September 6, 2016

Mr. Andy Slavitt
Acting Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1656-P
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted electronically via http://www.regulations.gov

RE: CMS-1656-P; Centers for Medicare & Medicaid Services (CMS) Calendar Year (CY) 2017 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Policy Changes, Quality Provisions, and Payment Rates Proposed Rule

On behalf of the International Society for Clinical Densitometry, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Calendar Year (CY) 2017 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Policy Changes, Quality Provisions, and Payment Rates Proposed Rule (CMS-1656-P).

The ISCD is a multidisciplinary, nonprofit organization that was founded in June of 1993. With approximately 3,000 members in more than 70 countries, the ISCD provides a central resource for a number of scientific disciplines with an interest in the assessment of musculoskeletal health. The ISCD is the only society of its kind with membership of physicians, technologists, other allied health providers and scientists representing 30 disciplines including family
practice, internal medicine, obstetrics, gynecology, endocrinology, gerontology, nephrology, orthopedics, pediatrics, radiology and rheumatology.

Our mission is to advance excellence in the assessment of skeletal health. As such, the ISCD offers comprehensive educational courses in bone densitometry and vertebral fracture assessment (VFA) as well as certification in dual-energy X-ray absorptiometry (DXA) acquisition, analysis, and interpretation for technologists and physicians. The ISCD also offers facility accreditation to validate the implementation of DXA best practices. This demonstrates to healthcare providers, payers and patients that a DXA testing facility meets the highest quality standards.

The Organization periodically holds Position Development Conferences, to address a variety of issues in the field, using a process whereby an international panel of experts makes recommendations based on reviews of the scientific literature by task forces associated with their Scientific Advisory Committee. Recommendations that are approved by the ISCD Board of Directors become Official Positions of the ISCD. See ISCD Official Positions at [http://www.iscd.org/official-positions/](http://www.iscd.org/official-positions/)

The ISCD objects to a provision in the proposed rule that would cut reimbursement for Axial DXA, CPT 77080, in the hospital outpatient setting from the current national average of $100.69 to $63.33 for the following reasons:

1. The CMS proposal to restructure the current Ambulatory Payment Classification (APC) from 17 to 8 APC’s is premature.

2. The proposed rule inappropriately assigns DXA to a new APC that results in grouping tests that are not clinically comparable and not comparable with respect to resources (Dual Energy Absorptiometry (DXA) v. Qualitative Ultrasound (QUS)) in violation of Section 1833 (t)(2)(B) of the Social Security Act.

3. DXA testing has already suffered a more than 70% reimbursement cut in the office setting, severely limiting patient access to a vital preventative test. The proposed cut to DXA in the hospital outpatient setting will further limit access to osteoporosis testing.

**Background on Osteoporosis**
In 2010, 54 of the 99 million Americans age 50+ years were at risk of suffering from a fracture caused by osteoporosis. A woman’s risk of having an osteoporotic fracture in one year is greater than her combined risk of having a heart attack, stroke or developing breast cancer. In U.S. women age 55+ years, bone fractures due to osteoporosis lead to more hospitalizations and greater healthcare costs than heart attack, stroke or breast cancer. Half of women over the age of 50 years will have a fracture caused by osteoporosis during their lifetimes. Medicare paid over $17 billion in 2010 for direct costs of new fractures that year which is projected to grow to over $25 billion by 2025.

It is estimated that 44% of women age 60 and up and 25% of men the same age will experience a bone break due to osteoporosis in their lifetimes. Given major public health implications associated with osteoporosis, the need to improve access to DXA testing and facilitate earlier and more effective osteoporosis treatment is urgent. Osteoporosis is a very prevalent disease in the United States, with 64.5% of the population age 65 years and above affected by osteoporosis (16.2%) or low bone mass (48.3%), placing them at higher risk of suffering from a fracture. Over 2 million fractures are caused by osteoporosis each year in the United States. Furthermore, research indicates that the hospital burden of fractures from osteoporosis for Medicare beneficiaries is greater than that of heart attacks, stroke or breast cancer for older women.

As with so many conditions, early diagnosis and treatment cost a small percentage of what Medicare will incur due to fractures that could have been prevented. The research clearly shows that when DXA testing is more widely

---


5 Looker AC and Frenk SM. “Percentage of Adults Aged 65 and Over With Osteoporosis or Low Bone Mass at the Femur Neck or Lumbar Spine: United States, 2005–2010.” CDC Division of Health and Nutrition Examination Surveys; August 2015.


available, the health and economic risks of osteoporosis are dramatically reduced. DXA screening is recommended by numerous clinical and patient organizations as the highest standard for osteoporosis diagnosis, and sound Medicare policy should incentivize higher utilization of these tests.

Osteoporosis is already one of the most costly chronic conditions in the Medicare program, and the increasing prevalence of this potentially-fatal disease in addition to the growing financial impact of bone fractures to the Medicare program, warrant expanded access to osteoporosis diagnostic tests.

1. **The CMS proposal to restructure the current Ambulatory Payment Classification (APC) from 17 to 8 APC’s is premature.**

We oppose the restructuring of the current APC system for CY 2017 for medical imaging services that would reduce the total number of APCs from 17 to 8. The current 17 APCs have only been in place for 8 months. Clearly, this is not long enough for the agency to adequately collect data, let alone evaluate the effect that the 17 classifications have had on patient access to services. Additionally, when CMS is proposing a restructuring of this magnitude, we would hope that it would consult with multiple stakeholders and give an appropriate amount of time for input.

While the agency has not divulged the methodology used in the restructuring of APCs, insuring access to life-saving preventive services was clearly not part of that calculus. For example, the proposed rule assigns two life-saving preventive services to the lowest paid APC - DXA, the gold standard test used to diagnose osteoporosis and Low-dose CT lung cancer screening (LDCT-LCS). The reimbursement rates for these vital services will be slashed by 37 and 44 percent, respectively. Both screening services have the potential to save lives, to lower costs to the Medicare program, and are already under utilized. Despite the proven patient benefits of both of these tests, CMS has randomly proposed reimbursement cuts that limit broad-based patient access to quality preventative medicine.

The ISCD respectfully asks CMS to provide: (a) the methodology used to form the new classifications; (b) the methodology used in the assignment of services to a particular APC; and (c) a reasonable opportunity to comment on such a large policy change. This lack of transparency, professional collaboration, and essential input from stakeholders is unacceptable.

At a minimum, whatever methodology is used to assign services to APCs, we urge CMS to look at the reimbursement for preventative services with a different eye. The methodology for reimbursement for these services must
tactor in both the need for broad community based access to Medicare beneficiaries as well as the long-term cost savings to the Medicare Program. A lack of stability in reimbursement for critical preventive services like DXA discourages continued provision and necessary expansion of these services. It makes no sense to repeatedly cut and inadequately reimburse services that have proven patient benefits and will yield substantial savings to Medicare.

2. **Services within the APC are not clinically comparable and not comparable with respect to resources, as required by Section 1833(t)(2)(B) of the Social Security Act.**

CMS disregarded the requirement that services in an APC be clinically comparable and comparable with regard to resources. Section 1833(t)(2)(B) provides:

"The Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates"

Under the proposed rule, tests for bone density would be reimbursed at the same rate of $63 even though axial DXA (CPT Code 77080) and QUS (CPT Code 76977) are not at all clinically comparable. The proposed APC grouping would slash the DXA reimbursement by 37% and more than double the reimbursement for QUS.

DXA is considered to be the gold standard for osteoporosis testing, while QUS has very limited clinical application. Only an axial DXA test (not QUS) can be used to make diagnostic classifications, assess fracture risk and monitor a patient’s response to osteoporosis therapy -- all of which are critical in the management of osteoporosis.  

**Comparison of DXA and QUS**

DXA of the lumbar spine and hip is a noninvasive test that measures bone mineral density (BMD), assess fracture risk, diagnose osteoporosis and monitor a patient’s response to treatment.

DXA provides a quantitative areal measurement of bone mass, routinely referred to as BMD. In the lumbar spine, a post-anterior (PA) measurement is

---

made with the patient in the supine position. BMD is calculated from measurement of the bone mineral content (BMC) and area of each of the four vertebral bodies L1, L2, L3 and L4. The measured BMC of each vertebrae is divided by the corresponding vertebral area to determine the BMD, the mean of these four vertebrae generates L1-L4 BMD. This measurement is used to calculate a T-score, which compares the BMD of the individual with that of a young normal control population. A low resolution PA image of the lumbar spine is generated for placement of soft tissue markers to determine the region of interest.

In contrast, QUS is not a bone density test but rather analyzes the transmission of ultrasound waves through bone at peripheral skeletal sites such as the finger, heel or forearm. QUS measurements can be used to assess fracture risk, but otherwise have very limited clinical applications. QUS cannot be used for the diagnosis of osteoporosis, as it does not produce a T-score that can be used with the World Health Organization (WHO) criteria. QUS cannot be used to monitor a patient’s response to osteoporosis therapy because QUS measurements change very little with treatment.

The greater clinical utility of DXA compared with QUS has been recognized by CMS in the 2007 National Coverage Determination for Bone Mass Measurement, that states “only an axial DXA test can be used to monitor a patient’s response to Medicare-covered osteoporosis drug therapies.”

This discordance of peripheral bone sites (fingers, forearm, feet) with central DXA (hip and spine) is well demonstrated by Figure 1 below. It shows that more than 50% of the women who are osteoporotic are not identified from peripheral bone measurements, independent of if QUS or peripheral DXA is used. QUS and peripheral DXA are not as accurate as central DXA as a diagnostic tool.

---

9 Ibid at 742.

10 Ibid.
Finally, to achieve this higher sensitivity and accuracy with central DXA requires technologists and physicians trained in quality practices and safety around using X-ray systems. DXA is regulated in a majority of states for safety and quality standards. Operators of QUS systems are not regulated by states to have minimum and demonstrated skills. In short, the diagnostic performance of central DXA has unique operational costs in terms of purchasing and maintaining the equipment, the skill of the technologist and the physician interpretation of the test, in violation of Section 1833(t)(2) (B).

Currently, the reimbursement code used for reimbursing peripheral DXA and QUS, 77081, is being grouped with the same APC as central DXA. For all the reasons above, central DXA should be reimbursed at a higher rate than QUS to encourage its use and maintain the highest diagnostic standards.

We urge CMS to comply with the federal law and review the clinical and resource values of axial DXA and place it in a higher reimbursement APC.

3. The proposed reimbursement cut in the hospital out patient setting will further limit access to DXA

DXA testing has already been severely curtailed following the Medicare reimbursement cuts to office based DXA testing that began in 2007. We urge
policy before implementing another reimbursement cut that will similarly debilitate the other part of the DXA provider community---those providers located in Hospital outpatient departments.

Over the past decade, Medicare reimbursement for DXA in the physician office setting (where two thirds of all DXAs are performed) has been cut by over 70%. The chain of events that followed those payment cuts was predictable, catastrophic to patient care, and will take years to reverse.

In 2008, the year following the first DXA cuts, the number of DXA providers began to decline. By 2014, there were 5,000 fewer DXA providers\textsuperscript{11}. DXA testing in Medicare older women has declined by 14% resulting in the loss of over 2.3 million DXA tests since 2009\textsuperscript{12}.

Even though the prevalence of osteoporosis is increasing, one year after the decline in testing began, there were 17% fewer diagnoses of osteoporosis in Medicare older women\textsuperscript{13}. If diagnosis rates had stayed at 2009 levels, half a million more women would have been diagnosed and treated\textsuperscript{14}. After 15 years of declining hip fracture rates, hip fracture rates plateaued for the past three years (2013-2015)\textsuperscript{15} resulting in 8,000 additional hip fractures costing Medicare an estimated $320 million and resulting in approximately 1,600 additional deaths related to hip fracture\textsuperscript{16}. See Attachment A.

**Summary**

There is a compelling need to improve access to DXA testing and limit as much as possible the growing burden on the Medicare budget caused by increased fractures. Instead of further dismantling the osteoporosis care network, CMS should be preparing for the projected increase in the prevalence of osteoporosis. Because CMS already reimburses DXA tests in the physician office setting at rates that are below the cost of the procedure,\textsuperscript{17}

\textsuperscript{11} Lewiecki EM 2016 Hip Fractures and Declining DXA Testing: At a Breaking Point? J Bone Miner Res 31 (Suppl 1).
\textsuperscript{12} Ibid.
\textsuperscript{13} Ibid.
\textsuperscript{14} Direct Research LLC, Medicare PSPS Master Files and Medicare 5 Percent Sample LDS SAF, analysis by Peter M. Steven, PhD.
\textsuperscript{15} Lewiecki EM 2016 Hip Fractures and Declining DXA Testing: At a Breaking Point? J Bone Miner Res 31 (Suppl 1).
\textsuperscript{16} Direct Research LLC, Medicare PSPS Master Files and Medicare 5 Percent Sample LDS SAF, analysis by Peter M. Steven, PhD.
access for Medicare beneficiaries will continue to decline and fracture rates will continue to increase.

We implore CMS to acknowledge and rectify the crisis in osteoporosis care caused by their failed payment policy before it implements even more payment cuts. To be clear, CMS payment policy that reversed a decade of osteoporosis prevention efforts and was followed by the loss of one quarter of experienced DXA providers, decreased testing, decreased diagnosis of osteoporosis and increased fractures in older women, has been a failure. We urge the Agency to take a more practical, common sense approach to setting rates for preventive services like DXA and review the entire network of care (both Office and Hospital settings) before imposing further payment cuts. Implementing payment policy in a piecemeal fashion has already cost lives and money. Continuing down the current path is not an option.

The ISCD appreciates the opportunity to offer these comments. Should you have any further questions, please contact the ISCD Legislative Counsel, Donna Fiorentino, Esq. at dfiorentino@iscd.org or by phone at 860-402-2159.

Sincerely,

John A. Shepherd, PhD, CCD
ISCD President

E Michael Lewiecki, MD, FACP, FACE, CCD
ISCD Public Policy Chair
Attachment A

Reimbursement Rates

DXA Office Providers

Percent of Women Tested

Direct Research LLC; Medicare's Master File; Medicare's Percent Sample LDS-SAF; analysis by Peter M. Stover, PhD.
Percent of Women Diagnosed with Osteoporosis

Percent of Hip Fractures with No Osteoporosis Diagnosis

Age-Adjusted Hip Fractures per 100,000 Elderly Women

Direct Research LLC; Medicare PSIP Master Files and Medicare 5 Percent Sample LOS SAS; analysis by Peter M. Stover, PhD.