Submitter : **Date: 09/28/2006**

Organization :

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

Reassignment of benefits rule is a great idea for radiology except for Nighthawk. Rural areas would greatly suffer if Nighthawk was not exempt from this reassignment rule. This new rule would stop the non-radiologists from entering the Outpatient Radiology field and would definitely put an end to self-referral. Self-referral is killing the system, end of story. The amount of orthopods and other specialists entering the radiology field is incredible. The STARK ancillary services carve-out is being abused daily. You used to get an x-ray for a sore knee, now it is right to the MRI/CT and get that extra bang for your pocket. It is disgusting. CMS needs to pass 'that the test be ordered by a physician that is financially independent of the person or entity performing the test and also of the physician performing that interpretation'. This aims at the heart of self-referral, radiologists don't order tests, specialists do, and what they are doing is sending to themselves. I commend CMS for taking these steps ASAP. CMS needs to ensure that they police these policies as well. These new rules would decrease the utilization immediately because there would be no financial incentive to refer to an outside entity to perform these radiology studies. The only reason to send for tests under the new proposed rules would be for the welfare of their patients, not their own pockets. If specialists want to become owners of diagnostic equipment, let them go back to school and retrain and then compete for the business based on expertise and service parameters.

I am sure most of the opposition will be from people who can self-refer, not the people that can't, I guarantee. Plus equipment manufacturers and other suppliers will put up people who say these rules will be ineffective, again, they can't sell as much inventory as in the past if you take away a segment that will not need to buy these items anymore. I hope CMS follows thru, these changes will save billions!!!!!

Submitter : **Mr. Angelo Vacirca** **Date: 09/28/2006**

Organization : **Tristate Imaging Consultants, LLC**

Category : **Other Health Care Provider**

Issue Areas/Comments

Background

Background

The 5.1% reduction will hurt the physician community, as there are ever increasing costs that are not currently considered by this reduction.

GENERAL

GENERAL

I think its about time CMS start to enforce the regulatoins in place. There is way too much going on with referrals to a center in which the dr has a financial interest. I think it would be prudent for CMS to focus more on the quality of the care for the patient. The proposed changes only make for health care professionals to now decide whether its prudent to practice medicine with little or no fair compensation.
The higher costs are directly related to many facets of healthcare that are not regulated by CMS. As an example, I offer the Insurance carriers. We just rec'd notice that our Healthcare premiums are increasing 22% for our employees and have no means to recoup these costs, and now CMS wants to reduce the reimbursemnet by 5.1%.

Another area of concern is the high cost of pharmacy drugs, which also have no regulation on their pricing to the public.

I would highly recommend that Congress and CMS take a hard look at all the issues before considering a reduction of this magnitude.

I would be more than happy to dicusss this issue with anyone or even tetsify before CMS or any committee of Congress, as I fell the enitre issue is not being represented fairly, so that a Congressinal body can be well informed on what occurs in the Health care environmet.

Respectfully submitted,

Angelo M. Vacirca, CPAM
Executive Vice-President

Submitter : **Dr. Nancy Murphy** **Date: 09/28/2006**

Organization : **Dr. Nancy Murphy**

Category : **Other Health Care Provider**

Issue Areas/Comments

Background

Background

The proposed cuts for Bone Density Measurement,DEXA, from approximately $140 to $40 would make it impossible for my practice to continue to offer this service to my patients. My cost for paying a certified technician plus the cost of the equipment would be much greater than my reimbursement from Medicare. I am a rheumatologist and the majority of my patients are Medicare patients who are at risk for osteoporosis. As you know, monitoring these patients for osteoporosis and treating them for osteoporosis is much less expensive than treating the fractures which they will inevitably have if not treated. It is in the best interest of these patients to have access to this test at a cost which allows me to continue to offer them.

GENERAL

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Submitter : **Mr. Aaron Montrose** **Date: 09/29/2006**

Organization : **Mr. Aaron Montrose**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1321-P-352-Attach-1.DOC

Attach
352

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.

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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, has clearly distorted the requirements of Section 1862(a)(1)(A) and 42 CFR 410.32 through its failure to understand the standard medical practice and the specificity of the treating physician's order for multiple/repeat of blood glucose testing. Generally, a treating physician's order for blood glucose testing states either the specific day or the specific time during the day for the facility to perform the blood glucose test. The treating physician order further specifies an acceptable range of a result for each test which is deemed as acceptable and which no actual phone contact is necessary; however, the testing is to be continued. The treating physician also generally specifies that a result outside the specified range (whether high or low) would require that the treating physician be contacted by phone and a determination is made by the treating physician for either a change in the treatment or scheduled testing should continue. As a

result, the treating physician is continually aware of the patient's overall condition based on the conduct of the SNF nursing staff.

Additionally, we believe that CMS' proposed rule constitutes a violation (prohibition) of Section 1801 of the Social Security Act.

CMS' proposed rule, *Blood Glucose Monitoring in SNFs* is clearly illogical and discriminatory and therefore, must be withdrawn.

Submitted by:

Aaron Montrose

September 28, 2006

Submitter : Mr. Aaron Montrose **Date:** 09/29/2006

Organization : Mr. Aaron Montrose

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attached

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Attachment
353

Reference File Code CMS-1321-P
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New Outpatient Clinical Diagnostic Laboratory Tests
Subsection (3) Other Laboratory Tests
Provision (b) Blood Glucose Monitoring in SNFs

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

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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 Program Memorandums AB-00-099 and AB-00-108 confirms that the Department of Health and Human Services has issued a compliance program guidance for laboratory service and sets forth conditions under which a physician's order for a repeat laboratory service can quality as an order for another laboratory service.

Notwithstanding the disagreement of whether a physician's order for repeat testing on a monthly basis constitutes a "standing order", Section #4 on page 14 of the HHS Compliance Manual states that laboratory compliance programs **may** permit the use of standing orders executed in connection with an extending course of treatment; however, HHS recommends that standing orders should be periodically monitored. Further, HHS recommends that the periodic review should occur at least annually...and a Medicare facility should confirm the continued validity of all existing standing orders at that time.

Because a physician order for repeat testing is clearly provided for (allowed) and Medicare has provided the coding numbers for same tests provided to a Medicare beneficiary on the same day (i.e. modified 91) the assertions made within the proposed rule exclusively for SNFs are clearly discriminatory and the proposed rule must be withdrawn.

Submitted by:

Aaron Montrose

September 28, 2006

Submitter : Mr. Aaron Montrose **Date:** 09/29/2006

Organization : Mr. Aaron Montrose

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

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COMMENT

CMS, in its proposed rule entitled *Blood Glucose Monitoring in SNFs* published in the Federal Register on August 22, 2006 page 49065, appears to have confused the terms Blood Glucose Testing (NCD) which represents the performance of blood glucose testing by a SNF participating provider (facility service) versus the Blood Glucose Monitoring which is a physician service.

These two terms are distinctly different and separate as the facility is entitled to payment for performing the blood glucose laboratory test. The physician's monitoring (which is defined as a periodic review of systematically planned test results) is separately paid to the physician as part of his evaluation and management component of his visit.

Blood Glucose testing (the facility service) is subject to coverage and payment in accordance with the Congressionally mandated NCD and Administrative (payment)

policies. Since this proposed rule directly conflicts with the binding NCD and Administrative Policies, the proposed rule must be withdrawn.

Submitted by:

Aaron Montrose

September 28, 2006

Submitter : **Mr. Aaron Montrose** **Date: 09/29/2006**

Organization : **Mr. Aaron Montrose**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

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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 a standing order. A standing order is generally associated with a non-patient specific order that applies to a group of the physician's patients. (See Journal of the American Medical Association, Vol. 292, No. 19, November 17, 2004) A similar example, as provided by CMS on their website, relates to the provision of flu shots to physician's patients who are residents of a SNF. These types of orders (standing orders) are not utilized for blood glucose testing in a SNF.

A physician does utilize an order for repeat testing of blood glucose (not a standing order) where the SNF Medicare Part B beneficiary is diagnosed as a "diabetic" and therefore has a continued risk of hypoglycemia or hyperglycemia. For a patient specific physician ordered blood glucose testing service, the treating physician reviews and approves the individual's plan of care subsequent to the resident's admission to the SNF. This plan of care, which specifies services, serves as the treating physician's certification of the services as needed over the short term (3

month period). This plan of care is provided to the Medicare program at least every 90 days or more frequently where there is a significant change in patient's condition.

Therefore, the CMS proposed rule and accompanying revision to 42 CFR 424.24(f) is statutorily prohibited by the provisions of the Balanced Budget Act of 1997 Section 4554(b). Accordingly, the CMS proposed rule, *Blood Glucose Monitoring in SNFs,* as well as the proposed change to 42 CFR 424.24(f) must be withdrawn.

Submitted by:

Aaron Montrose

September 28, 2006

Submitter : **Mr. Aaron Montrose** **Date: 09/29/2006**

Organization : **Mr. Aaron Montrose**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-356-Attach-1.DOC

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

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CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)
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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 makes reference to the word "routine" blood glucose monitoring. Blood glucose monitoring (physician performed service) is based on the test results performed by the SNF in accordance with the Treating Physician order issued or reviewed on a monthly basis. As specified in CMS' own publication (PM-AB-00-099 and PM-AB-00-108) CMS has clearly dictated that **"Denial of payment for a Part B covered laboratory service cannot be made on the basis that the service is routine care. Under Medicare, routine care determinations are applicable only for Part A nursing home services."**

Therefore CMS' proposal, including its amending of 42 CFR 424.24(f) relative to an order for routine blood glucose monitoring as not a covered service, is totally inappropriate and inaccurate and the proposed rule must be withdrawn.

Submitted by:

Aaron Montrose

September 28, 2006

Submitter : **Mr. Aaron Montrose** **Date: 09/29/2006**

Organization : **Mr. Aaron Montrose**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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Attachment
357

Reference File Code CMS-1321-P
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CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)
AUGUST 22, 2006 PUBLICATION OF PROPOSED RULE
BLOOD GLUCOSE MONITORING IN SNFs

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

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

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

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

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

COMMENT

In CMS' issuance of its proposed rule entitled *Blood Glucose Monitoring in SNFs* published in the Federal Register on August 22, 2006 page 49065, CMS asserts that the content of its Manual as contained in the Medicare Claims Manual Publication 100-04 Chapter 7 Section 90.1 is valid support for its proposed policy change. This Manual provision was issued initially on October 1, 2003 as part of a revision of a new manual references its basis as CMS Program Memorandum AB-00-108. However, the content of Section 90.1 is clearly contradictory to the provisions contained in PM-AB-00-108. Section 90.1 states that blood glucose monitoring is never covered in a skilled nursing facility whether provided under Medicare Part A or Part B.

This provision is clearly contrary to the Committee's National Coverage Determination for Blood Glucose Testing and its Administrative Policies.

Accordingly, CMS' arbitrary development of additional statutorily prohibited rules and instructions are now being officered to support and serve as the basis for the completely ridiculous provision in its proposed rule for blood glucose monitoring in a SNF (Federal

Register, August 22, 2006 at page 49065) and its related proposed modification to the Code of Federal Regulations 42 CFR 424.24(f) (see Federal Register, August 22, 2006 page 49084) must be withdrawn.

Submitted by:

Aaron Montrose

September 28, 2006

Submitter : Dr. Paul Radensky

Date: 09/29/2006

Organization : Prothrombin-time Self Testing Coalition

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-358-Attach-1.PDF

Hearing
358

September 29, 2006

Via electronic submission at http://www.cms.hhs.gov/eRulemaking
Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

RE: 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; Proposed Rule
Payment for home PT/INR monitoring (codes G0248, G0249, and G0250)

Dear Dr. McClellan.

On behalf of the Prothrombin-time Self Testing (PST) Coalition comprising HemoSense, Inc., International Technidyne Corporation and Roche Diagnostics Corporation, we are pleased to submit comments on the above-captioned Proposed Rule regarding Prothrombin Time (PT)/International Normalized Ratio (INR) home monitoring for anticoagulation management. Our comments in response to the Proposed Rule are substantially the same as those submitted on August 16, 2006 in response to the parallel Proposed Notice, entitled: "Medicare Program; Five -Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology" [CMS-1512-PN].[1]

The PST Companies are medical device manufacturers who have developed the technologies used in home PT/INR monitoring. Our companies have put significant resources into the clinical development of these technologies, which have been shown to reduce the incidence of serious adverse events (strokes and bleeding) among patients requiring anticoagulation with warfarin.

We appreciate Medicare's having provided coverage for home PT/INR monitoring beginning July 2002, and we were pleased to see clarifications on billing for these services published in several Program Transmittals and codified in the Medicare Claims Processing Manual, Chapter 32, Section 60. Medicare's allowed payments for home PT/INR monitoring under the Physician Fee Schedule in 2006 are adequate to cover physician and Independent Diagnostic Testing Facility (IDTF) costs for furnishing home PT/INR monitoring equipment, supplies, clinical staff support and physician interpretation and reporting of results.

By contrast, the Proposed Rule would result in reductions in payments for the training and technical component services of home PT/INR monitoring by approximately 40 to 50-percent over the next 4 years (codes G0248 and G0249). These reductions, if implemented, would result in payments well below physician and IDTF costs for furnishing home PT/INR monitoring and would likely shut down access to home PT/INR monitoring for Medicare beneficiaries. It appears the reductions are caused by application of the new practice expense methodology without considering that the current practice expense relative values for G0248 and G0249 were developed by CMS staff as an exception to the current practice expense methodology. Maintaining the "hard coded" practice expense values would assure fair payment for home PT/INR monitoring services and continued access to the technology for Medicare beneficiaries.

[1] 71 Fed Reg. 37170 (June 29, 2006).

I. Coding and Practice Expense Inputs for Home PT/INR Monitoring

Home PT/INR monitoring involves the furnishing, by a physician or IDTF, of a PT/INR monitor (a prothrombin time test meter), test strips to run in the monitor, lancets for collecting blood samples, and alcohol swabs for preparing the skin for the self-testing of prothrombin time by patients or their caregivers at home (or otherwise outside the physician's office setting) on a weekly basis[2] Home PT/INR monitoring is reported under the following three HCPCS codes to include the technical component service described above as well as an initial training session and physician review and interpretation of the test results:

Code	Descriptor	Equipment*	Supplies*	Clinical staff*
G0248	Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstrating use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing	Home INR monitor (50 min use)	INR test strips (4); lancets (4); batteries (3); alcohol swab pads (4); patient education booklet	RN/LPN/MTA (75 min total)
G0249	Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; per 4 tests	Home INR monitor (20 min use)	INR test strips (4); lancets (4); alcohol swab pads (4)	RN/LPN/MTA (13 min total)
G0250	Physician review, interpretation and patient management of home INR testing for a patient with mechanical heart valve(s) who meets other coverage criteria; per 4 tests (does not require face-to-face service)	None	None	Zero labor

* From the 2006 Final Rule Practice Expense Inputs.mdb

[2] The coverage policy limits coverage to testing no more than once per-week. The 4-test payment units under codes G0249 and G0250 may reflect weekly testing over a 4 week period or less frequent testing over a longer period.

II. Concern about the Practice Expense Relative Values in the Proposed Rule

Home PT/INR monitoring is an unusual service under the Physician Fee Schedule because it involves the furnishing of equipment and supplies by physicians or IDTFs for use by patients in their homes. Each PT/INR monitor is dedicated for use by one patient only. Therefore, although the practice expense input files show the monitor to be in use for only 20 minutes for each 4-test payment unit under code G0249, the monitors are effectively in use continuously by each patient. CMS staff recognized this when the practice expense relative values for home PT/INR monitoring were initially developed. The staff acknowledged that the "standard" model for assigning per-minute input costs for equipment should not be used for home PT/INR monitoring. The practice expense equipment model assumes that equipment can be used by multiple patients for up to 25 hours per-week. This assumption does not apply to home PT/INR monitoring. Therefore, staff did not apply the standard practice expense model, but rather, applied the equipment costs by considering a straight line amortization over the useful life of the meter.[3]

We are concerned that this exception to the standard practice expense input cost model was not recognized when the values were established for the Proposed Rule. Unless this exception is "hard coded" into the system and maintained with the proposed changes in the practice expense methodology, payments for home PT/INR monitoring will be cut in half, which will significantly limit access to this important technology.

When we met with staff from the Hospital and Ambulatory Policy Group in 2002 following the release of the coverage decision memorandum and prior to release of the implementing instructions, we expressed serious concern about access to home PT/INR monitoring by Medicare beneficiaries if the benefit were structured as a physician or diagnostic testing service paid under the Physician Fee Schedule. CMS staff assured us that they would monitor access to this new technology and would make changes to the payment policies to assure appropriate patient access. Current levels of payment under the Physician Fee Schedule appear adequate to support access to this technology. The practice expense values in the Proposed Rule, however, would result in payments that likely would shut down access to this service by Medicare beneficiaries.

III. Recommendation

Therefore, we urge CMS to maintain the current practice expenses for home PT/INR monitoring under codes G0248 and G0249 consistent with the values that were "hard coded" into the payment system since late 2002.[4]

* * * *

[3] Through 2004, the equipment was assigned a price of $2,000 and a useful life of 4 years. In the 2005 and 2006 practice expense input databases, the equipment was assigned a price of $2,000 and a useful life of 5 years.
[4] We would note that the payments for the professional service fee for review and interpretation of the PT/INR results (code G0250) do not include direct practice expenses and so are not negatively affected by the proposed change in practice expense methodology.

We appreciate the opportunity to comment on this Proposed Rule. Please contact our reimbursement counsel, Paul Radensky, M.D., J.D., at 305.347.6557 or by e-mail at pradensky@mwe.com if you have any questions about our comments or would like to discuss these further. Thank you for your consideration of our comments.

Sincerely,

/s/ Larry Cohen

Larry Cohen
President
International Technidyne Corporation

/s/ David Phillips

David Phillips
Vice President, Marketing
HemoSense, Inc.

/s/ John Ridge

John Ridge
Director, Reimbursement Affairs
Roche Diagnostics Corporation

Cc: Denise Garris, American College of Cardiology
Paul Radensky, M.D., J.D., McDermott, Will & Emery LLP

Submitter : **Mr. Aaron Montrose** **Date: 09/29/2006**

Organization : **Mr. Aaron Montrose**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-359-Attach-1.DOC

Attach
359

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)

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(monitoring). The issuance of these two instructions were the initial publications issued by CMS to its Medicare contractors.

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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, is intentionally aggressively furthering an admitted and fully documented conspiracy by both past and present CMS employees in order not to pay SNFs for blood glucose testing. Documentation of such conspired actions is fully documented in the attached documents. Since this proposed rule is purely offered in bad practice and for the sole purpose of refusing to pay Medicare benefits for beneficiaries who are afflicted with the diabetes illness and who have paid for such benefits, CMS must take immediate action and start by withdrawing this proposed rule.

Submitted by:

Aaron Montrose

September 28, 2006

Submitter : Mr. Jeffrey Voigt **Date:** 09/29/2006

Organization : Metrika, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-360-Attach-1.WPD

CMS-1321-P-360-Attach-2.WPD

HH . 11
360

RE: File code CMS-1321-P; Proposed Payment for a New Clinical Laboratory Test – Crosswalking and Gapfilling (414.408)- Comments to CMS proposed ruling on Gap fill – that appear in the August 22, 2006 Federal Register, Vo. 71, No. 162; p. 46064:

In determining a National Limitation Amount (NLA) for a new test code where no comparable, existing test is available:

- Requires that a contractor, CMS, or the carriers follow a specific methodology as outlined in the gap fill instructions (Medicare Claims Processing Manual, Chapter 23 – Fee Schedule Administration and Coding Requirements; Section 40.4 – Gap Fill Fees Submitted to CMS by Carriers) when establishing a gap fill amount. This methodology includes an evaluation for all the relevant resource costs including: all supplies (test supplies [cartridge, QC], ancillary, depreciation of capital equipment); labor for running the test, labor required for training, competency assessment and QA; clerical labor; allocation of overhead (rent, utilities, marketing, legal, etc.) and malpractice (if relevant). A template including all these cost items would be provided to ensure all were evaluated. Values would then be established for each cost item and then totaled. If any of the above costs are not considered, a detailed explanation is required which is further subject to public comment as outlined below. The gap fill methodology also includes an evaluation of charges from providers and an evaluation of payments by private insurers.
    - In order to collect relevant charge data, carriers are to ensure that a gap fill amount has been established and implemented/loaded by March 31, 2006 and that claims are being processed. This amount is to be made public by 3/31/06 to providers in the carrier area. A sufficient number of charges must then be evaluated to ensure that the data is statistically valid, meaningful, and unbiased. A median, mean, and standard deviation value must be calculated.
    - In order to collect relevant payment data, a contractor, CMS, or the carrier works with local providers to obtain a sufficient number of Explanation of Benefits (EOB's). These payments must then be evaluated to ensure that the data is statistically valid, meaningful, and unbiased. A median, mean, and standard deviation value must be calculated.
    - Sources of data in determining costs, charges, and payments include but are not limited to: industry, manufacturers, clinical studies, clinicians practicing in the area, medical associations, or other interested parties.

- If the carriers continue to collect data on charges, payments and costs, CMS is required throughout the gap fill process to monitor the carriers' methodology and data reporting, and provide oversight and feedback to ensure compliance with the instructions and that appropriate data is being collected.

- Data collected by the carrier, CMS, or a contractor is to be available for public review and comment prior to NLA determination – with review of the specific methodology, sources of information, and calculations used (cost, charges and payments) to ensure the gap fill instructions have been followed and to ensure a gap fill amount is fair and reasonable.
    - For carrier data collection only - requires CMS to eliminate those gap fill amounts that do not comply (not sufficient data to support a statistically valid, meaningful, and unbiased charge and payment value; relevant costs are not analyzed in resource analysis; or all 3 collectively – charges, payments, and costs are not evaluated to determine a gap fill amount) with the gap fill instructions.

- Allows CMS to consider and use external data (costs, charges, and payments) for establishing a NLA to ensure a fair and reasonable NLA determination. Sources of external data may include but are not limited to: industry, manufacturers, clinical studies, clinicians practicing in the area, medical associations, or other interested parties. External data is also subject to public comment as above.

- The NLA is established by CMS using all 3 data points – costs, charges (set @ 60% of charges[1,2]), and payments. If carriers are required to provide a gap fill amount to CMS, the amount submitted by each carrier is the average of all 3 (costs, 60% of charges, and payments). The median value of all the carrier data that is not eliminated after public comment due to questionable validity, is then used by CMS to establish a NLA. If there are not sufficient number (as determined by CMS) of carrier values to establish a NLA, CMS can consider and use external data for establishing a NLA. If a private contractor is used, the NLA is the average of all 3 (costs, 60% of charges, and payments). If any or all of the 3 data points established via a private contractor are eliminated after public comment due to questionable validity, CMS can consider and use external data to support the NLA.

- CMS is required to eliminate the carrier LCA in the gap fill process.

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[1] As described in Medicare Laboratory Payment Policy: Now and in the Future (2000), National Academies Press; page 89.

[2] Percent of charges may be adjusted by CMS based on charge experience over time

- CMS is required to establish a NLA by the end of the year in which the gap fill determination is initiated, and publish this amount in the carrier clinical laboratory fee schedules for the following year; with an effective date of that following year.

The above methodology/instructions should first be vetted with the public through a mechanism like CMS' new guidance development process used for coverage and evidence issues, or through a formal notice and comment regulatory process prior to establishing a final rule.