

9



Jon F. Strohmeyer, M.D., F.A.C.S.
Facial Plastic & Reconstructive Surgery

DEC 7 2007

November 20, 2007

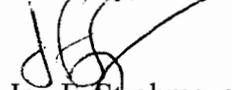
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-FC
PO Box 8020
Baltimore, MD 21244-8020

To Whom It May Concern:

The fees for 17312, 17313, 17314 should not be reduced by the multiple procedure payment reduction because a reduction in fees **ARLEADY EXISTS**. In order to clarify the multi procedure payment reduction policy regarding Mohs codes you have to first understand that each level of Mohs has a lowered price as it exists. In other words, there is already a multi procedure payment reduction in place for Mohs surgery procedures. Each consecutive Mohs level is reduced. To further discount the already discounted Mohs procedure codes is ludicrous. If each consecutive Mohs code fee was the same then I could understand a multiple procedure reduction being applied-but this is not the case.

Please call myself or other Mohs surgeons in order to further explain how Mohs surgery is performed.

Sincerely,



Jon F. Strohmeyer, M.D.
JFS/br

DEC 7 2007

Greg Reid, President
 Bob Hawley, President Elect
 Rebecca Smith, Immediate Past President
 Jimmy Johnson, Treasurer
 Ray Simpson, Secretary



OKLAHOMA AMBULANCE ASSOCIATION
 "Improving Oklahoma EMS by Enhancing Cooperation
 Between Industry Providers"

Ann Singer, NE Representative
 Vanessa Brewington, NW Representative
 Eddie Sims, Central Representative
 Brad Lancaster, SW Representative
 Wade Patterson, SE Representative
 Rita Diehl, At-Large Representative

November 27, 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: CMS0-1385-FC Medicare program; re: Beneficiary Signature for Ambulance Transport Services

To Whom It May Concern:

These comments are in response to the Final Rule published in the November 27, 2007 Federal Register that modifies the policies of CMS regarding beneficiary signatures on ambulance claims. For many years Oklahoma suppliers of ambulance services have understood that the CMS signature rule included the provision that a claim could be submitted on a Medicare beneficiary without a signature if the ambulance company documented that the patient was unable to sign giving the reason why and that no one else was available to sign on the patient's behalf at the time of transport. We have asked all patients to sign the patient care record at the time services are provided if the patient was mentally or physically able to sign at the time of transport. However many patients transported are not in condition to sign the patient care record and no authorized person is present when the patient is picked up that could sign the patient care record for the patient. In this situation, ambulance service personnel have signed the patient care form noting the deficit that prevents the patient from signing. This policy was entirely within the ambulance services ability to perform.

The modification to the signature rule requiring ambulance services to obtain signatures of facility personnel if the Medicare beneficiary cannot sign the patient care report or to obtain secondary verification from the facility after the fact requires ambulance suppliers to impose signing requirements on personnel who are not within the ambulance supplier's span of control. This may result in no signature or secondary verification being received. When this occurs, it will be neither the beneficiary's nor the ambulance provider/supplier's fault. Yet, the patient will be billed for the service that is Medicare's responsibility. It is our understanding that the modification of the signature policy is an attempt to insure that Medicare beneficiaries have been transported rather than to address either assignment of benefits or release of records issues. Since Medicare beneficiaries do not actually sign the claims that are submitted to Medicare [most are submitted electronically], the only way that CMS will be able to deter fraud is to audit companies suspected of filing false claims as you do now. It is difficult to understand how the modified policy will insure that fraud doesn't occur.

The members of the Oklahoma Ambulance Association hope that CMS will reconsider its decision to impose on ambulance providers/suppliers rules that it has permitted other medical providers/suppliers to ignore when there was just cause. There is no lack of just cause in the ambulance industry.

Sincerely,

Greg Reid, President

12-4-2007

Patricia Corcoran
Box 2807
South Padre Island, TX 78597

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Center for Medicare & Medicaid Services,
Attn: CMS-1385-FC

It has come to my attention that Jan. 1, 2008 Medicare reimbursement will change for Mohs surgery for skin cancer that means dermatologists will be forced to treat only one cancer per day & delay closure until the following day in order for them to receive reimbursement at 100%. I've had 16 skin cancers, most treated with Mohs surgery & more have recurred. This is why I travel 360 miles from South Padre to Austin as Mohs has a 98% cure rate. I had a stage 3 in May '07 & stage 2 in Oct '07. As 73 years old it is traumatic enough to have surgery

over

under a local & awake. It would seem
more likely that complications would occur
by waiting a day to do the closure, not to
mention the danger of being on the road and
waiting for the next day. This does not
represent good medical care!

I implore you to change this unwise
decision, as competent health care with
less risk of complications is in the best
interest of everyone!

Your attention to this matter is
appreciated

Sincerely,

Patricia Corcoran

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DEC 7 2007

James C. Pruitt, M.D.

Mark Wienpahl, M.D.

Robert B. Bricca, M. D.

Dan Keuning, F.N.P.

PAGOSA SPRINGS FAMILY MEDICINE CENTER

75 So. Pagosa Blvd.
Pagosa Springs, Colorado 81147
(970) 731-4131

November 26, 2007

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

To whom it may concern:

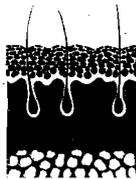
I am writing concerning the proposed Medicare and Medicaid payment decrease projected for the 2008 calendar year. Caring for Medicare and Medicaid patients is currently a labor of love, as reimbursement for these services barely covers costs. With a further reduction in payment, caring for these patients will become a financial impossibility for many providers. I am afraid you will see a great number of primary care providers, and particularly those in rural areas, simply refuse to participate in Medicare or Medicaid services, not for lack of concern, but strictly out of survival concerns. I am appalled that our senior citizens and disadvantaged patients should be treated so poorly, in this, the most affluent country in the world.

I strongly encourage you to reject this payment decrease, and rather insert ^{an adjustment} ~~one~~ more commensurate with cost of living realities. Please feel free to contact me at the number above.

Sincerely yours,



Robert B. Bricca, M.D.



DEC 7 2007

13

WILLIAM M. RAMSDELL, MD

D E R M A T O L O G Y

AESTHETIC LASER SURGERY

MOHS MICROGRAPHIC SURGERY

13 November 2007

To My Patients:

I am writing to let you know of pending changes in Medicare reimbursement that will seriously affect the treatment of skin cancer patients. Beginning January 1, 2008 reimbursement for wound closure following Mohs surgery for skin cancer will be cut by 50%. Any subsequent cancers treated **on the same day will also have the fees cut by 50%**. 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 dermatologists will be forced to treat only one cancer per day and then close the wound at a separate appointment on a different day. This is obviously extremely inconvenient for both physicians and patients and does not represent good medical care.

I am asking that you write your representatives on the Center for Medicare and Medicaid Services to implore them to change this very unwise decision. Time is of the essence as the ruling is scheduled to go into effect January 1, 2008.

Thank you.

Wm Ramsdell

William M. Ramsdell, M.D.

This wastes time, money & energy & increases CO2 in atmosphere. Also poor medical care. It should be changed - Paul Hime, 10 Tiburon Dr., Austin, TX 78738

Senator John Cornyn
Capital Office
United States Senate
Washington, DC 20510-0001

Senator Kay Bailey Hutchison
Capital Office
United States Senate
Washington, DC 20510-0001

Representative Lamar Smith
Capital Office
United States House of Representatives
Washington, DC 20510-0001

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

A

DEC 7 2007

12-02-2007

Dear Center for Medicare & Medicaid Services,

My dermatologist has informed me of this very unwise decision that you scheduled to go into effect on Jan 1, 2008. Regarding wound closure following Mohs surgery for skin cancer, and subsequent cancers treated on the same day. A lot of us on Medicare live on a very tight budget and this would mean more trips to the doctors office and very inconvenient. This would also be very inconvenient for the physicians. It also does not represent good medical care. If you have surgery to remove skin cancer the doctors should be able to close the wound on the same day as well as treat more than one cancer on the same day and be reimbursed ~~the~~ the full amount instead of having to spread this out over more appointments. Some of us seniors have to rely on someone else to get us to these appointments, and that can be very difficult at times. I also believe that if a wound is left open this gives germs a chance to invade the surgery site.

I am asking you to reconsider this ruling and don't put this hardship on many, many seniors. Please -

Sincerely,

Henry H Barta

American Academy of Home Care Physicians



December 3, 2008

DEC 7 2007

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

Gentlemen:

The Academy of Home Care Physicians wants to express thanks to Amy Bassano, Dr. Ken Simons, and other CMS staff for their decision to allow some upward movement in work values for home and domiciliary care codes.

We appreciated the opportunity to participate in the refinement process, which we know represented extra effort on CMS' part, and are pleased that CMS decided to take action on work values for these codes before the next Five Year Review Process.

While the erosion of house call practice capacity will no doubt continue as a result of other aspects of the payment formula, at least this action will sustain some, and permit their patients to be served.

Sincerely,

George Taler, MD
Past President, AAHCP
Chair, Public Policy Committee

- President**
Joe W. Ramsdell, M.D.
San Diego, CA
- Immediate Past President**
C. Gresham Bayne, M.D.
San Diego, CA
- Treasurer**
Stephen W. Holt, M.A., M.B.A.
Philadelphia, PA
- Secretary**
Jean A. Yudin, R.N., C., M.S.N.
Philadelphia, PA
- Executive Director**
Constance F. Row, LFACHE

P.O. Box 1037 ■
Edgewood, MD 21040-0337 ■

Phone: 410-676-7966
Fax: 410-676-7980
Email: aahcp@comcast.net
Web Site: <http://www.aahcp.org>

Marie and Joe B. McShane, Jr.

20 Club Estates Parkway

Austin, TX 78738

DEC 7 2007

November 19, 2007

Center for Medicare & Medicaid Services
Department of Health & Human Services
P. O. Box 8020
Baltimore, MD 21244-8020

Attention: CMS-1385-FC ,

We have just been informed of a pending change in Medicare reimbursement that will seriously affect the treatment of skin cancer patients that we find extremely disturbing, since we both have been treated for skin cancer several times. The common treatment of skin cancer after a positive biopsy is called Mohs surgery at which time the cancer is removed by a qualified dermatologist or plastic surgeon. After surgical removal the Dr. tests the margins of the removed tissue to be sure there are no cancer cells present, if he finds any malignant cells remaining, he again removes more of the tissue until the margins are free of malignant cells. This process is known as Mohs surgery. The Dr. then stitches the wound together and applies appropriate bandages.

Under the proposed new rule, beginning January 1, 2008 reimbursement for wound closure following Mohs surgery for excision of a skin cancer will be cut by 50%. If the patient is willing to come back to the doctors office the **following day** and have the wound closed after the excision of a skin cancer, the closure of the wound will be paid at **100% of the usual fee**. Not only is this ridiculous, but possibly very dangerous to the patient as in our cases we have had to have as many as 15 stitches to close the wound on the face with a lot of bleeding involved. **In addition to the above change any subsequent cancers treated on the same day will also have the fees cut by 50%.**

What this means, the dermatologists will be forced to treat only one cancer per day and then **close the wound at a separate appointment on a different day**. This is obviously extremely inconvenient for both patients and physicians but does not represent good medical care.

We ask that you would contact the Center for Medicare & Medicaid Services in the Department of Health & Human Services and protest these totally impractical changes to Medicare reimbursement. It seems common sense has gone out the window.

Yours truly,

Marie P. McShane

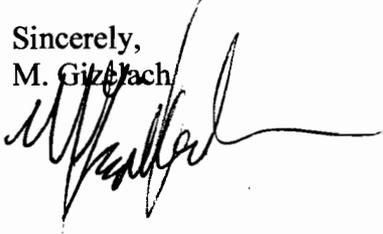
Joe B. McShane, Jr.

17 11-19-07

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

I strongly oppose the pending changes in Medicare reimbursement for wound closure after Mohs surgery for skin cancer.

Sincerely,
M. Gitzelbach

A handwritten signature in black ink, appearing to read 'M. Gitzelbach', with a long horizontal flourish extending to the right.

I am writing to let you know of pending changes in Medicare reimbursement that will seriously affect the treatment of skin cancer patients. Beginning January 1, 2008 reimbursement for wound closure following Mohs surgery for skin cancer will be cut by 50%. Any subsequent cancers treated on the same day will also have the fees cut by 50%. 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 dermatologists will be forced to treat only one cancer per day and then close the wound at a separate appointment on a different day. This is obviously extremely inconvenient for both physicians and patients and does not represent good medical care.

I am asking that you write your representatives or the Center for Medicare and Medicaid Services to implore them to change this very unwise decision. Time is of the essence as the ruling is scheduled to go into effect January 1, 2008.

Thank you.

[Redacted signature area]

Senator John Cornyn
Capital Office
United States Senate
Washington, DC 20510-0001

Senator Kay Bailey Hutchison
Capital Office
United States Senate
Washington, DC 20510-0001

Representative Lamar Smith
Capital Office
United States House of Representatives
Washington, DC 20510-0001

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

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

Dear Sirs:

I am a 67 year old male and this is the first time I have written a letter to my representative in Congress, so you can see how strongly I feel about this issue.

It is my understanding that there are some pending changes in Medicare reimbursement that will effect the treatment of skin cancer. Beginning January 1, 2008 reimbursement for wound closure following Mohs surgery for skin cancer will be cut by fifty percent. Any additional cancers treated the same day will also be cut by fifty percent. If the patient returns to the doctor's office the following day for the surgery closure, then the wound closure will be paid at 100% of the approved fee.

This will force doctors to treat a skin cancer one day then close that cancer the next day. Then if there is an additional cancer, it would be treated the next day and then closed the following day. So, what could be done in one day could require four or more trips.

People of my age rely on Medicare and Social Security. In many cases Social Security is our only method of a living income. So, we will do what is necessary to keep our costs down regardless of how many trips to the doctor's office we are forced to make.

I realize that Medicare is a very expensive program. However, cutting benefits is not the answer. In addition to being on Medicare, I am also a cancer survivor. I really do not want to be put in position where the doctor tells me that I have a skin cancer, and I tell him that I will have to put surgery off for a while because I can't afford to have it removed.

I will appreciate you consideration of this matter.

Sincerely,



Larry Hunt
1409 Hillcrest Drive
Austin, Texas 78723-1849



American Ambulance Association
8201 Greensboro Drive, Suite 300
McLean, Virginia 22102
Phone: (703) 610-9018
Fax: (703) 610-9005
Website: www.the-aaa.org

"The American Ambulance Association promotes health care policies that ensure excellence in the ambulance service industry and provides research, education, and communications programs to enable members to effectively address the needs of the communities they serve."

November 27, 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:

The American Ambulance Association (AAA) would like to take this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Final Rule with comment period entitled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions" ("Final Rule"), 72 Fed. Reg., No. 227 (November 27, 2007).

The American Ambulance Association is the primary trade association representing ambulance service providers that participate in serving communities with emergency and non-emergency ambulance services. The AAA is composed of more than 700 ambulance operations and has members in every state; transporting over 6 million patients every year. AAA members include private, public and fire and hospital-based providers covering urban, suburban and rural areas. The AAA was formed in 1979 in response to the need for improvements in medical transportation and emergency medical services. The Association serves as a voice and clearinghouse for ambulance service providers who view pre-hospital care not only as a public service but also as an essential part of the total public health care system. The comments submitted herein are on behalf of our members.

BENEFICIARY SIGNATURE FOR AMBULANCE TRANSPORT SERVICES

New Exception to Beneficiary Signature Requirement for Emergency Ambulance Services

The AAA is deeply disappointed that CMS chose to finalize its proposed exception to the beneficiary signature requirement for emergency ambulance services, with only minor modifications. In its explanation for why a new exception was warranted, CMS correctly noted the significant hardships faced by ambulance services in seeking to comply with the beneficiary signature requirements of 42 C.F.R. §424.36. However, it was our position that, as proposed, the new exception failed to provide ambulance services with meaningful relief from the present signature requirements. In fact, in trying to grant relief, the Final Rule would significantly add to the burden of ambulance services.

As adopted, the exception would permit an ambulance service, in an emergency, to sign a claim on the beneficiary's behalf and submit the claim to Medicare for payment, provided each of the following conditions was met:

1. The beneficiary was physically or mentally incapable of signing the claim at the time of service;
2. None of the individuals listed in 42 C.F.R. §424.36(b)(1) – (5) was available or willing to sign the claim on the beneficiary's behalf at the time the service was provided; and
3. The ambulance provider maintains specific information and documentation for at least 4 years from the date of service. The required information and documentation includes:
 - a. A contemporaneous statement from an ambulance employee present during the transport, stating that the beneficiary was physically or mentally incapable of signing, and that no other authorized person was available or willing to sign the claim on the beneficiary's behalf.
 - b. Documentation providing the date and time of the transport, and the name and location of the receiving facility.
 - c. Documentation from the receiving facility of the name of the beneficiary and the date and time the beneficiary was received, in the form of either:
 - i. A contemporaneous statement from a representative of the receiving facility, or
 - ii. A secondary form of verification from the receiving facility, which can include a patient medical record, hospital admission record, hospital log, etc.

The Final Rule amended the proposed exception to provide an additional means of obtaining the required documentation from the receiving facility. As originally proposed, the exception would have required a contemporaneous written statement from a representative of the receiving facility. The AAA, together with other commenters, noted that it was impractical to expect emergency department personnel to sign this statement at the time the beneficiary is brought to the hospital. In the Final Rule, CMS modified this

requirement to permit the documentation from the receiving facility to be obtained at a later date. While this modification would provide some relief from the requirement that the ambulance service obtain the receiving facility's statement at the time of transport, it still fails to address our primary concern, i.e., that ambulance services will be unable to obtain this documentation from hospitals, despite good faith efforts to meet the requirement.

In the Final Rule, CMS estimated the time needed to comply with the recordkeeping requirements of the proposed exception at five (5) minutes per transport¹. The AAA strongly disagrees with this estimation. If the experience of our members with the physician certification statement (PCS) requirement is any indication, ambulance services will frequently be unable to get this documentation from hospital emergency department personnel at the time of transport. The primary problem is emergency department overcrowding, as documented by the recent report by the Institute of Medicine (IOM) Committee on the Future of Emergency Care². The new exception would only serve to compound this problem, by requiring emergency department personnel to complete an additional piece of paperwork. The IOM report made clear that this time would be better spent moving patients through the patient care continuum. For a myriad of other reasons, emergency department personnel may refuse to sign documentation presented by an ambulance service at the time of transport. As a result, ambulance services will routinely be forced to seek secondary forms of verification, thereby greatly increasing the time and effort needed to comply with the new exception.

The new exception makes no allowances for the inevitable situations where the ambulance service makes a good faith effort to comply, but is ultimately unable to obtain the required documentation from the receiving facility. Here, the PCS requirement again provides a useful analogy. For non-repetitive patients, Medicare regulations permit an ambulance service to submit a claim without a PCS, provided the ambulance service properly documented its efforts to obtain the PCS. In other words, Medicare regulations acknowledge that compliance with the PCS requirement is, to some extent, outside the control of the ambulance service. It should be reiterated that the PCS requirement applies only to non-emergencies. At a minimum, the exception to the beneficiary signature requirement should contain a similar exception where the ambulance service properly documents its good faith efforts to comply.

New Interpretation of 42 C.F.R. § 424.36(b)(5)

42 C.F.R. § 424.36 sets forth the beneficiary signature requirement. The regulation requires the beneficiary's signature on a claim, unless the patient has died or one of the exceptions set forth in subparagraphs (b) – (d) applies. 42 C.F.R. § 424.36(b)(5) provides that, in some instances, the entity furnishing services to a Medicare beneficiary can sign on the beneficiary's behalf. To apply, the beneficiary must be physically or mentally

¹ Final Rule, page 908.

² The IOM determined that demands on hospital emergency departments (EDs) increased by 26% between 1993 and 2003, while the total number of EDs fell by 425. The IOM's report is discussed in greater detail in our August 13, 2007 comment letter to the Proposed Rule.

unable to sign the claim and no other authorized person must be available or willing to sign on the beneficiary's behalf.

In the Final Rule, CMS modified 42 C.F.R. §424.36(b)(5) to require that an entity furnishing services make "reasonable efforts" to obtain the signature of another authorized person before signing the claim on the beneficiary's behalf³. First, CMS modified 42 C.F.R. §424.36(b)(5) to require that an entity furnishing services make "reasonable efforts" to obtain the signature of another authorized person before signing the claim on the beneficiary's behalf. The AAA has no objection to this modification in concept, as we agree that the signature of an independent party is preferable to the signature of the entity furnishing the services. However, we have concerns regarding how CMS would interpret "reasonable efforts" in the context of ambulance services. Unlike hospitals, physicians and many other health care providers, ambulance services typically do not have an ongoing relationship with the beneficiary. Once the transport is completed, an ambulance service will have limited access to the beneficiary and/or his or her authorized representatives⁴. For this reason, we strongly urge CMS to issue guidance interpreting 42 C.F.R. §424.36(b)(5), in the context of ambulance services, to require that reasonable efforts be made only at the time of transport.

Moreover, we note that the modification to 42 C.F.R. §424.36(b)(5) would impact health care groups other than ambulance. Many of these entities would not have commented on the matter, since the exception set forth in the Proposed Rule dealt only with emergency ambulance services. Therefore, we believe that any modification of 42 C.F.R. §424.36(b)(5) should be effected only through notice-and-comment rulemaking, in order to provide all stakeholders with the opportunity for comment.

CMS also clarified that it interprets 42 C.F.R. §424.36(b)(5) to apply only to institutional providers, such as hospitals⁵. CMS stated further that:

"To the extent that ambulance suppliers have been relying on §424.36(b)(5) under any circumstances, such suppliers have been failing to follow the regulations, as this subparagraph does not pertain to suppliers."⁶

The AAA strongly disagrees with this new interpretation. While the actual language of 42 C.F.R. §424.36(b)(5) may reference only providers, it has been long-standing Medicare policy that both providers and suppliers could submit a claim to Medicare without the beneficiary's signature or an authorized representative's signature (i.e., rely on the exception set forth in 42 C.F.R. §424.36(b)(5)) so long as the provider or supplier documented that the beneficiary was unable to sign and that no one else could sign on the patient's behalf.

³ Final Rule, pages 576.

⁴ The Final Rule acknowledged that it would be impractical to later locate the beneficiary or their authorized representative to obtain a signature. Final Rule, page 570.

⁵ Final Rule, pages 575.

⁶ Final Rule, pages 576.

This long-standing policy has been communicated to providers and suppliers from time to time via CMS instruction. This policy is also set forth in various sections of the CMS Internet Only Manual, including Chapter 1 of the Medicare Claims Processing Manual (Pub. 100-04). Section 50.1.6 of that chapter provides, in pertinent part, as follows (emphasis added):

50.1.6 - When Beneficiary Statement is Not Required for Physician/Supplier Claim

A. Enrollee Signature Requirements

A request for payment signed by the enrollee must be filed on or with each claim for charge basis reimbursement except as provided below. All rules apply to both assigned and unassigned claims unless otherwise indicated.

3. When another person may sign on behalf of the enrollee:

c. Enrollee physically or mentally unable to transact business and full documentation is supplied that the enrollee has no one else to sign on his behalf: The physician, **supplier**, or clinic may sign.

The language of Section 50.1.6(A)(3)(c) makes clear that, when the patient is physically or mentally incapable of signing on his or her own behalf and no one else can sign on the beneficiary's behalf, a supplier can sign on the beneficiary's behalf.

Further evidence that Medicare permits ambulance suppliers to sign on the beneficiary's behalf can be found in Chapter 10 of the Medicare Benefit Policy Manual. This chapter deals exclusively with Medicare's coverage requirements for ambulance services. Section 20.1.2 of that chapter provides, in pertinent part, as follows (emphasis added):

20.1.2 - Beneficiary Signature Requirements

Medicare requires the signature of the beneficiary, or that of his or her representative, for both the purpose of accepting assignment and submitting a claim to Medicare. If the beneficiary is unable to sign because of a mental or physical condition, a representative payee, relative, friend, representative of the institution providing care, or a government agency providing assistance may sign on his/her behalf. A **provider/supplier** (or his/her employee) cannot request payment for services furnished except under circumstances fully documented to show that the beneficiary is unable to sign and that there is no other person who could sign.

In October 2002, the AAA wrote to CMS on this very issue. An email response from Susan Webster is enclosed, which provided CMS' interpretation of the old Medicare Carriers Manual. In that email, Ms. Webster reiterated that a supplier (including an ambulance supplier) could sign on the beneficiary's behalf, provided that the supplier fully documented that the beneficiary was unable to sign and that no other authorized representative was available.

In December 2002, CMS posted an answer to a similar question on the Frequently Asked Questions (FAQs) section of its Ambulance webpage. The question dealt with whether the beneficiary's signature was still required, in light of mandatory assignment for ambulance services. CMS's response to that question was as follows:

The beneficiary's signature is required for both accepting assignment and submitting a claim to Medicare. If the beneficiary is unable to sign because of a mental or physical condition, a representative payee, relative, friend, representative of the institution providing care, or a government agency providing assistance may sign on his or her behalf. *A supplier (or his or her employee) cannot request payment for services furnished except under circumstances fully documented to show that the beneficiary is unable to sign and that there is no other person who could sign.* (emphasis added)

The new interpretation of 42 C.F.R. §424.36(b)(5) set forth in the Final Rule would run contrary to prior CMS guidance on this issue. It would also run contrary to the guidance being offered to the ambulance industry by Medicare contractors. These contractors have repeatedly instructed ambulance services that they may submit claims (and answer that they have the signature on file for electronic claims), provided the ambulance service documented that the beneficiary was unable to sign and that no one was available to sign on their behalf. Several examples of letters from Medicare contractors to this effect are enclosed.

Under CMS' new interpretation of 42 C.F.R. §424.36(b)(5), an ambulance supplier would be prohibited from submitting a claim to Medicare unless and until the ambulance supplier obtained the signature of either the beneficiary or another authorized representative⁷. This would require ambulance suppliers to devote substantial time and effort to tracking down beneficiary's and/or their authorized representatives for signatures following the transport. At a time where Medicare is already reimbursing ambulance services below cost⁸, CMS' new interpretation would impose a significant additional administrative burden on ambulance services.

It is inevitable that, in some circumstances, the ambulance service will be unable to obtain the beneficiary's or an authorized person's signature. Under this new interpretation, the ambulance service would be required to bill the beneficiary in these situations⁹. Thus, the new interpretation would undermine the purpose behind mandatory assignment for covered ambulance services, which has been in place since April 2002.

⁷ Where the beneficiary was deceased, ambulance suppliers would still be permitted to submit the claim to Medicare without the beneficiary's signature.

⁸ The May 2007 Government Accountability Office (GAO) report entitled "Ambulance Providers: Costs and Expected Medicare Margins Vary Greatly" (GAO-07-383) determined that Medicare reimburses ambulance service providers on average 6% below their costs of providing services and 17% for providers in super rural areas.

⁹ Final Rule, page 582.

For the reasons set forth above, the AAA strongly urges CMS to abandon this new interpretation of 42 C.F.R. §424.36(b)(5), and to reaffirm that ambulance suppliers can continue to submit claims to Medicare for payment, so long as the ambulance supplier documented that the beneficiary was unable to sign and that no one was available to sign on their behalf.

Purpose of Beneficiary Signature

In the Final Rule, CMS stated its belief that the purpose of the beneficiary signature to file a claim is to “ensure that services were furnished and were furnished as billed.” In other words, CMS believes the beneficiary signature serves a vital program integrity function.

The AAA strongly disagrees with CMS that the beneficiary signature requirement was intended to serve a program integrity function. We believe any program integrity benefit derived from the beneficiary signature requirement to be minimal, and ancillary to the primary purposes of the beneficiary signature requirement: (1) to authorize the assignment of Medicare benefits to the health care provider or supplier and (2) to authorize the release of medical records to CMS and its contractors.

In support of our position that the primary purposes of the beneficiary signature requirement are to effect the assignment of benefits and authorize the release of records, we refer to the language set forth in Box #12 of the CMS-1500 form, which provides as follows:

“Patient’s or Authorized Person’s Signature. I authorize the release of medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment.”

Assignment of covered ambulance services has been mandatory since April 2002. 42 C.F.R. §424.55(c), adopted November 15, 2004 as part of the Final Rule on the Physician Fee Schedule (67 Fed. Reg. 6236), eliminated the requirement that beneficiaries assign claims to the health care provider or supplier in those situations where payment can only be made on an assignment-related basis¹⁰. With respect to the release of medical records, the regulations implementing the HIPAA Privacy Rule, specifically 45 C.F.R. §164.506(c)(3), permit a covered entity (e.g. an ambulance provider or supplier) to use or disclose a patient’s protected health information for the covered entity’s payment purposes, without a patient’s consent (i.e. his or her signature). For these reasons, we do not believe it is necessary to obtain the beneficiary’s signature to effect assignment or to authorize the release of records, i.e., the primary purposes of the beneficiary signature requirement.

¹⁰ The CMS Internet Only Manual also recognizes that the beneficiary’s signature is not needed to effect assignment, where payment can only be made on an assigned basis. Section 30.3.2 of Chapter 1 of the Medicare Claims Processing Manual (Pub. 100-04).

Program Integrity Concerns

For the reasons set forth above, we believe the primary purposes of the beneficiary signature requirement are to effect the assignment of benefits and to authorize the release of medical records to CMS, and not to serve a program integrity function.

Furthermore, we believe the beneficiary signature to be of limited value from a program integrity perspective. It is important to note that Medicare regulations require, with very few exceptions (e.g., ambulance providers with less than 10 claims per month), ambulance services to submit their claims electronically. Thus, beneficiaries do not sign claim forms. On electronic claims, the ambulance service is required to answer a question regarding whether the beneficiary's signature was obtained. If they answer that question "yes", the claim would be processed by the Medicare contractor. In other words, for ambulance services that submit claims electronically (i.e., the overwhelming majority), the beneficiary's signature is never seen by the Medicare contractor. If ambulance services answer "no", the claim can not be processed by the Medicare contractor; as a result, it becomes necessary to submit a paper claim, which defeats the whole purpose of requiring electronic claims.

It should also be noted that electronic claims submission is required for some other payers, including government payers such Medicaid, Champus, etc. To the AAA's knowledge, the majority of these other payers permit ambulance services to submit claims without the beneficiary's signature, provided the ambulance service properly documents that the beneficiary was unable to sign and that no one was available to sign on their behalf.

Moreover, to the extent the beneficiary signature requirement was intended to serve a program integrity function, we see little justification for distinguishing between emergency and non-emergency ambulance services. CMS correctly noted that, in the context of an emergency ambulance transport, it is often impossible to get the beneficiary signature at the time of transport, as many beneficiaries will be unconscious, have a diminished mental capacity, or otherwise suffer from physical distress. However, once the medical emergency has been resolved, the beneficiary may be in a position to sign. By contrast, for non-emergency ambulance transports, the beneficiary is frequently suffering from a chronic or terminal condition that would make it impractical to obtain the beneficiary's signature, not only at the time of transport, but also after the fact. In establishing the exception to the beneficiary signature requirement for emergency ambulance services, CMS apparently felt that the program integrity function was served by obtaining alternative documentation from the ambulance service and hospital. The AAA believes that the program integrity function would be equally served by permitting the ambulance service to obtain similar alternative documentation for non-emergency transports.

As we mentioned in our August 13, 2007 comment letter to the Proposed Rule, for every transport of a Medicare beneficiary, the ambulance crew completes a trip report listing the condition of the patient, treatment, origin/destination, etc. Furthermore, all covered

ambulance transports will be either to or from a medical facility, and these origin and destination facilities must complete their own records documenting the patient was sent via ambulance or arrived via ambulance, including the date and time of such transport. For most non-emergencies, ambulance services must also get a PCS, signed by a medical professional, which would set forth the date of the ambulance transport. All of these documents are readily available, if needed. The AAA believes the information contained on these forms should be sufficient to satisfy any program integrity concerns by CMS.

The AAA acknowledges that program integrity is a vital and necessary component of the Medicare program, and we support CMS' efforts in this area. However, we believe that whatever program integrity function is served by the beneficiary signature requirement is already accomplished by other means (e.g. by medical facility records) with equal or greater effectiveness, and with less of an administrative burden on ambulance services.

AAA Meeting with CMS

On August 15, 2007, representatives of the AAA met with CMS. The primary purpose of this meeting was to explore ways to reduce the administrative burden on ambulance services. One of the issues raised was the **elimination** of the beneficiary signature requirement, particularly for emergencies. At the conclusion of that meeting, CMS indicated its willingness to consider our proposal, provided it could do so in a manner that would not comprise program integrity or other vital CMS functions.

Conclusion

Ambulance services face significant hardships in attempting to comply with the current beneficiary signature requirements of 42 C.F.R. §424.36, and we commend CMS for attempting to provide administrative relief. Unfortunately, for the reasons discussed above and in our August 13, 2007 comment letter to the Proposed Rule, the AAA believes that the Final Rule would have the unintended effect of increasing the administrative burden on ambulance services.

Therefore, for the reasons set forth above, we respectfully request that CMS:

- Amend 42 C.F.R. §424.36(b)(6), as finalized in the Final Rule, to provide that the exception to the beneficiary signature requirement apply for both emergency and non-emergency ambulance transports.
- Work with the AAA and other stakeholders to develop additional means of satisfying the alternative documentation requirements of 42 C.F.R. §424.36(b)(6), to the extent the expansion of this exception to non-emergency ambulance transports would raise additional program integrity concerns.
- Exercise the authority granted to the CMS pursuant to 42 C.F.R. §424.36(e) to find that "good cause" exists to permit an ambulance service to sign a claim on the beneficiary's behalf, provided the ambulance service properly documented

that it used “reasonable efforts” to comply with the alternative documentation requirements of 42 C.F.R. §424.36(b)(6), for both emergency and non-emergency ambulance transports.

- Abandon the new interpretation of 42 C.F.R. §424.36(b)(5), and reaffirm that ambulance suppliers can continue to submit claims to Medicare for payment, so long as the ambulance supplier documented that the beneficiary was unable to sign and that no one was available to sign on their behalf.

Thank you for your consideration of these comments. If you or your staff have any questions regarding our comments, please contact myself or Tristan North, AAA Senior Vice President of Government Affairs, at 703-610-9018.

Sincerely,

A handwritten signature in black ink, appearing to read 'J McPartlon', with a stylized flourish at the end.

Jim McPartlon
President

Subj: **RE: Response to AAA Comments on Beneficiary Signature Q&A**
Date: 10/21/02 3:44:34 PM Eastern Daylight Time
From: Debby_Gault@amr-corp.com
To: SWebster@cms.hhs.gov
CC: DThompson2@cms.hhs.gov, DWalczak@cms.hhs.gov, GKendall@cms.hhs.gov,
DJGrinstead@HHLAW.com, DWerfel@aol.com, MScarano@foleylaw.com
File: **AssignmentQA20021001.doc** (29184 bytes) DL Time (24000 bps): < 1 minute
Sent from the Internet (Details)

Thanks, Susan. I have consulted with my team on this issue. In light of your comments, we can accept the original answer you submitted to us as attached to this e-mail. We do, however, disagree with your view that MCM Sections 3008 and 3057.A.3 require a provider or supplier to chase down a signature which is not available at the time of transport, either from the patient or a representative. There is nothing in either manual provision that would require such follow-up.

-----Original Message-----

From: Susan Webster [mailto:SWebster@cms.hhs.gov]
Sent: Thursday, October 17, 2002 10:44 AM
To: Gault, Debby
Cc: Donald Thompson; David Walczak; Glenn Kendall; DJGrinstead@HHLAW.com
Subject: Response to AAA Comments on Beneficiary Signature Q&A

Debby,

We have reviewed the AAA's suggested revisions to the beneficiary signature requirement Q&A, but are unable to accept these comments. While we agree that MCM § § 3008 and 3057.A.3 provide for alternative signatures when the beneficiary is unable to provide his or her signature because of a mental or physical condition, the supplier must make a good-faith effort to obtain the beneficiary/representative signature prior to submitting the claim. An attempt to obtain this signature at the time of transport is not sufficient to meet this requirement. Furthermore, a supplier may not sign in lieu of the beneficiary/representative except under circumstances when the beneficiary is unable to sign and that there is no other person who could sign, and the supplier must fully document such circumstances. Per MCM § 3057.A.3.b, other persons, including the beneficiary's representative payee, relative, friend, representative of the institution providing care, or a government agency providing assistance, may sign on the beneficiary's behalf. Thus, we foresee very few circumstances in which the supplier would be unable to obtain the signature of the beneficiary or that of his/her representative. Since the claims filing window is 15 to 27 months, the supplier has sufficient time to obtain the beneficiary/representative signature prior to submitting the claim without delaying payment (see 42 CFR § 424.44).

If you have any further questions about the beneficiary signature requirements for submitting a Medicare claim, please contact David Walczak at (410) 786-4475.

Susan Webster
CMS/CMM/PBG/DSCP
(410) 786-3384

Administar Federal

Medicare Part B

ADVANCE

[IMPLEMENTATION EFFECTIVE APRIL 1, 2002]

Fee Schedule Introduction

Section 4531 (b) (2) of the Balanced Budget Act (BBA) of 1997 added a new Section 1834 (1) to the Social Security Act which mandates implementation of a national fee schedule for ambulance services furnished as a benefit under Medicare Part B. To assist in the implementation of this legislature, the Centers for Medicare & Medicaid Services (CMS) provided Medicare carriers and fiscal intermediaries with payment and billing instructions to implement the fee schedule. The ambulance fee schedule applies to all ambulance services, including volunteer, municipal, private, independent, and institutional providers, i.e., hospitals, critical access hospitals, skilled nursing facilities and home health agencies.

The fee schedule is effective for claims with dates of service on or after April 1, 2002. Ambulance services covered under Medicare will then be paid based on the lower of the actual billed amount or the ambulance fee schedule amount. As discussed more fully later in this manual, the fee schedule will be phased in over a five-year period. When fully implemented, the fee schedule will replace the current retrospective reasonable cost reimbursement system for providers and the reasonable charge system for ambulance suppliers. During the transition period, the supplier's reimbursement will be based on its current billing methodology.

Mandatory Assignment Rules

Section 1834 (1) also requires mandatory assignment for all ambulance services. Ambulance providers and suppliers must accept the Medicare allowed charge as payment in full and not bill or collect from the beneficiary any amount other than any unmet Part B deductible and the Part B coinsurance amounts.

Mandatory Assignment and Claim Submittal Requirements

When an ambulance provider/supplier, or a third party under contract with the provider/supplier, furnishes a Medicare-covered ambulance service to a Medicare beneficiary and the service is not statutorily excluded under the particular circumstances, the provider/supplier must submit a claim to Medicare and accept assignment of the beneficiary's right to payment from Medicare.

Mandatory Assignment for Managed Care Provider/Suppliers

Mandatory assignment for ambulance services, in effect with the implementation of the ambulance fee schedule on April 1, 2002, applies to ambulance providers/suppliers under managed care as well as under fee-for-service. (The ambulance fee schedule is effective for claims with a date of service on or after April 1, 2002.) During the fee schedule transition period, Medicare payment for ambulance services is a blend of the reasonable cost/charge and fee schedule amount.

Mandatory Assignment and Beneficiary Signature Requirements

Medicare requires the signature of the beneficiary, or that of his or her representative, for both the purposes of accepting assignment and submitting a claim to Medicare. If the beneficiary is unable to sign because of a mental or physician condition, a representative payee, relative, friend, representative of the institution providing care, or a government agency providing assistance may sign on his/her behalf. A provider/supplier (or his/her employee) cannot request payment for services furnished except under circumstances fully documented to show that beneficiary is unable to sign and that there is no other person who could sign.



Medicare Part B

Medicare Professional Services
PO Box 890089
Camp Hill, PA 17089

March 11, 2002

Kim Shank
Ambulance Association of Pennsylvania
3438 Trindle Road
Camp Hill, PA 17011

Dear Kim:

This letter is in response to your email questions regarding the electronic reporting of signature on file for patients who are unable to sign due to their medical/mental condition at the time of transport.

According to the Medicare Carriers Manual section 3008 it states the following:

"A physician or supplier (or his/her employee) cannot request payment for services furnished except under circumstances fully documented to show that the enrollee is unable to sign and that there is no other person who could."

Based on the above MCM reference, in the situation where the beneficiary is unable to sign the request for payment of services, the signature form must be clearly documented as "patient unable to sign due to". This statement must indicate the medical reason that prohibits the patient's ability to sign and that no other person was available to sign on the patient's behalf.

Providers submitting claims electronically would use the "Y" indicator for signature on file and must maintain the appropriate documentation on file and be available to the carrier upon request.

Should you have any additional questions, please feel free to contact me.

Sincerely,

Amy G. Ascher
Communications Analyst
Medicare Professional Services

Cc: Jack Metz

HIGS ADMINISTRATORS
A HEALTH CARE FINANCING ADMINISTRATION COMPANY
Camp Hill, PA 17089
www.hgsa.com



**BlueCross BlueShield
of Alabama**

August 31, 1999

David Werfel, Esq.
Medicare Consultant
One Rabro Drive
Hauppauge, NY 11788

Dear Mr. Werfel,

I am responding to your recent inquiry relating to the "electronic signature" dated July 28, 1999.

We understand that there are situations where the patient may be physically or mentally incapable of signing a patient authorization. Our policy follows all Medicare regulations, addressing this situation by allowing someone other than the patient to authorize services. Proper supporting documentation describing the reason(s) why the patient was incapable of signing is required. When filing this claim electronically, "Yes" would be the response to the patient authorization question when situations like this arise.

If you need further assistance or details on the electronic claim format, please call me at the number listed below.

Sincerely,

Lisa W. Johnson
Manager, Network Data Operations
Health Care Networks
Blue Cross and Blue Shield of Alabama
(205) 733-7572

cc: Robert Orr

MEDICARE Administration
P.O. Box 1465
Nashville, TN 37202



CIGNA HealthCare

April 3, 1998

David Werfel
One Rabro Drive
Hauppauge, NY 11788

Dear Mr. Werfel:

This letter is in response to your request for information concerning the Signature on File requirement for electronic claim submission.

Providers who submit Medicare claims electronically to HCFA or to HCFA's contractors, agree to the provisions as described in the Electronic Data Interchange (EDI) enrollment form. One of the provisions is that the provider agrees to submit claims to Medicare on behalf of Medicare beneficiaries who have given their written authorization to do and to certify that required beneficiary signatures or legal authorized signatures on behalf of beneficiaries, are on file.

Section 3057A (3) (c), of the Medicare Carrier Manual states where the enrollee is physically or mentally unable to transact business and full documentation is supplied that the enrollee has no one else to sign on his or her behalf, the physician, supplier, or clinic may sign. The person signing for the beneficiary must include their name, title and address.

The supplier can indicate "Yes" for the beneficiary's signature when the facility or supplier signs for a beneficiary who meets the conditions described above. As always the documentation to support the situation must be available to Medicare, if requested. This applies to electronic and paper claim submission.

If the beneficiary refuses to authorize claims submission by not signing the claim form or signature card then the beneficiary is liable and no claim is filed (at least not until such time as the beneficiary authorizes it by providing their signature). Mandatory claim submission is based on the premise that the beneficiary does want a claim to be filed and that the beneficiary or his or her authorized representative will provide the required authorization for the provider to do so.

If I can be of further assistance, feel free to contact me at the above address.

Sincerely,

A handwritten signature in cursive script that reads "Wilma Johnson". The signature is written in dark ink and is positioned above the typed name.

Wilma Johnson
Policy Specialist

Medicare B

October, 1993

TO: KANSAS, WESTERN MISSOURI AND NEBRASKA AMBULANCE PROVIDERS

FROM: Courtney Hanna, Medicare Professional Communications

SUBJ: Ambulance Manual Revision 4

Enclosed is the fourth revision to the Medicare Ambulance Manual. Also enclosed are questions and answers to common problems of ambulance providers. The information in that letter has been incorporated into the manual for future reference.

Pages 129 and 130 of the manual have been deleted.

If you have any questions, please contact your Provider Relations Representative.

KANSAS
Claim Inquiries:
1133 S.W. Topeka Blvd.
Topeka, KS
66629-0001

KANSAS CITY AREA
Claim Inquiries:
P.O. Box 419840
Kansas City, MO
64141-6840

NEBRASKA
Claim Inquiries:
P.O. Box 3512
Topeka, KS
66601-3512

August 5, 1993

TO: Ambulance Providers

FROM: Scott Vondenkamp and Doug Klise
Professional Relations Department

Eastern Ambulance Service, Inc. hosted a Medicare seminar for ambulance providers in May of 1993. Research has been done to clarify some issues that were asked during the seminar. The clarification is formatted below as questions and answers.

Q. What is a one-time payment authorization?

A. In lieu of obtaining the signature of the beneficiary (or his representative) on each claim form, ambulance providers may obtain a beneficiary authorization for the submission of claims over an extended period of time. The ambulance provider should have the patient sign a brief statement substantially as follows:

"I request that payment of authorized Medicare benefits be made either to me or on behalf to _____ for any services furnished me by that ambulance provider. I authorize any holder of medical information about me to release to the Health Care Financing Administration and its agents any information needed to determine these benefits or the benefits payable for related services."

Once an ambulance provider has obtained the one-time authorization they may submit any later Medicare claims, on either an assigned or unassigned basis, without obtaining any additional signature of the patient. In submitting claims, they should indicate in the patient's signature space:

"Patient's request for payment on file."

Q. What if a Medicare beneficiary is unable to sign or is deceased?

A. Where a beneficiary is unable to execute a request for payment because of a mental or physical condition, the request may be executed on his/her behalf by a legal guardian, representative payee, relative, friend, representative of an institution providing him/her care or support, or of a governmental agency providing assistance. A physician or supplier (or his/her employee) cannot request payment for services furnished except under circumstances fully documented to show that the enrollee is unable to sign and that there is no other person who could.

For this purpose, "an institution providing him/her care" includes a long-term care facility, a hospital (whether psychiatric or general), a SNF, and a nursing home. Only an employee of the institution or agency may be authorized to act as its representative to sign claims on behalf of incompetent patients.

The name of the incompetent person should be shown on the signature line of the Request for Medicare Payment followed by "by" and the signature and address of the requestor.

If you have met the above requirements and file your claims electronically you may answer yes as to whether the signature is on file.

Q. Will Medicare Reimburse an ambulance provider if they provide services but no transportation is provided?

A. Reimbursement may be made for expenses incurred by a patient for ambulance services providing conditions 1, 2, and 3 listed below are met.

1. Patient was transported by an approved supplier of ambulance service.
2. The patient was suffering from an illness or injury which contradicted transportation by other means.
3. The patient was transported from appropriate from and to points.

Item two would not be met if transportation was not provided. Denials for this service would be made under section 1861(s)(7) of the act. The waiver of liability would not apply. Services are therefore billable to the patient as a noncovered service. There is one exception to the above, that is when services are furnished to a deceased beneficiary. An individual is considered to have expired as of the time he is



American Society
Clinical Pathology®

Washington Office

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Suite 250 F 202. 347.4453
Washington, DC 20005-6516 www.ascp.org

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.

Kerry N. Weems
December 17, 2007
Page 2

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,

Handwritten signature of Lee H. Hilborne MD, FASCP in black ink.

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

ROBERT MAGEE
6508 WHITEMARSH VALLEY
AUSTIN, TX 78746

December 11, 2007

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

The pending Medicare reimbursement changes for Mohs surgery are crazy! I just had Mohs surgery on my ear and it took 20 stitches to close. Waiting until the next day to close the wound would be unsanitary, bad medical practice and the pain would not be bearable. What these proposed Medicare changes do is to force the patients into paying extra out of their pocket to get wounds closed! Then Medicare has more money to spend on their bureau. But the money belongs to us tax payers!

Sincerely,



Robert Magee

Copies to:

Senator John Cornyn
Senator Kay Bailey Hutchison
Representative Lamar Smith

December 6, 2007

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

ATTN: Center for Medicare & Medicaid Services

Gentlemen:

I am very dismayed by the changes in Medicare reimbursement that will seriously affect the treatment of skin cancer patients. My doctor, Dr. William M. Ramsdell, M.D. informs me that reimbursement for wound closure following Mohs surgery for skin cancer will be cut by 50%. Any subsequent cancers treated on that same day will also have the fees cut by 50%. If I return the next day to his office after excision of a skin cancer, then the closure of the wound will be paid at 100% of the usual fee.

This means that dermatologists will be forced to treat only one cancer per day and close the wound at a separate appointment on a different day. I just can't imagine what my face would look like after waiting to have the wound closed and also the potential increase in scarring.

I implore you to change this very unwise decision, for the patient's sake.

Sincerely,

Sharon L. Morrow
Sharon L. Morrow
9311 Stallion Drive
Austin TX 78733



December 12, 2007

141 Northwest Point Blvd
Elk Grove Village, IL 60007-1098
Phone: 847/434-4000
Fax: 847/434-8000
E-mail: kidsdocs@aap.org
www.aap.org

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

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Berkeley, CA

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John S. Curran, MD, FAAP
Tampa, FL

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 Academy of Pediatrics (AAP) appreciates the opportunity to provide comments on the November 1st final rule titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008." Although very few pediatric services are included in the Medicare program, payment policies introduced in Medicare are frequently adopted by the Medicaid program and eventually by private payers. Therefore, the Academy offers these comments on the proposed rule to ensure that new policies appropriately accommodate the unique aspects of health care services delivered by primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists.

Publishing of RUC-Recommended Values

The Academy strongly applauds CMS for agreeing with the RUC-recommended relative value units (RVUs) for the non-face-to-face service codes (98966-98969 and 99441-99444, the medical team conference codes (99366-99368), and the initial day neonatal hospital care code (99477). It was especially encouraging to see that CMS agreed with the RUC's assessment that there is value inherent in non-face-to-face services.

Medicare Payment Policy for Non-Face-to-Face Services

With specific regard to the non-face-to-face services codes, CMS notes that it will not cover services that include conversations with parents/guardians since they are not the Medicare beneficiaries. This is very discouraging given that these codes were developed to apply across all specialties. This Medicare payment policy will have a detrimental effect on specialties such as pediatrics, where the parent/guardian is typically the patient surrogate. Given the prevalence of adoption of Medicare policies by non-Medicare payers (eg, Medicaid), CMS has a responsibility to implement policies that are equitable across all patient populations.

Echocardiography

CMS should be commended for agreeing to follow the RUC recommendation with regard to code 93325 (*Doppler echocardiography color flow velocity mapping*). CMS will maintain the 2008 work values for code 93325 at its 2007 level (0.07), thereby allowing the RUC to appropriately bundle codes 93320 and 93307 into 93325 when it is valued for 2009.

Budget Neutrality Factor

We are disappointed by CMS' decision to continue to apply a separate budget neutrality factor to all work relative value units (RVUs) rather than to the conversion factor. The Academy strongly objects to using work relative values as a mechanism to preserve Medicare budget neutrality. These adjustments to the work relative values cause confusion among the many non-Medicare payers that adopt the RBRVS payment system. According to a recent AMA survey, 77% of all public and private insurance payers rely on the RBRVS. We believe that this adjustment should have been transparent and advocate that any Medicare budget neutrality adjustments be made to the conversion factor rather than to the work relative values. The potential negative impact on the delivery of key Medicaid preventive services such as Early Periodic Screening, Diagnosis, and Treatment (EPSDT) is great in the several states that adopt the RBRVS reduced relative value units for the preventive medicine service codes (99381-99385, 99391-99395) and immunization administration (90465-90468, 90471-90474).

Moderate (Conscious) Sedation (99143-99150)

The moderate sedation codes continue to be included on the fee schedule as Status Indicator "C" (Carrier Priced), with no published RVUs. Given CMS' direct involvement in the development of these codes, it disappoints us that the Status Indicator for the codes is "C." Furthermore, we are dismayed that CMS continues not to accept the April 2005 RUC recommendations for the codes and publish them in the 2008 RBRVS final rule.

In its November 21, 2005 *Federal Register* 2006 Medicare Physician Fee Schedule comments, CMS stated that it was "uncertain whether the RUC assigned values are appropriate and has carrier priced these codes in order to gather information for utilization and proper pricing." While we appreciate CMS' reconsideration of paying for sedation services not previously covered and understand this is an interim position, we request that CMS consider the following arguments in revising its position.

These CPT codes (99143-99150) were surveyed by several specialty societies in order to provide the RUC with data necessary to appropriately value the service. Codes were developed to simplify reporting these services into age-specific categories. The RUC-recommended values for these six codes were based on valid surveys and carefully vetted through the RUC process. We are confident in the accuracy of the values assigned. While CMS has assigned these codes to Status Indicator "C," the Academy

believes that they should be listed with Status Indicator “A” (Active) and their RUC-recommended RVUs published.

Providing moderate sedation to patients undergoing certain outpatient procedures requires a certain level of provider skill and training and incurs medical legal liability, but is also associated with greater patient satisfaction, improved outcomes, and cost savings over similar procedures provided with anesthesia in an operating room. Furthermore, the far-reaching shortage of pediatric anesthesiologists at children’s hospitals has created the need for moderate sedation services provided by other hospital-based physicians. In most metropolitan areas of the United States, these children’s hospitals form the safety net for subspecialty care provided to children in the Medicaid program. This critical service is directly supported by the publication of relative values of these codes.

Appendix G (“Summary of CPT Codes That Include Moderate Sedation”) in the CPT manual was developed to identify services where sedation is an inherent part of the procedure. We firmly believe that any service performed that is *not* listed in Appendix G should be appropriately paid when reported with a moderate sedation code. There is significant additional cognitive skill required and this is reflected in The Joint Commission mandates addressing specific credentialing criteria for individuals providing moderate sedation. The work involved in providing sedation is *not* included in the RVUs for any procedure not included in Appendix G and the Academy believes that physicians should be adequately compensated for providing such services.

For these reasons, the Academy respectfully requests that CMS reconsider its decision to list the moderate sedation codes as carrier-priced. We urge CMS to publish the RUC-approved RVUs and assign these codes as Status Indicator “A” (Active) codes.

Preventive Medicine Services and the Medicare Primary Care Exception

Over the past four years, the Academy has made several requests for CMS to consider including preventive medicine services as part of the Medicare primary care exception. We take this opportunity to reiterate our request.

When CMS revised teaching physician rules (Medicare Carriers Manual Transmittal 1780, November 22, 2002), a “primary care exception” was established (§15016(C)(3)). This exception permitted the teaching physician to submit claims to Medicare for certain low and medium intensity Evaluation and Management services (99201-99203, 99211-99213) furnished by residents, subject to certain oversight rules, in a primary care clinic.

While the transmittal names pediatrics as one of the “residency programs most likely qualifying for this exception...” the rule itself has actually placed these residencies at a disadvantage. The primary reason is the available exempt codes. Medicare generally does not pay for the preventive medicine visits (99381-99387, 99391-99397). However, these are among the most common codes to be used in the pediatric primary care clinic.

Preventive well child care and EPSDT visits are responsible for a significant number of pediatric primary care clinic visits. By their nature, they are similar in intensity to the codes already included in the exempt list. Because these codes are not listed on the primary care exception list, it places an undue burden on the pediatric teaching physician who is unable to report these codes in the pediatric primary care setting under the exception. The fact that the primary care exception does not presently include preventive medicine services prohibits pediatric residents from partaking of the educational advantages enjoyed by their adult-based colleagues. Furthermore, given that the "introduction to Medicare" exam was added to the exempted list last year establishes a precedent for other preventive services of similar intensity and importance to be included.

Preventive services are key services in the teaching setting, particularly considering that most children's hospitals serve as the Medicaid safety net for children in their service regions and deliver preventive services for children through age 18 under the federal EPSDT program.

While the original intent of Transmittal 1780 was for Medicare reimbursement, it has become the de facto standard for many Medicaid and commercial payers, and the compliance policies of teaching hospitals now reflect these rules.

For these reasons, we ask that the pediatric preventive medicine and EPSDT codes be added to the primary care exception list. This will have no financial impact on Medicare or residency GME reimbursement, but will help improve and make more equal the educational experience for the pediatric resident as compared to non-pediatric residencies.

| <u>Preventive Medicine Service</u> | <u>New</u> | <u>Established</u> |
|---|-------------------|---------------------------|
| Infant (<1 year) | 99381 | 99391 |
| Early childhood (1-4 years) | 99382 | 99392 |
| Late childhood (5-11 years) | 99383 | 99393 |
| Adolescence (12-17 years) | 99384 | 99394 |

So302 Early Periodic Screening, Diagnosis, and Treatment (EPSDT)

The Academy appreciates the opportunity to provide comments on the November 1st final rule and looks forward to working with CMS to ensure that the physician fee schedule accurately reflects the work value of physician practice and pediatric care.

Sincerely,



Renée R. Jenkins, MD, FAAP
President

RRJ/ljw



DEC 18 2007

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December 7, 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

Re: Comments to Anti-Markup Provisions, File Code CMS-1385-FC

Dear Administrator Weems,

American Health Network (“AHN”) strongly urges CMS to reconsider the implementation of its revisions to the anti-markup provisions and to corresponding provisions in the reassignment rules. CMS proposed revisions to the anti-markup rules in the CY 2008 Proposed Physician Fee Schedule published last July; however, the revisions now *finalized* by CMS are far afield from the revisions *proposed* by CMS. In fact, if CMS were to implement the revisions as drafted in the CY 2008 Final Physician Fee Schedule (“2008 PFS”), the new anti-markup provisions would have the net effect of vitiating many of the physician self-referral rules currently relied upon, not only by AHN, but by vast numbers of physicians and physician practices throughout the nation. As a result, patient care will be seriously affected as physician practices eliminate the care their patients have come to rely on because they are either driven out of business, or forced to undergo drastic, unnecessary re-organization.

AHN is a multi-specialty physician owned and managed organization, with two physician group practices—one in Ohio and one in Indiana. In all, AHN employs approximately 200 physicians located at multiple practice sites. Some sites are occupied exclusively by AHN. Other sites have multiple tenants. AHN offers a wide range of diagnostic services to its patients, including comprehensive imaging and sleep studies. Several of the AHN offices offer on-site imaging, including one oncology practice site that offers PET-CT. These diagnostic test services are an integrated and vital part of AHN’s practice. AHN believes that access to convenient, full-range, and high-quality diagnostic services enhances the quality of the patient care provided by the practice. Further, many of AHN office

sites are located in areas where there is limited access to alternative diagnostic test service sites, or, if there are alternative sites, the quality of equipment at these sites is inferior to that used by AHN.

AHN operates its imaging sites under various different types of arrangements based on several factors, including the particular needs of the community, individual lease requirements, and practice specialties. All of these arrangements, however, have been structured to meet applicable laws and regulations. Several of the AHN imaging suites, including the PET-CT, are used by AHN exclusively. A minority of the imaging suites are shared with other lessees. In one location, the imaging suite is contiguous with—and opens into—a large physician practice site but is shared on a block time basis with another provider. Another location has an imaging suite that is located in a building that is shared only by AHN and an unrelated physician group practice. Both physician groups share the imaging suite.

Generally, AHN's landlords require the imaging equipment to be located on the first floor of the building, even if the physician office space is located on the second floor. AHN, in every instance, has a means of immediately accessing the imaging suite when an alarm is sounded indicating that a physician's assistance is needed on an urgent basis. That access may be via an internal stairway, or it may be down a common hallway. There are AHN physicians available at each site who are trained in advanced life support and who serve as imaging directors with responsibility for overseeing the equipment and personnel at the imaging suites.

AHN has invested in the systems necessary to read its patients' studies in its own centrally located "read suite," which is leased and staffed on a full-time, exclusive basis by AHN. AHN contracts with a radiology group to read all of its studies. The contracted radiologists come to the AHN suite to perform the reads. This assures not only that AHN has consistent quality of reads and a secure system for transmitting the images, but also that the images are read on state-of-the-art equipment. Importantly, by contracting with a radiology group in which the radiologists have specialized training in various sub-specialties (rather than hiring its own radiologist), AHN studies are read by an appropriate sub-specialty radiologist (as opposed to a general radiologist). Accordingly, patients benefit from superior quality interpretations. AHN has always paid these radiologists the entire professional component of the Medicare allowable fee for their professional services. This means that AHN absorbs the cost of billing/collection and other overhead expenses associated with studies billed to Medicare.

AHN has entered into commercial leases for physician practice space, including the imaging suites. These commercial leases generally have terms of 10-15 years, and are not terminable at will. Likewise, because of the caliber and sophistication of the imaging equipment selected by AHN, AHN has financed the equipment using commercial leases through GE Healthcare Finance. In some instances, AHN has been an early adopter of new technology, such as digital mammography, which was not immediately available to patients at other provider sites. These equipment leases are not sham, one-year leases with "easy out" provisions, but rather multi-year commercial leases with no early termination. In fact, because AHN is committed to compliance, all of these agreements were arranged with careful consideration of—and in complete reliance upon—all applicable laws, including the self-referral and anti-kickback laws and CMS billing rules.

AHN also has invested in a sleep laboratory in both states, and has employed physicians on a full-time basis who are (or are in the process of becoming) board-certified in sleep studies. In Ohio, the sleep lab is located in a "centralized building" and is not contiguous to a physician practice site, but

rather is located so that it is convenient to the largest number of AHN patients and practice sites. The Ohio sleep lab operates on a long-term lease that cannot be terminated without a significant financial penalty.

AHN is concerned that the new anti-markup rule will have a devastating impact on the quality of patient care within its practice. When AHN is forced to cease operating under its current arrangements, many patients will be forced to either travel significant distances to obtain the services, or settle for diagnostic tests from other providers whose equipment is dated and inferior. In virtually every instance, it will take more time for patients to obtain necessary diagnostic services because of the wait times that already exist for hospital-based services. In addition, AHN fears that the formula for computing “net charge” will not simply deny AHN a return on investment, but actually cause reimbursement to drop *below actual cost*, putting AHN—and countless other groups, who, like AHN, have long-term financial commitments to landlords and vendors—into a financial death spiral. This will inevitably have an adverse impact on patient care.

AHN recognizes that the genesis of the anti-markup rules was Congress’ concern that physicians should not profit from tests they do not perform. The statute simply states that if a physician (or another physician with whom the physician “shares a practice”) bills for a test without indicating on the claim that he or she personally performed (or supervised the performance of) the test (that is, if the claim indicates that a test was performed by a supplier), then the amount payable on that claim is limited to the lower of (1) the actual acquisition cost or (2) “the supplier’s reasonable charge.” If the claim fails to identify who performed the test, or, for a test performed by a supplier, the claim does not include the amount charged by a supplier, then no payment may be made. 42 USC 1395u(n)(1). That Congress was concerned with markups on *purchased* tests is evident in the legislative history:

The committee provision is based on the concern that excessive payments are being made for many purchased diagnostic tests. H. R. Rep. No. 100-39(II), at 953 (1987).

In fact, the reassignment laws (as well as CMS guidance) make it clear that a physician may not purchase (or bill for) a diagnostic test (the technical portion) unless he or she performs the interpretation. CMS’s new rule is not based on—and is in fact contrary to—this Congressional intent in passing the statute because it is applying the anti-markup provisions to not only to the professional component of tests which are actually performed (or supervised) by the billing physician (or a physician in the same practice), but also to tests that were never “purchased” by the billing physician in the first place.

In the Proposed 2008 Physician Fee Schedule, published on July 12, 2007 (“2008 Proposed PFS”), CMS proposed to “clarify” the anti-markup rule so that the anti-markup provision on the professional portion of a purchased diagnostic test would match the anti-markup provision already imposed on the technical component of such tests. In addition, CMS proposed to apply the anti-markup provision regardless of whether the billing entity purchased the technical or professional component outright *or received a reassignment of the right to bill*. Currently, so long as the test is not purchased, but properly re-assigned to the billing physician, the anti-markup provisions do not apply. However, as drafted, CMS’s proposed clarification would have excepted from the anti-markup provision tests that are performed by a *full-time employee* of the billing entity.

Much of the proposed rule focused on whether the person performing either the technical or professional component of a test was a full-time employee of the group practice, rather than a part-time employee or an independent contractor. The rule as finalized eliminates this distinction and simply imposes an anti-markup provision on the technical or professional component 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.

AHN was dismayed to learn that the rule CMS finalized is a wholly different test than what was proposed; that is, 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." In AHN's practice, diagnostic tests are not *purchased*, but *provided*, by the group. AHN physicians have ready access to tests they order and the opportunity to interact with technicians if the need arises. The radiologists meet regularly with other doctors in the group to discuss areas of concern. Under the new rule, it would make no difference that AHN is actually *providing* rather than *purchasing* these diagnostic tests. This is problematic because it is clear that Congress did not intend to apply an anti-markup provision to services that are provided rather than purchased. In fact, the statute specifically declines to apply the anti-markup provision when the test is performed by a physician in the practice. Thus, imposing the anti-markup in the case of AHN, as well as other practices throughout the country, is contrary to the statute.

In addition, requiring the test to be performed in the "space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally" is completely impractical, particularly for a large, multi-specialty group such as AHN. It is frequently not workable, nor efficient, to locate all specialties in the same location. Certain specialties, such as obstetricians and surgeons, must practice in or near hospitals. Group practices with such specialists could never provide the full range of services if it includes those services provided in hospitals or other facilities.

With respect to the calculation of the "net charge," the new rule requires that, for a diagnostic test provided in a place other than where a physician group provides substantially the "full range" of its patient care services, the group must treat the test as though it were purchasing the test from an outside supplier and include a "per procedure" charge on the Medicare claim. The practice will then be paid the lesser of the fee schedule amount or its internally generated "charge." CMS indicates in the preamble, however, that the only factor that may be used to determine the per procedure charge for services performed by an employed technician or physician would be the employee's salary. This requirement makes no sense when the tests are not be purchased, but rather provided by the technicians and physician of the practice. Further, CMS is not clear as to how to calculate the charge when the physicians and technicians are not being paid on a per test basis.

CMS notes in the preamble to the final anti-markup regulations that it is concerned with overutilization of tests. Such concerns should be addressed by the Stark self-referral statute and not through anti-markup rules. Nevertheless, CMS has improperly chosen to use the new anti-markup rule

to address self-referral issues. If changes are necessary to meet CMS's concerns regarding self-referrals, then these changes should be made to the Stark regulations, not the anti-markup rules. In essence, the new rule cripples 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 (two exceptions that are found within the Stark statute itself). As a result, AHN—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.

AHN believes that what CMS has done in finalizing the anti-markup rule (1) is contrary to the statute, (2) fails to make the critical and necessary distinction between tests that are *purchased* and tests that are *provided* by physicians, (3) has blindsided the healthcare community by finalizing a rule that was never proposed, and (4) lays waste to the self-referral rules upon which countless physician relationships, including those entered into by AHN, have relied. For these reasons, should this new rule become effective as finalized in the 2008 PFS, there will certainly be a detrimental impact on patient care. AHN therefore requests that CMS either reconsider the implementation of this rule, or hold it in abeyance until further dialogue may be had between the agency and the healthcare community.

Respectfully submitted,



Kristie L. Hill
General Counsel
American Health Network

Copy: Donald H. Romano, Director of Technical Program Payment

Enclosures: Two copies