September 2, 2014

Marilynn Tavenner
Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1613-P
P.O. Box 8013
Baltimore, MD 21244-8013

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

RE: CMS-1613-P Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated With Submitted Data; Proposed Rule

Comments to be offered on:

Proposed Rule Section II. A. 3. – Proposed Changes to packaged Items and Services

Dear Ms Tavenner:

The International Society for Clinical Densitometry (ISCD) welcomes the opportunity to comment on the CMS proposed rule CMS-1613-P Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated With Submitted Data; Proposed Rule published in the July 14, 2014 Federal Register.

The ISCD is a multidisciplinary, nonprofit organization that was founded in June of 1993 with approximately 3300 members in more than 70 countries. ISCD provides a central resource for a number of scientific disciplines with an interest in the assessment of
musculo skeletal health. The Society is the only one of its kind worldwide 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.

The ISCD’s 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 and interpretation for technologists and physicians. The ISCD now also offers facility accreditation to demonstrate to healthcare providers, payors and patients that a DXA testing facility meets accepted standards.

The ISCD will address the proposed changes to packaged items found in Section II A.3 of the rule.

**Proposed Rule Section II. A.3 - Proposed Changes to Packaged Items and Services**

The ISCD objects to the ancillary packaging policy articulated in the rule as it applies to Axial DXA, Appendicular DXA and Vertebral Fracture Assessment (VFA).

**Background on Osteoporosis**

Osteoporosis remains a major public health risk that disproportionately affects women who account for 71% of fractures and 75% of costs. 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. About 25% of women over the age of 50 who sustain a hip fracture die in the year following the fracture. In fact, more women die each year from complications following hip fractures than from breast cancer.

The cost to Medicare due to osteoporosis-related fractures has been estimated to be $22 billion (2008). When applied to the entire U.S. population, the cost is estimated to increase to more than $25 billion by 2025. In 2010, osteoporosis was the ninth ranked major illness among the top 5 percent highest cost Medicare beneficiaries (12 percent of all beneficiaries and 18 percent of high costs beneficiaries).

Due to an aging population, the U.S. Surgeon General estimates that the number of hip fractures and their associated costs could double or triple by 2020. For those who sustain a fracture, morbidity and mortality rate are high. Fully 50% of patients who sustain a hip fracture never walk independently again and 20% require permanent nursing home placement. Our ability to identify and treat patients at risk for osteoporotic fractures before they occur will decrease the incidence of fractures and associated healthcare costs.
Background on Axial Dual Energy Absorptiometry (Axial DXA - CPT 77080), Appendicular DXA (CPT 77081) and Vertebral Fracture Assessment (VFA- CPT 77082)

Axial DXA (77080): DXA of the lumbar spine and hip (CPT 77080) is a noninvasive test that measures bone mineral density and is used to diagnose and monitor the treatment response to osteoporosis. DXA is the best predictor of future fracture risk and the only test covered by CMS for monitoring response to drug therapy.

DXA provides a quantitative areal measurement of bone mass, routinely referred to as bone mineral density (BMD). In the 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.

Appendicular DXA (77081): In some cases a forearm measurement is used when determining bone density, a measurement of the forearm is performed in addition to, or in place of, the hip and spine measurement. When only a forearm measurement is performed on a DXA machine, it is billed as 77081. The forearm measurement is used if the hip and or spine cannot be measured using Axial DXA (for example in patients with (a) a hip replacement, or (b) in obese patients who are over the weight limit for the DXA machine). Additionally, forearm measurement is preferred to assess skeletal status in some diseases, such as hyperparathyroidism. See more at: http://www.iscd.org/official-positions/2013-iscd-official-positions-adult/#sthash.SrKhpLsP.dpuf

Vertebral Fracture Assessment: (77082) In contrast to Axial and Appendicular DXA (which are preventive screening services), vertebral fracture assessment (VFA) is a diagnostic test that provides a detailed visual image of a much larger part of the spine with evaluation typically performed from T4 through L4. VFA is performed on an Axial DXA machine with software that is either included on newer model DXA machines or is purchased separately and added to an Axial DXA machine. The healthcare provider would obtain VFA to determine the presence of vertebral fractures based on the image provided. The VFA image is diagnostic and can be used with near comparable specificity and sensitivity to plain radiographs when looking for moderate and severe vertebral fractures. Additional software incorporated in VFA allows for 6-point measurement of selected vertebrae.
Both DXA and VFA are used to assess an individual patient’s fracture risk but provide distinctly different information (BMD/T-score for DXA and presence of prevalent fracture for VFA). As noted in the current National Osteoporosis Foundation (NOF) Clinician’s Guide, treatment to reduce fracture risk using FDA approved pharmacologic therapy is recommended for the post-menopausal woman or older man with T-scores (using DXA) of less than or equal to -2.5. Treatment is also recommended if prevalent vertebral fracture (using VFA or plain radiograph) is identified. Similarly, FRAX incorporates a BMD/T-score measurement as well as a determination of prevalent fractures, including vertebral fracture, to calculate a 10-year risk for future fracture.

Indications for when to obtain a DXA or VFA are also different. The Bone Mass Measurement Act of 1998, as amended, provided a NCD for DXA testing in certain Medicare qualified beneficiaries: estrogen deficient women; those with vertebral abnormalities including osteoporosis, osteopenia or prior fracture; hyperparathyroidism; those on prednisone in doses of > 5 mg/d for > 3 mos., and those on pharmacologic therapy to monitor response.

The ISCD has provided indications for VFA testing in its 2007 Official Positions, updated in 2013. Unlike DXA, VFA is not viewed as a screening test but would be ordered in individuals where the finding of a vertebral fracture would alter the clinical treatment course. This would include individuals with osteopenia who had certain specified levels of historical and/or measured height loss, history of prior vertebral fractures not well documented or other secondary causes of metabolic bone disease associated with high risk for fracture.

In October 1999, the VFA software packages to allow Axial DXA devices to perform spinal imaging received FDA 501(k) marketing clearance. The AMA approved the CPT code 76077 for VFA effective January 1, 2005. VFA software may either be purchased separately as an add-on to a DXA machine or is included in some newer DXA models. When the VFA software is purchased separately, the cost is typically between $5,000 and $10,000.

**Intent of Ancillary Packaging Policy**

The intent of the proposed ancillary packaging policy is to continue the trend of moving away from a per service payment system to a prospective payment system and to encourage efficiency by developing larger payment bundles:

“Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals’ incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items,
and supplies that could be used to furnish a service, some of which are more expensive than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient’s needs, rather than to routinely use a more expensive item, which often results if separate payment is provided for the items.”

Current Reimbursement for Axial DXA, Appendicular DXA and Vertebral Fracture Assessment (VFA).

Currently, if performed individually, the reimbursement for these services below for CY 2014 is:

1. Axial DXA: (77080): $88.63;
2. Appendicular DXA: (77081), $50.34; and

If Axial DXA and VFA are performed on the same day, the hospital is paid for each service separately amounting to $145.01 for both. Similarly, if Appendicular DXA and VFA are performed on the same day, the reimbursement would be $106.72.

Current National Correct Coding Initiative (NCCI) edits prohibit Axial DXA (77080) and Appendicular DXA (77081) from being reimbursed separately when both services are performed on the same day. As such, the rate for performing both services would be $88.63 (the amount of the Axial DXA).

Packaging of VFA with Axial or Appendicular DXA or Both, Does Not Further the Intent of the Proposed Ancillary Packaging Policy.

CMS 1613-P proposes to conditionally package certain services that are integral, ancillary, supportive, dependent or adjunctive to a primary service. Specifically, the rule will limit the initial set of Ambulatory Payment Classifications (APCs) that contain packaged services to those ancillary service APCs with a proposed geometric mean cost of less than or equal to $100.

As the result of the assignment of the DXA services to particular APCs, the reimbursement for CY2015 would be:

1. Axial DXA, 77080, APC code 0261, $95.36
2. Appendicular DXA, 77081, APC code 0260, $59.63 and
3. VFA, 77082, APC code 0260, $59.63

While this looks on its face to be an increase over the current rate, the practical effect of packaging VFA to either Axial or Appendicular DXA) results in a lower overall payment of $99.85 and $62.43 respectively.

The proposed rule specifically exempts Axial DXA (77080) and Appendicular DXA (77081) from the ancillary packaging policy because they are preventive services.
“This proposed policy is consistent with our policy to exclude preventive services from the proposed ancillary services packaging policy, will encourage the provision of preventive services, and provide maximum flexibility to beneficiaries across different sites of service in receiving preventive services”.

As a practical matter, that preventive service exemption as applied to Axial DXA (77080) is meaningless. While 77080 has the illusory protection from being packaged as an ancillary service to another service, VFA (77082) could be packaged with Axial DXA. In fact, the only service that DXA would be performed with would be VFA and the only service that VFA would be performed with would be DXA. For DXA to benefit from the preventive exemption, CMS would need to include VFA in that category.

The intent of the packaging rule, to increase efficiency in the provision of services, is not furthered in this case. There is no efficiency of cost to be realized in the case of DXA and VFA as there are not a “variety of devices, drugs, items, and supplies that could be used to furnish a service” such as DXA and VFA. These are two distinct services that provide unique results and happen to be performed on the same machine. Reading and interpreting VFA is a different skill set than reading a DXA. There will be no motivation for physicians to become trained in the use of this service if there will be no reimbursement for it.

The packaging of VFA with DXA will essentially eliminate payment for one of the two services that are key to the diagnosis of osteoporosis. This action will further erode an already underutilized service. One in five postmenopausal women will suffer from a vertebral fracture, and vertebral fractures continue to be under-recognized and under-diagnosed. Vertebral fractures are the most common type of fragility fracture in that population.

The 65% reimbursement cut to Axial DXA in the office setting has forced many providers to give up their DXA machines. From 2008 to 2012, there was a 12.9% decrease in DXA providers overall. This has created an access problem for patients and a sharp decline in the number of patients tested. In 2012, one quarter million (229,000) fewer Medicare beneficiaries received an Axial DXA test than in 2011 in any setting (office or hospital outpatient). The decline in the number of Axial DXA machines that are available has resulted in a decline in VFA testing as well. This is particularly disturbing given the low utilization.

Vertebral fractures are the most common fracture in older women with one in 5 postmenopausal women having a vertebral fracture in their lifetime. If properly prescribed, VFA should be performed in approximately 20% of patients who have a DXA. In 2013, CMS received claims for 2.3 million axial DXA scans, and only 164,718 VFAs, instead of the 460,000 VFAs that should have been performed. The number of VFA claims submitted to CMS has declined from 164,718 to 145,062 tests in just the two years (2011-2013). Direct Research LLC, provider IDs in 5% sample LDS
SAF claims.

We urge CMS to add VFA as an exempt service, in order that Axial and Appendicular DXA can truly obtain the benefit of a preventive service exemption.

Thank you for the opportunity to comment on this proposed rule. For further questions, please contact Donna Fiorentino at dfiorentino@iscd.org or at 860-402-2159.

Diane C. Krueger, BS, CBDT
President, ISCD

Dr. Andrew Laster, M.D., FACR, CCD
Chair, ISCD Public Policy Committee


3 Gawande A. Slide referencing 2010 data from Centers for Medicare & Medicaid Services, presented at Care Innovations Summit, January 26, 2012, Renaissance Hotel, Washington, DC.


5 www.cdc.gov/.../falls/adulthipfx.html

6 2013 ISCD Official Postions- Adult

7 ibid.

8 79 FR 40958 (July 14, 2014)


10 79 FR 40959 (July 14, 2014)

11 79 FR 40960 (July 14, 2014)

12 ibid.

13 79 FR 40958 (July 14, 2014)


15 ibid.

16 Direct Research, LLC, Provider IDs in 5% sample LDS SAF claims; analysis by Alison King