May 4, 2020

The Honorable Seema Verma, M.P.H.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (PHE)
CMS-1744-IFC

Dear Administrator Verma:

The National Osteoporosis Foundation (NOF) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ (CMS’) Interim Final Rule entitled “Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” (the IFC). The NOF appreciates CMS’ broad approach to promote flexibilities that maximize health care provider resources and minimize the spread of the novel coronavirus, while providing necessary medical treatments for fragile patients such as those with osteoporosis.

The National Osteoporosis Foundation 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 in osteoporosis and bone health.

Our Policy Institute brings together the expertise, resources, and perspective of the full spectrum of bone health stakeholders to advocate for health policy initiatives that promote bone health and reduce both the personal and financial costs of fragility fractures. While the breadth of our mission extends beyond the bone health concerns associated with advancing age, we focus our comments toward protecting Medicare beneficiary access to osteoporosis treatment options in the care setting that most effectively addresses patient needs to minimize exposure to the novel coronavirus and permits compliance with social distancing guidelines.

NOF applauds the Administration’s focus on increasing the access points and modalities through which individuals can access needed health care, enabling patients to stay home when possible,
and minimizing the burden on providers. The flexibilities within the IFC are particularly important for individuals with chronic conditions such as osteoporosis, who would otherwise have to risk a potentially serious or fatal COVID-19 exposure to continue receiving their treatments. It is also critical to note the convergence of increased risks for both fracture and COVID-19 in our over-65 age population, who have an increased risk for fracture if anti-resorptive or anabolic therapy is discontinued because of fear of coming to a provider’s office.

Our comments provide a brief contextual background underscoring the importance of fragility fracture prevention during the COVID-19 pandemic and focus on areas within the IFC that osteoporosis patients and caregivers identify as highest priority during the PHE. At a minimum, it is essential that patients with diagnosed osteoporosis and a prescribed treatment continue their therapy, and that patients with new fragility fractures are evaluated and treated according to the standard of care. NOF’s comments focus on this goal:

- We support CMS’ initiative in modifying the definition of “homebound” for home health eligibility purposes to include clinician consideration of patient exposure to COVID-19 (or other pathogens), but continue to hear concerns from our patients about the increased financial hardship when receiving their treatments through Part D and the homebound certification pathway.

- NOF appreciates CMS’ increased flexibility to enable patients to receive their infused or injected treatments in their homes when safe and appropriate and urges CMS to ensure that patients receiving in-home injections and infusions do not face financial hardship accessing treatment.

- NOF appreciates CMS’ IFC provisions expanding use of telemedicine and the specific recognition in the agency’s second IFC for the need to increase the time and payment levels for the telephone visit codes.

- Through our stakeholder outreach and education activities, NOF has received questions and comments on the IFC implementation.

Background

As CMS is likely aware, osteoporosis is a common, chronic condition associated with significant preventable morbidity, mortality, and financial cost.

- Approximately 10 million Americans age 50 and older have osteoporosis and another 44 million have low bone density, placing them at increased risk for bone fracture.
- 80 percent of older Americans who suffer bone breaks are not tested or treated.
- According to an NOF-commissioned report analyzing 2015 Medicare fee-for-service data that was conducted by Milliman,1 over 40% of patients with any new osteoporotic fracture and 90% of hip fracture patients were hospitalized within a week.

1 https://www.bonehealthpolicyinstitute.org/full-milliman-report
• The Milliman study also found that 30 percent of hip fracture patients and nearly 20 percent of all fracture patients died within 12 months of the fracture.
• Only 9 percent of women covered by Medicare FFS who suffered an osteoporotic fracture received a DXA scan within six months following their fracture.
• An estimated 205,000 Medicare FFS beneficiaries, or about 15% of those who had a new osteoporotic fracture, suffered one or more subsequent fractures within 12 months of the initial fracture. (Milliman study, page 3)
• Within 12 months of a fracture event, 2% of beneficiaries became institutionalized (Milliman study, Figure 7, page 21)

The National Committee for Quality Assurance (NCQA) recently (February 2020) articulated the significant impact that fragility fractures have on patients and their ability to maintain health, function, and independence:

Osteoporotic fractures, particularly hip fractures, are associated with limited mobility, chronic pain and disability, loss of independence and decreased quality of life (Brauer 2009). . . . Most hip fractures require surgery, yet 50% of hip fracture patients are unable to walk without assistance after surgery. Of those who survive the fracture, 40% never return to pre-fracture functional status—often needing long-term nursing home care (USDHHS 2004).2

While there have been advancements in care, the persistent and profound morbidity and mortality of hip fractures has been confirmed by recent global registry reviews3 4 and through the NOF Milliman Study (2019) which showed Medicare beneficiaries with a hip fracture had the highest mortality of osteoporotic fractures, with 30% mortality rate within 12 months of the fracture.5

Although therapeutic and lifestyle modification interventions, including prescription medications, can disrupt disease trajectory and significantly reduce the risk of osteoporotic fracture, under-utilization of DXA as a primary prevention tool 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 bone mineral density (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.

NOF remains committed to reducing the care gap in osteoporosis and bone health. We have significant concerns that the PHE could widen that gap at a time when fragility fractures pose a heightened danger to patients. While there is never a good time for a patient to fracture their hip, 

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5 Milliman (2019), page 3
the PHE presents additional, potentially deadly risks for patients requiring acute care in the inpatient setting followed by a stay in a rehabilitation facility. We have no precedent to rely upon in projecting the impact of social distancing measures on frequency of falls among older individuals, but we can be proactive in mitigating the consequences of those falls by addressing bone fragility with appropriate osteoporosis treatment.

**NOF appreciates CMS’ increased flexibility to enable patients to receive their infused or injected treatments in their homes but continues to hear concerns from our patients about the increased financial hardship when receiving their treatments through Part D and the homebound certification pathway.**

NOF appreciates CMS’ insight and initiative in making in-home administration of Part B treatments available for Medicare beneficiaries. We believe that CMS’ unprecedented breadth and scope of policy refinements and flexibilities represents a critical step toward meeting the challenges of the COVID-19 PHE. We agree with CMS’ call for system-wide changes across stakeholders to address the PHE:

> We believe that this increased risk produces an immediate change, not only in the circumstances under which services can safely occur, but also results in an immediate change to the business relationships between providers, suppliers, and practitioners.

While NOF is hopeful that providers, suppliers, and practitioners will be able to meet CMS’ unprecedented set of Medicare program flexibilities with adaptations to their own practices and business arrangements, we know that patient access to care conforming to the social-distancing realities of this PHE could be variable. We appreciate that the Agency created two pathways through which Medicare beneficiaries can receive their medications at home to account for divergent provider practice patterns, health care personnel shortages, and any geographic-specific factors that could make it difficult for clinician practices to successfully arrange for home administration of Part B treatments.

Patients with osteoporosis, and their clinicians, have expressed concerns with the possibility that their Part B medications could be administered in a way that pushes coverage into Part D. The very high, immediate out-of-pocket cost burden associated with Part D coverage could drive patients to the conundrum CMS seeks to avoid, i.e., a choice between risking exposure to the virus in a clinic or infusion center setting (if such sites for administration are even open and available), or foregoing treatment. Many, if not most patients rely on purchase of a Medicare supplemental plan to ensure that the out-of-pocket costs associated with their Part B medications are covered. To the extent that business practices between suppliers and providers could push the costs of Part B drugs administered in the home to the Part D benefit, the patient would experience a substantial cost increase while the supplemental plan experiences a substantial cost reduction. NOF does not expect that this potential result was an intended element of the IFC.

**We urge CMS to reduce the potential for unexpected increases in out-of-pocket costs that could deter access and:**
Identify an add-on payment that would apply to lower-cost medications and ensure that the payment to providers is sufficient to enable contractual arrangements for in-home administration;

Consider feasibility of a mechanism that would continue cost-sharing support from supplemental plans for Part B drug copayments even if the drug administration does not fit precisely within the “incident to” requirements for Part B drug payment; or

Temporarily allow patients to seek copayment assistance directly from manufacturers until the catastrophic benefit is reached, without raising concerns about fraud and abuse violations.

The most feasible for turnkey implementation would be to have HHS waiver enforcement of the antikickback statute and let companies provide the same assistance they do on the commercial pharmacy benefit treatments. NOF further urges CMS to ensure that clinicians and providers fully understand the scope and breadth of the flexibilities contemplated in the IFC. CMS’ identification of home health agencies and home infusion suppliers as potential sources for provider home-infusion/injection arrangements could constrain practices from seeking arrangements with other entities such as visiting nurse associations, specialty pharmacies with infusion capabilities, or even with in-house nursing staff for patients in long-term care facilities experiencing lockdown due to the PHE.

**NOF appreciates CMS’ initiative in modifying the definition of “homebound” for home health eligibility purposes to include clinician consideration of patient exposure to COVID-19 (or other pathogens).**

NOF supports CMS’ clarification of the definition of “homebound” for home health eligibility purposes to include instances of confirmed or suspected COVID-19, and circumstances where leaving the home would be contraindicated due to patient risk factors and the potential for contracting COVID-19. We agree that the CDC recommendations and guidelines are appropriate for clinician use in determining whether a patient should be considered “confined to the home,” and urge CMS to enable streamlined provider certifications, and care planning requirements.

We note that the home health pathway was identified in the IFC as an additional channel through which Medicare beneficiaries can receive in-home administration of Part B medications ordinarily administered within a physician office or hospital outpatient setting. We urge CMS to identify and implement policy refinements and flexibilities that would enable beneficiaries to receive their medications through a home health provider without the additional out-of-pocket cost burden associated with specialty drugs under Part D. For example, the NOF understands that osteoporosis drugs can be administered by home health agencies, within the patient’s home, and remain a covered Part B benefit under the limited circumstances where the patient:

- Meets the criteria for the Medicare home health benefit;
- Has a bone fracture that a doctor certifies was related to post-menopausal osteoporosis;
- Is certified by their physician as unable to learn how to self-inject the medication; and
- Has no family member or caregiver willing and able to inject the medication.

Although the modifications to the “homebound” requirement for home health eligibility will broaden access to this important benefit, we are concerned that Medicare beneficiaries will find it difficult to receive their in-home administration of Part B drugs through the home health
channel. Specifically, the requirement that a clinician certify that their patient is unable to self-administer or learn how to self-inject creates an implied obligation that the provider actively promote self-injection of Part B drugs despite the fact that the FDA has not labeled these products for self-administration. The NOF urges CMS to clarify that for any osteoporosis drugs covered under Part B and not labeled for self-administration, the physician certification requirements for self-administration would not apply.

**NOF appreciates CMS’ IFC provisions expanding use of telemedicine and recognition of our providers’ concerns that the time and payment levels for the telephone visit codes were insufficient in capturing the level of care rendered remotely.**

For patients experiencing or recovering from a fragility fracture during the PHE, the need to meet in person with a clinician for a bone fragility evaluation would be a significant impediment to much-needed care. The NOF appreciates that CMS has:

- Increased the payment for remote patient encounters;
- Enabled clinicians to deliver evaluation and management services through telemedicine visits and receive payment as if the encounter were within the office setting;
- Permitted use of a cellphone with audio and visual capabilities to qualify as a telemedicine platform; Clarified that non-physician practitioners can perform patient care duties within the limits of their licenses, and utilize telemedicine when appropriate; and
- Provided assurances that clinicians utilizing telemedicine to deliver care, and acting in good faith, will not be subject to civil money penalties or other HIPAA enforcement actions.

NOF supports CMS in these initiatives and has heard from clinicians using telemedicine who have expressed that their patients are relieved that they are able to receive medical care without leaving their homes and risking COVID-19 exposure. We had also received several reports from clinicians treating Medicare beneficiaries that do not have cellphone audio and visual capabilities, but have care needs requiring significant time through audio-only telephone visits. These clinicians have found that the time and payment levels for the telephone visit codes are insufficient in capturing the level of care rendered remotely. NOF appreciated CMS recognition in last week’s new IFC of this issue in establishing mechanism that enables clinicians to bill for extended telephone consultations for patients without the means to fully utilize telemedicine services with both audio and visual capabilities.

**The National Osteoporosis Foundation has identified several questions with implementation of the IFC.**

As you may be aware, the National Osteoporosis Foundation has maintained a continuing dialogue with our stakeholder community both before and after CMS issued the IFC. Our patient and provider outreach efforts have included a Fact Sheet and Webinars, and we have sought and received comments and questions on both. The insufficient time and value levels for telephone consults was raised to us in this dialogue, as were the following:

1. How can patients gain access to in-home administration of Part B osteoporosis treatments?
NOF has encouraged patients to take an active, if not guiding, role in determining where to receive their infusions/injections for their bone health. We understand that many patients express concerns that receiving treatment within a provider setting is too risky, and others may be uncomfortable with a provider coming into their home after treating other patients. The perception and perceived acceptability of risks can also vary based on the prevalence of the novel coronavirus within the patient’s community. We have encouraged providers and patients to have an open dialogue about all of the available options for continuing their injected or infused osteoporosis treatments, including the risks and potential increase in costs associated with each option.

We ask that CMS strongly encourage providers to engage their patients in these discussions, stress the importance of continuing their prescribed treatments, and take a patient-centered approach when offering options to minimize the risk of COVID-19 exposure.

2. If a patient has their medication moved from Part B coverage to Part D coverage, will they have to pay the cost sharing obligation before getting their treatment?

NOF expects that CMS intends for patients to continue to receive their needed medications without increased out-of-pocket costs. We have expressed this belief to patients and providers within the osteoporosis community, and assured stakeholders that we would urge CMS to continue to craft flexibilities that focus on patients and their health care needs. We believe that CMS can, through a combination of temporary provisions for manufacturer copayment assistance, clarifications on home health coverage of osteoporosis drugs under Part B, and provider adaptations to business practices, ensure that Medicare beneficiaries can continue their medical care without increasing their risk of COVID-19 exposure.

3. How long will this exception for in-home infusions/injections be available?

We have heard from stakeholders outside the health care delivery system expressing the belief that the PHE is a short-lived inconvenience presenting a marginal risk to patients. Although there are ongoing discussions about “re-opening” the nation, the NOF does not anticipate that the danger of COVID-19 exposure will sufficiently resolve in the short-term to justify eliminating social-distancing recommendations for osteoporosis patients and other high-risk individuals. In fact, we expect that the need for a home infusion/injection option would ideally extend beyond the point at which the general public starts to move toward re-opening.

We urge CMS to reinforce to the provider community the need for vulnerable patients to maintain social distancing while continuing their treatments. We believe that providers will be more likely to adapt their business practices and arrangements, including offering telehealth services, if they are not expecting that the changes and IFC flexibilities will be reversed by CMS within the near-term.

**Conclusion**

Once again, NOF appreciates the significant leadership role CMS has taken in facilitating patient-centered care during this unprecedented COVID-19 PHE. We believe CMS’ IFC
represents a strong step toward addressing the challenges faced by patients, providers, payers, and policy makers. We welcome the opportunity to work with the Agency as it continues to craft policy refinements and implements flexibilities to Medicare and Medicaid requirements in response to the PHE.

If you have any questions or would like to discuss the issues raised in our comments, please contact me at 703.647.2025 or claire.gill@nof.org.

Sincerely,

Claire Gill
Interim CEO