Submitter : Dr. William McGinnis

Date: 09/23/2006

Organization : Dr. William McGinnis

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-286-Attach-1.DOC

Attach 11
286

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

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,

William McGinnis, MD

William McGinnis, MD
Iowa Methodist Medical Center
Radiation Oncology
1221 Pleasant Street, Suite A11
Des Moines, IA 50309
515-241-4330

cc. Senator Charles Grassley, Chairman, Senate Finance Committee
Senator Tom Harkin, Ranking Member, 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. lily chen** **Date: 09/23/2006**

Organization : **East Bay Anesthesiology Medical Group**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

please reconsider cuts in medicare payments to Anesthesiologist. This reduction is based on erroneous statistics/ studies. This will unfairly penalize Anesthesiologist.

Date: 09/24/2006

Submitter :

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT"

CMS-1321-P-288-Attach-1.DOC

Attach #
288

CHARLESTON SURGICAL ASSOCIATES, P.A.

General Surgery Surgical Oncology Laparoscopy

J. Chris Hawk, III, M.D., F.A.C.S.
Stanley M. Wilson, M.D., F.A.C.S.
Telephone: 843-577-7550

125 Doughty Street, Suite 660
Charleston, SC 29403
Fax: 843-853-5588

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:

We appreciate the opportunity to provide comment on the CMS proposed Physician Rule #CMS-1321-P. We would like to highlight the negative impact these proposed rates will have on breast conservation therapy.

We currently recommend a 5-day radiation therapy treatment option (balloon brachytherapy) for clinically specific Medicare beneficiaries. We find the patients are more compliant versus the standard course of radiation treatments which can run from 6-8 weeks.

CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for breast brachytherapy. The RVUs are scheduled to reduce each year in the transition period and the total reduction for this treatment is -31% as illustrated in the table below. This is unacceptable.

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 that a woman is eligible for breast brachytherapy after meeting strict patient selection criteria, we must surgically implant the balloon catheter that delivers the radiation. This procedure may take place in the Operating Room or, in some cases, in the Physician's office / procedure room.

Because of the time involved in planning and catheter implantation along with device cost, the proposed RVU reduction will result in this procedure no longer being available as an option for insertion in the physician's office for Medicare women. The cost of the procedure will exceed the proposed reimbursement.

Negative surgical margins of excision must be rendered on Pathology before implantation of the device. The office is the preferred site of service. Office placement should be available to reduce unnecessary Operating Room costs.

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 am willing to provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC. This will help CMS make a more informed proposal in the readjustment of the RVUs which apply to breast brachytherapy.

Stanley M. Wilson, M.D.

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carol Bazell, MD, Director, Division of Outpatient Care
Carolyn Mullen, Deputy Director, Division of Practitioner Service
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Dr. Kathryn Jean Lucas **Date:** 09/24/2006

Organization : Diabetes

Category : Physician

Issue Areas/Comments

Impact

Impact

Bone densities are done to detect early bone loss and revent hip and spinal fractures by starting therapy before the bones are broken. Less reimbursement will mean less machines available and less people will be screened.

Submitter : Dr. Daniel Grum **Date:** 09/25/2006

Organization : University of Toledo Cllege of Medicine

Category : Physician

Issue Areas/Comments

Impact

Impact

I would like you to consider the potentially serious negative impact that the financial changes of the proposed legislation will have on health care in the USA. Anesthesiologists are the doctors responsible for keeping sick patients alive and well in the operating room. Contrary to what you may think, the practice of anesthesiology is not simply "putting someone to sleep." As the population of this country continues to age, and as people with serious illnesses live longer and require more surgical procedures, highly skilled doctors will be needed to take care of these patients in the operating room and post-operatively. The 10% cut in Medicare payment over the next 4 years, plus the 50% penalty in payments to medical school anesthesiology faculty supervising 2 residents whose cases overlap in time (a rediculous singling out of our specialty, since this rule DOES NOT APPLY to any other specialty)unfairly punishes our practice and makes academic anesthesiology in specific, and the entire field in general, unattractive to both young doctors and medical students. Who do you think will take care of the aging, increasingly sick (think of the obesity epidemic and all of the related medical problems that this one condition causes!) population in this country? If you think that nurse anesthetistas can safely replace us, please think again! Would you rather have a nurse or a highly trained physician specialist to take care of your sick, aging mother during heart surgery or other complex procedures? If you continue to single out our specialty for extra onerous cuts in reimbursement, you will see ever dwindling numbers of American medical school graduates entering anesthesiology. In addition, it will be increasingly difficult to attract any anesthesiologist, let alone the brightest and the best, into academic anesthesiology practice to teach medical students and residents, if financial compensation becomes less attractive year after year. I ask you to exercise common sense and stop singling out anesthsiologists for the most restrictive regulations regarding financial compensation for medical service rendered to the oldest and sickest group of patients. Remember, some day you will be older that age 65, and may need to have a highly trained individual take care of you in the operating room. Please help to ensure that our specialty will be able to attract enough of our American medical students to supply your and everyone else's needs!

Submitter : Dr. Wilson Garrett **Date:** 09/25/2006

Organization : Texas Vascular Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-291-Attach-1.TXT

Attach #
291

September 29, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
P.O. Box 8010
Baltimore, MD 21244-8010

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 – **"DRA Proposals."**

Dear Dr. McClellan:

As a vascular surgeon who practices in Dallas, Texas and as a member of the Society for Vascular Surgery (SVS), I am writing in response to the publication of 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, specifically the section regarding implementation of Section 5102 (b) (1) of the Deficit Reduction Act (DRA) and the list of imaging services that the Centers for Medicare and Medicaid Services (CMS) has included within the scope of "imaging services" defined by the DRA provision.

I am concerned that CMS has proposed to include non-invasive vascular diagnostic studies, CPT codes 93875 – 93990 and G-code 0365, in the list of imaging codes that are defined by Section 5102(b) of the DRA when in fact these studies contain no imaging or are predominately non-imaging in nature. Given the inclusion criteria that CMS has proposed, there are numerous reasons that these studies should not be listed in Addendum F.

The CPT manual is very clear that non-invasive physiologic studies are performed using equipment that is separate and distinct from the duplex scanner. In a vascular surgeon's practice, we perform physiologic studies on Medicare patients where there are signs and symptoms of peripheral arterial disease and we use physiologic vascular studies, CPT codes 93922, 93923 and 93924 to confirm presence of disease, assess the severity, allow accurate delineation of prognosis and provide a measure of effectiveness of treatments including exercise programs, percutaneous intervention and bypass surgery. Because these codes **do not contain imaging**, CMS should remove them from the list of services included under the imaging provisions of the DRA in the Final Rule, just as it has done in the proposed rule for nuclear medicine services that are "non-imaging diagnostic services" and radiation oncology services that are "not imaging services".

CMS should also exclude duplex scans of arteries (CPT codes 93880, 93883, 93925, 93926, 93930, 93931 and 93990) from DRA because the most important component of these procedures is collection of Doppler velocity data, **a non-imaging ultrasound modality**. For example, CPT 93880 is a non-invasive duplex scan of extracranial arteries; a complete bilateral study. B-mode imaging ultrasound is used to find the arteries in the neck, but non-imaging Doppler-based blood flow velocities are the most important data collected during the exam. Non-imaging Doppler-based blood flow velocities are the most important elements on which arterial stenosis measurements are based, and the stenosis determination is the criterion on which clinical treatment decisions are made. In summary, the single main reason for "imaging" in the carotid duplex scan is to find the correct location to obtain Doppler velocity measurements.

In addition, I believe there is confusion regarding the term "Doppler" and the information that this modality provides to a vascular surgeon for use in diagnosing vascular disease. There are several forms of Doppler ultrasound used in non-invasive vascular diagnosis (continuous-wave Doppler, pulsed-wave Doppler, color-flow Doppler velocity mapping), but all Doppler modalities have one thing in common – they measure blood flow. In the absence of blood flow, the Doppler measures nothing: there is no audible sound, velocity determination or flow mapping. The Doppler does not provide images of body parts. Thus, **Doppler techniques do not meet CMS's definition for inclusion, as these services do not provide "visual" information.** Duplex scans should be excluded from the DRA provisions in the Final Rule because the most important information provided by these tests is based on Doppler.

I recently participated in a survey conducted by the SVS of its members with office-based vascular labs regarding the impact of cuts on non-invasive vascular diagnostic studies, if they are erroneously included under DRA. The dramatic results demonstrate that Medicare beneficiaries' access to these services would be severely affected: 54 percent of vascular surgeons with office-based vascular labs would no longer provide or would reduce vascular laboratory services to Medicare beneficiaries and 24 percent would close the lab entirely or reduce services; 35 percent estimate that Medicare beneficiaries would wait three to four weeks to receive services if they had to go elsewhere and 22 percent estimate that patients would have to travel more than 20 miles to receive suitably high-quality vascular lab studies.

Given this level of impact and the fact that non-invasive vascular diagnostic studies do not meet CMS's proposed criteria for inclusion under DRA and instead meet the criteria CMS is proposing to exclude certain diagnostic services, I respectfully request that CMS remove these codes from Addendum F – Proposed CPT/HCPCS Imaging Codes Defined by Section 5102(b) of the DRA.

I greatly appreciate this opportunity to provide CMS with information and I would be happy to answer any questions. Please do not hesitate to contact me at janella@greenhillfarm.net or 214-821-9600.

Sincerely,

Wilson V Garrett, MD

Submitter : Dr. Robert Weller **Date:** 09/25/2006

Organization : Dr. Robert Weller

Category : Physician

Issue Areas/Comments

Impact

Impact

I am an anesthesiologist practicing in an academic setting in North Carolina, and I would like to comment on the proposed reductions in Medicare payments to physicians, and to anesthesiologists in particular, resulting from application of the SGR formula and proposed changes in the CMS formulae for physician reimbursement. Without action by Congress, these changes are projected to produce a 10% reduction of reimbursement to anesthesiologists over the next four years on top of the SGR cuts. As a faculty member involved in teaching future anesthesiologists, I am already subject to a 50% Medicare reimbursement penalty whenever I supervise two patients cared for by resident anesthesiologists; this reduction is not applied in any other medical specialty.

I am aware that the cost of medical care for Medicare and Medicaid recipients continues to strain the nation s budget deficit, now even more since the prescription drug benefit has been added. Because of increased uninsured populations, economic slowdown, and the rising median age of our citizens, though, logic would dictate that the cost of such care should increase faster than inflation. It is difficult for me to understand the expectation that reductions to payments to physicians for care of the Medicare beneficiary can be reduced or even stay stable at the same time that the number of elderly patients requiring medical care is increasing, and these same patients require more and more complex and challenging medical decision-making due to their multiple medical diseases and age-related reduction of organ function and reserve. Our tertiary care medical center provides care for a disproportionate share of my area s Medicaid and Medicare patients, but faces an economic crisis that threatens that care.

The relatively low Medicare reimbursement rate for physicians in general, and anesthesiologists in particular, has made it very difficult for practitioners to provide quality care to this complicated group of surgical patients. More and more physicians will not be able to afford to care for these patients, and access to quality medical care for our nations elderly will likely suffer. I would respectfully request that the work provided by anesthesiologists in operating rooms, pain clinics and intensive care units be fairly and properly valued, appropriate increases in payments provided, and the SGR formula be eliminated as unworkable.

Submitter : Dr. James Theen **Date:** 09/25/2006

Organization : James W Theen MD PC

Category : Physician

Issue Areas/Comments

Impact

Impact

I am a board certified endocrinologist in Medford, OR and provide high quality DXA (dual energy x ray absorptiometry) bone density services to my medicare and non medicare patients. Our in-office test includes spine, both hips and wrist density and the interpretation takes a minimum of 15 minutes and more often 30 minutes to do correctly. The proposed decrease in reimbursement would make it necessary to limit and possibly even stop seeing medicare patients for this test. Your recent proposals for an initiative to increase the utilization of this test seem to contradict this proposal. You want us to do more of the tests but are not willing to pay for them. There is no volume discount for the test: the test takes the same amount of time no matter how many you do and in fact the medicare population has more limited mobility and takes LONGER to do the test if anything. The cuts will also decrease the impact of your own "Healthy People 2010" initiative. Realize that the cost of treating osteoporotic fractures in the US is increasing dramatically and this test will decrease that burgeoning cost if allowed to be used correctly. The mortality of hip fractures is an astounding 50% within 18 months of that fracture at a HUGE cost to the system.
Our 'typical' patient is an elderly and possibly frail woman with a variety of medical problems. Analysis of the test includes a careful appraisal of the data and comprison to past reports and my reports include suggestions for treatment, further evaluation of the cause of the low bone density and recommendations for the interval to the next test. Contrast this to the reports that I see from some of my colleagues that is a 1/2 page summary of the data or "T-scores". If you are using this to determine your rules for payment then you need to look further into the situation and realize that those of us who strive for excellence in our care and test reports require more time and expertise than these new rules will give us credit for and will make it necessary to stop accepting medicare patients into our practice. Please do some additional information gathering and assessment before you put this rule into effect. I believe it is flawed as it does not adequately reflect the work that at least some of us are doing, that it represents s short-sighted and "dollars only" approach to budgeting and will ultimately cost more in the long run than it will save. Thank you for your time and attention to my comments. If I can provide any further input or be of any further assistance feel free to contact me at jwtheen@charter.net

Submitter : Mrs. Cari Thomason **Date:** 09/25/2006

Organization : Internal Medicine Associates of Grand Junction

Category : Other Health Care Professional

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 : Cynthia Waystack **Date:** 09/25/2006

Organization : The Radiology Group

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The new reassignment rules should apply to radiology.

Radiology should NOT be exempt from being required that the test be ordered by a physician financially independent from the person and entity performing the test, and that the physician interpreting does not see the patient, and that the group billing for the interpretation must perform the TC of the test.

If you make these requirements the quality of the study for the patient will be much greater and Medicare will save a tremendous amount of money because only studies that really need to be performed for the patient's care will be ordered.

Submitter : **Dr. Margaret Thurmond-Anderle** **Date: 09/25/2006**

Organization : **ME Thurmond-Anderle, MD, PA**

Category : **Physician**

Issue Areas/Comments

Provisions of the Proposed Rule

Provisions of the Proposed Rule

To Whom It May Concern:

Allow me to introduce myself. My name is Margaret E. Thurmond-Anderle, M. D., and I am a rheumatologist practicing in Amarillo, Texas. I am writing to voice my concern about the proposals to the Coverage of Bone Mass Measurement (BMM) Tests (document number 1321-P). As a single practice rheumatologist, it will be very difficult to provide my patients with the highest possible medical care if the proposed budget cuts take effect. The majority of my practice is Medicare, and the proposed Federal cuts would directly affect my practice.

I understand that Medicare believes most bone densitometry machines across the country are idle half the time. This, in my opinion, does not justify Medicare cutting reimbursement costs in half. If the proposed cuts go into effect, many of these machines will never be used. The cost of the maintenance will far outweigh the reimbursement costs. Due to the number of Medicare patients in my practice, I am afraid these individuals will be denied proper medical treatment due to insurance reasons. This consequence is already occurring throughout the country on both Medicare patients and commercial insurance patients.

Recently, CMS added DXA as a perspective service. These proposed cuts go against their own initiative to increase the utilization of these machines. These cuts also diminish the impact of CMS s own Healthy People 2010 initiative. I thought CMS wanted to reduce the annual costs of hip replacement surgery and the subsequent therapy involved. By allowing these cuts to go through, CMS will defeat their purpose and the annual costs will increase. I do agree the requirements for steroid dosage should be 5.0 mg.

A standard DXA procedure takes about 30 minutes to perform. My technologist reviews the patient s medical history with them to look for indications, risk factors, etc. before performing any testing. Once the testing begins, our standard procedure is an AP Spine, Dual Femur and Forearm which takes about 15 minutes. Based on these results, I then determine the effectiveness of the therapy and what changes may need to occur.

I believe feel an emphasis should be placed on the skill of performing DXA testing. I believe this would increase utilization of these machines, and ensure proper interpretation of the results. Both my technologist and I are certified through the International Society for Clinical Densitometry to perform and read these tests. Many practices, physicians and radiologists using this equipment have not received the proper training to perform and interpret these tests.

I also believe the assumptions used to recalculate the MPFS are inaccurate. The new methodology should not be a trial and error policy. I also believe inaccurate data was used to calculate the bone densitometer. There are many differences and advantages between the pencil beam and the fan beam densitometers. The majority of systems sold today are fan beams, and I personally prefer the fan beam densitometer because it is easier to use on older patients. Our fan beam equipment is used in our office about 75% of the time, not 50% of the time as speculated by various studies.

In addition, I strongly encourage Texas legislators to delay the DRA until a complete and thorough analysis can be conducted using cost figures based on the appropriate technology. I also request congress to intervene and stop the reduction of the conversion factor. I feel strongly Congress should act on this matter before their October adjournment.

I sincerely hope my opinion will be taken into consideration on this matter.

CMS-1321-P-296-Attach-1.PDF

Attach #
296

M. E. THURMOND-ANDERLE, M. D., P. A.
6701 Woodward Street • Amarillo, Texas 79106
Phone (806) 379-7732 • Fax (806) 379-6740

September 25, 2006

Department of Health and Human Services
Attention: CMS-1502-P (Document Number 1321-P)
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

To Whom It May Concern:

Allow me to introduce myself. My name is Margaret E. Thurmond-Anderle, M. D., and I am a rheumatologist practicing in Amarillo, Texas. I am writing to voice my concern about the proposals to the Coverage of Bone Mass Measurement (BMM) Tests (document number 1321-P). As a single practice rheumatologist, it will be very difficult to provide my patients with the highest possible medical care if the proposed budget cuts take effect. The majority of my practice is Medicare, and the proposed Federal cuts would directly affect my practice.

I understand that Medicare believes most bone densitometry machines across the country are idle half the time. This, in my opinion, does not justify Medicare cutting reimbursement costs in half. If the proposed cuts go into effect, many of these machines will never be used. The cost of the maintenance will far outweigh the reimbursement costs. Due to the number of Medicare patients in my practice, I am afraid these individuals will be denied proper medical treatment due to insurance reasons. This consequence is already occurring throughout the country on both Medicare patients and commercial insurance patients.

Recently, CMS added DXA as a perspective service. These proposed cuts go against their own initiative to increase the utilization of these machines. These cuts also diminish the impact of CMS's own "Healthy People 2010" initiative. I thought CMS wanted to reduce the annual costs of hip replacement surgery and the subsequent therapy involved. By allowing these cuts to go through, CMS will defeat their purpose and the annual costs will increase. I do agree the requirements for steroid dosage should be 5.0 mg.

A standard DXA procedure takes about 30 minutes to perform. My technologist reviews the patient's medical history with them to look for indications, risk factors, etc. before performing any testing. Once the testing begins, our standard procedure is an AP Spine, Dual Femur and Forearm which takes about 15 minutes. Based on these results, I then determine the effectiveness of the therapy and what changes may need to occur.

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I also believe the assumptions used to recalculate the MPFS are inaccurate. The new methodology should not be a trial and error policy. I also believe inaccurate data was used to calculate the bone densitometer. There are many differences and advantages between the pencil beam and the fan beam densitometers. The majority of systems sold today are fan beams, and I personally prefer the fan beam densitometer because it is easier to use on older patients. Our fan beam equipment is used in our office about 75% of the time, not 50% of the time as speculated by various studies.

In addition, I strongly encourage Texas legislators to delay the DRA until a complete and thorough analysis can be conducted using cost figures based on the appropriate technology. I also request congress to intervene and stop the reduction of the conversion factor. I feel strongly Congress should act on this matter before their October adjournment.

I sincerely hope my opinion will be taken into consideration on this matter.

Sincerely,

M. E. Thurmond-Anderle MD

M. E. Thurmond-Anderle, M. D.

Board Certified Rheumatology & Internal Medicine
www.dranderle.com

Submitter : Dr. James Woods **Date:** 09/25/2006

Organization : Dr. James Woods

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-297-Attach-1.DOC

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,

James H. Woods, MD

James H. Woods, MD
10400 West North Avenue, Suite 480
Milwaukee, WI 53226-2425
414-778-6670

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. Jolly Li **Date:** 09/25/2006

Organization : ASA

Category : Physician

Issue Areas/Comments

Impact

Impact

As the policy currently stands, anesthesiologists and other specialties face huge payment cuts to supplement the overhead cost increases for a handful of specialties. Anesthesiologists face a 10% cut in Medicare payment over the next four years due to changes in practice expense and work values. If payments are cut in 2007, Medicare physician payment rates will have fallen 20 percent below the government s conservative measure of inflation in medical practice costs in just six years. Potential SGR-related reductions, on top of further proposed cuts, could irreparably damage the medical specialty of anesthesiology.

The current SGR formula, based as it is on changes in the gross domestic product, has proven unworkable essentially because changes in economic growth have little to do with the demand for medical services or the increasing cost of delivering them.

The proposed change in PE methodology hurts anesthesiology more than most specialties, because the data that CMS uses to calculate overhead expenses is outdated and appears to significantly underestimate actual expenses.
CMS should gather new overhead expense data to replace the decade-old data currently being used.

CMS must address the issue of anesthesia work undervaluation or our nation s most vulnerable populations will face a certain shortage of anesthesiology medical care in operating rooms, pain clinics, and throughout critical care medicine.

Submitter : **Ms. Beth Pierpoint** **Date: 09/26/2006**

Organization : **One Nineteen Health & Wellness**

Category : **Other Health Care Provider**

Issue Areas/Comments

Background

Background

I oppose the changes that are being discussed for Bone Densitometry. This CPT has been set up to increase the initiative for Healthy People 2010, and restrictions to this service for payment will detrimentally affect the outcome of osteoporosis and the will increase the number of pathologic fractures that will occur as more people will not have the opportunity to seek out bone density as a screening tool.

The primary reason why they will not be able to receive screening is that bone density is some of the most under utilized modalities in free standing IDTF's. Our bone density machine performs around 35 scans per month. Cutting reimbursement will decrease the affordability for physicians to add those services, which will decrease the utilization of those services.

Fractures are far more costly than the Bond Denstiy Test, and even if the goal is to stop over utilization in physician offices, I see that the patient will suffer.

With the population aging I feel that this is a step in the opposite direction.

Impact

Impact

I would delay the DRA until there can be a more throrough and complete analysis using the appropriate technology.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Director of Clinical Services in an Independent Diagnostic Testing Facility.

Submitter : **Dr. Gerald Rogan** **Date: 09/26/2006**

Organization : **Rogan Consulting**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

IDTF issues See attachment

CMS-1321-P-300-Attach-1.DOC

CMS-1321-P-300-Attach-2.DOC

Attach 1F
300

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COMMENT TO CMS ON 1321-P

Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1231-P
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COMMENT TO: "IDTF Issues" CMS proposed rule 1321-P, for CY 2007

OUTLINE:

1. Financial Liability of the Supervising Physicians
2. Qualifications of IDTF Testing Personnel
3. Place of Service for G0248 and G0249
4. IDTF Surety Bond
5. IDTF Enrollment Fee
6. Review IDTF – Physician Contract Documents
7. Beneficiary Disenrollment from Medicare part B
8. Make No Payment for an IDTF Service that is Readily Available from Licensed Practitioners
9. IDTF Look -alike Physician Practices
10. CMS Comments to OIG Inspections
11. Exclude Payment for the PC and Global Fees
12. Monitor New IDTFs
13. Limit IDTF Services to Those Validated at Enrollment
14. Provide a Report of All Payments Made to an IDTF to Affected Parties

CMS states in its preamble to the proposed rule:

> *The actual growth of IDTFs is not a problem, however, the results of the OIG audit make it clear that we need to closely monitor IDTFs and establish standards to ensure quality care for Medicare beneficiaries.*

I support the recommendations proposed in **§ 410.33 of CMS-1321-P**. However, the proposals are not sufficient to safeguard the Program vulnerabilities identified in OIG report A-03-03-00002 and subsequent vulnerabilities discovered in several markets, including Los Angeles, CA and Miami, FL. CMS is using the DMEPOS supplier restrictions as a model for IDTF compliance assurance. However, several inspections by the OIG have shown the DMEPOS restrictions are not effective to prevent fraud and abuse. Therefore, additional recommendations must be developed and considered.

I have interviewed several HHS *insiders* and read several Medicare related publications to develop recommendations for your consideration. Additional comments are based on my personal experience as a Carrier Medical Director, and from attending ALJ hearings, working with federal and state law enforcement, the Medical Board of California, the California Department of Licensing and Certification, the California Radiologic Health Branch; as an officer of a hospital medical staff, officer and leader of professional societies, owner of a primary care medical practice, emergency room physician; and, currently from consulting to the medical industry and health care lawyers.

CONFLICT OF INTEREST STATEMENT:
I am a paid consultant to an IDTF company that provides INR support services but no diagnostic tests. I am a paid consultant to a diagnostic test manufacturer that eschews IDTFs. My comments are my own and are not subject to the approval of any client.

The basic principles guiding my comments are:

- IDTF providers, physician supervisors, and physician practices must be held financially accountable for their actions that could harm the Program.
- The only possible justification for IDTFs to exist is for beneficiary access.
- Beneficiaries must be held accountable for their actions that harm the Program by risking their opportunity to receive services under fee-for-service Medicare Part B.
- The advertising of Program vulnerabilities invites fraud.

An IDTF is a facility that provides diagnostic services that is independent of a hospital and physician office.[1] Its sole purpose is to provide diagnostic tests to patients whose conditions are treated elsewhere. The owner of the facility is not a licensed medical professional.

(b) ***Supervising physician.***

RECOMMENDATION #1: FINANCIAL LIABILITY OF THE SUPERVISING PHYSICIAN:

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1 http://www.medpac.gov/public_meetings/transcripts/042204_ASCs_AW_transc.pdf#search=%22IDTF%20payments%22

I support the proposed additional supervising physician requirements, including restricting a supervising physician to 3 IDTFs. The carrier must compile a physician supervisor data base to monitor compliance. However, even with an enforceable limitation, supervisory performance is not assured. Failure to provide adequate supervision is not a violation of medical practice act in some states (e.g. California) when patients are not harmed, and no other penalty against the physician applies. Physicians have not been held accountable for supervising fraudulent IDTFs. Physicians cannot be expected to monitor IDTFs without a penalty for failure to do so.

Reports have shown many IDTFs fail to comply with current anti-kickback laws as demonstrated by widespread beneficiary solicitation and payments to beneficiaries to submit to tests[2]. IDTFs and supervising physicians can violate CMS manual instructions such as by no physician supervision, billed services not performed, service performed but billed under an incorrect CPT code, fabricated test results, substandard quality of diagnostic services, inadequate pre-test patient evaluation, no follow-up on abnormal test results, use of diagnostic tests for screening purposes not covered by Medicare and not supported by scientific evidence, billing for unreasonable and unnecessary services, and other unacceptable behaviors. Ongoing compliance enforcement is necessary in addition to the new requirements in the proposed rule. Chasing overpayments documented by the OIG report and carrier presentations is not sufficient to safeguard the Program.

Because IDTF owners are can escape overpayment by changing business, and because physician supervisors are not liable for IDTF overpayments, no licensed medical professional at risk for overpayments. This is an unusual situation for Medicare.

To assure trust fund dollars are properly spent, I propose the following additional requirements and enforcement.

PROPOSAL #1: FINANCIAL LIABILITY OF THE SUPERVISING PHYSICIAN:

1) The Program shall hold the IDTF supervising physician liable for repayment of all Medicare payments made to an IDTF. If an overpayment is assessed, the supervising physician shall be jointly and severally liable to repay Medicare. The IDTF may purchase a surety bond from a CMS qualified bond company, in order to indemnify the physician from personal financial liability.
   a) All surety bond requirements listed elsewhere in these comments shall apply.
   b) The supervising physician must re-enroll in that capacity annually.
   c) The supervising physician shall provide to the carrier an initial and annual written attestation of acceptance of the supervising position, which shall include:
      i) A statement of supervisory responsibilities,
      ii) A complete list of each service to be supervised by CPT code,
      iii) Acceptance of financial liability for Medicare repayments, and
      iv) Related attestations sufficient to provide legal notice and liability.

[2] Comments from California Program Safeguard personnel

v) CMS shall consult with OIG and DOJ to assure the attestation is enforceable in court.

d) The supervising physician shall attest he/she provided supervisory services for all services billed by singing a periodic statement listing each specific patient service that had been billed by the IDTF which he/she has supervised.
   i) The attestation shall be kept on file and made available to the carrier for review upon request.
   ii) All claims billed to Medicare by the IDTF must be listed on the attestation.
   iii) The carrier shall deny or recover any payment made for a service not listed on an attestation.
   iv) The carrier may implement a method to review the attestation before making payment.
   v) The carrier shall audit the IDTF and supervising physician periodically to assure the supervisory requirements are met.

e) If a supervising physician does not fulfill the supervising requirements,
   i) The carrier shall audit at least 30 medical records of the personal practice(s) of the supervising physician,
   ii) The carrier shall audit all aspects of any other IDTF which employs or contracts with that physician for supervision or test interpretation, and
   iii) The carrier shall notify all other carriers of the supervising physician who is not compliant so that the other carriers may determine whether the supervising physician is providing IDTF supervisory services in other states, and if so, audit those IDTFs.

(e) ***Multi-State entities.***

RECOMMENDATION #2: QUALIFICATIONS OF IDTF TESTING PERSONNEL

I support these requirements. In a physician office, the respective States may specify the qualifications of the testing personnel incident to a physician. In the absence of a State requirement, the supervising physician must assure the auxiliary person who performs a test is qualified to do so. Typically, an auxiliary person who performs a service in a physician's office signs the service in the medical record so that the physician knows who performed the service. The same requirements are reasonable to impose on IDTFs. Therefore, I propose these additional requirements:

PROPOSAL #2: QUALIFICATIONS OF IDTF TESTING PERSONNEL

2) The proposed requirements shall apply to all IDTFs, including those operating in only one State, and for any IDTF operating in one or more State: (some of these requirements may already be in force)
   a) For any technician service that requires no state license or certification, the supervising physician shall attest in writing that the technician is qualified to perform each relevant test according to accepted standard of medical care.
   b) The attestation shall specify each diagnostic test the technician shall perform.

c) The IDTF shall include a copy of the attestation in its employment files and in its enrollment and reenrollment applications and, between application dates, shall be mailed to the carrier on or before the date a technician is hired.
d) For IDTF services, the carrier may specify additional technician qualifications for each test through the Local Coverage Determination (LCD) process (not applicable to physician office practices including IDTF "look-alike" practices).
e) The identification of the technician who performs the test shall be included on each test report the technician provides.
   i) The technician shall sign the report to attest his/her performance of the test above the typed or printed name of the technician.
   ii) If the test report is not available, the technician shall sign the test requisition above the typed or printed name of the technician.
   iii) The signature page shall specify the test that is performed, the date of the technical component of the test, the physical location where the technical component of the test is performed, and beneficiary identification.
   iv) The information shall be kept on file in the IDTF patient file and made available to the carrier for review upon request.
   v) The technician attestation shall be of sufficient nature to hold the technician legally liable for making a false statement.
   vi) The IDTF shall maintain in its employment file a signature page that the carrier may use to identify each technician signature.
   vii) If an IDTF is found to bill for services not provided, the carrier shall track each technician employed by the IDTF and audit any other practice or IDTF that employs that technician in that carrier's jurisdiction, and shall provide the technician's information to other carriers so they may track the technician.
f) The IDTF that provides X-ray services shall provide a State X-ray machine certification and operating permit to the carrier.

(e) (2) *The point of the actual delivery of services is the Place of Service on the claim form. When an IDTF performs a diagnostic test at the beneficiary's residence, the beneficiary's residence is the Place of Service.*

RECOMMENDATION #3: PLACE OF SERVICE FOR G0248 AND G0249

Two IDTF services are not diagnostic tests: G0248 and G0249. These services support patient self-testing of the International Normalized Ratio (INR) for anticoagulation management. The services are similar to DME services. The services are not the self-test itself. The services support the self-test. The location of the support services includes the IDTF location, the location of the beneficiary (which may vary at different time), the location of a mail carrier, and the physician's office (which may be more than one office if the patient has multiple residences). The self-test is performed wherever the beneficiary is located.

Optimum program safeguards is accomplished for G0248 and G0249 by allowing one carrier to receive all the claims for services an IDTF provides to all its beneficiaries in all carrier jurisdictions. Reporting all claims to one carrier will prevent duplicate billing and allow one carrier to tract all payments for each beneficiary.

PROPOSAL #3: PLACE OF SERVICE FOR G0248 AND G0249

3) Please clarify in the final rule that the place of service for G0248 and G0249 shall be the IDTF office, not the beneficiary's residence; and that an IDTF may service beneficiaries in other states from one location for G0248 and G0249 services.

(g) *Application certification standards.*

RECOMMENDATION #4: IDTF SURETY BOND

I support this standard, but it is not sufficient. Securing a comprehensive liability insurance policy is a sound business practice, but does not assure Medicare that the IDTF will repay Medicare when appropriate. The problem is a comprehensive liability insurance policy does not insure taxpayers should an IDTF steal Medicare Program funds. Other programs in Government are governed more closely so that potential losses are prevented. For example, in order to operate a motor vehicle, the California Department of Motor Vehicles requires one of the following types of financial responsibility:

- *Valid liability insurance policy, for damage to someone else's property or person;*
- *A $35,000 surety bond;*
- *A DMV issued self-insurance certificate;*
- *DMV acknowledgement of a $35,000 cash deposit.*

Violation results in suspension of one's driver's license.

By comparison an IDTF owner is enrolled in Medicare without providing any financial guarantee to Medicare to be honest. IDTF owners may invest less in their business than the cost of a vehicle, yet cause millions of dollars of damage to taxpayers. IDTF owners have disappeared and kept Medicare overpayments. CMS does not have the administrative funding from Congress to chase after them. Given the IDTF problems identified in OIG report and IPLs before that, additional Program safeguards are required to assure Medicare dollars are not lost though ineffective pay and chase, or failure to conduct effective pre-pay audits, such as by monitoring services on a beneficiary basis (episode grouper)[3]. Therefore, I propose the following additional requirements.

PROPOSAL #4: IDTF SURETY BOND:

4) As a condition of receiving and maintaining a provider number, each IDTF company must provide a surety bond (like a bail bond) that insures the Medicare Program against wrongful actions of the IDTF, including fraud.

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[3] See MedPAC Report to the Congress, June 2006.

a) The surety bond would assure IDTF compliance with all Medicare rules, regulations, and statutes.
b) When a Medicare contractor requires a provider to repay Medicare payments, the bond company or the IDTF shall make payment within the required time specified by the carrier, with any applicable interest.
c) If an overpayment demand is appealed, the bond company would be liable to repay the money with any applicable interest when the appeal is concluded.
d) The carrier shall monitor active coverage of the surety bond in the same manner as banks monitor homeowner's insurance coverage of its mortgage holders' homes.
    i) If the surety bond is cancelled, the surety bond company shall notify the carrier immediately.
    ii) When notified, the carrier shall stop all Medicare claim payments immediately, including IDTF claims in the system for payment for services provided before the expiration of the surety bond.
    iii) The carrier shall then secure a surety bond from a CMS designated bond company, similar to the methods banks use to provide homeowner's insurance when the homeowner does not.
    iv) The carrier shall apply all payments that otherwise would be made to the IDTF to pay for the surety bond.
    v) The carrier shall establish a surety bond administration section and fund its operation with IDTF enrollment fees.
    vi) The amount of the bond shall the greater of $300,000.00 or one-hundred fifty percent (150%) of the sum of the average of payment for each service the applicant intends to provide.
    vii) The carrier shall calculate the payment bond amount based upon:
        (1) Payment to all IDTFs in the same geographic area for each relevant service, using data from the most recent consecutive 4 quarters for which data is available,
        (2) The carrier shall have the discretion to choose a peer group of IDTF from a geographic area that includes several contiguous counties or a single zip code.
        (3) The carrier shall post on its web site the minimal surety bond requirement for each CPT code provided by an IDTF, and update the amount for each CPT code at least annually.
        (4) Payment for this service shall be from IDTF enrollment fees.
e) The surety bond must be in force and effect as a condition of issuing a provider number and throughout the period the provider number is active.
f) CMS shall establish a list of qualified surety bond companies.
    i) The IDTF provider must provide a bond from one of these companies.
    ii) CMS shall update the list of qualified surety bond companies quarterly.
    iii) CMS shall establish criterion for surety bond companies.
    iv) No owner of the surety bond company may be related to the IDTF owner, legally, financially, or through family ties.

(g) ***Application certification standards.***

RECOMMENDATION #5: IDTF ENROLLMENT FEE:
Medicare payments for IDTF services come from the Part B budget, which is subject to the sustainable growth rate calculation. The Part B budget includes payment for physician services. Payments to IDTFs for fraud, abuse, and waste reduce the funds available to pay physicians. The more money CMS pays to IDTFs, the less money CMS pays to physicians. Therefore, it is reasonable to compare the financial risks of physicians to IDTFs should Medicare be defrauded.

Physicians must invest substantial time and money to become a physician, become licensed, maintain the license, and maintain professional qualifications. IDTF owners are business laypersons who have no such requirements. A physician must renew his/her medical license periodically. In California, the required renewal is every 2 years and costs $790.00. Most states require continuing medical education (CME) for license renewal. Failure to comply with CME requirements carries substantial risk, including financial penalties for misstatements and employment risk. IDTF owners have no such requirements.

In California, the license fee is used to police the medical profession. Other professions pay fees which are used to police its industry. The Clinical Laboratory Improvement Act (CLIA) requires the clinical laboratory to pay a fee in order to perform clinical laboratory tests. CLIA fees are used to police clinical laboratories.

The State of California Department of Health Services Department of Licensing and Certification does not review IDTF facilities for compliance under California Health and Safety Code Sections 1200-1209, unless a complaint against a specific IDTF is filed. From my work with a national ultrasound credentialing organization, reportedly most State governments do not license or oversee ultrasound or MRI technical component providers. An IDTF owner pays no fees for licensure or oversight other than a standard municipal business license.

CMS has attested in the 2001 OIG report that it does not have administrative dollars available sufficient to police IDTFs. Various other deficiencies exist in the IDTF provider enrollment process, mostly due to carrier underfunding. CMS states in the preamble to its proposed rule:

> *Also, these IDTFs are growing at a rate faster than CMS can survey these facilities.*

Therefore, it seems reasonable to assess an enrollment fee from each IDTF provider applicant and an annual re-enrollment fee. This recommendation is patterned after CLIA fees and Medical Board licensure fees.

PROPOSAL #5: IDTF ENROLLMENT FEE:

5) IDTF shall pay an enrollment fee and annual reenrollment fee.
   a) If an IDTF fails to meet the enrollment or reenrollment requirements, the fee is not refundable.
   b) CMS shall use that fee to fund IDTF enrollment and compliance functions by the carrier.
   c) The enrollment fee is in addition to a surety bond.
   d) The amount of the fee shall be sufficient to administer the IDTF enrollment and compliance program across all states.
   e) CMS may allocate fee payments across carrier jurisdictions, because assurance efforts may have to be more robust in some jurisdictions.

(g) ***Application certification standards.***

RECOMMENDATION #6: REVIEW IDTF – PHYSICIAN CONTRACT DOCUMENTS:

Reports indicate IDTFs compensate physicians for referrals to IDTFs for testing. Contracts are created to give the appearance of compliance with anti-kickback statutes. Some contracts may not comply with the anti-kickback statutes. Enforcement of anti-kickback statutes against physicians and IDTFs has been deficient at times. Violations of anti-kickback statues are criminal, so the level of evidence required for a conviction is "beyond a reasonable doubt" which is more difficult to prove than under tort law: "preponderance of the evidence." It is appropriate to notify a supervising or referring physician when an IDTF contract proposal places the physician and the Program in jeopardy.

Other agencies of government do not assume a contract complies with federal rules without a review. An example is the IRS requirement for a predetermination letter to approve a qualified retirement plan. In addition, the SEC requires proper financial reporting by publicly traded corporations. Evidence shows physicians have been induced to participate in illegal referral schemes for compensation. Some of these physicians have been paid for the professional component of unnecessary IDTF tests when the lack of necessity should be abundantly clear to the interpreting physician. Some IDTFs pay referring physicians for unnecessary and duplicative test supervision.

In order for a physician to be licensed in a State, the physician must supply detailed evidence that all licensure requirements are met. An IDTF does not have to validate its business contracts are legal, so long as the physician is happy with the payment for referrals. Therefore, it seems reasonable to require contract compliance as a condition for payment of Medicare funds to an IDTF layperson owner.

PROPOSAL #6: REVIEW IDTF – PHYSICIAN CONTRACT DOCUMENTS

6) IDTF layperson providers must submit to the carrier a complete dossier of all contracts between the IDTF and all the physicians with whom the IDTF has a financial relationship, including supervising physicians, interpreting physicians,

physicians from whom the IDTF rents space, and, if applicable, physicians from whom the IDTF receives referrals.

a) CMS shall hire a CMS approved contract review contractor to review these contracts for compliance with federal laws and regulations.
   i) This contractor shall employ at least one lawyer specializing in contract law.
   ii) The contractor may post approved template contracts on its web site.
b) Before the IDTF may receive a provider number, the CMS contract review contractor must provide to the carrier an approval letter for each contract and a contract control number.
c) If the contract document is deficient, the CMS contract review contractor shall provide an explanation of the deficiency to the provider applicant and the carrier.
d) If an IDTF contract is found deficient, the CMS legal review contractor may review a revised contract on payment by the IDTF to the carrier of an additional 50% of the enrollment fee.
e) A current contract with original signatures of all parties must be supplied to the carrier with each annual re-enrollment.
f) If the contract is changed in any way, another review is required and the IDTF provider number is suspended until the new contract is approved.
g) In order to avoid a disruption in service, during the contract year, the IDTF provider may submit a new contract to the carrier for approval in advance of the contract anniversary, and secure pre-approval.
h) For late filing of contracts, an established IDTF may continue to be paid for no more than 1 month based on carrier discretion.
   i) Services provided during a period when payment is denied will be covered if the IDTF successfully renews its provider number within the time available to appeal a denied claim.
   ii) CMS shall encourage the carrier to review the IDTF claims data prior to exercising late filing discretion.
i) The IDTF shall be assessed a fee for each contract review and approval, in addition to the enrollment fee and bond requirement. The fees shall cover the entire cost of the contract review service.
j) The findings of the CMS contract review contractor shall be sent to all parties who sign each contract.
k) The opinion of the CMS contract review contractor may be appealed to the office of the inspector general for a compliance letter.
l) CMS shall select its legal contractor under the guidance and approval of the OIG and DOJ.

(g) ***Application certification standards.*** (5) I support the business phone requirement. Investigators have had difficulty contacting IDTF providers. Enforcement may be assured through other recommendations proposed herein.

(g) ***Application certification standards.***(7)

RECOMMENDATION #7: BENEFICIARY DISENROLLMENT FROM MEDICARE PART B.

I agree support this solicitation prohibition, but it is not sufficient to stop IDTF solicitation of patients.

Evidence shows the beneficiaries have participated in schemes to defraud Medicare, even if unintentional.[4] For example, beneficiaries have been paid to receive a diagnostic test, provide confidential Medicare billing information, answer personal health questions, but not receive test services. Some beneficiaries have been tested but know or reasonably could be expected to know the test, if performed is not used to manage a medical problem. From the time money was invented, it has been almost impossible to police a financial solicitation and cash payment between willing parties. The Medicare benefit is a covenant between the beneficiary and the taxpayer. It is reasonable to hold the beneficiary accountable for an improper response to an IDTF solicitation that facilitates payment for a non-payable service. CMS should assume solicitation payments will not be discovered. CMS should also assume some beneficiaries will not call Medicare when they receive an EOMB that shows Medicare payment was made for a service that was not performed.

PROPOSAL #7: BENEFICIARY DISENROLLMENT FROM MEDICARE PART B.

7) When more than 20% of services provided to a beneficiary by an IDTF or a physician office are found non-payable on post-pay review, the carrier may assume the beneficiary received consideration to support the provision of an unnecessary service or fraud.
   a) CMS may limit payment for Medicare Part B services for that beneficiary to services provided in facility based places of service (e.g. hospital outpatient) or through an HMO.
   b) CMS need not show that the beneficiary received valuable consideration from the provider for cooperating with a provider to receive an unauthorized or improper Medicare payment.
   c) The beneficiary limitation shall apply for a minimum of one year.
   d) If the beneficiary returns to fee-for-service Medicare Part B, and the problem recurs, CMS may make the limitation permanent.
   e) The beneficiary may appeal a limitation to an ALJ.
   f) The beneficiary enrollment process shall set forth this new limitation in English and, if applicable, in the native language of the beneficiary.
   g) CMS shall provide a dedicated confidential hot line that beneficiaries may use to report providers who offer valuable consideration in exchange for an office visit, diagnostic service, of other Medicare benefit.
   h) In circumstance when the beneficiary co-operates with the carrier to recover and/or law enforcement to indict an unscrupulous or fraudulent provider, or

[4] Communication from Program safeguard specialists.

recover overpayments administratively, the DOJ or CMS respectively may waive the Part B limitation for that beneficiary.

i) Medicare carriers shall be instructed to follow data of beneficiaries using episode grouper methods described by MedPAC.

(g) ***Application certification standards.*** (10) I support the financial disclosure requirement. However it is not sufficient to protect the trust fund. To assure compliance, a surety bond should also be required. The recommendation is above. Also, CMS should not expect an IDTF owner who has defrauded Medicare or received payment for unnecessary services to offer this information. CMS should assume that ownership, financial, control, and legal information that will impair enrollment will not be disclosed. To offset this expectation, the provider enrollment staff must include suitably trained investigators with a robust data base. The IDTF enrollment application can fund this provider enrollment investigation.

(g) ***Application certification standards*** (11), (12), (13), and (14). I support these requirements, but they cannot be enforced without additional funding of compliance officers. Therefore, I recommend a provider enrollment fee and reenrollment fee.

(h) ***Failure to meet standards.*** I support this requirement, but it is not sufficient to protect the trust fund. Annual reenrollment should be required. Physicians must renew their license every 2 years in some states. The Department of Motor Vehicles requires renewal of vehicle registration annually. IDTF owners have no medical training and no professional license requirements. Given the problems with IDTFs and IPLs before that, careful monitoring on an annual basis is reasonable and recommended.

(h) ***Failure to meet standards***

RECOMMENDATION #8: MAKE NO PAYMENT FOR AN IDTF SERVICE THAT IS READILY AVAILABLE FROM LICENSED PRACTITIONERS

In the preamble to the proposed rule CMS states:

- *Moreover, we emphasize that services provided by an IDTF are also readily available to beneficiaries through other avenues such as physicians' offices, outpatient laboratories, outpatient radiology facilities, and outpatient clinics.*

- *The increased rates of utilization within IDTFs is likely to be unrealistic due to an increase in the need of diagnostic testing within California's Medicare population.*

- *The increased use of IDTF services has not lowered the use of diagnostic testing within other settings.*

- *Moreover, in recent years, CMS and its contractors have determined that a number of IDTFs in California and other States are perpetrating schemes to defraud the Medicare program.*

OIG report A-03-03-00002 shows 56% of IDTFs complied with Medicare rules, 42% did not. It also shows 68% of IDTF services were non-compliant, and 87% of IDTFs did not comply with the initial enrollment application and subsequent update requirements. The OIG estimated a total extrapolated overpayment of $71.5 million. The sample size was 682,950 beneficiaries. In 2001 the fee-for-service Medicare population was about 32 million. The OIG sample was 2.1% of the total. Assuming the IDTF non-compliance rate is the same for the 43 jurisdictions not sampled, the total loss to the Program in 2001 was $3.4 billion.

However, other data shows in 2002 Medicare spent about $740 million for IDTF services including the beneficiary co-pay of 20%.[5] The OIG report A-03-03-00002 suggests 68% of IDTF services are not compliant. This suggests Medicare wastes $503 million on IDTF services annually, or about 1.0% of Medicare B spending for physician services.

In 2002, imaging procedures accounted for about 85 percent of all IDTF spending, or $630 million. IDTFs accounted for about 8% of the total spending for medical imaging. Between 2000 and 2002 medical imaging increased 27%: much faster than other Medicare services. Spending for the portion of imaging services provided in IDTFs grew more than three times as fast during this period.[6] Other common IDTF tests are electrocardiograms, cardiac stress tests, and neurodiagnostic studies including anal manometry. During my 25 years of practice in family and emergency medicine in various locations in California, none of my patients ever needed an IDTF for any service. Medical imaging and cardiac tests are readily available from hospitals and physician offices, as are all the other diagnostic tests IDTFs provide, excepting perhaps anal manometry.

Some IDTF services include cardiac catheterization services. Does CMS continue to have a reason to pay non-licensed persons to control the facility that provides these services? CMS should revisit these IDTFs to determine if these businesses can be organized under practitioner or hospital ownership, instead of layperson ownership. Based on the lack of IDTF compliance and findings from audits of IDTF supervising physicians, which motivated CMS to propose to restrict a physician supervisor to 3 IDTFs, CMS cannot rely on physician supervision to assure IDTF compliance. Even worse is the risk non-

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[5] Notes from a 2004 MedPAC public meeting
http://www.medpac.gov/public_meetings/transcripts/042204_ASCs_AW_transc.pdf#search=%22IDTF%20payments%22

[6] Ibid.

licensed persons bring to the program should profits supersede a minimal professional standard imperative.

Congress and taxpayers have gone to great lengths to assure Medicare beneficiaries have access to necessary and reasonable medical care. The IDTF provider type is the only Part B provider type that is not licensed to practice medicine in some form, with the possible exception of a slide preparation facility.[7] An IDTF may be owned by a business person who is not licensed to practice medicine, is not trained in any medical service, and provides service in order to make a profit from the tests performed by employed personnel. This layperson provider shares in the Medicare Part B benefit dollars that otherwise are earmarked for practitioner services. IDTFs and, before them IPLs, have clearly demonstrated a high percentage of non-compliance. Payment to layperson providers for diagnostic services under the Part B medical benefit has been a failure for 10 years, and diminishes the payment for services licensed medical practitioners provide. The California Medi-Caid program does not pay IDTFs. CMS should check with private insurers to determine if any pay IDTFs for any service and why.

CMS should revisit the reason IPLs were established. The only possible justification for IDTFs to exist is for beneficiary access. CMS should document the need for this access in each carrier jurisdiction as a condition of continued coverage for IDTF providers, and for each specific service.

In California, State law does not allow IDTFs to exist as a provider type for any insurance program and for any patient; yet NHIC, the California contractor pays them anyway. The California Medical Association (CMS) explained this restriction in a July 21 letter to Mr. Jeff Flick at the CMS San Francisco Regional Office. The California Medicaid program does not recognize IDTFs as a provider type.

Under 42 C.F.R. § 410.33(f), Medicare requires an IDTF to "comply with the applicable laws of any State in which it operates."

> *(f) Applicability of State law. An IDTF must comply with the applicable laws of any State in which it operates.*

Therefore, even if CMS does not wish to eliminate IDTFs throughout the country, it must comply with 42CFR410.33 and, in conjunction with California authorities, instruct its carrier, NHIC to take appropriate corrective action, by not paying and IDTF for a diagnostic service. The only service an IDTF provides that is not diagnostic is G0248 and G0249. IDTFs that provide this service do not violate California state law because no medical service is provided: only training, equipment, and supplies similar to DME.

Medicare assigns to carriers the authority to determine which self-injectable drugs is a Medicare benefit. CMS determines which surgical assistant services is a Medicare

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[7] CMS-855B

benefit. CMS determines which surgical procedures may be provided in an ambulatory surgery center. Congruently, CMS through its carriers should determine which IDTF services shall be made available in a local jurisdiction, when State law permits IDTFs to exist. The determination should be based only upon documented beneficiary need for access to care, not on a layperson's need to make a profit from Medicare. The Medicare program is designed to support beneficiaries, not create full-employment for a layperson provider which category includes a high and increasing percentage of fraudsters.

Some IDTF owners are very clever. A common fraudster scheme is when a mobile IDTF pays the referring physician for a supervision service that requires only general supervision which is already provided by another physician who is registered with the carrier on Form 855B. The physician may think the payment for supervision is appropriate if he/she confuses the direct supervision requirement for an incident to test with the general supervision requirement of an IDTF test, where applicable.

Payment to the referring physician for unnecessary and duplicative supervision seems to be a payment for referral. The IDTF payment for the referral can motivate the referring physician to order unnecessary tests. The OIG reports 87% IDTF non-compliance with Form 855B. Might an IDTF also perform more tests than are needed if the carrier is not looking closely, particularly since the principal reason for the business is to make a profit?

When a referring physician is paid to provide supervision, but is not qualified to supervise, does not supervise, is not registered with the carrier to supervise, or duplicates the (general) supervision provided by another IDTF contracted physician, any IDTF payment for supervision by the referring physician may be considered a payment for the patient referral which may be illegal under 42USC§1395nn ("Stark anti-referral law). The argument would be that payment for a physician supervisor who is unqualified, not performing the service, not registered, or duplicative is not an arm's length/fair market value transaction required under the statue. The IDTF would not pay the referring physician but for the value of the referral. The supervisor role of the referring physician would be a hoax.

Similarly, an unscrupulous mobile IDTF can leverage this confusion to persuade the referring physician not to purchase a test and not to provide the test directly, in favor of securing a referral of the test to the IDTF. The mobile IDTF may rent testing space from the referring physician to perform the test, pay the referring physician rent and for unnecessary supervision. When a carrier IDTF LCD requires a specialty qualification for the interpreting physician, a primary care physician may be led to believe incorrectly that he/she cannot perform the interpreting service if the test were performed incident to. Because both an IDTF LCD and a separate LCD governing the test can coexist, the physician can confuse the IDTF rules with the incident to rules. The IDTF may convince the primary care physician that an IDTF must provide the test to comply with misrepresented physician office incident to testing rules.

The OIG reports show that often Medicare makes payment to a layperson for a medical diagnostic service that is not reasonable and necessary to diagnose or treat an illness or injury. This is not surprising since IDTF owners are laypeople who have no training to understand when medical diagnostic tests are reasonable and necessary.

The time has come for CMS to revisit the entire paradigm of IDTF providers. CMS should restrict IDTF services to locations only where absolutely necessary to assure beneficiary access to tests, and then heavily regulate them and robustly enforce the regulations. Continued payment of Medicare funds to laypersons, in States where it is not illegal, should demand a compelling beneficiary need that is well documented and available for the public to review.

Based on evidence in the OIG report and the narrative in the CMS proposed rule, IDTFs have not been held accountable, cannot be held accountable, and have, therefore, diminished the Medicare Program. The impairment includes chronic underfunding of physician services, particularly primary care physician services for evaluation and management of a patient's illness, injury, or deformity; and overpayment for imaging services. Proper evaluation and management is a necessary requirement before determining whether or not a diagnostic test is reasonable and necessary. IDTF documentation often shows frequent absence of proper evaluation and management.

CMS' support of the IDTF provider type sets a terrible precedent for the Medicare program and for the Medical profession as a whole. CMS is stating that it supports tests controlled by and paid to laypersons in favor of evaluation and management services performed by and paid to licensed physicians. CMS discounts the value of thinking in favor of testing. This implicit communication, easily understood from CMS's tolerance of IDTF fraud is destructive and must stop.

PROPOSAL #8: MAKE NO PAYMENT FOR AN IDTF SERVICE THAT IS READILY AVAILABLE FROM LICENSED PRACTITIONERS

8) Restrict the services IDTF providers may supply to those services not otherwise sufficiently available to Medicare beneficiaries from other provider types in each carrier jurisdiction.
   a) If all IDTFs together in a carrier jurisdiction provide less than five percent (5%) of the total services of all provider types for a specific CPT or HCPCS code in a carrier jurisdiction, the carrier shall not cover an IDTF provider type for that service. This recommendation is patterned after the method CMS uses to determine which surgical assist services are covered by Medicare and after the method carriers use to determine whether or not an injectable drug is a benefit of Medicare Part B in that jurisdiction.
   b) When a carrier finds the IDTF provider type coverage requirement appears met for a particular service (the IDTFs collectively provide ≥5% of a specific service to Medicare beneficiaries in that jurisdiction), the carrier shall audit a random sample of medical records of all the IDTFs in its jurisdiction for that service.

i) The carrier shall exclude from the calculation those IDTF services that fail to meet all Medicare payment requirements, subject to appeal by the IDTF.
ii) The carrier review shall require affirmative evidence that all physician supervision requirements are met and documented.
iii) For example, if all IDTFs in a jurisdiction collectively provide 10% of CPT code 95900, but on post-pay review only 32% of the 95900 services provided by IDTFs are payable, then the IDTF will have provided less than the 5% requirement.
(1) The services found not payable, after any proper appeal, shall be subtracted from the numerator and the denominator for the purpose of the calculation.
(2) The carrier may assume that the services paid to all other providers in the denominator are proper and need not be audited.
(3) In this situation, 95900 would not be covered in that carrier's jurisdiction when provided by any IDTF.

c) The implementation of these proposed restrictions will improve the quality of services provided to Medicare beneficiaries by all providers without any associated beneficiary access limitations, because the need for IDTF services will be measured in each carrier jurisdiction.
d) By implementing these standards, the oversight to control an acceptably high rate of fraud, abuse, and waste will be reduced.
i) The funds lost to the program may be retained for patient care, instead of lost to "pay and chase" of persons who are not licensed individuals.
ii) The funds available to laypersons, motivated by profits to induce physicians to support fraud, abuse, and waste will be reduced.
iii) The funds not paid to laypersons may be used to pay physicians to provide direct patient care, including funds needed to determine whether or not a beneficiary needs a diagnostic test.

RECOMMENDATION #9: IDTF LOOK-ALIKE PHYSICIAN PRACTICES

NHIC has identified physician practices that behave like IDTFs. The principle services provided are diagnostic tests. Beneficiaries are solicited to come to a physician's office, see a physician extender, help create a medical record for physician review, and receive several diagnostic tests that are not reasonable and necessary. The "incident to" requirements for physician supervision are not met. Sometimes the tests performed are not provided. Sometimes the carrier discovers services billed are not performed, and sometimes not.

Based on information received from case reviews, there is reason to suspect some of these IDTF look-alike physician practices are owned in whole or in part by laypersons. Layperson ownership of a physician practice is illegal in California. Under Business & Professions Code §§2052 and 2400, California law broadly prohibits lay individuals, organizations, and corporations from practicing medicine. This prohibition generally

prohibits lay persons or entities from hiring or employing physicians or other health care practitioners, from otherwise interfering with a physician or other health care practitioner's practice of medicine, or from engaging in the business of providing health care services indirectly by contracting with health care professionals to render such services. In addition, the Moscone-Knox Act (Corporations Code §§13400 *et seq.*) specifically prohibits persons other than certain health professionals licensed under their respective licensing boards, from becoming shareholders or directors of corporations engaged in rendering medical services. For additional information *See* Corporations Code §13401.5; *Marik v. Superior Court*, Cal. App.3d 1136, 1139 236 Cal. Rptr. 751 (1987).

Two physicians who have been subject to Medicare repayment demands in excess of $500,000 have told me laypersons in their clinics direct physician assistants who work in these offices to order unnecessary tests on Medicare beneficiaries, some of whom are paid to come to the clinic. Some of these laypersons are in jail. The doctors who comply with this arrangement have been subject only to administrative recovery of some of the Medicare payments and continue to practice medicine elsewhere. Unnecessary payments made outside the audit period are not recovered. The Medicare contractors have not been able to control the hemorrhage of Medicare funds. It appears the physician is used by the look-alike clinic investor to provide cover from an allegation of violation of the medical practice act and finds a way to share in the profits from unnecessary and unreasonable tests, usually 3-7 performed during each unnecessary visit.

Recovery of overpayment is subject to appeal under the question of medical necessity. While some sponsors of these clinics may go to jail, the physician is generally subject to administrative recovery only. When an overpayment is assessed, the carrier may not follow the physician to other practices to obtain recovery of funds that are paid to the physician for Medicare services for other beneficiaries through another practice.

Several associated independent physician specialists may assist the clinic by providing unnecessary professional services including blood tests, medical imaging interpretation, cardiac test interpretations, nerve conduction interpretations, and other tests. Some of these interpreting physicians have been disciplined by the Medical Board of California. These operations are equally unacceptable as those identified by the OIG for IDTFs.

For these physician office schemes, CMS should take action by applying the same restrictions proposed for IDTFs, with special adjustments appropriate when the payment is made to a physician as opposed to a layperson.

PROPOSAL #9: IDTF LOOK-ALIKE PHYSICIAN PRACTICES SURETY BOND

9) For primary care physician practices that act in the same manner as IDTF providers, Medicare shall require a surety bond. The "same manner" is behavior that suggests the principle income (e.g. >50%) of the primary care practice is through provision of diagnostic tests by the physician practice or in conjunction with IDTFs that provide services in the physician's office and bill under the IDTF provider number.