September 27, 2019

**BY ELECTRONIC DELIVERY**

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Ave, SW  
Washington, DC 20201

RE: Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies  
CMS-1715-P

Dear Administrator Verma:

The National Osteoporosis Foundation (NOF) is pleased to submit its comments to the above-referenced proposed rule revising and updating Part-B payment policies and refining the Quality Payment Program. Our comments focus on protecting Medicare beneficiary access to timely osteoporosis diagnosis and appropriate treatment options through payment policies that align with our shared goal of reducing the incidence of, and improving the care for, fragility fractures in the Medicare population.

The NOF is the nation’s leading resource for patients, health care professionals and organizations seeking up-to-date, medically sound information and program materials on the causes, prevention and treatment of osteoporosis. Established in 1984 as America’s only voluntary, nonprofit health organization dedicated to reducing the widespread prevalence of osteoporosis, the foundation has grown to include a network of diverse stakeholders that
support its goals to increase public awareness and knowledge, educate physicians and health care professionals, and support research activities concerning osteoporosis and related areas.

Our comments are briefly outlined below:

- Osteoporosis remains under-diagnosed and under-treated, with preventable fragility fractures exacting a high burden on patients and the Medicare program;
- Insufficient DXA reimbursement has impeded early diagnosis and treatment of osteoporosis;
- The NOF applauds CMS’ recognition that care management services are an important and under-utilized element of high-value health care;
- Quality measures should align with and improve adherence to clinical guidelines on detecting, diagnosing, and treating osteoporosis and fragility fractures;
- Despite CMS’ inclusion of bone-health quality measures in the QPP, there are gaps and inconsistencies between QPP measures and best practices in fragility fracture prevention;
- The QPP has an existing set of practice improvement that can be connected to bone health quality measures;
- CMS should consider developing a Fracture Liaison Service payment bundle; and
- The NOF generally supports CMS’ strategic vision to transform MIPS.

**Osteoporosis remains under-diagnosed and under-treated, with preventable fragility fractures exacting a high burden on patients and the Medicare program.**

Osteoporosis is a common bone disease that has long been recognized as a major public health problem.\(^1\) Approximately half of Caucasian women will experience an osteoporosis-related fracture as will approximately one in five men.\(^2\) For women, the prevalence of osteoporosis increases for each decade of life after age 50. In men, the prevalence remains fairly stable between the ages of 50 and 80, but increases substantially in men older than 80.

Individuals with osteoporosis have an increased risk of bone fracture due to low bone mass, deterioration of bone tissue, disruption of bone architecture, and compromised bone strength. Osteoporosis is an identifiable, treatable risk factor for fracture just as hypertension is for stroke. Osteoporotic fractures decrease quality of life and increase the likelihood of functional impairment, morbidity, and mortality. For the health system, the costs are significant; for patients, fragility fractures can have a catastrophic impact on the duration and quality of their lives. Typically, half of women with hip fracture do not recover full functionality post-fracture,

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\(^2\) Id.
and approximately 30% of older adults will die within the year following hip fracture. Although men have a lower incidence of hip fracture, they are at an increased risk of associated mortality.

Ideally, osteoporosis is diagnosed through bone mineral density (BMD) testing as part of routine preventive care. Therapeutic and lifestyle modification interventions, including prescription medications, can change disease trajectory. Despite availability of reliable screening and diagnostic tools, and effective treatment options, however, osteoporosis remains under-diagnosed and under-treated. This means that for many patients, the first sign of osteoporosis is a fragility fracture event. Even then, only 23% of women age 67 or older who have an osteoporosis-related fracture receive either a BMD test or a prescription for a drug to treat osteoporosis in the 6 months after a fragility fracture. Most patients remain undiagnosed and unaware of both their increased risk of a future fracture and the availability of FDA-approved therapies to reduce that risk.

Failures at both primary and secondary prevention of fragility fractures are costly to the Medicare program and its beneficiaries. In women over 55, fragility fractures are responsible for more hospitalizations and greater health care costs than heart attack, stroke, or breast cancer. In 2018, the annual direct medical costs associated with osteoporotic fracture were estimated to be $48.8 billion.³ If the annual number of fractures increases (as projected) from 1.9 million to 3.2 million, care costs for osteoporotic fractures will reach $97 billion by 2040.

**Insufficient DXA reimbursement has impeded early diagnosis and treatment of osteoporosis.**

Dual energy x-ray absorptiometry (DXA) is the recognized “gold standard” for use in osteoporosis screening, diagnosis and management. It is more powerful in predicting fractures than cholesterol is in predicting myocardial infarction or blood pressure in predicting stroke. Although DXA is associated with improved clinical outcomes, it has been consistently under-utilized. Medicare payment cuts initiated in 2007 appear to have further reduced appropriate utilization of DXA in both primary and secondary prevention of fragility fractures.

The NOF strongly believes that our health care system can do a better job of reducing costly osteoporotic fractures by appropriately reimbursing providers for diagnosing and managing low bone density, including osteoporosis. DXA testing increased steadily through 2007, leveled off in 2007-2009 when Medicare reimbursement was reduced, and then declined starting in 2010; the annual prevalence of hip fractures declined steadily for a decade before leveling off in 2013.

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Had the gains in osteoporosis screening and diagnosis and decline in hip fractures continued beyond 2013, over 14,000 additional hip fractures and 2,800 associated deaths may have been prevented, and over $560 million in health care costs might have been avoided.

Although DXA testing has been consistently under-utilized across risk groups, payment reductions intended to reduce costs associated with over-utilized imaging studies were applied to reduce DXA payment by 40 percent in 2007. The impact of the 2007 payment reduction was exacerbated by CMS changes in calculating practice expense when assigning Relative Value Units (RVUs) and reduction in physician work associated with DXA interpretation. Combined, these actions resulted in a decrease in DXA reimbursement to levels that are below the cost of providing the procedure at many facilities. Since 2006, Medicare reimbursement for DXA in the physician office setting has shrunk by 70 percent.

We urge CMS to re-examine its payment for DXA testing by reaching out to the Endocrine Society, American Association of Clinical Endocrinologists, ASBMR and American College of Rheumatology to ascertain the physician work and practice expense associated with these services. Setting Medicare payment at a level likely to encourage physician offices to incorporate DXA into their practices is a much-needed step toward reducing the trend in under-utilization of this test. Similarly, we urge the Agency to expand reimbursement for emerging technologies that offer clinicians and patients alternative means for assessing fracture risk and determining whether to follow-up with further testing or a prescription osteoporosis treatment.

The NOF applauds CMS’ recognition that care management services are an important and under-utilized element of high-value health care.

The NOF applauds CMS’ efforts to appropriately prioritize and incentivize the care management services that play a crucial role in encouraging appropriate post-fracture follow-up to address bone fragility and effective management of this chronic disease. We agree that clinicians should be encouraged to provide covered care management and treatment-planning services when they can be most useful, including following discharge from an acute care setting to a rehabilitation hospital or the patient’s home. We share CMS’ concern that chronic care management (CCM) services, including complex CCM services, continue to be underutilized and support CMS’ proposals to:
• Clarify that the Transitional Care Management (TCM) code can be reported with an evaluation and management (E&M) visit or with another Care Management Code if all reported services are medically necessary;
• Implement additional codes for complex and non-complex CCM services with 20-minute increments to ensure that payment is adequate to facilitate appropriate utilization;
• Increase reimbursement for TCM services; and
• Create two new codes for principal care management (PCM) services to appropriately reimburse clinicians treating patients for a single serious chronic condition requiring substantial care management.

While an osteoporotic fracture is an acute condition, the underlying osteoporosis is a chronic condition requiring lifelong management. We ask that CMS reinforce applicability of its TCM policy to post-fracture services addressing diagnosis and management of bone fragility, and explicitly confirm that osteoporosis is among the diagnoses eligible for chronic care management services.

Quality measures should align with and improve adherence to clinical guidelines on detecting, diagnosing, and treating osteoporosis and fragility fractures.

The Quality Payment Program. (QPP) has the potential to be a driving force to close the care gap between clinical guidelines and the real-world care patients receive. The threshold issue, however, is that quality measures must align with clinical guidelines and be sufficient to reflect the shared goal of reducing the incidence and consequence of osteoporotic fractures. The National Osteoporosis Foundation (NOF) 2014 Guide to Prevention and Treatment of Osteoporosis offers concise recommendations regarding prevention, risk assessment, diagnosis, and treatment of osteoporosis in postmenopausal women and men age 50 and older. The Guide includes indications for bone densitometry and fracture risk thresholds for intervention with pharmacologic agents. The absolute risk thresholds at which consideration of osteoporosis treatment is recommended were guided by a cost-effectiveness analysis. We attach the NOF Clinician’s Guide.

With respect to specific provisions of the Proposed Rule related to quality measures, the NOF has the following comments:

a. Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment: Percentage of patients regardless of age with an inflammatory bowel disease encounter who were prescribed
prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year.

We appreciate CMS’ rationale for removing this measure rather than adopting the measure steward’s revision. The NOF agrees that the measure would be more robust if it were revised to take into account risk factors identified by specialty societies and require the appropriate clinical action.

b. The NOF expressed its concern last year with CMS’ inclusion of an “Appropriate Use of DXA” measure. CMS adopted the measure for 2019 and is proposing to change the denominator exclusion for the Fracture Risk Assessment Tool FRAX® ten-year probability of all major osteoporosis related fracture from 9.3% to 8.4% to align with US Preventive Services Task Force (USPSTF) recommendations. While we generally support revisions to measures that align with evolving clinical guidelines, we remain concerned that adopting any measures to discourage DXA use are more likely to discourage appropriate use of this grossly under-utilized preventive care service than to address an over-utilization problem. This is particularly true when Medicare payment is insufficient to support utilization that reflects clinical guidelines.

As we noted in comment to the 2019 proposal to adopt this measure, a mere 23% of patients at greatest risk of osteoporosis-related fractures, i.e., women over age 67 with an osteoporotic fracture, are offered the diagnostic testing and/or treatment they need to reduce risk of another fracture. Moreover, the measure’s rubric for calculating risk factors that would justify DXA in women under age 65 is so complex that it would deter clinicians from even considering osteoporosis screening in this population regardless of patient-specific risk factors. The NOF urges CMS to identify or develop measures that incentivize clinicians for assessing fracture risk and utilizing evidence-based tools to detect and treat osteoporosis.

c. The NOF urges CMS to designate the quality measures identified below as high-priority measures, and consider their inclusion in mandatory-reporting and/or population-based measure sets in future years:

**Quality Measure -- Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.

**Quality Measure -- Falls: Risk Assessment:** Percentage of patients aged 65 years and
older with a history of falls that had a risk assessment for falls completed within 12 months.

**Quality Measure -- Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.

**Quality Measure -- Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient’s on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis testing or treatment.

**Quality Measure -- Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.

The NOF urges CMS to align this measure with clinical guidelines by emphasizing the need to appropriately treat osteoporosis. We believe that a test-or-treat option inappropriately rewards clinicians that diagnose osteoporosis and then fail to appropriately address it.

Qualifying reporting entities -- Beginning with the 2021 performance period and for future years, CMS proposes to require qualified registries to support all three performance categories: quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. CMS’ review of existing 2019 qualified registries revealed that approximately 70% of qualified registries are currently supporting all three performance categories. NOF urges CMS to ensure that all existing reporting entities have ample time to accommodate. CMS’ proposed change and that it consider a mechanism for exempting or “grandfathering” 2019 qualifying entities that submit a rationale for not supporting all three performance categories.

**Despite CMS’ inclusion of bone-health quality measures in the QPP, there are gaps and inconsistencies between QPP measures and best practices in fragility fracture prevention.**

The National Quality Forum (NQF) has led much of the development of quality measures across care settings and specialties and applies an episode of care model to osteoporosis measure development. The Joint Commission has also developed a set of quality measures, many of which were submitted to NQF for endorsement. These measures were intended to be voluntary and are not now part of any accreditation process or quality reporting program.
The NOF recognizes that measure development and testing are time-intensive endeavors. We believe, however, that CMS can make incremental improvements in the near-term that would facilitate identification of at-risk patients without unduly burdening clinicians. For example, Medicare’s initial visit and annual wellness visit, and the quality measures reflecting appropriate preventive care, currently fall short of capturing two very easily-identified risk factors for osteoporosis – height loss and BMI below 20 mg/kg. Although the “Welcome to Medicare” visit directs clinicians to measure and record patient height, subsequent wellness visits do not; there are no quality measures in adult populations to ensure that clinicians record height from year-to-year or note and follow-up on findings of height loss. Although BMI is incorporated into the annual wellness visit and its use is reinforced with quality measures (E measure ID: CMS69v6), a BMI between 18.5 and 20 is deemed “normal” despite its association with a heightened risk of osteoporosis.

Similarly, existing quality measures developed by the Joint Commission could enable Medicare to more accurately measure fracture-prevention and osteoporosis care quality. The table below briefly describes Joint Commission measures that have been tested and could be adopted, with or without refinements, within the QPP.

<table>
<thead>
<tr>
<th>Measure Title</th>
<th>Settings</th>
<th>Description</th>
<th>Entity/Steward</th>
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<tr>
<td>Secondary Causes -- Laboratory investigation for secondary causes of osteoporosis.</td>
<td>Hospital Inpatient Emergency Department Subacute Care Ambulatory Care Long Term Care Rehabilitation Facility and Inpatient Rehabilitation Facility</td>
<td>Patients w/new osteoporosis diagnosis who have had appropriate minimal laboratory investigation ordered or performed prior to discharge or within three months of initial osteoporosis diagnosis.</td>
<td>Joint Commission</td>
</tr>
<tr>
<td>Activity Counseling, Osteoporosis</td>
<td>Ambulatory Care Subacute Care Long Term Care Home Health Rehabilitation Facility and Inpatient Rehabilitation Facility</td>
<td>Patients with osteoporosis who have received documented activity education appropriate to their age and condition or a referral for activity counseling within the most recent 36 months.</td>
<td>Joint Commission</td>
</tr>
<tr>
<td>Dietary Education, Osteoporosis</td>
<td>Ambulatory Care Subacute Care Long Term Care Home Health Rehabilitation Facility and Inpatient Rehabilitation Facility</td>
<td>Patients w/osteoporosis diagnosis, or the caregivers of such patients, who have received education regarding calcium and Vitamin D intake within the most recent 12 months.</td>
<td>Joint Commission</td>
</tr>
<tr>
<td>Pharmacotherapy for Osteoporosis</td>
<td>Ambulatory Care Subacute Care Long Term Care Home Health Rehabilitation Facility and Inpatient Rehabilitation Facility</td>
<td>Patients over 50 w/osteoporosis who have had pharmacotherapy for osteoporosis prescribed within the most recent 12 months.</td>
<td>Joint Commission (same as measure by NCQA) (similar measure by Active Health Management)</td>
</tr>
<tr>
<td>Smoking/Alcohol Education</td>
<td>Hospital Inpatient Emergency Department</td>
<td>Patients w/osteoporosis of any age, and those over 50 w/a fracture who have</td>
<td>Joint Commission</td>
</tr>
</tbody>
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The QPP has an existing set of practice improvement activities that can be connected to bone health quality measures.

CMS proposes that beginning with the 2020 call for measures process, MIPS quality measure stewards must link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. The practice improvement component of the MIPS offers CMS the opportunity to identify and respond to emerging public health concerns, care deficiencies, and care delivery and coordination inefficiencies by encouraging clinicians to invest in practice improvements that further programmatic and/or public policy goals. The NOF urges CMS to ensure that the primary care practices and other clinicians who are in the best position to implement diagnostic and treatment interventions that might prevent a second osteoporotic fracture, or even identify and treat osteoporosis before an initial fracture event, have a robust set of incentives for doing so.

While we encourage the Agency to adopt a robust set of improvement activities incentivizing bone health, several of the practice improvement activities currently incorporated in the QPP could encourage improvements that reduce patient risk of a potentially catastrophic osteoporotic fracture:

- Care Transition Documentation Practice Improvements
- Chronic Care and Preventative Care Management for Empaneled Patients
- Implementation of Analytic Capabilities to Manage Total Cost of Care for Practice Population

These activities encourage clinicians to implement practices/processes that would be likely to improve care for patients at risk for a first or subsequent osteoporotic fracture, particularly when reported as part of a mandatory measure set promoting bone health.
Osteoporotic fracture patients are too-frequently discharged from the acute care setting without a clear action plan for addressing their underlying bone fragility. Similarly, individuals who have received an osteoporosis diagnosis often remain untreated or stop taking prescribed medication. The activities identified above would align with primary and secondary fracture prevention quality measures to improve care transitions from acute care and rehabilitation facilities following a fracture and increase the primary prevention strategies most likely to reduce costs and improve outcomes.

The NOF also believes that osteoporosis diagnosis, prevention, and management are high-value services that are analogous to the NCQA Diabetes Recognition Program (DRP) and the NCQA Heart/Stroke Recognition Program (HSRP) and meet the chronic care and preventive care management improvement activity objectives.

**CMS should consider developing a Fracture Liaison Service payment bundle.**

CMS seeks feedback on opportunities for bundled payments under the physician fee schedule. We encourage CMS to work with the NOF and other stakeholders to devise a payment bundle that aligns with the Fracture Liaison Service (FLS) model for post-acute fragility fracture care.

The FLS model is extremely well-suited to a bundled payment since it is an easily-identified episode that requires information sharing among providers directed toward both a population-health measure and patient-specific outcomes.

An FLS program is a coordinated care system headed by an FLS coordinator (a nurse practitioner, physician’s assistant, nurse, or other health professional) who utilizes established protocols to ensure that individuals who suffer a fracture receive appropriate diagnosis, treatment, and support. Many FLS programs incorporate a pharmacist in the care team to enable prompt resolution of patient concerns related to prescribed medications and improved medication adherence. Patient assessment and follow-up care are generally prompted through a database-driven patient-specific timeline.

FLS programs have been implemented successfully in a number of closed and open settings over the last 15 years, both in the US (including the American Orthopedic Association Own the Bone program) and internationally. These programs have accomplished a reduction in
secondary fracture rates as well as reduction in health care costs. Kaiser Permanente’s Healthy Bones program has reduced the expected hip fracture rate by 38% since 1998; Geisinger Health System achieved $7.8 million in cost savings over 5 years.

**The NOF generally supports CMS’ strategic vision to transform MIPS.**

The NOF appreciates CMS’ interest in refining the QPP to focus on patient-centered care, innovation, and outcomes. We agree that the flexibility in selecting measures has reduced the effectiveness of the MIPS pathway in improving value, reducing burden, helping patients compare clinician performance, and better informing patient choice in clinician selection. The proposed MIPS value pathways (MVP) would identify smaller sets of condition- or specialty-specific groups of cost, quality, and improvement measures so that resulting scores are more meaningful.

The NOF agrees that MVPs should:

- Be comprised of limited sets of measures and activities that are meaningful to clinicians, reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and improve patient’s ability to compare scores among providers;
- Include measures and activities that:
  - provide comparative performance data that is valuable to patients;
  - encourage performance improvements in high priority areas; and,
  - are, where feasible, part of alternative payment models (APMs).

We urge CMS to include bone fragility and fracture prevention in its set of high priority areas. In addition to addressing secondary prevention of osteoporotic fractures, we urge CMS to prioritize osteoporosis diagnosis and management within any preventive care MVP. Specifically, we ask that a Preventive Care MVP include measures reflecting appropriate use of screening DXA in male and female populations at risk for an osteoporotic fracture, and appropriate diagnosis and pharmaceutical management in individuals who have experienced one or more osteoporotic fractures.
Conclusion

The NOF appreciates the opportunity to provide feedback as CMS considers implementing the policy refinements outlined in the Proposed Rule. We remain eager to work with CMS as it continues to transform the Medicare program toward a value-based, patient-centered payment system.

If you have any questions or wish to discuss our concerns in greater detail, please contact me at 703-647-3020 or Susan L. Greenspan M.D. at (412) 692-2472.

Very truly yours,

Elizabeth Thompson
Chief Executive Officer
National Osteoporosis Foundation