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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-1321-P Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule

Comments:

- **PROVISIONS:**
  - **BONE MASS MEASUREMENT TESTS**
  - **DRA PROPOSALS**
- **IMPACT:**
  - **Addendum B: Relative Value Units and Related Information Used in Determining Medicare Payments for 2007**
  - **Addendum C: Codes to Which We Received PERC Recommendations on PE Direct Cost**

Dear Dr. McClellan:

OVERVIEW

Osteoporosis is a major health care problem in the United States with annual costs of more than $18 billion dollars. Currently 300,000 Americans are hospitalized annually for hip fractures with one in five (20%) dying within the first year following fracture. Given population demographics, osteoporotic fractures are projected to increase for the foreseeable future emphasizing the importance of effective prevention and treatment strategies. To this end, the Centers for Medicare & Medicaid Services (CMS) is to be commended for establishing bone density testing as a key preventive service available for Medicare beneficiaries and highlighting the role of axial DXA (dual energy x-ray absorptiometry) in diagnosis and monitoring response to therapy. Despite this, bone density screening remains underutilized. **Efforts to increase screening rates for axial DXA above the current level of 20% require a different approach within the existing framework that values access over efficiency.** Importantly, it is necessary to appropriately value osteoporosis screening procedures such as axial DXA and VFA (Vertebral Fracture Assessment) which are increasingly being performed by primary care physicians in their offices. Unfortunately, if the currently proposed Medicare Physician Fee Schedule is enacted for axial DXA and/or Section 5102(b) of the Deficit Reduction Act takes effect on January 1, 2007, axial DXA testing will disappear from the non-facility setting as physicians' operating costs will be greater than reimbursement for the tests. **These regulatory and legislative actions will severely restrict patient access to bone density testing thereby undermining the effort by CMS to effectively screen Medicare beneficiaries for osteoporosis.**

These same regulatory and legislative actions will further curtail appropriate identification of individuals in need of fracture prevention efforts by reducing reimbursement for densitometric VFA. In addition to the

76% decline in reimbursement for axial DXA, VFA reimbursement will decline by 40%. As with axial DXA, the profound drop in reimbursement for VFA will lead to its disappearance from the non-facility setting, further impairing physicians' ability to optimally target osteoporosis care.

INTRODUCTION

The International Society for Clinical Densitometry (ISCD) welcomes the opportunity to comment on the recent CMS proposal **1321-P: Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule**. Specifically, we would like to address CPT codes 76075 (DXA bone density, axial) and 76077 (Vertebral Fracture Assessment or VFA). We have previously commented on CMS proposal 1512-PN: Five Year Review of Work Relative Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology as it relates to DXA and VFA. In this letter we will expand on the importance of successful promotion of high quality screening for key preventive services in the primary care setting. We will also comment on new provisions that will impact skeletal health assessment; specifically revisions to "Medicare Coverage of and Payment for Bone Mass Measurements" (63 FR 34320) and Section 5102(b) of the Deficit Reduction Act.

The ISCD is a multidisciplinary, non-profit organization with 6,365 members, 93% of whom practice in the United States. Approximately 60% of our members are physicians and 40% are densitometry technologists. The membership is diverse spanning over 20 disciplines including 43% in Primary Care (Internal Medicine, Family Practice, Gynecology, Pediatrics, Geriatrics) with the remainder in subspecialty Internal Medicine (Rheumatology, Endocrinology, Nephrology), Orthopedics, and Radiology.

The mission of the ISCD is to promote excellence in the assessment of skeletal health. We offer a four-hour introductory course in osteoporosis for those just beginning in the field, a twelve-hour intensive educational course in bone densitometry and a five-hour course in vertebral fracture assessment. These courses are given throughout the United States as well as internationally and use a standardized syllabus that is continuously updated by a scientific advisory committee. Faculty selection is highly competitive. Physicians who successfully pass a written certification exam are designated as Certified Clinical Densitometrists (CCD) while technologists are designated as Certified Densitometric Technologists (CDT). In the United States there are currently 7,058 physicians and 3,759 technologists with ISCD certification.

To further promote quality standards in osteoporosis assessment, the ISCD has developed, and is currently beta testing, a bone densitometry accreditation program that will ensure DXA centers meet specific criteria for the high quality performance and interpretation of bone densitometry according to accepted standards of practice in the United States. We anticipate that this will be available by the end of the 2006 calendar year.

Moreover, as the field of osteoporosis is rapidly evolving, questions often arise as to the appropriate indications and limitations of new and existing technologies, software enhancements, reference databases, and reporting methodologies. To address such issues and enhance standardization, the ISCD has held Position Development Conferences (PDCs) in 2001 (Denver), 2003 (Cincinnati) and 2005 (Vancouver). Preparations are underway for the 2007 PDC (Lansdowne, VA) and the first Children PDC (June 2007, Montreal, Canada). At these PDCs, select panels of international experts review and make recommendations after presentations by ISCD PDC task forces, public comment and internal discussion. PDC recommendations that are subsequently approved by the ISCD Board of Directors become Official Positions of the ISCD. These Official Positions promote uniformity in DXA and VFA performance, thereby enhancing patient care. A copy of the most recent Official Positions is amended to this report (Appendix A).

PROVISIONS: BONE MASS MEASUREMENT TEST

The ISCD is in agreement with the revisions made to the 1998 Balanced Budget Act 42 CFR 410.31 (Bone Mass Measurement: Conditions for Coverage and Frequency Standards). Specifically, we laud CMS for introducing the important concept of quality and standardization in axial DXA testing and reporting. *"As there are many sources of variability in the measurement of BMD, a quality control system related to both the methodology and reporting of test results is important to ensure the validity of DXA analysis."* Axial DXA is also cited for its superior accuracy and precision as it compares to older technologies. As such, the ISCD agrees with the CMS recommendation to restrict monitoring over time to axial DXA technology; *"DXA is precise, safe and low in radiation exposure and permits more accurate and reliable monitoring of individuals over time."* We share the CMS concern that to ensure accurate and reproducible bone density measurement, DXA centers must perform a precision assessment on their equipment and patients be followed over time on the same machine to determine if a true change in BMD has occurred. We note that this will be disrupted if physicians in non-hospital practice settings are forced to abandon axial DXA testing.

We also are in agreement with the CMS decision to lower the cut point for DXA testing in patients on glucocorticoids from less than or equal to 7.5 mg for at least 3 months to less than or equal to 5 mg a day for at least 3 months. This change is supported by the current literature and brings the CMS recommendations for a qualified individual into line with those of the American College of Rheumatology (Arthritis Rheum. 2001;44(7):1496-1503).

PROVISIONS: DEFICIT REDUCTION ACT

Section 5102(b) of the Deficit Reduction Act (DRA) enacted by Congress on February 28, 2006 would have a substantial impact on reimbursement of DXA and would further undermine CMS attempts to improve the percentage of Medicare beneficiaries screened for osteoporosis. Under this provision, the Medicare payment for the technical component of an imaging service would be set at the Hospital Outpatient Department (HOPD) payment rate, if the HOPD rate is lower than the Medicare Physician Fee Service (PFS) payment rate. Both axial DXA and VFA are listed in Addendum F of CMS 1321-P as imaging codes affected by Section 5102(b).

Due only to the regulatory changes proposed in the Medicare Physician Fee Schedule, axial DXA reimbursement would decline from $139.46 in 2006 to $110.29 in 2007. Application of an additional 10% reduction in the work RVU to maintain budget neutrality reduces this further to $109.53. The additional application of the changes legislated by Section 5102(b) of the DRA will reduce axial DXA reimbursement further to $84.50. The calculations leading to this conclusion are as follows: applying the changes legislated by Section 5102(b) in 2007 when the HOPD technical component (TC) for axial DXA is $73.89 the non-facility TC component would have an RVU of 2.65 and using the $37.90 conversion factor the TC fee would be $100.44. As this is greater than the HOPD of $73.89, the HOPD would apply, dropping the total payment for axial DXA (76075-TC + 76075-26) to $84.50 ($73.89 + [.28 x $37.90]). Thus the drop in total non-facility payment for 76075 from $139.46 in 2006 to $84.50 in 2007 would amount to a decline of 39.4% instead of the 21% without the DRA. While the intent of CMS was to phase in changes to the Medicare Physician Fee Schedule over 4 years, this drastic drop would have an immediate effect on access to bone density testing as we anticipate physician operating costs per axial DXA would be greater than the reimbursement rate (see below).

Medicare physician reimbursement for VFA would not be altered by Section 5102(b) of the DRA as the technical component of 76077 in 2007 at $26.90 would be lower than the HOPD TC of $44.78. It should be noted that the non-facility reimbursement for the technical component of VFA is 60% of the HOPD technical component for the same service and underscores flaws in the current system.

IMPACT

In CMS 1321-P Addendum B: Relative Value Units and Related Information Used in Determining Medicare Payments for 2007, the Practice Expense RVU for axial DXA (CPT code 76075) is further reduced from 0.67 to 0.61 (the RVU listed in CMS 1512-PN). In our earlier comments to CMS 1512-PN, we documented our concerns about the marked decline in RVU assigned to axial DXA and the chilling effect this would have on physicians' ability to identify and treat the millions of Americans with osteoporosis. We detailed flaws in input for the physician work and practice expense RVUs and a resultant rank order anomaly when axial DXA was compared to peripheral DXA. We also presented the results of an ISCD sponsored clinical society survey nearly identical in format and content to the 2005 American College of Radiology (ACR) Relative Value Update Committee (RUC) survey used to determine physician work value. As the reimbursement for axial DXA has now been further reduced in the current proposal, we would like to take this opportunity to expand on our earlier comments.

The ISCD remains gravely concerned about the current proposed Medicare Physician Fee Schedule which would decrease payment for axial DXA (76075) by 76% and VFA (76077) by 40% when the additional reduction in the PE RVU for DXA and the 10% adjustment for budget neutrality are factored into final payments for both axial DXA and VFA. We will provide an estimated range of operating costs incurred for axial DXA in the non-facility setting in the United States to demonstrate that such reductions in reimbursement will lead most physicians in private practice to abandon axial DXA testing.

Over 10 million Americans have osteoporosis and 34 million more have low bone mass and are at risk for future fracture. Appropriately, CMS has recognized the dramatic impact that osteoporosis has on the health of Medicare beneficiaries and osteoporosis screening is now a key preventive service that is provided at the time of the first exam and covered at least once every 24 months thereafter. Although axial DXA testing has increased significantly in the last decade as evidenced by 77,133 claims in 1994, 1.265 million in 1999 and 2.43 million in 2004, this still represents less than 20% of Medicare beneficiaries who have been tested. In comparison, mammography screening rates were approximately 68% in 2000. This was considered "suboptimal" by CMS which recently embarked on the national Medicare Mammography Campaign *"to improve beneficiaries' knowledge of breast cancer screening and awareness of Medicare's annual screening mammography benefit."* The campaign also targets health care providers to encourage them to promote screening mammography to their patients. (http://www.cms.hhs.gov/mammography/)

The ISCD suggests that in order for CMS to be successful in raising screening rates for osteoporosis several assumptions must be made.

- Unlike other diagnostic imaging services, axial DXA and VFA as screening technologies need to be performed by primary care physicians throughout the country in rural, suburban and urban settings.
- Screening services by their very nature are not efficient; if one demands efficiency one will sacrifice access.
- The work involved to screen greater segments of the population increases incrementally as the percentage of patients screened increases.
- Quality cannot be sacrificed. Therefore, physicians need to invest in certification, continuing education and facility accreditation programs.

Given these assumptions, osteoporosis screening differs from other diagnostic imaging services.

Consistent with axial DXA being a screening tool and differing from other diagnostic imaging services that have seen recent rapid growth, Medicare claims data (which we presented in our letter of August 18, 2006; copy enclosed) demonstrates that the percentage of DXA studies being done by primary care (now at 30%) has rapidly increased over the last decade. In contrast, the proportion of DXA studies done by radiology has remained constant (40%) while the percentage performed by specialists (endocrinology

and rheumatology) has declined. Appropriately, primary care uptake needs to be actively promoted to improve current screening rates.

Unlike other procedures where an increase in volume is assumed to lead to increased efficiency and less work, this does not appear to be the case for DXA. In the ACR RUC survey of 51 radiologists, 59% of the radiology respondents felt that the complexity of DXA had increased within the last 5 years. Similarly, in the ISCD sponsored clinical society survey of 453 physicians from multiple specialties (30% of whom were primary care), 61% felt that complexity had increased. Only 12% of radiologists and 19% of the clinical society survey respondents felt that DXA had become "more familiar" (less work). These results are at odds with the RUC subgroup that rejected the recommendations of the ACR and ruled that the physician work RVU for axial DXA should be reduced from 0.3 to 0.2 because the procedure was felt to be "less intense and more mechanical than the ACR survey results would indicate." To our knowledge, data to support this contention does not exist.

The analysis and interpretation of an axial DXA study is complex**.** Specifically, an appropriate study involves reviewing images of the spine, hip and/or forearm for optimal positioning, placement of bone and soft tissue markers and regions of interest. Artifacts, degenerative changes and other abnormalities are noted and specific sites are excluded from evaluation when necessary. The accepted physician interpretation of an initial study includes comments on diagnosis using the World Health Organization (WHO) criteria where applicable, estimation of fracture risk, consideration of secondary causes, treatment recommendations, and if/when the test should be repeated. The ability to provide an appropriate interpretation requires the physician to be aware of the patient's history either from their own medical records or a patient questionnaire containing past medical history, family history, medications, and a directed review of systems. Review of previous radiographs and other medical records may also be necessary. Given the above noted complexity of axial DXA performance, it is not surprising that Lewiecki et. al., found that errors in analysis and interpretation of DXA studies are not uncommon. (Lewiecki EM, Binkley N, Petak SM. Impact of DXA quality on patient care: clinician and technologist perceptions. J Bone Miner Res. 2006;21(Suppl 1):S354)

The ISCD is committed to establishing standards for both DXA and VFA. Our educational courses, certification exam, Position Development Conference (PDC) Official Positions and facility accreditation programs are all integral parts of this effort which involve both physicians and technologists. We have championed the importance of precision assessment in DXA analysis and offer a tool to calculate precision on our website. Quality axial DXA and VFA performance takes time, requires extra work and adds to the complexity and intensity of both procedures.

Moreover, as more patients are identified as being at high fracture risk and are started on pharmacologic therapy, the interpretation and reporting for follow-up bone density studies substantially increases the complexity of DXA interpretation. Comparison of two or more DXA studies must be performed with the same attention to analysis detail as noted above to ensure study comparability. Additionally, use of the same or a cross-calibrated densitometer and performance of precision assessment is essential to determine if a significant BMD change over time has occurred. Physician interpretations may include recommendations on further therapy, possible secondary causes of osteoporosis or other causes of drug therapy failure.

Viewed in this way, the axial DXA report has many elements of an E/M visit. As such, it is not surprising that in the ISCD clinical society survey, the key reference codes selected most often were 99213 (19.9% of respondents), followed by 99212 (16.3%) and 99214 (15.9%) with RVUs of 0.67, 0.45 and 1.10 respectively. The ISCD clinical society survey also demonstrated internal consistency in that the median estimated work RVU for axial DXA was 0.5 (with 25th percentile of 0.35 and 75th percentile of 1.00).

Consistent with an E/M type approach being taken by clinicians, a substantial difference was seen between the ACR RUC survey and the ISCD sponsored clinical society survey in physician work time. As we previously reported, the median physician work time for a DXA study was 25 minutes (5 minutes pre-service, 10 minutes intra-service, and 10 minutes post-service). For radiologists who were surveyed in

the ACR RUC survey, the median physician work time was either 6 or 8 minutes[1] (1-2 minutes pre-service, 4 minutes intra-service, and 1-2 minutes post-service). **Such differences in physician work time could in part be explained by what are considered "essential elements" of an axial DXA report. If the report were to only provide a densitometric diagnosis without reviewing the patient's history, risk factors and providing broad treatment recommendations, the work time would be anticipated to be substantially less.**

In our earlier letter, we demonstrated other apparent flaws in the input and assumptions used to determine physician work and practice expense. The ISCD sponsored clinical society survey also underscores some of those key points as follows:

1. 93% of respondents have a fan-beam axial DXA system which is valued at $85,000. Only 7% currently use an older pencil-beam system valued at $41,000. The Practice Expense survey used a pencil beam densitometer at $41,000 for calculation of machine costs.
2. Utilization rates across all locations in the ISCD sponsored clinical society survey were calculated to approximate 21%. This is vastly different than the 50% utilization rate used in the Practice Expense methodology for all procedures. Rates of 50% and often higher are more typically seen in large diagnostic imaging centers where patients are referred and devices are used for multiple disease states.
3. Median service contracts of $5,000, software upgrades of $2,000 per year and phantom costs were listed by the ISCD clinical society survey respondents. None of these expenses were included in the Practice Expense survey.

Additionally, it is important to recognize that osteoporosis care in the United States, and worldwide, is on the verge of a WHO driven paradigm shift based on international consensus that optimal targeting of individuals for receipt of pharmacologic intervention should be determined using an estimate of absolute 10-year hip fracture risk. The National Osteoporosis Foundation (NOF) is developing a United States-specific absolute fracture risk WHO prediction model that will identify the fracture probability at which treatment intervention becomes cost effective. This model will specifically input femoral neck BMD (necessitating axial DXA) and specific risk factors including history of prior fracture after age 50 for calculation of fracture probability and thus need for pharmacologic intervention. VFA can be performed at the same time and location as an axial DXA study, providing information about prior vertebral fractures. This will provide clinicians with essential point-of-care information for appropriate assessment of need for therapeutic intervention. Thus, the future of osteoporosis care in the United States will be based on present day axial DXA equipment, upgraded with special software provided by the WHO and NOF (following FDA approval) that will automatically link the patient's BMD and prior fracture status (as well as the other risk factors) into the aforementioned NOF cost effectiveness model that will be reported by axial DXA equipment.

Given the importance of axial DXA and VFA screening as key preventive services, one could argue that not only do the services need to be appropriately valued compared to other CPT codes, but that value could be set higher to further increase incentives and improve the proportion of beneficiaries screened. MEDPAC in their report to Congress in March 2006 outlined the dangers of undervaluing a service noting that physicians may opt not to provide the service, thereby threatening access to care. Additionally, Medicare would not be spending taxpayer money wisely by not paying enough for the undervalued service.

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[1] The ISCD identified two ACR physician work survey documents with different results for the time involved (enclosed). The first survey done before final RUC input listed pre-service time of 2 minutes, intra-service time of 4 minutes and post-service time of 2 minutes for a total time of 8 minutes. The second survey identified included the RUC work value of 0.2 and listed pre-service time as 1 minute, intra-service time of 4 minutes and post-service time of 1 minute for a total time of 6 minutes.

What is an appropriate reimbursement for axial DXA?

We have begun to explore the operating costs per axial DXA study for physicians in the non-facility setting realizing that costs may vary for each of the specific inputs identified. We have taken a range of fixed and variable costs incorporating input from a number of different practices in the United States (Table 1).

Table 1: Estimation of DXA Cost

Fixed costs		
Depreciation of axial DXA	$85,000/ 5years	$17,000
Interest on loan	6% for 5 yrs	$2,600
Maintenance contracts		$6,000 – $9,000
Space	150 sq ft @ $16 – $30/sq ft.	$2,400 – $4,500
Overhead		$10,000 – $40,000
	Total fixed costs	**$38,000 – $73,100**
Variable costs		
Technologist salary + fringe	$50,000 – $70,000 x 30 min.	$12.02 – $16.83
Receptionist salary + fringe	$30,000 – $40,000 x 20 min.	$4.88 – $6.51
Billing salary + fringe	$50,000 – $70,000 x 15 min.	$6.01 – $8.41
MD salary + fringe [interpretation]	$150,000 – $250,000 x 25 min.	**$30.00 – $49.28**
	Variable costs per DXA	**$52.91 – $81.03**

Assumptions:

- Fan beam DXA at $85,000
- Work calculated on 2080 hrs/year
- Overhead calculated as percent of total clinic overhead that is associated with DXA. Percent is derived from DXA revenue/ total clinic revenues
- Physician time of 25 minutes is based on ISCD clinical society survey
- Divide number of DXA studies done/year in to total fixed costs to determine total fixed costs/ DXA then add that to total variable costs/DXA for total expenses/DXA

We then examined the effect of varying the number of axial DXA studies performed over the range of operating costs (Table 2)

Table 2: Estimated Costs per DXA Study Based on Number Performed

# studies / mo	# studies / yr	Cost / DXA (low)	Cost/DXA (high)
10	120	$369.58	$690.20
20	240	$211.24	$385.61
30	360	$158.47	$284.09
36	432	$139.87	$250.24
40	480	$132.08	$233.32
50	600	$116.24	$202.86
60	720	$105.69	$182.56
70	840	$98.15	$168.05
80	960	$92.49	$157.18
100	1200	$84.58	$141.95
102	1224	$83.96	$140.75
120	1440	$79.30	$131.79
2030	24,366	$54.47	$84.03

We estimate that at the current reimbursement rate for axial DXA of $139.46 (not factoring in the Geographic Adjustment Factor), to meet operating costs a practice would need to perform approximately 36 studies per month (432 studies per year) at the low end of operating costs and 102 studies per month (1224 per year) at the high end of operating costs. Once the projected reimbursement rate of $84.50 for axial DXA takes effect on January 1, 2007, (applying the MPFS and Section 5102(b) of the DRA but not SGR) the number of studies that would have to be performed to meet operating costs would nearly triple to 100 studies per month (1200 per year) at the low end and increase 200 fold to 2,030 studies per month or 24,366 per year at the high end.

From the ISCD clinical society survey we obtained the median number of axial DXA studies performed per month in varying locations and practice types. Using the corresponding range of operating costs as estimated above, we then examined how practices would fare given the current reimbursement of $139.46 per axial DXA study, the projected reimbursement of $84.50 to take effect on January 1, 2007, and the anticipated reimbursement of $33.73 that would apply on January 1, 2010, after the 4 year incremental phase in (Table 3).

Table 3: Range of Estimated Operating Costs per DXA Based on Practice Location and Type

Practice location	Median number of studies per month	Low Operating Costs per DXA	High Operating Costs per DXA
Rural	50	$116.24	$202.86
Suburban	60	$105.69	$182.56
Urban	80	$92.49	$157.18
Practice type			
Solo	35	$143.39	$255.08
Single specialty	60	$105.69	$182.56
Multi-specialty	90	$88.10	$148.72
Med school faculty	120	$79.30	$131.79

As one might predict, axial DXA utilization rates are lower in rural locations and solo practice settings and highest in urban locations, multi-specialty and medical school faculty settings. The greater the number of studies performed, the lower the expense per study. At current reimbursement rates and even allowing for low operating costs, solo practitioners are currently just covering their costs. At the high end of operating costs, only medical school faculty are performing enough studies to avoid losing money.

If one now looks at **the anticipated reimbursement of $84.50** that would take effect on January 1, 2007 (excluding the effects of the SGR), only medical school faculty using low operating cost assumptions would be able to avoid a loss. All practice models, in all locations, under any reasonable operating cost assumption will lose money when the reimbursement drops to $33.73 in 2010. The reimbursement rate in 2008 of $83.76 and $59.12 in 2009 are equally onerous. The results of the ISCD clinical society survey coupled with our operating cost analysis unequivocally demonstrates that DXA testing would be abandoned by almost all practitioners in all settings if the proposed changes take effect in January 2007.

As CMS is interested in a successful screening program for osteoporosis, an increasing number of physicians in solo practice and rural settings will have to be added; work and complexity will increase and quality will need to be maintained. Viewed in this way one must conclude that the reimbursement for axial DXA will have to increase above the current rate of $139.46.

What are the potential consequences of profoundly undervaluing DXA?

Physicians in non-facility/private practice settings will abandon axial DXA testing if the current Medicare Physician Fee Schedule is enacted as reimbursement in 2007 will be less than the operating cost to perform the study. Enactment of Section 5102(b) of the Deficit Reduction Act alone would also accomplish the same result. With removal of bone density measurement capability from physicians' offices, osteoporosis screening will be curtailed; the personal and societal expense of osteoporotic fractures would be expected to increase.

Although current screening rates of 20% are low, the dramatic increase in claims over the last 10 years implies significant potential for improvement, but only if the service is appropriately valued. By their very nature, screening services are less efficient than diagnostic procedures. Identifying patients not yet tested will require extra time and work. If screening services are to be successful, it seems reasonable that the total number of DXA units must increase, not decrease as seems certain will occur if the above noted regulatory and legislative changes are adopted.

Physician office-based axial DXA and VFA centers presently perform 71% of the total number of DXA studies for Medicare beneficiaries. Physician offices (non-facility) performed 1.7 million DXA examinations in 2004 (latest figures available) of which 46% were completed by primary care physicians. Hospital outpatient facilities are unable to handle the additional number of patients required to increase screening rates above the current level of 20%. Patient access will be further restricted and long waits for an appointment will discourage many. Additionally, by shifting patients to the hospital outpatient setting, the ability to measure response to current therapy will be lost.

Optimal patient care may be compromised. A Medicare patient who has their axial DXA performed in their doctor's office has an important advantage over general radiological facilities in that their DXA study may be done the same day as they see their physician, thus improving convenience. Additionally, their study is either interpreted by their personal physician or by other physicians in the same clinic that have their medical records available for review. Personal knowledge of the patient's medical history, or access to such data in the medical record, provides the bone density interpreter with important information that may directly influence study interpretation. The difference in time spent performing and interpreting a DXA study between the ACR survey (6-8 minutes) and the ISCD clinical society survey (25 minutes) suggests there are substantial differences in the interpretation and reporting of bone density examinations in clinician's offices.

With enactment of the CMS reductions in reimbursement, bone density assessment and VFA will be severely undervalued. DXA centers that do elect to continue offering these services are unlikely to offer their physicians and technologists the additional education that is necessary for continued performance of high quality testing. Additional expenses such as service contracts will not likely be extended and software upgrades not purchased.

With the loss of physician office-based axial DXA availability, future osteoporosis care in the United States will become a two-tiered system of the haves and have nots. Individuals having sufficient personal financial resources to pay up front for bone densitometry will do so at their physician's central DXA center, if still operational. In contrast, the vast majority of patients will have to wait for an appointment and travel to a hospital to have a bone density assessment performed without the benefit of having their physician's clinical expertise integrated into the final interpretation. This two-tiered Medicare system is contrary to present Federal directives as iterated by the United States Preventive Services Task Force recommendations of 2002, the Surgeons General's 2004 report on Osteoporosis and Bone Health, and the Balanced Budget Act of 1998.

Summary of input errors in the physician work and practice expense surveys for axial DXA

The ISCD stated in its initial comments to CMS (August 18, 2006, see enclosed copy) and have again reiterated in the aforementioned text that significant flaws exist in the input data that was used in calculation of the work and practice expense RVU for axial DXA. CMS agreed with the AMA RUC that axial DXA work RVU should be 0.20 which is contrary to the specialty society survey (ACR) work RVU of 0.30 and the clinical society survey work RVU of 0.50. The work RVU of 0.20 for axial DXA will now be identical to another imaging densitometric procedure called radiographic absorptiometry (RA), CPT code 76078. However, axial DXA requires substantial depth of knowledge, meticulous attention to detail, appreciation of published standards and guidelines, regular updates of one's skills and a proficiency of skeletal health assessment at the DXA center itself (facility accreditation) that can only be attained through additional and ongoing post graduate medical education and financial expenditure. This should be contrasted with radiographic absorptiometry that uses a simple digitized x-ray to measure finger density in comparison to an aluminum wedge and reports "RA" units rather than BMD. RA cannot be used for diagnosing osteoporosis or monitoring patients on therapy. Either we accept the opinion of the RUC that these two technologies are identical, which is unrealistic, or the RUC analysis of the ACR survey is flawed resulting in a significant rank order anomaly that cannot be reconciled in its present form. The axial DXA work RVU of 0.50 supported by the clinical society work survey should be considered as the true physician work related to this imaging procedure.

Additionally, the practice expense RVU as calculated by CMS in their "bottom up" methodology contains flawed data input. Present day central DXA equipment, called fan beam DXA, costs $85,000 instead of older pencil beam instruments costing $41,000 that were included in the CMS calculations. Moreover, the additional expense associated with service contracts, software upgrades, quality control phantoms, initial training and continuing medical education of technologists, axial DXA certification and future facility accreditation were not included in the CMS calculations. Lastly, inappropriate DXA machine utilization rates of 50% were used by CMS in their calculations instead of "single disease state" imaging procedure utilization rates of 15-20% for axial DXA and VFA performed by primary care physicians, rheumatologists, and endocrinologists as a point-of-care service.

The case for VFA

The ISCD is aware that VFA is currently not considered a preventive service by CMS. Moreover, since VFA was only recently assigned a CPT code, we do not have claims data to review. However, given the CMS commitment to screening patients for osteoporosis and treating those at highest risk, incorporating VFA into current benefits has much to recommend. 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. 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 radiography in the identification of moderate and severe fractures in post-menopausal women being evaluated for osteoporosis, including those with low bone mass (osteopenia).

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. VFA also offers advantages above and beyond those of DXA. For example, 14-20% of Medicare beneficiaries with osteopenia by WHO criteria, who might not be otherwise treated, have vertebral fractures on VFA and have a clinical diagnosis of osteoporosis. Such individuals are at substantially increased risk for fracture and require pharmacologic therapy. However, since two-thirds of vertebral fractures are clinically unappreciated, neither the patient nor their physician would be aware of their increased fracture risk. Therefore, VFA combined with DXA has the capability to identify those at greatest fracture risk allowing improved targeting of pharmacologic therapy. VFA will play an even more critical role in patient care with release of the NOF United States-specific absolute fracture risk WHO prediction model that will identify the fracture probability at which treatment intervention becomes cost effective based on axial DXA hip BMD and the presence of VFA documented prevalent spine fragility fractures as noted above.

As VFA is a software addition to current fan-beam axial densitometers, this allows primary care physicians who lack access to plain spine radiography in their office the ability to screen for vertebral fractures. This allows more appropriate targeting of treatment in the primary care setting to Medicare beneficiaries who are at highest risk for osteoporotic fractures. CMS 1321-P did not address the work RVU for VFA (76077) but reduced the Practice Expense RVU from 0.81 to 0.41, thereby reducing reimbursement by 40% over the next four years when the 10% adjustment for budget neutrality is applied to the physician work RVU. The current reimbursement of $39.41 would be reduced to $23.61 by 2010. We note that the HOPPS reimbursement would be $53.50, thus the non-facility reimbursement for the technical component of VFA would be 60% of the HOPD technical component for the same service. ISCD recommends that CMS consider VFA as a screening tool and apply special resource considerations that will appropriately value this service.

CONCLUSION

CMS has identified osteoporosis as a major health care concern in the United States. Moreover, CMS has designated axial DXA as the key diagnostic tool for the screening of Medicare beneficiaries and for monitoring response in patients on pharmacologic therapy. Efforts to increase axial DXA screening rates above the current level of 20% will require a different approach within the existing framework that values access over efficiency and assigns an appropriate value to a screening procedure increasingly performed by primary care physicians in the office (non-facility setting).

Unfortunately, if the current proposed Medicare Physician Fee Schedule is enacted for axial DXA and/or Section 5102(b) of the Deficit Reduction Act takes effect on January 1, 2007, axial DXA testing will disappear from the non-facility setting as physicians operating costs will be greater than reimbursement for the test. Enactment of this policy will result in severe limitations in patient access to skeletal health assessment and will undermine the CMS initiative to screen beneficiaries for osteoporosis and monitor their response to medical therapy.

We encourage CMS to re-examine the input data and assumptions used to determine reimbursement for central DXA and VFA and have offered suggestions for changes in the data used to determine work and PE RVUs. Accordingly, the ISCD urges CMS to review the proposed cuts and at the very least keep reimbursement at the current levels. Moreover, based on the ISCD clinical society survey, the ISCD cost analysis and the CMS initiative to attain 100% screening of Medicare beneficiaries, an increase in axial DXA and VFA reimbursement is warranted. Finally, the ISCD proposes that special resource

considerations are necessary for both DXA and VFA to ensure widespread availability, and enhance utilization of high quality osteoporosis screening in the United States.

The ISCD appreciates this opportunity to comment on the proposed changes to the Medicare Physician Fee Schedule. We welcome any further dialogue with the Centers 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.

Sincerely,

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