December 4, 2017

United States Preventive Services Task Force
540 Gaither Road
Rockville, MD 20850
VIA ELECTRONIC SUBMISSION

RE: Draft Research Plan for Osteoporosis: Screening

Dear USPSTF Coordinator:

The undersigned National Organizations applaud the U.S. Preventive Services Task Force's (USPSTF) leadership and work on preventive issues through its review of and recommendations regarding clinical preventive health care services. We also commend USPSTF for its continued attention to the issue of screening for osteoporosis.

We would like to thank the USPSTF for continuing to support screening for osteoporosis with bone measurement testing in women aged 65 and older, and in postmenopausal women younger than 65 with increased risk of osteoporosis.

Osteoporosis and its related bone fractures have a staggering impact on the U.S. health care system, accounting for approximately 300,000 hip fracture hospitalizations, with costs projected to grow to over $25 billion by 2025. Because the risk of osteoporosis increases as bones become thinner with age, Medicare beneficiaries, in particular, need access to bone density screening services. Approximately 44% of all women and 25% of men over the age of 60 will experience a bone break due to osteoporosis in their lifetime. These high rates of osteoporosis and low bone mass result in over 2 million related fractures each year in the United States. The Draft Recommendation Statement adequately reflects the public health crisis associated with osteoporosis.

However, our organizations would like to offer comments on three points of disagreement with the Draft Recommendation Statement.

First, we would like to express our concern with the point made in the draft statement pertaining to screening intervals that states, "Limited evidence suggests no benefit from repeating bone measurement testing between 4 and 8 years after the initial screening." In fact, many patients have significant changes in their BMD in this time period that would cause a clinician to alter a patient's therapy, including those on prednisone, chemotherapy or heparin.

Second, we would encourage the Task Force to clarify the mechanism by which health care providers will determine if a patient they are evaluating has a comparable or greater fracture risk than an otherwise healthy "65 year old with no additional risk factors" and a 10 year risk for major osteoporotic fracture of 8.4%. It appears that one would input all relevant data into FRAX. Should this include "glucocorticoids" (question 8) and "secondary osteoporosis" (question 10),

or are these to be considered as "osteoporosis secondary to another condition" which the draft statement indicates are exclusions from the current screening recommendations?

Finally, the undersigned organizations continue to appreciate that the USPSTF addresses men in its draft recommendation. In its discussion around the category of men, the Task Force supports the conclusions of higher mortality rates for men with osteoporosis. However, the Task Force maintains its prior conclusion that "there is still insufficient evidence on screening for osteoporosis in men."

We believe that convincing evidence exists to support a favorable recommendation for osteoporosis screening applicable to at least some class of men. The National Osteoporosis Foundation (NOF) guidelines, for example, recommend screening in all men ages 70 and older. We support the NOF guidelines and would encourage the Task Force to reconsider the available data, which show both that there are clinical benefits to treating osteoporosis in men when diagnosed early, and high costs and burden when men are not screened. In prior years comments, we have suggested the following studies. *See, e.g., Orwoll E et al. N Engl J Med 2000;343:604-10; Ringe JD et al. Rheumatol Int 2006;26:427-31;Kaufman JM et al. Osteoporos Int 2005; 16:510-6; Orwoll ES et al. J Bone Miner Res 2003;18:9-17.*

Recent studies targeting osteoporosis screening in men have shown effectiveness in high-risk subgroups, including a large, recent Veteran's Affair study. (See citations below).

Colon-Emeric C, Pieper C, Lyles K, VanHoutven C, LaFleur J, Adler R. 2017 Primary Osteoporosis Screening in U.S. Male Veterans is Effective in High Risk Subgroups, but not Overall. J Bone Miner Res 32 (Suppl 1).

Smith D, Berman N, Tenner C, Pike V, Pillinger M, Honig S. 2017 Evaluation of Current Screening and Treatment Patterns in Males at the Veteran Affairs Healthcare System. J Bone Miner Res 32 (Suppl 1).

Despite the USPSTF's draft decision regarding recommendations for screening men in the general population for osteoporosis, we request that your recommendations reiterate the utility of bone densitometry in men who have clinical risk factors for fracture. These would include men suffering any low trauma fracture, those with known hypogonadism or receiving anti-androgenic therapy, those receiving glucocorticoids, and those with family histories of hip fracture.

The per-protocol analysis of a randomized, controlled study by Barr et al is the first of its kind to demonstrate that screening of women leads to fewer fractures. *See Barr, R. J., Stewart, A., Torgerson, D. J. & Reid, D. A. Population screening for osteoporosis risk: a randomised control trial of medication use and fracture risk. Osteoporos. Int. doi:10.1007/s00198‑009‑1007‑x.* The results strengthen the conclusions of two observational studies that showed that osteoporosis disease management led to fewer than expected fractures. *See ED Newman et al, Osteoporosis disease management in a rural health care population: hip fracture reduction and reduced costs in postmenopausal women after 5 years. Osteoporos Int 2003;14:146-51; D Greene and RM Dell, Outcomes of an osteoporosis disease-management program managed by nurse practitioners. J Am Acad Nurse Pract 2010;22:326-9.* Designing, funding, and executing a randomized trial to corroborate these studies and extend them to men will be extremely

difficult. Contamination, potential ethical issues, and cost make such trials unlikely. Thus, the undersigned National Organizations continue to urge the USPSTF to consider mentioning these three studies as evidence that screening can potentially lead to salutary outcomes.

While there are no randomized controlled trials that met the standards for the Agency for Healthcare Research and Quality demonstrating that screening leads to decreased fracture incidence, two observational studies suggest that osteoporosis disease management will likely result in fewer fractures. *See ED Newman et al, Osteoporosis disease management in a rural health care population: hip fracture reduction and reduced costs in postmenopausal women after 5 years. Osteoporos Int 2003;14:146-51. See also, D Greene and RM Dell, Outcomes of an osteoporosis disease-management program managed by nurse practitioners. J Am Acad Nurse Pract 2010;22:326-9.*

Another shows screening older women and men resulted in 36% fewer hip fractures over a 6-year period: *Kern LM. Ann Inter Med 2005; 142; 173-181. Association between screening for osteoporosis and the incidence of hip fracture.*

The USPSTF might consider mentioning the work in the Geisinger and Kaiser systems as evidence (though not of the highest quality) that screening can potentially lead to salutary outcomes. However, two trials are currently underway: SCOOP and SALT, and results of the former show similar results to *Kern et al*.

The undersigned organizations applaud USPSTF's leadership and work on preventive issues through its review of and recommendations regarding clinical preventive health care services.

We strongly support the USPSTF's efforts to expand screening to more women, and we applaud its recommendation for "screening for osteoporosis in women ages 65 years and older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old woman who has no additional risk factors."

On behalf of the undersigned national organizations, we appreciate this opportunity to comment on the USPSTF's draft Recommendation Statement on screening for osteoporosis.

List of Organizations Signing

National Osteoporosis Foundation
American Society for Bone and Mineral Research
American Association of Clinical Endocrinologists
Coalition of State Rheumatology Organizations
International Society for Clinical Densitometry