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Marilyn Tavenner, RN, BSN, MHA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Submitted Electronically to AdvanceNotice2016@cms.hhs.gov

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter

Dear Administrator Tavenner:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and more than 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to provide comments in response to the Centers for Medicare and Medicaid Services' (CMS) Advance Notice of Payment Changes and the 2016 Draft Call Letter for Medicare Advantage (MA) and Prescription Drug plans.

Heart disease and stroke are the No. 1 and No. 5 killers, respectively, in the United States and inflict an enormous human and financial toll on our nation. An estimated 44 million adults age 60 and over have at least one type of cardiovascular disease (CVD).[i] About 42 percent of Medicare beneficiaries have a heart condition and 12 percent have had a stroke.[ii] CVD in individuals age 65 and over accounted for nearly $100 billion in direct medical costs in 2011, accounting for higher health expenditures than any other disease category.[i] Clearly, Medicare, including Parts C and D, is important to the health and financial security of many patients with heart disease and stroke.

Changes in Part C Payment Methodology for CY2016

Clinical Trials Coverage (Section E)

We are disappointed that CMS is once again not correcting a long-standing inequity in Medicare coverage by failing to require in the final 2016 payment methodology and call letter that Medicare Advantage (MA) plans provide

coverage for clinical trials. As the policy currently stands, individuals in MA plans are required to relinquish their MA coverage and revert to standard fee-for-service (FFS) Medicare if they wish to participate in a clinical trial. Providing coverage as part of MA plans – which typically have lower copayments and out-of-pocket costs – rather than Medicare "paying on a fee-for-service basis" is important to the participants who enroll in these plans. MA enrollees typically chose these plans because they result in lower out-of-pocket costs than FFS coverage and provide more comprehensive coverage. Treatments for serious or life-threatening diseases can be very costly for the patients involved, regardless of whether the patient participates in a clinical trial.

Ensuring MA plan coverage for clinical trials is very important for both the individuals who can benefit from this coverage and for our society as a whole. There is a greater public good to encouraging increased patient participation in clinical research. The benefit of clinical trial participation accrues to all of us through the advancement of medical knowledge, and participation in such research should therefore be encouraged through the removal of this coverage barrier. In addition, failing to allow MA enrollees to receive coverage for clinical trial participation directly through their MA plan runs counter to efforts by the National Institutes of Health and the Food and Drug Administration to promote enrollment into clinical trials.

We are concerned with the requirement that MA enrollees revert to FFS coverage to participate in a clinical trial. The policy is confusing, may deter MA enrollees from participating in clinical trials, and will likely result in a cost-differential for MA enrollees – when comparing FFS and MA out-of-pocket costs. Most MA plans have lower cost-sharing for Medicare-covered services, and MA enrollees often do not have supplemental coverage. Therefore, the out-of-pocket costs of participating in a clinical trial through FFS will likely be more than if the MA enrollee were participating in the trial through their MA coverage. MA enrollees, while participating in a clinical trial under the FFS reimbursement, are required to cover all deductibles, copays, and the 20 percent coinsurance for all charges associated with clinical trial care. CMS seemed to acknowledge this in its 2011 call letter when it stated that "MA organizations are responsible for reducing cost sharing for clinical trials to the amount that their MA plan members would have for similar services provided by in-network providers."

Our strong preference is for CMS to require MA plans to directly cover the routine costs of clinical trial participation. However, if CMS decides to continue the current policy of requiring MA beneficiaries to relinquish their MA coverage and revert to a FFS Medicare plan, then at the very least there should be better transparency for enrollees. In that event, we urge the Agency to promote greater transparency for patients by updating its "Medicare & Clinical Research Studies" brochure (www.medicare.gov/Pubs/pdf/02226.pdf). Specifically, the brochure should clarify that MA enrollees are eligible to receive "the difference between Original Medicare cost-sharing and the MA plan's in-network cost-sharing for the same category of items and services" (as is stated in the Medicare Managed Care Manual). While the brochure mentions that MA plans cannot "keep you from joining a clinical research study," it should also inform Medicare beneficiaries that the MA plan is required to provide cost-sharing assistance.

2016 Draft Call Letter, Section I

New Medication Therapy Management (Part D) Measure

We strongly support the inclusion of an MTM performance measure in the Star Rating system. MTM programs are an important intervention that can improve medication adherence. We are concerned that poor medication adherence is particularly common among patients with cardiovascular disease. Research suggests that 24 percent of patients who suffer a heart attack do not fill their medications within seven days of discharge, and 34 percent of heart attack patients with multiple prescriptions stop taking at least one of them within one month of discharge. The risk of hospitalization, re-hospitalization, and premature death among patients with high blood pressure who do not adhere to their medications is more than five times higher compared to high blood pressure patients who are taking their medications. Moreover, patients with high cholesterol who do not adhere to their medications have a 26 percent greater likelihood of a cardiovascular-related hospitalization compared to patients who adhere to their prescriptions. Research also indicates that medication adherence programs, including MTM programs, can lead to better health outcomes, reduce the risk of adverse events and help control healthcare costs.

We believe that the use of an MTM measure in the Star Rating system has the potential to help align incentives to emphasize medication management and increase medication adherence among patients with cardiovascular disease. While we support the addition of an MTM measure, we encourage CMS to expand the proposed measure's denominator to include all MTM-eligible beneficiaries – not just those that are enrolled in the MTM program. We recognize the need to improve program participation for those enrolled, 25 percent of all Part D beneficiaries are eligible for MTM programs, but only 11 percent are currently enrolled. Therefore, it is very important to implement plans to ensure more eligible beneficiaries enroll in the program.

Controlling Blood Pressure (Part C) Measure

The Association has very serious concerns with the Agency's proposal to modify the Controlling Blood Pressure (Part C) measure to reflect the "Joint National Committee (JNC) 8 Guidelines," which recommend increasing the target blood pressure to 150/90 for persons age 60 years and older. CMS incorrectly refers to the JNC 8 document as "guidelines". This document was published by a group originally empaneled as JNC 8 and the report by 12 of the 17 panel members of that writing group was published last year in the *Journal of the American Medical Association*; they are NOT official guidelines. The report was not sanctioned or endorsed by the National Heart, Lung, and Blood Institute nor was it endorsed by the American Heart Association, the American College of Cardiology, or several other organizations from whom endorsement was sought. Thus the recommendations are not formally recognized as JNC 8 recommendations.

In addition, five members of the original panel objected to the report's recommendation to increase the target blood pressure to 150/90 in persons 60 and older.[1] Like the

[1] (See the minority report, Evidence Supporting a Systolic Blood Pressure Goal of Less Than 150 mm Hg in Patients Aged 60 Years or Older: The Minority View, published by Jackson T. Wright Jr., MD, PhD;

authors of the minority report, we are extremely concerned that following the writing group's target and treatment recommendation for persons 60 or older will adversely affect public health and believe the higher systolic blood pressure (SBP) target in the 60-plus age group will increase health disparities among populations at greatest risk, especially African Americans and patients with multiple risk factors, including those with existing cardiovascular disease. There is currently insufficient evidence from randomized controlled trials (RCTs) to support a differential hypertension treatment benefit for patients older and younger than 60 years. Furthermore, the recommendation that serves as the basis for CMS' proposal failed to consider evidence beyond the use of RCTs and did not consider the totality of evidence, including observational studies, meta-analyses, and expert opinion.

Finally, a target SBP of <140 mm Hg for patients younger than 80 years would also be in line with guidelines from Europe, Canada, the American College of Cardiology Foundation and the American Heart Association, the United Kingdom, and the American Society of Hypertension and the International Society of Hypertension. The writing group report in JAMA is the only national or international report to recommend raising the SBP target in patients as young as age 60. With evidence demonstrating a reduction of coronary heart disease and stroke mortality in this country and particularly in the 60-plus age group, we believe the evidence to raise the SBP target should be at least as strong as the evidence that would be required to lower it. We ***strongly*** believe that the blood pressure control measure must remain at <140/90 to ensure that hypertension is appropriately managed in patients until we have more scientific studies about the likely impact of raising the SBP goal on cardiovascular disease and stroke.

Because the writing group report is controversial, is not an official JNC guideline, and may place patients, particularly older Americans, at risk, we urge CMS to abandon its plan to revise the Controlling Blood Pressure measure.

Retirement of CV Cholesterol Screening Measure

We do not object to the retirement of the three NCQA cholesterol-related measures. As CMS noted, this action is consistent with the 2013 American College of Cardiology/ American Heart Association (ACC/AHA) blood cholesterol guidelines.

Potential New Statin Measures

The Association appreciates that CMS is considering statin therapy measures that focus on patients with clinical atherosclerotic cardiovascular disease and patients with diabetes for future inclusion as part of the MA Star Rating system and supports CMS's attempts to align these measures with the 2013 ACC/AHA blood cholesterol guidelines. These guidelines are essential to making sure statin treatment is used for those people who can benefit and reducing these individuals' risk of cardiovascular disease and stroke. As CMS works with stakeholders to develop these measures, it is important to note that while our guidelines recommend statins for these groups of patients, statin therapy must also be made in the context of shared decision-making between physician and patient, including a discussion of the risks and benefits of statin

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Lawrence J. Fine, MD, DrPH; Daniel T. Lackland, DrPH; Gbenga Ogedegbe, MD, MPH, MS; and Cheryl R. Dennison Himmelfarb, PhD, RN, ANP. *Ann Intern Med*. 2014;160(7):499-503. doi:10.7326/M13-2981).

treatment, potential drug interactions, and patient preferences. It is also important to recognize that the guidelines consider allowing for exclusions of patients with absolute or relative contraindications or who refuse treatment. We recognize capturing this information may be difficult, but a measure that takes these factors into account would more accurately reflect the number of patients that receive and adhere to the ACC/AHA guideline recommended care, and thus better capture the quality of care a patient receives.

2016 Draft Call Letter, Section II

Medical Services Performed in Multiple Health Care Settings

We support CMS's proposed clarification that services that may be performed in different health care settings should only be placed in the dedicated Plan Benefit Package (PBP) category for that service. We particularly applaud CMS for highlighting the need for MA organizations to place cost-sharing for cardiac and pulmonary rehabilitation services only in PBP Service Category 3 (Cardiac and Pulmonary Rehabilitation Services) so that CMS can accurately track and analyze cost-sharing for these services and ensure that cost-sharing requirements are being met.

We have heard concerns from Medicare beneficiaries that high levels of cost-sharing for cardiac rehabilitation (CR) in MA plans is serving as a major barrier to participation in this evidence-based, highly effective service. Medicare covers up to 36 cardiac rehabilitation sessions per event. Beneficiaries in fee-for-service Medicare are responsible for nominal co-pays that average $21 per session. MA plans can charge co-pays that differ from the amounts beneficiaries in fee-for-service Medicare would pay as long as the overall cost-sharing under the plan is actuarially equivalent to that under Medicare and does not discriminate against sicker beneficiaries. Based on our review of a sample of MA plans in 17 states, many charged $40 or more per session, with some charging more than $100 per session. The total cost to beneficiaries, exclusive of applicable deductibles, for 36 sessions at $50 each, is $1,800 (compared to $756 in fee-for-service Medicare). Despite its efficacy, CR is underutilized, particularly among women and minorities, with the overall utilization rate for medically qualified Medicare beneficiaries at only roughly 14 percent.[iii] We encourage CMS's vigilance in ensuring that CR cost-sharing is not discriminatory but rather is affordable so that MA beneficiaries are not discouraged from participating.

Adequate Networks and Current Provider Directories

We applaud CMS for the steps it outlines to ensure greater transparency and accuracy in MA provider directories. MA beneficiaries rely on directory information when choosing a plan and their health care providers and inaccurate information can have significant financial consequences. Given that most plans do update their directories frequently based on the information they receive from providers, but severe directory inaccuracies persist, we believe it is wholly appropriate for CMS to require plans to communicate regularly with their providers to determine whether they are still available and accepting new patients and to have a protocol in place to follow through on inquiries and complaints from enrollees related to their inability to access a listed provider. We also support CMS's plans to implement a three-pronged approach to monitoring compliance with network adequacy regulatory requirements through direct verification of online

provider directories, development of a new audit protocol, and use of compliance and/or enforcement actions.

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Thank you for this opportunity to submit recommendations related to strengthening the Medicare Advantage program and Medicare prescription drug plans. We appreciate your consideration of our comments.

Sincerely,

Elliott M. Antman, MD, FAHA
President

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[i] Mozaffarian, D., et al. Heart Disease and Stroke Statistics-2015 update: A Report From the American Heart Association. *Circulation*. 2015; 131(4): e29-e322.

[ii] Kaiser Family Foundation analysis of CMS Medicare Current Beneficiary Survey Cost and Use file, 2006

[iii] Suaya JA, Shepard DS, Normand SL, et al. Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. *Circulation*. 2007;116:1653-1662.