Good morning. I am John Clymer, executive director of the National Forum for Heart Disease & Stroke Prevention and adjunct professor at the Loma Linda University School of Public Health. My comments today are on behalf of the National Forum. I have no financial interests or conflicts of interest.

The National Forum supports the American Heart Association and American Medical Association’s request to the Centers for Medicare & Medicaid Services for a Benefit Category Determination that self-measured blood pressure devices are durable medical equipment.

As CMS states, “Hypertension is the number one chronic condition of Medicare beneficiaries.”[1] There is strong evidence that SMBP improves hypertension control, which will reduce the incidence of myocardial infarction, stroke, and heart failure.

CMS based its preliminary decision that SMBP devices do not qualify as DME on its interpretation that “SMBP devices are generally not used by the patient to self-manage hypertension, but rather require clinical intervention to manage their medical condition.”[1] The National Forum is pleased that CMS seeks additional information to inform its final decision.

The evidence shows that SMBP devices are used for both patient self-management and obtaining data to share with clinicians.

- The 2020 Surgeon General’s Call to Action to Control Hypertension reported that SMBP involves a clinician/patient “feedback loop [that] enhances patient engagement in care and provides timely information to the clinical team to improve care.”[2]
A Community Preventive Services Task Force systematic review of evidence found, “as patients become more aware of their blood pressure readings, they may also become more motivated to improve other lifestyle behaviors such as healthful eating, physical activity, and smoking cessation.”

Clinical guidelines recommend using SMBP home monitoring devices, which are widely utilized. For example, Kaiser Permanente has a remote patient monitoring program for diabetes and hypertension. This program empowers KP members with diabetes and hypertension to better manage chronic conditions by monitoring blood pressure or blood sugar levels from their homes and making self-directed behavior modifications.

The TASMIN-R trial showed that “among patients with hypertension at high risk of cardiovascular disease, self-monitoring with self-titration of antihypertensive medication compared with usual care resulted in lower systolic blood pressure at 12 months.”

A recently published study modeled data from the 2019 Behavioral Risk Factor Surveillance System and the published literature. It showed that compared to usual care, adopting SMBP was estimated to reduce myocardial infarction cases by 4.9 percent and stroke cases by 3.8 percent, saving an average of $7,794 in healthcare costs per person over 20 years.

In light of the evidence that SMBP devices are used for patient self-management and clinical care, the National Forum strongly urges CMS to classify SMBP devices as DME.

Classifying SMBP devices as DME would be an essential step towards removing a barrier for underserved populations to an intervention proven to reduce “the number one chronic condition of Medicare beneficiaries.” It would be a significant step towards realizing the CMS Office of Minority Health’s vision that All those served by CMS have achieved their highest level of health and well-being and we have eliminated disparities in healthcare quality and access.

Speaking now for myself, as co-chair of the Million Hearts Collaboration and founding co-chair of the National Hypertension Control Roundtable, classifying SMBP devices as DME would support CMS’s commitment as co-lead of Million Hearts. Not doing so and, therefore, preventing Medicare coverage for a proven
hypertension control intervention would be inconsistent with Million Hearts’ goal and purpose.

Thank you for the opportunity to address you and recap the evidence that SMBP devices meet all five criteria for classification as durable medical equipment.

References: