



342 North Main Street
West Hartford, CT 06117
PH: 860.586.7563
Fax: 860.586.7550
www.ISCD.org

August 27, 2008

Kerry Weems
Administrator Designate
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1403-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1403-P Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; Proposed Rule

Comments to be offered on:

- 1. Proposed Rule Section II. (I) - Independent Diagnostic Testing Facility (IDTF) Issues**
- 2. Proposed Rule Section II. A (2) (b) - Equipment Time-In-Use (Utilization Rate)**
- 3. Proposed Rule Section II. A (2) - Undervalued Reimbursement for Osteoporosis Testing**

Dear Mr. Weems:

The International Society for Clinical Densitometry (ISCD) welcomes the opportunity to comment on the CMS proposed rule 1403-P: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; Proposed Rule, published in the July 7, 2008 Federal Register.

The ISCD is a multidisciplinary nonprofit professional society whose mission is to enhance knowledge and quality of skeletal health assessment among health care professionals. It seeks to educate clinicians and technologists, increase patient awareness and access to bone densitometry, and to support clinical and scientific advances in the field. Presently, there are over 5,500 members (60% clinicians, 40% technologists) in 70 countries, 90% who practice in the United States. Membership spans more than 20 health care disciplines, including internal medicine, family practice, pediatrics, gerontology, gynecology, rheumatology, endocrinology, orthopedics, radiology and nephrology.

We will address three areas of this proposed rule: Independent Diagnostic Testing Facilities (IDTF's), equipment time-in-use, and reimbursement for osteoporosis testing.

1. Proposed Rule Section II. (I) - Independent Diagnostic Testing Facility (IDTF) Issues

Issue

The proposed rule, CMS-1403-P, would require physicians performing diagnostic imaging services in their offices to enroll as an IDTF and comply with certain standards to be eligible for Medicare reimbursement.

ISCD Recommendation

The International Society for Clinical Densitometry (ISCD) is opposed to recommendations proposed in CMS-1403-P that would require physicians providing diagnostic imaging services in a non-facility setting to comply with regulations that already exist for Independent Diagnostic Testing Facilities (IDTFs). As drafted, this proposal would not ensure quality testing for bone mass measurement (specifically dual energy X-ray absorptiometry or DXA) and would further restrict access to DXA testing at a time when osteoporosis remains under recognized despite multiple Federal initiatives to increase DXA testing. However, If CMS is determined to enact a regulatory scheme for these imaging services in physicians' offices the Agency should establish uniform nation-wide criteria to ensure competency both for physicians and non-physician personnel. Competence for the physician should not be based solely upon their specialty, but by demonstration of training in specific skill sets unique to the imaging service being utilized. Specifically for bone densitometry and DXA testing, an ISCD certification program for physicians currently exists. For non-physician technologists, certification by either ARRT or ISCD represents the two options currently available.

The Argument against Adoption of the IDTF Proposal

The intent of 42 CFR 410.33, was to regulate imaging procedures performed in a facility (IDTF), whose sole function is to provide imaging services separate from a therapeutic patient-care setting. Accordingly, the Agency passed a rule, among other things, imposing licensure and certification requirements for non-physician personnel in an IDTF. It also required an IDTF to designate a qualified supervising physician for each diagnostic test.

While the requirement of a qualified supervising physician is commendable, of substantial concern is the manner in which carriers have implemented the existing IDTF regulations, 42 CFR 410.33 as it applies to DXA testing. In the states where carriers have adopted local coverage determinations, over one-half have required that the supervising physician be a radiologist, and in most other states, the carriers only allow the supervising physician to be a radiologist or an internist. Additionally, ISCD technologist certification is not recognized by a vast majority of the local Medicare carriers. Thus the proposed rule, if applied to the non-facility setting in the form currently existing for IDTFs, would exclude a substantial, and highly skilled portion of the provider community by disallowing reimbursement to many appropriately trained and ISCD certified physicians and non-physician technologists. (See below for a more detailed description of the ISCD certification program for physicians and technologists). As such, this regulatory scheme does not make sense when superimposed in a wholesale manner on DXA testing performed in physicians' offices. Therefore, the ISCD is opposed to applying parts of the existing regulatory scheme designed for independent diagnostic testing facilities (IDTF's), 42 CFR 410.33.

It is important to emphasize that adoption of 42 CFR 410.33 as it would apply to bone density testing in the non-facility setting creates significant problems as follows:

1. By restricting reimbursement to supervising physicians who are radiologists and /or internists, the proposed rule would **limit availability of DXA testing at a time when osteoporosis is reaching epidemic proportions. Such restriction is directly at odds with Federal initiatives actively promoting DXA testing to improve osteoporosis recognition among Medicare beneficiaries.** Currently, two-thirds of DXA testing is performed in the non-facility setting. This essential preventive service is performed by a diverse group of physicians; based on 2006 CMS claims data radiologists perform only 24% of DXA studies. The majority of DXA studies are performed by primary care physicians (family practitioners, internists, and gynecologists) and skeletal health experts (rheumatologists and endocrinologists). This is in stark contrast to advanced diagnostic imaging (e.g., MRI, PET and CT scans) which is performed almost entirely by radiologists. **Disqualification of many qualified current providers from performing DXA testing would severely restrict access to this essential test.**
2. The CMS proposal would be expected to create regional disparities within the US in the definition of who could be a supervising physician for DXA testing. The current proposal would default to the local Medicare carrier's criteria. Based upon existing IDTF experience where carriers have addressed this issue, DXA testing would be limited to radiologists or, less frequently, radiologists and internists. In addition to excluding internists from being a supervising physician in over half of the states, the proposal would also exclude other qualified subspecialists who are certified as internists (e.g., rheumatologists, endocrinologists and geriatricians). The new proposal would exclude qualified physicians that routinely perform DXA studies who are neither internists nor radiologists (e.g., family practitioners and gynecologists) in the vast majority of states.
3. Additionally, the proposed rule **creates a dichotomous system** in which non-physician personnel are appropriately required to demonstrate "training and proficiency as evidenced by licensure or certification by the appropriate State health or education department...or by an appropriate national credentialing body". However, the supervising physician's proficiency is simply based on certification in a specific medical specialty. Such an approach does not guarantee competence in the diagnostic test being regulated.
4. Finally, it would appear that the proposed rule is soliciting comments on an issue that has recently been considered and resolved by Congress:
 - (a) The recently enacted Improvement for Patients and Providers Act of 2008 (Public Law No: 110-275) addresses the qualifications of non-physician personnel and the qualifications of supervising physicians providing **advanced diagnostic imaging services**. This law was adopted in July 2008 about two weeks after CMS published this proposed rule. Congress has made a clear determination that, at this time, credentialing requirements to ensure quality in diagnostic testing under Medicare should apply only to advanced imaging services.

(b) The new law, cited above, determines competency demonstrated by the credentialing and certification of physicians. The CMS rule appears to conflict with this new law by determining physician competency base solely on clinical specialty.

The Case for ISCD Certification Programs

If CMS should decide to regulate all imaging services, then we urge the Secretary to publish an annual, modifiable list of acceptable certifying organizations that meet certain criteria to ensure quality diagnostic testing. The Medicare Payment Advisory Commission (MedPAC) supports this concept in its March 2005 Report to Congress stating "... CMS should develop criteria that are flexible enough to allow physicians of different specialties to receive payment for interpreting imaging studies. Similar to the requirements set by private addresses accreditation organizations for interpreting physicians, Medicare's standards should be based on some combination of physician training, experience, and continuing education." (MedPAC Report to the Congress: Medicare Payment Policy, March 2005, page 162) Further, in the same report, MedPAC concurs that Medicare should not "limit payment [for imaging services] to specific specialties". (MedPAC Report to Congress: Medicare Payment Policy, March 2005, p.162). It is clear that the Agency should be responsible for setting the standards as opposed to leaving it up to carrier implementation which has resulted in disparate reimbursement policies for the same imaging services.

In the case of DXA testing, ISCD certification programs meet rigorous standards and therefore services provided by these qualified individuals should be reimbursed regardless of specialty. Improving and insuring quality in skeletal assessment of skeletal health is at the heart of our organization. The Society seeks to educate clinicians and technologists, increase patient awareness and access to bone densitometry, and supports clinical and scientific advances in the field. CMS recognized the ISCD as a leading resource in the December 2006 Revisions to the Bone Mass Measurement Act. (Fed. Reg. Vol.71, No.62, p.49060 (Aug.22, 2006)). The ISCD certifies both physicians and technologists in central DXA acquisition and interpretation. Since its inception in 1996, the ISCD has certified thousands of technologists and physicians in the United States. Currently, there are 11,769 clinicians and technologists holding ISCD certification.

For technologists, the ISCD is in the process of applying to the National Commission for Certifying Agencies (NCCA), the accreditation body of the National Organization for Competency Assurance (NOCA). Technologists applying for certification must pass a closed-book examination covering the following topics: osteoporosis, basic science of bone densitometry, device operation principles, x-ray science, radiation safety and quality assurance, quality control, computers in bone densitometry, anatomy in bone densitometry, patient care in the bone densitometry lab, patient positioning, scan acquisition, scan analysis, results and interpretation, clinical management of the osteoporotic patient, evaluating DXA scans and vertebral fracture assessment.

Technologists who have passed the written exam recognized as Certified Bone Densitometry Technologists (CBDT) for a 3-year period. ISCD assures that CBDTs keep their skills up to date and maintain their awareness of important developments in

the field of bone densitometry by requiring applicants for recertification to fulfill a continuing education requirement of 35 hours during the 3-year certification period.

For physicians, the ISCD also maintains a professional certification in the field of bone densitometry, with a designation of Certified Clinical Densitometrist (CCD). The certification program for clinicians is the only one of its kind in the United States and is designed to achieve the highest level of quality in the interpretation of bone density scans. This program is designed specifically for physicians, nurse practitioners, and physician assistants who interpret bone densitometry examinations and meet specified knowledge requirements through a standardized testing process. This exam covers the principles and concepts of bone density testing including basic science of bone densitometry, device operating principles, x-ray science, radiation safety, quality assurance, clinical utility of bone densitometry, use of bone densitometry for diagnosis of osteoporosis, assessment of fracture risk, and monitoring with bone densitometry.

Request

ISCD requests that CMS not apply the IDTF regulations to imaging services performed in physicians' offices. If CMS should determine that a regulatory scheme is necessary, the ISCD urges CMS to adopt the philosophy and framework of the recently enacted law: to ensure that competency is determined based on physician training, education and experience rather than clinical specialty and to publish an annual modifiable list of certifying organizations for both physicians and non-physician personnel.

2. Proposed Rule Section II. (A) (2) (b) – Equipment Time-in-Use (Utilization Rate)

Issue

CMS is proposing a change in equipment utilization for two CPT codes (93012 and 93271) by decreasing the previously assigned equipment utilization rate from 100 percent (at the standard rate of 525,000 maximum minutes of use) to the standard utilization rate of 50 percent (at the standard 525,000 maximum minutes of use). The proposed rule corrects a previous determination by CMS that set the utilization rate for these services at 100%---a deviation from the 50% rate CMS generally assigns to other services.

ISCD Recommendation

ISCD requests that CMS adopt a 13% utilization rate for DXA, a preventive health service which utilizes equipment designed to diagnose and treat a single disease. Consistent with the findings of the Lewin Group study, the 13% will more accurately reflect the actual utilization rate of this service. (See Attachment A)

Argument

The initial determination by CMS to deviate from the standard utilization rate reflects a policy that ISCD strongly endorses-- to assign utilization rates in a more targeted and accurate manner. Despite the fact that CMS subsequently determined that the standard utilization rate was more appropriate for these two CPT codes, we urge CMS to continue down the path of assigning utilization on a case by case basis rather than applying the uniform 50% to all services. This will result in a more precise assignment of equipment time in use which will translate into more appropriate reimbursement rates

for those services. **The current CMS practice of applying a standard utilization rate for all procedures results in distorted reimbursement rates, in particular for equipment that has a far lower utilization rate than 50%.**

We agree with the AMA's RVS Update Committee (RUC), which recommended on several occasions that the existing 50% standard utilization rate for all equipment should be changed as it is not an accurate measure of equipment time in use. ISCD also concurs with the RUC recommendation that CMS should permit specialty societies to provide clinical or geographic evidence to support more accurate utilization rates.

A more precise assignment of the amount of time equipment is actually in use is particularly critical in the case of services using equipment to diagnose and treat a single disease that may tend to have lower utilization rates. **Given that CMS has already deviated from the standard assignment of the 50% utilization rate in other cases, we urge CMS to substitute the actual utilization rate of 13% for DXA for the current 50%. The ISCD further requests that CMS establish and publish clinical or geographical criteria/guidelines necessary for specialty societies to support the assignment of more accurate utilization rates.**

It is important to note that the 50% utilization rate used by CMS is not based upon survey data, but was provided as an estimate by consultants to the Agency. CMS continues to apply this rate to almost all procedures including advanced diagnostic imaging services. In a recent MedPAC report (MedPAC, Report to the Congress: Increasing the value of Medicare, 2006), MRI machines were found to have a utilization rate of greater than 90% and CT machines a utilization rate of greater than 70%.

In contrast to the advanced diagnostic testing instrumentation noted above, DXA is a lower cost single disease state preventive procedure. Unlike other high volume procedures where patients are referred to dedicated imaging centers, DXA is frequently performed by primary care physicians, family practitioners, gynecologists, rheumatologists and endocrinologists and offered as point-of-care service. This type of care has been the driving force behind the much-needed increases in osteoporosis screening rates over the past decade. While offering testing in the physician office setting has helped to increase screening rates by making testing more convenient, volume in the office setting will tend to be lower than in imaging centers. Volume will also be lower for a preventive service aimed at diagnosing a silent disease, such as osteoporosis, where patients who are asymptomatic are not motivated to be tested. Low volume preventive services such as DXA, should not be penalized by a formula weighted to favor high volume diagnostic services. Instead, CMS should encourage physicians to continue to provide this valuable service in their offices by ensuring the reimbursement is fair and accurately reflects the cost of providing the test.

The recent Lewin Group study determined the non-facility DXA utilization rate to be 13%. This study also found the operational minutes for DXA to be 131,340 as opposed to the 262,500 that CMS uses. Conducted in July of 2007, the Lewin Group study was based upon 163 complete surveys from physicians from 8 specialties. Primary care comprised 39% of respondents, while rheumatology accounted for 37%, endocrinology 13%, and radiology 3%.

An important part of the CMS mission is to increase access to critical preventive services. Unfortunately, DXA continues to be under utilized with only approximately 12% of female Medicare beneficiaries receiving this test in 2007. Moreover, as a result of the recent ~40% cuts in DXA reimbursement resulting from the most recent 5 year review, DXA is an undervalued service, further undermining the mission to increase preventive service access. Specifically, the aforementioned Lewin Group Study found the median cost to perform a DXA study to be \$134.13, as opposed to the \$75.00 reimbursement rate for 2009. At the 2008 reimbursement rate of approximately \$81, only 14% of practices are covering their operating costs based on the Lewin study. (See Attachment B)

One of the factors that contributed to the artificially low and inaccurate reimbursement rate has been an inflated utilization rate in the formula. This has resulted in a reimbursement rate for DXA that does not accurately reflect the cost of providing the service. A distorted or inaccurate utilization rate for DXA has caused this key preventive service to be undervalued. Undervalued services will decrease in volume and thus will undermine CMS' very own efforts to improve recognition of osteoporosis through increased DXA testing. In the case of central DXA, the current RVUs from this most recent 5 year review are so far below operating costs for the procedure that over 90% of physicians in the non-facility setting have indicated that they will stop performing DXAs by 2010. (See Attachment C)

Data from the first two quarters of 2008 suggests that the undervaluing of DXA may be leading to a reduction in percentage of women receiving DXA scans. This comes despite DXA testing rates for women in the Medicare program falling far short of the "routine screening" of all women aged 65 years and older recommended by the U.S. Preventive Services Task Force. For example, based on utilization during the first two quarters of 2008, only 11.2% of women and less than 2% of men in fee-for-service Medicare are projected to receive a DXA test this year. Though modest progress was made from 2001-2007 in that the fraction of women receiving a DXA scan annually grew from 8% to 11.6%, a decline is now projected for 2008, perhaps in response to substantial cuts in Medicare payment for DXA tests conducted in the physician office setting. This is in marked contrast to almost all other diagnostic imaging services which have demonstrated continued growth. This downward trend in DXA testing could continue as more physicians are unable to cover their operating costs, turn back leases and decide not to replace older equipment. With the marked reduction in DXA testing in the non-facility setting, the infrastructure for identifying patients are high risk for fracture and delivering osteoporosis care may dwindle. This could have a devastating effect on patient care ultimately leading to an increase in preventable fractures with its attendant increase in Medicare expenditures.

Request

ISCD requests that CMS consider the reliable survey data demonstrating a lower utilization rate and adopt a 13% utilization rate for DXA, a preventive health service which utilizes equipment designed to diagnose and treat a single disease. Consistent with the findings of the Lewin Group study 13% will more accurately reflect the actual utilization rate of this service.

3. Proposed Rule Section II. A (2) – Undervalued Reimbursement for Osteoporosis Testing

Issue

CMS is proposing to reduce reimbursement for axial DXA testing (CPT code 77080) to approximately \$75 in 2009 which represents a 49% decrease from the reimbursement rate for DXA in 2006.

ISCD Recommendation

CMS should reevaluate both the Practice Expense and Physician Work components for axial DXA to more accurately reflect the cost of providing the service.

Argument

CMS 1403-P marks the third consecutive year of reimbursement cuts for axial DXA, the most accurate test available for diagnosing and treating osteoporosis. These cuts were first announced in 2006 as part of the Medicare Five Year Review. Reimbursement for DXA has dropped from approximately \$139 in 2006 to \$82 in 2007 and 2008 and is scheduled to drop again to approximately \$75 in 2009. DXA testing is profoundly undervalued relative to other bone mass measurements and other imaging services with the current reimbursement rate having no relationship to the actual cost of providing the service.

CMS could more accurately value central DXA testing by recognizing that utilization rates for diagnostic imaging are not all the same. Although, currently a utilization rate of 50% is applied to DXA as well as CT scans and MRI, data from the Lewin Group survey indicates that for central DXA performed in the non-facility setting a utilization rate of 13% is more appropriate. (See comment section on Equipment Time-in-Use above) Additionally, the Physician Work RVU is grossly undervalued and creates a rank order anomaly with other bone mass measurement technologies. Specifically, as a result of the last Five Year Review of the MPFS, the physician work RVU for central DXA was assigned the same value as radiographic absorptiometry of the finger and a lower amount than peripheral DXA, despite objections by the American College of Radiology, the American College of Rheumatology and the American Association of Clinical Endocrinologists.

An analysis of operational costs per DXA studies in the non facility setting performed by the Lewin Group in July of 2007 demonstrated a median cost of \$134. (See Attachment A) This figure closely approximates the 2006 CMS reimbursement for DXA of \$139. At the current reimbursement rate of approximately \$82, only 14% of non-facility practices are able to cover their operating costs based on findings from the same Lewin Group survey.

The ISCD and other interested parties have repeatedly cautioned that the inevitable outcome of undervaluing DXA will be to curtail patient access to this important diagnostic tool. The Lewin study found that, in 2009, 90% of physicians will lose money performing DXA scans. Physicians will stop purchasing equipment, cancel or not renew leases, put off attending and participating educational programs and will discontinue providing DXAs.

The inevitable detrimental effect on patients is already being realized. Based upon CMS claims figures for the second quarter of 2008, the rate of central DXAs performed in 2008 is projected to **decrease for the first time** since the passage of the Bone Mass

Measurement Act in 1997. For the first two quarters of 2008 a decline in DXA claims rate reported in Medicare fee for service beneficiaries (FFS) was noted. Based on data for the first two quarters of 2008, it's estimated that 11.2% of women in Medicare FFS will receive a DXA scan in 2008, a decline in the scanning rate compared to 2007. This is in contrast to almost all other diagnostic imaging services which have demonstrated continued growth.

The claims data represent only one part of the evidence demonstrating the decline in the delivery system for osteoporosis. In addition, in 2007, the first year of cuts, there was a 25% decline in the sale of DXA equipment by Hologic, Inc., as noted in their most recent annual report. (Hologic 2007 Annual Report, p. 54- 55) During the same period, participation in ISCD education programs for physicians and technologists in the field of bone density dropped dramatically. From 2006 to 2007, participation in ISCD courses decreased by 29%. Course attendance in the first half of 2008 has dropped again by another 13%. Since DXA reimbursement in the office setting is currently far below operating costs and is slated for additional reductions by 2010, it is not surprising that a 2007 survey found that virtually all physicians in non-facility settings will stop DXA testing of Medicare patients (See Attachment C) These declines represent an across the board impact from the reimbursement cuts.

Despite osteoporosis screening being a service emphasized by CMS in their recent preventive services campaign, in 2006 only 9.3% of qualified women enrolled in Medicare had a DXA test. The severe cuts are already compromising Medicare's efforts over the past decade to increase the percentage of Medicare beneficiaries receiving DXA testing. The decline in DXA claims in the first two quarters of 2008 runs counter to the trend of many other imaging services. While other imaging services continue to increase, DXA, a preventative test, is waning.

MedPAC has warned about the effect of undervaluing services:

“The Commission is concerned that differences in the profitability across physician services create financial incentives for physicians to favor furnishing some procedures and services over other, less profitable ones. In this environment, beneficiary access to relatively undervalued services -- and to the providers that perform them — may be threatened...Misvalued services should be identified and payments corrected...Also, revisiting the RBRVS may be needed to explore the possibility of including other factors—in addition to input costs—in the pricing of individual services.” (MedPAC Report to Congress, Medicare Payment Policy, March 2007, p.118)

While MedPAC's warning focuses on services that are “less profitable”, services that will lose money for virtually all providers are destined to disappear. The result is that screening rates which previously saw annual increases but remained sub-optimal, are now declining. Paradoxically, by undervaluing DXA instead of saving money, a decline in reimbursement rates for DXA will lead to increased costs as fracture rates increase. In fact the Lewin Group conducted a Congressional Budget Office (CBO)-style scoring analysis of the 5 year costs to Medicare if the DRA and Medicare Physician Fee Schedule reimbursement cuts were reversed, thus restoring the DXA reimbursement rate to the 2006 level of \$139. The Lewin analysis found that program costs over a five-year period resulting from the increase in direct DXA payment would equal \$648 million. (see Attachment A). However, after accounting for savings associated with avoided

fractures and the cost of treating at-risk individuals, restoring DXA payments will actually save the Medicare program \$1.14 billion over the same five year period. (see Attachment A)

CMS has the ability to change physician behavior—to encourage rather than discourage the use of this life saving, low cost test. Improving DXA testing rates is dependent upon central DXA being fairly valued. Unless CMS reviews and assigns a more appropriate valuation to this service, the current trend of declining DXA testing will continue with devastating personal and societal costs.

Request

ISCD requests that CMS review the reimbursement for CPT 77080, including, but not limited to, the utilization rate and the physician work RVU, and correct the undervaluation of this key preventive service.

Conclusion

The proposed rule represents another assault on the availability of quality DXA testing. Over the past decade, CMS has recognized the importance of DXA in fighting the war on osteoporosis by including the test in the “Welcome to Medicare Exam”, as well as highlighting the importance of DXA testing in The Physician Quality Reporting Initiatives (PQRI). The proposed rule undermines the CMS mission to increase patient access and use of this critical preventative service.

The reimbursement cuts that were enacted in 2006 have resulted in DXA being an undervalued service. CMS should reevaluate the reimbursement for DXA including the practice expense and work RVU’s to more accurately reflect the cost of the service. Specifically, CMS should consider the reliable survey data demonstrating a lower utilization rate and adopt a 13% rate for DXA. Unless CMS addresses the undervaluation of this service, the downward trend in the percentage of patients accessing this important test will continue.

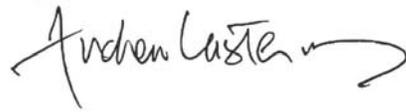
Imposing the IDTF regulatory scheme on DXA testing performed in physicians’ offices would limit access to this service at a time when osteoporosis is reaching epidemic proportions. First, it excludes a substantial and highly skilled portion of the provider community. Second, this proposal determines competence for physicians based solely on their specialty when the key to quality DXA testing is the training and education of the physician. Finally, Congress has made a clear determination that credentialing requirements for diagnostic testing for Medicare should apply only to advanced imaging services at this time.

ISCD appreciates the opportunity to offer comments on this proposed rule. We welcome any further dialogue with CMS regarding these issues. If you should have any questions regarding ISCD’s comments, please contact our legislative counsel, Donna Fiorentino at (860) 402-2159 or dfiorentino@iscd.org.

Sincerely,



Neil Binkley, MD, CCD
Co-Chair Public Policy, ISCD



Andrew Laster, MD, FACR, CCD
President Elect ISCD
Co-Chair Public Policy, ISCD



Assessing the Costs of Performing DXA Services in the Office-based Setting

Final Report

Prepared for:

American Association of Clinical Endocrinologists (AACE)
International Society for Clinical Densitometry (ISCD)
The Endocrine Society (TES) and
American College of Rheumatology (ACR)

Prepared by:

The Lewin Group, Inc.
Dobson | DaVanzo, LLC

October 31, 2007

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Prepared by:

The Lewin Group, Inc.
Audrey El-Gamil

Dobson | DaVanzo, LLC
Joan E. DaVanzo, PhD, MSW
Allen Dobson, PhD

October 31, 2007

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EXECUTIVE SUMMARY

Introduction and Purpose

Osteoporosis is a disease that is characterized by low bone mass and a deterioration of bone structure that results in bone fragility and an increased risk of fracture. The disease affects 10 million older Americans and is associated with significant mortality and morbidity. An additional 34 million individuals have osteopenia (low bone mass) and are at increased risk of fracture at some time in their lives.

In order to reduce the impact of osteoporosis, it is most important to diagnose it prior to fracture and initiate treatment for those at high risk. Dual-energy x-ray absorptiometry (DXA) is recognized as the “gold standard” for diagnosing osteoporosis and monitoring the response to therapy.

Numerous clinical trials document that the use of FDA approved drugs in women with osteoporosis significantly reduce fracture risk.^{1,2,3} Despite these findings, other studies have highlighted the underutilization of DXA testing for osteoporosis in the high-risk group of females older than 65 years of age.⁴

There have been several important Federal initiatives to promote the use of DXA. CMS has incorporated central DXA testing as a key preventive service, and it is now part of the “Welcome to Medicare” exam. The 2002 United States Preventive Services Task Force recommends screening for all women over the age of 65, and those 60-65 years of age with a body mass less than 70 kilograms.⁵ The 2004 Surgeon General’s report on Bone Health and Osteoporosis cited bone mass measurement as “one of the most significant advances in the last

Key Background Facts

- *Due to Deficit Reduction Act and Medicare Physician Fee Schedule (MPFS) cuts:*
 - *DXA payment was reduced from \$139 to \$82 and further to approximately \$35 in 2010.*
 - *VFA payment was reduced from \$40 to less than \$25 and further to approximately \$19 in 2010.*
- *At least two million individuals experience an osteoporotic fracture each year, with direct health care costs estimated to be approximately \$16.9 billion.*
- *By 2025, the number of osteoporotic fractures is estimated to be over three million and result in costs of approximately \$25 billion.*
- *Less than 20% of eligible Medicare beneficiaries receive a DXA scan within the recommended two year interval.*
- *By 2010, 93% of physicians said that they would no longer be performing DXA in their offices, based on the proposed payment.*
- *Patient access to DXA testing could be severely compromised if DXA reimbursement is undervalued.*

¹ Harris ST, Watts NB, Genant HK, et al. (1999). (Effects of risedronate treatment on vertebral and nonvertebral fractures in women with postmenopausal osteoporosis: a randomized controlled trial. *JAMA* 282: 1344-1352.

² Kanis J, Barton I, Jonell O. (2005). Risedronate decreases fracture risk in patients selected solely on the basis of prior vertebral fracture. *Osteoporosis Int.* 16:475-482.

³ Quandt S, Thompson D, Schneider D, et al. (2005). Effect of alendronate on vertebral fracture risk in women with bone mineral density T-scores of -1.6 to -2.5 at the femoral neck: The Fracture Intervention Trial (FIT). *Mayo Clin Proc* 80(3): 343-349.

⁴ Patton E, Fischer H. (2005). Screening for Osteoporosis in Postmenopausal Women: Adherence to the 2002 USPSTF Guidelines. Presented at the Sixth International Symposium on Osteoporosis: Current Status, Future Directions. Washington D.C.

⁵ Nelson H, Helfand M, Woolf SH, Allan J. (2002). Screening for postmenopausal osteoporosis: A review of the Evidence for the U.S. Preventive Services Task Force. *Annals of Internal Medicine* 137(6), pp. 529-541.

quarter century.”⁶ The August 2006 Federal Register revisions to Coverage of Bone Mass Measurement restricted reimbursement to central DXA as the only technology to monitor response to FDA approved drug therapy.

Vertebral fracture assessment, or VFA, is a recent advance which permits imaging of the spine to identify vertebral fractures. The software that permits one to do this can be placed on a DXA machine. Two thirds of vertebral fractures are clinically unappreciated but convey a significant increased risk for future osteoporotic fractures, not only at the spine but also hip and wrist. Thus VFA paired with DXA allows for identification of those who are at high fracture risk and who need medical therapy.

Reductions in Medicare reimbursement of DXA and VFA in the non-facility or physician office setting recently have been enacted. MedPAC asserts that when services are undervalued, providers cease furnishing them, threatening beneficiaries’ access to care.⁷ The Deficit Reduction Act of 2005 (DRA) limited technical component reimbursement for imaging services that are performed in physician offices to the lesser of either the payment under the Medicare Physician Fee Schedule (MPFS) or that under the hospital Outpatient Prospective Payment System (OPPS). Methodological changes to the MPFS from CMS-1321-FC resulted in further Medicare payment reductions over a four year transition period beginning in CY 2007.⁸ Due to DRA and MPFS changes effective January 1, 2007, payment for DXA dropped by 40%, from approximately \$139 to \$82, and will drop to approximately \$35 (an overall 75% reduction) when the MPFS is fully implemented in 2010.⁹ Reimbursement for VFA in 2007 also will drop from approximately \$40 to less than \$25, a 38% reduction. By January 2010, VFA reimbursement will have dropped approximately 50% from the 2006 payment to \$19.

Evaluation and treatment rates for osteoporosis in older individuals with fractures currently fall far below national recommendations,¹⁰ suggesting that a reduction in the availability of DXA will exacerbate access problems further. Since approximately two-thirds of all DXA scans are performed in the non-facility setting, patient access to bone mass measurement and assessment will be compromised severely if physicians discontinue providing these tests in their offices. Barriers to the use of DXA that have been cited in the literature include cost, availability of services, travel time and transportation, and health system factors like intake procedures, facility open times, and appointment availability. These factors tend to erect greater barriers to access at the hospital outpatient departments than in the local physician offices.¹¹ Furthermore, for preventive services,

⁶ U.S Department of Health and Human Services. "Bone Health and Osteoporosis. A Report of the Surgeon General". Rockville, MD: U.S. Department of Health and Human Services, Office of the Surgeon General, 2004. www.surgeongeneral.gov/library

⁷ Medicare Payment Advisory Commission: Report to the Congress. Promoting Greater Efficiency in Medicare. June 2007.

⁸ CMS-1321-FC finalized methodological changes to the calculation of Practice Expense RVUs under the Medicare Physician Fee Schedule.

⁹ DXA payments modeled with budget neutrality adjustor of 10.1% to work RVU and SGR reduction of 5% per year through 2010. We assumed conversion factor of \$30.85 for 2011 and 2012 as it was felt that assumptions beyond 2010 would not be credible.

¹⁰ Feldstein A, Elmer PJ, Orwoll E et al. (2003) Bone mineral density measurement and treatment for osteoporosis in older individuals with fractures: A gap in evidence-based practice guideline implementation. *Arch Int Med* 163(18):2165-2172.

¹¹ Scheppers E, van Dongen E, Dekker J, et al. (2006). Potential barriers to the use of health services among ethnic minorities: a review. *Family Practice* 23(3):325-348.

the perception that it is not needed urgently also may represent a major obstacle.¹² Research on mammography shows that delayed referral was associated independently with patient age over 65 and the presence of more than one chronic illness.¹³

The American Association of Clinical Endocrinologists (AACE), the International Society for Clinical Densitometry (ISCD), the American College of Rheumatology (ACR), and The Endocrine Society (TES), commissioned The Lewin Group to survey office-based providers of DXA, in order to develop estimates of the costs associated with providing DXA services to Medicare beneficiaries. There have been concerns that current and future levels of reimbursement for both DXA and VFA are below operating costs, but a detailed cost analysis previously had not been performed. Given the new methodology employed by CMS in the last five-year review and the provider cost data being somewhat dated, this study assumes greater importance. This study should assist policymakers and others to determine whether the current Medicare reimbursement for DXA approximates real world operating costs.

Through a mixed mode distribution (i.e., internet, mail and fax with telephone follow-up) of a multi-specialty survey, Lewin collected cost information from 163 physician practices. Lewin then estimated all costs associated with providing DXA and VFA, including practice expense, malpractice expense, and physician work. Practice expense and malpractice expense estimates were developed using financial information collected through The Lewin Group survey. Physician work estimates were based on information that had been collected previously by the ISCD in a clinical survey of densitometry professionals concerning the time required for clinical input (in minutes) for all aspects of DXA provision. The three types of costs (practice expense, malpractice expense, and physician work) were summed to yield total costs. Finally, Lewin compared the total costs to the global reimbursement for DXA and VFA services in the office-based setting.

In addition, Lewin was asked to develop a cost estimate for a policy proposal to maintain payment for DXA in physician offices at the 2006 MPFS amount. Supported by analyses of secondary data and expert judgment, The Lewin Group used a cost accounting methodology similar to that used by the Congressional Budget Office (CBO), to determine the budgetary impact to Medicare over one and five years of restoring DXA reimbursement to the 2006 payment of \$139.46.¹⁴ The purpose of this report is to present the findings of both sets of activities.

Summary of Findings

Study findings are organized into two sections. First, we present our median total cost per procedure for DXA and VFA, based on information from our survey of 163 providers and other study activities. Second, we present an estimate of the five-year gross and net costs to Medicare of implementing the proposal to restore DXA reimbursement to the 2006 MPFS amount of \$139.46.

¹² Strickland J, Strickland DL. (1996). Barriers to Preventive Health Services for Minority Households in the Rural South. *J Rural Health*, 22 (4): 367-374.

¹³ Gimotti et al. (2002). Delivering Preventive Health Services for Breast Cancer Control: A Longitudinal View of a Randomized Controlled Trial. *Health Services Research* 37 (1): 63-83.

¹⁴ We used multiple sources of data for this analysis, including secondary Medicare claims and preliminary Part B Extract and Summary System File (BESS) data for 2006, the results of a clinical survey of multi-specialty densitometry professionals conducted in early 2007, the 2007 Medicare Trustees Report, CMS changes to physician payment under Part B rulemaking, and the Medicare Fee Schedule contained in the 2006 Federal Register. In addition, we used evidence contained in the peer-reviewed literature.

1. Cost of Performing DXA and VFA in Office-based Setting - Survey Results

a. Cost of Performing DXA

We found a 2007 median total cost per DXA procedure of \$134.13, which is \$5 less than the 2006 MPFS reimbursement and about \$50 more than the 2007 Medicare reimbursement. This finding represents the costs of performing DXA in a practice that may or may not perform VFA as well. Costs are developed per practice and are reflective of each practice's individual procedure-mix. The 2007 reimbursement of \$82 represents 61% of our median cost. The median number of DXA procedures performed per year was 768. See Figure ES-1.

Key Findings

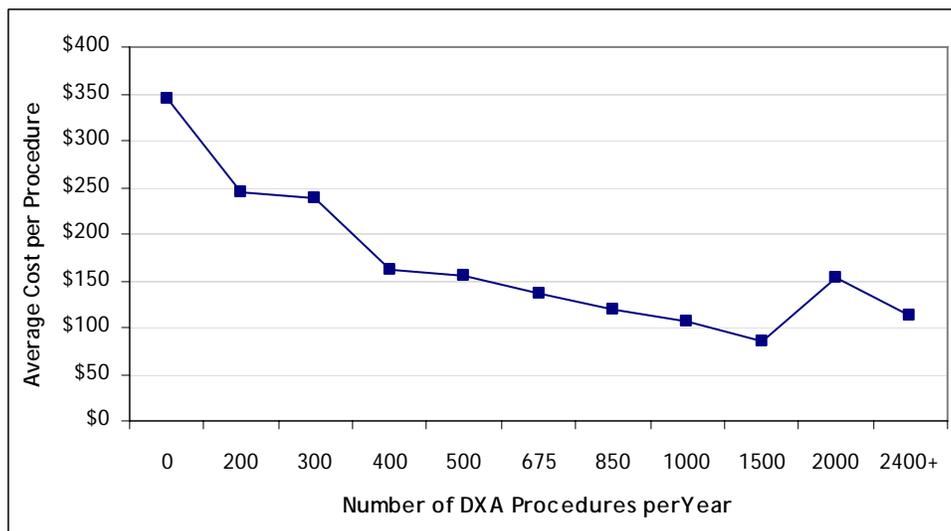
- *The median cost per DXA procedure is \$134.13, \$5 less than the 2006 Medicare reimbursement.*
- *Unlike other imaging equipment, DXA machines have a utilization rate of 13% for DXA (15% for DXA and VFA).*
- *Only 14% of survey respondents are currently reimbursed by Medicare at or above their costs. No provider will be adequately reimbursed for DXA in 2010.*

Figure ES-1: Ratio of 2007 Payment to Cost per DXA Procedure by 25th, 50th and 75th Percentile

Percentile	2007 Cost	2007 Payment	Loss per Procedure	Ratio Payment:Cost
25th percentile	\$95.07	\$82	\$13.07	86%
50% (median)	\$134.13	\$82	\$52.13	61%
75th percentile	\$195.02	\$82	\$113.02	42%

An inverse relationship between the average cost per procedure and the number of DXA procedures performed in a year would be anticipated under basic economic theory. However, this does not extend beyond 1500 procedures per year. As Figure ES-2 below demonstrates, there is a steady decrease in the average cost per procedures as practices increase the number of procedures performed per year, until they reach 1500 procedures per year. The increased cost per procedure at this volume possibly may be attributed to the extra fixed costs and overhead that are associated with operating a high capacity practice.

Figure ES-2: Relationship between Number of DXA Procedures Performed and Average Cost per Procedure



Across all practices represented in the survey, there is an overall utilization rate for DXA machines of 13%, defined as total annual hours equipment is used for patient care, divided by total annual hours equipment is available for DXA.¹⁵ This is substantially lower than the CMS assumption that all imaging equipment is utilized 50% of the time the machine is available for patient care. Unlike advanced imaging services, such as MRI and CT which are used for multiple disease states, DXA is used for just a single disease. Rather than being located in a stand alone imaging center, DXA machines usually are located in the primary care or specialty provider's office. Furthermore, DXA is not subject to overuse since its indications are legislated in the Bone Mass Measurement Act. DXA and VFA tests are integral to providing quality care to patients, as they support both initial diagnosis as well as ongoing monitoring of osteoporosis therapies.

After accounting for cost inflation and the continual decline of DXA payments through 2010, very few providers will be financially able to deliver DXA services to Medicare beneficiaries in the coming years. No provider will be reimbursed by Medicare at or above their costs in 2010. In the course of our data collection, we found that a number of large providers either have closed their doors or totally eliminated DXA as a provided service. If the very largest providers who know their costs best discontinue DXA service, others are likely to follow.

b. Cost of Performing VFA

Our analysis produced a 2007 median total cost per VFA procedure of \$65.83, almost \$26 more than the 2006 MPFS payment amount for VFA performed in the office setting, and about \$30 more than the 2007 reimbursement. This represents the costs of performing VFA as a tandem procedure to DXA. The

Key Findings

- *The median cost per VFA procedure (as a tandem procedure to DXA) is \$65.83, \$26 more than the 2006 Medicare reimbursement.*
- *About 17% of providers are being reimbursed adequately for VFA in 2007, while only 1% will be reimbursed adequately in 2010.*

¹⁵ We found the overall utilization rate for DXA machines used both for DXA and VFA procedures to be 15%.

2007 payment of \$35 represents 53% of our median cost estimate (See Figure ES-3.) With a median number of procedures of only 180 per year, it is evident that most DXA procedures are not accompanied by a VFA.

Figure ES-3: Ratio of 2007 Payment to Cost per VFA Procedure by 25th, 50th and 75th Percentile

Percentile	2007 Cost	2007 Payment	Loss per Procedure	Ratio Payment:Cost
25th percentile	\$43.59	\$35	\$8.59	80%
50% (median)	\$65.83	\$35	\$30.83	53%
75th percentile	\$119.88	\$35	\$84.88	29%

c. Sensitivity Analysis

In developing the Notice of Proposed Rule Making (NPRM), CMS assumed indirect practice expenses account for 63% of the total practice expense. Indirect and direct practice expenses are defined in Figure ES-4 below. The 2007 MPFS indicates that practice expense represents approximately 70% of the total DXA per procedure cost and 78% of the total VFA per procedure cost, based on the allocation of relative value units (RVUs) across practice expense, malpractice expense, and physician work.¹⁶

Figure ES-4: Components of Practice Expense, Indirect and Direct

Indirect Practice Expenses	Direct Practice Expenses
Non-clinical (administrative) labor	Direct labor for clinical personnel
Office space	Equipment expenses
All other expenses not related to directly performing the procedures	Medical supplies and equipment

Results of the Lewin survey show a median indirect percentage for DXA of 37% (\$34) of the total practice expense cost and 47% (\$24) of the VFA total practice expense cost.

As a sensitivity test, we applied the CMS indirect proportion (63%) to our direct practice expense cost of \$60.12, resulting in total practice expense costs of \$162.50. Combining the costs of practice expense, physician work, and malpractice expense produces a total per procedure DXA cost of \$202.33, higher than our base analysis of \$134.13. See Figure ES-5.

¹⁶ Medicare procedure payments often are used as a proxy for cost.

Figure ES-5: Allocation of Practice Expense by Allocation Methodology for DXA, Lewin Survey vs. CMS NPRM Inputs

Methodology	Median Total Cost	Practice Expense			Physician Work	Malpractice
		Indirect	Direct	Total	Total	Total
Lewin Survey	\$134.13	\$34.17	\$60.12	\$94.29	\$38.49	\$1.34
CMS NPRM	\$202.33	\$102.37	\$60.12	\$162.50	\$38.49	\$1.34

Using the same methodology for VFA, we calculate a total practice expense cost of \$73.40 and a total per procedure cost of \$87.63, as compared to our base analysis of \$65.83.

2. CBO-style Estimate of the Costs and Potential Savings to Medicare of a Proposal to Restore DXA Reimbursement to the 2006 MPFS Payment Amount

Per CBO scoring convention, our analysis consisted of the following three steps:

- Develop a baseline estimate of Medicare spending for DXA under the current reimbursement for the five years, 2008-2012.
- Develop an estimate of Medicare spending under a proposal to restore payment for DXA to the 2006 MPFS amount of \$139.46.
- Develop an estimate of potential savings to the Medicare program of avoiding osteoporotic fractures by identifying beneficiaries at-risk using DXA and treating them with pharmaceutical therapy.

First, we present the estimated one- and five-year gross costs of the proposal to restore DXA reimbursement to the 2006 level under Medicare. Then, we present our estimates of the potential cost offsets (savings) from identifying and treating beneficiaries at-risk of an osteoporotic fracture. Potential savings accrue from the avoided cost of treating osteoporotic fractures for a subset of the identified population, net of the costs of implementing the proposal and the costs of providing pharmaceutical treatment to the identified at-risk individuals.

a. Estimated Cost to Medicare of Restoring DXA Reimbursement to the 2006 Level for 2008-2012¹⁷

- The one-year estimate (2008) of net costs (with Part B premium offsets) to Medicare of reimbursing DXA at the 2006 level is approximately \$94 million. (See Figure ES-6, where Medicare outlays are indicated by brackets.)

Key Findings

- The five-year estimate (2008-2012) of costs to Medicare of reimbursing DXA at the 2006 level is approximately \$648 million.
- About 4,256,510 DXA procedures would be "recovered" between 2008-2012 if the 2006 payment level was maintained.

¹⁷ We estimated 10 year baseline Medicare spending at \$220 million; incremental Medicare spending under the proposal of \$1.9 billion, with a 10 year net cost of the proposal of \$1.5 billion. The baseline estimate of DXA procedures is 6.1 million (4 million over five years), with the proposal recovering 11.8 million DXA procedures.

- The five-year estimate (2008–2012) of costs (with Part B premium offsets) to Medicare of reimbursing DXA at the 2006 level is approximately \$648 million (See Figure ES-6.)
- We estimate that the volume of DXA procedures will remain at 1.6 million in 2008, with 8.3 million procedures over the five years, 2008–2012, if DXA reimbursement is restored to the 2006 level. About 4,256,510 DXA procedures would be “recovered” over the five-year period.¹⁸

Figure ES-6: Estimated Cost of Proposal

	2008	2009	2010	2011	2012	Total
Estimated Baseline Medicare Spending for DXA Under DRA and Changes to Physician Part B Payment (in millions)						
Uses data from CMS Preliminary Part B Extract and Summary System File, 2006	[\$74]	[\$39]	[\$18]	[\$16]	[\$15]	[\$162]
Total Estimated Medicare Spending for DXA Under Proposal to Restore DXA Reimbursement to 2006 Levels (in millions)						
Uses data from CMS Preliminary Part B Extract and Summary System File, 2006, also Medicare Trustees Report, 2007	[\$199]	[\$202]	[\$205]	[\$208]	[\$212]	[\$1,026]
Incremental Medicare Spending for DXA Under Proposal Relative to Baseline Spending						
Calculated	[\$125]	[\$164]	[\$187]	[\$192]	[\$196]	[\$864]
Estimated Net Cost of Proposal (in millions)						
Medicare spending minus the 25% premium adjustment	[\$94]	[\$123]	[\$140]	[\$144]	[\$147]	[\$648]

Our baseline estimate of Medicare spending under the DRA and other cuts for DXA for 2008 is \$74 million, and for the five-year period of 2008-2012 is \$162 million. We estimate that the annual volume of DXA procedures under the DRA and other cuts will decline to 1,236,298 in 2008 and to 4,048,103 over the five years 2008-2012.¹⁹

A March 2007 ISCD multi-specialty survey found that 8% of physicians already had discontinued providing DXA in their offices due to cuts in reimbursement, and 36% reported that they would discontinue the procedures over the next year. By 2010, 93% of respondents said that they no longer would be performing DXA in their offices. We used this data to model a decline in DXA testing in the non-facility setting of 25% for 2008 and 2009, and 10% for 2010 through 2012.

If the proposal to restore DXA reimbursement to the 2006 level is implemented, we estimate Medicare spending for DXA to be \$199 million in 2008 and \$1,026 million over five years 2008-2012. After netting out baseline Medicare spending and a 25% premium adjustment, the 2008 net cost of the proposal is \$94 million. For 2008-2012, the net cost of the proposal is \$648 million.

¹⁸ Per CMS correspondence, office-based DXA volume in 2006 was 1.55 million procedures.

¹⁹ We assumed that volume would decline by 25% per year in 2008, 2009, and 2010, and 10% in 2011 and 2012. Our 25% rate is based on conversations with providers who felt that some physicians would be able to shift costs and would continue providing services to Medicare beneficiaries as a clinical accommodation and despite fiscal loss.

b. Estimated Cost Offsets of Avoided Osteoporotic Fractures due to Increased DXA under Proposal for 2008-2012²⁰

- The estimated cost offsets (gross savings) to Medicare of avoiding increased osteoporotic fractures from the recovery of approximately 4,256,510 DXA procedures under the proposal is **\$175 million** in 2008 and **\$2.1 billion** over the five years 2008-2012.
- Performing approximately 360,951 more DXA procedures in 2008 and 4,256,510 more DXA procedures over the five-year period would allow for identification and treatment of patients with osteoporosis, preventing approximately 18,048 osteoporotic fractures in 2008 and 212,826 fractures over the five years 2008-2012. Approximately 3,406,877 individuals could receive treatment over the five years at a cost to Medicare Part D of \$25 million in 2008 and \$294 million over the five years.²¹
- After the cost of the proposal and the resulting increased DXA utilization (\$94 million) and the cost of treating identified individuals for osteoporosis with drug therapy (\$25 million), the one-year estimate (2008) of potential savings (after Part D premium offsets) to Medicare is approximately **\$56 million** (see Figure ES-7).
- After the cost of the proposal and the cost of treating identified individuals for osteoporosis with drug therapy, the five-year estimate (2008–2012) of net savings (after Part D premium offsets) to Medicare of preventing fractures by identifying and treating at-risk beneficiaries using DXA is approximately \$1.144 billion.

Key Findings

- *The estimated savings to Medicare for using DXA to identify at-risk individuals and avoiding fractures by maintaining the 2006 payment rates from 2008 to 2012 is \$2.1 billion.*
- *Considering the cost of the proposal and the cost of treating identified individuals with drug therapy, the five-year estimate of net savings to Medicare of preventing fractures is approximately \$1.144 billion.*

²⁰ Our 10 year estimate of recovered DXA procedures under the proposal is 11.8 million procedures. We estimate preventing 586,000 osteoporotic fractures, saving Medicare \$4.5 billion over 10 years. We estimate treatment costs to be \$810 million. We estimate a net savings to Medicare over 10 years after treating at-risk beneficiaries to be \$3.7 billion.

²¹ Based on results of the FRAME study (Fracture Reduction Affects Medicare Expenditures), we assumed that, for every 100 scans, five fractures would be prevented.

Figure ES-7: Estimated Cost Offsets Using DXA for Identifying and Treating Individuals At-Risk of Osteoporotic Fractures

	2008	2009	2010	2011	2012	Total
Number of DXA Procedures "Recovered" Under Proposal (in thousands)						
Number of DXA procedures not lost due to DRA and other cuts	361	694	950	1,069	1,182	4,256
Number of Fractures that Could Be Prevented by DXA (in thousands)						
Assumes a 1/20 fracture/scan ratio	18	35	48	53	59	213
Savings to Medicare Under the Proposal to Restore DXA Reimbursement (in millions)						
Assumes \$9,699 per fracture cost after beneficiary co-payments and deductibles in 2008 inflated to 2012	\$81	\$214	\$320	\$381	\$442	\$1,438
Estimated Net Cost of Proposal (in millions)						
Difference between spending under DRA and other cuts and Act	[\$94]	[\$123]	[\$140]	[\$144]	[\$147]	[\$648]
Cost to Medicare of Treating At-risk Individuals (in millions)						
Annual cost to Medicare of \$900 incurred by each at-risk individual for drug therapy after cost management factor, beneficiary premium, and availability of generic drug	[\$25]	[\$48]	[\$66]	[\$74]	[\$81]	[\$294]
Savings to Medicare of Avoided Osteoporotic Fractures after Cost of Proposal to Restore DXA Reimbursement and Treatment of Identified At-risk Individuals (in millions)						
Net savings to Medicare of maintaining payment for DXA at 2006 rates	\$56	\$166	\$254	\$308	\$360	\$1,144

Discussion

Osteoporosis care has become a focus worldwide as the population ages. CMS recognizes the impact of osteoporosis on beneficiary health by providing osteoporosis testing at the "Welcome to Medicare" physical exam for qualified beneficiaries and by covering osteoporosis testing at least every two years.²²

Given the importance of DXA and VFA as integral to the prevention of osteoporotic fractures, the results of this study indicate that the recent Medicare payment reductions for DXA and VFA are ill advised on several grounds.

First, the level of payment reduction is such that physician costs averaging about \$135 to perform DXA no longer will be covered, and the losses will be too large to be cross-subsidized within their practices. When larger practices with low unit DXA costs indicate that they no longer are able to provide DXA services, it suggests that the payment rates are too low. This finding is particularly troublesome, because it means that typical practices with generally low

²² DHHS press release dated January 10, 2005: HHS Promotes New Medicare Preventive Benefits for Better Senior Health. www.hhs.gov/news/press/2005pres/20050110.html

DXA volume where services are provided as part of ongoing patient care will find that providing DXA is no longer feasible.

Second, if physicians discontinue DXA services in their offices, beneficiary access to DXA will be reduced significantly. Currently less than 20% of eligible Medicare beneficiaries receive a DXA study within a two-year interval, despite the efforts of providers and the Medicare program to promote the service. Even for patients who sustain fractures, within one to two years after the fracture, only 12%-24%^{23,24} had undergone DXA testing.

Third, because approximately 63% of DXA and VFA services currently are provided in physician offices, the loss of these services will be significant. Other sites of service (i.e., hospital outpatient departments) will not be able to meet demand. Furthermore, introducing barriers such as complicated intake procedures and/or additional time and travel expense will hinder patient compliance with obtaining the recommended DXA test.

Finally, given the evidence that identification of at-risk individuals using DXA, together with treatment of these individuals, can reduce osteoporotic fractures, the loss of DXA services could mean an increase in osteoporotic fractures, if access to DXA by Medicare beneficiaries is reduced.

The net result, as we have indicated in this study, is the unintended consequence that reductions in payment for DXA actually cost, rather than save, Medicare dollars. This appears to be an instance in which prevention serves the role society asks of it – that is, to reduce morbidity and health care expenditures. Medicare is not serving its beneficiaries well to essentially eliminate office-based DXA services.

From this perspective, the Medicare goal of increasing beneficiaries' use of preventive services is undercut by the large reduction in DXA payment rates. To reduce DXA payment by 75%, thereby reducing access to services, can only exacerbate this already low attainment of an important public policy goal.

²³ National Institutes of Health Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy. (2001). *JAMA* 285:785-795.

²⁴ Cuddihy MP, Gabriel SE, Crowson C, et al. (2002) Osteoporosis intervention following distal forearm fracture. *Arch Int Med* 162: 421-426.

I. INTRODUCTION

Osteoporosis is a disease that is characterized by low bone mass and a deterioration of bone structure that results in bone fragility and an increased risk of fracture. The disease affects 10 million older Americans and is associated with significant mortality and morbidity. An additional 34 million individuals have osteopenia (low bone mass) and are at increased risk of fracture at some time in their lives.

Osteoporosis-related fractures represent a serious illness burden and are a major cause of disability among Medicare beneficiaries. Fractures occur at multiple sites, not only the lumbar spine, hip, wrist, and forearm, but also the humerus, clavicle, patella, and hands/fingers.²⁵

At least two million individuals experience an osteoporotic fracture each year, with approximately 70% of fractures occurring in people aged 65 and over. Direct health care costs currently associated with osteoporotic fractures are estimated to be approximately \$16.9 billion each year.²⁶ By 2025, the number of osteoporotic fractures is estimated to be over three million and will incur costs of \$25.3 billion.

Osteoporotic fractures in the United States each year lead to more than half a million hospitalizations, over 800,000 emergency room encounters, more than 2,600,000 physician office visits, and the placement of nearly 180,000 individuals into nursing homes. Hip fractures are by far the most devastating type of fracture, accounting for about 300,000 hospitalizations each year.²⁷

In order to reduce the impact of osteoporosis, it is most important to diagnose it prior to fracture and initiate treatment for those at highest risk. Dual-energy X-ray Absorptiometry (DXA) is the “gold standard” for diagnosing osteoporosis, using World Health Organization (WHO) criteria.²⁸ Numerous clinical trials have shown that fractures can be reduced if an individual knows their individual fracture risk and is able to initiate drug therapy, if needed.^{29, 30, 31}

Vertebral fracture assessment, or VFA, is a recent advance which permits imaging of the spine to identify vertebral fractures through imaging the spine. The software that permits one to do this can be placed on a DXA machine. While two-thirds of vertebral fractures are clinically unappreciated, they convey a significant increased risk for future osteoporotic fractures, not only at the spine, but also the hip and wrist. Thus, VFA paired with DXA allows for identification of those who are at the very highest risk for future fracture and who need pharmaceutical therapy.

²⁵ Burge R, Dawson-Hughes B, Solomon DH, et al. (2007) Incidence and economic burden of osteoporosis-related fractures in the United States, 2005-2025. *Journal of Bone and Mineral Research* 22(7): 465-475.

²⁶ Tosteson A, Jonsson B, Grima DT, et al. (2001). Challenges for model-based economic evaluations of postmenopausal osteoporosis interventions. *Osteoporosis Int.* 12: 849-857.

²⁷ Department of Health and Human Services. (2004) *Bone Health and Osteoporosis. A Report of the Surgeon General, 2004.*

²⁸ Blake GM, Fogelman I. (2007). The role of DXA bone density scans in the diagnosis and treatment of osteoporosis. *Postgrad Med J* 83(982): 509-517.

²⁹ Harris ST, Watts NB, Genant HK, et al. (1999). (Effects of risedronate treatment on vertebral and nonvertebral fractures in women with postmenopausal osteoporosis: a randomized controlled trial. *JAMA* 282: 1344-1352.

³⁰ Kanis J, Barton I, Jonell O. (2005). Risedronate decreases fracture risk in patients selected solely on the basis of prior vertebral fracture. *Osteoporosis Int.* 16:475-482.

³¹ Quandt S, Thompson D, Schneider D, et al. (2005). Effect of alendronate on vertebral fracture risk in women with bone mineral density T-scores of -1.6 to -2.5 at the femoral neck: The Fracture Intervention Trial (FIT). *Mayo Clin Proc* 80(3): 343-349.

Recent cuts to Medicare payment for imaging services enacted as part of the DRA of 2005, coupled with changes in the Medicare Physician Fee Schedule (MPFS), have resulted in reductions in Medicare reimbursement of DXA from \$140 to \$82 in 2007 and to approximately \$35 when fully implemented in 2010. Reimbursement for VFA in 2007 also will drop from approximately \$40 to less than \$25, a 38% reduction. By January 2010, VFA reimbursement will have dropped approximately 50% to \$19. These reductions in Medicare payment mean that physicians no longer will be able to offer DXA in their offices, resulting in significant reductions in access.

If physicians are not able to perform DXA, Medicare costs for treating osteoporotic fractures will likely rise significantly. Osteoporotic fractures result in significant pain and disability. Approximately 20% of hip fracture patients die. The mortality rate for osteoporotic fractures in women is greater than the combined mortality rates from breast and ovarian cancers.³² Implementation of a proposal to restore DXA reimbursement to the 2006 MPFS payment amount could result in net savings to Medicare through the avoidance of osteoporotic fractures, even taking into account the treatment of identified at-risk individuals.

³² Hanley DA, Josse RG. (1996) Prevention and management of osteoporosis: consensus statements from the Scientific Advisory Board of the Osteoporosis Society in Canada. *CMAJ* 155: 921-923.

II. SCOPE OF WORK

The American Association of Clinical Endocrinologists (AACE), the International Society for Clinical Densitometry (ISCD), the American College of Rheumatology (ACR), and The Endocrine Society (TES), commissioned The Lewin Group to survey office-based providers of DXA and VFA to develop estimates of the costs associated with providing DXA and VFA services to Medicare beneficiaries.

Amid recent changes in Medicare reimbursement methodology, providers had become concerned that payment for DXA and VFA was below operating costs. However, a systematic study of the cost to perform a DXA procedure had not been conducted.

The Lewin Group surveyed providers across specialties and collected cost information from 163 physician practices. Lewin then estimated all costs associated with providing DXA and VFA, including practice expense, malpractice expense, and physician work. Practice expense and malpractice expense estimates were generated using financial information collected through The Lewin Group survey. Physician work estimates were based on information that had been collected previously by the ISCD in a clinical survey of densitometry professionals concerning the time required for clinical input (in minutes) for all aspects of DXA and VFA provision. The three types of costs (practice expense, malpractice expense, and physician work) were summed to yield total costs. Finally, Lewin compared these costs to the global reimbursement for DXA and VFA in the physician office-based setting.

In addition, Lewin was asked to develop a cost estimate for a policy proposal to restore Medicare payment for DXA in physician offices to 2006 levels. The Lewin Group used a cost accounting methodology similar to that used by the Congressional Budget Office (CBO) to determine the budgetary impact to Medicare over one and five years if DXA reimbursement was restored to \$139.46. (We also developed estimates of the 10-year gross and net costs to Medicare of the proposal. Results are in Appendix C.)

Our cost offsets are associated with the avoidance of increased osteoporotic fractures by detecting at-risk individuals and treating them with medication. Consistent with CBO cost accounting rules, Part B, and Part D premium offsets are calculated.

After a discussion of the methodologies employed in each of the two parts of the study, this report provides both sets of findings.

III. METHODOLOGY

The work for this study involved two different sets of activities, both of which are described in detail in this section of the report. A mixed mode survey of DXA and VFA providers was administered to collect information on each individual practice's cost to perform DXA and VFA. Using the survey information, we first estimated total aggregate DXA and VFA costs for each practice, then generated a practice expense and malpractice expense cost per DXA and VFA procedure for each practice. We then derived physician work using information from an earlier 2006 clinical survey of multi-specialty densitometry professionals that had been administered by the ISCD.

The second set of activities involved developing CBO-style estimates of the cost and potential savings to Medicare that could result from restoring reimbursement for DXA to the 2006 MPFS payment amount, or \$139.46. We used multiple sources of data, including secondary Medicare claims and BESS data, the results of a 2007 ICSD industry survey, the 2007 Medicare Trustees Report, CMS changes to physician payment under Part B under rulemaking, and the Medicare Fee Schedule contained in the 2006 Federal Register. In addition, we used evidence contained in the peer-reviewed literature.

A. Provider Survey

1. Practice Expense and Malpractice Expense

a. Lewin Survey Administration

The Lewin Group survey was distributed electronically to 14,537 members of AACE, ISCD, ACR, and TES. The survey was accessible via the Internet, with the option of completing the survey on paper and faxing a copy to The Lewin Group. The survey collected information on the characteristics of the practice and physician (e.g., specialty, geographic region, hours practice is open and available to perform DXA), as well as equipment expenses and financial information (e.g., total salaries, office expenses, malpractice insurance). See Appendix A for the survey instrument.

One hundred sixty-three useable surveys were received, representing approximately 1% of the sample. Respondents who provided incomplete survey data were contacted via telephone for needed clarification. Any respondent who was not able to be contacted was excluded from our analysis. As an incentive to complete the survey, The Lewin Group offered to provide each individual practice their calculated cost of providing DXA and VFA. An e-mail was sent out at the end of the study with the overall study findings, as well as their individual cost for 2007.

b. Generating Practice Expense and Malpractice Expense Cost Components

The Lewin survey collected expenses for each entire practice.³³ The analyses consisted first of estimating total aggregate costs, then generating a practice expense and malpractice cost per DXA and VFA procedure for each practice. We report the median cost, 25th percentile, and 75th percentile statistics. Lewin also investigated the range of expenses for different cost categories,

³³ For the purpose of this survey, "practice's expenses" are defined as all expenses that are captured in a Profit and Loss (Income) Statement for all services the practice provides. Respondents were not to differentiate between divisions that provide DXA and all other services provided.

as well as the effect procedure volume has on per DXA procedure costs. Consistent with CMS methodology, Lewin presents the median as our metric of central tendency, to reduce the effect of data outliers.

Financial and utilization measures were collected for the most recent complete fiscal year. To make the costs comparable to the current 2007 payments for DXA and VFA, practice expense and malpractice expense cost categories were inflated by the Consumer Price Index for urban consumers (CPI-U), approximately 4.1% for 2007.

Total practice and malpractice expense per procedure was calculated based on the sum of the three cost components, divided by the proportion of time the costs are allocated to DXA versus VFA procedures. For example, if a practice performed a total of 1000 procedures per year on a DXA machine, of which 60% were DXA and 40% were VFA, practice expense and malpractice expenses would be allocated to DXA and VFA proportionately. Each proportion of costs (DXA proportion and VFA proportion) then was divided by the number of procedures (DXA or VFA) performed annually for each practice. Since DXA and VFA were performed on the same machine, the methodology was the same for allocating DXA and VFA practice expense. We describe each component below:

- Equipment costs
- Space allocated to DXA
- An allocation of overhead expenses attributed to DXA and VFA (e.g., malpractice expense, non-clinical labor and expenses, medical supplies and materials)

Equipment Costs

Equipment costs contained expenses that practices incur annually in the maintenance and upkeep of their DXA machines. These expenses for DXA machines included: 1) cost of interest on loans used to purchase the machine; 2) cost of service contracts; 3) costs of software upgrades; and 4) the cost of the last picture archiving communication (PAC)/Digital Imaging and Communications in Medicine (DICOM) software upgrades. These expenses were totaled at the practice level for all machines reported.

Space Allocated to DXA

Respondents indicated the total amount of square footage in their practice, as well as the square footage attributed to providing DXA and VFA. Again, the square footage and space allocation was the same for DXA and VFA. Respondents were to include only areas of their practice that were solely used for DXA (i.e., area where the machines were located, and exam rooms reserved for DXA patients). The square footage allocated to DXA multiplied by the indicated lease per square foot was included in the cost for providing DXA, to be allocated back to the procedure cost. As noted below, we also used the proportion of square feet attributed to DXA service provision to allocate indirect expenses back to DXA procedures.

Allocation of Overhead Expenses Attributed to DXA and VFA

Practices incurred numerous indirect expenses that need to be allocated back to DXA and VFA. Based on the proportion of square feet attributed to DXA to the total number of square feet in the practice, overhead expenses were allocated. Costs in this allocation included:

- Professional medical liability/malpractice insurance
- Salaries for administrative and clerical staff
- Non-clinical office expenses
- Medical materials and supplies
- All other indirect expenses

Survey respondents additionally provided total clinical non-physician payroll expenses (i.e., radiology technicians and registered nurses) and total provider (i.e., physician, physician assistants) payroll expenses. To eliminate the potential for “double-counting” salary expenses for personnel who provided direct labor in DXA procedures, the “non-clinical non-physician payroll expense” category was excluded in its entirety, due to the inability to indicate which percent of the expenses were attributed to indirect supports. Additionally, total provider payroll expenses were excluded, with the assumption that time spent by the physician would be captured in “physician work” on a per-task basis.

As a result, the percent of indirect costs allocated back to DXA may be conservative, for we expect some personnel in these categories to provide DXA services that were not identified in the task breakdown. Bad debt expense also was excluded from the analysis, consistent with CMS’ methodology for identifying reimbursable expenses.

Additionally, in order to provide VFA services in the office-based setting, providers must purchase VFA software which is used with the DXA machine. For practices that provided VFA, the cost of purchasing this software was included into the survey category of “all other indirect expenses”. This line item, however, only would be included in the survey if they purchased the software in fiscal year 2006. Otherwise, this line item may be excluded. The inability to separate the VFA software expense from the rest of the indirect expenses results in an allocation of the software to both DXA and VFA services. As a result, our VFA figures may be slightly conservative.

2. Physician Work and Clinical Labor

a. Survey Administration

Physician work and clinical labor was derived from a 2006 clinical survey of multi-specialty densitometry professionals. Administered by the ISCD, this survey was distributed electronically to 2884 office-based providers of DXA who were members of AACE, ACR, ISCD, TES, American Society for Bone and Mineral Research (ASBMR), or North American Menopause Society (NAMS). The survey collected information on the characteristics of the practice and the average time and personnel required to perform each task associated with performing a single DXA and VFA procedure. Four hundred fifty-three useable responses were received, or about a 15% response rate.

Survey data on the average time it took to perform each task were analyzed, resulting in an estimate of a median time per task (in minutes). The proportion of instances where personnel types were performing indicated tasks was calculated as well (i.e., what percent of the time are technicians performing this task as opposed to registered nurses?).

b. Generating Labor Costs Attributed to Providing DXA and VFA

To cost the labor associated with physician and other clinical work, The Lewin Group analyzed the raw data from the 2006 clinical survey of multi-specialty densitometry professionals that had been conducted earlier. Personnel salary data were obtained from the United States Department of Labor, Bureau of Labor Statistics (BLS), May 2006, "National Occupations Employment and Wage Estimates". Benefit costs also were provided by BLS in their "Employer Costs for Employee Compensation" survey, September 2006, and included in the salary estimates. A weighted average annual salary was generated based on the proportion of time each personnel category was responsible for performing an indicated task within a DXA procedure. The annual weighted salary then was calculated as a per-minute cost (based on the number of hours the practice was open) and multiplied by the median number of minutes reported for each task. All tasks were totaled to generate a total "labor cost" per DXA procedure.

Since VFA often is performed in tandem with DXA, it was necessary to remove select tasks from the VFA calculation of labor costs and only include those tasks that were performed independently both for the VFA and the DXA procedure. These tasks include:

- Positioning patient and acquiring images
- Reviewing images, comparing with prior study(s), manually correcting any errors in acquisition, and performing image analyses

The remainder of the tasks were only performed one time, even if a VFA was performed in tandem with a DXA. These tasks were included in the DXA cost, but not the VFA cost.

Physician work time was calculated based on these data as well. The survey collected the amount of time (in minutes) that physicians spent for patient care per DXA procedure. The total cost for physician work was based on the same methodology as the labor costs, but based solely on the annual salary for physicians. To capture the physician work value for VFA, it was important to include only the physician work that was directly related to the mutually exclusive tasks for VFA. This time estimate was collected through a separate survey of thirty-one physicians who provided VFA services in the office-based setting.³⁴

This labor costing methodology generated a conservative estimate for the cost per procedure. Some practices indicated that they were open in excess of eight hours per day. In theory, this could require two staff members, rather than one. Dividing the annual salary per staff member by fewer hours open would result in a higher cost per minute, and ultimately a higher cost per task and procedure. Being unfamiliar with the structure of each practice and the number of staff members providing the service, we assumed one staff member per task, regardless of the number of hours the practice was open.

³⁴ Physician work for VFA was collected through a separate on-line survey distributed to 300 office-based providers of DXA. A random sample was drawn the attendee list of a series of ISCD sponsored VFA courses given in the United States in 2006 and 2007. Physicians were e-mailed a survey with two questions: "Do you provide VFA?" and "How much of your own time (in minutes) do you spend reading a typical VFA?" It was imperative that we excluded any technologist time or any physician time that related to pre-service and post-service activities.

3. *Generating a Per Procedure DXA and VFA Cost*

Survey respondents indicated an average number of DXA procedures and VFA procedures performed per month per DXA machine. Lewin calculated the average number of DXA procedures per year for each practice. This calculation was used to denominate the sum of the practice expense, malpractice, and physician work costs to calculate cost per DXA and VFA procedures.

4. *DXA Equipment Utilization Rate*

Lewin calculated an overall utilization rate for DXA machines based on the number of hours DXA equipment was used to provide patient care and number of hours equipment was available for DXA:

- **Total available equipment hours:** We calculated total available equipment hours for each practice by multiplying the reported hours available each week by the total indicated hours per year the practice was open.
- **Total patient-use equipment hours:** We calculated the hours for total patient-use by multiplying the number of DXA procedures performed per year by the RUC approved time per procedure (15 minutes). Due to the inability to estimate the amount of time DXA machines were used in each practice, this estimate may be conservative.
- **Utilization Rate:** Total patient-use equipment hours divided by total available equipment hours.

5. *Sample Characteristics*

Responses to The Lewin Group survey were received from eight different specialties. Rheumatology represents 37% of the sample while primary care (internal medicine, family medicine, and gynecology) collectively represent 39% of the responses. Additionally, we compared our sample of respondents to the distribution of respondents to the ICSD 2006 multi-specialty provider survey.

In order to determine the extent to which our sample was representative of the universe of providers, we analyzed the 2004 Medicare standard analytic file (SAF) carrier claims and found that 28% of DXA claims are from internal medicine and 24% are from radiology. As a test for representativeness, we re-weighted the final results of our study based on the CMS claims data distribution by specialty and obtained comparable median costs per DXA procedure. This ensured that specialty distribution did not affect our analytic results. Figure 1 contains these distributions.

Figure 1: Distribution of Specialty for Lewin and Multi-specialty Survey Compared to 2004 CMS SAF Claims Analysis

Specialty	Lewin Survey (2007)	Multi-Specialty Densitometry Study (2006)	CMS Claims Analysis (Office-based in 2004)
Rheumatology	37%	37%	12%
Internal Medicine	20%	11%	28%
Endocrinology	13%	22%	5%
Family Practice	10%	7%	11%
OB/GYN	9%	9%	7%
Other	6%	6%	14%
Radiology	3%	5%	24%
Orthopedics	2%	3%	-

Responses from the 2006 clinical survey of multi-specialty densitometry professionals represented 18 specialties, which are presented in Figure 1. Rheumatology represents 37% of the sample (identical to the Lewin survey), whereas Endocrinology represents 22%. Primary Care (Internal Medicine, Family Medicine, and Gynecology) collectively represents 27% of the total sample.

B. CBO-style Cost Accounting Study

In this study, The Lewin Group used a cost accounting methodology similar to that used by the CBO to determine the impact of a proposed action (payment proposal) on the federal budget. This methodology entailed first estimating both the **price** and **volume** of the services that were or would be provided under the baseline scenario. In this analysis, the baseline scenario reflected the cuts made in DXA reimbursement from both the DRA and the changes in the methodology underlying the MPFS. Figure 2 contains the reimbursement rates for DXA that were used in the baseline scenario.

Figure 2: Baseline Reimbursement for DXA³⁵

Year	DXA Reimbursement
2007	\$82.33
2008	\$81.66
2009	\$56.82
2010	\$35.48
2011	\$35.48
2012	\$35.48

Using a combination of secondary data and expert judgment, we developed an algorithm to determine the budgetary impact to Medicare if DXA reimbursement was restored to \$139.46. Our methodology is presented in two sections. First, we present the methods used to estimate

³⁵ DXA payments modeled with budget neutrality adjustor of 10.1% to work RVU and SGR reduction of 5% per year through 2010. We assumed conversion factor of \$30.85 for 2011 and 2012, as it was felt that assumptions beyond 2010 would not be credible.

one and five year costs of the proposal to restore DXA payment. Then, we present the methods used to estimate the potential cost offsets from identifying and treating beneficiaries at-risk of an osteoporotic fracture. Potential savings accrue from the avoided cost of treating osteoporotic fractures for a subset of the identified population, given the costs of implementing the proposal and the costs of providing pharmaceutical therapy to the identified at-risk population.

1. Step One: Estimate Medicare Spending Under DRA and Other Cuts for 2008-2012

- **Number of procedures:** Uses CMS Preliminary Part B Extract and Summary System File (BESS), 2006 and Q1 2007. Approximately 60% of procedures were performed in physician offices, and 40% in hospital outpatient departments. Reduction in the number of procedures beginning in 2007 was estimated using the results of an ISCD Task Force Survey, dated March 2007. The survey reported that 8% of respondents already had stopped providing DXA in their offices due to cuts in Medicare reimbursement. Approximately 36% of respondents reported that they would stop providing DXA by the end of 2007. By 2010, 93% of respondents would not provide these services in their offices. We reduced the number of procedures by 25% each in 2009 and 2010 and by 10% each in of 2011 and 2012. We assumed that some practices would continue to provide DXA as an accommodation to existing patients.
- **Baseline Medicare spending:** Uses BESS, 2006 and Q1 2007. Reimbursement rates for 2008-2010 from MPFS contained in Figure 2 above were multiplied by the number of estimated procedures. (See Figure 3.)

Figure 3: Medicare Spending under DRA and Other Cuts 2008-2012

	2008	2009	2010	2011	2012	Total
Global DXA payments under physician fee schedule 2008-2010, flat in 2011 and 2012	\$81.66	\$56.82	\$35.48	\$35.48	\$35.48	
Estimated number of DXAs (uses CMS BESS 2006 and Q1 2007 data as base, then modified ISCD survey results)	1,236,298	927,223	695,418	625,876	563,288	4,048,103
Total estimated baseline Medicare spending for DXA under the DRA and other cuts	\$74,000,808	\$38,617,982	\$18,085,613	\$16,277,051	\$14,649,346	\$161,630,800

2. Step Two: Estimate Medicare Spending under a Proposal to Restore Medicare Reimbursement for DXA to 2006 Levels

- **Number of procedures:** uses CMS BESS, 2006 and Q1 2007 inflated at projected rates of beneficiary population growth (1.5% per year until 2011, when rate increases to 3% from Medicare Trustees Report, 2007).
- **Estimated Medicare spending:** uses CMS BESS, 2006 and Q1 2007. Reimbursement rates for 2006 restored through 2012 per proposal. (See Figure 4.)

Figure 4: Estimated Medicare Spending Under Proposal

	2008	2009	2010	2011	2012	Total
Global DXA payments under proposal 2008-2010, flat in 2011/2012	\$139.46	\$139.46	\$139.46	\$139.46	\$139.46	
Estimated number of DXAs (uses CMS BESS 2006 and Q1 2007, then escalation proportionate to growth in beneficiary population)	1,597,249	1,621,208	1,645,526	1,694,892	1,745,738	8,304,613
Total estimated Medicare spending for DXA under proposal	\$199,114,370	\$202,101,086	\$205,132,602	\$208,209,591	\$211,332,735	\$1,025,890,385

3. Step Three: Estimate Net Medicare Spending Under Proposal to Restore DXA Reimbursement to 2006 Levels and Number of Procedures “Recovered”³⁶

- Determine cost of the proposal by taking the difference in spending for DXA between the baseline scenario in Step One and the estimates in Step Two.
- Deduct Part B premium adjustment equal to 25% of new spending.
- Determine net cost of proposal.
- Determine number of DXA procedures that will be “recovered” under proposal. (See Figure 5.)

Figure 5: Cost of Proposal

	2008	2009	2010	2011	2012	Total
Baseline spending for DXA under DRA and other cuts	\$74,000,808	\$38,617,982	\$18,085,613	\$16,277,051	\$14,649,346	\$161,630,800
Total estimated Medicare spending for DXA under proposal	\$199,114,370	\$202,101,086	\$205,132,602	\$208,209,591	\$211,332,735	\$1,025,890,385
Gross cost of proposal	\$125,113,563	\$163,483,104	\$187,046,990	\$191,932,540	\$196,683,389	\$864,259,585
Net cost of proposal after Part B premium of 25%	\$93,835,172	\$122,612,328	\$140,285,242	\$143,949,405	\$147,512,542	\$648,194,689
Number of DXA procedures recovered under proposal	360,951	693,984	950,108	1,069,016	1,182,450	4,256,510

4. Step Four: Determine Potential Cost Offsets from Reduced Osteoporotic Fractures using Peer Reviewed Literature³⁷

- Determine both current and 2008-2012 number and cost of osteoporotic fractures among Medicare beneficiaries. Approximately 70% of the 2 million osteoporotic fractures are among individuals aged 65 and older. These calculations were based on the compound rate of growth in peer-reviewed literature of 0.0459 corroborated with

³⁶ We estimated 10 year baseline Medicare spending at \$220 million; incremental Medicare spending under the proposal of \$1.9 billion, with a 10 year net cost of the proposal of \$1.5 billion. The baseline estimate of DXA procedures is 6.1 million (4 million over five years), with the proposal recovering 11.8 million DXA procedures.

³⁷ Our 10 year estimate of recovered DXA procedures under the proposal is 11.8 million procedures. We estimate preventing 586,000 osteoporotic fractures, saving Medicare \$4.5 billion over 10 years. We estimate treatment costs to be \$810 million. We estimate a net savings to Medicare over 10 years after treating at-risk beneficiaries to be \$3.7 billion.

growth in beneficiary population from Medicare Trustees Report (2007) with the cost of fractures inflated at CPI.³⁸

- Estimate number and cost of osteoporotic fractures avoided through “recovered” procedures. This calculation was based upon evidence contained in the peer reviewed literature³⁹ wherein, in 2008, if approximately 361,000 additional individuals were scanned, approximately 18,048 fractures could be prevented because identified at-risk individuals would receive a medication to improve bone density. (In essence, we assume that for every 100 DXA scans, five fractures will be prevented.) This calculation is dependent upon the mix of individuals with osteoporosis/osteopenia who are screened, and also the compliance rate of those individuals given a prescription. Compliance rates have been observed to be generally low for patients who are prescribed medication to prevent or treat osteoporosis. Furthermore, we expect that because alendronate will be available in generic form in 2008, compliance rates will improve significantly, further improving the chance of preventing osteoporotic fractures.
- Estimate total cost savings from avoiding an increase in osteoporotic fractures. Per fracture cost calculated using peer reviewed literature (net \$9,699 after beneficiary co-payment and deductible of 20%).⁴⁰ (See Figure 6.)

Figure 6: Potential Cost Offsets from Identifying Individuals At-risk for Osteoporotic Fracture, 2008-2012

	2008	2009	2010	2011	2012	Total
Number of annual osteoporotic fractures among patients aged 65 and older (71% of total of 2 million)	1,592,181	1,665,262	1,741,698	1,821,642	1,905,255	8,726,039
Per fracture cost after beneficiary co-payment and deductible of 20%	\$9,699	\$9,695	\$9,690	\$9,829	\$9,970	
Number of DXA scans “recovered” under proposal	360,951	693,984	950,108	1,069,016	1,182,450	4,256,510
Number of fractures prevented by each scan: .05 (King et al, 2005)	18,048	34,699	47,505	53,541	59,123	212,826
Gross savings to Medicare of avoiding osteoporotic fractures through DXA before cost of proposal and treatment of at-risk individuals	\$175,040,214	\$336,397,008	\$460,350,535	\$525,392,608	\$589,477,113	\$2,086,657,478
Net savings to Medicare after cost of proposal	\$81,205,042	\$213,784,180	\$320,065,293	\$381,443,203	\$441,964,571	\$1,438,462,789

Sensitivity Analysis

We performed a sensitivity analysis on the rate of fracture prevention for each scan and re-calculated it using a 4% rate. There is no available literature concerning the number of fractures that could be prevented if a population of at-risk individuals is screened, with the exception of a

³⁸ Burge R, Dawson-Hughes B, Solomon D, et al. (2007) Incidence and economic burden of osteoporosis-related fractures in the United States, 2005-2025. *Journal of Bone and Mineral Research* 22(3): 465-475.

³⁹ King AB, Saag KG, Burge RT (2005). Fracture reduction affects Medicare economics (FRAME): impact of increased osteoporosis diagnosis and treatment. *Osteoporosis Int.* 16: 1545-1557.

⁴⁰ Burge *ibid.*

single peer-reviewed study.⁴¹ In this study, entitled FRAME (Fracture Reduction Affects Medicare Economics), the rate of fracture prevention varied in proportion to the fracture risk of the population tested, treatment rate, and adherence to therapy.

During several telephone conversations with the principal investigator of the FRAME study, we learned that the fracture prevention rates cited in the study were conservative, and that a 4%-5% rate was likely more realistic than the rate used when the study was first published. Under our sensitivity analysis using 4%, the number of avoided fractures declined to 170 million from 213 million. Medicare savings after the cost of the proposal would be reduced to \$1 billion from \$1.4 billion in the base case. See Figure 7.

Figure 7: Sensitivity Analysis - Potential Cost Offsets from Identifying Individuals At-risk for Osteoporotic Fracture

	2008	2009	2010	2011	2012	Total
Number of DXA scans "recovered" under proposal	360,951	693,984	950,108	1,069,016	1,182,450	4,256,510
Number of fractures prevented by each scan: .04 (King et al, 2005)	14,438	27,759	38,004	42,761	47,298	170,260
Gross savings to Medicare of avoiding osteoporotic fractures through DXA before cost of treatment of at-risk individuals	\$140,032,172	\$269,117,606	\$368,280,428	\$420,314,086	\$471,581,690	\$1,669,325,985
Net savings to Medicare after cost of proposal	\$46,197,000	\$146,505,279	\$227,995,186	\$276,364,685	\$324,069,149	\$1,021,131,294

5. Step Five: Determine Cost of Treating Identified At-risk Individuals

- Determine gross cost of medications for beneficiaries found to be at-risk of osteoporotic fractures under Medicare Part D. We used evidence from the FRAME study that showed that, for one million individuals screened, 440,000 would be treated with a bone-specific medication. Annual cost of treatment was assumed to be \$900 per individual (assumed each individual filled the prescription and took the medication). In our base analysis, if 360,951 individuals were screened and treated, 18,048 fractures would be avoided.
- Reduce gross cost of medications under Part D for enrollment (approximately 58% of beneficiaries enrolled in Part D) and for the plan cost management factor (which is a 27% discount on branded drugs achieved by Part D plans in 2007).⁴²
- Part D premium adjustment equal to 25.5% of new spending per CBO.
- Reduce net cost of generic medications beginning in 2008 by 60%,⁴³ when alendronate goes off patent and the generic is available. (See Figure 8.)

⁴¹ King et al, 2005.

⁴² Congress of the United States: Congressional Budget Office. A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit. July, 2004.

⁴³ Statement of Lester M. Crawford, D.V.M., Ph.D. Acting Commissioner of Food and Drugs before the Committee on the Judiciary, United States Senate on "The Law of Biologic Medicine". June 23, 2004: "Generic drugs cost 50-70% less than their brand-name counterparts."

Figure 8: Estimated Cost of Treating At-risk Individuals, 2008-2012

	2008	2009	2010	2011	2012	Total
Cost of treatment if .44 individuals are given Rx and all beneficiaries are covered under Part D	\$142,936,697	\$274,817,843	\$376,242,932	\$423,330,315	\$468,250,309	\$1,685,578,096
Cost of medications for the 58.5% of beneficiaries covered under Part D	\$83,617,968	\$160,768,438	\$220,102,115	\$247,648,234	\$204,075,191	\$734,617,074
Cost of medications after Part D premium of 25.5% per CBO	\$62,295,386	\$119,772,486	\$163,976,076	\$184,497,934	\$204,075,191	\$734,617,074
Cost of medications once generic alendronate is available (60% discount)	\$24,918,154	\$47,908,995	\$65,590,430	\$73,799,174	\$81,630,076	\$293,846,830

6. Step Six: Determine Net Cost (Savings) from Reduced Osteoporotic Fractures through "Recovered" DXA Procedures Minus the Cost of Treatment

- Subtract cost of proposal and cost of treatment from the cost of the avoided fractures. (See Figure 9.)

Figure 9: Estimated Net Savings to Medicare after Cost of Proposal and Cost of Treating At-risk Individuals, 2008-2012

	2008	2009	2010	2011	2012	Total
Gross savings to Medicare of avoiding osteoporotic fractures through DXA before cost of proposal and treatment of at-risk individuals	\$175,040,214	\$336,397,008	\$460,350,535	\$525,392,608	\$589,477,113	\$2,086,657,478
Net savings to Medicare after cost of proposal	\$81,205,042	\$213,784,180	\$320,065,293	\$381,443,203	\$441,964,571	\$1,438,462,789
Cost of medications once generic alendronate is available (60% discount)	\$24,918,154	\$47,908,995	\$65,590,430	\$73,799,174	\$81,630,076	\$293,846,830
Net savings to Medicare after cost of proposal and cost of treating at-risk individuals	\$56,286,888	\$165,875,686	\$254,474,862	\$307,644,029	\$360,334,495	\$1,144,615,960

IV. FINDINGS

Findings are organized into two sections. First, we present the median total cost per procedure for DXA and VFA based on information from our survey of 163 providers and other study activities. Second, we present an estimate of the one- and five-year gross and net costs to Medicare of implementing a proposal to restore DXA reimbursement to 2006 levels. Then, we present our estimates of the potential cost offsets from identifying and treating beneficiaries at-risk of an osteoporotic fracture. Potential savings accrue from the avoided cost of treating osteoporotic fractures for a subset of the identified population, given the costs of implementing the proposal and the costs of providing pharmaceutical treatment to identified at-risk individuals.

A. Cost of Performing DXA and VFA in Office-based Setting: Survey Results

1. Cost of Performing DXA

We found a 2007 median total cost per procedure for DXA of \$134.13, which is \$5 less than the 2006 MPFS reimbursement for DXA performed in the office setting and about \$50 more than the 2007 Medicare reimbursement. This represents the costs of performing DXA in a practice that may or may not perform VFA as well. In other words, the cost represents the reality that some practices provide DXA and VFA, while others only perform DXA. Costs are generated per practice and are reflective of their individual procedure-mix. The 2007 reimbursement of \$82 represents 61% of our median cost. The 2007 payment level represents 86% of the 25th percentile cost (\$95.07) and 42% of the 75th percentile costs (\$195.02). Furthermore, we found that, in 2007, only 14% of survey respondents are being reimbursed by Medicare at or above their costs. Our findings suggest that no provider will be reimbursed adequately at the fully implemented payment rates in 2010 of \$35. (See Figure 10.)

Figure 10: Ratio of 2007 Payment to Cost per DXA Procedure, by 25th, 50th and 75th Percentile

Percentile	2007 Cost	2007 Payment	Loss per Procedure	Ratio Payment:Cost
25th percentile	\$95.07	\$82	\$13.07	86%
50% (median)	\$134.13	\$82	\$52.13	61%
75th percentile	\$195.02	\$82	\$113.02	42%

We also found considerable variation in the cost of providing DXA procedures, with a minimum value of \$42.57 and a maximum value of \$788.09. (See Figure 11.) The median number of DXA procedures performed per year was 768 (25th percentile number of procedures performed = 360 procedures; 75th percentile number of procedures performed = 1572 procedures).

Figure 11: 2007 Median Cost per DXA Procedure

Procedure	Median # of Procedures per Year	Cost per Procedure		
		Median	Minimum	Maximum
DXA	768	\$134.13	\$42.57	\$788.09

In addition, we found that there is an inverse relationship between average cost per procedure and the number of DXA procedures performed in a year, until the number of procedures performed exceeds 1500 procedures per year. Providers with high procedure volume are typically thought of as being efficient and operating with lower costs per procedure. However, for a number of reasons, DXA is different. As Figure 12 demonstrates, there is a steady decrease in the average cost per procedures as practices increase the number of procedures performed per year, until they reach 1500 procedures per year. Procedures in excess of 1500 per year have a higher per procedure cost, possibly attributable to the extra fixed costs and overhead associated with operating a practice that can handle the capacity.

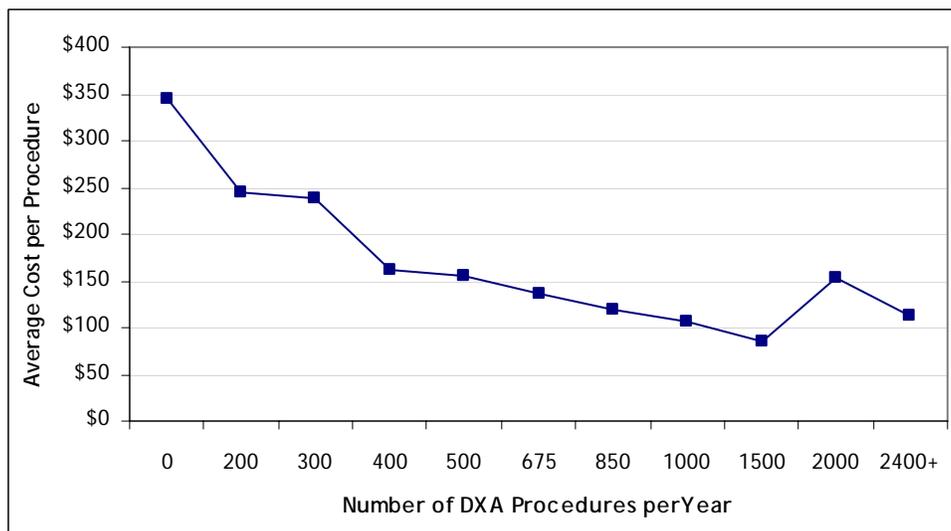
Across all practices represented in the survey, there is an overall utilization rate for DXA machines of 13%, defined as total annual hours equipment is used for patient care, divided by total annual hours equipment is available for DXA.⁴⁴ This is substantially lower than the CMS assumption that all imaging equipment is utilized 50% of the time the machine is available for patient care. This difference in the utilization rate is attributable to the use of DXA machines as only one aspect of patient care, and the fact that physicians from a number of specialties who provide DXA also typically are evaluating and treating patients who have a variety of diseases in addition to osteoporosis. Furthermore, DXA is not subject to overuse since its indications are legislated in the Bone Mass Measurement Act.

Of those practices that have unit DXA costs under \$82, they perform, on average, 2125 procedures per year. This high average number of procedures per year is influenced by a small number of practices performing DXA in excess of the 90th percentile of the number of procedures performed in a year by respondents. This procedure volume is significantly higher than the median number of procedures performed per year of 768, or approximately 3 procedures per day. The vast majority (86%) of providers have costs that are not covered by Medicare reimbursement.

After accounting for cost inflation and the continual decline of DXA payments through 2010, very few providers will be financially able to deliver DXA services to Medicare beneficiaries in the coming years, with no provider being reimbursed by Medicare at or above their costs in 2010. In the course of our data collection, we found that a number of large providers either have closed their doors or totally eliminated DXA as a provided service. If the very largest providers, who know their costs best, discontinue DXA service, others likely are to follow.

⁴⁴ The overall utilization rate for DXA machines based on DXA and VFA procedures is 15%.

Figure 12: Relationship Between Number of DXA Procedures Performed and Average Cost per Procedure



2. Cost of Performing VFA

Our analysis yielded a 2007 median total cost per procedure for VFA of \$65.83, almost \$26 more than the 2006 MPFS reimbursement for VFA performed in the office setting and about \$30 more than the 2007 reimbursement. This represents the costs of performing VFA as a tandem procedure to DXA. Regardless of whether or not the VFA procedure is performed with a DXA, MPFS requires that the payment for VFA remains the same. Since VFA often is performed in tandem to DXA (more than 50% of the time), the relative values (RVUs) that determine payment are reduced to reflect only the aspects of care that are not captured within the DXA procedure. As a result, practices that do perform VFA as a separate procedure are likely to have their cost per procedures far exceed the Medicare payment.

For a tandem procedure, 2007 payment of \$35 represents 53% of our median cost estimate. This payment level also represents 80% of the 25th percentile cost (\$43.59) and 29% of the 75th percentile costs (\$119.88) (See Figure 13).

Figure 13: Ratio of 2007 Payment to Cost per VFA Procedure, by 25th, 50th and 75th Percentile

Percentile	2007 Cost	2007 Payment	Loss per Procedure	Ratio Payment:Cost
25th percentile	\$43.59	\$35	\$8.59	80%
50% (median)	\$65.83	\$35	\$30.83	53%
75th percentile	\$119.88	\$35	\$84.88	29%

In 2007, only 17% of respondents were being reimbursed by Medicare at or above their costs. In 2010, only one provider (1% of sample) will be reimbursed adequately at the fully implemented payment rate of \$19.

Similar to the cost of providing DXA, there is wide variation in the cost of providing VFA procedures, with a minimum value of \$18.03 and a maximum value of \$545.67. With a median number of procedures of only 180 per year (25th percentile = 96 procedures; 75th percentile = 600 procedures), it is evident that most DXA procedures are not accompanied by a VFA.

There continues to be an inverse relationship between the average cost per procedure and the number of VFA procedures performed per year. There is a decrease in the average cost per procedure as practices increase the number of procedures (total procedures and/or number of VFA procedures) performed per year. The few practices that have costs below the Medicare payment for 2007 perform, on average, 904 VFA procedures per year.

A practice both with high VFA procedure volume and high DXA procedure volume will have more procedures over which to allocate their indirect expenses. Alternatively, practices with low VFA procedure volumes but proportionately more DXA procedures also could have low VFA costs per procedure. In this situation, there is only a proportionately small amount of the indirect costs allocated to VFA. The only additional costs to be allocated per procedure would be the direct labor for the procedure that is separate from DXA. For example, a practice with only 100 VFA procedures per year but 2000 DXA procedures per year would have only 0.5% of the practice expense and malpractice expense allocated to VFA.

3. Sensitivity Analysis

In developing the Notice of Proposed Rulemaking (NPRM), CMS assumed indirect expenses account for 63% of the total practice expense. Indirect and direct expenses are defined in Figure 14 as the following:

Figure 14: Components of Practice Expense, Indirect and Direct

Indirect Practice Expenses	Direct Practice Expenses
Non-clinical (administrative) labor	Direct labor for clinical personnel
Office space	Equipment expenses
All other expenses not related to directly performing the procedures	Medical supplies and equipment

The 2007 MPFS indicates that practice expense represents approximately 70% of the total DXA per procedure cost and 78% of the total VFA per procedure cost, based on the allocation of RVUs for practice expense, malpractice expense, and physician work.⁴⁵ Results of the Lewin survey show a median indirect percentage for DXA of 37% of the total practice expense cost, or \$34 of the approximately \$94 of practice expense (our median total cost was \$134.13). For VFA, results of The Lewin Group survey show a median indirect percentage of 47%, or \$24 of the approximately \$52 of practice expense (our median total cost was \$65.83).

As a sensitivity test, when we apply the CMS indirect proportion (63%) to our direct practice expense cost for DXA of \$60.12, we calculate total practice expense costs of \$162.50. Adding

⁴⁵ Medicare procedure payments often are used as a proxy for cost.

physician work of \$38.49 and malpractice of \$1.34 produces a total cost per DXA procedure of \$202.33. (See Figure 15.) Overall, this sensitivity analysis produces a higher total cost per DXA procedure of \$202.33, as compared to our base analysis of \$134.13.

Figure 15: Allocation of Practice Expense by Allocation Methodology for DXA, Lewin Survey vs. CMS NPRM Inputs

Methodology	Median Total Cost	Practice Expense			Physician Work	Malpractice
		Indirect	Direct	Total	Total	Total
Lewin Survey	\$134.13	\$34.17	\$60.12	\$94.29	\$38.49	\$1.34
CMS NPRM	\$202.33	\$102.37	\$60.12	\$162.50	\$38.49	\$1.34

When we perform a sensitivity test for VFA using the same methodology, we calculate a total practice expense cost of \$73. Adding physician work of \$13.11 and malpractice of \$1.12 produces a total cost per VFA procedure of \$87.63. (See Figure 16.) Overall, this sensitivity analysis produces a higher total cost per VFA procedure of \$87.63, as compared to our base analysis of \$65.83.

Figure 16: Allocation of Practice Expense by Allocation Methodology for VFA, Lewin Survey vs. CMS NPRM Inputs

Methodology	Median Total Cost	Practice Expense			Physician Work	Malpractice
		Indirect	Direct	Total	Total	Total
Lewin Survey	\$65.83	\$24.44	\$27.16	\$51.60	\$13.11	\$1.12
CMS NPRM	\$87.63	\$46.24	\$27.16	\$73.40	\$13.11	\$1.12

B. CBO-style Estimate of the Costs and Potential Savings to Medicare of a Proposal to Restore DXA Reimbursement to 2006 Levels

Using multiple sources of secondary data, our analysis consisted of the following three steps:

- Develop a baseline estimate of Medicare spending for DXA under the current reimbursement for the five years, 2008-2012.
- Develop an estimate of Medicare spending under a proposal to restore payment for DXA to not less than 100% of the reimbursement rate as of December 31, 2006 for the five years 2008-2012 (\$139.46).
- Develop an estimate of potential savings to the Medicare program of avoiding osteoporotic fractures through identifying and treating those beneficiaries at-risk using DXA.

First, we present the estimated one- and five-year gross costs of the proposal to restore DXA to the 2006 MPFS payment amount. Then, we present our estimates of the potential cost offsets (savings) from identifying and treating beneficiaries at-risk of an osteoporotic fracture. Potential savings accrue from the avoided cost of treating osteoporotic fractures for a subset of the identified population, net of the costs of implementing the proposal and the costs of providing pharmaceutical treatment to the identified at-risk individuals.

1. Estimated Cost to Medicare of Restoring DXA Reimbursement to 2006 Levels for 2008-2012

- The one-year estimate (2008) of net costs (with Part B premium offsets) to Medicare of reimbursing DXA at 2006 levels is approximately **\$94 million**. (See Figure 17, where gross and net costs to Medicare are indicated by brackets.)
- The five-year estimate (2008–2012) of costs (with Part B premium offsets) to Medicare of reimbursing DXA at 2006 levels is approximately **\$648 million** (See Figure 17.)
- We estimate that the volume of DXA procedures will remain at 1.6 million in 2008, with 8.3 million procedures over the five years, if DXA reimbursement is restored to 2006 levels. About 4,256,510 DXA procedures would be “recovered” over the five-year period if 2006 payment levels are maintained.

Figure 17: Estimated Cost of Proposal

	2008	2009	2010	2011	2012	Total
Estimated Baseline Medicare Spending for DXA Under DRA and Changes to Physician Part B Payment (in millions)						
Uses data from CMS Preliminary Part B Extract and Summary System File, 2006	[\$74]	[\$39]	[\$18]	[\$16]	[\$15]	[\$162]
Total Estimated Medicare Spending for DXA Under Proposal to Restore DXA Reimbursement to 2006 Levels (in millions)						
Uses data from CMS Preliminary Part B Extract and Summary System File, 2006, also Medicare Trustees Report, 2007	[\$199]	[\$202]	[\$205]	[\$208]	[\$212]	[\$1,026]
Incremental Medicare Spending for DXA Under Proposal Relative to Baseline Spending						
Calculated	[\$125]	[\$164]	[\$187]	[\$192]	[\$196]	[\$864]
Estimated Net Cost of Proposal (in millions)						
Medicare spending minus the 25% premium adjustment	[\$94]	[\$123]	[\$140]	[\$144]	[\$147]	[\$648]

Our baseline estimate of Medicare spending under the DRA and other cuts for DXA for 2008 is \$74 million, and for the five-year period of 2008-2012 is \$162 million. We estimate that the annual volume of DXA procedures under the DRA and other cuts will decline to 1,236,298 in 2008 and to 4,048,103 over the five years, 2008-2012. A March 2007 ISCD industry survey found that 8% of physicians had already discontinued providing DXA in their offices, and 36% reported that they would discontinue the procedures over the next year. By 2010, nearly all respondents said that they no longer would be performing DXA in their offices. These estimates, while large, are in line with the level of Medicare’s DXA payment reductions.

If the proposal to restore DXA reimbursement to 2006 levels is implemented, we estimate Medicare spending for DXA to be \$199 million in 2008 and \$1,026 million over the five years 2008-2012. After netting out baseline Medicare spending and a 25% premium adjustment, the 2008 cost of the proposal is \$94 million and for 2008-2012 is \$648 million.

2. *Estimated Cost Offsets of Avoided Osteoporotic Fractures due to Increased DXA Under Proposal for 2008-2012*

- The estimated cost offsets (gross savings) to Medicare of avoiding increased osteoporotic fractures from the recovery of approximately 4,256,510 DXA procedures under the proposal is **\$175 million** in 2008 and **\$2.1 billion** over the five years 2008-2012.
- Performing approximately 360,951 additional DXA procedures in 2008, 4,256,510 more DXA procedures over the five-year period under the proposal would prevent approximately 18,048 osteoporotic fractures in 2008 and 212,826 fractures over the five years, 2008-2012. Approximately 158,818 individuals could receive pharmaceutical treatment in 2008 at a cost to Medicare Part D of \$25 million, \$294 million over the five years, 2008-2012.⁴⁶
- After the cost of the proposal (\$74 million) and the increased utilization and cost of treating identified individuals for osteoporosis with drug therapy (\$25 million), the one-year estimate (2008) of potential savings (after Part D premium offsets) to Medicare of preventing fractures by identifying and treating at-risk beneficiaries using DXA is approximately **\$56 million**. (See Figure 18).
- After the cost of the bill and the cost of treating identified individuals for osteoporosis with drug therapy, the five-year estimate (2008–2012) of potential savings (after Part D premium offsets) to Medicare of preventing fractures by identifying and treating at-risk beneficiaries using DXA is approximately \$1.14 billion (See Figure 18).

⁴⁶ This assumption is based upon the FRAME study in which the .44 of people tested were given a prescription.

Figure 18: Estimated Cost Offsets of Identifying and Treating Individuals At-risk of Osteoporotic Fracture using DXA

	2008	2009	2010	2011	2012	Total
Number of DXA Procedures "Recovered" Under Proposal (in thousands)						
Number of DXA procedures not lost due to DRA and other cuts	361	694	950	1,069	1,182	4,256
Number of Fractures that Could Be Prevented by DXA (in thousands)						
Assumes a 1/20 Fracture/Scan Ratio	18	35	48	53	59	213
Savings to Medicare Under the Proposal to Restore DXA Reimbursement (in millions)						
Assumes \$9,699 per fracture cost after beneficiary co-payments and deductibles in 2008 inflated to 2012	\$81	\$214	\$320	\$381	\$442	\$1,438
Estimated Net Cost of Proposal (in millions)						
Difference between spending under DRA and other cuts and proposal	[\$94]	[\$123]	[\$140]	[\$144]	[\$147]	[\$648]
Cost to Medicare of Treating At-risk Individuals (in millions)						
Annual cost to Medicare of \$900 incurred by each at-risk individual for drug therapy after cost management factor, beneficiary premium, and availability of generic drug	[\$25]	[\$48]	[\$66]	[\$74]	[\$81]	[\$294]
Savings to Medicare of Avoided Osteoporotic Fractures After Cost of Proposal to Restore DXA Reimbursement and Treatment of Identified at-risk Individuals (in millions)						
Net savings to Medicare of Restoring Payment for DXA to 2006 Rates	\$56	\$166	\$254	\$308	\$360	\$1,144

Appendix B contains the full model for the five-year estimates and Appendix C contains the full model for the 10-year estimates.

V. DISCUSSION

The results of this analysis support concerns that the marked reduction in Medicare reimbursement for DXA and VFA may be ill advised. At a median cost of \$135 to perform a DXA study, and an estimated reimbursement of \$35 by 2010, no physician will be able to cover their operating costs regardless of the volume of DXA studies performed. Indeed, the losses incurred performing DXA will be too large to be cross-subsidized within physician practices. At a current reimbursement rate of approximately \$81, a number of large practices with high DXA volume and very low unit costs have already closed their doors. This runs counter to current dictum that higher volumes are associated with greater efficiency and thus lower operating costs.

The methodology used to determine reimbursement in the hospital outpatient department is different from the non-facility/office setting. The MPFS sets payment for both the professional and technical component of procedures performed in the non-facility setting. In contrast, the technical component of procedures performed in the hospital outpatient department is determined by the Outpatient Prospective Payment System (OPPS) while the professional component follows the MPFS. The hospital OPPS uses the Ambulatory Payment Classification (APCs) in which similar procedures are grouped together and assigned a single payment that includes the bundle of services associated with the procedure. The APC payment is designed to cover the hospital's capital and operating costs (facility fee). Although the most recent five-year review of the MPFS set fees in the office setting through 2010, the OPPS announces their reimbursement rates for the hospital and outpatient departments only one year at a time. Given the recent trend of reducing Medicare reimbursements for imaging services, it is not unreasonable to expect that DXA payments in the hospital and outpatient departments will decrease as well in the coming years. This expectation will likely deter hospital providers from increasing their DXA capacity.

Section 5102 of the DRA, which took effect on January 1st 2007, reimbursed the technical component of advanced diagnostic imaging services such as CT, MRI, PET scans as well as DXA at the lower of the MPFS or the OPPS reimbursement. This is why DXA reimbursement in the office setting dropped 40% in one year to \$81. If this legislation had not been in place, DXA reimbursement from the MPFS would have been approximately \$110 for 2007. In contrast, the hospital outpatient payment remained relatively stable between 2006 and 2007 at \$84 (\$72.70 facility fee plus \$11.30 professional fee).

When office practices close down their DXA units, patients may be referred to the hospital outpatient department to obtain DXA testing. However, hospitals will likely not have the capacity to absorb the potential influx of patients, creating access to care issues. Furthermore, the increased complexities of receiving care in the hospital (i.e., receiving care from another provider at a different location, and the need to send and receive medical records and test results) will likely discourage some patients from visiting the hospital outpatient department to be tested.

The difference in co-payments for Medicare beneficiaries may also deter patients from the hospital outpatient setting. 2006 payments resulted in a co-payment for DXA of \$28 for a

physician office and \$40 for the hospital outpatient.⁴⁷ Reductions in payment for office-based procedures will decrease co-payments for both sites of service compared to 2006, but will result in higher co-payments when patients are transferred from physician offices to the hospital outpatient department (from \$16 to \$35 for each DXA procedure in 2007).⁴⁸ These financial issues will likely lead to a further decline in the number of qualified Medicare beneficiaries who are diagnosed with osteoporosis using DXA.

Given the study's findings, access to care will most likely be compromised if physicians are unable to offer DXA services to patients in their office. Out-of-pocket costs, additional travel time and expense, appointment availability, and the like have been shown to be barriers to access, especially for preventive services that often are perceived as being "not needed," especially if costly to the patient.⁴⁹

Practices providing VFA services are also facing reductions in reimbursement from the MPFS amounting to 50% by 2010. The rules of Section 5102 of the DRA do not apply to VFA as the technical component for VFA is slightly higher in the MPFS than the OPPS. When VFA is performed in tandem with DXA, losses will total approximately \$83 (\$52 loss for DXA and \$31 loss for VFA).

One of the guiding principles for the MPFS is that services be appropriately valued. The Medicare Payment Advisory Commission (MedPAC) advises Congress on Medicare payments. In their March 2007 report they stated that "The Commission is concerned that differences in the profitability across physician services create incentives for physicians to favor furnishing some procedures and services over other, less profitable ones. In this environment, beneficiary access to relatively undervalued services – and to the providers that perform them – may be threatened. Misvalued services should be identified and payments corrected."⁵⁰

The Medicare goal of increasing beneficiaries' use of preventive services is undercut by the large reduction in DXA and VFA payment rates. Despite CMS' efforts to promote DXA testing to detect osteoporosis, fewer than 20% of eligible Medicare beneficiaries had been tested within a two-year interval. To reduce DXA reimbursement by 75% and VFA by 50% will only further undervalue this service and undermine federal initiatives to improve recognition and treatment of osteoporosis in the Medicare population.

The unintended consequence of the marked reductions in reimbursement for DXA and VFA will serve to spend, rather than save, Medicare dollars. The case of DXA and VFA is an instance in which prevention serves the role society asks of it – that is, to reduce morbidity and health care expenditures. Medicare is not serving its beneficiaries well to essentially eliminate office-based DXA and VFA services.

⁴⁷In the physicians office for 2006, Medicare beneficiaries pay 20% of the global MPFS payment (\$28), while beneficiaries pay close to 40% of the DXA 2006 APC payment (\$29) plus 20% of the physician fee schedule amount (\$11), resulting in a total out-of-pocket expense of \$40 per procedure.

⁴⁸Co-payment for physician office is equal to 20% of \$82. Hospital outpatient co-payment is equal to \$29 plus 20% of the physician fee schedule amount (\$6), resulting in a total out-of-pocket expense of \$35 per procedure. In 2008, the physician office co-payment will stay roughly the same at \$16, while the hospital outpatient co-payment will increase to \$36.

⁴⁹Scheppers E, van Dongen E, Dekker J, et al. (2006). Potential barriers to the use of health services among ethnic minorities: a review. *Family Practice* 23(3):325-348.

⁵⁰MedPAC. (2007). Report to the Congress: Medicare Payment Policy. March 2007.

APPENDIX A: SURVEY INSTRUMENT

Office Based (Non-Facility) DXA Cost
Survey Questionnaire
July 9, 2007

Thank you for agreeing to participate in this important survey to help understand DXA costs.

Instructions

To accurately assess DXA costs, we need to collect information on a variety of clinic operating expenses. To ensure the most accurate information, **we suggest that you share this survey with your clinic administrator and/or business manager so they can assist you in its completion.** Please make sure you include all of your practice(s)'s expenses (unless specified), not just those attributed to DXA. The time spent completing this will be invaluable in arriving at a true cost analysis that may **result in a more accurate reimbursement.**

This survey will collect practice level information regarding procedure volume and equipment costs and professional expenses for your most recently completed fiscal year.

To submit this paper survey:

- **Print, complete and fax responses to Audrey El-Gamil at The Lewin Group at 703-269-5501, or**
- **Complete electronically and email responses to Audrey El-Gamil at The Lewin Group at audrey.el-gamil@lewin.com.**

Please make sure that you insert your log-in information at the top of the first page of the survey!

Again, we assure you that The Lewin Group is treating all information as confidential. Under no circumstances will individual practice information be reported or shared with anyone. Furthermore, The Lewin Group will provide only aggregated data across providers.

If you have questions or wish to discuss any issues related to the survey, please call Audrey El-Gamil at The Lewin Group between the hours of 9 am ET and 6 pm ET, or leave a message, at (703) 269-5771. Alternatively, you can email Audrey at audrey.el-gamil@lewin.com.

Information about You

(Please complete this survey only if you are not a hospital based practice billing under the Hospital Outpatient Prospective Payment System (OPPS))

A-1	Your name:
A-2	City where practice is located:
A-3	State where practice is located:
A-4	Zip code of practice:
A-5	Location of practice: (check one) <input type="checkbox"/> Urban <input type="checkbox"/> Suburban <input type="checkbox"/> Rural
A-6	Specialty you practice: (check one) <input type="checkbox"/> Endocrinology <input type="checkbox"/> Family Practice <input type="checkbox"/> Gynecology <input type="checkbox"/> Internal Medicine <input type="checkbox"/> Orthopedics <input type="checkbox"/> Rheumatology <input type="checkbox"/> Radiology <input type="checkbox"/> Other (specify: _____)
A-7	Years practicing specialty: _____ years
A-8	Are you ISCD Certified as a CCD (Certified Clinical Densitometrist)? <input type="checkbox"/> Yes <input type="checkbox"/> No
A-9	Is your practice based in a hospital? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, do you bill for DXA using the Hospital Outpatient Department (HOPD) rate also referred to as the Hospital Outpatient Prospective Payment System (OPPS)? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If you answered "yes" to both questions, please do not complete the rest of the survey. This survey is only for office-based/non-facility based practices whose payment is based on the Medicare Fee Schedule. Thank you for your time! Please fax your responses to Ted Kirby at 703-269-5501.</i>

Information about Your Practice

B-1	<p>How many: <input type="text"/> physicians are in your practice? <input type="text"/> of those physicians, how many are reading DXAs?</p> <p>Do you have non-physician providers (NP, PA) who read DXAs? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, how many? <input type="text"/> non-physician providers</p>
B-2	<p>Which central sites do you routinely measure? <input type="checkbox"/> spine only <input type="checkbox"/> one hip only <input type="checkbox"/> spine and one hip <input type="checkbox"/> spine and both hips</p>
B-3	<p>Do you do forearm DXAs? <input type="checkbox"/> Yes <input type="checkbox"/> No* <i>Skip to Question B-6</i></p>
B-4	<p>If you do forearm DXAs, do you do them: <input type="checkbox"/> in all patients having central DXA?* <i>Skip to Question B-6</i> <input type="checkbox"/> only in selected patients?</p>
B-5	<p>If only in selected patients, what percent of patients having central DXAs also have forearm DXAs? <input type="text"/> percent having central DXA and forearm DXA <input type="text"/> percent having only forearm DXAs</p>
B-6	<p>How much of your DXA volume comes from your own practice and how much is referred to you from outside of your practice? (total must equal 100%) <input type="text"/> % from your practice <input type="text"/> % referred to you</p>
B-7	<p>When you bill for DXA, do you bill the global fee or the professional component? <input type="checkbox"/> global fee <input type="checkbox"/> professional component only (-26)</p>

B-8	<p>What is the average number of hours per week that your office is open for business?</p> <p>_____ hours per week</p>
B-9	<p>How many days of the week is your office open for business?</p> <p>_____ days of the week</p>
B-10	<p>How many weeks of the year is your office open for business?</p> <p>_____ weeks of the year</p>
B-11	<p>What is the average number of hours per week that DXA is available/offered in your office?</p> <p>_____ hours per week</p>
B-12	<p>How many central DXA procedures are performed in an average month per machine?</p> <p>_____ procedures</p>

Information about VFA

C-1	<p>Do you have VFA capability?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
C-2	<p>Do you read VFA?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No* <i>Skip to next section</i></p>
C-3	<p>How many VFA procedures are performed in an average month per machine?</p> <p>_____ procedures</p>
C-4	<p>How many machines are used for VFA?</p> <p>_____ machines</p>

For the next sections, we suggest that you share the questionnaire with your clinic administrator and/or business manager so they can assist you. The time spent completing this will be invaluable in arriving at a true cost analysis that may result in a more accurate reimbursement for central DXA.

Information about Your Equipment Costs

Total number of DXA machines in your practice: _____

Please fill out one row in the following table for each DXA machine in your practice.

Please specify if the manufacturer is:

- Hologic,
- Norland/Cooper, or
- GE/Lunar

Machine Number	Manufacturer	Fan or Pencil Beam	Year Purchased	Annual Depreciation Cost per Year	Days per Year Machine is Down for Maintenance
1					
2					
3					
4					

D-2 Cost per year of interest on loan(s) used to purchase your DXA machine(s):
\$_____ per year

D-3 Cost per year of any service contract(s) for your DXA machine(s):
\$_____ per year

D-4 Cost per year of software upgrade(s) for your DXA machine(s):
\$_____ per year

D-5 Cost of the last PAC/DICOM upgrade(s) (ability to transmit radiographic images electronically):
\$_____

Information about Your Professional Expenses (your last full fiscal year)

Please answer the remaining sections based on your last full fiscal year.

Make sure to include your entire practice's expenses, rather than those just attributed to DXA. We will use this information to calculate the proportion of your clinic's overhead expenses that are attributed to DXA procedures.

For the purpose of this survey, "practice(s)'s expenses" are defined as all expenses that are captured on your Profit and Loss (Income) Statement for all services your practice provides. Do not differentiate between DXA and all other services provided. We list some examples of expenses you should and should not include in your totals:

Do include:

- Rent and utilities for your entire practice, not just areas attributed to DXA services
- Salary amounts (and benefits) for visiting physicians or support staff that are paid by your practice, but also serve or support other practices

Do not include:

- Salaries for visiting physicians that use your clinic space but are not paid a salary from your practice
- Rent for neighboring practices that share space (i.e., waiting rooms)

If you have any further questions, please call Audrey El-Gamil at The Lewin Group at (703) 269-5771

E-1	<p>What is the start and end date of your last full fiscal year?</p> <p>Start Date: Month _____ Year _____</p> <p>End Date: Month _____ Year _____</p>
E-2	<p>What is the total square footage for your practice? (If practice has more than one location include total square footage of all offices) _____ sq ft.</p> <p>What is the total square footage attributed to DXA use? (If an exam room is set aside for DXA only, then you would provide the square footage of the exam room itself. If part of the room where DXA machine is located is used for other purposes, then you would list the square footage of that portion of the room reserved for DXA. If practice has more than one DXA machine include square footage reserved for each machine.) _____ sq ft.</p> <p>What is the lease per square foot for your practice(s)? \$ _____</p>
E-3	<p>What was your practice's professional medical liability or malpractice insurance premium for your last full fiscal year, to the nearest thousand dollars?</p> <p>\$ _____ Premium Amount</p>
E-4	<p>What were your practice's non-clinical non-physician payroll expenses for your last full fiscal year were solely for individuals involved with administrative, secretarial, or clerical activities (to the nearest thousand dollars)? Include all sites for which your practice bears these costs (e.g. practice managers, schedulers, billing personnel, record clerks, clerical, etc.).</p> <p>\$ _____</p>

E-5	<p>What were your practice's total clinical non-physician payroll expenses for your last full fiscal year, including fringe benefits (to the nearest thousand dollars)? Include all sites for which your practice bears these costs (e.g. nurses, technicians).</p> <p>\$ _____</p>
E-6	<p>What were your practice's total provider payroll expenses for your last full fiscal year, including current or deferred compensation (to the nearest thousand dollars)? (Physicians, Nurse Practitioners, Physician Assistants). Include all sites for which your practice bears these costs (e.g. salaries, bonuses, dividends, and pension funds).</p> <p>\$ _____</p>
E-7	<p>What were your overall practice's expenses for medical materials and supplies not separately reimbursable that are used for clinical purposes for your last full fiscal year (to the nearest thousand dollars)? Include all sites for which your practice bears these costs (e.g. X-ray films, processor chemicals, laundry and disposable medical supplies). Do not include expenses for non-clinical office supplies or medicines which are separately reimbursable.</p> <p>\$ _____</p>

Information about Your Non-Clinical Expenses (your last full fiscal year)

F-1	<p>What were your practice's non-clinical office expenses for your last full fiscal year, including non-clinical office equipment and supplies, rent, mortgage interest, depreciation and maintenance costs on office and medical buildings, commercial property insurance, property taxes, utilities and telephone, supplies for billing, scheduling and business functions (to the nearest thousand dollars)? Include all sites for which your practice bears these costs.</p> <p>\$ _____</p>
F-2	<p>What were your practice expenses for all other expenses for your last full fiscal year, including marketing expenses, legal fees, accounting, office management services, contracted billing expenses, professional car upkeep and depreciation, professional association memberships, professional journals, continuing education (CME), all employee-provided insurance other than malpractice, and other expenses that have not been listed (to the nearest thousand dollars)?</p> <p>\$ _____</p>
F-3	<p>What were your practice's bad debts for services provided in your last full fiscal year (to the nearest thousand dollars)?</p> <p>\$ _____</p>

Do you have any additional comments?

Congratulations, you have finished the survey!

*Thank you for your responses.
To submit your complete survey, please fax it to
Audrey El-Gamil at the Lewin Group, 703-269-5501*

APPENDIX B: 5-YEAR MODEL

Cost Estimation of Keeping 2006 Medicare DXA Reimbursement						
	2008	2009	2010	2011	2012	Total 2008-2012
Baseline DXA Spending Under DRA and Other Cuts						
Projected number of Medicare beneficiaries with outpatient claims	35,848,239	36,385,962	36,931,752	38,039,704	39,180,895	
Decline from prior year	25%	25%	25%	10%	10%	
Number of central DXA procedures performed in physician offices	1,236,298	927,223	695,418	625,876	563,288	4,048,103
Global DXA payments 2007-2010 per Medicare physician fee schedule	\$81.66	\$56.82	\$35.48	\$35.48	\$35.48	
Allowed charges from CMS correspondence	\$100,956,082	\$52,684,832	\$24,673,414	\$22,206,073	\$19,985,465	\$220,505,866
Total Medicare payment for DXA from CMS correspondence	\$74,000,808	\$38,617,982	\$18,085,613	\$16,277,051	\$14,649,346	\$161,630,800
Estimated DXA Spending Under Proposal to Restore Rates at 2006 Levels (with proportionate escalation in procedure volume)						
Global payment for central DXA under proposed freeze in rates to 2006 levels	\$139.46	\$139.46	\$139.46	\$139.46	\$139.46	
Number of central DXA procedures in physician offices under proposal holding 2006 payment levels with volume increases proportionate to beneficiary population growth	1,597,249	1,621,208	1,645,526	1,694,892	1,745,738	8,304,613
Estimated Medicare spending in physician offices under freeze with volume increases proportionate with growth in beneficiary population	\$199,114,370	\$202,101,086	\$205,132,602	\$208,209,591	\$211,332,735	\$1,025,890,385
Difference between estimated spending under DRA and other cuts and spending under proposal to freeze rates (cost of proposal)	\$125,113,563	\$163,483,104	\$187,046,990	\$191,932,540	\$196,683,389	\$864,259,585
Total Estimated Medicare Spending for DXA Under Proposal						
Total baseline Medicare spending for DXA under DRA and other cuts	\$74,000,808	\$38,617,982	\$18,085,613	\$16,277,051	\$14,649,346	\$161,630,800
Total estimated Medicare spending in physician offices under freeze with volume increases proportionate with growth in beneficiary population	\$199,114,370	\$202,101,086	\$205,132,602	\$208,209,591	\$211,332,735	\$1,025,890,385
Total difference in DXA spending under DRA and other cuts and spending under freeze (Total cost of proposal)	\$125,113,563	\$163,483,104	\$187,046,990	\$191,932,540	\$196,683,389	\$864,259,585
Net cost of proposal after beneficiary Part B premium	\$93,835,172	\$122,612,328	\$140,285,242	\$143,949,405	\$147,512,542	\$648,194,689

	2008	2009	2010	2011	2012	Total 2008-2012
Cost Savings from Reduced Fractures after Implementation of Proposal						
Number of annual osteoporotic fractures among patients aged 65 and older (71%) inflated by .0459 per year beginning in 2006 per Burge et al, 2007	1,592,181	1,665,262	1,741,698	1,821,642	1,905,255	8,726,039
Annual cost to Medicare of osteoporotic fractures with \$16.9 billion in 2005 dollars (87% of costs for age 65+) increased by CPI and growth in beneficiary population = roughly equivalent to .0466 compound rate of growth per year per Burge et al, 2007	\$19,302,867,272	\$20,180,182,589	\$21,097,371,888	\$22,382,201,836	\$23,745,277,928	\$106,707,901,513
Per fracture cost calculated, as. \$12,134 per Burge, Dawson-Hughes, Solomon et al, 2007.	\$12,124	\$12,118	\$12,113	\$12,287	\$12,463	
Net per fracture cost after beneficiary Part B copays and deductibles (20%)	\$9,699	\$9,695	\$9,690	\$9,829	\$9,970	
Number of DXAs performed under DRA cuts - from above	1,236,298	927,223	695,418	625,876	563,288	4,048,103
Number of central DXA procedures under proposal	1,597,249	1,621,208	1,645,526	1,694,892	1,745,738	8,304,613
Number of central DXA procedures lost under DRA and other cuts if proposal not implemented	360,951	693,984	950,108	1,069,016	1,182,450	4,256,510
Total number of lost procedures under DRA	360,951	693,984	950,108	1,069,016	1,182,450	4,256,510
Number of fractures prevented by each screen: .05 assumption of 75% women treated having osteoporosis and 25% having osteopenia per King et al sensitivity analysis	18,048	34,699	47,505	53,451	59,123	212,826
Total net cost to Medicare of increased fractures from losing DXA procedures under DRA and other cuts - after beneficiary co-pay	\$175,040,214	\$336,397,008	\$460,350,535	\$525,392,608	\$589,477,113	\$2,086,657,478
Medicare savings from reduced fractures taking into account the cost of proposal/cost of increased fractures minus cost of freeze - 2007 is a cost to Medicare, outyears are savings	\$81,205,042	\$213,784,680	\$320,065,293	\$381,443,203	\$441,964,571	\$1,438,462,789
Annual Cost of Treatment @ \$900 per Beneficiary under Part D						
Cost to Medicare of medications under Part D if all beneficiaries covered under Part D - for every scan (n=3,406,877), .44 prescriptions are written per King et al	\$142,936,697	\$274,817,843	\$376,242,932	\$423,330,315	\$468,250,309	\$1,685,578,096
Cost of medications with 58.5% beneficiaries in Part D - rest uninsured or other plans	\$83,617,968	\$160,768,438	\$220,102,115	\$247,648,234	\$273,926,431	\$986,063,186
... and cost management factor per CBO - 27% discount on branded drugs from the plans prior to 2008	\$83,617,968	\$160,768,438	\$220,102,115	\$247,648,234	\$273,926,431	\$986,063,186
... and 25.5% beneficiary Part D premium for average cost plan per CBO	\$62,295,386	\$119,772,486	\$163,976,076	\$184,497,934	\$204,075,191	\$734,617,074
Generic discount averaging 60% beginning in 2008	\$24,918,154	\$47,908,995	\$65,590,430	\$73,799,174	\$81,630,076	\$293,846,830
Medicare savings from reduced fractures taking into account the cost of the treatment - these are savings	\$56,286,888	\$165,875,686	\$254,474,862	\$307,644,029	\$360,334,495	\$1,144,615,960

APPENDIX C: 10-YEAR MODEL

Cost Estimation of Keeping 2006 Medicare DXA Reimbursement							
	Total 2008-2012	2013	2014	2015	2016	2017	Total 2013-2017
Baseline DXA Spending Under DRA and Other Cuts							
Projected number of Medicare beneficiaries with outpatient claims		40,356,322	41,567,012	42,814,022	44,098,443	45,421,396	
Decline from prior year		10%	10%	10%	10%	10%	
Number of central DXA procedures performed in physician offices	4,048,103	506,959	456,263	410,637	369,573	332,616	6,124,152
Global DXA payments 2007-2010 per Medicare physician fee schedule		\$36.54	\$37.64	\$38.77	\$39.93	\$41.13	
Allowed charges from CMS correspondence	\$220,505,866	\$18,526,526	\$17,174,090	\$15,920,381	\$14,758,194	\$13,680,845	\$300,565,903
Total Medicare payment for DXA from CMS correspondence	\$161,630,800	\$13,579,944	\$12,588,608	\$11,669,640	\$10,817,756	\$10,028,060	\$220,314,807
Estimated DXA Spending Under Proposal to Restore Rates at 2006 Levels (with proportionate escalation in procedure volume)							
Global payment for central DXA under proposed freeze in rates to 2006 levels		\$143.64	\$147.95	\$152.39	\$156.96	\$161.67	
Number of central DXA procedures in physician offices under proposal holding 2006 payment levels with volume increases proportionate to beneficiary population growth	8,304,613	1,798,111	1,852,054	1,907,616	1,964,844	2,023,789	17,851,027
Estimated Medicare spending in physician offices under freeze with volume increases proportionate with growth in beneficiary population	\$1,025,890,385	\$217,672,717	\$224,202,899	\$224,202,899	\$230,928,986	\$230,928,986	\$2,153,826,872
Difference between estimated spending under DRA and other cuts and spending under proposal to freeze rates (cost of proposal)	\$864,259,585	\$204,092,773	\$211,614,291	\$212,533,259	\$220,111,230	\$220,900,926	\$1,933,512,064
Total Estimated Medicare Spending for DXA Under Proposal							
Total baseline Medicare spending for DXA under DRA and other cuts	\$161,630,800	\$13,579,944	\$12,588,608	\$11,669,640	\$10,817,756	\$10,028,060	\$220,314,807
Total estimated Medicare spending in physician offices under freeze with volume increases proportionate with growth in beneficiary population	\$1,025,890,385	\$217,672,717	\$224,202,899	\$224,202,899	\$230,928,986	\$230,928,986	\$2,153,826,872
Total difference in DXA spending under DRA and other cuts and spending under freeze (Total cost of proposal)	\$864,259,585	\$204,092,773	\$211,614,291	\$212,533,259	\$220,111,230	\$220,900,926	\$1,933,512,064
Net cost of proposal after beneficiary Part B premium	\$648,194,689	\$153,069,580	\$158,710,718	\$159,399,944	\$165,083,422	\$165,675,694	\$1,450,134,048

	Total 2008-2012	2013	2014	2015	2016	2017	Total 2013-2017
Cost Savings from Reduced Fractures after Implementation of Proposal							
Number of annual osteoporotic fractures among patients aged 65 and older (71%) inflated by .0459 per year beginning in 2006 per Burge et al, 2007	8,726,039	1,992,707	2,084,172	2,179,835	2,279,890	2,384,537	19,647,179
Annual cost to Medicare of osteoporotic fractures with \$16.9 billion in 2005 dollars (87% of costs for age 65+) increased by CPI and growth in beneficiary population = roughly equivalent to .0466 compound rate of growth per year per Burge et al, 2007	\$106,707,901,513	\$25,191,365,354	\$26,725,519,504	\$28,353,103,641	\$30,079,807,653	\$31,911,667,939	\$248,969,365,604
Per fracture cost calculated, as. \$12,134 per Burge, Dawson-Hughes, Solomon et al, 2007.		\$12,642	\$12,823	\$13,007	\$13,194	\$13,383	
Net per fracture cost after beneficiary Part B copays and deductibles (20%)		\$10,113	\$10,258	\$10,406	\$10,555	\$10,706	
Number of DXAs performed under DRA cuts - from above	4,048,103	506,959	456,263	410,637	369,573	332,616	6,124,152
Number of central DXA procedures under proposal	8,304,613	1,798,111	1,852,054	1,907,616	1,964,844	2,023,789	17,851,027
Number of central DXA procedures lost under DRA and other cuts if proposal not implemented	4,256,510	1,291,151	1,395,791	1,496,978	1,595,271	1,691,173	11,726,875
Total number of lost procedures under DRA	4,256,510	1,291,151	1,395,791	1,496,978	1,595,271	1,691,173	11,726,875
Number of fractures prevented by each screen: .05 assumption of 75% women treated having osteoporosis and 25% having osteopenia per King et al sensitivity analysis	212,826	64,558	69,790	74,849	79,764	84,559	586,344
Total net cost to Medicare of increased fractures from losing DXA procedures under DRA and other cuts - after beneficiary co-pay	\$2,086,657,478	\$652,898,194	\$715,933,813	\$778,847,580	\$841,890,446	\$905,302,268	\$5,981,529,779
Medicare savings from reduced fractures taking into account the cost of proposal/cost of increased fractures minus cost of freeze - 2007 is a cost to Medicare, outyears are savings	\$1,438,462,789	\$499,828,614	\$557,223,095	\$619,447,635	\$676,807,024	\$739,626,574	\$4,531,395,731
Annual Cost of Treatment @ \$900 per Beneficiary under Part D							
Cost to Medicare of medications under Part D if all beneficiaries covered under Part D - for every scan (n=3,406,877), .44 prescriptions are written per King et al	\$1,685,578,096	\$511,295,895	\$552,733,041	\$592,803,475	\$631,727,177	\$669,704,630	\$4,643,842,315
Cost of medications with 58.5% beneficiaries in Part D - rest uninsured or other plans	\$986,063,186	\$299,108,099	\$323,348,829	\$346,790,033	\$369,560,398	\$391,777,209	\$2,716,647,754
... and cost management factor per CBO - 27% discount on branded drugs from the plans prior to 2008	\$986,063,186	\$299,108,099	\$323,348,829	\$346,790,033	\$369,560,398	\$391,777,209	\$2,716,647,754
... and 25.5% beneficiary Part D premium for average cost plan per CBO	\$734,617,074	\$222,835,534	\$240,894,878	\$258,358,574	\$275,322,497	\$291,874,020	\$2,023,902,577
Generic discount averaging 60% beginning in 2008	\$293,846,830	\$89,134,213	\$96,357,951	\$103,343,430	\$110,128,999	\$116,749,608	\$809,561,031
Medicare savings from reduced fractures taking into account the cost of the treatment - these are savings	\$1,144,615,960	\$410,694,401	\$460,865,144	\$516,104,206	\$566,678,025	\$622,876,966	\$3,721,834,700



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memorandum

Date: February 20, 2008

To: Sara Milo, AACE; Donna Fiorentino, ISCD

From: Audrey El-Gamil, The Lewin Group

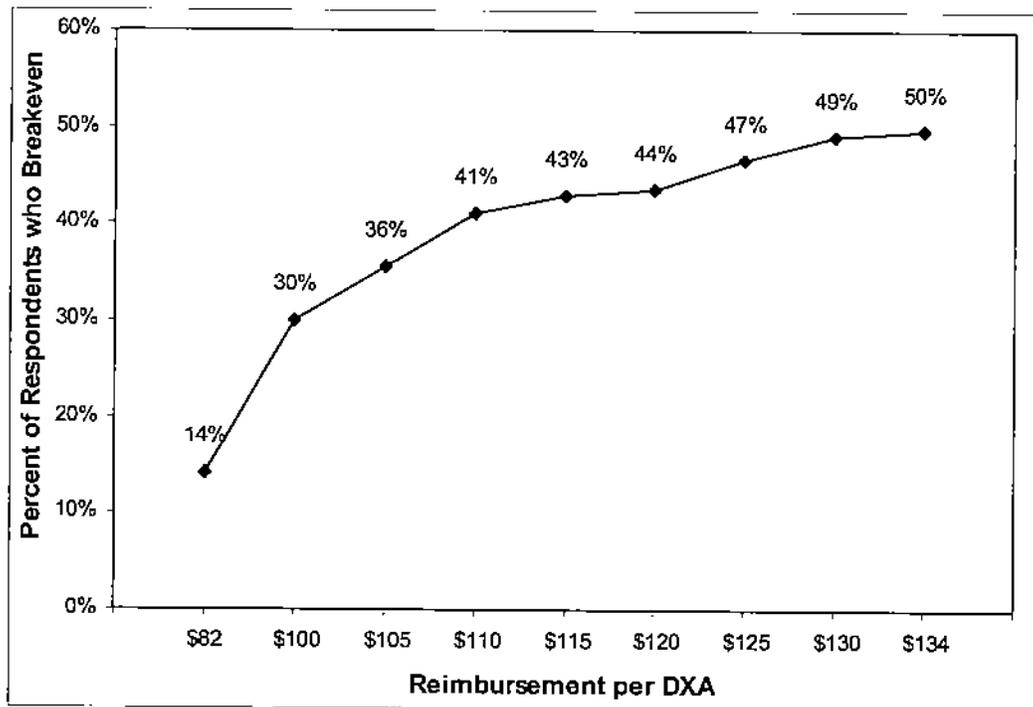
Re: Distribution of Breakeven points per DXA procedure

It is important to understand how specific reimbursement rates will affect providers' financial viability in order to respond to rate setting proposals for DXA services. Our original analysis compared providers' costs to the Berkley bill - which proposed to set DXA payments at \$140. As new proposals are being developed, the implications on providers must be considered. It is important to understand what proportion of DXA providers will have costs¹ that exceed this reimbursement.

Additional analyses were conducted to identify what percent of providers have costs equal to or less than a given reimbursement rate (referred to as "breakeven"). This analysis is based on providers' costs for 2007, and therefore reflects the proportion that would have had costs equal to or less than reimbursement rates in 2007. As Figure 1 shows, only 14 percent of DXA providers would have operated below the breakeven point with reimbursement rates of \$82, while 50 percent of providers would have operated below breakeven at \$134. Between \$110 and \$120, there is little variation in the proportion of providers who would have had their costs covered. This is due to the few providers who have costs in this range. Furthermore, only 6 percent more providers would have had costs less than or equal to reimbursement of \$134 than those who would breakeven at \$120.

¹ For the purpose of this analysis, providers' costs are defined as all expenses associated with performing DXA, including physician work, practice expense and malpractice expense.

Figure 1: Distribution of Providers' Breakeven Reimbursement per DXA Procedure, 2007

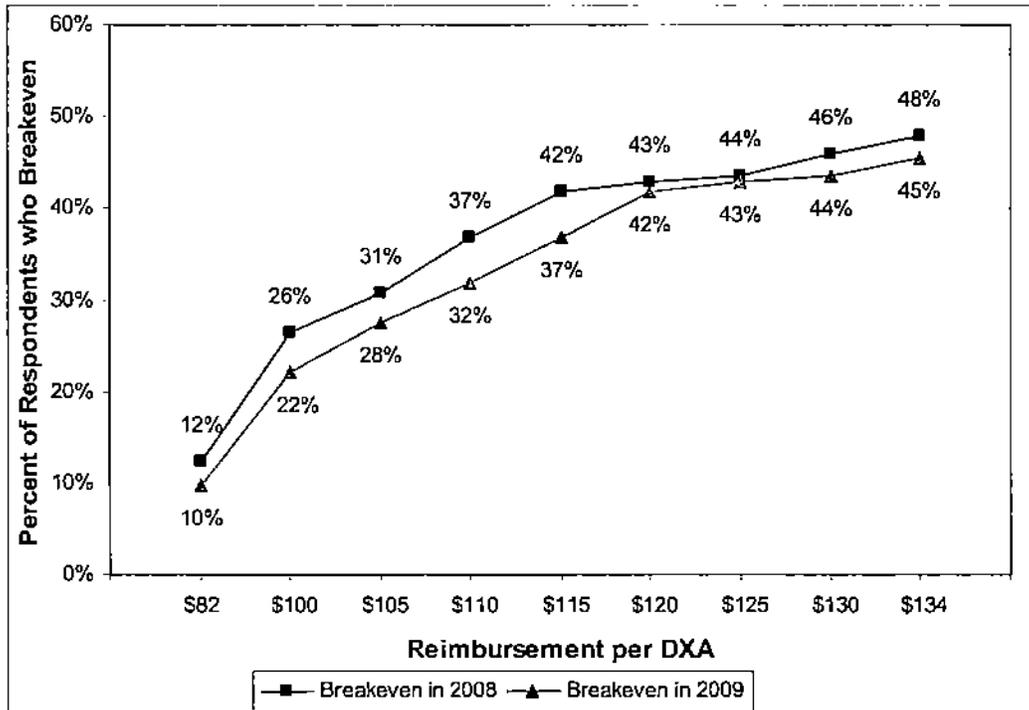


When considering these proposed reimbursement rates for 2008 or later one must consider the increase in costs providers will incur as a result of inflation². For example, while 43 percent of providers operated below the breakeven point at a reimbursement of \$115 in 2007, only 42 percent of providers would breakeven in 2008. Furthermore, in 2009, the proportion of providers who will breakeven will further decline to 37 percent for reimbursement of \$115. It is important to note that a proposal to freeze payments at a set reimbursement rate for more than one year will negatively affect providers' margins more in the second year than in the first, as their costs still continue to increase. For 50 percent of providers to breakeven, reimbursement must be set at \$139.76 in 2008 and \$145.63 in 2009 - more than \$10 higher than the median cost for 2007. See Figure 2 for the distribution of providers who will breakeven in 2008 and 2009.

² CPI-U projections for medical care are unavailable for 2008 and 2009. As a result, we used the average CPI-U for 2003 through 2007, resulting in an average of 4.2 for 2008 and 2009. The CPI-U for medical care for 2003 was 4.0%, 2004 was 4.4%, 2005 was 4.2%, 2006 was 4.0%, and 2007 was 4.4%. Note that in the original analysis we used 4.1% for 2007. This is because at the time of the analysis, only estimates for the first half 2007 were available, estimated to be 4.1%.

Ms. Sara Milo and Ms. Donna Fiorentino
 February 20, 2008
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Figure 2: Distribution of Providers' Breakeven Reimbursement per DXA Procedure, 2008 - 2009



Impact of DXA Reimbursement Cuts

As you know, DXA reimbursement in the physician's office (non-facility) setting was reduced by ~40% this year. Unless Congress acts, DXA payments will incrementally drop by ~75% in 2010. VFA reimbursement will be cut by ~50% by 2010.

A group of societies with an interest in bone health is collecting information about how reimbursement cuts for DXA and VFA procedures may affect physicians and patients. This information will be used by these societies on Capitol Hill as we pursue legislative relief from the revisions to the Medicare Physician Fee Schedule and the Deficit Reduction Act. Your participation and input in this survey is important and will contribute to the success of these efforts. **Please complete this survey if you are a physician who performs DXA in the office (non-facility) setting.**

Please note: You may receive this survey from more than one organization, please only complete the survey once.

Thank you.

1 Do you perform DXA primarily in the office (non-facility) setting?

- Yes 78%
- No 22%

2 Have you discontinued performing DXA in your office as a result of the recent Medicare reimbursement cuts?

- Yes 7%
- No 93%

3 We are collecting information regarding how the cuts have already affected patient access to DXA. If you have discontinued DXA service, please provide your name, email, and the date DXA service was discontinued. This information will be used to tell the DXA story in Washington.

If you do not wish to share your name with us, simply skip this question and click submit to continue.

Name:
 Email:
 Date DXA was
 Discontinued:

4 I am a member of the following organization(s) (check all that apply):

- American Association of Clinical Endocrinologists (AACE) 39%
- American College of Rheumatology (ACRheum) 16%
- International Society for Clinical Densitometry (ISCD) 68%
- The Endocrine Society (TES) 29%
- None of the above 7%

5 Identify Your Primary Area of Practice:

6 Identify Geographic Practice Setting:

- Rural 17%
- Suburban 45%
- Urban 37%

7 Identify Primary Type of Practice:

- Solo Practice 23%
- Single Specialty Group 44%
- Multi-specialty Group 27%
- Medical School Faculty Practice Plan 6%

8 Does Your Practice Own or Lease DXA Equipment?

- Own 75%
- Lease 25%

9 You indicated that your practice owns DXA equipment. Are you still making payments or have you paid in full for the equipment?

- I am making payments on this equipment. 40%
- I have paid in full for this equipment. 60%

10 Will Medicare payment cuts affect your ability to pursue professional development activities in the field of osteoporosis for physicians and/or technologists (i.e.: attending courses, obtaining certification and/or facility accreditation)...

- at 2007 rates of approximately \$82 ? Yes 73% No 27%
- at 2008 rates of approximately \$80 ? Yes 75% No 25%
- at 2009 rates of approximately \$57 ? Yes 67% No 4%
- at 2010 rates of approximately \$35 ? Yes 97% No 3%

11 Will Medicare payment cuts for DXA cause you to stop seeing Medicare patients...

- at 2007 rates of approximately \$82 ? Yes 73% No 76%
- at 2008 rates of approximately \$80 ? Yes 75% No 68%
- at 2009 rates of approximately \$57 ? Yes 67% No 33%
- at 2010 rates of approximately \$35 ? Yes 71% No 29%

12 Will Medicare payment cuts for DXA cause you to stop providing DXA procedures for your Medicare patients...

- at 2007 rates of approximately \$82 ? Yes 36% No 64%
- at 2008 rates of approximately \$80 ? Yes 45% No 55%
- at 2009 rates of approximately \$57 ? Yes 91% No 9%
- at 2010 rates of approximately \$35 ? Yes 93% No 7%

13 Will Medicare payment cuts for DXA procedures cause you to stop accepting new Medicare patients...

- at 2007 rates of approximately \$82 ? Yes 30% No 70%
- at 2008 rates of approximately \$80 ? Yes 35% No 65%
- at 2009 rates of approximately \$57 ? Yes 66% No 34%
- at 2010 rates of approximately \$35 ? Yes 69% No 31%

14 Will Medicare payment cuts for DXA cause you to cancel plans to purchase or lease new DXA equipment...

- at 2007 rates of approximately \$82 ? Yes 80% No 20%
- at 2008 rates of approximately \$80 ? Yes 84% No 16%
- at 2009 rates of approximately \$57 ? Yes 94% No 6%
- at 2010 rates of approximately \$35 ? Yes 94% No 6%

15 Will Medicare payment cuts for DXA cause you to lay off staff or delay hiring new staff...

- at 2007 rates of approximately \$82 ? Yes 52% No 48%

at 2008 rates of approximately \$80 ? Yes 59% No 41%
at 2009 rates of approximately \$57 ? Yes 84% No 16%
at 2010 rates of approximately \$35 ? Yes 86% No 14%

16 If you were unable to perform DXA in your office due to the Medicare payment changes, would your patients have access to DXA within a reasonable proximity to where they live?

Yes 66%
 No 34%

17 If you decide to discontinue providing VFA services, what level of reimbursement will affect your decision?

\$39 to \$33 40%
 \$32 to \$27 15%
 \$26 to \$21 7%
 \$20 to \$ 0 6%
 Already discontinued 32%

Thank you for participating in this survey. The results of this survey will be used on Capitol Hill as we pursue a legislative remedy to the DRA and Medicare Physician Fee Schedule changes.