American Heart Association | American Stroke Association
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Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510-6200

Re: Chronic Care Working Group Policy Options

Dear Chairman Hatch, Ranking Member Wyden, Sen. Isakson, and Sen. Warner:

On behalf of the American Heart Association, including the American Stroke Association and more than 30 million volunteers and supporters across the country, we congratulate members of the Finance Committee and the Chronic Care Working Group for the release of their policy document and the significant effort they have given to the goal of improving health outcomes for Medicare beneficiaries living with multiple chronic conditions.

Our organization is dedicated to building healthier lives, free of cardiovascular disease (CVD) and stroke. While we have made tremendous progress towards achieving this goal, we know that many in the Medicare population still live with high blood pressure, high cholesterol, coronary heart disease, heart failure, or stroke – with many beneficiaries suffering from more than one of these and other conditions. This is why we remain committed to working with you to address these leading causes of death and disability, and ensure that patients suffering from these diseases receive high quality, coordinated care.

We are particularly grateful that the Working Group included a policy option that would expand the use of telehealth for individuals with stroke. Below, we offer additional comments on this proposal and our strong support for its inclusion in a final policy document.

We also recognize that implementing policies that facilitate increased care coordination, incentivize high quality care, and increase the Medicare program's efficiency while improving health care outcomes and reducing costs is a considerable challenge with no single policy solution. Overall, we support the direction and primary goals of the policy document and applaud the Working Group for the inclusion of a number of policies in the final policy or legislation proposal, that we believe take significant steps forward to improving care coordination for individuals with chronic diseases. For example, we support the inclusion of policies that would continue access to MA Special Needs Plans, establish a high severity chronic care management code, promote chronic disease quality measure development, waive copays associated with the chronic care management code, and provide Medicare Part B payment for prediabetes education programs.

We also have more detailed comments on other telehealth proposals and the proposed studies on medication synchronization and obesity drugs. Finally, we strongly suggest that the Working Group include in its final policy proposal language that would allow certain non-physician practitioners to directly supervise cardiac rehabilitation programs under Medicare. We have included our rationale for this provision below.

Expanding Use of Telehealth for Individuals with Stroke
We thank the Working Group for including our recommendation to expand access to telestroke for Medicare beneficiaries. We strongly support including this policy in any final proposal or legislative text. As we described in our June 2015 letter, and reference above, allowing Medicare to reimburse for telestroke services that originate in urban and suburban areas, as well as in rural areas, clearly meets the goals set out by the Working Group: it increases stroke care coordination among providers; incentivizes the appropriate level of care for stroke patients; and, facilitates the delivery of high quality care and improves patient outcomes all while reducing Medicare spending. We strongly encourage the Working Group to include this policy it its final proposal and thank the Working Group for recognizing the important role that this policy would play in improving the diagnosis, treatment, and outcomes for individuals who suffer a stroke.

Increasing Convenience for Medicare Advantage Enrollees through Telehealth
We appreciate the Working Group's recognition of the role that telehealth can play in increasing the accessibility and effectiveness of care for patients with chronic conditions and the attention paid to it in several of the proposed policy options. We support permitting MA plans to include certain telehealth services in its annual bid contract. In doing so, the services offered should not be limited to those allowable under traditional Medicare, but instead include additional services, such as on-line internet assessments, critical care (i.e.telestroke), computerized clinical data analysis, the collection and interpretation of physiological data (i.e. "store and forward" and remote patient monitoring technologies), and mobile health technologies such as smartphone applications, biosensors, and wireless implantables.

Providing ACOs the Flexibility to Expand Use of Telehealth
Similarly, we support the proposed policy to increase ACO flexibility to expand the use of telehealth. We recommend that the geographic requirement be removed entirely. Eighty percent of Medicare beneficiaries reside in a Metro area. Medicare's current requirement falsely presumes that individuals automatically have access to care if they live within a "big city" and this limitation also aggravates current racial disparities in the healthcare system.[1] In this way, we support removing the geographic requirement for currently-reimbursable originating sites, and including those which lie in a metropolitan country.

Adapting and Expanding Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees
We support proposals that would give MA more flexibility to vary benefit structures based on chronic condition and offer a wider array of supplemental benefits than they currently do, by allowing plans to encourage beneficiaries to select high quality, cost effective health care services. In particular, designing plans that offer preventive care, wellness visits, and certain high value treatments, such as medications to control blood pressure, at little or no cost to beneficiaries can promote prevention, healthy behaviors, and treatment adherence, all of which

[1] Lyerly, M. J., et al. (2015). "The effects of telemedicine on racial and ethnic disparities in access to acute stroke care." J Telemed Telecare.

may save money by reducing future expensive medical procedures.[2,3]

We also strongly encourage the Working Group to allow MA plans to offer care improvement and wellness programs. Tailored nutrition and physical activity services, such as exercise prescription and behavioral counseling, are important components in programs that address chronic conditions. For example, elderly men with high blood pressure can lower their risk of death with even moderate levels of fitness compared to those who are less fit. Studies have also shown that increased levels of physical activity are associated with reduced incidence of coronary heart disease and hypertension. The U.S. Preventive Services Task Force has also found evidence that intensive behavioral counseling programs, which included counseling on a healthful diet and physical activity, can help adults who are overweight or obese and are at increased risk for CVD improve their diet and increase physical activity, helping people reduce their risk for CVD through weight loss and lowered blood pressure and cholesterol levels. These behavioral counseling interventions were delivered by specialty trained professionals such as dietitians and nutritionists.[4]

In short, providing access to care improvement and wellness programs that include physical activity and nutrition counseling can help people with high blood pressure, high blood cholesterol, or other chronic diseases lead healthier lives and make them less likely to die prematurely than inactive people with these conditions. We would also strongly encourage the Working Group to ensure that MA plans provide access to nutritionists and dietitians as well as health and fitness professionals as these individuals can play an important role in the primary and secondary prevention of CVD and managing patient care.

Establishing One-Time Visit Code Post Initial Diagnosis of Alzheimer's/Dementia or Other Serious or Life-Threatening Illness

We support the policy concept to establish a code for a one-time visit after an individual has been diagnosed with a serious or life-threatening illness. Patients with vascular dementia brought on by stroke or those with heart failure, for example, could very much benefit from this type of benefit. These are conditions for which the diagnoses may be overwhelming or confusing and for which prognosis is uncertain. In this way, we look forward to this proposal being included in future policy options documents. In that context, we hope that the Working Group can elaborate upon potential components of the visit, as well as how this visit and reimbursement would differ from recently implemented payment vehicles such as the code for advance care planning discussions.

Study on Medicare Synchronization

We support the inclusion of language in a final policy proposal that would require a study to examine the feasibility of implementing medication synchronization programs in Medicare. There are a number of reasons that patients with heart disease do not take their medicines as prescribed, and these patients are more likely than adherent patients to have adverse health events that increase costs to them and the health care system. We also know that there are a number of interventions that may help improve medication adherence, and medication synchronization programs may be one of them. We appreciate the Working Group's interest in finding ways to increase medication adherence and their interest in understanding how medication synchronization programs can play a role in addressing adherence barriers. We

[2] Chernew, M. E., et al. (2008). "Impact of decreasing copayments on medication adherence within a disease management environment." Health Aff (Millwood) 27(1): 103-112.
[3] Choudhry, N. K., et al. (2010). "Assessing the evidence for value-based insurance design." Health Aff (Millwood) 29(11): 1988-1994.
[4] LeFevre ML, on behalf of the U.S. Preventive Services Task Force. Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors: U.S. Preventive Services Task Force Recommendation Statement. Ann Intern Med. 2014;161:587-593.

would also suggest that a study on medication synchronization include an examination of any potential unintended consequence of these programs, such as a patients' inability to afford all medications at once, and ways to minimize the impact of these consequences. We strongly support the inclusion of this study and other policies that seek to reduce barriers and increase adherence for patients with a chronic disease in a final proposal.

Study on Obesity Drugs

We also support the Working Group's inclusion of a study on obesity drugs in the final policy proposal. Obesity is a primary target for the American Heart Association's efforts to improve the cardiovascular health of all Americans by 20 percent by 2020. We believe that the type of research proposed in this policy option is critical to informing efforts to bring about reductions in obesity across all ages, races, ethnicities, and genders. To this end, we are offering a few suggestions as to how to best structure the study so that it is most effective for these efforts.

A complex disorder, obesity is a major health risk factor linked to increased CVD, stroke, cancer, hypertension, diabetes, and early death.[5] Obesity is also costly. In 2010, the estimated nationwide cost for obesity was $315.8 billion.[6] If current trends continue, the costs of obesity could reach 16 percent to 18 percent of U.S. health expenditures by 2030.[7]

Obesity drugs can be an adjunct to the very important lifestyle and behavior changes that should be the main focus of obesity treatment regimens. The drugs may produce weight loss by biologic means or reinforce behavior change. They may also have health benefits beyond weight loss. It is necessary, therefore, that the report's research protocol account for and address these different levels of impact and roles for obesity drugs. Given the significant economic impact of the condition, an economic analysis on cost-effectiveness as part of the research would also be very informative.

We would also like to draw your attention to a report based on a series of stakeholder group meetings, led by the STOP Obesity Alliance and in which the association participated.[8] The report outlines outstanding research questions and topics, and we would encourage you to include these in subsequent, more detailed versions of this policy option. Those questions and topics are:

- What health or quality of life benefits accrue, beyond weight loss, with drugs for obesity treatment: how are they demonstrated, and does the importance of these benefits vary based on the degree of an individual's obesity and associated risk factors, or the length of time the weight loss is maintained;
- Evaluate the unique risks associated with the sheer number of people who may seek to use a new obesity drug: from those seeking to address the substantial limitations that obesity places on their feeling, functioning, and survival, to those without obesity who wish to lose weight for cosmetic or other reasons; and
- Ensure the safe and effective use of pharmaceutical interventions designed to help those with obesity and most effectively prevent inappropriate use by those for whom the risks of use outweigh the benefits.

[5] Flegal KM, et al. Association of All-Cause Mortality with Overweight and Obesity Using Standard Body Mass Index Categories. JAMA, 2013; 309: 71 – 82.
[6] Cawley J, et al. Savings in Medical Expenditures Associated with Reductions in Body Mass Index Among US Adults with Obesity, by Diabetes Status. Pharmacoeconomics. 2014: doi:10.1007/s40273-014-0230-2
[7] Wang Y, et al. Will all Americans become overweight or obese? Estimating the progression and cost of the US obesity epidemic. Obesity (Silver Spring). 2008;16:2323–2330
[8] George Washington School of Public Health. Obesity Drug Outcome Measures: A Consensus Report of Considerations Regarding Pharmacologic Intervention. Accessed January 6, 2016 at: https://publichealth.gwu.edu/pdf/obesitydrugmeasures.pdf

Allowing Non-Physician Practitioners to Supervise Cardiac Rehabilitation Programs
We strongly encourage the Working Group to include language in its final policy document that would allow physician assistants, nurse practitioners, and clinical nurse specialists to supervise cardiac and pulmonary rehabilitation programs on a day-to-day basis under Medicare. This policy (S. 488) has strong bipartisan support and clearly meets the goals of incentivizing the appropriate level of care for beneficiaries, facilitating the delivery of high quality care, and producing improved patient outcomes.

Cardiac rehabilitation is a medically supervised program designed for patients with certain cardiovascular diseases or after suffering a cardiac event – like a heart attack – that consist of exercise training, education on heart-healthy living, and counseling to reduce stress. These programs help patients return to an active lifestyle and recover more quickly. The benefits of these programs are clear and tangible: research has shown that cardiac rehabilitation reduces mortality by more than 50 percent compared with those patients who do not participate and can also reduce the likelihood of hospital readmissions for all causes by 25 percent.[9,10] Simply put, these programs reduce the risk of a future cardiac event by stabilizing, slowing, or even reversing the progression of CVD.[11] Research also suggests these programs reduce health care costs. A study presented at the Canadian Cardiovascular Congress found that cardiac rehabilitation reduced costs associated with hospital readmissions from a heart attack by $8.5 million a year, and another study in Vermont found that hospitalization costs over the follow-up period for cardiac admissions were roughly $900 less for patients who completed a cardiac rehabilitation program.[12,13]

Unfortunately, the utilization rate for eligible Medicare beneficiaries is only 12 percent.[14] One reason for low participation in cardiac rehabilitation programs is the lack of program availability and access as a result of current requirements under Medicare that require a level of direct physician supervision for cardiac and pulmonary rehabilitation programs that is inappropriately and unnecessarily stringent. These requirements in particular lead to reduced access to these services in physician shortage areas and add unnecessary costs.

S. 488 would change existing Medicare program requirements that require a physician to be immediately available for each cardiac rehabilitation session and instead allow a physician assistant, nurse practitioner, or clinical nurse specialist to directly supervise these programs. A physician would still be required to serve as a Medical Director to ensure that the programs are safe, comprehensive, cost effective, and medically appropriate for individual patients. The safety of cardiac rehabilitation in a medically supervised, community-based program is well established, and non-physician practitioners are highly trained to respond should emergencies arise.[15,16]

We strongly encourage the Working Group to include S. 488 in any final policy document or

[9] Dunlay, SM et al. Participation in cardiac rehabilitation, readmissions, and death after acute myocardial infarction. The American journal of medicine.2014. 127.6: 538-546.
[10] Plüss, Cet al. Long-term effects of an expanded cardiac rehabilitation programme after myocardial infarction or coronary artery bypass surgery: a five-year follow-up of a randomized controlled study. Clinical rehabilitation. 2011. 25.1 : 79-87.
[11] Balady GJ., et al., Referral, enrollment, and delivery of cardiac rehabilitation/secondary prevention programs at clinical centers and beyond: a presidential advisory from the American Heart Association. Circulation. 2011; 124:2951-2960.
[12] Humen D, et al. A Cost Analysis of Event Reduction Provided by a Comprehensive Cardiac Rehabilitation Program. Canadian Journal of Cardiology. 2014; 29.10: S156.
[13] Ades PA, et al.Cardiac rehabilitation participation predicts lower rehospitalization costs. American heart journal. 1992; 123.4: 916-921.
[14] Suaya, JA., et al. Cardiac rehabilitation and survival in older coronary patients. J Am Coll Cardiol.2009. 54(1): 25-33.
[15] Safety of Monitoring Exercise for Early Hospital-based Cardiac Rehabilitation. Chul Kim, Chang Jin Moon, Min Ho Lim. Ann Rehabil Med. 2012 April; 36(2): 262–267.
[16] Safety of cardiac rehabilitation in a medically supervised, community-based program. Scheinowitz M, Harpaz D. Cardiology.

legislative proposal to ensure Medicare beneficiaries have access to critical cardiac rehabilitation programs that are proven to improve health outcomes, reduce health care costs, and lead to a better quality of life.

We strongly believe that the policies detailed above should be included in any final policy document or legislative proposal brought forth to the full Committee, especially policies to expand access to telestroke and to ensure access to cardiac rehabilitation programs. Again, we appreciate the Finance Committee and Chronic Care Working Group for addressing the challenging issues related to caring for Medicare patients with multiple chronic conditions. We greatly appreciate the thought and deliberations that went into the development of the policy options document, and we thank you again for your consideration of these comments.

We also appreciate your dedication to a deliberate and transparent process for allowing stakeholder input. We look forward to continuing to work with the Committee and Working Group to provide input on this initiative in the future. If you have any questions or would like to discuss any of these comments further, please contact Madeleine Konig at madeleine.konig@heart.org or Kevin Kaiser at kevin.kaiser@heart.org.

Sincerely,

Mark A. Creager, MD, FAHA
President
American Heart Association