax 202 350 5510
www.astrazeneca-us.com

AstraZeneca

We are pleased that, after reviewing public comments on this issue, CMS has decided not to amend its policy at this time. As we noted in our formal comments on the proposed rule, AstraZeneca has strong concerns about allowing approved CAP vendors to repackage CAP drugs. We agree with CMS's current policy that it is inappropriate for CAP vendors to perform pharmacy admixture services when furnishing CAP drugs, because such services require specialized staffing, training, and equipment that a CAP vendor may not possess. Modifying this policy could compromise the integrity of CAP drugs and jeopardize patient care. That is why we urged CMS to maintain its policy providing that, when product labeling provides for a single dose vial, CAP vendors are not allowed to repackage the product or allow for its use as a multi-dose vial.

In the Final Rule With Comment Period, CMS reiterated the many operational and policy considerations that must be weighed before making such a change to allow CAP vendors to repackage drugs. Applicable laws and regulations, along with serious product stability and product integrity concerns, make it inadvisable to change CMS requirements either now or in the future. We therefore urge CMS to continue to exercise caution and ensure that quality of care is preserved for patients and physicians participating in the CAP program by maintaining the current safeguards in the CAP regulations.

II. Drug Compendia: AstraZeneca requests that CMS approve at least one additional drug compendium as soon as possible

We urge CMS to expedite its review of outstanding requests for compendia status that are before the agency. While we commend CMS for putting a more formal review process in place, we believe that immediate action is required on pending requests to ensure continued Medicare beneficiary access to the most current treatment options that are available. We are concerned that the implementation of CMS's new review process, coupled with the fact that there is currently only one approved compendia, may limit patient access to these options for those who are critically-ill and cannot wait for the regulatory process to resolve this issue. We would welcome an opportunity to meet with CMS to discuss our concerns in greater detail.

* * *

Again, AstraZeneca appreciates the opportunity to share our views on the Final Rule With Comment Period. Please do not hesitate to contact me at 202-350-5525 if you have any questions or need further information about these comments.

Sincerely,

Sandra Leonard

Director, Government Reimbursement

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30

sanofi aventis

Because health matters

Edward F. GREISSING
Vice President

December 31, 2007

BY ELECTRONIC SUBMISSION

Kerry N. Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Dear Acting Administrator Weems:

Sanofi-aventis appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) interim final rule with comment regarding revisions to payment policies under the Medicare physician fee schedule, published in the Federal Register on November 27, 2007 (the Interim Final Rule). 1/ As a pharmaceutical company backed by world class research and development, we develop innovative therapies to help Medicare beneficiaries lead longer, healthier, and more productive lives. Our portfolio is focused in seven major therapeutic areas: cardiovascular disease, thrombosis, oncology, diabetes, central nervous system, internal medicine, and vaccines.

Sanofi-aventis is committed to the fight against disease throughout the world. In the new millennium, we have taken up the major challenges of discovering new compounds that are essential to the progress of medical science and launching pharmaceutical products all over the world that constitute real

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

therapeutic progress for patients. Our mission is to discover, develop, and make available to physicians and their patients innovative, effective, well-tolerated, high quality treatments that fulfill vital health care needs.

These comments are in addition to the comments we provided to you on the proposed rule that preceded this Interim Final Rule. 2/ Specifically, we are concerned that although the Interim Final Rule provided interim relative value units (RVUs) for Current Procedural Terminology (CPT) codes 99441, 99442, 99443, 98966, 98967 & 98968, CMS assigned status indicator "N" to these codes in Addendum C, identifying them as non-covered services. CPT codes 99441, 99442, and 99443 describe telephone evaluation and management services provided by a physician to an established patient, parent or guardian. CPT codes 98966, 98967, and 98968 describe telephone evaluation and management services provided by a qualified non-physician health care professional to an established patient, parent or guardian. Full reimbursement of these codes is essential to promoting care coordination by physicians, care coordinators and case managers, and we ask that CMS reconsider its decision in the Interim Final Rule and fully reimburse these codes.

These codes describe services that are critical to providing quality care and satisfying quality measures included in the Physician Quality Reporting Initiative (PQRI). Patients frequently are transferred between care settings, such as between primary care and specialty physicians, different departments in the hospital, and multiple facilities. During these transitions, it can be difficult to ensure sufficient communication between providers or across care settings in order to provide continuity of care to a patient and ease the burden borne by patients and their families with regard to follow up care. In our previous comments, we asked that CMS continue to work with measure developing organizations and stakeholders such as the National Transitions of Care Coalition to include measures in the PQRI and the other reporting programs that will provide incentives for care coordination. We applaud CMS for adopting measures that facilitate coordination among treating physicians (for example, PQRI measure #24 -Osteoporosis: Communication with Physician Management Ongoing Care Post Fracture and measure #46 – Medication Reconciliation).3/ We encourage CMS to continue to work with stakeholders to develop measures and requirements that further care coordination. In addition to developing these quality measures, we also encourage CMS to fully reimburse for the services required to implement these measures and encourage care coordination. Changing the status of CPT codes 99441, 99442, 99443, 98966, 99867 and 98968 from "N" to "A" would allow payment for care coordination services that are essential to appropriate transitions of care.

2/ 72 Fed. Reg. 38122 (July 12, 2007).
3/ 72 Fed. Reg. 38200.

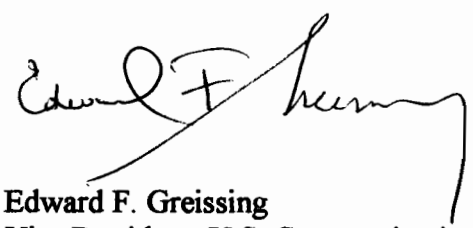
Implementation of the care coordination measures and payment for care coordination are consistent with the recommendations of the National Quality Forum (NQF) which has identified care coordination as a "priority area." The NQF has endorsed a standard definition of care coordination and a framework for measuring it, but to our knowledge has endorsed only one specific standard for care coordination. NQF has identified several areas as essential to care coordination:4/

- Medical home for each patient;
- Proactive plan of care and follow-up for each patient;
- Use of standardized, integrated information systems;
- Standardized data elements for patient's personal medication record;
- Standardized data elements for medication reconciliation; and
- Standardized care guidelines for transitions between care settings that include medication reconciliation and care plan and communication plan between medical team members, patients, and caregivers.

It has been well documented that poor transitions of care may result in poor health outcomes resulting from incorrect treatments, medication errors, delay in diagnosis and treatment and readmissions. These outcomes can be prevented through adequate and comprehensive care coordination. We urge CMS to continue to encourage care coordination in its programs and to provide reimbursement for the services necessary to provide those services.

We thank you for your consideration of these comments and hope we can continue to work with you to advance Medicare beneficiaries' access to high quality, state-of-the-art care. Please contact me or Mark Coin at (202) 281-8524 if you have any questions on these comments.

Respectfully Submitted,



Edward F. Greissing
Vice President, U.S. Communications and
Federal Government Relations

4/ NQF, *NQF-Endorsed Definition and Framework for Measuring Care Coordination* (May 2006).

LAMAR
COLORADO FIRE/AMBULANCE
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505 SOUTH MAIN
LAMAR, COLORADO 81052-3224
719/336-7330

December 21, 2007

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

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

Dear Mr. Weems:

I am writing to you on behalf of Lamar Ambulance Service. We are small, rural, and City-owned providing services to the citizens of both the City of Lamar and to approximately two-thirds of Prowers County, Colorado. We provide both emergency and non-emergency transport and use both B.L.S. and A.L.S. means. We have a very limited budget and always operate at a financial loss. Our region is very economically depressed. As the account clerk, I can speak for myself and our staff, in stating that Medicare requirements become more and more difficult to attain. The ambulance fee schedule has not given the annual increases as promised, creating further financial stress. The new signature requirement is yet another burden for us and is frustrating to say the least.

I realize that Medicare must be prudent when paying all claims and that there is a constant awareness of possible fraud. I do understand that, however, I have been billing Medicare for over fifteen years for this ambulance service. I do my work in an honest manner. It seems that a few dishonest providers have caused the honorable ones to be punished and further scrutinized. The Medicare system has already become so complex and difficult; please do not add to that by enacting these further signature requirements. It is an unfair burden.

I urge you to eliminate this new requirement completely. Thank you for your consideration of these comments.

Sincerely,

LAMAR AMBULANCE SERVICE

Marie Buhrer

Marie Buhrer
Account Clerk

/mb

Citizens' Ambulance Service Inc.
SINCE 1964

BLAIRSVILLE
ELDERTON
HILLSDALE
INDIANA
PLUMVILLE
WHEATFIELD

December 21, 2007

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

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

Dear Mr. Weems:

I am writing to you on behalf of Citizens' Ambulance Service, Inc. Citizens' Ambulance is a nonprofit corporation which provides emergency and non-emergency ambulance service to persons within the service area of Indiana County and portions of Armstrong, Westmoreland and Clearfield Counties of Pennsylvania. Emergency services are dispatched from three (3) separate 911 communication centers.

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

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

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

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

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

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

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

Finally, to comply with all these changes we will need to retrain all of our crew members, billing staff and other personnel. We will also need to develop new forms and educate the medical facilities we work with (both on the new exception for emergency and on the new interpretation for non-emergencies). In addition to being very costly, this training will take time. The January 1, 2008 effective date will not give us nearly enough time to retrain all of our personnel to comply with the new requirement. **For this reason, we urge you to delay implementation for a few months, in order to give ambulance services like ours the time to make these needed changes.**

Thank you for your consideration of these comments.

Sincerely,

Ginger Unrue
Director of Finance/Administration
Citizens' Ambulance Service, Inc.

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Tuesday, December 18, 2007

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

Re: **Medicare Program – Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 [CMS-1385-FC]**

Dear CMS:

Vista Radiology, P.C. ("Vista"), representing Thirty (30) radiologists, appreciates the opportunity to submit written comments about the "Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" published in the *Federal Register* as a final rule with comment period on November 27, 2007. Our comments focus on issues related to the physician self-referral and the anti-markup provisions contained in the final rule.

Vista shares the concerns of CMS about over-utilization of physician-owned diagnostic services and applauds CMS's efforts in adopting the anti-markup provisions of the final rule to prohibit physicians from profiting from self-referred tests performed at sites other than the office of the referring physician. Moreover, Vista strongly urges CMS to revisit the Stark in-office ancillary services exception to curtail the expansion of the Stark regulation in a manner which promotes physician ownership of, and self-referral to, advanced imaging tests such as CT, MRI and PET.

Non-radiologist physicians groups have entered this sophisticated imaging market, unchecked, in an effort to garner significant revenue from these so-called "ancillary" services. Yet, it strains credulity to suggest, as physicians justifying their investments often do, that these imaging examinations (which require the expertise of radiologists and highly trained technologists) are necessary to assist the physician at the time of the patient's visit. That was the rationale underlying Congress's establishing the in-office ancillary services exception, but this Stark exception, as interpreted by the healthcare industry, has expanded physician ownership of truly "ancillary" services such as simple x-ray and lab tests well beyond the original intent of Congress.

As cited in the overutilization discussion on pages 66311-66312, there is certainly little doubt that non-radiologist investment in, or leasing arrangements involving, expensive

imaging equipment comes with a built-in incentive to maximize referrals to that imaging equipment, adversely affecting the practitioner's medical decision-making. The oft-cited increased utilization trends mean that more patients are receiving imaging services from physicians who are not trained as radiologists and who may be compromising patient safety by repeated exposure to excess radiation. Consider, for example, that many non-radiologist physicians are content, in the name of patient convenience, to refer their own patients to the one-slice CT scanner they just purchased on the used equipment market, rather than send that same patient to the new 320-slice CT scanner available from a nearby hospital at the same reimbursement. By denying their patients access to the latest technological advancements, self-referring physicians may also be subjecting their patients to substantial increases in radiation exposure. To allow non-radiologists to make that judgment, when also motivated by financial incentives, is directly contrary to the original intent of Congress in establishing the in-office ancillary services exception.

Certainly, there are diagnostic services which are, and should be, considered truly ancillary to a physician's practice. For example, Vista supports the use of the in-office ancillary services exception to allow obstetricians to use ultrasound on their patients or cardiologists to run EKG's on their patients. These examples are consistent with the underlying rationale for allowing truly ancillary services which are necessary to the diagnosis and treatment of the condition at the time of the physician's office visit. On the other hand, advanced tests such as MRI, CT and PET require radiologist expertise to train technologists, establish testing protocols and interpret complex imaging studies, the results of which will likely be used by the physician for developing long-term treatment plans for patients. Accordingly, Vista urges CMS to change the in-office ancillary services exception to ensure that these more sophisticated imaging services are not considered "ancillary" and cannot be performed by non-specialist physicians.

Vista is hopeful that the anti-markup provisions of the final rule will discourage physician ownership in, and joint ventures involving, these more advanced imaging services as such physicians discover that they may no longer profit from their usual self-referral patterns. Accordingly, Vista urges CMS to interpret the final rule in such a way that broadens its impact on self-referring physicians, whether in the same building or in a centralized building location.

We appreciate the opportunity to convey our concerns to CMS. If you need any additional information about our position, please don't hesitate to contact our practice administrator, Charles McRae.

Very truly yours,

Charles McRae, MBA
Vice President and CFO

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December 28, 2007

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

Re: Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Weems:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusion

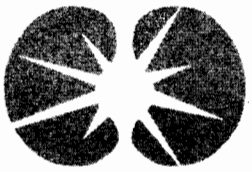
COCA believes that CMS has no interest in supporting a flawed process that would drive non-facility cardiac catheterization centers out of business. We base this belief not only on our previous meetings with CMS, but also on the statement CMS made in the July 2, 2007 Proposed Rule when expressing concern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

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

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

Sincerely yours,

Steve Blades
President



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December 28, 2007

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

Dear Administrator Weems:

I am a urologist who practices in Lancaster, Pennsylvania in a 7 physician group. Our patient population is comprised of 54% Medicare patients who are treated for all types of urological diseases including prostate cancer. Our practice has the highest percentage of prostate cancer patients in our region due to our 10 year history of clinical research and our expertise in treating prostate cancer.

In order to improve the quality of laboratory services available to our practice and our patients, we have contracted with our uropathologist who manages our specialized laboratory. This individual has unique expertise in the analysis of urological specimens and samples, especially biopsies, to determine if a patient has prostate or another kind of urologic cancer.

Our practice has an emphasis on tertiary care of urology in a private practice setting. In the July 9, 2006 US News and World Reports, we were interviewed because of our excellent patient outcomes in prostate cancer care. We continuously have managed more than 2,500 patients with prostate cancer for the last ten years.

As an example, we have been participants in a large clinical trial for patients with a pre-cancerous condition of the prostate known as high-grade prostatic intraepithelial neoplasia (PIN). All patients had their biopsy forwarded to Dr. David Bostwick, considered a world-renowned expert, for his review. Our pathologists correctly called PIN on 70% of our biopsies as determined by Dr. Bostwick.

When we made the change to our uropathologist, this number changed to 100%. That means 30% of our patients were incorrectly designated as having PIN which would lead to a second and unnecessary biopsy. Thus, by contracting our own specialized uropathologist, we have helped control costs by more accurately diagnosing this condition.

*Michael Rommel, M.D. • *Paul R. Sieber, M.D. • *Chris G. Theodoran, D.O.
*Robert D. Hong, M.D. • *Michael A. Del Terzo, M.D. •*Paul J. Russinko, M.D. • *Christopher A. Woodard, M.D.
Leanne S. Schimke, CRNP, CUNP
*Board Certified in Urology & Urological Surgery
*C. Edward Pohl, M.D. Emeritus • *Henry W. Huffnagle, M.D. Emeritus
*Joseph A. Breslin, M.D. Emeritus • *Victor E. Agusta, M.D. Emeritus

I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

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

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

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

The changes proposed in these rules will have a serious impact on the way my group of urologists practice medicine and will not lead to the best medical practices. These rules will impact the quality of, and access to, diagnostic tests for Medicare beneficiaries. The proposed changes to the anti-markup rule will make it difficult, if not impossible for me to provide accurate (100%) prostate biopsy tests to 54% of our patients.

Based on the Stark regulations, my practice developed our uropathology lab to comply with the regulations. It cost $110,000 and took one year to create a state of the art uropathology lab to provide quality services to my patients. Based on the new anti-markup regulations, it will not be possible for my practice to offer these services without operating at a loss. As a result, when these services are no longer available, 54% of our patients will lose access to quality services.

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

Than you for your consideration,

Paul R Sieber

Paul R. Sieber, M.D.

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Submitter: Concerned Physician 12/01/2007

Organization: Private Practice

Category: Physician

Issue Area/Comments: **PHYSICIAN SELF-REFERRAL PROVISIONS CMS 1385-FC**

Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests

Anti-Markup Rule

In-Office Ancillary Services (IOAS) Exemption

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

Dear Administrator Weems:

I am commenting on the recently released CMS revisions to the rule prohibiting the mark-up of diagnostic tests, as well as reaction to the document. The challenge that CMS faces is how to prohibit abusive arrangements such as "pods" without having significant unintended consequence of limiting legitimate diagnostic testing. A letter sent by thirty-three organizations (see attachment 1) correctly points out problems with relying on this methodology. The theme of that letter reflects these societies' concern that location is the test employed to determine appropriateness rather than physician skills or a combination of location and skills. Regrettably, the authors of this letter offer no solutions for curbing the rampant patient abuse costing our government many hundreds of millions of dollars yearly. They ask to delay implementation of the finalized rules rather than to propose an acceptable solution. I would like to propose a solution.

The portion of the document cited in **bold** are quotes from the **Federal Register** or other identified government sources. Normal font will be my narrative and my suggestions for diminishing over utilization.

CMS should state the **Anti-Markup Rule** simply. Physicians and Physician Groups should not bill Medicare for any tests performed apart from locations where **"core medical services are routinely delivered"** and for tests which no **"physician in the group"** has the training to perform.

This concept is simple and any physician could analyze these words without consulting a lawyer. The In–Office Ancillary Service (IOAS) exemption has been clearly stated in the past. The intent is clear and need not be changed. The **Final Rule in the Federal Register vol. 66 page 885, Section 1877(b) (2) (A) (ii) (I) of the Act** says, **"We believe the underlying intent is to allow physicians to furnish DHS that are ancillary to the physician's core medical practice in the locations where the core medical services are routinely delivered. ...Simply stated, the DHS should be ancillary to physician services that are not DHS, and not the other way around. The exception was intended as an accommodation to physician's customary practice of medicine and not as a loophole for physicians and group practices to operate DHS enterprises that are unconnected –or only marginally connected—to their medical practice."**

CMS should acknowledge skill (**physician's core medical practice**) and location (**where the core medical services are routinely delivered**) as mutual and inseparable requirements for payment of DHS. This would make a strong statement and target more abusive contracts than would be ended by the **Anti-Markup Rules of November 27, 2007**. At the same time, CMS will express an understanding of the valid concerns discussed in the letter submitted by the thirty-three medical societies. Let me explain.

The **Anti-Markup Rules** of November 27, 2007 may stop "condo" or "pod" lab proliferation; however, the rules as presently written fall short of halting the proliferation of Designated Health Services (DHS) imaging companies with the attendant inappropriate physician self-referrals and the patient abuse that these schemes encourage.

In citing the location as the major criterion to determine the "full range of services," CMS has created ambiguities that will make practicing medicine harder especially for the larger, more integrated group practices providing a broad range of services in several locations. No single location may provide the "full range" of services. Moreover, since a "full range of services" is not clearly defined, liberal interpretations will lead to abuse. Conservative interpretations could restrict many appropriate IOAS referrals that I do not believe CMS is trying to restrict.

A more precise manner to determine which practices will be reimbursed for DHS services is to base the payments of DHS contingent upon the Physician Group possessing the skills necessary to administer and interpret tests at the location that the Physician Group usually practices medicine.

This could be accomplished by allowing payment of the technical component (TC) only to those groups that bill the professional component (PC) at the same location that the TC was originated. **Stark II Part III rules** state that independent contractors are considered a **"physician in the group"** only during the time the independent contractor is in the Group's office. Thus, the independent contractors would be unable to interpret studies remotely and must be at the group's office to receive reimbursement. Without having the interpreting doctor at the location where the DHS was performed, the Physician Group could no longer bill the TC.

The ability of "pod" labs and imaging companies to flourish and proliferate is contingent upon utilization of skills and services that are not core to the Physician Group. The ability to generate the TC is often completely outsourced to a low-cost Supplier with no substantive business risk to the Physician Group. The interpretive skills are then outsourced with the result being in essence a "test that is purchased". The true cost of the test is then marked up to Medicare. The profit is made on the spread between the amount collected from Medicare minus the cost of the test from the Supplier and interpreting physician. This spread may involve the TC, PC, or both TC and PC. Two examples illustrate the points.

The following are examples:

1) A Physician Group performs a prostate biopsy in their office and sends the biopsy for pathology evaluation to their "pod" lab 100 miles away to be read by their pathology "pod" physician who works as an "independent contractor" for the group while in the "pod". The Group could not bill Medicare for the TC or PC of the pathology because the location for the interpretation is different than the location where the biopsy was performed.

However, if the Physician Group employed a pathologist independent contractor who came to the office where the biopsy was performed, the pathologist would be considered a **"physician in the group"** while at the office and an appropriate TC and PC would be billed by the Physician Group. Since the pathologist is acting as a **"physician in the group,"** he would be paid directly by the group and would not be able to bill Medicare separately. There would be the potential of direct interaction between the pathologist and the members of the Physician Group. As pathologists are unlikely to drive from physician office to physician office with the equipment needed to process and interpret biopsies, the present abusive practice will be severely curtailed.

2) An imaging Supplier (see attachment 2) leases a nuclear cardiology camera and technician to a Physician Group. The Supplier provides all management, supplies, and requisite licenses to create a "turn-key" operation. The supplier arranges the interpretation of the study by a Specialist via the internet at a remote location 100 miles away. The Physician Group bills the TC and the remote interpreting Specialist bills the PC or is paid by the Supplier. This scenario would be disallowed since the location of the TC and PC is different. The tax ID numbers of the Physician Group and the interpreting Specialist would also be different and would easily identify a charge to be disallowed.

However, if the interpreting physician came to the Physician Group's office to provide the interpretation, and was thus a **"physician in the group"** while performing the interpretation, the TC and the PC billed by the Physician Group would be allowed. Again, the specialist would not be able to bill Medicare directly. Since most specialists would not drive from physician office to physician office to interpret studies, and since the profit margin would be much less for the Physician Group as they would be required

to pay the Medicare PC reimbursement to the specialist, the abusive practices would be curtailed.

I will now describe a second approach, which also utilizes existing rules.

Clever lawyers from "pod" labs and imaging companies have exploited **Section 424.80 (b)(2)** which states **"Exceptions to the basic rule- (2) *Payment to an entity under a contractual arrangement.* Medicare may pay an entity enrolled in the Medicare program if there is a contractual arrangement between the entity and the supplier under which the entity bills for the supplier's services, subject to the provisions of paragraph (d) of this section."** Having the Physician Group contract with the "pod" or DHS company for one year circumvents the **Anti-Markup Rule**. Functionally this allows any doctor to profit by ordering any test that a company can supply in his office, so long as there is a conforming contract between the Supplier and the Physician Group.

This liberal definition of a "purchased test" is a loophole in the IOAS that desperately needs to be closed. Intuitively one would consider a test that is wholly purchased from a Supplier to be a "purchased test". This is to say, the Supplier of the "purchased test" provides all the equipment, personnel and incidentals. The technicians are W-2 employees of the Supplier. The lab certification is provided by the Supplier. The marketing may also be done by the Supplier. The interpretation is arranged by the Supplier. Thus, a sensible person would say that the test was "purchased" from the Supplier.

However, that sensible person would be wrong. If a contractual relationship existed between the Supplier and the Physician Group, this test would be "**reassigned to an entity under a contractual relationship**". The arrangement would fall outside the **Anti-Markup Rule** and would permit the Physician Group to receive reimbursement from Medicare.

The common thread that "pod" labs or DHS Suppliers have is the existence of a **"contractual relationship designed to permit the Supplier to do indirectly what it can not do directly; that is, pay the Physician Group a share of the profits from their laboratory referrals." OIG Advisory Opinion No. 4-17.**

In addition, the **OIG Special Advisory Bulletin on Contractual Joint Ventures focuses on questionable contractual arrangements where a health care provider in one line of business (hereafter referred to as the "Owner") expands into a related health care business by contracting with an existing provider of a related item or service (hereafter referred to as the "Manager/Supplier") to provide the new item or service to the Owner's existing patient population, including federal health care program patients. The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier – otherwise a potential competitor – receiving**

in return the profits of the business as remuneration for its federal program referrals.

CMS also has acknowledged the potential for abuse of **424.80 in 20.2.4.2(D)**.

20.2.4.2 - Payment to Physician for Purchased Diagnostic Tests
(Rev. 135, 04-02-04)
D - Questionable Business Arrangements
No special charge or payment constraints are imposed on tests performed by a physician or a technician under the physician's supervision. There are two requirements for all diagnostic tests under §1861(s)(3) of the Act, as implemented by 42 CFR §410.32 and section 10 of chapter 13 of this publication and section 80, chapter 15 of Pub. 100-02BP. Namely, the test must be ordered by the treating practitioner, and the test must be supervised by a physician. However, attempts may be made by the medical diagnostic community to adjust or establish arrangements which continue to allow physicians to profit from other's work or by creating the appearance that the physician has performed or supervised his/her technicians who are employed, contracted, or leased. Some of these arrangements may involve cardiac scanning services and mobile ultrasound companies leasing their equipment to physicians for the day the equipment is used, and hiring out their staff to the physicians to meet the supervision requirement. The bonafides of such arrangements may be suspect and could be an attempt to circumvent the prohibition against the mark-up on purchased diagnostic tests. If you have any doubt that a particular arrangement is a valid relationship where the physician is performing or supervising the services, this should be investigated. The Office of the Inspector General (OIG) has responsibility for investigating violations of §1842(n) of the Act.

In conclusion contractual arrangements by "pod" lab Suppliers and imaging Suppliers are being used to circumvent the **Anti-Markup Rules**. By focusing solely on the "geography" instead of the "skill sets" of the **"physicians in the group,"** CMS creates ambiguities that will be exploited further by these Suppliers, while simultaneously inhibiting physicians from being able to seamlessly coordinate care within their groups.

Why are these business arrangements allowed to flourish? Please consider my above revisions to the **Anti-Markup Rules**. The changes I have outlined will allow large and small medical practices to provide appropriate DHS under the IOAS exemption, while excluding potentially abusive contractual joint ventures.

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Patrick J. Kostic
ECEMS Manager

December 19, 2007

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

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

Dear Mr. Weems:

I am writing to you on behalf of Escambia County Emergency Medical Services. We are located in Pensacola, Florida and our community has long standing ties with the U.S. Military. We are the primary provider for both Advanced Life Support and Basic Life Support Services for our community. We are a county government department providing Emergency Medical Services to the entire area of Escambia County, Florida, which is approximately 663 square miles. Our population is approximately 300,00 residents and we respond to nearly 45,000 requests for service, of which 7000 of those requests are for non-emergency transports annually. We have three level two trauma centers and one pediatric trauma center in our community and serve a large retired military and senior population. We utilize a fleet of 25 ambulances and a staff of nearly 125 employees to respond to these requests for service.

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

While the new exception for emergency ambulance transports, listed in 42 C.F.R. §424.36(b)(6), provides a little more flexibility, it will not resolve the problem in most

cases. Further, we face problems with getting the patient's signature for non-emergencies as well. For our non-emergency transports, the patient is frequently suffering from a chronic or terminal condition—in fact, this may be the very reason they need an ambulance—that makes it extremely difficult to get the patient's signature, not only at the time of transport, but also after the fact. **Therefore, we ask that you expand this new exception to include both emergency and non-emergency transports.**

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

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

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

While we understand CMS' desire to verify that transports were actually provided before payment is made, we believe there are more effective means of verifying that the transport was completed. Nearly all covered ambulance transports will be to or from a medical facility. These facilities must keep records as to how the patient arrived or was

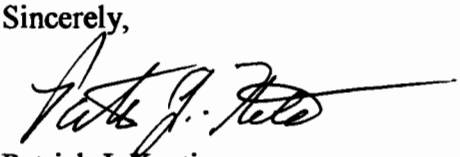
discharged. Thus, in the event it becomes necessary to prove an ambulance transport was provided, CMS could request the records of the medical facility. Also, since the overwhelming majority of claims are submitted electronically, the patient is not signing the actual claim form anyway. Instead, they are signing a separate piece of paper.

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

Finally, to comply with all these changes we will need to retrain all of our crew members, billing staff and other personnel. We will also need to develop new forms and educate the medical facilities we work with (both on the new exception for emergency and on the new interpretation for non-emergencies). In addition to being very costly, this training will take time. The January 1, 2008 effective date will not give us nearly enough time to retrain all of our personnel to comply with the new requirement. **For this reason, we urge you to delay implementation for a few months, in order to give ambulance services like ours the time to make these needed changes.**

Thank you for your consideration of these comments.

Sincerely,



Patrick J. Kostic
EMS Manager
Escambia County Emergency Medical Services

The Specialty Biotech Distributors Association
1501 K Street, NW
Washington, DC 20005

December 21, 2007 DEC 21 2007

Hand Delivery

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

Re: Comments on CMS-1385-FC: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (CAP Provisions)

Dear Administrator Weems:

The Specialty Biotech Distributors Association ("SBDA") submits the following comments to the Centers for Medicare and Medicaid Services ("CMS" or "the Agency") on the Final Rule with Comment Period ("Final Rule"): CMS-1385-FC: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008. We appreciate the opportunity to provide comments in response to CMS' request for recommendations on possible methods for structuring a proposal to permit transportation between physician practice locations of drug furnished under the Competitive Acquisition Program ("CAP") for Medicare Part B drugs.

Background on SBDA

SBDA is comprised of companies dedicated to maintaining the integrity and efficiency of the specialty distribution system in physician offices and other settings. Our member companies include AmerisourceBergen Specialty Group; Cardinal Health, Inc.; Curascript; Health Coalition, Inc.; OTN, a McKesson Specialty company; and U.S. Oncology. Together, we represent over eighty percent of the volume of drugs delivered to physician offices in the United States.

Specialty distributors provide tremendous value and efficiency to federal health care programs. While often not visible to the public, specialty distributors manage the increasingly

complex handling and delivery requirements of drugs and costly new biologics for virtually all physician offices in the country. These distributors perform important services, such as warehousing products, providing specialty handling and shipping services (such as packaging, refrigeration, or customized dosing), and ensuring the timely delivery of drugs and biologics to physicians and providers.

Comments on CAP Provisions

Although the Final Rule's listing of topics on which CMS is accepting comments in the "Supplementary Information" section of the Final Rule does not include CAP provisions, CMS specifically states in the preamble that it "welcome[s] comments on how to structure" a proposal to permit transportation of CAP drugs.[1] Our comments respond to this specific request for recommendations.

Before discussing our detailed suggestions for structuring this proposal, we note that the Final Rule incorporates multiple changes to CAP that go beyond those required by the Medicare Improvements and Extension Act of 2006 (Division B of the Tax Relief and Health Care Act of 2006) ("MIEA-TRHCA"). Although we commend CMS for implementing changes to CAP that enhance the attractiveness of the program to physicians and vendors, we again urge CMS to refrain from making substantial modifications midstream during performance of the vendor contract. CMS should delay implementation of any changes until all interested entities are provided an opportunity to compete for a vendor contract.

SBDA also continues to believe that the CAP statute permits waiver of the Federal Acquisition Regulation ("FAR") only to the extent that the waiver promotes competition.[2] To this end, we believe that the purpose of CAP is to promote competition among potential vendors – not physicians, as CMS has stated in the preamble to the Final Rule[3] – in order to achieve lower prices on CAP drugs and, thus, reduce the Medicare Program's spending on Part B drugs.

Structure of Proposal for Transportation of CAP Drugs Between Physician Practice Locations

CMS indicates in the preamble that it plans to issue a proposal in the Physician Fee Schedule for CY 2009 proposed rule to permit CAP drug transportation between physician offices under specific circumstances. The Agency anticipates that the proposal likely will allow transportation of CAP drugs where a voluntary agreement is executed between the vendor and physician that complies with all applicable Federal and State laws and regulations and product liability requirements.

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[1] 72 Fed. Reg. 66,222, 66,268 (Nov. 27, 2007).
[2] 42 U.S.C. § 1395w-3b(a)(1)(C) (2007).
[3] *See* 72 Fed. Reg. at 66,261 ("[W]e believe these changes promote competition because they make the program a more attractive option for physicians, which will provide physicians who compete among one another a more meaningful choice between the CAP and the ASP methodology.").

Absent clear agreements between physicians and vendors to ensure full compliance with all laws, regulations, and product labeling requirements, we are concerned that allowing physicians to transport drugs between offices could compromise the integrity, sterility, and stability of CAP drugs. Such agreements should be documented in writing and set forth how the vendor and physician will remain in compliance with the statutory obligations of CAP and all other laws and product liability requirements. The agreements should allow for audits from the vendors, provide for quality assurance in the care and handling of CAP drugs, and properly allocate risk to the party that violates the contract terms and conditions. Rather than establishing a required contract template, SBDA recommends that CMS grant discretion to vendors and physicians to establish the terms and conditions of the contract, such as the particular drugs that may and may not be transported between offices. Since all drugs require different processes to remain in full compliance with their FDA labels, no form agreement would be appropriate.

Conclusion

SBDA appreciates this opportunity to provide comments to CMS on future modifications to CAP. We would welcome the opportunity to engage further with CMS on any potential proposals to permit transportation of CAP drugs between offices.

Respectfully Submitted,

John F. Akscin
President
Specialty Biotech Distributors Association

FYI - 39
Reg Staff

SPECTRUM REHABILITATION SERVICES, INC.

2007 DEC 18 PM 1:30

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December 11, 2007

Centers for Medicare & Medicaid Services
Baltimore, Maryland

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

Dear Sir:

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

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

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

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

by Medicare. These codes represent assessment and management services to beneficiaries such as:

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

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

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

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

Sincerely,

Janice A Nixon
RN, BSN, MA, CDMS, CRC, CCM, LRC, CLCP

638599

F-II-40
Reg Staff

December 19, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 314-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201-0004

Dear Acting Administrator Weems:

I am writing to strongly protest a recent ruling which has removed Mohs micrographic surgery (CPT codes 17311, 17313) from the Multiple Procedure Reduction Rule (MPRR) exemption list.

Despite a long-standing exemption of Mohs surgery from the multiple procedure reduction rule (MPRR), which covers certain specialized procedures from unfair reimbursement cuts, CMS now intends to reduce payments to dermatologists by 50% by reapplying the MSRR to Mohs surgery. The MSRR reduces payments on multiple surgeries performed on the same day as a way to minimize the cost of repetitive procedures.

Over 80% of the work involved in Mohs surgery (CPT codes 17311, 17312, 17313, and 17314) involves lab work, not surgical work. Each Mohs procedural code entails meticulous mapping of the specimen, physician orientation and dyeing of the specimen, cryostat preparation and freezing , subsequent cutting of 5-7 micron frozen sections, the preparation of microscopic slides, staining of these slides and subsequent physician microscopic evaluation of the frozen sections. Each Mohs stage typically takes over one hour in our lab.

For this reason it is inappropriate to consider these codes to have "efficiencies that occur when multiple (surgical) procedures are performed in one session". This has been previously discussed and ruled upon in 1991 when CMS agreed that Mohs excisions are "separate staged procedures; they will be paid separately with no multiple surgery reduction." This rule was placed in the Federal Register at that time (Federal Register, November 25, 1991, Vol. 56, #227, pg 59602).

CMS has acknowledged, Mohs excisions are "separate staged procedures," rather than repetitive surgeries, and therefore should not be penalized by the MPRR. Since Mohs surgery is a complicated procedure that necessitates several separate stages with extensive laboratory work all on the same day, the MPRR exemption alone allows dermatologists to be fairly compensated.

Mohs surgery is generally "in-office", saving the patients from outpatient facility charges, anesthesia charges, separately billed frozen section pathology charges, as well as lab, EKG and radiology charges. Theses add-on charges, compounded by multiple visits for multiple skin cancers can cost a patient many times the bill that could be covered by the "bundled" service Mohs fee.

The effect of taking the Mohs procedure off the MPRR exemption list is that we will not be able to cover our costs for lab personnel, equipment, and physician time needed to perform the procedure. If surgical repairs were, by financial necessity, delayed to another day (due to the effect of the reimbursement being cut in half) the patients would also be greatly inconvenienced. Many patients require time off work, their accompanying transportation cannot be available for a second visit and many patients are elderly or come hundreds of miles away. Risks for bleeding or infection are also increased by waiting for the surgery to be done on another day.

Patient's having more than one cancer to be excised on the same day (approximately 15% of my practice) would have to come back for multiple visits. The idea that the second Mohs procedure should be subjected to the multiple procedure reduction rule (MPRR) makes no sense, as literally twice as much lab work, lab supplies and time have to be spent when two specimens are analyzed on the same patient on the same day. There is no efficiency of work when the twice the amount of lab work has to be done.

Please consider the extra and unnecessary burdens on Medicare patients that this recent Medicare coverage ruling would cause. I request that you do everything possible to reverse this pointless and costly ruling. It will have a very negative effect on healthcare delivery for patients with skin cancer. Mohs surgery is the most effective procedure in curing basal cell carcinoma and squamous cell carcinomas (98-99% cures rates). It thus reduces the costs of repetitive surgeries for the same lesion done by less effective modalities.

Sincerely,

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ATHENA G. KAPORIS, M.D.
MEREDITH K. KOSANN, M.D.
ROSS ZELTSER, M.D.

December 26, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Room 314-G, Hubert H. Humphrey Building
Washington DC 20201

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

Instead of saving, Medicare will lose ungodly amounts of money with this ruling! The Mohs surgeons who work in offices will be forced to refer repairs out to plastic, facial plastic, and oculoplastic surgeons who uniformly work in hospitals or certified surgical centers. These facilities employ conscious sedation whether needed or not (overwhelmingly not). Thus, Medicare will have to pay facility and anesthesia fees on all these repairs; even simple intermediate and complex closures. It's just simple math.

Respectfully,

RZ

Ross Zeltser, MD

RZ/lb

December 28, 2007

Mr. Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Room 314-G, Hubert H. Humphery Building
200 Independence Avenue, S.W.
Washington, D.C. 20201-0004

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

Dear Acting Administrator Weems:

I am writing to express my opposition to the proposed application of the Multiple Procedure Payment Reduction to the codes for Mohs micrographic surgery (17311 through 17315). I feel that this proposal is an unfair reduction in compensation based on work performed and will restrict patients' access to proper care. I appreciate the opportunity to offer comment on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule. The rationale for my opposition is delineated below:

1) There is no efficiency gained in the performance of multiple Mohs procedures on separate sites. The Mohs procedure consists of pre-operative evaluation of the patient and site, prepping the surgical field, anesthetizing the surgical area surgical tissue for frozen sectioning, cutting and staining frozen section slides, and pathological interpretation of those slides. Aside from the pre-operative evaluation of the patient, each of these steps must be duplicated in its entirety for each step of the Mohs procedure if more than one site is performed on the same day. Thus, no significant efficiency is gained and no reduction in pay is warranted.

   As one of only five physicians, who are fellowship-trained in this technique in Middle Tennessee, my patients routinely drive one to two hours from surrounding rural areas for this procedure. In approximately 20% of my patients, two or more aggressive skin cancers of the head and neck region are removed in that one visit. As skin cancer predominantly affects elderly individuals, this is done as a matter of convenience for those individuals who often do not have ready access to care. The proposed reduction would not adequately cover the costs for two skin cancers to be addressed at one visit. This proposed change may consequently result in decreased access to proper care for aggressive tumors of the skin.

2) The repair of a defect following Mohs surgery is a completely separate procedure from that of Mohs surgery itself. There is no reduction in work, aside from the pre-operative evaluation of the patient, in these procedures when performed on the same day or separately. Each of these tasks requires a completely separate thorough evaluation of the pre-operative site, sterile prepping of the surgical field, anesthetizing of the surgical site, the corresponding surgical procedure, and the post-operative evaluation of the patient following that procedure. Many of these tasks are not duplicated when a standard excision is performed with repair of the resulting defect; however, due to the time-intensive same day pathological examination of 100% percent of the surgical margin, each of these tasks must be duplicated in their entirety when Mohs surgery is performed followed by repair of the resulting defect.

3) Although intended to contain costs, the proposed Multiple Procedure Payment Reduction for Mohs surgery will likely result in a paradoxical escalation of costs in the management of the nationwide epidemic of skin cancer. This is supported by several epidemiological studies published in peer-reviewed journals documenting Mohs micrographic surgery as the most economical, as well as the most effective, treatment modality of non-melanoma skin cancer.

   The proposed Multiple Procedure Payment Reduction for Mohs surgery will not limit the number of skin cancers in the United States, but only the access of patients to Mohs surgery for their treatment. As access to Mohs surgery is limited, tumor removal will result in larger defects requiring more extensive repairs, such as cutaneous flaps and grafts, and more repairs requiring ambulatory surgery centers and inpatient hospitalization, and increased utilization of radiation therapy for cutaneous malignancies. In addition to being more costly, each of these results has the added unfortunate consequence of higher rates of recurrence of skin cancers, which ultimately affects the most importance variable, patient outcome and morbidity.

In conclusion, I believe that careful analysis of the proposed Multiple Procedure Payment Reduction for Mohs surgery reveals this to be an unwise and unfair decision on many fronts as outlined above. I appreciate the opportunity to offer comment on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule and urge you to reconsider this proposal.

Sincerely,

Brent Pennington MD

Brent E. Pennington, MD

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IDAHO DERMATOLOGIC SURGERY & LASER CENTER

TERI J. COTTINGHAM, MD

December 12, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 314-G, Hubert H. Humphrey Building
Washington, DC 20201

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

Dear Acting Administrator Weems:

As a Mohs surgeon I am deeply concerned about the proposed rule to remove Mohs surgery from the Multiple Procedure Reduction Rule (MPRR) exemption list. This proposal represents a dramatic reversal of sixteen years of the Centers for Medicare and Medicaid Services' (CMS) own determination that the Mohs codes are and should be exempt from the MPRR. I believe this proposal will negatively impact Medicare beneficiaries' access to timely and quality care. In addition, application of this proposal will not likely generate significant cost savings and may paradoxically increase costs of providing care to these patients.

Currently, more than 10% of patients undergoing Mohs micrographic surgery have more than one tumor treated with Mohs on the same day. Application of the proposed rule to a second tumor treated on the same day will mean that reimbursement for the second procedure does not cover the cost of providing the service. Therefore, physicians will have difficulty affording the option of treating more than one tumor in the same patient on the same date. This will affect Medicare beneficiaries disproportionately, since the incidence of skin cancers peaks in Medicare-age patients, who are most likely to have multiple tumors. Additionally, patients who are immuno-suppressed from organ transplantation, cancer chemotherapy, infection or other diseases are at significantly higher risk for skin cancers and often have multiple tumors; many of these patients are also Medicare beneficiaries. These immuno-suppressed patients are not only at higher risk for cancers but also at higher risk for potential metastases and possibly death from skin cancers, especially squamous cell carcinoma. The elimination of the MPRR exemption would mean that those patients most likely to have multiple tumors and most likely to have undesirable outcomes from their tumors will sustain delays in their

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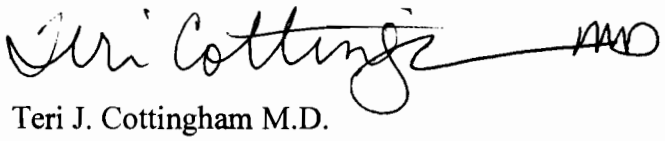
treatment and additionally-increased risk for adverse outcomes, if physicians are asked to provide treatment at less than the cost of providing the service.

Although perhaps intended as a cost-saving measure, application of this rule will not likely generate significant cost savings and may paradoxically increase cost of providing care to these patients. When Mohs procedures are performed with higher-valued repairs such as flaps or grafts, application of the MPRR to the Mohs codes will result in reduced reimbursement for Mohs that doesn't cover the cost of the procedure. Likewise, for lower-valued repairs such as intermediate and complex layered closures, which are the most commonly performed repairs, reduced reimbursement will not cover the cost of the repair. The result in both scenarios will be an increase in referral of patients to other reconstructive surgeons for repair. Since most Mohs surgeons operate in low-cost office surgical suites but most plastic, oculoplastic, and head and neck surgeons operate in ambulatory surgery centers or hospitals, where the costs of reconstruction are greater, costs associated with repairs may actually increase. This is particularly true of patients treated in academic or group practice settings, where high volumes of patients are treated and where ready access to other reconstructive surgeons exists.

In light of the concerns raised above, I am requesting that CMS reconsider their plan to remove Mohs surgery from the MPRR exemption list and feel it would be appropriate to place Mohs surgery on the exemption list permanently. As this proposed change is due to take effect on January 1, 2008, the leaders of the American College of Mohs Surgery, the American Academy of Dermatology, the American Society of Dermatologic Surgeons, and the American Society for Mohs Surgery would appreciate the opportunity to meet with CMS to discuss possible solutions to the problem as soon as possible.

Respectfully,



Teri J. Cottingham M.D.

44

RECEIVED

DEC 2 1 2007

OSORA, DIVISION
OF CORRESPONDENCE
MANAGEMENT

John G. Hancox, MD, FAAD
Mountain State Medical Specialties
399 Emily Drive
Clarksburg WV 26301

December 14, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Room 314-G, Hubert H. Humphery Building
200 Independence Avenue, S.W.
Washington, D.C. 20201-0004

Dear Mr. Weems,

I am writing to explain my opposition to the CMS-1385-P (Mohs Surgery and the multiple surgery reduction rule).

I am one of only two skin cancer surgeons in the state of West Virginia with specialized fellowship training to perform this procedure. I have removed approximately 1600 cancers from patients since July 2006 alone using Mohs micrographic surgery. My patients come to me from an average of 45 miles away and many travel 3 hours or more. This rule may require us to limit the number of cancers treated per patient and require more waiting and repeat visits.

Skin cancer is the most common form of cancer, and the incidence in Medicare patients is expected to rise 32% by 2010, based on Medicare's own data. So this rule change will cause longer wait times for WV patients.

There are no economies or efficiencies in performing multiple procedures because I must start the process for each surgery from the beginning and then microscopically examine each tissue sample from each surgery separately. Reducing the payment for multiple procedures by 50% will not cover our groups' expenses. The Mohs procedures were first placed on the MPRR exemption list in 1992 and there have been no new technologies or techniques since then that allow the surgeon to perform the procedure in less time than it took in 1992.

In essense, this rule will cause us to NOT be reimbursed enough to cover our expenses if we perform more than one procedure per patient per day. For example, if I remove a 3 inch cancer from a patient's scalp, the new rule will not pay enough to cover the expenses of putting a skin graft on the wound.

I implore you on behalf of my patients not to implement the MSRR to Mohs Surgery. Severely cutting the reimbursement (especially limiting the number of cancers being treated) may greatly limit access to care.

Sincerely,

John G. Hancox, MD, FAAD

MANAGED WORKERS' COMPENSATION HEALTH PLAN

P.O. Box 97
St. Clairsville, OH 43950-0097
PH: 1.740.695.7678
Hearing Impaired: 1.800.622.3925
Toll Free: 1.888.847.7810
Toll Free Fax: 1.877.847.6927

2007 DEC 11 PM 3:34

UTC -ACCREDITED CASE MANAGEMENT

FYI - Resc 45

December 4, 2007

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Sir:

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

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

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

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

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

Failure to provide appropriate incentives and funding for these codes affects the alignment of care coordination quality between providers, especially at the various levels for transitions of care within

settings, between settings, and between health states. Poor transitions of care may result in poor outcomes such as incorrect treatments, medication errors, delay in diagnosis and treatment, readmissions, patient complaints, increased health care costs).

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

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

Sincerely,

_____

Signature

46

Hayes, Yolanda K. (CMS/OSORA)

From: Lafferty, Tiffany R. (CMS/OSORA) on behalf of Shortt, Michelle R. (CMS/OSORA)
Sent: Wednesday, January 02, 2008 1:28 PM
To: Hayes, Yolanda K. (CMS/OSORA); Johnson, Sharon B. (CMS/OSORA)
Subject: FW: CMS-1385-FC

>-----Original Message-----
>From: White, Jacquelyn Y. (CMS/OSORA)
>Sent: Monday, December 31, 2007 12:31 PM
>To: Shortt, Michelle R. (CMS/OSORA); Nixon, Karen E.
>(CMS/OSORA); Bailey, Glenda G. (CMS/OSORA)
>Subject: FW: Removal of Exemption Ruling (Mohs)
>
>For regs comment and correspondence control. Thanks.
>
>>-----Original Message-----
>>From: Kerry Weems (OA)
>>Sent: Monday, December 31, 2007 12:03 PM
>>To: White, Jacquelyn Y. (CMS/OSORA)
>>Subject: FW: Removal of Exemption Ruling (Mohs)
>>
>>
>>
>>>-----Original Message-----
>>>From: Arash Kimyai-Asadi, M.D. [mailto:akimyai@yahoo.com]
>>>Sent: Monday, December 31, 2007 8:25 AM
>>>To: Weems, Kerry (CMS/OA)
>>>Subject: Removal of Exemption Ruling (Mohs)
>>>
>>>
>>>Mr. Kerry Weems, Administrator
>>>Centers for Medicare and Medicaid Services Department of Health and
>>>Human Services, Room 314-G Washington, DC 20201
>>>
>>>
>>>Re: CMS 1385-P: 2008 Medicare Fee Schedule Coding - Multiple
>>>Procedure Payment Reduction for Mohs Surgery
>>>
>>>VIA EMAIL
>>>
>>>Dear Mr. Weems:
>>>
>>>We are submitting comment to you regarding the 2008 Medicare Fee
>>>Schedule: Proposed Rule and the explicit withdrawal of the multiple
>>>procedure reduction rule (MPRR) exemption for Mohs surgical
>>>procedures. We submitted our comments and concerns in
>August of 2007,
>>>along with comments from approximately 1000 people who are directly
>>>affected by this change. The letters illustrated the impact that the
>>>proposed changes would have on individuals who depend on our
>services.
>>>We are asking that you reconsider the removal of the MPRR exemption
>>>for Mohs surgical procedures.
>>>
>>>This action will unduly impact not only those Medicare beneficiaries
>>>who have or will be diagnosed with skin cancer but also
>those surgical
>>>dermatologists who provide these services.
>>>In addition, we believe this proposal will negatively impact
>Medicare
>>>beneficiaries' access to timely and quality care. The application of

>>>the Multiple Procedure Reduction Rule will not likely generate
>>>significant cost savings and will likely paradoxically increase the
>>>cost of providing care to these patients.
>>>
>>>Mohs micrographic surgery uniquely includes two distinct components,
>>>surgery and pathology, both of which are performed wholly by
>the Mohs
>>>surgeon, with the pathology component comprising half of the
>service.
>>>The nature of Mohs surgery requires that the entire procedure,
>>>including processing and interpretation of the
>histopathology slides,
>>>be completed before any consideration is given to the excision of
>>>additional tissue or to repair of the resulting defect. The
>>>recurrence rate of cancers after being treated with the Mohs
>technique
>>>is less that 1%.
>>>
>>>We feel strongly that removing the exempt status of the Mohs codes
>>>will negatively impact our patients' access to timely and quality
>>>care. Currently, 30% of our patients undergoing Mohs micrographic
>>>surgery in our practice have more than one tumor treated
>with Mohs on
>>>the same day. Application of the proposed rule to a second tumor
>>>treated on the same day will mean that reimbursement for the second
>>>procedure does not cover the cost of providing the service.
>This will
>>>affect Medicare beneficiaries disproportionately, since the
>incidence
>>>of skin cancers peaks in Medicare-age patients, and these
>patients are
>>>the ones most likely to have multiple tumors. Our patients
>>>continually tell us how much they appreciate being seen in
>one day for
>>>multiple procedures - especially those who travel long distances to
>>>see our physicians.
>>>
>>>In addition, patients who are immuno-suppressed from organ
>>>transplantation, cancer chemotherapy, infection or other
>diseases are
>>>at significantly higher risk for skin cancers and often have
>multiple
>>>tumors. Many of these patients are also Medicare
>beneficiaries. These
>>>immuno-suppressed patients are not only at higher risk for
>cancers but
>>>also at higher risk for potential metastases and possibly death from
>>>skin cancers, especially squamous cell carcinoma.
>>>
>>>When Mohs procedures are performed with higher-valued
>repairs such as
>>>flaps or grafts, application of the MPRR to the Mohs codes
>will result
>>>in reduced reimbursement for Mohs that doesn't cover the cost of the
>>>procedure. Likewise, for lower-valued repairs such as
>intermediate and
>>>complex layered closures, which are the most commonly performed
>>>repairs, reduced reimbursement will not cover the cost of
>the repair.
>>>This will force the Mohs surgeon to refer the patient to another
>>>specialist, such as a plastic surgeon or ocular-plastic surgeon,
>>>increasing the cost by use of anesthesia and OR services.
>>>
>>>In light of the concerns raised above, we respectfully request
>>>reconsideration of the proposed rule. We would happily discuss our
>>>concerns in support of a continued exemption.
>>>

>>>Sincerely,
>>>
>>>
>>>Arash Kimyai-Asadi, M.D.
>>>
>>>
>>>
>>>_____
>_____
>>>____
>>_
>>>_____
>>>Never miss a thing. Make Yahoo your home page.
>>>http://www.yahoo.com/r/hs
>
>

47

Hayes, Yolanda K. (CMS/OSORA)

From: Braxton, Shawn L. (CMS/OSORA)
Sent: Tuesday, January 08, 2008 10:58 AM
To: Hayes, Yolanda K. (CMS/OSORA)
Subject: FW: Public Submission

Shawn Braxton
Technical Advisor
Division of Regulations Development-B
Regulations Development Group
Office of Strategic Operations & Regulatory Affairs
(410) 786-7292
shawn.braxton@cms.hhs.gov
>-----Original Message-----
>From: OC AIMS Support [mailto:AIMSSupport@OC.FDA.GOV]
>Sent: Tuesday, January 08, 2008 8:16 AM
>To: Braxton, Shawn L. (CMS/OSORA); Jones, Martique S. (CMS/OSORA)
>Subject: FW: Public Submission
>
>
>
>-----Original Message-----
>From: no-reply@erulemaking.net [mailto:no-reply@erulemaking.net]
>Sent: Monday, January 07, 2008 7:53 PM
>To: OC AIMS Support
>Subject: Public Submission
>
>Please Do Not Reply This Email.
>
>Public Comments on Medicaid Program; Optional State Plan Case
>Management Services:========
>
>Title: Medicaid Program; Optional State Plan Case Management Services
>FR Document Number: 07-05903 Legacy Document ID:
>RIN: 0938-AO50
>Publish Date: 12/04/2007 00:00:00
>Submitter Info:
>
>
>First Name: Joel
>Last Name: Hornstein
>Category: Individual - I0001
>Mailing Address:
>City:
>Country: United States
>State or Province:
>Postal Code:
>Organization Name:
>
>Comment Info: ================
>
>General Comment:Please don't implement these proposed regulations.
>They will only serve to harm special needs children and adults who need
>more funding, not less.
>

48-0

Centre for Medicare & Medicaid Services
Dept of Health & Human Services
Attention: CMS-1385-FC
PO Box 8020
Baltimore, MD 21244-8020

27 December 2007

Re: Medicare Reimbursement of Skin Cancer patients

Dear Sirs,

It is with much disappointment I recently learned that on 1 January 2008 Medicare will cut its reimbursement for wound closure following Mohs surgery for skin cancer by 50%. Also, any subsequent cancers treated on the same day will also have fees cut 50%. However, if the patient returns to the office the day after excision of a skin cancer, then the closure of the wound will be paid at 100% of the usual fee.

What this means is that skin cancer patients on medicare like my father, retired and on a fixed income, can only have one cancer treated per day and then have to have the wound closed on a different day. I do not believe this is good medical care.

I am concerned not only for my father, but for the thousands like him who are affected by skin cancer. Please help stop ridiculous inefficiencies like this, which only make it more difficult and more expensive for patients who might have several spots of skin cancer to be treated. Not only does this make it more inconvenient for the patient, but also affects their caregivers and has a knock on effect to their families.

This is not a good treatment plan and I am writing to ask you to please change this very unwise decision.

Thank you.

Yours sincerely,

Christina Sauer-Dechant
5201 Greenheart Drive
Austin TX 78745

Johnson, Sharon B. (CMS/OSORA)

49

From: Heidi Jackson [heidi@dermsurgery.org]
Sent: Friday, December 28, 2007 4:36 PM
To: Weems, Kerry (CMS/OA)
Subject: Removal of Exemption Ruling (Mohs)
Importance: High

December 28, 2007

Mr. Kerry Weems, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services, Room 314-G
Washington, DC 20201

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

VIA EMAIL

Dear Mr. Weems:

We are submitting comment to you regarding the 2008 Medicare Fee Schedule: Proposed Rule and the explicit withdrawal of the multiple procedure reduction rule (MPRR) exemption for Mohs surgical procedures. We submitted our comments and concerns in August of 2007, along with comments from approximately 1000 people who are directly affected by this change. The letters illustrated the impact that the proposed changes would have on individuals who depend on our services. We are asking that you reconsider the removal of the MPRR exemption for Mohs surgical procedures.

This action will unduly impact not only those Medicare beneficiaries who have or will be diagnosed with skin cancer but also those surgical dermatologists who provide these services. In addition, we believe this proposal will negatively impact Medicare beneficiaries' access to timely and quality care. The application of the Multiple Procedure Reduction Rule will not likely generate significant cost savings and may paradoxically increase the cost of providing care to these patients.

Mohs micrographic surgery uniquely includes two distinct components, **surgery and pathology**, both of which are performed wholly by the Mohs surgeon, with the pathology component comprising half of the service. The nature of Moths surgery requires that the entire procedure, including processing and interpretation of the histopathology slides, be completed before any consideration is given to the excision of additional tissue or to repair of the resulting defect. The recurrence rate of cancers after being treated with the Mohs technique is less that 1%.

We feel strongly that removing the exempt status of the Mohs codes will negatively impact our patients' access to timely and quality care. Currently, 30% of our patients undergoing Mohs micrographic surgery in our practice have more than one tumor treated with Mohs on the same day. Application of the proposed rule to a second tumor treated on the same day will mean that

reimbursement for the second procedure does not cover the cost of providing the service. This will affect Medicare beneficiaries disproportionately, since the incidence of skin cancers peaks in Medicare-age patients, who are most likely to have multiple tumors. Our patients continually tell us how much they appreciate being seen in one day for multiple procedures - especially those who travel long distances to see our physicians.

In addition, patients who are immuno-suppressed from organ transplantation, cancer chemotherapy, infection or other diseases are at significantly higher risk for skin cancers and often have multiple tumors. Many of these patients are also Medicare beneficiaries. These immuno-suppressed patients are not only at higher risk for cancers but also at higher risk for potential metastases and possibly death from skin cancers, especially squamous cell carcinoma.

When Mohs procedures are performed with higher-valued repairs such as flaps or grafts, application of the MPRR to the Mohs codes will result in reduced reimbursement for Mohs that doesn't cover the cost of the procedure. Likewise, for lower-valued repairs such as intermediate and complex layered closures, which are the most commonly performed repairs, reduced reimbursement will not cover the cost of the repair. This will force the Mohs surgeon to refer the patient to another specialist, such as a plastic surgeon or ocular-plastic surgeon, increasing the cost by use of anesthesia and OR services.

In light of the concerns raised above, we respectfully request reconsideration of the proposed rule. We would happily discuss our concerns in support of a continued exemption. Respectfully submitted on behalf of our physicians and patients.

Heidi Jackson, BS, MPA, Dermsurgery Associates, PA

7515 South Main Street, Suite 240 Houston, TX 77030 Direct: 832-213-5454

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FMI- Reg Staff BC

50

Florida Society of Dermatologic Surgeons

11891 Magnolia Falls Dr. • Jacksonville, FL 32258 • Phone 904/292-0051 • Fax 904/886-0114
www.floridaskinsurgeons.com • Email: FSDS82@aol.com

2007 DEC 10 PM 5:03

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Executive Director
Paula Baumgardner

November 14, 2008

Kerry Weems
Acting Adminstrator
Centers for Medicare and Medicaid Sermivcs
U.S. Department of Health and Medicaid Sermices
Room 314-G, Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Re: CMS 1385-P: 2008 Medicare Fee Schedule

Coding – Multiple Procedure Payment Reduction for Mohs Surgery

Dear Acting Administrator Weems:

As Immediate Past-President of the Florida Society of Dermatologic Surgeons (FSDS), and as the representative of the entire board and membership of the FSDS, a 277 member organization created solely for the education of Dermatologic physicians treating skin cancer, I wish to represent our extreme concern about the proposed rule change presented in the 2008 Medicare Fee Schedule concerning Mohs Surgery, and wish to comment on this proposed rule change, if I may. I am referring to Section II.E.2(P-122) of the 2008 Medicare Fee Schedule in which it states:

"Based on the revisions to the code descriptors and a clearer understanding regarding the technical elements of the procedure, the CPT Editorial Panel removed the Mohs procedure from the -51 modifier list. The code descriptors for Mohs surgery codes were developed to take into account the different level of physician work intensity based on anatomic site. The RVUs associated with the codes for each anatomic location were assigned, as they are for other procedures, after a thorough discussion by the RUC of all aspects of the service.

RVUs were developed for each Mohs surgery base code based on an assumption that each code is performed separately. Because the RVUs for these services do not take into account the efficiencies that occur when multiple procedures are performed in one session, we do not believe that these codes should continue to be exempt from the multiple procedure payment reduction. Therefore, we are proposing to eliminate the modifier -51 exemption and apply the multiple procedure payment reduction rules to these codes."

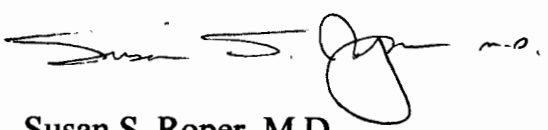
Mohs Surgery is a cost-saving procedure in most cases. Over the years, Medicare has saved millions, maybe billions, by having difficult skin cancers treated economically in the Mohs surgeon's office, rather than in the hospital. Prior to Mohs surgery being performed by Dermatology in office, most skin cancers were removed by a plastic or general surgeon in the hospital, with all of the expenses involved: the operating room, the frozen tissue sections, the pathologist, the anesthesiologist, etc. Mohs Surgery eliminates the separate charge of a patholgist for frozen sections, since this is bundled with the Mohs Surgery codes: the Mohs Surgeon is the pathologist checking the tissue, as well as processing the tissue. Most Mohs Surgeons do not need the expense of a hospital or ambulatory surgery suite to perform their procedures, unless there are concerns for the patient, as in tumors that may extend into the skull or the orbit, or in large defects that require an extensive repair. As it is now, Medicare allows the Mohs Surgeon to repair the patient's skin cancer defect the day of surgery, or remove more than one cancer that requires removal on a different body site on the same date, without being penalized by the multiple reduction rules. With the proposed rule change, the patient will need to be rescheduled for a different date for more surgery if they need repair of their wound, or perhaps referred to an outside Plastic Surgeon who will want to use expensive hospital services, etc, to repair the wound. With the proposed rule change, when there are multiple serious skin tumors present, the Mohs surgeon will need to reschedule the patient for more surgery on a different date in order to remove the other tumors, if there is more than one cancer that requires Mohs surgery. The expense of operating a Mohs surgery suite, which includes the hefty salary of the histotechnologist preparing the tissue, the experienced nurses involved in patient care, as well as the front office staff, building and equipment expenses, etc., does not allow the Mohs surgeon to give discounts and stay in business . The procedure itself has already given a huge discount to Medicare in the treatment of skin cancer.

Since Florida treats more skin cancer than any other state in the nation, the burden of this Proposed Rule Change will fall principally on the shoulders of our Floridian skin cancer patients. If the Mohs Surgeon cannot afford to operate efficiently by removing multiple cancers and repair multiple defects in a timely fashion, because of the extreme discount Medicare is taking with the Proposed Rule Reduction, then the need for more Mohs Surgeons will increase as patients find themselves waiting longer and longer for Mohs Surgery appointments. Theoretically, the Proposed Rule Reduction could backfire and increase utilization of Mohs Surgery by creating a need for more Mohs Surgeons.

The Proposed Rule Reduction also penalizes our skin cancer patients, many of them veterans from World War 2, Korea, and Vietnam. These veterans do not take kindly to rationing of care. They prefer to visit the Mohs Surgeons in private practice or in the academic centers rather than overburden the overtaxed VA system, where one has to wait 6 months or longer to have a skin cancer removed in some cases. When the cancer is finally removed at the VA Hospital, it may be done on the Plastic Surgery Service and require much more extensive surgery than would be required in a Mohs Surgeon's office surgery suite. I personally attend the VA Dermatology clinic at the James Haley VA Hospital in Tampa, Florida, as a volunteer physician, having done so for 20 years, and am aware of the problems there with skin cancer. We do not have a Mohs Surgeon assigned to the VA. If it wasn't for the Mohs Surgeons in private practice and in the academic centers, the veterans having skin cancer problems would have complained a lot more than they do now. This will change, if the Proposed Rule Reduction for Mohs Surgery is implemented.

In summary, the Florida Society of Dermatologic Surgeons, respectfully requests that the Proposed Rule, Section II.E.2(P-122) of the 2008 Medicare Fee Schedule **NOT** be implemented. We respectfully request that the Medicare system continues to exempt the Mohs procedure base codes, 17311 and 17313, from the multiple procedure reduction rule, and that this exemption be permanent. As I have previously mentioned, it is in our patients' best interest to maintain this cost-effective and tissue sparing procedure, and not to penalize the Mohs Surgeons for cost effectively doing the job in one visit that would normally take 2-3 specialists to do much more expensively. I would appreciate the opportunity to discuss this issue with CMS anytime you are available. Please feel free to contact me at my office or by e-mail.

Respectfully,



Susan S. Roper, M.D.
Immediate Past - President, Florida Society of Dermatologic Surgeons

Director, Countryside Dermatology and Laser Center
Clearwater, Florida
Clinical Associate Professor
University of South Florida School of Medicine
Tampa, Florida
csdermatology@aol.com
727-791-1411
727-791-1419 fax

cc: Terrence Kay, Director, Hospital and Ambulatory Policy Group
Amy Bassano, Director, Practitioner Services Division
Diane Baker, MD, President, American Academy of Dermatology
David Brodland, MD, President, American College of Mohs Surgery
Alastair Caruthers, MD, President, American Society of Dermatologic Surgery
Sharon Tiefenbrunn, MD, President, American Society for Mohs Surgery

December 22, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 314-G, Hubert H. Humphrey Building
Washington, DC 20201

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

Dear Acting Administrator Weems:

As the President of the American College of Mohs Surgery and as a Mohs surgeon in practice dedicated solely to the care of skin cancer patients, I am deeply concerned about the recent ruling to remove Mohs surgery from the Multiple Procedure Reduction Rule (MPRR) exemption list. As such, I appreciate the opportunity to comment on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Coding – Multiple Procedure Payment Reduction for Mohs Surgery.

Based on the wording of the explanation for the rule, I have to assume that there is a very fundamental misunderstanding about the nature of Mohs surgery. The passage from II E.2 that I refer to is as follows:

Because the RVUs for these services do not take into account the efficiencies that occur when multiple procedures are performed in one session, we do not believe that these codes should continue to be exempt from the multiple procedure payment reduction. Therefore, we are proposing to eliminate the modifier -51 exemption and apply the multiple procedure payment reduction rules to these codes." (Italics and underlining added)

Sixteen years ago, this issue was reviewed by CMS (then HCFA) and correctly determined that Mohs excision and reconstruction occur at separate surgical sessions. As such, there **are no efficiencies** that occur because of the separation of these surgical sessions by time, which usually amounts to hours. The patient leaves the operating suite after the excision

and awaits the processing of the tissue and the pathologic interpretation of the slides by the Mohs surgeon. If all cancer is found to have been removed, then the patient is brought back to the room for planning and execution of the repair. Therefore, unlike when I perform a standard excision and immediately proceed to closure during the same session, I am not able to benefit from the efficiencies which normally occur with multiple procedures.

Furthermore, when more than one cancer is treated simultaneously, there is not the 50% efficiencies found in standard excisions since, in addition to the excision, each specimen is processed with mapping, tissue marking, pathologic processing and pathologic specimen examinations independent of one another. Indeed, 50% of the value of Mohs excision is the pathology component which is universally reimbursed at a rate of 100% of its value no matter how many specimens are processed. There is no redundancy of work that produces the efficiencies that are suggested in the excerpt above. The only economy of effort would be in the pre and post operative component of the procedure and this equals no more than 20% of the value of the service when more than one tumor is treated.

Therefore, a 50% reduction ruling for multiple Mohs procedures or a Mohs procedure combined with a repair of the wound is illogical and financially draconian. In many practices, the severity of this cut will make current practice of Mohs unsustainable and I fear will not likely generate significant cost savings. In fact, it may paradoxically increase costs of providing care to these patients. This would seem likely since the cost of performing more than one Mohs excision will exceed the reimbursement with the 50% reduction of second and subsequent excisions.

The cost of wound repair, since it is performed at a separate session from the Mohs excision, will likely exceed the reimbursement in many cases also. One of the hidden values of Mohs excision for both the patient and CMS is that Mohs surgery is done with smaller margins, resulting in smaller defects that can be closed with smaller repairs. However, with a 50% reduction in reimbursement, these smaller repairs will likely cost more to perform by the Mohs surgeon than will be reimbursed. Of course, if excision and closure were performed at the same surgical session, this would not be so. However, there are no efficiencies gained whatsoever for Mohs excision and eventual closure at a later session.

I could envision that such pressures could lead to limiting the number of cancers excised from a patient on a given day, thus altering access to timely care. The pressures could conceivably lead to more frequent referral of wound repairs to hospital based physicians who I believe would be more likely to reconstruct with costlier closures than I may select since my training has taught me to use the smallest practical closure of a given

wound. The increased costs associated with doing the closures in the hospital setting would obviously increase costs over current practice. Ultimately, the consumer/patient will bear the brunt of whatever adjustments physicians will have to make given the unsustainability of current practices.

A workable solution is possible, however. Two adjustments that would reflect true "efficiencies that occur when multiple procedures are performed" would be to reduce the reimbursement of the 2nd and subsequent Mohs surgery by the amount not included in the intraservice component of the value. Secondly, keeping the reimbursements of the 1st repair of a wound at 100% and reduce subsequent repairs by 50% to reflect the fact that wound repair occurs at separate surgical sessions, a characteristic unique to Mohs excision.

Unfortunately, there is currently no AMA CPT modifier that would accurately identify these adjustments, so a 2% adjustment to the Mohs procedure base code physician work RVUs, (20% percent correction for multiple Mohs sites which occurs 10% of the time) with reinstatement of the multiple procedure reduction rule exemption might be a fair and sustainable solution.

In summary, the explanation as excerpted from Section II.E.2 (P-122) above is fundamentally in error with regards to the Mohs procedure. It goes against the correct 1992 ruling on the same issue without accurate justification. I also feel that it is likely that the ruling will result in decreased access to care for skin cancer patients without a cost savings to Medicare. I do feel there is a reasonable solution that is sustainable and allows physicians to continue to provide quality care for skin cancer patients. I believe continued communication will be necessary to reach a tenable solution in this matter. To be sure, my organization, the American College of Mohs Surgery will look forward to and be available for any such opportunity.

Sincerely,

David G. Brodland M.D.
President, American College of Mohs Surgery

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UROPA

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December 28, 2007

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

Dear Administrator Weems:

I am a urologist who practices medicine as a member of Uropartners, LLC, a single specialty group practice in the metropolitan Chicago area. Uropartners was formed in the summer of 2005 through the merger of 11 separate urology practices. These practices came together because of a shared belief that patients benefit from the resources and efficiencies of a large, single-specialty group. Today, Uropartners has over 35 urologists treating patients at 20 different office locations. Many of our patients are Medicare beneficiaries. I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

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

When the anti-markup rule applies to a diagnostic test, the amount of payment is affected by requiring that a "net charge" be calculated. CMS has given little guidance with respect to calculating the "net charge" when a service is provided by the employed technologists and physicians of a practice where those individuals are not compensated based on a per test basis.

In addition, the CMS rules require that the "net charge" be calculated without regard to any overhead, including the cost of equipment or leased space.

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

After Uropartners was formed, our physician leadership began exploring the possibility of furthering our mission by bringing pathology services in-house. Initially, we were approached by several companies offering us the ability to participate in "condo lab" arrangements. That model did not appeal to Uropartners because we felt it did not give us the control over quality and service that we were seeking. In addition, we believed that this model potentially violated the spirit of the applicable regulations. We ultimately built our own laboratory in a building that is centrally located to our clinics. We invested almost $700,000 in state-of-the art lab equipment and facilities, hired three board certified pathologists to work exclusively in the lab, and hired a staff of technicians and office personnel that has grown to 10 full-time equivalent employees. Based on the new anti-markup regulations, it will not be possible for our practice to offer these services without operating at a loss. As a result, when these services are no longer available, patients will lose access to quality services.

The changes proposed in these rules will have a serious impact on the way our urology group practices medicine and will not lead to the best medical practices. These rules will adversely impact the quality of, and access to, diagnostic tests for Medicare beneficiaries. The proposed changes to the anti-markup rule will make it difficult, if not impossible for Uropartners to continue to provide pathology services to our patients. Since its opening in 2006, the Uropartners lab has proven to be very beneficial for patient care. Some of the specific benefits our patients have received that are attributable to the Uropartners lab are:

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

2. Uropartners' urologists controlled the selection of the pathologist. Uropartners conducted an extensive search to find pathologists for our lab who met our

standards for competency and responsiveness. The pathologists we hired met, and continue to meet, those standards. Consequently, we have a high degree of confidence and trust in the pathologist making the diagnosis.

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

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

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

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

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

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

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

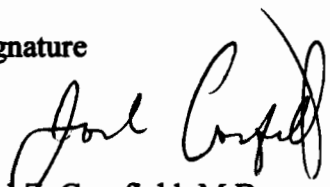
10. Our patients get one bill from one place. When an outside lab is used, the patient often times gets 3 separate bills - one from the urologist, one from the lab, and one from the pathologist. This leads to confusion for the patient. It is also inefficient.

The sweeping changes to the anti-markup rules go far beyond what is necessary to protect the Medicare program from fraud and abuse. I respectfully request that CMS reconsider its position in light of the potentially devastating impact on the quality of care for Medicare beneficiaries and

delay the implementation of the rule until CMS has had time to understand the full impact of these rules.

Thank you for your consideration,

Signature



Joel Z. Cornfield, M.D.
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December 14, 2007

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

Attention: CMS-1385-FC

Dear Acting Administrator Weems:

On behalf of the American Society for Clinical Pathology's (ASCP) 140,000 members, I am writing in support of the reassignment/self-referral provisions included in the Centers' for Medicare and Medicaid Services (CMS) 2008 final Physician Fee Schedule rule. ASCP is strongly opposed to any delay of the implementation of this rule.

ASCP writes in strong support of CMS' efforts to block abusive billing arrangements that profit from the referral of pathology services. Allowing providers to profit from the referral of pathology services can distort medical decision-making, undermine patient trust in the medical profession and adversely affect patient care. The Agency has promulgated an important set of patient and programmatic protections, and it is to be commended for its work.

The anti-markup rule represents a balanced policy compromise by CMS after appropriate consideration of issues such as the overutilization of medical services, proliferation of pod labs, etc. We also believe that CMS provided stakeholders in histology laboratories adequate opportunity to comment on the proposal after soliciting comments in the proposed Physician Fee Schedule for CY 2007 (71 FR 48982) and the proposed Physician Fee Schedule for CY 2008 (72 FR 38179).

The ASCP is a nonprofit medical specialty society representing 140,000 members. Our members are board certified pathologists, other physicians, clinical scientists, certified medical technologists and technicians, and educators. ASCP is one of our nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

ASCP is committed to working with CMS to stop the proliferation of any schemes that enable physicians and group practices to profit from the self-referral of pathology services. The anti-markup rule is an important tool to prevent abusive Medicare billing practices. If ASCP can be of further assistance, please do not hesitate to contact me or Matthew Schulze, ASCP's Senior Manager for Federal and State Affairs, at (202) 347-4450.

Sincerely,

Lee H. Hilborne MD, FASCP

Lee H. Hilborne, MD, MPH, FASCP
President, ASCP

cc: Don Romano, Centers for Medicare and Medicaid Services
Lisa Ohrin, Centers for Medicare and Medicaid Services
Joanne Sinsheimer, Centers for Medicare and Medicaid Services
David Walczak, Centers for Medicare and Medicaid Services

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THE MOHS COALITION

SUBMITTED ELECTRONICALLY

December 21, 2007

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

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

Dear Mr. Weems:

On behalf of the members of the American Academy of Dermatology Association (AADA), the American College of Mohs Surgery (ACMS), the American Society for Dermatologic Surgery (ASDS), and the American Society for Mohs Surgery (ASMS), we are very disappointed that the final 2008 Medicare physician fee schedule withdrew the Multiple Procedure Reduction Rule (MPRR) exemption for Mohs surgical procedures. As we stated in our proposed rule comments, and during in-person meetings with CMS staff, and as many patients and legislators have reiterated, the health and quality of life of our older patients with skin cancer is of paramount concern to us. Withdrawal of the MPRR exemption for Mohs surgical procedures will have an adverse impact on the health of these patients without generating significant savings.

As we have said before, the unique nature of the excision and pathology components of Mohs surgery necessitates separate surgical sessions for excision of a cancer and any subsequent repair procedure performed after confirmation of clear, cancer-free margins. The work of excising, processing, and interpreting one tumor is also almost entirely independent of any work involved with treating another tumor on the same day. The efficiencies assumed in other procedures subject to the MPRR thus do not exist with respect to Mohs procedures. CMS payment policy has recognized this essential fact since 1992. Yet, without furnishing any data in support of reversing this precedent from CMS, the RUC, or the CPT panel, CMS will eliminate the exemption.

Removal of the MPRR exemption for the Mohs base codes (CPT codes 17311 and 17313) will lead to reimbursement that is far less than the cost of performing these

procedures. Specifically, the policy change will make it very difficult to offset the losses incurred in performing Mohs excision when treating older patients who, during the course of one office visit, require reconstruction of the wound following removal of the cancer or have multiple skin cancer lesions requiring treatment. Our concern is that these effects will negatively influence the current level of access to skin cancer care using Mohs surgery for the Medicare population, who is disproportionately affected by skin cancer.

Furthermore, the Part B Extract and Summary System (BESS) data file maintained by CMS shows that patient utilization of Mohs represents only 20 percent of current skin cancer treatment. Yet, patient utilization of Mohs will continue to grow as more Americans become Medicare eligible. For example, based on BESS data for 2005 (the last year available), Medicare covered a total of 2,039,479 skin cancer procedures, and as previously noted, of these procedures only 20 percent (N = 425,945) were Mohs surgery. It is also worth noting that the frequency of Mohs procedures is an excellent proxy for skin cancer because one cannot render treatment without a positive biopsy. The proposed policy change will therefore make it prohibitively costly for many Mohs surgeons to furnish Mohs surgical procedures to Medicare patients at a time when skin cancer incidence is projected to rise 32 percent by 2010.

We acknowledge efforts by CMS to prevent procedure "bundling" and to save taxpayer funds for better use through an MPRR policy. However, instead of modifying payment policy in an ad hoc manner, procedure by procedure, we believe that CMS should examine the MPRR policy in its entirety and issue an updated policy that comprehensively identifies the circumstances in which exemption is warranted

Accordingly, we respectfully request that CMS reconsider its decision and allow Mohs procedure codes to retain their historic exemption from the MPRR. Indeed, given the rising incidence of skin cancer in elderly patients, Medicare's payment policies should encourage access to Mohs surgery so they can obtain proven and effective treatment of skin cancer.

If you have questions, please feel free to contact the following staff from the Mohs Coalition:

Norma Border (AADA) at nborder@aad.org or 847-240-1814
Georgeanne Dixon (ACMS) at gdixon@mohscollege.org or 414-347-1103
Lisle Soukup Poulsen (ASDS) at lpoulsen@asds.net or 847-956-9126
Novella Rodgers (ASMS) at execdir@mohssurgery.org or 714-379-6262

Thank you for your consideration.

Respectfully,

Diane Baker, MD,
President, American Academy of Dermatology

David G. Brodland, M.D.
President, American College of Mohs Surgery

Darrell S. Rigel, MD
President, American Society for Dermatologic Surgery

Sharon Tiefenbrunn, MD,
President, American Society for Mohs Surgery

DRB/DGB/DR/ST

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Rupal Trivedi, MD

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December 14, 2007

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

RE: CPT Code 68815 and 68816

Dear Sir/Madam:

I am a pediatric ophthalmologist in full time academic practice and regularly treat children with lacrimal disorders. The proposed fee schedule associated with the above two codes is totally inadequate for the complexity and work they require. The reasons for this are:

- All procedures in children are performed under general anesthesia.
- Virtually all procedures relate to previously failed nasolacrimal duct probing (68811).
- The insertion of balloons or stents can be technically difficult. In particular, lacrimal intubation is frequently challenging in small children.
- While these procedures tend to be highly effective, facility fee reimbursement also needs to be adequate to properly cover costs. A proposed ASC payment of $434 is woefully inadequate. I have been in pediatric ophthalmology practice for 30 years and have performed both procedures for as long as they have been in existence. It is my professional opinion that when compared with NLD probing (68811), balloon dilation should be assigned at least *double* and lacrimal intubation *triple* the RVUs assigned the basic general anesthesia probing procedure.

Sincerely,

Richard A. Saunders, MD
Miles Professor of Ophthalmology
Professor of Pediatrics

RAS/mg

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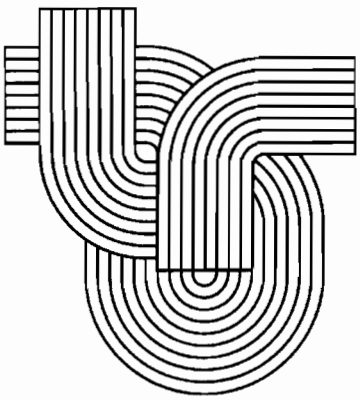

NORTH AMERICAN SOCIETY FOR CARDIOVASCULAR IMAGING
(Established 1973)

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December 28, 2007 http://www.cms.hhs.gov/eRulemaking

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

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

Dear Mr. Weems:

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

Cardiac MRI Codes

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

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

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

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Web site: www.nasci.org

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusion

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

Respectfully Submitted,

Pamela K. Woodard, MD
President

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

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South Shore Skin Surgeons, PC

SPECIALISTS IN DERMATOLOGIC AND MOHS MICROGRAPHIC SURGERY

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December 17, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 314-G, Hubert H. Humphrey Building
Washington, DC 20201

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

Dear Acting Administrator Weems:

I am a Mohs surgeon in Massachusetts and I am troubled by the plan to remove Mohs surgery from the Multiple Procedure Reduction Rule (MPRR) exemption list. The removal of Mohs from this exemption list will have a negative impact on the ability of Medicare beneficiaries' to obtain access to the high quality care that they deserve and may increase the cost of the care rather than result in cost savings.

In my practice a significant number, probably around 10-15%, of patients undergoing Mohs micrographic surgery have more than one tumor treated on the same day. When this rule goes in to effect (as it did in the early months of 2006 prior to its reversal based on a procedural issue), it will no longer be cost effective to treat more than one lesion on a patient in one day. Patients will have to make multiple trips to the doctor in order to have their lesions treated. For elderly patients who often depend upon family members for transportation, this will create a significant inconvenience both in their own lives and in the lives of their families. In addition, even when one lesion is treated by the Mohs procedure, the reduction in reimbursement for the Mohs code (when it is performed with a flap or a graft) will not allow adequate compensation for the cost of performing the procedure. This can result in patients being referred to other physicians such as head and neck surgeons or plastic surgeons for surgical repairs. Head and Neck and plastic surgeons often operate in an operating room (rather than in an office setting as occurs when a Mohs surgeon performs a repair) which will increase the overall cost of care for the patient. The patient will also be subject to increased risk for the

procedure if they have to undergo general anesthesia rather than local anesthesia as occurs with Mohs surgerons.

Additionally, patients who are immuno-suppressed from organ transplantation, cancer chemotherapy, infection or other diseases are at significantly higher risk for skin cancers and often have multiple tumors; many of these patients are also Medicare beneficiaries. These immuno-suppressed patients are not only at higher risk for cancers but also at higher risk for potential metastases and possibly death from skin cancers, especially squamous cell carcinoma. The elimination of the MPRR exemption will mean that those patients most likely to have multiple tumors and most likely to have undesirable outcomes from their tumors could sustain delays in their treatment and additionally-increased risk for adverse outcomes, if physicians are asked to provide treatment at less than the cost of providing the service.

In light of the concerns raised above, I am requesting that CMS change the ruling that will remove Mohs surgery from the MPRR exemption list and feel it would be appropriate to place Mohs surgery on the exemption list permanently. As this proposed change is due to take effect on January 1, 2008, the leaders of the American College of Mohs Surgery, the American Academy of Dermatology, the American Society of Dermatologic Surgeons, and the American Society for Mohs Surgery would appreciate the opportunity to meet with CMS to discuss possible solutions to the problem as soon as possible.

Respectfully,

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Hayes, Yolanda K. (CMS/OSORA)

From: lysherman@aol.com
Sent: Sunday, December 30, 2007 6:22 PM
To: Weems, Kerry (CMS/OA)
Subject: From Dr. Alysa Herman, Miami, Florida

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services U.S. Department of Health and Human Services
Room 314-G, Hubert H. Humphrey Building Washington, DC 20201

Re: CMS

1385-P: 2008 Medicare Fee Schedule

Multiple Procedure Payment

Reduction for Mohs Surgery

Dear Mr. Weems,

I am a Mohs surgeon who, along with other Mohs surgeons in the country, is very concerned about the proposed initiative to remove Mohs surgery from the Multiple Procedure Reduction Rule (MPRR) exemption list.

I practice in Miami, Florida and can tell you that there is a very high incidence of skin cancer here. In addition to many patients having more than one skin cancer, a significant proportion of my Medicare patients travel significant distances to see me for treatment--many come from the Florida Keys and many fly over from The Bahamas (US citizens living abroad) because there is no access to Mohs surgery where they live. Under the proposed changes, as you are respectfully aware, this new rule will mean that if a patient has a second skin cancer, the reimbursement in 2008 will not cover the physician's cost of providing the treatment. Therefore, it will likely not be possible to offer patients the convenience of treating the individual's second tumor on the same date. As a result, patients will need to return for multiple office visits for treatment and, unfortunately, bear the burden of this inconvenience as well as delay of treatment and theoretical further growth of their skin cancers. Further, scheduling many of our elderly Medicare patients is often challenging because many of them do not drive and need a family member to accompany them to their Mohs surgery appointment. This often means that the family member, usually the patient's son or daughter, needs to take time off of work to do so. The impact of the above-mentioned changes will therefore also affect many families of Medicare patients.

Please note that when my Medicare patients were informed of these potential changes in Medicare reimbursement of Mohs surgery, more than 500 of these patients were motivated to write letters to their congressmen making them aware of the negative impact that such legislation would have on their access to care.

I trust that you have been made aware of the additional consequences that these changes will likely have on Medicare patients. For example, Mohs surgeons who commonly perform reconstruction of the wound on the same day of surgery may now refer patients for such wound closure to other surgical colleagues (plastic surgeons), many of whom operate in hospitals and ambulatory surgical facilities which each cost significantly more than the Mohs surgeons' outpatient office. Since reimbursement of the repair of the wound will be reduced by 50% under the proposed changes, such a reduction in fees will simply mean that it is not cost-effective to provide such a service to patients. Although these changes are intended to produce cost savings to the CMS, I truly believe that they may paradoxically increase costs of providing care to these patients.

This proposal represents a dramatic reversal of sixteen years of the Centers for Medicare and Medicaid Services' (CMS) own determination that the Mohs codes are and should be exempt from the MPRR.

In sum, I respectfully request that the CMS reconsider its plan to remove Mohs surgery from the MPRR exemption list. Such changes will dramatically affect the way many of us efficiently and cost-effectively treat skin cancer patients on an outpatient basis.

I thank you kindly for your attention to this correspondence and would be pleased to have the opportunity to provide you with any further information that you may require.

Sincerely,

Alysa R. Herman, MD

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MICHAEL J. HUETHER, M.D., P.C.
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12/30/2007

Mr. Kerry Weems
Acting Administrator
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 314-G, Hubert H. Humphrey Building
Washington, D.C. 20201
Kerry.Weems@CMS.hhs.gov

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

Dear Mr. Weems:

I am writing to share my concerns about the negative impact that the proposed rule to remove Mohs skin cancer surgery from the Multiple Procedure Reduction Rule (MPRR) exemption list. I am certain that this will negatively impact Medicare beneficiaries' access to timely care.

When the reduction of payment for additional services (as proposed) results in a payment below the actual cost of providing the procedure, it will be very difficult to justify treating more than one skin cancer tumor in one day. For many patients, it is not possible to come to the office for multiple treatment sessions and will likely delay timely treatment.

Even though it seems like asking physicians to provide additional services below their cost of providing the service will save CMS money, it may in fact generate more costs for CMS since Mohs surgeons may have to refer patients out to other hospital-based surgeons since they cannot make ends meet by doing procedures which pay below the cost of performing the actual procedure.

Please reconsider the proposal to remove Mohs surgery from the MPRR exemption list, and again put it back on the exemption list as it has been for the last 16 years. Medicare beneficiaries will appreciate this decision.

Sincerely,

Mike

Michael J. Huether, M.D.

Fellow, American College of Mohs Surgery
Fellow, American Society for Dermatologic Surgery
Fellow, American Academy of Dermatology
Diplomate, American Board of Dermatology

B85-FC

~~CMS-0016-P-5~~

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Submitter : **Dr. Jeanie Smith** **Date: 12/20/2007**

Organization : **Harding University College of Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Adoption of NCPDP SCRIPT 8.1

Adoption of NCPDP SCRIPT 8.1

Faxing prescriptions into a pharmacy from a remote computer at a prescribers clinic is a huge part of my practice. If faxing or this 'pseudo' e-prescribing is removed a huge burden will return to both the staff at the pharmacy as well as the staff at the clinic. More time on the phone for pharmacists, technicians, nurses and doctors. All of the clinics that fax in via computer entry have the prescriber perform the data entry and transmission. There is no middle man such as a PA or nurse calling the prescription in. This cuts down on the chance of error. Also, these requests come across typed and not handwritten which is another way to decrease the chance of making an error on the prescription. Please allow this wonderful addition to the medical world to remain in place - to reduce the chance of errors and to save staff valuable time.

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Submitter : **Dr. William Drake** **Date: 12/20/2007**

Organization : **Advanced Care**

Category : **Pharmacist**

Issue Areas/Comments

General

General

The elimination of efaxing will have a significant financial effect on our pharmacy operation, with almost minimal benefit. Over time we have invested money and time in enhancing our technology to minimize prescription errors, and prescribing issues. Forcing us to only use eprescribing will cause an immediate cost that have been forced upon the pharmacys by the switch companies. The rate is anywhere from $0.25 to $0.50 EACH prescription. There is no method to pass this cost on, and the minimal benefits by eprescribing does not give a typical pharmacy any cost savings, only cost increases. Most pharmacies already have fax machines. Many physician practices already can do efaxing. To continue this process has minial if no cost. The safety and security of prescribing is maintained with this process has it has been for year. The issue is not between efaxing and eprescribing. The issue is with hand written prescripion. Foreing eprescribing only benefits those who will collect the many fees from the process. Efaxing is an effective method of prescribing when evaluated by those who truly do the job each and every day.

December 31, 2007

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

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

Dear Mr. Weems:

The North American Spine Society appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Final Rule on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year 2008, published in the November 27, 2007 *Federal Register.*

Moderate Sedation - CPT codes 99143 – 99150

In 2005, six new codes for performance of moderate sedation were created by the American Medical Association's (AMA) CPT Editorial Panel and valued by the AMA's RVS Update Committee (RUC). This was the culmination of several years of work by the AMA. The entire Medicare fee schedule was reviewed and codes were separated into two categories: those procedures for which moderate sedation was inherent with the cost inputs bundled into the valuation (these codes are identified separately in appendix D), and those procedures for which if moderate sedation is required, it should be coded in addition to the primary procedure. Great care was taken to assure that physician and clinical staff times, equipment and supplies were excluded from valuation of those codes for which moderate sedation would be separately billable. A coalition of medical societies worked in conjunction with the RUC to reach a consensus recommendation for these codes which was accepted by the RUC in April 2005.

In the November 2005 final rule, CMS decided to assign carrier pricing to the moderate sedation codes, while awaiting utilization data. That data now exists, and yet, in the 2008 fee schedule, CMS continues to recommend carrier pricing for these codes. Several carriers have developed local policies that cover moderate sedation when indicated.

NASS respectfully requests that CMS examine the utilization data and accept the previously established RUC relative value for these codes. If there is concern about the RUC recommended
valuation or the usage of these codes, we request that CMS convey that concern to the RUC or that CMS assign a refinement panel to decide a valuation.

Sincerely,

Charles Mick

Charles Mick, MD, RUC Advisor
North American Spine Society

Tim Shahbazian, DDS, RUC Advisor
American Association of Oral and Maxillofacial Surgeons/American Dental Association

Steve Krug, MD, RUC Advisor
American Academy of Pediatrics

James Perri, MD, RUC Advisor
American College of Emergency Physicians

c: Tom Faciszewski, MD, President, NASS
Eric Muehlbauer, Executive Director, NASS
William L. Rich, III, MD, Chair, AMA RVS Update Committee
Sherry Smith, Director, AMA RVS Update Committee

December 31, 2007

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

Ref: Physician Payment Level for new CPT® 68816

Dear Administrator:

This correspondence is in reference to the physician payment for new CPT® code 68816. In the final rule, the 2008 payment for this code is $530 (non-facility) and $181 (facility).

Quest Medical

Quest Medical, Inc. develops, manufactures, and distributes medical devices for a variety of medical and surgical markets. The markets our products provide solutions for include cardiac surgery, ophthalmic surgery, oncology, IV fluid and anesthesia delivery, and hemodialysis. Quest Medical makes several products for treatment of eye disorders, including several manual ophthalmic surgical devices used for less invasive treatments of occluded lacrimal ducts. LacriCATH® is our newest product line. The LacriCATH® balloon catheters are available in various sizes and configurations to accommodate both pediatric and adult patients. Pediatric ophthalmologists are the primary customers for this technology.

Balloon Catheter Dilation of the Nasolacrimal Duct

As background, the 68816 procedure is described as *Probing of nasolacrimal duct, with or without irrigation; with transluminal balloon catheter dilation.* In this procedure, the typical patient is placed under anesthesia. The puncta are dilated. The lacrimal system is probed in the customary fashion, and the presence of the probe in the nose is confirmed. The probe is removed, and a balloon catheter is passed through the superior punctum, canalicular system and into the nasolacrimal duct down to the nasal floor. The presence of the balloon catheter in the nose is then confirmed. An inflation device is filled with sterile water or saline, connected to the balloon catheter, and the balloon is inflated for 90 seconds. The balloon is then deflated by releasing the lock mechanism on the inflation device. The inflation procedure is repeated a second time for 60 seconds, and again the balloon is deflated. The balloon is pulled proximally and positioned within the lacrimal sac and nasolacrimal duct. The balloon is inflated and deflated again using the same method described above. The balloon is deflated fully by aspirating residual fluid out of the balloon. The catheter is then rotated clockwise to minimize the profile of the deflated balloon and is gently withdrawn from the lacrimal system. Proper drainage is confirmed using an irrigating fluid with fluorescein dye.

This procedure has gained prominence. In the largest series reported, patients received balloon treatment after failed probing. Patients experienced duct clearance in a single treatment. In all cases, those patients receiving a stent instead of a balloon required a second physician encounter to remove the stent after the end of the global period. In addition, balloon treatment

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Hayes, Yolanda K. (CMS/OSORA)

From: Lafferty, Tiffany R. (CMS/OSORA) on behalf of Shortt, Michelle R. (CMS/OSORA)
Sent: Tuesday, January 15, 2008 7:51 AM
To: Jones, Martique S. (CMS/OSORA); Hayes, Yolanda K. (CMS/OSORA); Johnson, Sharon B. (CMS/OSORA)
Subject: FW: Electronic and Faxed signatures

Public Comment - I believe this is PFS - 1385-FC. Martique, please correct me if I'm wrong.

Thanks,
Tiffany

From: White, Jacquelyn Y. (CMS/OSORA)
Sent: Monday, January 14, 2008 9:39 AM
To: Nixon, Karen E. (CMS/OSORA); Bailey, Glenda G. (CMS/OSORA)
Cc: Clybourn, Olen D. (CMS/OSORA); Shortt, Michelle R. (CMS/OSORA)
Subject: FW: Electronic and Faxed signatures

Karen/Glenda – For control. Thanks.

From: Weems, Kerry (CMS/OA)
Sent: Monday, January 14, 2008 8:20 AM
To: White, Jacquelyn Y. (CMS/OSORA)
Subject: FW: Electronic and Faxed signatures

From: Lamb Beatriz [mailto:beatriz.lamb@ssfhs.org]
Sent: Monday, January 14, 2008 8:12 AM
To: Weems, Kerry (CMS/OA)
Subject: Electronic and Faxed signatures

We object to the new restriction that hospices may not obtain the physician's certification of terminal illness electronically nor a hand written certification via facsimile machine. This runs counter to the current, widely used and CMS-encouraged move toward technology. There is nothing about a hand written signature that provides insurance against fraud. Electronic signatures offer more protection and faxes provide information about the sender. A legal opinion expressed that faxing signatures is just another method of delivering a hand written signature. At this point, we are not sure what CMS will accept and cannot believe the intent is to revert to allowing only hand written physician certifications that must be mailed to the hospice in order to meet this regulation.

We request that CMS allow hospices to obtain electronic signatures for physician certification of terminal illness and also permit the option to obtain faxed hand written physician certifications of terminal illness. It is also important that the effective date of CR 5550 be delayed until CMS reaches a decision on the ability of hospices to use electronic signatures for certification of terminal illness and faxes of hand written certification signatures.

We thank you for your attention to this very important matter. Your response seriously impacts the operations of Medicare-certified hospices throughout the country

Thank you,
Bea Lamb RN, MBA
Regional Director Home Health and Hospice
St. Elizabeth Regional Health
765-423-6877 phone
765-449-5192 fax

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65AA

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Robert M. Levin, Ph.D.
Adjunct Professor of Surgery

Anita S. Mannikarottu, Ph.D.
Adjunct Assistant Professor of Surgery

J. Andre Melendez, Ph.D.
Adjunct Associate Professor of Surgery

23 December 2007

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

Dear Administrator Weems:

I am a urologist who practices in academic group practice setting with a large Medicare population. I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

The final rule imposes an anti-markup provision on the technical and professional components of diagnostic tests that are ordered by a billing physician or other supplier (or a related party) if the technical or professional component is purchased from an "outside supplier" or if it is performed at a site other than the office of the billing physician or other supplier. This is a wholly different test than what was proposed. Rather than focusing on whether the test was purchased or not, the new rule applies the anti-markup provision simply based on where the test is furnished. Under the final version of the rule, to avoid the anti-markup provisions, a test would have to be furnished "in the office of the billing physician or other supplier," i.e., the "space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally."

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

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

The changes proposed in these rules will have a serious impact on the way urologists practice medicine and will not lead to the best medical practices. These rules will impact the quality

of, and access to, diagnostic tests for Medicare beneficiaries. The proposed changes to the anti-markup rule will make it difficult, if not impossible for me to provide expeditious and quality pathology services to our patients in our research labs, which are distinct from our office suite where we provide the full range of services of our medical practice. Indeed, it will also be much more expensive to Medicare to provide these services in a hospital lab.

Based on the Stark regulations my practice developed a pathology service to comply with the regulations. It cost thousands of dollars and took over a year to create a state of the art lab to provide quality services to my patients. Based on the new anti-markup regulations, it will not be possible for my practice to offer these services without operating at a loss. As a result, when these services are no longer available, patients will lose access to quality services.

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

Thank you for your consideration,

Barry A. Kogan, M.D.
Chief, Division of Urology
Albany Medical Center

66

Cosme A Gomez MDFACS
UROLOGY SPECIALTY GROUP LLC
7265 SW 93 AVENUE, SUITE 201
MIAMI, FL 33173

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

Dear Administrator Weems:

I am a urologist who practices in Miami, Florida, as part of a 25 person single specialty urology group practice, Urology Specialty Group LLC. We provide urologic services for a 2 county area in South Florida. I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

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

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

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

The changes proposed in these rules will have a serious impact on the way Urology Specialty Group LLC practices medicine and will not lead to the best medical practices. These rules will impact the quality of, and access to, diagnostic tests for Medicare beneficiaries. The proposed changes to the anti-markup rule will make it difficult, if not impossible for our group of 25 urologists to provide prompt access to highly specialized diagnostic imaging services to our patients. Based on the new anti-markup regulations, it will not be possible for my practice to offer these services without operating at a loss. As a result, when these services are no longer available through us, patients will have to resort to non specialized, independent diagnostic centers, over which we have no say on quality control. Many of these centers, operated by non physician entrepreneurs, do not have the same commitment to excellence and quality that we uncompromisingly adhere to.

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

Thank you for your consideration,

Cosme A Gomez, MDFACS

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Hayes, Yolanda K. (CMS/OSORA)

From: Lafferty, Tiffany R. (CMS/OSORA) on behalf of Shortt, Michelle R. (CMS/OSORA)
Sent: Tuesday, January 15, 2008 7:52 AM
To: Jones, Martique S. (CMS/OSORA); Johnson, Sharon B. (CMS/OSORA); Hayes, Yolanda K. (CMS/OSORA)
Subject: FW: Physician Certification of Terminal Illness

From: White, Jacquelyn Y. (CMS/OSORA)
Sent: Monday, January 14, 2008 9:38 AM
To: Nixon, Karen E. (CMS/OSORA); Bailey, Glenda G. (CMS/OSORA)
Cc: Shortt, Michelle R. (CMS/OSORA); Clybourn, Olen D. (CMS/OSORA)
Subject: FW: Physician Certification of Terminal Illness

Karen/Glenda – For control. Thanks.

From: Weems, Kerry (CMS/OA)
Sent: Friday, January 11, 2008 6:27 PM
To: White, Jacquelyn Y. (CMS/OSORA)
Subject: FW: Physician Certification of Terminal Illness

From: Joe Hafkenschiel [mailto:jhafkenschiel@cahsah.org]
Sent: Friday, January 11, 2008 6:27 PM
To: Weems, Kerry (CMS/OA)
Cc: Wilson, Laurence D. (CMS/CMM); Deutsch, Terri (CMS/CMM); Anderson, Lori L. (CMS/CMM); Bastinelli, Sandra (CMS/OFM); Schwartz, Daniel (CMS/OFM)
Subject: Physician Certification of Terminal Illness

We object to the new restriction that hospices may not obtain the physician's certification of terminal illness electronically nor a hand written certification via facsimile machine. This runs counter to the current, widely used and CMS-encouraged move toward technology. There is nothing about a hand written signature that provides insurance against fraud. Electronic signatures offer more protection and faxes provide information about the sender. A legal opinion expressed that faxing signatures is just another method of delivering a hand written signature. At this point, we are not sure what CMS will accept and cannot believe the intent is to revert to allowing only hand written physician certifications that must be mailed to the hospice in order to meet this regulation.

We request that CMS allow hospices to obtain electronic signatures for physician certification of terminal illness and also permit the option to obtain faxed hand written physician certifications of terminal illness. It is also important that the effective date of CR 5550 be delayed until CMS reaches a decision on the ability of hospices to use electronic signatures for certification of terminal illness and faxes of hand written certification signatures.

We thank you for your attention to this very important matter. Your response seriously impacts the operations of Medicare-certified hospices throughout the country.

Joseph H. Hafkenschiel, CAE

President
California Association for Health Services at Home(CAHSAH)
(916) 641-5795, ext. 118
(916) 641-5881 (fax)
jhafkenschiel@cahsah.org

68-0

THE UROLOGICAL INSTITUTE OF NORTHEASTERN NEW YORK

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Barry A. Kogan, M.D.
Falk Chair in Urology
Professor, Surgery and Pediatrics
Chief, Division of Urology
Albany Medical College

Elise J.B. De, M.D.
Assistant Professor of Surgery

Hugh A.G. Fisher, M.D.
Associate Professor of Surgery

Ronald P. Kaufman, Jr., M.D.
Associate Professor of Surgery

Badar M. Mian, M.D.
Associate Professor of Surgery

Donald J. Rivard, M.D.
Clinical Associate Professor of Surgery

Mark D. White, M.D.
Associate Professor of Surgery

Harry J. Wilbur, M.D.
Associate Professor of Surgery

Carl E. Diaz-Parker, R.P.A.-C.
Instructor of Surgery

Jenny H. Dinh, R.P.A.-C.

Karla M. Giramonti, F.N.P., M.S.
Instructor of Surgery

Ralph Buttyan, Ph.D.
Adjunct Professor of Surgery

Gennadi V. Glinski, M.D., Ph.D.
Adjunct Professor of Surgery

Robert M. Levin, Ph.D.
Adjunct Professor of Surgery

Anita S. Mannikarottu, Ph.D.
Adjunct Assistant Professor of Surgery

J. Andre Melendez, Ph.D.
Adjunct Associate Professor of Surgery

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

Dear Mr. Weems,

I am a urologist who practices in Albany, New York, with a group of urologists at an academic institution. Over 50% of my patients are using Medicare as their primary health insurance. I am writing to comment and express my concerns on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

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

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

Finally, the new rule prohibits full payment for physician arrangements that were structured to meet the Stark requirements of the in-office ancillary services

exception with respect to the provisions concerning "same" and "centralized" buildings (locations which are specifically identified within the Stark statute itself). As a result, thousands of physician practices, including ours, after relying upon CMS guidance with respect to the physician self-referral laws and regulations, will not be reimbursed for equipment, facility, overhead, or any other related expenses for providing imaging or other diagnostic procedures to its patients.

The changes proposed in these rules will have a serious impact on the way our group practices medicine and will not lead to the best medical practices. These rules will impact the quality of, and access to, diagnostic tests for Medicare beneficiaries. The proposed changes to the anti-markup rule will make it difficult, if not impossible for me to provide state of the art histopathology services, including special immunostaining and cell ploidy, which are essential in making the correct diagnosis for many cancers. We have assembled a team of professionals that has vast experience in this filed. Sending the specimens elsewhere will raise concerns about the quality of test results and lead to undue delay in diagnosis for our patients who are anxiously waiting to hear the news about the presence of cancer.

Based on the Stark regulations my practice developed a histopathology service in a manner that was compliant with the regulations. It cost us over $ 80,000 and took nearly 14 months to create a state of the art facility to provide quality services to my patients. Based on the new anti-markup regulations, it will not be possible for my practice to offer these services without operating at a loss. As a result, when these services are no longer available, patients will lose access to quality services.

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

Thank you for your consideration,

Hugh Fisher

Hugh Fisher, M.D.
Associate Professor of Surgery

WAYNE UROLOGICAL ASSOCIATES, P.A.
HUNTINGTON OFFICE PARK • 1112 GRACIE PLACE • GOLDSBORO, NORTH CAROLINA 27534
TELEPHONE: (919) 735-1635 • FAX (919) 735-6699

WILLIAM B. TURNER, III, M.D. JOHN V. KASPAR, M.D. MARK S. LAFAVE, M.D. SHERMAN HAWKINS, M.D.

69-0

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

Dear Administrator Weems:

I am a urologist who practices with a small group in Goldsboro, NC. We have a Large Medicare population that needs high quality urologic care. I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

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

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

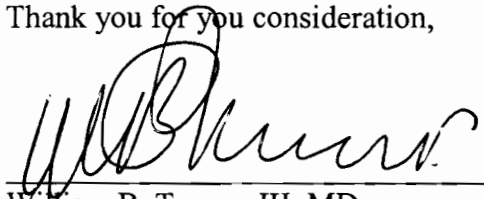
Finally, the new rule prohibits full payment for physician arrangements that were structured to meet the Stark requirements of the in-office ancillary services exception with respect to the Provisions concerning "same" and "centralized" buildings (locations which are specifically identified within the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

The changes proposed in these rules will have a serious impact on the way my small group practices medicine and will not lead to the best medical practices. These rules will impact the quality of, and the access to diagnostic tests for Medicare beneficiaries, the proposed changes to the anti-markup rule will make it difficult, if not impossible for me to continue to be a Medicare provider. We deliver high quality urology, urologic imaging (Ct and ultrasound) and pathology to our patients. We can no longer tolerate or accept Medicare cuts and rues that limit what we can afford to deliver as care to our patients.

Based on the Stark regulations my practice developed imaging and pathology services to comply with the regulations. The financial cost and risk has been great, but the result were worth it to provide quality services to my patients. Based on the new anti-markup regulations, it will not be possible for my practice to offer these services without operating at a loss. As a result, when these services are no longer available, patients will lose access to quality services.

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

Thank you for you consideration,



William B. Turner, III, MD

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Mrs. Leon Schmidt
3920 Balcones Drive
Austin, Texas 78731

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

The pending changes in Medicare reimbursement for skin cancer doctors on Mohs surgery makes no sense at all and penalize Medicare patients, mostly older folks like myself. Doctors will have to treat fewer Medicare patients, because this change lengthens the time it takes on each surgery unnecessarily and puts a hardship on patient and doctor.

There needs to be a sliding scale of payments for Medicare. Those who can afford to should be allowed to personally pay for our doctors' services. Those dependent on Medicare should get good medical care, not legislated by Congress or the Federal government.

Our doctors are our life line to longer living. Your help is needed to rescind this change.

Sincerely
Barbara and Leon Schmidt

NASW
...the power of social work
National Association of Social Workers
Office of the Executive Director
Elizabeth J. Clark, PhD, ACSW, MPH
Executive Director

December 12, 2007

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

Subject: CMS-1385-FC. Interim Final Rule. Revisions to Payment Policies Under the Physician Fee Schedule.

Dear Sir/Madam:

I am writing to you on behalf of the National Association of Social Workers (NASW) and its 150,000 members. NASW appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services "Interim Final Rule: Revisions to Payment Policies Under the Physician Fee Schedule."

NASW participated in the development of the Non-Face-to-Face Non-Physician Telephone Services CPT Codes: 98966, 98967, and 98968. We are happy to see them added to the list of CPT Codes for 2008. Telephone services are an integral part of case management services for social workers who work with Medicare beneficiaries in diverse health settings as they transition to different levels of care. We are recommending CMS to reconsider the payment rule on CPT Codes 98966, 98967, and 98968 from an "N" status to payable codes by Medicare. Failure to provide appropriate funding for these codes may affect quality care coordination among providers.

Thank you for your consideration of these comments. If you have any questions, please do not hesitate to contact me at 202-336-8200.

Sincerely,

Elizabeth J. Clark

Elizabeth J. Clark, PhD, ACSW, MPH
Executive Director

Control 72

December 5, 2007

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

Attention CMS-1385-FC

Dear Acting Administrator Weems:

The undersigned organizations are writing to encourage the Centers for Medicare and Medicaid Services (CMS) to implement without delay the revisions to the Reassignment Rule that are part of the final Physician Fee Schedule for Calendar Year 2008. We oppose any delay in implementation of the anti-markup rule for pathology services. The undersigned organizations represent a broad spectrum of physicians, providers and health care professionals involved in laboratory medicine.

We applaud CMS for instituting changes to the Reassignment Rule to stop abuses in the billing for pathology services. We believe that the anti-markup rule represents a balanced policy compromise by CMS after appropriate consideration of the pod lab issue. We also believe that CMS gave stakeholders in histology laboratories adequate opportunity to remark on the proposal after soliciting comments in the proposed Physician Fee Schedule for CY 2007 (71 FR 48982) and the proposed Physician Fee Schedule for CY 2008 (72 FR 38179). We do not believe there is a need for delay in implementing the rule.

The undersigned organizations are dedicated to working with CMS to stop the proliferation of laboratory schemes that allow physicians and group practices to profit from their self-referrals for anatomic pathology services. We believe that the anti-markup rule is an important first step in preventing abuses against the Medicare program and look forward to working with CMS on future rulemaking to establish additional safeguards.

We thank CMS for their consideration to this matter. Any questions should be directed to Donna Meyer with the College of American Pathologists at 202-354-7112 (dmeyer@cap.org).

Respectfully Submitted By,

American Clinical Laboratory Association
American Society for Clinical Pathology
Association of Directors of Anatomic and Surgical Pathology
Association for Molecular Pathology
Association of Pathology Chairs
College of American Pathologists
United States and Canadian Association of Pathology

Cc: Don Romano, Centers for Medicare and Medicaid Services
Lisa Ohrin, Centers for Medicare and Medicaid Services
Joanne Sinsheimer, Centers for Medicare and Medicaid Services
David Walczak, Centers for Medicare and Medicaid Services