Submitter : **Dr. Mark Ono** **Date: 09/27/2006**

Organization : **Ironwood Cancer Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1321-P-338-Attach-1.DOC

Attachment
335

September 28, 2006

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

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B

Dear Administrator:

Thank you for allowing me to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 22, 2006. This letter is written to share my concern regarding the proposed reduction in professional fees for radiation/oncology brachytherapy services.

Brachytherapy is considered an important service that must be available to Medicare beneficiaries when clinically appropriate. However with the proposed reductions in RVUs along with the conversion factor reduction, would make it impossible to run a free standing center and offer the full scope of radiation services to Medicare beneficiaries. Brachytherapy is not only an alternative to Breast cancer, but also prostate, gynecological, head and neck, lung, and esophageal cancers. CMS is urged to consider the importance and value of the free standing center and the cost effective efficiencies it can extend to the system especially when compared to the Outpatient Hospital setting. With that said, the preparation and effort to properly create a treatment plan is quite time consuming. In addition, I must reconfirm correct placement before each fraction is given. The proposed reduction to all brachytherapy codes, especially CPT 77781, will not adequately cover the time and involvement required to prepare a patient for brachytherapy. If the reduction does take place, CMS will be limiting access to brachytherapy for Medicare patients.

The CPT 77781 code requires a tremendous amount of staff and physician time and work, not to mention overhead associated with each delivery. For example, both the NRC and our state (rightly so) require that a medical physicist and physician be present for all remote afterloader deliveries. Additionally the source requires frequent (typically quarterly) replacement which is a tremendous expense, recovered solely within the 77781 code. A 74% reduction in 77781 is absolutely unreasonable and will preclude the vast majority of centers, including ours, from offering high dose rate brachytherapy to Medicare beneficiaries.

CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for HDR breast brachytherapy. They are scheduled to reduce by 20% each year in the transition period and the total reduction for this treatment is -55% as illustrated in the table below.

CPT Code	Description	Units	2006 RVU	2006 Average Rate	2010 RVU	Variance 2010 to 2006	Variance 2010 to 2006
99245	office consult, comprehensive	1	5.91	$224	6.25	$1	0%
77263	physician	1	4.41	$167	4.16	($18)	-10%

	treatment planning, complex						
77470	special treatment procedure	1	14.64	$555	4.55	($391)	-71%
76370	CT for planning	1	4.29	$163	5.48	$35	21%
77370	special medical physics consult	1	3.68	$139	2.51	($49)	-35%
77290	simulation, complex (contour volumes)	1	9.02	$342	15.22	$206	60%
77326	Brachytherapy isodose plan	1	3.78	$143	3.89	($3)	-2%
77300	dose calc	10	2.26	$856	1.80	($209)	-24%
77336	weekly medical physics consult	1	3.15	$119	1.08	($81)	-67%
77280	simulation, simple	5	4.62	$875	5.27	$72	8%
77781	Afterloading HDR brachy (1-4 source positions)	10	23.69	$8,978	6.58	($6,611)	-74%
						($7,049)	***-56%***

NOTE: 2006 CF is $37.8975 with assumption for 2010 using proposed CF of $35.9647; applicable to Physician Fees

The alternative radiation treatment is Whole Breast External Beam Radiation Therapy where women must endure 6 weeks of radiation. Alternatively, the RVUs for a course of External Beam will increase by 55% or $6,000 during the transition period and will be reimbursed at a proposed rate of more than $9,000 than HDR Breast Brachytherapy. This treatment is extremely beneficial for the patient in that it irradiates less healthy tissue and allows them to return back to their life activities in just five days, however, HDR breast brachytherapy does require more time for the radiation oncologist to plan, calculate and treat with HDR breast brachytherapy. These proposed cuts in RVUs are insufficient to cover the cost and time required to administer HDR breast brachytherapy and will result in limiting access to this radiation treatment for women who are Medicare beneficiaries. Comparatively, equal or more work is involved for a patient treated with brachytherapy when compared to an entire course with External Beam Radiation and each should be given at least equal RVU weight.

My recommendation is that CMS reconsider the proposed RVU reduction for brachytherapy. Please consider an increase in the brachytherapy codes, or if needed at most, make a reduction to the conversion factor. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Mark Ono, MD

Mark Ono, MD
Radiation Oncologist
Ironwood Cancer and Research Center
695 S Dobson Rd
Chandler, AZ 85224

cc: Senator John Kyl, AZ, (R)

cc: Carolyn Mullen, Deputy Director,
Division of Practitioner Services

cc: American Society of Therapeutic Radiation and Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

Submitter : Dr. Charles Woo **Date:** 09/27/2006

Organization : Ironwood Cancer Research Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1321-P-339-Attach-1.DOC

Attach
339

September 28, 2006

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

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B

Dear Administrator:

Thank you for allowing me to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 22, 2006. This letter is written to share my concern regarding the proposed reduction in professional fees for radiation/oncology brachytherapy services.

Brachytherapy is considered an important service that must be available to Medicare beneficiaries when clinically appropriate. However with the proposed reductions in RVUs along with the conversion factor reduction, would make it impossible to run a free standing center and offer the full scope of radiation services to Medicare beneficiaries. Brachytherapy is not only an alternative to Breast cancer, but also prostate, gynecological, head and neck, lung, and esophageal cancers. CMS is urged to consider the importance and value of the free standing center and the cost effective efficiencies it can extend to the system especially when compared to the Outpatient Hospital setting. With that said, the preparation and effort to properly create a treatment plan is quite time consuming. In addition, I must reconfirm correct placement before each fraction is given. The proposed reduction to all brachytherapy codes, especially CPT 77781, will not adequately cover the time and involvement required to prepare a patient for brachytherapy. If the reduction does take place, CMS will be limiting access to brachytherapy for Medicare patients.

The CPT 77781 code requires a tremendous amount of staff and physician time and work, not to mention overhead associated with each delivery. For example, both the NRC and our state (rightly so) require that a medical physicist and physician be present for all remote afterloader deliveries. Additionally the source requires frequent (typically quarterly) replacement which is a tremendous expense, recovered solely within the 77781 code. A 74% reduction in 77781 is absolutely unreasonable and will preclude the vast majority of centers, including ours, from offering high dose rate brachytherapy to Medicare beneficiaries.

CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for HDR breast brachytherapy. They are scheduled to reduce by 20% each year in the transition period and the total reduction for this treatment is -55% as illustrated in the table below.

CPT Code	Description	Units	2006 RVU	2006 Average Rate	2010 RVU	Variance 2010 to 2006	Variance 2010 to 2006
99245	office consult, comprehensive	1	5.91	$224	6.25	$1	0%
77263	physician	1	4.41	$167	4.16	($18)	-10%

	treatment planning, complex						
77470	special treatment procedure	1	14.64	$555	4.55	($391)	-71%
76370	CT for planning	1	4.29	$163	5.48	$35	21%
77370	special medical physics consult	1	3.68	$139	2.51	($49)	-35%
77290	simulation, complex (contour volumes)	1	9.02	$342	15.22	$206	60%
77326	Brachytherapy isodose plan	1	3.78	$143	3.89	($3)	-2%
77300	dose calc	10	2.26	$856	1.80	($209)	-24%
77336	weekly medical physics consult	1	3.15	$119	1.08	($81)	-67%
77280	simulation, simple	5	4.62	$875	5.27	$72	8%
77781	Afterloading HDR brachy (1-4 source positions)	10	23.69	$8,978	6.58	($6,611)	-74%
						($7,049)	***-56%***

NOTE: 2006 CF is $37.8975 with assumption for 2010 using proposed CF of $35.9647; applicable to Physician Fees

The alternative radiation treatment is Whole Breast External Beam Radiation Therapy where women must endure 6 weeks of radiation. Alternatively, the RVUs for a course of External Beam will increase by 55% or $6,000 during the transition period and will be reimbursed at a proposed rate of more than $9,000 than HDR Breast Brachytherapy. This treatment is extremely beneficial for the patient in that it irradiates less healthy tissue and allows them to return back to their life activities in just five days, however, HDR breast brachytherapy does require more time for the radiation oncologist to plan, calculate and treat with HDR breast brachytherapy. These proposed cuts in RVUs are insufficient to cover the cost and time required to administer HDR breast brachytherapy and will result in limiting access to this radiation treatment for women who are Medicare beneficiaries. Comparatively, equal or more work is involved for a patient treated with brachytherapy when compared to an entire course with External Beam Radiation and each should be given at least equal RVU weight.

My recommendation is that CMS reconsider the proposed RVU reduction for brachytherapy. Please consider an increase in the brachytherapy codes, or if needed at most, make a reduction to the conversion factor. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Charles Woo, MD

Charles Woo, MD
Radiation Oncologist
Ironwood Cancer and Research Center
695 S Dobson Rd
Chandler, AZ 85224

cc: Senator John Kyl, AZ, (R)

cc: Carolyn Mullen, Deputy Director,
Division of Practitioner Services

cc: American Society of Therapeutic Radiation and Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

Submitter : Dr. Doug Widman **Date:** 09/27/2006

Organization : Dr. Doug Widman

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-340-Attach-1.DOC

HHachff
340

September 13, 2006

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

RE: CMS-1321-P; Physician Fee Schedule

Dear Administrator:

I am writing to express my concern regarding the proposed reduction in professional fees for radiation brachytherapy services. Thank you for this opportunity to comment on The Centers for Medicare and Medicaid Services' proposed rule, as published in the Federal Register on August 23, 2006.

The proposed reduction to the work RVU's will significantly impact my ability to offer the most appropriate treatment options to my Medicare patients. Brachytherapy is an important treatment option for my breast cancer patients in that it allows the radiation process to move very quickly so that other treatments (chemotherapy) may be initiated as well. The changes proposed may affect my ability to offer this treatment option to my Medicare patients. The preparation and effort to properly create a treatment plan is quite time consuming. Additionally, I must reconfirm correct catheter placement before each fraction is given. The proposed reduction to all brachytherapy codes, especially CPT 77781, will not adequately cover the time and involvement required to prepare a patient for brachytherapy. If the reduction does take place, CMS will be limiting access to brachytherapy for Medicare patients even though those patients may meet the patient selection criteria.

As a physician focused on breast cancer treatment, I urge CMS to reconsider the proposed Work RVU reduction for brachytherapy. Please leave brachytherapy codes as is so that I can continue to offer this choice to my patients as appropriate. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Doug W. Widman, MD

Doug W. Widman, MD
495 Cooper Road, Ste 120
Westerville, OH 43081

cc. Senator Mike DeWine, Senate Appropriations Labor-HHS Subcommittee and Senate Health, Education, Labor and Pensions Committee
Carolyn Mullen, Deputy Director, Division of Practitioner Services
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

Submitter : **Dr. James Satterfield** **Date: 09/27/2006**

Organization : **Dr. James Satterfield**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-341-Attach-1.DOC

Attachment
341

September 23, 2006

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

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 22, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296, performed in-office, over the next few years.

The proposed reduction of the conversion factor by 5.1%,which I am aware is tied to the cost of living, in conjunction with an RVU decrease will negatively impact medicare beneficiaries.

Access to partial breast irradiation (PBI) is crucial for many patients. With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. PBI allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction takes place, I may no longer be able to provide PBI to my Medicare patients; therefore limiting access to treatments for this deadly disease. As a result, my Medicare patients may be required to have services scheduled at the hospital which will add a greater cost to the Medicare system, as well as impede quick access and scheduling for patients with a confirmed diagnosis of breast cancer.

I am a practitioner focusing on breast cancer treatment, I strongly urge CMS to reconsider the proposed RVU reductions. I recommend preserving RVUs system , and if needed, make reductions to the conversion factor. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact of the proposal.

Sincerely,

James E. Satterfield, MD FACS
86-90 188 Street
Hollis, NY 11423

CC Senator Hillary Clinton, Senate Health, Education, Labor and Pensions Committee

Submitter : **Dr. Beth Seiling** **Date: 09/27/2006**

Organization : **he Breast Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-342-Attach-1.DOC

Attachment
342

September 25, 2006

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

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 22, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296, performed in-office, over the next few years.

The proposed reduction of the conversion factor by 5.1%,which I am aware is tied to the cost of living, in conjunction with an RVU decrease will negatively impact medicare beneficiaries.

Access to partial breast irradiation (PBI) is crucial for my patient population. With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. PBI allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction takes place, I may no longer be able to provide PBI to my Medicare patients; therefore limiting access to treatments for this deadly disease. As a result, my Medicare patients may be required to have services scheduled at the hospital which will add a greater cost to the Medicare system, as well as impede quick access and scheduling for patients with a confirmed diagnosis of breast cancer.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reductions. I recommend preserving RVUs system , and if needed, make reductions to the conversion factor. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact of the proposal.

Sincerely,

Beth Seiling MD
900 Main St Suite 101
Southbury, Ct 06488

CC Senator Chris Dodd, Senate Health, Education, Labor Committee
Representative Rosa DeLauro, Appropriations Labor-HHS Subcommittee
Representative Nancy Johnson, Chair,Ways and Means Health Subcommittee
Representative Christopher Shays

Submitter : Mr. Thomas Bruno **Date:** 09/28/2006

Organization : Carmel Richmond Healthcare & Rehabilitation Center

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-343-Attach-1.TXT

Attachment
343

Carmel Richmond Healthcare & Rehabilitation Center
88 Old Town Road
Staten Island, NY 10304

September 28, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: Federal Register, August 22, 2006
Proposed Rules for Blood Glucose Testing

Dear Sir:

I believe the proposed rule for blood glucose testing does not meet the spirit and intent of the Medicare program. The proposed regulation is unduly restrictive and contrary to the Act, the governing regulations, inconsistent with Medicare's National Coverage Decision (PM-AB-02-110) and contrary to standards of medical practice.

The NCD (PM-AB-02-110) recognizes that blood glucose testing is necessary for patients with diabetes and other defined medical conditions. The NCD specifically states that testing "using a device approved for home monitoring or by using a laboratory assay system using serum or plasma" is covered. It is also clear that this coverage determination encourages use of devices for home monitoring. The NCD goes on to say that the "convenience of the meter or stick color method allows a patient to have access to blood glucose values in less than a minute or so and has become a standard of care for control of blood glucose, even in the inpatient setting. The NCD does not place any specific limitations on the frequency of testing. In fact the NCD simply states that "frequent home blood glucose testing by diabetic patients should be encouraged".

CFR 410.32(a) requires that in order for a diagnostic test to be considered reasonable and necessary it must be ordered by a physician and the ordering physician must use the result in the management of the beneficiary's specific medical problem. In the case of an SNF, a physician orders blood glucose testing usually based on a sliding scale for a month at a time. These are explicit instructions to the attending RN to provide X amount of insulin for Y reading with instructions for immediate physician contact on

outlier readings (unreasonably high or low readings). The physician reviews the results of these tests on his monthly visit, considering changes in patient's diet, change of medications that may affect glucose levels, physical or cognitive issues etc. The physician either modifies or renews his testing and insulin orders as a result of his review of the test results achieved. Thus it is quite clear that the physician utilizes these results in the patient's plan of care. It is ludicrous to expect a physician to be contacted several times a day to transmit test results and it is certainly contrary to current standards of medical practice.

CMS Pub 100-8 Chapter 13.5.1 states that in pertinent part that a service is considered reasonable and necessary when "furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition", is "ordered and furnished by qualified personnel" and "meets, but does not exceed, the patient's medical need". In an SNF, the accepted standard of medical practice is for the physician to order these glucose tests to treat the patient. Orders are executed by an RN qualified to administer the test, read the results and act on the physician's order to dispense insulin. These procedures are the "accepted standard of medical practice" today. For this proposed regulation to summarily state that a physician's standing order will not be acceptable as reasonable and necessary clearly violates Pub 100-8 Chapter 13.5.1.

It is interesting to note that CMS does not apply the above standard uniformly throughout all the covered services paid by Medicare. For example, enteral services are paid under Medicare Part B. The doctor executes a Certificate of Medical Necessity (CMN) for a patient under his care that is in effect for as long as the patient remains on that service. The doctor is not required to constantly update this order. It is a standard medical practice to continue an order for a required service until such time as the service needs to be changed or terminated. Enternal services are required to keep the patient alive. Blood glucose services are needed to ensure that a patient does not go into diabetic shock. Both services are administered by nursing staff authorized and trained to do so. Both are required services to ensure the health and safety of the patient. Yet blood glucose has an unrealistic physician notification requirement.

The proposed regulations are also referring to doctor ordered blood glucose testing as "routine blood glucose monitoring." PRM I section 2203.1 and 2203.2 define routine and ancillary services respectively. The doctor ordered blood glucose test does not meet the definition of "routine" services. Routine services are defined as services routinely furnished to ALL patients such as room, dietary, medical social services, general nursing, general supplies and equipment that is reusable and expected to be available in an SNF. While the definition of an ancillary service found in section 2203.2 are services directly identifiable to a patient, NOT generally furnished to most patients, are not reusable and represent a cost for each application. A blood glucose test meets ALL of these criteria in addition to being doctor ordered for the patient's specific medical need. The classification of these ancillary tests as "routine blood glucose monitoring" is erroneous and not consistent with Medicare regulations.

For the reasons cited above, I respectfully request that CMS modify the proposed regulation to conform to the cited authorities and accepted standards of medical practice prevalent in the medical community today. To deny an SNF from availing itself of state of the art medical technologies and techniques to care for their residents in favor of a restrictive, not realistic, draconian approach to patient care effectively shifts the cost of practicing good patient care to the SNF. Instead CMS should be issuing instructions to their FIs through regulatory changes and updates to conform to the aforementioned NCD developed under the authority of the Negotiated Rulemaking Act.

Respectfully yours,

Thomas F. Bruno
Vice President/Assistant Administrator

Submitter : **Mr. Aaron Montrose** **Date: 09/28/2006**

Organization : **Mr. Aaron Montrose**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-344-Attach-1.DOC

Attach
344

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

BACKGROUND

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

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

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

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

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

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

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

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

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

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

COMMENT

CMS' proposed rule regarding Blood Glucose Testing (Monitoring) in a skilled nursing facility (SNF) published in the August 22, 2006 Federal Register (page 49065) is contrary to current medical practice and is not required by law or current regulation. The proposed regulation requires that all Medicare Part B diabetic residents of a SNF must have their treating physician issue a separate physician order and a separate physician certification for each blood glucose test performed while they are a resident of a SNF.

This proposed rule attempts to codify a CMS 2000 instruction issued to Medicare contractors that has been superseded by the Congressionally mandated Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests' (Committee) National Coverage Determination (NCD) and Administrative Policies pursuant to Section 4554(b) of the Balanced Budget Act of 1997 (BBA-1997). The treating physician currently already certifies that the services for each diabetic SNF resident are medically necessary through the overall review and approval of each beneficiary's Resident Assessment Instrument (RAI) and the resulting individualized resident care plan. Each resident's overall care plan is reviewed and revised no less often than once every

three (3) months. Additionally, the physician reviews the results of the resident's testing at least on a monthly basis (more frequently if needed). At this time the physician will either renew the order to continue the periodic testing of the resident's blood glucose levels on a predetermined schedule or change the order for the frequency of the blood glucose testing service. Accordingly, this proposed rule is both illegal and statutorily prohibited and therefore must be withdrawn.

Submitted by:

Aaron Montrose

September 28, 2006

Submitter : **Dr. JOe Doe** **Date: 09/28/2006**

Organization : **Healthcare**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Mr. Richard Nee **Date:** 09/28/2006

Organization : RMS Lifeline

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Mr. Aaron Montrose **Date:** 09/28/2006

Organization : Mr. Aaron Montrose

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1321-P-347-Attach-1.DOC

Attachment
347

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

BACKGROUND

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

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

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

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

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

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

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

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

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

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

COMMENT

CMS' issuance of Program Memorandums AB-00-099 and AB-00-108 which included the additional requirement that the test result be communicated to the treating physician before the next test was clearly issued in bad faith. The asserted but unsupported provisions contained in these instructional memorandums were in direct conflict or violation of the Final Agreement entered into by CMS (formerly known as HCFA) as a participating member of the Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests pursuant to the proposed rule published in the Federal Register on March 10, 2000. This alleged **"implicit"** requirement stated therein PM AB-00-108 is not included in 42 CFR 410.32(a). The treating physician reviews the results on a monthly basis upon his visit of the Medicare Part B beneficiary (more frequently, if needed). The treating physician specifies a range of expected test report values and specifically directs the facility to contact the physician's office if any test result falls outside of the range. A multitude of recent ALJ decisions have clearly discarded the consideration of unsupported as evidenced by over 50 Fully Favorable ALJ decisions on this issue (service).

The tests provided to a Medicare Part B beneficiary are clearly payable in accordance with 42 CFR 410.32(d)(vii). Accordingly, the proposed rule of the treating physician being contacted and physician certification for each test is clearly unlawful and in violation of the prohibition by federal employees from affecting the practice of medicine as contained in Section 1801 of the Social Security Act. Therefore, the proposed rule and accompanying proposed CFR Section 42 CFR 424.24(f) must be withdrawn.

Submitted by:

Aaron Montrose

September 28, 2006

Submitter : Mr. Aaron Montrose **Date:** 09/28/2006

Organization : Mr. Aaron Montrose

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1321-P-348-Attach-1.DOC

Attach # 348

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

BACKGROUND

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

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

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

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

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

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

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

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

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

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

COMMENT

CMS, in its proposed rule entitled *Blood Glucose Monitoring in SNFs* published in the Federal Register on August 22, 2006 page 49065, makes reference to its long standing policy. CMS' policy was initially developed in 2000; however, is statutorily prohibited from being in existence as of the publication date of the Congressionally mandated Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests' Final Rule published in the Federal Register on November 23, 2001. This federal register publication contained uniform Administrative Policies and a National Coverage Determination (NCD) for Blood Glucose Testing. This NCD and Administrative Policies supersede all prior policies whether issued by CMS or its contractors pursuant to Section 4554(b) of the BBA-1997.

Therefore, the proposed rule which singles out a SNF is discriminatory and in violation of the Committee's Administrative Policies. Specifically on page 58806 of the Federal Register dated November 23, 2001, CMS published a clarification that states "the administrative policies discussed in the preamble to the March 10, 2000 Committee's proposed rule and the (blood glucose testing) NCD in the Addendum to the March 10, 2000 proposed rule apply equally to all settings (hospital and non-hospital)."

Therefore, because such a rule is discriminatory and violates the Committee's Administrative Policies as clarified by CMS, CMS must withdraw this proposed rule from any further consideration or implementation.

Submitted by:

Aaron Montrose

September 28, 2006