

Submitted electronically

June 10, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

**RE: CMS–1808–P
Medicare and Medicaid Programs and the Children’s Health Insurance Program;
Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the
Long- Term Care Hospital Prospective Payment System and Policy Changes and Fiscal
Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes**

Dear Administrator Brooks-LaSure:

The Bone Health and Osteoporosis Foundation (BHOFF) appreciates the opportunity to submit comments on the above-referenced proposed rule updating and refining payment policies under the Hospital Prospective Payment System (IPPS proposed rule). We have, for the past several years, submitted comments to the Physician Fee Schedule proposed rules asking that the Centers for Medicare & Medicaid Services (CMS) recognize, prioritize, and address the significant care gap in secondary prevention of osteoporotic fractures by implementing mechanisms to facilitate a widely adopted care coordination model known as Fracture Liaison Services (FLS).

The BHOFF 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 bone health related areas.

Our comments to this IPPS proposed rule focus on CMS’ proposal to address high costs associated with hip and vertebral fractures through a Transforming Episode Accountability Model (TEAM) initiative. As further detailed below, BHOFF is disappointed that CMS intends to

focus on these presumptive osteoporotic fractures through the narrow lens of an acute episode rather than as sentinel events indicative of a treatable chronic condition (osteoporosis) that dramatically increases the risk of subsequent, preventable fractures. We fear that the model will work as intended – to shape the care this predominantly female population receives in the wake of an osteoporotic fracture – and that any episode-based savings within the TEAM initiative will be outpaced by the lost opportunity to avoid the cost of subsequent, preventable fractures suffered by beneficiaries.

Our comments provide:

- Background on the care gap in osteoporotic fracture prevention, its costs in terms of Medicare spending and beneficiary lives, and the significant savings that might accrue if Medicare implemented effective secondary fracture prevention strategies.
- A discussion of the historic failure to resolve the osteoporosis care gap through reliance on post-fracture referral to primary care practitioners and an overview of the FLS coordinated care model, its implementation in the U.S. and throughout the world, and the likely roadblocks to use of this proven model if TEAM is implemented as proposed.
- An outline of our interactions with CMS over the past several years, including the consensus-based proposal to improve health outcomes and reduce costs associated with osteoporotic fractures.
- Recommendations on refinements to the TEAM proposal that align its contours and goals with quality care for beneficiaries suffering an osteoporotic fracture of the hip or vertebrae, including:
 - Recognizing the deficit in osteoporotic fracture follow-up experienced by Medicare beneficiaries.
 - Designating an alternative pathway that facilitates evidence-based FLS secondary fracture prevention care.
 - Creating a separate “specialty code” for FLS practices so that CMS and its claims processing contractors recognize these services (and practitioners) as a preferred care pathway for post-fracture follow-up.
 - Ensuring that FLS practices are appropriately reimbursed for their services and that acute care practitioners and providers are incentivized, or at a minimum not disincentivized, for FLS referrals.

Given the significant deficiencies U.S. patients experience in both primary and secondary osteoporotic fracture prevention services, it is not surprising that hip fracture and vertebral fractures were identified as drivers of high costs to the Medicare program and selected for inclusion in the TEAM initiative. Unfortunately, CMS is focusing on the wrong “problem” and devising a solution that could all but halt the efforts BHOFF and other bone health stakeholders have prioritized to reduce **both** the costs and suffering associated with fractures through

effective delivery of secondary fracture prevention services.

I. BACKGROUND

Despite availability of screening, diagnostic, and treatment tools, most Medicare beneficiaries with osteoporosis fail to receive care that might prevent osteoporotic fractures.

The National Institutes of Health (NIH) defines osteoporosis as “a bone disease that develops when bone mineral density and bone mass decrease, or when the quality or structure of bone changes. This can lead to a decrease in bone strength that can increase the risk of fractures (broken bones)”¹ Osteoporosis is the major cause of fractures in postmenopausal women and in older men, with fractures most frequently occurring in bones of the hip, vertebrae in the spine, and the wrist. These fractures occur without high-impact or high-trauma events, and often result from a fall from standing height. An estimated 10 million Americans have osteoporosis; an additional 44 million Americans have low bone density that places them at increased risk of a fracture.²

Unlike many other debilitating conditions, outcomes in osteoporosis can be significantly improved without substantial investment in research, new breakthrough therapies, or new legislative and/or regulatory provisions. Therapeutic and lifestyle modification interventions, including prescription medications, can change disease trajectory and significantly reduce the risk of osteoporotic fracture. Unfortunately, under-utilization of DXA as a primary prevention tool means that for many patients, the first sign of osteoporosis is a fragility fracture. Even then, only 23% of women aged 67 or older who have an osteoporotic fracture receive medication to treat osteoporosis in the 6 months after the fracture.³ 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.

- Medicare beneficiaries suffered approximately 2.1 million osteoporotic fractures in 2016.⁴
- Analysis of 2016 claims data revealed that just 9% of female Medicare FFS beneficiaries were evaluated for osteoporosis with a bone mineral density (BMD) test within six months following a new osteoporotic fracture despite CMS’ reinforcement of this standard of care through quality measures.⁵

¹ [Osteoporosis Causes & Symptoms | NIAMS \(nih.gov\)](#)

² Wright N.C., et al. (2014). The Recent Prevalence of Osteoporosis and Low Bone Mass in the United States Based on Bone Mineral Density at the Femoral Neck or Lumbar Spine. *Journal of Bone and Mineral Research*, 29(11), 2520-2526. DOI: 10.1002/jbmr.2269.

³ Yusuf AA, et al., Utilization of osteoporosis medication after a fragility fracture among elderly Medicare beneficiaries. *Arch Osteoporos*. 2016; 11: 31.

⁴ [Medicare cost of osteoporotic fractures: 2021 updated report \(milliman.com\)](#)

⁵ Id.

The statistics confirming the care gap in both primary and secondary osteoporotic fracture prevention reflect real world experience for Medicare beneficiaries when CMS directs post-fracture follow-up through “referral to primary care.” It is the status quo that the TEAM initiative will likely cement despite its failure to curb the staggering cost of fragility fractures. Under this care delivery model, Medicare fee-for-service beneficiaries with an osteoporotic fracture disproportionately suffered poor health outcomes, including significantly increased mortality, subsequent fractures, hospitalization, and loss of the ability to live independently.

- The mortality rate for osteoporotic fracture patients is over three times that of the general Medicare FFS beneficiary population.
 - ***Those with a hip fracture have the highest mortality; 30% died within 12 months of the fracture.***⁶
 - Approximately 245,000 Medicare FFS beneficiaries (154,00 women and 91,000 men) or 19% of those with a new osteoporotic fracture died within 12 months.⁷
- 41,900 Medicare FFS beneficiaries with osteoporotic fractures became institutionalized in nursing homes within three years of a new fracture.
- Health system failures in delivering the standard of care in bone health disproportionately burden women. Female beneficiaries had 76% higher rates of new osteoporotic fracture than males, after adjusting for age and race.
- Osteoporotic fracture patients have three times the annual rate of new fractures within a year as compared to the overall Medicare FFS population.
- Over 4% (approximately 56,800 Medicare FFS beneficiaries) with an osteoporotic fracture became newly eligible for Medicaid within three years.⁸

These outcomes are neither anticipated by nor accounted for within the framework of TEAM and most will occur well after the 30-day TEAM episode has concluded.

The table below was presented to CMS staff and included in our comments to both the 2023 and 2024 PFS proposed rules. It delineates the real-world failures in secondary prevention of osteoporotic fractures. This care gap has persisted despite incremental efforts directing communication from the practitioner treating the fracture to the patient’s primary care practitioner. Unfortunately, primary care physicians, even when informed of a fracture, may not see the patient in the near-term or inquire beyond the patient’s recovery from the acute episode.

⁶ Id.

⁷ Id.

⁸ Id.

Heart attack and fractures are both acute, sentinel events within a chronic underlying condition and both have established care pathways to mitigate the risk of future events and poor health outcomes. Although nearly all of the predominantly male heart attack patient population receives the standard of care, the same cannot be said about the primarily female osteoporotic fracture patient population. Failures in delivering the right care at the right time means that these patients remain at high risk of a future fracture. The TEAM initiative is more likely to widen than address this care gap as it focuses on the acute episode and cost-reduction in a chronic condition that has long been and remains under-diagnosed and under-treated.

	Events/Year	1-year post-event risk	Diagnostics performed?	Treatment plan and follow-up
<p>Osteoporotic Fractures</p> <p>70.5% of patients are female</p>	<p>2.1 M osteoporotic fractures</p> <p>300K hip fractures (Milliman, 2021 update)</p>	<p>14 % of patients have a risk of a subsequent fracture within 1 year of hip fracture.</p> <p>19% die within 1 year after any osteoporotic fracture</p> <p>30% of hip fracture patients die within 1 year of their fracture</p>	<p>9% of patients receive a bone mineral density test w/in 6 months</p>	<p>Approximately 20% of hip fracture patients (two studies with slightly different numbers) receive medication.</p>
<p>Acute Myocardial Infarction (AMI)</p> <p>Approx. 70% of patients are male</p>	<p>805,000 AMIs (2020) (605K new; 200K recurrent) (AHA 2020)</p>	<p>9.2% of patients have a risk of subsequent AMI hospitalization within 1 year of their initial AMI</p> <p>5-10% AMI patients surviving acute episode die w/in first year</p>	<p>Monitoring and assessment are performed to devise treatment plan for all/nearly all patients.</p>	<p>96% of patients receive medication (beta blockers) post AMI.</p> <p>Quality measures and evaluation drive quality care for patients.</p>

Medicare expenditures associated with preventable osteoporotic fractures are significant and could be reduced with greater focus on identifying and managing underlying osteoporosis.

Medicare sustains significant costs for both initial and subsequent osteoporotic fractures. A report by the actuarial firm, Milliman, found that the per patient, per month (PPPM) medical costs were over \$2,000 per month between months 3 and 11 (\$2,097 per month), nearly 20% greater than the average monthly allowed cost in the year prior to the new osteoporotic fracture event (\$1,775 per month).⁹ Beneficiaries with a subsequent fracture within the three-year “episode” incurred annual costs over \$30,000 higher in the year following a new osteoporotic fracture compared to the year before the fracture.

- The total annual cost for osteoporotic fractures among Medicare beneficiaries was \$57 billion in 2018.¹⁰
- Absent health system changes to detect, diagnose and treat the chronic, progressive disease of osteoporosis, annual costs of fragility fractures are expected to grow to over \$95 billion in 2040).¹¹
- Annual allowed medical costs to Medicare for beneficiaries in the 12-month period beginning with the new osteoporotic fracture were more than twice their costs in the year prior to their fracture, with incremental annual allowed medical costs for those with an osteoporotic fracture of \$21,564 per beneficiary covered by both Medicare Parts A and B in 2016.¹²
- The incremental annual medical costs in the year following a new osteoporotic fracture increased 263% for skilled nursing facility (SNF) services compared to the year prior to the fracture, accounting for nearly 30% of the total incremental annual medical cost.
- Beneficiaries suffering a subsequent fracture within three years of an initial fracture accounted for an estimated \$5.7 billion in Medicare FFS direct costs.
 - o Actual total costs are significantly higher as these estimates do not include costs related to the loss of productivity, absenteeism, non-skilled home and nursing home care, or prescription drugs¹³.

The Milliman report used its estimates on the costs of secondary fractures and assumptions informed by the literature on secondary fracture prevention to model the potential savings to Medicare from preventing a portion of subsequent fractures in the Medicare FFS population. Table 15 in the Milliman report provides a summary of the estimated national savings under

⁹ [Medicare cost of osteoporotic fractures: 2021 updated report \(milliman.com\)](#)

¹⁰ Lewiecki EM, et al. Hip fracture trends in the United States, 2002 to 2015. *Osteoporos Int.* 2018; 29: 717-722

¹¹ Id.

¹² Milliman, supra.

¹³ Id.

three scenarios that use different percentages for the subsequent fractures that would be prevented and different percentages for additional BMD testing.

- Preventing between 5% and 20% of subsequent fractures among FFS beneficiaries with both Part A and Part B coupled with performing BMD tests on an additional 10% to 50% of patients with new osteoporotic fractures, could have saved between \$250 million (95% CI: \$243 million to \$258 million) and \$990 million (95% CI: \$962 million to \$1,021 million) during a new osteoporotic fracture follow-up period of up to three years.
- Extrapolating the estimated cost of Part A services associated with a subsequent fracture to beneficiaries covered only by Part A could have added between \$23 million and \$89 million in savings when preventing between 5% and 20% of subsequent fractures among beneficiaries covered only by Part A.
- Total Medicare savings under these scenarios is between \$272 million and \$1.1 billion for the Medicare FFS program.

Substantial inequities and disparities exist in fracture incidence, care, and deaths.

Although Black men and women are generally less likely to suffer from osteoporosis and sustain a fragility fracture, they are more likely to die from an osteoporotic fracture than their White counterparts. The Milliman report found that “fracture rates varied substantially by race/ethnicity,” with North American Natives suffering fractures at a rate 20% higher than the national average. White beneficiaries had a fracture rate 6% higher than the national average. Black beneficiaries (50% lower), Asian beneficiaries (32% lower) and Hispanic beneficiaries (19% lower) had the lowest rates of new osteoporotic fractures.

Rates of subsequent fractures within 12 months following an initial osteoporotic fracture ranged from 11% of Black beneficiaries to 15% for White beneficiaries. Hispanic, Asian, and North American Native beneficiaries all suffered subsequent fractures within 12 months at the national average rate of 14%.

While suffering fewer initial fractures and subsequent fractures, Black Medicare FFS beneficiaries have higher hospitalization rates, higher death rates following fractures, and lower bone mineral density (BMD) screening rates. Black patients suffering an osteoporotic fracture in 2016 had worse outcomes, including higher mortality, and were less likely to receive any follow-up care to address their underlying bone fragility. Once again, this data reflects the real-world care Medicare beneficiaries receive when the CMS-directed post-fracture follow-up is a primary care referral.

- 45% were hospitalized within 7 days of the fracture, compared to a national average of 42%.

- 22% died within 12 months of an initial osteoporotic fracture, exceeding the national average rate of 19% and comparable rates for White (19%), Asian (16%), Hispanic (18%) and North American Native beneficiaries (18%).
- ***Just 5% were tested within six months of a new osteoporotic fracture – when the need for treatment and action is highest – versus 8% among all beneficiaries with a fracture.***

The Milliman report noted that other studies have reported racial disparities in fracture incidence and post-fracture outcomes and have echoed the findings of higher rates of mortality and debility following a fracture among Black individuals versus the population as a whole. The report also found divergence across subpopulations with respect to the types of osteoporotic fractures likely to present as a sentinel event of osteoporosis. Secondary prevention strategies that fail to cast a wide net with respect to identifying osteoporotic fractures will likely perpetuate, and may even widen, racial disparities in access to care and outcomes related to bone fragility.

“Fracture Liaison Services” (FLS) are an effective, evidence-based intervention for preventing secondary osteoporotic fractures. The TEAM initiative will threaten existing FLS programs and deter initiation of new ones.

It has become clear that encouraging communication from acute to primary care has not closed the care gap in secondary prevention of fragility fractures. Efforts to date have relied on primary care yet failed to ensure that bone fragility follow-up is performed and/or that osteoporosis treatment is prescribed. The TEAM initiative would penalize facilities for the added cost of performing even a cursory inquiry into osteoporosis or other underlying causes of bone fragility, despite acknowledgment among bone health experts that a hip fracture in an individual over age 50 is clearly indicative of osteoporosis warranting timely, aggressive treatment and ongoing disease management.

It is worth noting that the osteoporosis care gap is not unique to the US; the United Kingdom (UK) and European Union (EU) have become increasingly concerned about the rising incidence of osteoporotic fractures. This concern, however, has been accompanied by a recognition that focusing solely on the acute, sentinel event of a fracture and/or relying on primary care practitioners to assess and respond to fracture risk is not the solution. Systemic changes must be implemented to reduce the potential that preventable fractures associated with aging populations could exceed health care resources. A recent report from the International Osteoporosis Foundation entitled [‘Osteoporosis in Europe: A Compendium of Country-Specific Reports’](#) reveals that in several European countries the high burden of osteoporosis combined with suboptimal osteoporosis care, service provision, and treatment uptake mirrors that of the US health care system. A June 2022 review article outlines osteoporosis care gaps and FLS

program adoption efforts throughout Europe.¹⁴ It notes the utility of FLS in addressing the UK osteoporosis crisis:

There is growing awareness that the FLS model is becoming a “standard of care.” . . . An FLS should deliver a seamless journey for the patient from diagnosis of a fragility fracture onward. Delivering the right care close to patients’ residences has been on the NHS agenda for years and there is an established framework of support to ensure local delivery meets expected benefits for patients. With Integrated Care Systems becoming active in UK planning of health and social care, FLSs are optimally placed to identify those patients who have complex needs. There are clear whole system benefits available from identifying this cohort of patients as they have an associated high health resource requirement.¹⁵

Similarly, a recent **Lancet *Diabetes & Endocrinology*** article discussed the osteoporosis care gap in the U.S., noting:

The persistent divergence between real-world treatment experience and the standard of care following an osteoporotic fracture underscores the complex fragmentation of services for patients as they move from acute episode to rehabilitative care and community-based primary care. Fracture Liaison Services (FLS), which facilitate diagnosis, treatment planning, and long-term care management of patients with a fracture, are recognized internationally as the gold standard for secondary prevention of osteoporotic fractures.¹⁶

The first Fracture Liaison Service was established in the early 2000s, and FLS utility in reducing future fractures has been confirmed through multiple studies. A 2018 meta-analysis of FLS impact identified a total of 159 publications, including 74 controlled studies (16 RCTs; 58 observational studies). Compared with patients receiving usual care (or those in the control arm), patients receiving care from an FLS program had:

- Less than half the rates of subsequent fracture (13.4% among patients in the control arm and 6.4% in the FLS arm)
- Lower mortality (15.8% in the control arm and 10.4% in the FLS arm).
- Higher rates of BMD testing (48.0% vs 23.5%)
- Higher rates of treatment initiation (38.0% vs 17.2%)
- Greater adherence (57.0% vs 34.1%).

¹⁴ Chesser T, et al., Overview of fracture liaison services in the UK and Europe: standards, model of care, funding, and challenges. OTA International: June 2022 - Volume 5 - Issue 3S - p e198 doi: 10.1097/OI9.000000000000198

¹⁵ Id.

¹⁶ . [Osteoporosis in the USA: prevention and unmet needs - The Lancet Diabetes & Endocrinology](#)

This coordinated care intervention is usually headed by an FLS coordinator (a physician, nurse practitioner, physician assistant) who utilizes established protocols to ensure that individuals who suffer a fragility fracture are identified and receive appropriate diagnosis, evaluation, secondary prevention, treatment planning, follow-up, and support. The patient journey starts with identifying suspected fragility fracture patients for post-acute follow-up, moves through collection of medical history, evaluation and management services, diagnostic testing, and, for patients at high risk of fracture, results in treatment planning and necessary follow-up to ensure that patients remain adherent to medications or are offered alternative therapeutic options if needed. FLS programs also reach out to other practitioners responsible for the patient's care, and ascertain patient needs, including physical therapy, fall risk assessment and prevention, and caregiver support needs with a goal of addressing fracture risk factors. Patient assessment and follow-up care are generally prompted through a database-driven, patient-specific timeline.

Unfortunately, existing Medicare payment mechanisms and policies impede adoption of FLS. The TEAM initiative will not only disrupt the referral pathway upon which FLS programs rely, but act as an implicit, if not explicit, CMS endorsement of post-fracture care that ignores the underlying cause of the fracture and diverts referrals away from bone health professionals and FLS programs.

BHOF recently surveyed existing and potential FLS practices on the logistic hurdles they face in implementation. Virtually all of these impediments will be exacerbated with TEAM implementation as proposed:

- Acute hip fractures are reimbursed through bundled payments with 90-day global periods and do not account for secondary fracture prevention follow-up.
- Existing structures for treatment and follow-up in acute care settings approach fractures as any other acute episode rather than as a sentinel event indicative of underlying bone fragility.
- Multiple care settings complicate tracking and referral of patients with known or suspected osteoporotic fractures.
- Comprehensive care models and advanced payment models focus on acute episodes, do not account for osteoporosis as a chronic disease, and assess "cost" and "value" within timeframes too narrow to capture FLS cost-effectiveness.
- The limited sets of quality reporting mechanisms do not sufficiently incentivize the standard of care in preventing a subsequent fracture, and there is significant uncertainty as to which practitioner is ultimately responsible for delivering that care.
- Many patients are lost to follow-up due to care received within a rehabilitation hospital or other facility in the immediate post-acute period.

- Provider-assumed risk and quality reporting periods do not fully encompass the time period for heightened risk for a repeat fracture.

Despite these impediments, leading U.S. health systems, including Geisinger and Kaiser Permanente, have successfully implemented the FLS framework to reduce repeat fractures and lower costs.

- The Healthy Bones Program run by the Kaiser Southern California health-maintenance organization led to a decrease of 37.2% in hip fractures with savings of \$30.8 million.
- Geisinger Health System achieved \$7.8 million in cost savings over 5 years with its FLS implementation.

The American Orthopaedic Association has offered an initiative known as Own the Bone® since 2008 to address the emerging epidemic of osteoporosis-related fragility fractures. Own the Bone enables hospitals and practices to help evaluate and treat these patients using a Fracture Liaison Service (FLS). AOA provides a toolkit, including a ten-step program and registry to document the bone health management of osteoporotic fracture patients.

- Over 270 hospitals and practices have participated in this program.
- Patients enrolled in the program by participating centers are twice as likely to receive bone health interventions post fracture; over 53% had a BMD test ordered or were prescribed pharmacologic therapy for osteoporosis.
- Recommendations for osteoporosis management (BMD testing and/or pharmacologic treatment), care coordination, and other secondary fracture prevention measures were addressed for these patients with 74-98% compliance.
- ***The TEAM initiative's referral pathway will deter access to FLS for patients at highest risk of a future fracture, i.e., hip and vertebral fracture patients. Rather than receiving coordinated post-fracture follow-up from an Own the Bone® practitioner, beneficiaries within the model would have their episode of care closed by the hospital after 30 days and referral to a primary care practitioner.***

The American Geriatrics Society's (AGS') CoCare®: Ortho is another example of a specialty society initiated, multi-disciplinary program to address post-fracture follow-up. This Geriatrics-Orthopedics Co-Management model integrates geriatrics professionals or specially trained geriatrics co-managers (e.g., hospitalists) into the care team with orthopedic surgeons to coordinate and improve the perioperative care of older adults with hip fractures.

- Because a geriatrics co-manager is involved in the older person's care immediately upon or soon after hospital admission, risk factors for harmful events such as delirium, falls,

adverse drug events, or infections are identified and proactively addressed to prevent and optimally manage risks throughout the older adult's hospital stay.

- The AGS CoCare[®]: Ortho model of Geriatrics-Orthopedics Co-Management has been shown to reduce complications and enhance function after the older adult returns home, two goals at the heart of quality geriatrics care.
- This model also proactively facilitates referral for diagnosis, treatment, and management of osteoporosis to reduce future fracture risk.
- ***Although geriatricians are primary care practitioners, the CoCare[®] model delivers enhanced services directed beyond the acute fracture episode. The costs of these services are not accurately reflected in aggregate data CMS will use to benchmark costs for an episode of care. We expect that the TEAM initiative will drive unintentional disincentives that deter practitioners and facilities from using CoCare[®]-Ortho.***

BHOF provides an FLS Training Program. This On-Demand program includes 23 individual sessions (synchronized slide/audio presentations) from the 2022 Interdisciplinary Symposium on Osteoporosis (ISO2022), held virtually in May 2022. Participants must complete each session, including post-test and session evaluation, to receive BHOF's FLS Certificate of Completion. The program emphasizes the importance of appropriate patient assessment, treatment initiation, medical follow-up, and care coordination for the post-fracture patient. In addition, the BHOF Guide to Prevention and Treatment of Osteoporosis offers concise recommendations regarding prevention, risk assessment, diagnosis, and treatment of osteoporosis in postmenopausal women and men aged 50 and older. The Guide includes indications for bone densitometry and fracture risk thresholds for intervention with pharmacologic agents.

Throughout the past several years, BHOF and its advocacy partners have urged CMS to adopt a consensus-based proposal to improve health outcomes and reduce costs associated with osteoporotic fractures.

The BHOF, together with a diverse set of bone health stakeholders, has focused considerable effort on informing CMS of the continuing disparity between the evidence-based care Medicare beneficiaries **should** receive following a fracture and the lack of osteoporosis-related services they **actually** receive. We have met with CMS staff numerous times and presented the stark statistics on the costs preventable osteoporotic fractures exact on the Medicare program, its beneficiaries, and their families. In collaboration with our advocacy partners, we identified (and presented to CMS) a proven collaborative care coordination intervention, known as Fracture Liaison Services (FLS) that is recognized internationally as the "gold standard" for secondary

prevention of osteoporotic fractures.

We have urged CMS to recognize the FLS coordinated care intervention by identifying appropriate coding and payment mechanisms so that FLS programs could identify individuals who have suffered an initial osteoporotic fracture and provide the set of medically necessary services to give them the best chance possible of avoiding a subsequent and potentially catastrophic osteoporotic fracture. Finally, together with the American Society for Bone and Mineral Research (ASBMR), we prepared a document (Attachment 1) outlining a pragmatic Medicare coding approach to enable FLS care. The organizations listed below expressed their support for incorporating FLS care into the Medicare program as well as for the coding proposal. These stakeholders joined us in urging CMS to implement a set of payment codes to adequately capture the time and resources required to deliver evidence based FLS care:

- American Academy of Nurse Practitioners (AANP)
- American Association of Hip and Knee Surgeons (AAHKS)
- American Association of Orthopaedic Surgeons (AAOS)
- American Academy of Physician Assistants (AAPA)
- American Bone Health (ABH)
- American Geriatric Society (AGS)
- American Orthopaedic Association (AOA)
- American Society for Bone and Mineral Research (ASBMR)
- American Society of Endocrine Physician Assistants (ASEPA)
- Bone Health and Osteoporosis Foundation (BHOFF) (previously known as the National Osteoporosis Foundation (NOF))
- Fragility Fractures Alliance (FFxA) – American Academy of Orthopaedic Surgeons (AAOS), American Orthopaedic Association (AOA) & AOA Own the Bone, Orthopaedic Trauma Association (OTA), National Association of Orthopaedic Nurses (NAON), American Geriatrics Society (AGS), International Geriatric Fracture Society (IGFS), American Board of Orthopaedic Surgeons, U.S. Bone and Joint Initiative (USBJI)
- International Society for Clinical Densitometry (ISCD)
- National Spine Health Institute (NSHI)
- North American Spine Society (NASS)
- Orthopaedic Trauma Association (OTA)
- The Endocrine Society (TES)
- US Bone and Joint Initiative (USBJI)

Throughout 2021, BHOFF and ASBMR facilitated meetings between CMS and their policy experts, together with Dr. Andrea Singer (Chief Medical Officer for BHOFF) and Dr. Paul Anderson (former chair of the “Own the Bone” Steering Committee of the American Orthopaedic Association). When the 2022 PFS proposed rule failed to include any discussion on the care gaps in post-fracture osteoporosis follow-up, the BHOFF and ASBMR, with sign-on from 28 bone health, women’s health, and health equity stakeholders, submitted comments reiterating the impact that preventable fractures have on Medicare and its beneficiaries. We further noted that

“[e]ffective FLS care could be facilitated through CMS adoption of a code set with payment tailored to the resources required to effectively identify or refer post-acute fracture patients and ensure treatment planning and follow-up consistent with the standard of care for addressing osteoporosis and reducing the risk of a future fracture.” Neither our engagement throughout the year nor our comments to the proposed rule were acknowledged or discussed within CMS’ discussion of comments and Agency determinations in the final PFS rule for 2023.

Discussions with CMS and HHS staff and leadership continued throughout the remainder of 2022 and early 2023. These discussions reiterated and reinforced our messages from 2021, focusing on the alignment between our FLS coding and payment proposal and the Administration’s interest in reducing health disparities, particularly within the context of under-utilized services. Our clinical and scientific experts, as well as our health policy and coding/payment consultants, answered questions related to the lack of sufficient coding mechanisms, the uniquely “concentrated” nature of FLS care making chronic care management payment mechanisms insufficient or inappropriate, and CMS leadership interest in the utility of FLS to address high-priority Agency and Administration concerns such as fall prevention, reduction in nursing home admissions, and curbing high-dose and/or long-term opioid use related to fractures.

Although CMS’ 2024 Proposed Rule reinforced the utility of Medicare-specific code sets (G codes) to address coding and payment gaps that compromise care for Medicare beneficiaries, there was, again, no indication that the Agency intended to address gaps related to the uniquely-Medicare problem of preventable osteoporotic fractures. Similarly, CMS has not asserted the existence of, much less identified, a set of existing codes that could be used by FLS programs seeking Medicare reimbursement.

Throughout our discussions with CMS, we have emphasized that the primary care referral pathway reinforced in CMS’ sets of quality measures has proven to be ineffective. FLS programs have one overarching purpose - to ensure that patients at high risk of a future fracture (hip fracture patients are at highest risk) are identified and can receive the standard of care to address their long- and short-term future fracture risk. Unless CMS refines the TEAM initiative, the Medicare program will be taking the unique position of proactively discouraging and impeding access to the practitioners best positioned to deliver secondary fracture prevention services.

CMS should refine the TEAM initiative to facilitate, rather than impede, access to evidence based FLS secondary fracture prevention services.

The BHOF urges CMS to implement a set of pragmatic refinements to the TEAM initiative as applied to episodes involving hip fractures and spinal fusion procedures in patients with known or suspected osteoporosis. These refinements include:

- Enabling referral to an FLS practice as an alternative to primary care. FLS programs coordinate with primary care practitioners as well as other specialties in delivering secondary fracture prevention care.
- Exempt episodes for which an FLS referral is made and FLS services are initiated from the model.
 - Since benchmark costs will reflect the existing deficiencies in secondary fracture prevention, including cases with referral to FLS would ultimately deter access.
 - In addition, FLS care goals focus beyond the acute episode and “quality” cannot be determined within a 30-day episode.
 - We believe this approach is more workable than benchmarking FLS costs and assigning differential episode payment amounts, and more likely to benefit CMS than simply excluding all hip fractures, and spinal fusions in individuals with known or suspected osteoporosis from the model.
- Assigning a specialty code to identify FLS practices. This would be a secondary specialty since FLS programs are operated within orthopedic, endocrinology, rheumatology, women’s health, primary care, and other practice types. The specialty code would be reported by FLS practices, including those that:
 - Participate in AOS’ Own the Bone initiative, OR
 - Deliver FLS care through participation in AGS CoCare-Ortho, OR
 - Have received a certificate of completion for training administered through BHOFF or the International Osteoporosis Foundation and deliver FLS care.
- Work with BHOFF and the CMS Physician Fee Schedule team to identify or create a reimbursement mechanism that captures the services delivered within evidence based FLS programs. BHOFF and its advocacy partners have interviewed FLS programs, ascertained the set of services provided by these programs, and developed crosswalk scenarios reflecting the time and resources required in a typical FLS care episode.

Finally, the bone health community needs a clear statement from CMS acknowledging existing deficiencies in secondary fracture prevention as well as the perceived coding and payment gap associated with FLS care. Practitioners and facilities contemplating continuing or starting an FLS program need either (a) a set of actionable instructions on the codes CMS will accept within the context of FLS care, e.g., permitting use of existing codes to receive reimbursement for FLS visits and non-face-to-face services performed on a day other than the date of the office visit, enabling use of principal care management or transition care management codes, including add-on codes, etc., or (b) interim guidance for claim submission throughout 2024 and 2025, with an intent to implement sufficient coding mechanisms in a future rulemaking cycle.

Conclusion

BHOF appreciates the opportunity to submit its comments to the 2025 IPPS Proposed Rule. While we are disappointed that our advocacy efforts to date failed to gain CMS' attention and action, we remain hopeful that the TEAM initiative will be implemented to facilitate rather than impede quality care for beneficiaries suffering an osteoporotic fracture.

If you have any questions, please contact me at 703.647.2025 or cgill@bonehealthandosteoporosis.org if you or your staff have questions or would like to discuss these issues in greater detail.

A handwritten signature in black ink that reads "Claire Gill". The signature is written in a cursive style and is centered within a light gray rectangular box.

Claire Gill, CEO
Bone Health and Osteoporosis Foundation