Date: 09/20/2006

Submitter : **Bradley Prestidge**

Organization : **Texas Cancer Clinic**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

General Comment

CMS-1321-P-238-Attach-1.DOC

HHac11 FF
238

September 11, 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 (CMS-1321-P), published in the Federal Register on August 22, 2006.

By reducing the RVU's for CPT 77781, in addition to reducing the conversion factor, CMS will significantly cripple my ability to offer the full scope of radiation services to Medicare beneficiaries. As a result, many Medicare beneficiaries will have to schedule brachytherapy services in the hospital radiation center, which will impede/delay the treatment process of Medicare beneficiaries diagnosed with breast or prostate cancer and burden the Medicare system with unnecessary costs compared to the cost-effective efficiencies of a free-standing radiation center.

In order for me to continue to provide access and availability of these radiation services to Medicare beneficiaries in this free-standing radiation center, I am requesting that CMS stabilize or freeze the current RVU's for CPT 77781.

Thank you for your careful consideration of the impact your decision will make on Medicare beneficiaries with regard to access to these very important radiation services in the treatment of breast and prostate cancer. I urge you to reconsider your proposal or run the risk of severely limiting access to brachytherapy services for Medicare beneficiaries.

Sincerely,

Bradley R. Prestidge, MD

Bradley R. Prestidge, MD
Texas Cancer Clinic
9102 Floyd Curl
San Antonio, TX 78240
(210) 247-0888

Cc: Senator Kay Bailey Hutchison, Senate Appropriations Labor-HHS Subcommittee

Representative Joe Barton, Chairman, Energy and Commerce Committee

Representative Michael Burgess, Energy and Commerce Health Subcommittee

Representative Kay Granger, Appropriations Labor-HHS Subcommittee

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, M.D., Chair, American Society of Therapeutic Radiation and Oncology

Submitter : Dr. Manoj Shaw

Date: 09/20/2006

Organization : Dr. Manoj Shaw

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-239-Attach-1.DOC

Attach #
239

September 20, 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 the opportunity to provide comment on the proposed revisions to the Physician Fee Schedule for 2007 and especially to voice concern regarding the impact these proposed rates will have on breast conservation therapy in those patients diagnosed with breast cancer.

The changes as proposed would have a significant impact on my practice, and particularly on the treatment options I would be able to present to my breast cancer patients. Access to partial breast irradiation which is delivered in the course of 5 days as opposed to whole breast irradiation over 6-7 weeks is an important treatment option for these patients. CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for breast brachytherapy, making this option almost impossible to preserve. As currently planned, CMS is scheduled to reduce each year in the transition period and the total reduction for this treatment is -31% as illustrated in the table below.

CPT Code	Description	2006 RVUs	2010 RVUs	Variance
19296	Placement of a radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application	129.74	89.31	-31%

Once it is determined women are eligible for breast brachytherapy based on strict patient selection criteria, the catheter that delivers this radiation must be surgically implanted. This procedure may take place in the operating room or, in some cases, in the physician's office in the procedure room. Because of the time involved in planning and implanting the catheter, as well as the cost of the device, the proposed RVU reduction will result in this procedure no longer being available as an option for insertion in the physician's office, since the cost of the procedure will exceed the proposed reimbursement. The office is a preferred site of service for some women and this option should be available for them.

There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor of 5% reduction and this floor should remain in effect during the required time for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, breast brachytherapy. I may be willing to

provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC in order to make a more informed proposal in the readjustment of these RVUs applicable to breast brachytherapy.

Sincerely,

Manoj Shaw, MD
Parkside Center
1875 Dempster, Ste 280
Park Ridge, IL 60068
847-723-5990

cc. Carolyn Mullen, Deputy Director, Division of Practitioner Services
Helen Pass, MD, FACS, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Dr. Michael Kinney

Date: 09/20/2006

Organization : Dr. Michael Kinney

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-240-Attach-1.DOC

Attach #
240

September 21, 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 the opportunity to provide comment on the proposed revisions to the Physician Fee Schedule for 2007 and especially to voice concern regarding the impact these proposed rates will have on breast conservation therapy in those patients diagnosed with breast cancer.

The changes as proposed would have a significant impact on my practice, and particularly on the treatment options I would be able to present to my breast cancer patients. Access to partial breast irradiation which is delivered in the course of 5 days as opposed to whole breast irradiation over 6-7 weeks is an important treatment option for these patients. CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for breast brachytherapy, making this option almost impossible to preserve. As currently planned, CMS is scheduled to reduce each year in the transition period and the total reduction for this treatment is -31% as illustrated in the table below.

CPT Code	Description	2006 RVUs	2010 RVUs	Variance
19296	Placement of a radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application	129.74	89.31	-31%

Once it is determined women are eligible for breast brachytherapy based on strict patient selection criteria, the catheter that delivers this radiation must be surgically implanted. This procedure may take place in the operating room or, in some cases, in the physician's office in the procedure room. Because of the time involved in planning and implanting the catheter, as well as the cost of the device, the proposed RVU reduction will result in this procedure no longer being available as an option for insertion in the physician's office, since the cost of the procedure will exceed the proposed reimbursement. The office is a preferred site of service for some women and this option should be available for them.

There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor of 5% reduction and this floor should remain in effect during the required time for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, breast brachytherapy. I may be willing to

provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC in order to make a more informed proposal in the readjustment of these RVUs applicable to breast brachytherapy.

Sincerely,

Michael R. Kinney, MD
850 W. Central Road, Suite 7300
Arlington Heights, IL 60005
847-797-9099

cc. Carolyn Mullen, Deputy Director, Division of Practitioner Services
Helen Pass, MD, FACS, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 09/21/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

September 11, 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 CMS Administrator:

Thank you for allowing me the opportunity to provide comments on the CMS proposed Physician Fee Schedule changes, file #CMS-1231-P. As the Governor s Advisor for the North Carolina Cancer Control Program and the North Carolina State Chair for the American College of Surgeons Cancer Liaison Program, I am extremely concerned about the proposed changes.

Roughly 170,000 women are diagnosed annually with early stage breast cancer. These patients move on to lumpectomy followed by Radiation Therapy; however, the statistics show many of these women do not complete their 6-8 weeks of Radiation Therapy. Therefore I recommend Partial Breast Irradiation Therapy for carefully selected Breast Cancer patients.

With Partial Breast Irradiation Therapy, a woman can complete her Radiation treatments in five days. The women are more compliant and can return to work and families in a timely fashion.

With the proposed Physician Fee Schedule changes, specifically, the proposed changes to the RVUs associated with 19296 and 19297, I will no longer be able to offer Breast Conservation Surgery with Partial Breast Irradiation Therapy to your Medicare patients. I recommend that CMS not reduce the RVUs for 19296 and 19297 in both sites of service (11 and 22).

Again, I appreciate the opportunity to comment and endorse careful consideration in this very important matter. I strongly urge CMS to reconsider the proposed changes and keep the current RVUs in tact for the foreseeable future.

Regards,

Terry Sarantou, M.D., F.A.C.S.
Medical Director, Cancer Center
Frye Regional Medical Center

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee, Co-Chair, House Cancer Caucus

Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee

Carolyn Mullen, Deputy Director, Division of Practitioner Services

Helen Pass, MD, FACS, President, American Society of Breast Surgeons

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

CMS-1321-P-241-Attach-1.DOC

Attach #
241

Hickory Surgical Clinic, Inc.
General, Thoracic, Oncologic and Vascular Surgery

Michael W. Dickinson, M.D., F.A.C.S.
Leland J. Cook, M.D., F.A.C.S.
Peter H. Bradshaw, M.D., F.A.C.S.
Charles S. Kiell, M.D., F.A.C.S.
Terry Sarantou, M.D., F.A.C.S.
Kenneth L. Parish, M.D., F.A.C.S.
Montgomery H. Cox, M.D.

Michele F. Haynes,
Practice Administrator

September 11, 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 CMS Administrator:

Thank you for allowing me the opportunity to provide comments on the CMS proposed Physician Fee Schedule changes, file #CMS-1231-P. As the Governor's Advisor for the North Carolina Cancer Control Program and the North Carolina State Chair for the American College of Surgeons Cancer Liaison Program, I am extremely concerned about the proposed changes.

Roughly 170,000 women are diagnosed annually with early stage breast cancer. These patients move on to lumpectomy followed by Radiation Therapy; however, the statistics show many of these women do not complete their 6-8 weeks of Radiation Therapy. Therefore I recommend Partial Breast Irradiation Therapy for carefully selected Breast Cancer patients.

With Partial Breast Irradiation Therapy, a woman can complete her Radiation treatments in five days. The women are more compliant and can return to work and families in a timely fashion.

With the proposed Physician Fee Schedule changes, specifically, the proposed changes to the RVU's associated with 19296 and 19297, I will no longer be able to offer Breast Conservation Surgery with Partial Breast Irradiation Therapy to your Medicare patients. I recommend that CMS not reduce the RVU's for 19296 and 19297 in both sites of service (11 and 22).

Medical Specialties Center
415 North Center Street, Suite 102, Hickory, N.C. 28601
Tel: (828) 327-9178 • Fax: (828) 304-0202

Again, I appreciate the opportunity to comment and endorse careful consideration in this very important matter. I strongly urge CMS to reconsider the proposed changes and keep the current RVUs in tact for the foreseeable future.

Regards,

Terry Sarantou, M.D., F.A.C.S.
Medical Director, Cancer Center
Frye Regional Medical Center

cc: Representative Sue Myrick, Energy and Commerce Health Subcommitt, Co-Chair, House Cancer Caucus

Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee

Carolyn Mullen, Deputy Director, Division of Practitioner Services

Helen Pass, M.D., F.A.C.S., President, American Society of Breast Surgeons

Mark A. Malangoni, M.D., F.A.C.S., Chair, American College of Surgeons

Submitter : **Ms. Brenda Bland** **Date: 09/21/2006**

Organization : **GELunar**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Impact

Impact

I am writing to ask that the committee consider leaving the DXA reimibursement for the Bone Mass Measurement tests untouched. Currently physicians are able to integrate the DXA testing as part of the normal checkup during prostrate exams, mammograms and /or pap smears. This makes the DXA testing available to all women and men who are under regular physician care. With the proposed decreases in reimbursement, this would push many of the physicians out of the business of DXA as the cost of the equipment would outway the benefits. This would remove the convenience of DXA from the physicians office or imaging center, making it far less likely to happen.

As a preventative test, DXA can be used to assist the physician in making health decisions that can treat, affect or even prevent osteoporosis related fractures. The estimated cost of one femur fracture was $84,000 in 2001, and the cost has only increased since that time. In addition, over 50% of those who fracture will not be able to live unassisted after this type of injury. The cost of in-home care would be in addition to the cost of the original fracture.

The increasingly aging population of baby boomers means that osteoporotic related fractures will also increase, unless we take action. Access to DXA testing must be made available and easy for all people. Part of that access is a test that is both physically available, and covered by insurance and/or medicare. Without making this geographically and financially avaialable, we will be going backwards in the treatment and healthcare of Bone Mass Measurement.

The cost of DXA devices, technicians, physicians and training continue to increase over time. Cutting the reimbursement of DXA would only decrease the amount of DXA available as fewer offices could then afford to stay in the business of DXA. As mentioned above, this would adversely affect the availability and hence the health of our aging population.

Thank you for your time,
Brenda Bland
GELunar
Customer Service

Submitter : Dr. Robert Rosenbloom **Date:** 09/21/2006

Organization : Dr. Robert Rosenbloom

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-243-Attach-1.DOC

Attach 11
243

September 20, 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 the opportunity to provide comment on the proposed revisions to the Physician Fee Schedule for 2007 and especially to voice concern regarding the impact these proposed rates will have on breast conservation therapy in those patients diagnosed with breast cancer.

The changes as proposed would have a significant impact on my practice, and particularly on the treatment options I would be able to present to my breast cancer patients. Access to partial breast irradiation which is delivered in the course of 5 days as opposed to whole breast irradiation over 6-7 weeks is an important treatment option for these patients. CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for breast brachytherapy, making this option almost impossible to preserve. As currently planned, CMS is scheduled to reduce each year in the transition period and the total reduction for this treatment is -31% as illustrated in the table below.

CPT Code	Description	2006 RVUs	2010 RVUs	Variance
19296	Placement of a radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application	129.74	89.31	-31%

Once it is determined women are eligible for breast brachytherapy based on strict patient selection criteria, the catheter that delivers this radiation must be surgically implanted. This procedure may take place in the operating room or, in some cases, in the physician's office in the procedure room. Because of the time involved in planning and implanting the catheter, as well as the cost of the device, the proposed RVU reduction will result in this procedure no longer being available as an option for insertion in the physician's office, since the cost of the procedure will exceed the proposed reimbursement. The office is a preferred site of service for some women and this option should be available for them.

There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor of 5% reduction and this floor should remain in effect during the required time for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, breast brachytherapy. I may be willing to

provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC in order to make a more informed proposal in the readjustment of these RVUs applicable to breast brachytherapy.

Sincerely,

Robert David Rosenbloom, MD
1555 Barrington Road
Suite 2550
Hoffman Estates, IL 60194
847-884-7700

cc. Carolyn Mullen, Deputy Director, Division of Practitioner Services
Helen Pass, MD, FACS, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Kevin Carroll **Date:** 09/21/2006

Organization : Summerlin Imaging

Category : Other Health Care Professional

Issue Areas/Comments

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Regarding IDTF self referral changes to rules, it would appear that CMS is missing a major cost cutting opportunity. Internal Medicine and family practice physicians who buy their own MRI/CT or Nuclear scanners and self refer all their patients into it. Since they are NOT IDTF's they are not watched or regulated. We know of a phyisican in Ft Myers who claims he has a license to print money! CMS is constantly looking at IDTF's as if they are all criminal enterprises, whereas many are operated cleanly and within all the guidelines. Looking at the pending changes to IDTF's, it appears that this is the only place CMS think's that there could be abuse. Look at the self-referral patterns of physicians who place imaging into their own office. The in-office ancillary exception rule under Stark should be abolished and the savings would be tremendous.

Kevin Carroll
561-371-4521
Owner of an IDTF

Submitter : Ms. Hazel Chandler **Date:** 09/21/2006

Organization : Ms. Hazel Chandler

Category : Individual

Issue Areas/Comments

Impact

Impact

I am really cocerns about the cut to Physician reimbursement. We must keep our health care system strong by keeping adequate reimbursement of physician.

Submitter : Mr. Michael Bohl

Date: 09/21/2006

Organization : Radiology Group, PC, SC

Category : Radiologist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-246-Attach-1.DOC

Attach # 246

Radiology Group p.c., s.c.

1970 E. 53rd Street | Davenport, Iowa 52807 | 563.359.3931 | fax 563.355.1159 | www.rgimaging.com

9/21/2006

CMS-1321-P
REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

Issue #1: Whether diagnostic tests in the DHS category of radiology and other imaging services should be excepted from any of these provisions.

Discussion: It is imperative that Radiology services should be INCLUDED under these provisions. As the Executive Director of a medical group providing interpretations, and as one who communicates regularly with other practices providing interpretations, I support this proposal and believe it must apply to radiology services in order to stem rampant abuse occurring under reassignment. The current in-office ancillary exception to self-referral results in tremendous over-utilization at great expense to all federal payment programs. What is often not well understood is the magnitude of abuse occurring under the guise of reassignment. Reassignment, under the current rules, allows self-referring groups to profit from both the TC and PC by paying the interpreting physician less than what the billing entity collects for that interpretation. Any discounts and savings should be realized by the Medicare program, not placed in the self-referring physicians' pockets.

Issue #2: Should the anti-markup provision apply to the reassignment of the PC of diagnostic tests performed under contractual arrangement.

Discussion: In order to stem some of the abuse seen in self-referral, the anti-markup provisions should apply. See discussion under Issue #1.

Issue #3: How to determine the correct amount that should be billed to the Medicare program

Discussion: Having experience in this area, as well as speaking with others who provide interpretive services, there are really only variations of 3 methodologies used to pay for interpretations under reassignment: 1) A flat fee per study; 2) a percentage of collections; or, 3) a discount from billed charges. In my experience, the vast majority of arrangements (90+% ?) fall into some variation of methods #1 or #2. The problem begins in that these claims are almost always submitted as a global charge, not separated on the claim as TC and PC. The first step would be to mandate separate billing for the PC and TC. However, you should be careful to write the rules in such a way that they apply ONLY to self-referring groups and IDTFs who contract with physicians outside their group for interpretation services under reassignment; the rules should not apply to physicians and medical groups that provide both the TC and PC components within the group, i.e., radiology practices. Keep in mind that in virtually all radiology groups, every physician "reassigns" their benefits to the group.

At the end of the day, the rule should mandate that 100% of all receipts collected for reassignment interpretations should be paid to the physician providing the interpretation, with no portion being kept by the entity providing the TC. The easiest way would be to require that the actual amount charged by the interpreting physician should be reflected on the claim. If the

"charge" is greater than the payment received, the rules should mandate that the entire amount received by the entity for the interpretation be paid to the physician providing the interpretation in these settings. If the interpreting physician is paid a flat fee, this flat fee should be entered on the billing entity's initial claim form, not some inflated fee. The rules should prohibit paying the physician under reassignment a percentage of collections as enforcement of any anti-markup provisions will prove to be impossible. There should be no reductions in the fees paid to the interpreting physician for the cost of collections since the entity is already experiencing those costs when they bill for the TC.

Issue #4: The test must be ordered by a physician that is financially independent of the person or entity performing the test and also of the physician or medical group performing the interpretation; the physician or medical group performing the interpretation does not see the patient; the physician or medical group performing the interpretation does not see the patient; and, the physician or medical group billing for the interpretation must have performed the TC of the test.

Discussion: I support all proposals in Issue #4. This set of rules, in and of itself, is the most important of all proposals, and will go a long way to stemming reassignment abuse. However, I believe it is in Medicare's interest to enact all proposed provisions.

Additional comments: While I wholeheartedly support the proposed changes, I believe the financial attraction is so great that many self-referring groups obtaining interpretations under reassignment will simply change the process by which they obtain interpretations from qualified physicians. I believe that many of these groups will simply give a cursory review of the images for gross pathology, make a note in the chart (calling that a dictation), then file the claim for the PC. They then will contract with an outside group to provide "over-reads" for their interpretations. However, they will typically want the over-read physician to provide a full and complete report, which would then be used as the official report in the medical record. I encourage you to consider MedPACS' recommendation to implement a designated reader program which requires physicians to have a modicum of training prior to receiving any payments for providing image interpretations.

If you have any questions, need additional information, or would like to discuss these issues with me, please call me at 563.359.3949, x233 or reply to this e-mail.

Sincerely,

Michael Bohl, Executive Director
Radiology Group, PC, SC / P2P Medical Management, LLC
1970 E. 53rd St.
Davenport, Iowa 52807
563.359.3949, x233
mbohl@rgimaging.com

Date: 09/21/2006

Submitter : Mr. Michael Christopherson

Organization : LGD Management

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-247-Attach-1.DOC

Attach #
247

September 21, 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 (underline added). 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 through out 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. Enteral 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.

Sincerely,

Michael L. Christopherson

Date: 09/21/2006

Submitter : Debbie Gonzalez

Organization : St. Louis Hematology Oncology Specialists

Category : Other Health Care Professional

Issue Areas/Comments

Provisions of the Proposed Rule

Provisions of the Proposed Rule

'ASP Issues' I am a practice manager for a one physician onoclogy practice. I work with reimbursement issues everyday and I have seen first-hand what ASP has done to drug prices. It has forced the drug manufacturers to increase their prices and has, in fact, rewarded higher prices with a higher ASP. ASP discourages any one time sales, free drug for patients who can not afford drug, and even penalties prompt pay discounts, therefore, we don't see much of this anymore. Refunds and rebates have become a game you cannot afford not to play if you plan on giving the drug in your office. Not all physician groups are eligible for rebates or refunds, only those groups that can buy the required volume. Even those that can buy the volume are then forced to continue buying at the same pace ,even if their patient volume declines, or lose the rebate which would then mean a loss of thousands of dollars to a practice that has bought drug at a price mucher higher than ASP, as there as few drugs that can be bought at ASP or less. This practice has 30 drugs out of 85 we stock that we cannot buy at ASP. We depend on a rebate to make us whole on the pricing or administration codes to break even. Physician practices are not the winners and neither is CMS, but ,in fact, it's the private insurance carriers that are reaping the benefit of this chaos that has and will continue to close small and rural onoclogy practices. I hope not too people are depending on access to qualify oncology care in the future.

Date: 09/21/2006

Submitter : Dr. Steven Wong

Organization : Dr. Steven Wong

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1321-P-249-Attach-1.DOC

Attach #
245

September 15, 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,

Steven Wong MD F.A.C.S.
254 Canal St.
New York, NY 10013

CC Senator Hillary Clinton, Senate Health, Education, Labor and Pensions Committee
Mark A. Malangoni, MD, FACS,Chair, American College of Surgeons