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August 18, 2006

Mark McClellan MD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1512-PN  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**RE: CMS-1512-PN: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology**

**Comments:**

- **Work RVU 76075 (Dual Energy X-ray Absorptiometry)**
- **Practice Expense 76075 (Dual Energy X-ray Absorptiometry); 76077 (Vertebral Fracture Assessment)**
- **Regulatory Impact Analysis 76075 and 76077**

Dear Dr. McClellan:

**Summary**

Osteoporosis is a major health care issue in the United States. DXA (dual energy x-ray absorptiometry) and VFA (vertebral fracture assessment) are crucial for the detection of osteoporosis and identification of those at highest fracture risk. Federal initiatives to identify patients with osteoporosis have led to the increased utilization of DXA and VFA; however, the vast majority of affected individuals continue to remain undiagnosed and untreated. The proposed changes in the physician fee schedule would reduce DXA reimbursement from approximately \$140 to \$40 and VFA from \$40 to \$25. These reductions will force physicians to discontinue offering these vital services, resulting in a severe limitation of patient access to high quality bone densitometry and vertebral fracture assessment. In this letter, the ISCD enumerates flaws in data input, data omission and erroneous assumptions that have contributed to these reductions in reimbursement. In view of these flaws, we request that CMS review the proposed cuts, and, at the very least, keep reimbursement at the current levels. This approach would resolve the inconsistency with the agency's preventive health care mission. In doing so,

we suggest that special resource considerations are necessary for DXA and VFA to assure the widespread availability of high-quality screening in the United States.

## **Introduction**

The International Society for Clinical Densitometry (ISCD) welcomes the opportunity to comment on the **CMS-1512-PN: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology**. Specifically, we would like to address CPT codes 76075 (DXA) and 76077 (Vertebral Fracture Assessment or VFA).

The ISCD is a multidisciplinary, nonprofit organization founded in 1993 that provides a central resource for scientific disciplines with an interest in bone mass measurement. Presently, the ISCD has 6,392 members in 56 countries. 93% of our members practice within the United States; 60% are physicians and 40% are densitometry technologists. Our membership spans more than 20 health care disciplines including Endocrinology, Family Practice, Gynecology, Internal Medicine, Nephrology, Orthopedics, Radiology, and Rheumatology.

The mission of the ISCD is to promote excellence in the assessment of skeletal health. As such, the ISCD provides approximately 25 comprehensive bone densitometry educational courses and 8 vertebral fracture assessment courses annually in the United States as well as certification in DXA performance and interpretation for technologists and physicians. Physicians who successfully pass the certification exam are designated Certified Clinical Densitometrists (CCD), while technologists are designated Certified Densitometry Technologists (CDT). Currently in the United States there are 5,750 physicians and 3,160 technologists with ISCD certification.

With the evolution in the field of bone densitometry, differences in technologies, acquisition techniques, reference databases, reporting methods, and terminology have developed. These differences may have adverse effects on patient care and the exchange of scientific information. To address these issues, the ISCD periodically holds Position Development Conferences (PDCs), a process whereby an international panel of experts makes recommendations after reviewing scientific literature presented by ISCD PDC Task Forces. Recommendations that are approved by the ISCD Board of Directors become Official Positions of the ISCD. A copy of the most recent Official Positions is amended to this report (Appendix A). These Official Positions promote uniformity in DXA and VFA performance, thereby enhancing clinical care.

Consistent with our goal of promoting excellence in skeletal health assessment, the ISCD has developed, and is currently beta-testing, a bone densitometry facility accreditation program that will soon be available. We anticipate this ISCD Facility Accreditation Program will assure patients, health care providers, CMS, and other health care payers that patients will receive high-quality bone density measurement nation-wide.

## **Osteoporosis: Scope, Consequence and Diagnosis**

Osteoporosis is a common disease, wherein bone strength is reduced and fracture risk is increased, that affects at least 10 million Americans. An additional 34 million have low bone mass (osteopenia) and are at increased risk for future fracture. The overall lifetime risk for fracture is estimated to be approximately 40% for a 50-year old white woman and 20% for a man. African-Americans, Hispanics and Asians are also significantly impacted. At least 1.5 million people suffer an osteoporotic fracture annually leading to greater than 500,000 hospitalizations, over 800,000 emergency room visits, more than 2.6 million physician office visits and the placement of almost 180,000 into nursing homes. Direct health care costs related to osteoporotic fractures range from \$12.2 to \$17.8 billion each year measured in 2002 dollars. Indirect costs are estimated to add billions more.<sup>1</sup> As you are well aware, osteoporosis is associated with significant morbidity and mortality. In fact, more deaths occur annually due to complications following hip fracture than from breast cancer.<sup>2</sup> To reduce the individual and societal impact of osteoporosis it is essential that osteoporosis be diagnosed prior to fracture with initiation of appropriate medical therapy for those at high risk. Bone density testing using central DXA (hip and spine) is currently the gold-standard and the only technology accepted for diagnosing osteoporosis by World Health Organization criteria and additionally allows physicians the ability to monitor response to therapy.

VFA is a recent advance using central DXA instruments, which permit thoracic and lumbar spine imaging for the detection of vertebral compression fractures. Software packages that permit DXA devices to perform VFA first received FDA 501(k) marketing clearance in October 1999. A newly created CPT code, 76077, for VFA was approved by the AMA and took effect on January 1, 2005. VFA is an attractive alternative to standard radiography for vertebral fracture identification in that radiation exposure is low (only 3-8 microsieverts compared to 700-800 microsieverts for a lateral radiograph of the lumbar and thoracic spine).<sup>3, 4</sup> Additionally, VFA has the added convenience of being done at the same time and location as a DXA study thus allowing immediate integration of bone density and fracture knowledge into an estimation of the individual's risk for future fracture. Importantly, VFA has comparable accuracy to plain radiograph in the identification of moderate and severe fractures in post-menopausal women being evaluated for osteoporosis, including those with low bone mass (osteopenia).<sup>5, 6, 7, 8</sup>

Thus, VFA has enhanced the ability of health care providers to detect vertebral fractures in patients who are being evaluated for osteoporosis. Since two-thirds of vertebral fractures are clinically unappreciated,<sup>9</sup> but convey substantially increased risk for future osteoporotic fractures, VFA combined with DXA has the potential to identify those at greatest risk for future fracture. This allows for improved targeting of pharmaceutical therapy to those at highest risk. Unlike many other imaging techniques, which are expensive and of unproven benefit in altering outcomes, multiple clinical trials have demonstrated that knowledge of bone density and/or vertebral fracture status can reduce fracture risk when drug therapy is initiated.<sup>10,11,12,13,14,15,16,17,18</sup> VFA will play an even more critical role in patient care with release of the World Health Organization fracture predictive model for estimating absolute fracture risk that includes prevalent fragility fractures and the National Osteoporosis Foundation recommendations for initiating pharmacologic therapy based upon fracture probability. In summary, DXA and

VFA are essential to the clinical identification and monitoring of people at risk for osteoporotic fracture.

### **Previous Health Care Policy and Effect on Bone Density Measurement**

Despite the above noted impact of osteoporotic fracture on health care outcomes, this disease continues to be substantially under-recognized by patients and health care providers alike. In fact, 95% of people who suffer an osteoporotic fracture are never evaluated or treated for this disease.<sup>19</sup>

In appreciation of the importance, but under-recognition, of osteoporosis as a major health care problem, a number of initiatives at the Federal level have been introduced during the last decade. The Balanced Budget Act of 1997 established DXA testing for qualified Medicare beneficiaries for both the diagnosis and monitoring response to therapy. In 2002 the United States Preventive Services Task Force recommended routine DXA testing for all women aged 65 and older and for women aged 60 and older if certain risk factors were present.<sup>20</sup> In 2004 the Surgeon General's Report on Bone Health and Osteoporosis called on health care professionals to proactively assess, diagnose and treat patients at risk for osteoporosis.<sup>1</sup> The Surgeon General hailed development of non-invasive tools to measure bone density as "one of the most significant advances in the last quarter century... Thanks to the development of bone mineral density testing, fractures need not be the first sign of poor health. It is now possible to detect osteoporosis early and to intervene before a fracture occurs."<sup>1</sup> Recognizing the necessity of bone density measurement, the Health Plan Employer Data and Information Set (HEDIS) now tracks the percentage of women aged 67 and older who have had a bone density test or started medical therapy within six months of sustaining an osteoporotic fracture.<sup>21</sup> Finally, bone mass measurement is one of the preventive services offered by Medicare and was recently highlighted as part of the Initial Preventive Physical Examination (IPPE) ("Welcome to Medicare" Physical Exam).<sup>22</sup> The Medicare Learning Network dedicates one of its six brochures on Medicare Preventive Services to bone mass measurement.<sup>23</sup> Thus, the importance of osteoporosis and its diagnosis has been clearly recognized at the Federal level. Ideally, such Federal recognition of a societal health problem would translate to alteration of clinical care, in this case to improved availability and use of bone mass measurement technology.

A review of CMS claims filed for central DXA (CPT codes 76075 and 76075-26) demonstrates that improved availability and increased use has occurred. Specifically, the number of DXA claims has increased from 77,133 in 1994 to 1,331,271 in 1999 and 2,555,727 in 2004 (Table 1). Unlike other imaging studies whose volume increases have been driven by single specialty society use, increases in DXA testing result from multiple specialties (Figure 1). Importantly, there have been major increases in DXA use by primary care specialties (Family Practice, Internal Medicine, and Gynecology), while Radiology has remained constant and the Rheumatology and Endocrinology proportion has declined (Figure 2). *Driven by the patient-based Federal initiatives listed above, these increases can be seen to be appropriate and not an over-utilization of services.*

*Despite these increases there is evidence that DXA testing still remains under-utilized.* In a recent study of a random sample of a representative Medicare population of 43,802 women eligible for osteoporosis screening, only 23% were tested between 1999 and 2001. Of greater concern, among women at highest fracture risk due to advancing age, BMD testing declined by 4-6% for each 5-year age increment after age 75.<sup>24</sup> Data from HEDIS in 2003 indicated that only 18% of female Medicare beneficiaries who had a fracture received either a BMD or prescription for drug therapy within 6 months of the date of the fracture. In 2004, that number had increased to 19%.<sup>25</sup> In summary, though progress has been made with an increase in the number of people tested, this disease continues to be neglected in most individuals at high risk for fracture.

### **Proposed Changes: Effect on Access and Quality of Care**

With the above as background, *the ISCD is seriously concerned about the revised Medicare Physician Fee Schedule that would decrease payment for DXA (76075) by 71% (current payment of \$139.46, 2010 payment of \$39.80) and VFA by 37% (current payment of \$39.41, 2010 payment of \$24.64) assuming a constant conversion factor.* [Note that potential further reductions factoring in the proposed 10% decrease in physician work RVU to preserve budget neutrality and Section 5102 of the Deficit Reduction Act of 2005 for non-facility services are not included in these calculations.] In reviewing the proposed changes in RVUs for DXA and VFA (see Table 2) we note a 30% decline in work RVU and a 79% decline in Practice Expense (PE) RVU for DXA. For VFA, we note a 48% decline in PE RVU. (Department of Health and Human Services; Centers for Medicare and Medicaid Services. Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology; Notice. (CMS-1512-PN, RIN 0938-AO22) Federal Register. Vol 71, No. 125. Thursday, June 26, 2006. p 37170-37430. <http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/cms1512pn.pdf>)

**The ISCD is concerned that this will markedly reduce the availability of high quality bone mass measurement and thus have a profound adverse impact on patient access to appropriate skeletal health care.** We believe that many physicians will discontinue performing these essential services, as it will not be fiscally viable to continue doing so either with existing equipment or by replacing aging machines. Moreover, despite the under-utilization noted above, physicians who are contemplating adding DXA and VFA capabilities to their practice will now be dissuaded from doing so. This reduction of access could be expected to be of greatest consequence in rural areas.

In addition to reducing access, the proposed changes seem destined to lower the quality of measurements performed. As noted above, a major focus of the ISCD is to promote excellence in skeletal health assessment through education, certification and standardization. We recognize that quality bone mass measurement requires specific education and expertise for both the physician and technologist. It is essential that densitometers are appropriately maintained and that physician and technologist skills be continually updated. With inadequate reimbursement, such quality measures, continuing professional development, and ultimately patient care, seem destined to suffer.

## **Analysis of the Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to Practice Expense Methodology**

The ISCD extensively reviewed the current Work surveys for DXA and VFA and the Practice Expense data for DXA and VFA and has identified specific flaws in data input and important data omissions, which when combined with use of other CMS methodology for calculation of the PE, results in the aforementioned severe reductions in DXA and VFA reimbursement.

**The ISCD respectfully submits that flaws exist in the calculation of the Practice Expense RVU component for DXA (76075) and VFA (76077). Specific areas of concern are as follows:**

- **Inappropriate application of equipment costs.** While the equipment cost is appropriately listed for VFA using current fan beam densitometers at \$85,000, in contrast, DXA is assigned a cost of \$41,000 based on pencil beam instrumentation. Of the two largest United States manufacturers of DXA instruments, one no longer produces pencil beam machines and for the other such low-end instruments comprises less than 20% of sales. Thus, fan beam densitometers make up the vast majority of densitometers currently available in practice, and therefore the ISCD would argue that the equipment cost for DXA should be listed at \$85,000.
- **Inappropriate utilization rates.** Utilization rates for DXA and VFA are listed at 50%. This rate has been applied to all procedures, despite the fact that “single disease state” imaging procedures such as DXA and VFA have utilization rates that have been estimated at 15-20%. Unlike other high volume procedures where patients are referred to dedicated imaging centers, DXA and VFA are frequently obtained by primary care physicians, rheumatologists and endocrinologists and offered as point-of-care service. Based on 2002 Medicare data, 70% of DXA studies are performed in office (30% in hospital settings) and 60% are performed by non-radiologists.
- **Other densitometry costs are omitted.** For example, the cost of phantoms, necessary service contracts/software upgrades and office upgrades to allow digital image transmission are not included.

**The ISCD also believes that flaws exist in determination of the physician work RVU component for DXA (76075). Specific areas of concern are as follows:**

- **RUC subcommittee decreases work RVU.** The American College of Radiology (ACR) polled a broad range of radiologists to perform the physician work survey and recommended that the work RVU remain at 0.3. However, subsequently, a working group comprised of six RUC members recommended that the value be reduced to 0.2 (the 25th percentile of the ACR survey) stating that “... *the (RUC) workgroup believed that the actual work is less intense and more mechanical*”

*than the specialty society's description of the work."* It is worth noting that this RUC subcommittee was comprised of a vascular surgeon, anesthesiologist, general surgeon, pulmonologist, psychiatrist, and a family practitioner. Only one of these physicians could be expected to be knowledgeable about DXA interpretation. We believe this reduction to be inappropriate in that DXA reporting is not simple mechanical reporting of data generated by the DXA machine software. Rather, the optimal reporting of DXA data requires specialized knowledge and expertise. That the need for such expertise is often unappreciated is emphasized by a recent survey of over 700 physicians conducted by the ISCD in which 71% of physicians reported finding incorrect DXA interpretations at least once per month and 98% reporting that poor quality DXA reports were harmful to patient care.<sup>26</sup> Moreover, the RUC recommendation to reduce the physician work RVU places DXA in a unique group of only 29 other codes (out of a total of approximately 500) which the RUC recommended for cutbacks.

- **Clinical vignette.** A clinical vignette of a typical patient is provided to assist in assigning an appropriate value to the average physician work effort. A series of questions references this vignette in assigning a value to complexity/intensity, mental effort/judgment, technical skill/physical effort, and psychological stress. The 2005 survey was compared to the original survey in 1994 to determine if the work value differed (under or over-valued). Strikingly, "the typical patient" listed in both surveys was not the same. In 1994 it was *"a 55 year old menopausal woman presents with a family history of osteoporosis and is considering estrogen therapy."* In 2005 the "typical patient" is *"A 66 year old woman (who) had previous bone density demonstrating severe osteoporosis. The patient has been on hormone replacement therapy for one year and a follow-up DXA scan is ordered."* Since the survey vignettes are substantially different, a comparison of work involved in DXA interpretation using this vignette with the prior survey vignette is problematic.

**This flawed methodology leads to inappropriate rankings of procedures sometimes known as a "Rank Order Anomaly."** Physician work in terms of corresponding RVUs can be ranked from least to greatest intensity. The greater degree of physician work, the higher the RVU. Examples include physicians work reading an EKG is 0.17 versus reading a series of lumbar spine radiographs is 0.36. This would imply that reading lumbar spine radiographs has over twice the physician work related to that activity compared to reading an EKG. A rank order anomaly would be defined as a CPT code that, despite having greater amount of physician work, is ranked below one in which less work is involved. The summation of the aforementioned flaws in accuracy of data input, important data omissions and use of the CMS designed bottom-up methodology for calculation of the PE taken together result in such a "Rank Order Anomaly" in which tests that are clearly less intensive than DXA are more highly valued. Specifically, peripheral DXA studies (CPT 76076) would carry a greater physician work RVU (0.22) than central DXA (CPT 76075) (0.20) despite the fact that central DXA is clearly more labor intensive and of greater complexity.

## Clinical Society Survey Results

We appreciate that CMS did request input on CPT code 76075 for review by all interested societies and that the current ACR survey results for DXA and VFA were based on 51 completed surveys sent to 240 radiologists. However, we believe that clinical societies were remiss by not participating in the prior survey. As such, the ISCD, in cooperation with the American Society for Bone and Mineral Research (ASBMR), the American Association of Clinical Endocrinologists (AACE), The Endocrine Society (TES), the North American Menopause Society (NAMS), and the American College of Rheumatology (ACR – Rheum) completed an independent Work and PE RVU survey almost identical to the 2005 ACR RUC survey to provide additional clinical perspective. We were kindly assisted by the ACR in this process. As such, an electronic survey was created by an ISCD task force and distributed to all physician members of the aforementioned societies. A summation of these results follows.

The ISCD received a total of 453 surveys completed by physicians. Respondents identified themselves as practicing in the following medical specialty areas:

Specialty	% of total respondents
Rheumatology	36.7%
Endocrinology	22.2%
Internal Medicine	11.2%
OB/GYN	9.2%
Family Practice	6.9%
Radiology	4.7%
Other	9.2%

Of responding physicians, 16% identified their practice location as rural, 42% suburban and 42% urban. Additionally, they identified their practice type as 28% solo practice, 39% single specialty group, 24% multispecialty group, and 9% medical school faculty.

The ISCD welcomes the opportunity to share the full results of this survey with CMS. Several key survey questions and their results are as follows:

### Clinical Society Physician Work Survey Results

#### Time Question:

*“How much of your own time (day of procedure) is required per patient treated for each of the following steps in patient care related to this procedure? Indicate your time (in minutes) for DXA CPT code 76075. (Record time in minutes.)”*

#### Time in Minutes

	Low	25 <sup>th</sup> %	Median	75 <sup>th</sup> %	High	Mean
Pre-Service	0	2	5	10	60	6
Intra- Service	0	5	10	15	60	9.8
Post-Service	0	5	10	12	37	9.2

It is apparent that the time required per patient for DXA CPT code 76075 is substantially higher than recorded in the ACR survey, which noted a median **intra-service time** of 4 minutes and a 25<sup>th</sup> percentile of 2 minutes.

**Work RVU Question:**

*“Based on your review of all previous steps, please provide your estimated physician work RVU for the DXA CPT code 76075.”*

	<b>Low</b>	<b>25<sup>th</sup> %</b>	<b>Median</b>	<b>75<sup>th</sup> %</b>	<b>High</b>	<b>Mean</b>
DXA 76075	.17	.35	.50	1.00	3.68	.76

The work RVU values for DXA CPT code 76075 are substantially higher than that recorded in the ACR survey, which noted a median work RVU of 0.3 and a 25<sup>th</sup> percentile of 0.2.

Thus, for both the physician time component and the physician work RVU, substantially higher values were obtained when 453 physicians from multiple disciplines were surveyed in contrast to 51 physicians from a single specialty (radiology).

**Clinical Society Practice Expense Survey Results**

- **Equipment costs:** Although we did not ask for invoice cost of DXA machines, we did survey for the type of machine used. 93% of the machines utilized were fan beam and only 7% were pencil beam. This corroborates our earlier statement that the vast majority of densitometers in clinical practice are fan-beam technology, to which CMS has previously assigned a value of \$85,000.
- **Utilization rates.** The following questions were asked to determine utilization rates:
  - “Number of DXA procedures done in an average month per machine?”
  - “Number of hours per week that practice (where machine is located) is open for operation?”
  - “Average number of days per month (where machine is located) is open for operation?”

A median of 60 DXA procedures were performed in an average month at a median intra-service time for non-facility and facility of 34 minutes per procedure. The median hours per week were 40 and the median number of days per month 20, to arrive at a utilization rate of 21%. This is in line with previous estimates for single-disease state imaging of 15-20% and vastly different from the 50% utilization rate used in the original PE calculation. It is important to note that the 50% utilization rate was not surveyed, but provided as an estimate by consultants to CMS.

- **Additional costs:** Our survey identified median service contract costs of \$5,000 per year and median software upgrades of \$2,000 per year documenting the additional costs associated with DXA performance which were not previously accounted for.

In summary, this larger survey supports our premise that specific flaws were present in data input and data omissions in calculation of the physician work and practice expense RVUs.

### **Conclusion:**

In view of the aforementioned flaws used to capture and calculate work and practice expense RVU, the resultant rank order anomaly, and the discordance of results from this larger specialty society survey, **the ISCD respectfully requests that that CMS review the proposed cuts, and, at the very least, keep reimbursement at the current levels for DXA (CPT code 76075) and VFA (CPT code 76077).** This approach would resolve the inconsistency with the agency's preventive health care mission. As noted above, osteoporosis is a major health care issue in this country. Federal initiatives to detect this disease using DXA and VFA, and appropriately treat individuals at high risk, are crucial. CMS claims data indicates that testing is increasing, however it still remains vastly under utilized. Our survey data underscores the additional time involved in the performance of DXA and VFA studies that has not been captured by prior survey methods. Moreover, additional costs associated with machine upgrades, phantoms for quality control and continuing education of technologists and physicians are required to assure that this essential service is performed optimally. As such, we propose that special resource considerations are necessary, for both DXA and VFA, to assure widespread availability of high-quality screening in the United States.

**We strongly believe that if the new RVUs are enacted, the very same initiatives that CMS has championed to increase the diagnosis and treatment of osteoporosis will be severely undermined.** Reducing DXA reimbursement from approximately \$140 to \$40 and VFA from \$40 to \$25 will force primary care physicians and specialists to abandon testing and limit future purchases by other health care providers. Limited access to DXA and VFA testing will be particularly severe in rural areas where there are fewer facilities and distances to travel are greater.

We appreciate that the problems in the field of health care are complex. However, testing for osteoporosis using DXA and VFA are low cost options that can be incorporated into the primary care setting. Coupled with increased knowledge of non-pharmacologic approaches to fracture prevention and an expanding array of medications for osteoporosis prevention and treatment, these tests are of proven benefit in reducing future fractures and improving the quality of life for our patients. The Surgeon General's report on Bone Health and Osteoporosis calls on the Federal government to play a "vital leadership role...in promoting bone health. To play this role effectively, elected policymakers and other government leaders need to recognize the long-term financial and social costs of the status quo (less than optimal bone health status) and appreciate the potential to reduce these costs and improve quality of life through prevention, early detection and early treatment."<sup>1</sup> President Bush has declared 2002-2011 as the "Decade of the Bone and Joint." The ultimate irony would be to honor this by limiting the availability of DXA and VFA in the United States.

We are sensitive to economic concerns that try to preserve budget neutrality for medical care to Medicare beneficiaries. However, reducing DXA and VFA payments appears to be short-sighted. Given the increasing age of the United States population, coupled with the anticipated further limits on osteoporosis testing one can only expect dramatic increases in fracture-related health care costs above the current levels of \$12-17 billion per year.

The ISCD appreciates this opportunity to comment on the proposed changes to the Medicare Physician Fee Schedule. We welcome any further dialogue with the Center for Medicare and Medicaid Services regarding the issues we have outlined in this letter. If you have any questions concerning ISCD's comments, please contact Donna Fiorentino (Manager Public Policy Affairs) at 860.586.7563 Ext. 553 or at [dfiorentino@iscd.org](mailto:dfiorentino@iscd.org).

Sincerely,



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Sanford Baim, MD, FACR, CCD  
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Nelson B. Watts, MD, FACP, MACE, CCD  
Past-President, ISCD

**Table 1: Claims to CMS for DXA (Provided by the AMA)**

<b>CPT Code</b>	<b>Year</b>		
	<b>1994</b>	<b>1999</b>	<b>2004</b>
<b>76075</b>	61,862	853,144	1,593,796
<b>76075-26</b>	15,271	412,352	832,565
<b>76075-TC</b>	3,129	65,775	129,366
<b>Total</b>	80,262	1,331,271	2,555,727
<b>76075 and 26</b>	77,133	1,265,496	2,426,361

Note: 76075-26 = professional component only; 76075-TC = technical component only

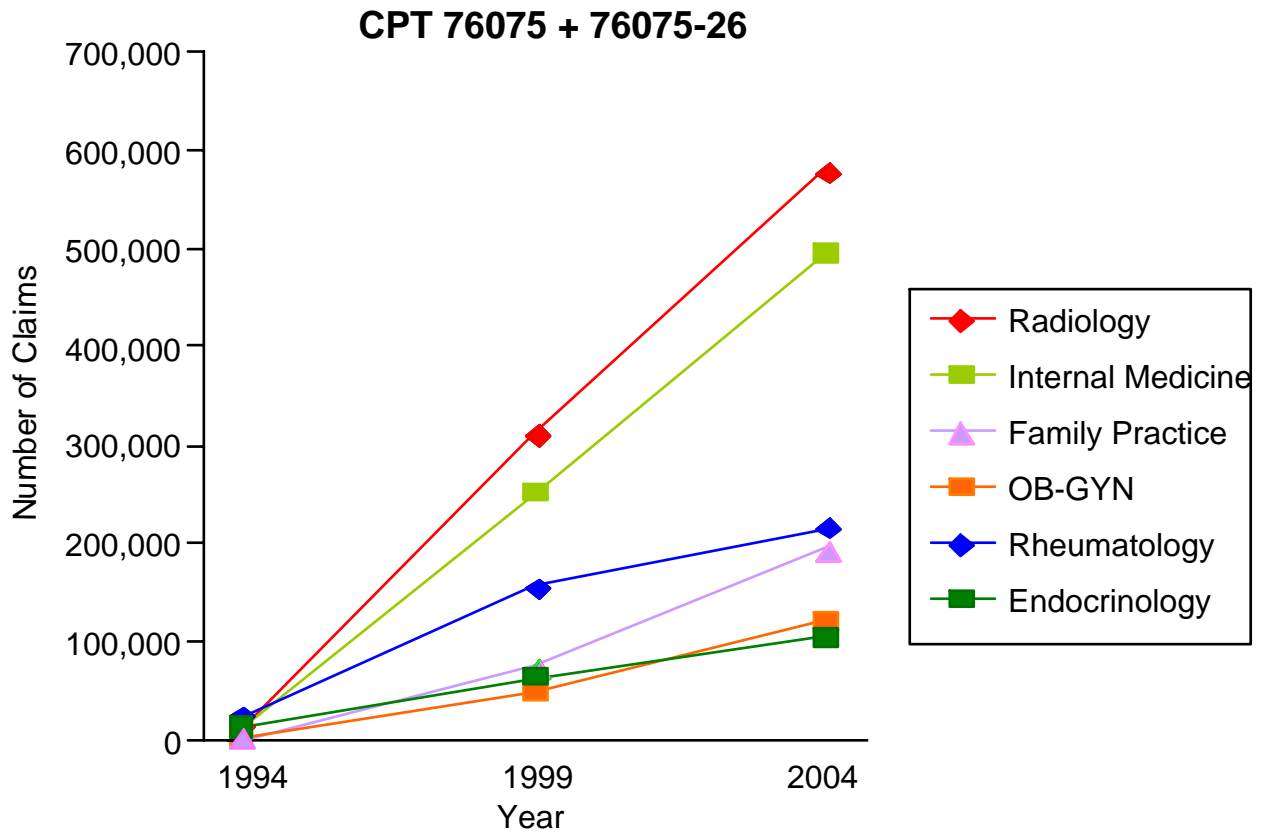
Excerpted from claims data provided by the AMA's Department of Physician Payment Policy and Systems

**Table 2: Proposed Changes in RVUs for DXA and VFA**

76075	(Total)					
		Non-Facility	(Office)			
Year	Work	PE	Liability	Total	Conversion	Payment
2006	0.3	3.2	0.18	3.68	\$37.90	\$139.46
2007	0.2	2.57	0.18	2.95	(\$37.90)	\$111.81
2008	0.2	1.9	0.18	2.28	(\$37.90)	\$86.41
2009	0.2	1.3	0.18	1.68	(\$37.90)	\$63.67
2010	0.2	0.67	0.18	1.05	(\$37.90)	\$39.80
	<b>(Professional)</b>					
2006	0.3	0.1	0.01	0.41	\$37.90	\$15.54
2007	0.2	0.09	0.01	0.3	(\$37.90)	\$11.37
2008	0.2	0.08	0.01	0.29	(\$37.90)	\$10.99
2009	0.2	0.07	0.01	0.28	(\$37.90)	\$10.61
2010	0.2	0.06	0.01	0.27	(\$37.90)	\$10.23
	<b>(Technical)</b>					
2006	0	3.1	0.17	3.27	\$37.90	\$123.92
2007	0	2.48	0.17	2.65	(\$37.90)	\$100.44
2008	0	1.86	0.17	2.03	(\$37.90)	\$76.94
2009	0	1.23	0.17	1.4	(\$37.90)	\$53.06
2010	0	0.61	0.17	0.78	(\$37.90)	\$29.56
76077	(Total)					
2006	0.17	0.81	0.06	1.04	\$37.90	\$39.41
2007	0.17	0.71	0.06	0.94	(\$37.90)	\$35.63
2008	0.17	0.61	0.06	0.84	(\$37.90)	\$31.84
2009	0.17	0.52	0.06	0.75	(\$37.90)	\$28.43
2010	0.17	0.42	0.06	0.65	(\$37.90)	\$24.64
	<b>(Professional)</b>					
2006	0.17	0.08	0.01	0.24	\$37.90	\$9.10
2007	0.17	0.07	0.01	0.24	(\$37.90)	\$9.01
2008	0.17	0.07	0.01	0.23	(\$37.90)	\$8.91
2009	0.17	0.06	0.01	0.23	(\$37.90)	\$8.82
2010	0.17	0.05	0.01	0.23	(\$37.90)	\$8.72
	<b>(Technical)</b>					
2006	0	0.75	0.05	0.8	\$37.90	\$30.52
2007	0	0.66	0.05	0.71	(\$37.90)	\$26.91
2008	0	0.56	0.05	0.61	(\$37.90)	\$23.12
2009	0	0.47	0.05	0.52	(\$37.90)	\$19.71
2010	0	0.37	0.05	0.42	(\$37.90)	\$15.92

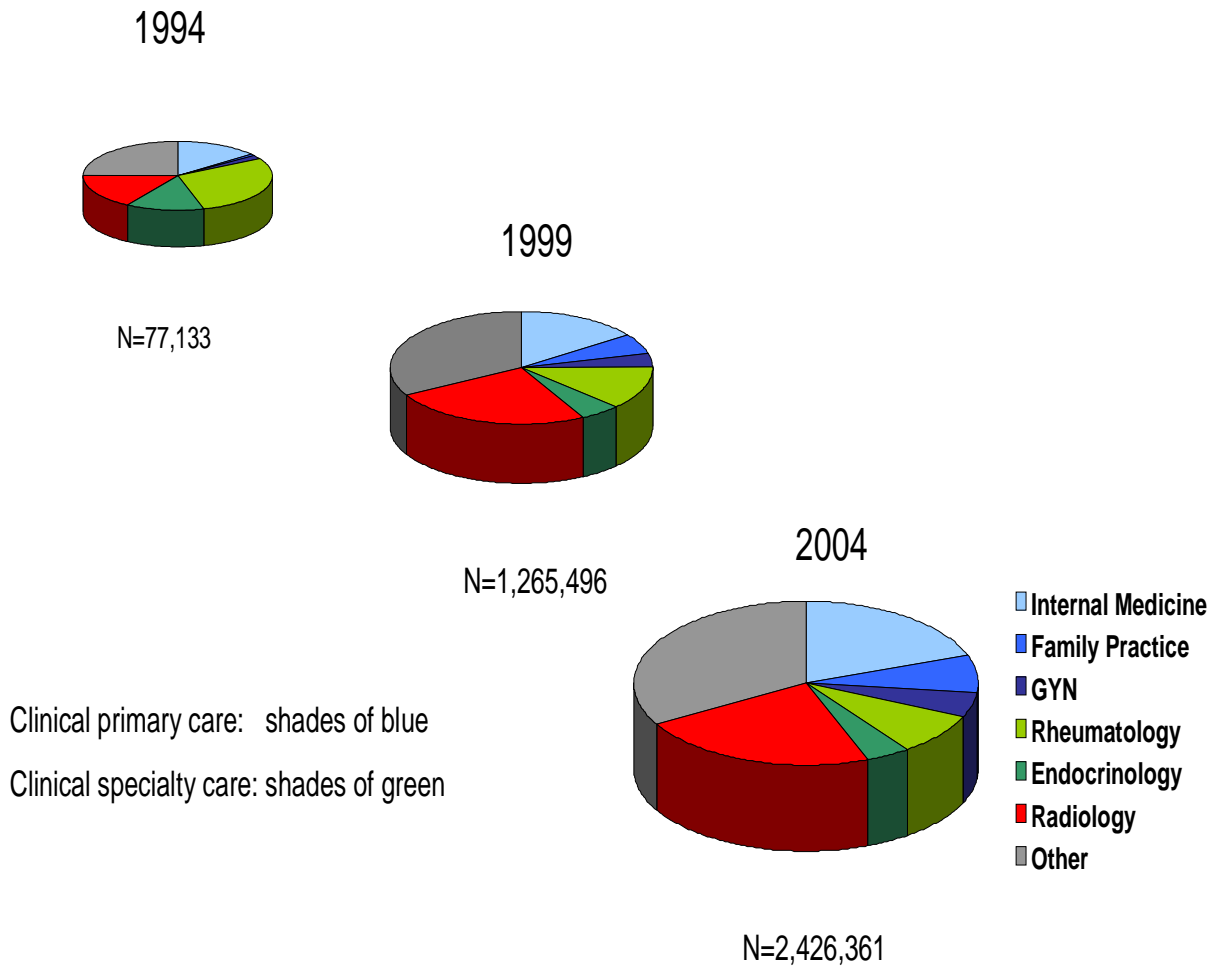
Data from Medicare Physician Fee Schedule 2006 and 2010

**Figure 1: Increase in DXA testing over time**



Excerpted from claims data provided by the AMA's Department of Physician Payment Policy and Systems

**Figure 2: Change in DXA Usage by Specialty Based on Claims to CMS**



Excerpted from claims data provided by the AMA's Department of Physician Payment Policy and Systems

## Appendix A: Official Positions of the International Society for Clinical Densitometry

The International Society for Clinical Densitometry (ISCD) is a not-for-profit multidisciplinary professional society with a mission to enhance knowledge and quality of bone densitometry among healthcare professionals, educate clinicians and technologists, increase patient awareness and access to bone densitometry, and support clinical and scientific advances in the field.

With the evolution of bone densitometry, differences in technologies, acquisition techniques, reference databases, reporting methods, and terminology have developed. These differences may have adverse effects on patient care and the exchange of scientific information. To address these issues, the ISCD periodically holds Position Development Conferences, a process whereby an international panel of experts makes recommendations based on reviews of the scientific literature by the ISCD's Scientific Advisory Committee. Recommendations that are approved by the ISCD Board of Directors become Official Positions of the ISCD.

All ISCD Official Positions are for worldwide application except where otherwise noted. These are the Official Positions of the ISCD as updated in 2005. **The Official Positions that are new or revised since 2003 are in bold type.** These Official Positions may also be viewed and downloaded as a text file or PowerPoint presentation from the ISCD Web site at [www.ISCD.org](http://www.ISCD.org).

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### INDICATIONS FOR BONE MINERAL DENSITY (BMD) TESTING

- Women aged 65 and older.
- Postmenopausal women under age 65 with risk factors.
- Men aged 70 and older.
- Adults with a fragility fracture.
- Adults with a disease or condition associated with low bone mass or bone loss.
- Adults taking medications associated with low bone mass or bone loss.
- Anyone being considered for pharmacologic therapy.
- Anyone being treated, to monitor treatment effect.
- Anyone not receiving therapy in whom evidence of bone loss would lead to treatment.

Women discontinuing estrogen should be considered for bone density testing according to the indications listed above.

### REFERENCE DATABASE FOR T-SCORES

- Use a uniform Caucasian (non-race adjusted) female normative database for women of all ethnic groups.\*
- Use a uniform Caucasian (non-race adjusted) male normative database for men of all ethnic groups.\*
- **The NHANES III database should be used for T-score derivation at the hip regions.**

\*Note: Application of recommendation may vary according to local requirements.

### CENTRAL DXA FOR DIAGNOSIS

- **The WHO international reference standard for osteoporosis diagnosis is a T-score of -2.5 or less at the femoral neck.**
  - **The reference standard from which the T-score is calculated is the female, white, age 20-29 years NHANES III database.**
- **Osteoporosis may be diagnosed in postmenopausal women and in men age 50 and older if the T-score of the lumbar spine, total hip or femoral neck is -2.5 or less:\***
  - **In certain circumstances the 33% radius (also called 1/3 radius) may be utilized.**

**\*Note: Other hip regions of interest, including Ward's area and the greater trochanter, should not be used for diagnosis. Application of recommendation may vary according to local requirements.**

- Skeletal sites to measure
  - Measure BMD at both the PA spine and hip in all patients.
  - Forearm BMD should be measured under the following circumstances:
    - Hip and/or spine cannot be measured or interpreted.
    - Hyperparathyroidism.
    - Very obese patients (over the weight limit for DXA table).
- Spine Region of Interest
  - Use PA L1-L4 for spine BMD measurement.
  - Use all evaluable vertebrae and only exclude vertebrae that are affected by local structural change or artifact. Use three vertebrae if four cannot be used and two if three cannot be used.
  - **BMD based diagnostic classification should not be made using a single vertebra.**
  - **If only one evaluable vertebra remains after excluding other vertebrae, diagnosis should be based on a different valid skeletal site.**
  - **Anatomically abnormal vertebrae may be excluded from analysis if:**
    - **They are clearly abnormal and non-assessable within the resolution of the system;**  
**or**
    - **There is more than a 1.0 T-score difference between the vertebra in question and adjacent vertebrae.**
  - **When vertebrae are excluded, the BMD of the remaining vertebrae is used to derive the T-score.**
  - Lateral spine should not be used for diagnosis, but may have a role in monitoring.
- Hip Region of Interest
  - **Use femoral neck or total proximal femur, whichever is lowest.**
  - BMD may be measured at either hip.
  - There are insufficient data to determine whether mean T-scores for bilateral hip BMD can be used for diagnosis.
  - The mean hip BMD can be used for monitoring, with total hip being preferred.
- Forearm Region of Interest
  - Use 33% radius (sometimes called one-third radius) of the non-dominant forearm for diagnosis. Other forearm regions of interest are not recommended.

#### **FRACTURE RISK ASSESSMENT**

- **A distinction is made between diagnostic classification and the use of BMD for fracture risk assessment.**
- **For fracture risk assessment any well-validated technique can be used, including measurements of more than one site, where this has been shown to improve the assessment of risk.**

#### **USE OF THE TERM “OSTEOPENIA”**

- **The term “osteopenia” is retained, but “low bone mass” or “low bone density” is preferred.**
- **People with low bone mass or density are not necessarily at high fracture risk.**

#### **PERIPHERAL BONE DENSITOMETRY**

- The World Health Organization (WHO) criteria for diagnosis of osteoporosis and osteopenia should not be used with peripheral BMD measurement other than 33% radius.
  - Peripheral measurements:
    - Are useful for assessment of fracture risk.

- Theoretically can be used to identify patients unlikely to have osteoporosis and identify patients who should be treated; however, this cannot be applied in clinical practice until device-specific cut-points are established.
- Should not be used for monitoring.

#### **BMD REPORTING IN POSTMENOPAUSAL WOMEN AND IN MEN AGE 50 and OLDER**

- T-scores are preferred.
- The WHO densitometric classification is applicable.

#### **BMD REPORTING IN FEMALES PRIOR TO MENOPAUSE AND IN MALES YOUNGER THAN AGE 50**

- Z-scores, not T-scores, are preferred. This is particularly important in children.
- A Z-score of -2.0 or lower is defined as “below the expected range for age” and a Z-score above -2.0 is “within the expected range for age.”

#### **Z-SCORE REFERENCE DATABASE**

- Z-scores should be population specific where adequate reference data exist. For the purpose of Z-score calculation, the patient's self-reported ethnicity should be used.

#### **DIAGNOSIS IN CHILDREN (MALES OR FEMALES LESS THAN AGE 20)**

- T-scores should not be used in children; Z-scores should be used instead.
- T-scores should not appear in reports or on DXA printouts in children.
- The diagnosis of osteoporosis in children should not be made on the basis of densitometric criteria alone.
- Terminology such as "low bone density for chronologic age" or "below the expected range for age" may be used if the Z-score is below -2.0.
- Z-scores must be interpreted in the light of the best available pediatric databases of age-matched controls. The reference database should be cited in the report.
- Spine and total body are the preferred skeletal sites for measurement.
- The value of BMD to predict fractures in children is not clearly determined.
- There is no agreement on standards for adjusting BMD or bone mineral content (BMC) for factors such as bone size, pubertal stage, skeletal maturity, and body composition. If adjustments are made, they should be clearly stated in the report.
- Serial BMD studies should be done on the same machine using the same scanning mode, software and analysis when appropriate. Changes may be required with growth of the child.
- Any deviation from standard adult acquisition protocols, such as use of low-density software and manual adjustment of region of interest, should be stated in the report.

#### **SERIAL BMD MEASUREMENT**

- Serial BMD testing can be used to determine whether treatment should be started on untreated patients, because significant loss may be an indication for treatment.
- Serial BMD testing can monitor response to therapy by finding an increase or stability of bone density.
- Serial BMD testing can evaluate individuals for non-response by finding loss of bone density, suggesting the need for reevaluation of treatment and evaluation for secondary causes of osteoporosis.
- Follow-up BMD testing should be done when the expected change in BMD equals or exceeds the least significant change (LSC).
- Intervals between BMD testing should be determined according to each patient's clinical status. Typically one year after initiation or change of therapy is appropriate, with longer intervals once therapeutic effect is established.
- In conditions associated with rapid bone loss, such as glucocorticoid therapy, testing more frequently is appropriate.

## PHANTOM SCANNING AND CALIBRATION

The Quality Control (QC) program at a DXA facility should include adherence to manufacturer guidelines for system maintenance. In addition, if not recommended in the manufacturer protocol, the following QC procedures are advised:

- Perform periodic (at least once per week) phantom scans for any DXA system as an independent assessment of system calibration.
- Plot and review data from calibration and phantom scans.
- Verify the phantom mean BMD after any service performed on the densitometer.
- Establish and enforce corrective action thresholds that trigger a call for service.
- Maintain service logs.
- Comply with government inspections, radiation surveys and regulatory requirements.

## PRECISION ASSESSMENT

- Each DXA facility should determine its precision error and calculate the LSC.
- The precision error supplied by the manufacturer should not be used.
- If a DXA facility has more than one technologist, an average precision error, combining data from all technologists, should be used to establish precision error and LSC for the facility, provided the precision error for each technologist is within a pre-established range of acceptable performance.
- Every technologist should perform an in vivo precision assessment using patients representative of the clinic's patient population.
- Each technologist should do one complete precision assessment after basic scanning skills have been learned (e.g., manufacturer training) and after having performed approximately 100 patient scans.
- A repeat precision assessment should be done if a new DXA system is installed.
- A repeat precision assessment should be done if a technologist's skill level has changed.
- To perform a precision analysis:
  - Measure 15 patients 3 times, or 30 patients 2 times, repositioning the patient after each scan.
  - Calculate the root mean square standard deviation (RMS-SD) for the group.
  - Calculate LSC for the group at 95% confidence interval.
- **The minimum acceptable precision for an individual technologist is:**
  - **Lumbar Spine: 1.9% (LSC=5.3%)**
  - **Total Hip: 1.8% (LSC=5.0%)**
  - **Femoral Neck: 2.5% (LSC=6.9%)**
  - **Retraining is required if a technologist's precision is worse than these values.**
- Precision assessment should be standard clinical practice. Precision assessment is not research and may potentially benefit patients. It should not require approval of an institutional review board. Adherence to local radiologic safety regulations is necessary. Performance of a precision assessment requires the consent of participating patients.

## CROSS-CALIBRATION OF DXA SYSTEMS

- **When changing hardware, but not the entire system, or when replacing a system with the same technology (manufacturer and model), cross-calibration should be performed by having one technologist do ten phantom scans, with repositioning, before and after hardware change.**
  - **If a greater than 1% difference in mean BMD is observed, contact the manufacturer for service/correction.**
- **When changing an entire system to one made by the same manufacturer using a different technology, or when changing to a system made by a different manufacturer, one approach to cross-calibration is:**
  - **Scan 30 patients representative of the facility's patient population once on the initial system and then twice on the new system within 60 days.**
  - **Measure those anatomic sites commonly measured in clinical practice, typically spine and proximal femur.**
  - **Facilities must comply with locally applicable regulations regarding DXA.**

- Calculate the average BMD relationship and least significant change between the initial and new machine using the ISCD Cross Calibration Tool.
- Use this least significant change for comparison between previous and new system. Inter-system quantitative comparisons can only be made if cross calibration is performed on each skeletal site commonly measured.
- Once a new precision assessment has been performed on the new system, all future scans should be compared to scans performed on the new system using the newly established intra-system least significant change.
- If a cross-calibration assessment is not performed, no quantitative comparison to the prior machine can be made. Consequently, a new baseline BMD and intra-system LSC should be established.

#### **BMD COMPARISON BETWEEN FACILITIES**

- It is not possible to quantitatively compare BMD or to calculate a least significant change between facilities without cross-calibration.

#### **VERTEBRAL FRACTURE ASSESSMENT NOMENCLATURE**

- Vertebral Fracture Assessment (VFA) is the correct term to denote densitometric spine imaging performed for the purpose of detecting vertebral fractures.

#### **INDICATIONS FOR VFA**

- Consider VFA when the results may influence clinical management.
- When BMD measurement is indicated, performance of VFA should be considered in clinical situations that may be associated with vertebral fractures. Examples include:
  - Documented height loss of greater than 2 cm (0.75 in) or historical height loss greater than 4 cm (1.5 in) since young adult.
  - History of fracture after age 50.
  - Commitment to long-term oral or parenteral glucocorticoid therapy.
  - History and/or findings suggestive of vertebral fracture not documented by prior radiologic study.

#### **METHOD FOR DEFINING AND REPORTING FRACTURES ON VFA**

- The methodology utilized for vertebral fracture identification should be similar to standard radiological approaches and be provided in the report.
- Fracture diagnosis should be based on visual evaluation and include assessment of grade/severity. Morphometry alone is not recommended because it is unreliable for diagnosis.
- The severity of vertebral fractures may be determined using the semiquantitative (SQ) assessment criteria developed by Genant. [Genant HK et al. J Bone Miner Res. 1993;8:1137-1148] Severity of deformity may be confirmed by morphometric measurement if desired.

#### **INDICATIONS FOR FOLLOWING VFA WITH ANOTHER IMAGING MODALITY**

- The decision to perform additional imaging must be based on each patient's overall clinical picture including the VFA result.
- Consider additional imaging when there are:
  - Equivocal fractures.
  - Unidentifiable vertebrae between T7-L4.
  - Sclerotic or lytic changes or findings suggestive of conditions other than osteoporosis.

**Note:** VFA is designed to detect vertebral fractures and not other abnormalities.

#### **BASELINE DXA REPORT: MINIMUM REQUIREMENTS**

- Demographics (name, medical record identifying number, date of birth, sex).
- Requesting provider.
- Indications for the test.

- Manufacturer and model of instrument used.
- Technical quality and limitations of the study, stating why a specific site or region of interest (ROI) is invalid or not included.
- BMD in g/cm<sup>2</sup> for each site.
- The skeletal sites, ROIs, and, if appropriate, the side, that were scanned.
- The T-score and/or Z-score where appropriate.
- WHO criteria for diagnosis in postmenopausal females and in men age 50 and over.
- Risk factors including information regarding previous nontraumatic fractures.
- A statement about fracture risk. Any use of relative fracture risk must specify the population of comparison (e.g., young- adult or age-matched). The ISCD favors the use of absolute fracture risk prediction when such methodologies are established.
- A general statement that a medical evaluation for secondary causes of low BMD may be appropriate.
- Recommendations for the necessity and timing of the next BMD study.

#### **FOLLOW-UP DXA REPORT: MINIMUM REQUIREMENTS**

- Statement regarding which previous or baseline study and ROI is being used for comparison.
- Statement about the LSC at your facility and the statistical significance of the comparison.
- Report significant change, if any, between the current and previous study or studies in g/cm<sup>2</sup> and percentage.
- Comments on any outside study including manufacturer and model on which previous studies were performed and the appropriateness of the comparison.
- Recommendations for the necessity and timing of the next BMD study.

#### **DXA REPORT: OPTIONAL ITEMS**

- Recommendation for further non-BMD testing, such as x-ray, magnetic resonance imaging, computed tomography, etc.
- Recommendations for pharmacological and nonpharmacological interventions.
- Addition of the percentage compared to a reference population.
- Specific recommendations for evaluation of secondary osteoporosis.

#### **DXA REPORT: ITEMS THAT SHOULD NOT BE INCLUDED**

- A statement that there is bone loss without knowledge of previous bone density.
- Mention of "mild," "moderate" or "marked" osteopenia or osteoporosis.
- Separate diagnoses for different regions of interest (e.g., osteopenia at the hip and osteoporosis at the spine).
- Expressions such as "She has the bones of an 80-year-old," if the patient is not 80 years old.
- Results from skeletal sites that are not technically valid.
- The change in BMD if it is not a significant change based on the precision error and LSC.

#### **COMPONENTS OF A VFA REPORT**

- **Patient identification, referring physician, indication(s) for study, technical quality and interpretation.**
- **A follow-up VFA report should also include comparability of studies and clinical significance of changes, if any.**
- **Optional components include fracture risk and recommendations for additional studies.**

#### **DXA NOMENCLATURE**

- DXA - not DEXA.
- T-score - not T score, t-score, or t score
- Z-score - not Z score, z-score, or z score

## **DXA DECIMAL DIGITS**

Preferred number of decimal digits for DXA reporting:

- **BMD:** 3 digits  
(example, 0.927 g/cm<sup>2</sup>)
- **T-score:** 1 digit  
(example, -2.3)
- **Z-score:** 1 digit  
(example, 1.7)
- **BMC:** 2 digits  
(example, 31.76 g)
- **Area:** 2 digits  
(example, 43.25 cm<sup>2</sup>)
- **% reference database:** Integer  
(example, 82%)

## **Glossary**

**BMC** - bone mineral content

**BMD** - bone mineral density

**DXA** - dual-energy x-ray absorptiometry

**ISCD** - a not-for-profit multidisciplinary professional society with a mission to enhance knowledge and quality of bone densitometry among healthcare professionals, educate clinicians and technologists, increase patient awareness and access to bone densitometry, and support clinical and scientific advances in the field.

**LSC** - least significant change

**NHANES III** - National Health and Nutrition Examination Survey III

**PA** - posterior anterior

**QC** - quality control

**ROI** - region of interest

**VFA** - Vertebral Fracture Assessment

**WHO** - World Health Organization

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