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December 31, 2018

The Honorable Seema Verma Administrator
Centers for Medicare & Medicaid Services Attn: CMS-1701-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD. 21244-8013

RE: Advance Notice of Proposed Rulemaking: International Price Index Model for Medicare Part B Drugs
CMS-5528-ANPRM

Dear Administrator Verma:

The National Osteoporosis Foundation (NOF) is pleased to submit its comments to the above-referenced International Price Index Model (IPI Model) notice. NOF understands that the IPI Model would leverage both the waiver authority of the Center for Medicare and Medicaid Innovation (CMMI) and the statutory provisions authorizing a Part B drug Competitive Acquisition Program (CAP) to test changes in both how clinicians obtain Part B drugs and the Medicare reimbursement basis for those treatments. We have significant concerns that this proposal could have the unintended consequence of exacerbating real-world deficiencies in osteoporosis care for Medicare beneficiaries and, ultimately, increase rather than decrease the already-high cost and morbidity of fragility fractures.

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 bone health related areas.

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 and aligning CMS payment policies with our shared goal of reducing the incidence of and improving the care for fragility fractures in the Medicare population.

The NOF supports CMS in its efforts to curb the rising cost of prescription drugs and reduce patient out-of-pocket expenses for medically necessary treatments. The Centers for Medicare &

Medicaid Services' (CMS') goals of improving competition, promoting better negotiation, lowering list prices, and reducing out-of-pocket costs are well-aligned with NOF Policy Institute priorities. Our comments on the proposed IPI Model reflect our concern that any savings it achieves may be counterbalanced by negative impacts on patient safety, access to care, and patient choice.

Among NOF's core missions is to stimulate education and research toward advancing appropriate use of existing therapies and development of new treatment options. Existing and future treatment options in disease states that, like osteoporosis, disproportionately affect Medicare's elderly population will be disproportionately and, potentially adversely impacted by the IPI Model. Specifically, we are concerned that:

- Osteoporosis is an emerging health policy crisis – it is both underdiagnosed and undertreated. Because there is no over-utilization of osteoporosis drugs to curb, the IPI Model could deter **appropriate** use of osteoporosis treatments within the Part B benefit and significantly undermine NOF education and outreach efforts to close the care gap and reduce undertreatment;
- Because the IPI Model injects multiple untested variables, it does not have the scientific soundness required for reliable and meaningful evaluation;
- CMS has not fully explored the impact the IPI Model might have on patient access and outcomes;
- Failure of the original Part B Drug CAP justifies a cautious approach to implementing a similar initiative; and
- The expanded set of potential CAP vendors gives rise to beneficiary concerns that the model would implement utilization management structures to further curtail access to treatment options thereby further reducing treatment and expanding the care gap.

The IPI Model could deter appropriate use of osteoporosis treatments under the Part B benefit and significantly undermine NOF education and outreach efforts to close the osteoporosis care gap.

In 2014, NOF released an update to its prevalence data, revealing that an estimated 10.2 million adults in the U.S. have osteoporosis and another 43.4 million have low bone mass. This means 54 million U.S. adults, representing 50 percent of the U.S. adult population over age 50, are at risk of a fragility fracture.[1] Our healthcare system is armed with both the tools to detect and diagnosis low bone mass and osteoporosis, and an understanding of the risk factors signaling the need for testing and treatment. Individuals in whom osteoporosis is detected have a variety of therapeutic options to effectively address their condition and reduce their risk of a fragility fracture.

Despite our ability to identify and manage osteoporosis, Medicare patients continue to suffer fragility fractures at an alarming rate, with an annual cost of over $20 billion. NOF finds it particularly jarring that a significant majority of US hip fracture patients are released from the inpatient setting without any evaluation for osteoporosis; most do not receive evaluation or treatment within the 12 months following the fracture.[2] While over 80% of patients with an

[1] Office of the Surgeon General (US) (2004) Bone health and osteoporosis: a report of the Surgeon General. Office of the Surgeon General (US), Rockville (MD). Available from: http://www.ncbi.nlm.nih.gov/books/NBK45513/.
[2] Id.

acute myocardial infarction receive a diagnosis, evalution and therapy, less than 20 percent of those with an acute hip fracture are diagnosed or treated for their underlying condition. These patients are at a high risk of future fractures due to failure to treat and manage progression of this chronic condition.

Individuals experiencing a fragility fracture have a marked decrease in quality of life and an increased 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. For otherwise-healthy patients, an osteoporotic hip fracture can change the trajectory of where and how they age. Typically, half of women with hip fracture do not recover full functionality post-fracture, and approximately 1 in 5 older adults will die within the year following a hip fracture. Although men have a lower incidence of hip fracture, they are at an increased risk of associated mortality.

Unfortunately, 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. Hip fractures disproportionately occur among women age 80 and older, yet this group is the least likely to receive recommended care and remain at an unnecessarily high risk for subsequent fracture. While we expect the quality of our healthcare to improve with introduction of new diagnostic and treatment options, the care gap in osteoporosis has actually worsened over time.

Any opportunity to transform our approach to fragility fractures in the US cannot be realized without the full partnership of CMS and the Medicare program. CMS has invested considerable time and resources into reducing preventable illnesses and injuries, and aligning incentives toward high-quality, cost-effective care. We share CMS' belief that incentive alignment is key to shaping clinician behaviors toward increased quality and reduced avoidable care costs and have previously urged the Agency to prioritize bone health within the Quality Payment Program (QPP) to advance the change urgently needed if we are to mitigate the $25.3 billion projected 2025 costs of fragility fractures. Unfortunately, without a sound, predictable, and reliable means for clinicians to acquire and secure reimbursement for osteoporosis treatments fitting within the Part B benefit, any initiatives on the quality front will remain insufficient to incentivize cost-effective care.

NOF is similarly concerned that CMS has not considered the potential impact of the IPI Model on primary care clinicians and their decision on whether or not to offer Part B drug administration within their practice. These clinicians are in the best position to identify fracture risk in the Medicare population and reduce the incidence of preventable fractures. They are the recipient of fracture-related care coordination communications from acute care settings and responsible for appropriate follow-up care. Whether a patient who suffers a fragility fracture or is otherwise within guidelines for osteoporosis screening or treatment actually receives that care, is, for most patients, largely dependent on their primary care provider.

NOF is unaware of any evidence indicating that primary care providers choose treatment options based on an expectation of enhanced reimbursement associated with a particular therapy. We believe that some form of CAP might be welcomed by primary care clinicians and other specialties that do not commonly administer Part B drugs due to the risks of "buy and bill." We

are, however, concerned that the novelty, complexity, and potential perceived risks associated with this CMMI model test would make it less likely that our outreach and education efforts would be successful in driving appropriate osteoporosis treatment in the primary care setting. Although referral to an endocrinologist for treatment, or to an outpatient hospital department, may appear to be a viable option, it is unclear whether these settings would welcome or have the capacity to accommodate additional patients requiring drugs falling within the IPI Model test. We expect, therefore, that the IPI Model could have a clear and direct deterrent effect on any use of Part B drugs currently marketed or in development for osteoporosis.

Because the IPI Model injects multiple untested variables, it does not have the scientific soundness required for reliable and meaningful evaluation

While NOF agrees in principle with CMS in ensuring that U.S. patients and payers do not subsidize steep discounts extended to global markets, we are concerned that broad-brush application of an international pricing index may place beneficiaries randomized to the model test at risk of suboptimal care when compared to their "control group" counterparts. Our concerns are heightened by the layering of this approach with a new version of the Part B drug CAP. Benchmarking Part B drug payments to prices in international markets has not been tested or modeled to assess what, if any, impact it may have on patient access. Although CMS has previously implemented a CAP as a voluntary alternative to the buy and bill framework, that program was terminated by CMS due to its failure to reduce costs and reliably get Part B drugs to patients needing them. Combining these two test "variables" into a mandatory model, while adding a change in provider add-on payments, makes it unlikely that the model will reduce costs in its initial year(s) and injects significant uncertainty with respect to patient care. NOF opposes any model that has the potential for increasing Medicare costs, even in the short-term, unless it is primarily designed to improve patient access to care and enhance patient outcomes.

Similarly, the proposal appears to envision a model test that would be nearly impossible to evaluate. CMMI model tests generally have a research "question" related to the tested intervention. Research designs that combine multiple, previously untested variables do not lend themselves to scientific inquiries on whether the interventions were successful in meeting any of their goals and may potentially lead us to incorrect and harmful conclusions. For example, if CMMI encountered data indicating changes in treatment decisions with some good and some bad consequences, there would be no means of distilling a clear conclusion on any single intervention or their combination. We may not be able to determine what was a successful intervention and what was not. NOF urges CMS to ensure that all CMMI model tests meet the research and patient-centeredness requirements of Section 1115A of the Social Security Act.

As more fully detailed below, we support CMS' exploration of an improved, voluntary CAP as an alternative to the buy and bill mechanism currently applicable to all Part B drugs. We hope that CMS will continue its outreach to stakeholders to identify a patient population for which a CAP alternative model test would respond to care deficits common in that population.

CMS has not fully explored the impact the IPI Model might have on patient access and outcomes.

The NOF applauds CMS for its "Innovation Center New Direction" initiative, and its affirmation that Medicare transformation would be pursued with an eye toward affordable, accessible,

patient-centered care.[3] We agree that CMS should focus innovation efforts on improving care for chronically ill patients, and promote market-driven reforms that empower beneficiaries, provide price transparency, increase choice and competition, reduce costs, and improve outcomes.[4]

NOF understands that CMS' IPI Model announcement was designed to provide the Agency's preliminary thoughts on the model, and not to fully discuss its implementation details. We are concerned, however, that when, as here, the goals focus primarily on costs rather than patient outcomes, there is an increased risk that design elements may not improve (or even maintain) care, preserve access, or protect patients.

The authority to waive provisions of the Medicare law to test models uniquely positions CMMI to take the lead in moving Medicare toward value rather than volume. Two key components of CMMI models that justify waiving existing law are (1) identification of patient populations with care deficits and discrete interventions likely to improve outcomes at reduced costs; and (2) the ability to evaluate the effectiveness of the model through patient-centered outcomes. CMMI models are intended to be well-designed research studies that foster program improvements without presenting a risk to patients.

Section 1115A's reliance on patient-centeredness in evaluating models similarly underscores the importance of the patient perspective in initial model selection and design. NOF urges CMS to maintain its "patients first" focus and to approach its model tests with the threshold questions of "what are the associated risks across the patient populations we would study," and "is the risk of harm for **all** patients sufficiently negligible to require patients to participate in the research." Any inability to identify or quantify patient risk should give CMS pause and, at a minimum, justify a patient-centered opt-out consistent with CMS' long-standing standards of shared decision making and informed consent in connection with medical care. This is particularly important for individuals with chronic diseases like osteoporosis for whom access hurdles can have enormous, life-altering, and potentially life-threatening, consequences. Many models have been designed to include notification requirements and the opportunity for patients to opt out of demonstrations.

The NOF believes that the proposed IPI Model presents the types of changes that patients would want to know about and fully understand. We expect that CMS shares our belief that failing to fully inform Medicare beneficiaries of any research that could impact treatment choices would be inappropriate. We hope that CMS agrees that models that incorporate multiple untested interventions, randomize patients, through their providers, to either an experimental or control arm, and are designed primarily to reduce costs should not impose blinded, mandatory participation among Medicare's elderly and disabled population.

Failure of the original Part B Drug CAP justifies a cautious approach to implementing a similar initiative.

The NOF recognizes that there is a potential opportunity for cost savings with a reconstituted Medicare Part B Competitive Acquisition Program (CAP), and that cost-savings could be

[3] https://innovation.cms.gov/Files/x/newdirection-rfi.pdf

[4] Centers for Medicare & Medicaid Services: Innovation Center New Direction https://innovation.cms.gov/initiatives/direction/

associated with increased, rather than decreased access to care. Unfortunately, the CAP's prior failure raises significant concerns among both providers and clinicians.

We appreciate that the preliminary thoughts on the IPI Model reflect consideration of past failures and an effort to avoid them. Clearly, the original CAP had inherent inefficiencies, including use of a single vendor and a single drug-claims processing contractor that would "match" drug and administration claims before paying the CAP vendor. Practices could not stock CAP drugs, and often encountered difficulties receiving Part B drugs when needed.

For many provider types and specialties, a CAP could be viewed as a welcomed alternative offering improved efficiencies and reduced risks to practices. The NOF supports CMS' implementation of a successful CAP alternative to buy and bill. We believe this means that the program should:

- be voluntary for clinicians and practices;
- start with short enrollment periods (e.g., quarterly enrollment);
- by accompanied by QPP mechanisms that adjust the MIPS "cost" category to reflect CAP participation;
- track impact on patient cost-sharing and access in real-time; and
- pass savings on to patients in the form of reduced out-of-pocket costs.

The IPI Model would permit providers to maintain stock of CAP drugs rather than order on a patient-specific, as-needed basis and relieve vendors of the burden of collecting beneficiary copayments. Although these modifications could facilitate CAP viability, we are concerned that some of the proposed "fixes" may inject uncertainties and unintended consequences. It is difficult to predict whether the IPI Model would run smoothly and as intended, or create significant inconveniences and access hurdles.

The NOF is, for example, concerned with CMS' proposed reliance on vendor/provider agreements to "include appropriate guardrails to protect all parties, including beneficiaries and the Medicare program." While this may be designed to encourage competition and free market mechanisms, it would function to place beneficiary protections delegated to CMS into the hands of private parties within the context of a commercial transaction. We urge the Agency to ensure that it maintains responsibility for beneficiary protection through clearly outlined requirements and oversight to ensure compliance.

Similarly, we are concerned that a model design that would have vendors paying manufacturers if and when a drug is administered will likely frustrate the potential for practices to maintain stock of CAP drugs. It is likely that some, if not most, manufacturers would resist extending deep discounts to vendors unless there is some means of ensuring that product returns are minimal and payment is relatively prompt. We are concerned that this element of the program design could lead to the same access issues and frustrations that accompanied the original CAP. A significant delay in administration of a scheduled dose of medication could not only impact effectiveness and reduce fracture protection, but could inadvertently increase risk and cause harm. Moreover, this additional wrinkle in the IPI Model creates an added level of uncertainty that could not only threaten patient access, but complicate any subsequent evaluation of the model's effectiveness.

The expanded set of potential CAP vendors gives rise to beneficiary concerns that the model would implement utilization management structures to further curtail access to treatment options.

CMS has stated its intention to broaden the set of entities that would qualify as a CAP vendor. While this may lead to increased provider choice of vendors, it also creates a level of uncertainty with respect to the role vendors might play in treatment decisions. Pharmacy Benefit Managers (PBMs), for example, are highly involved players who typically take an activist role in determining which drugs are available for specific patients. The NOF strongly opposes vendor use of formularies, utilization management tools, or any other mechanisms that direct or influence provider decisions on the best treatment for a particular patient.

We are similarly concerned that the vendor risks associated with claim denials on administered drugs could, over time, introduce access concerns for patients. This issue was identified in the original CAP and may have deterred vendor participation. Because vendors do not see patients or have access to their medical records, the NOF is concerned that they will seek to limit the risk associated with denied claims by specifying the patients for whom the drug can be administered, and requiring that providers secure an executed Advance Beneficiary Notice (ABN) for patients outside those specifications. This practice could be even more difficult for patients to navigate than traditional utilization management tools for which appeals mechanisms are available. The real-world impact to patients under those circumstances is that they may decline a medically necessary, prescribed treatment rather than risk having to pay out-of-pocket.

We urge CMS to ensure that any model test incorporates safeguards for patients to ensure that vendor risk aversion does not impede patient access to the treatments that they, in conjunction with their providers, determine are the best option.

Conclusion

Once again, the NOF appreciates the opportunity to provide feedback as CMS considers implementing an IPI Model within the Medicare program. While we have significant concerns that the Agency's preliminary thoughts on this model do not incorporate the design elements that would be necessary to ensure that patients with bone fragility receive appropriate treatment, we look forward to working with CMS toward our shared goal of improved patient outcomes at a lower cost to the Medicare program.

If you have any questions or wish to discuss our concerns in greater detail, please contact me at 703-647-3020 or our Chief Mission Officer, Clair Gill, at 703-647-3025.

Very truly yours,

Elizabeth Thompson
Chief Executive Officer
National Osteoporosis Foundation