American Heart Association | American Stroke Association

March 7, 2014

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-4159-P

Dear Sir or Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments in response to the proposed policy and technical changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs for contract year 2015.

AHA's comments focus on two areas of the proposed rule:

1) The eligibility criteria for Medication Therapy Management (MTM) programs, and
2) The removal of immunosuppressants from the drug categories or classes of clinical concern.

AHA strongly supports the proposed MTM program changes; the revised definitions for "multiple chronic diseases" and "multiple Part D drugs" and the lowered annual cost threshold will significantly expand patient access to these valuable programs, and the new requirement that plan sponsors develop effective outreach strategies will help ensure that all MTM-eligible beneficiaries can access these services. We are also pleased by the Agency's decision to expand the list of core diseases to include additional forms of cardiovascular disease (CVD). We do, however, request that CMS clarify that Medicare beneficiaries with two or more forms of CVD would meet the "multiple chronic diseases" requirement even though CMS has proposed placing all forms of CVD under a single "cardiovascular disease" umbrella group.

We also request that CMS reconsider its proposal to remove immunosuppressants from the drug categories or classes of clinical concern. Removing immunosuppressants from the list of protected classes could threaten patient access to these lifesaving medications and result in poor health outcomes, increased risk for graft failure, and increased long-term costs. Because immunosuppressant drugs are generally not interchangeable and must

be selected based on an individual transplant recipient's risk factors and rejection history, health care providers must have access to all immunosuppressive drugs. To ensure patient access, CMS should withdraw its proposal and keep immunosuppressants on the list of drug categories or classes of clinical concern.

We expand on these comments below.

Medication Therapy Management Program Under Part D

According to the proposed rule, CMS is concerned that participation in MTM programs is very low, with eligibility rates at less than 8% in 2011.[1] To increase participation, the Agency has proposed revising the eligibility criteria for Medicare beneficiaries. The new criteria would lower the thresholds a beneficiary must meet in order to qualify. Beneficiaries with two or more chronic diseases, taking two or more Part D drugs, and at least $620 in annual drug costs would now be eligible. This is a significant improvement from the existing criteria which allow plans to require beneficiaries to have three or more chronic diseases, at least eight Part D drugs, and $3,144 in annual drug expenses.

We strongly welcome these proposed changes. Based on our review of the evidence, we believe that medication therapy management can improve medication adherence and the quality of prescribing while maintaining or reducing overall health care costs, particularly among patients with cardiovascular conditions. We believe the changes the Agency has proposed will expand and broaden that impact. If finalized, the proposed rule could expand MTM services to more than half of all Medicare Part D beneficiaries, many with cardiovascular disease.

Multiple Chronic Diseases

We applaud CMS for redefining "multiple" in the first criterion as two or more chronic diseases. According to 2013 data, nearly 82% of Medicare Part D plans developed MTM programs that targeted beneficiaries with at least three chronic conditions – the maximum number a plan can require, while only 18% targeted beneficiaries with as few as two chronic conditions.[2] Requiring plans to lower the threshold to two or more diseases will expand participation significantly and we are pleased with this change. We would, however, prefer if the threshold was lowered even further to include beneficiaries with a single costly disease.

We understand that based on current statute, CMS is unable to include patients with one chronic condition. For this reason, we have worked with stakeholders to introduce the *Medication Therapy Management Empowerment Act of 2013* (S.557/H.R.1024), which would allow beneficiaries with a single costly chronic condition – like hypertension or heart failure – to be eligible for MTM services. Just one chronic condition can have a major health impact. For example, it is estimated that 46,000 deaths may be avoided each year if 70% of patients with hypertension were treated to goal.[3] Furthermore, reducing average population systolic blood pressure by only 10 mmHg could reduce stroke by 41%, coronary heart disease by 22%, and cardiovascular disease

[1] 79 FR at 1947

[2] CMS, 2013 Plan MTM Program Eligibility Information, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html.

[3] Valderrama AL, Gillespie C, King SC, George MG, Hong Y, Gregg E. Vital Signs: awareness and treatment of uncontrolled hypertension among adults- United States, 2003-2010. MMWR. 2012; 61:703-9

mortality by 25%.[4] Yet the research shows that approximately 50% of patients diagnosed with hypertension who have been prescribed medications stopped taking them within one year of the initial prescription.[5] Although we appreciate the change to two chronic conditions, we intend to continue to advocate for the passage of S.557/H.R.1024 in order to ensure that a greater number of Medicare beneficiaries receive access to MTM services.

In addition to lowering the number of chronic diseases, CMS has proposed revising the list of core diseases that plan sponsors must target when designing their MTM programs. The Agency intends to combine hypertension and congestive heart failure under the umbrella of "cardiovascular disease", which would also encompass acute myocardial infarction, cerebral hemorrhage and effects of stroke, vascular disease, specified heart arrhythmias, and hypertensive heart disease. We strongly support the inclusion of these other forms of CVD in the list of core chronic diseases. However, we are concerned that grouping multiple forms of CVD under one umbrella category could have unintended consequences. Plan sponsors could argue that beneficiaries with two forms of CVD, such as hypertension and heart failure, do not qualify for MTM services because they have <u>one</u> disease – cardiovascular disease – rather than recognizing each form of CVD as a separate, qualifying condition. We do not believe this was the Agency's intent. Beneficiaries with multiple forms of CVD, who often juggle multiple medications, could benefit greatly from a MTM program. This would be especially important when the cardiovascular disease involved two different organs or systems, such as the patient with a previous stroke and heart failure, or the patient with peripheral vascular disease and coronary artery disease. There are separate clinical practice guidelines for each of these CVD conditions, and the complexity of having more than one is significant. We therefore urge CMS to clarify in the final rule that patients with two forms of CVD would qualify as having multiple diseases and meet the eligibility criteria for MTM services.

We also recommend that CMS further expand the forms of CVD that are included under the proposed "cardiovascular disease" umbrella. This category should also include congenital heart disease, valvular heart disease, pulmonary hypertension, ischemic (coronary) heart disease, rheumatic heart disease, and atherosclerosis. These additions will help the cardiovascular disease umbrella group better reflect the many forms of this disease.

Finally, we request that CMS use the term "heart failure" rather than "congestive heart failure" in the cardiovascular disease listing. This change would recognize that they are multiple types of heart failure (left-sided systolic, left-sided diastolic, right-sided, congestive) and encourage plan sponsors to focus on patients with any type of heart failure, not just congestive heart failure.

<u>Multiple Part D Drugs</u>

CMS is also proposing to change the second criterion, again redefining "multiple" as two or more covered Part D drugs. This perhaps has been the most restrictive requirement for CVD patients. Approximately 60% of Medicare Part D plans set eight Part D drugs as the minimum for eligibility.[6]

[4] Law MR, et al . Use of blood pressure lowering drugs in the prevention of cardiovascular disease: meta-analysis of 147 randomized trials in the context of expectations from prospective epidemiological studies. BMJ: 2009;338:b1665

[5] Vrijens B, Vincze G, Kristanto P, Urquhart J, Burnier M. Adherence to prescribed antihypertensive drug treatments: longitudinal study of electronically compiled dosing histories. *BMJ*. 2008;336:1114 –1117.

[6] CMS, 2013 Plan MTM Program Eligibility Information, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html.

Moreover, nearly 66% of Medicare Part D plans require that in order for a beneficiary to be eligible, only drugs specific to the chronic condition can be considered, while a quarter allow any Part D drug to qualify.[7] We believe that any Part D drug should qualify and we are pleased that CMS has included both of these changes in the proposed rule.

Annual Cost Threshold

CMS has also proposed changing the annual drug cost threshold from $3,144 to $620. Since many brand name drugs have gone off-patent and new generic drugs are available, the previous cost threshold did not accurately reflect the average beneficiaries' cost. We are encouraged by this proposed change and believe that a significant number of CVD beneficiaries will now be eligible as a result.

Plan Outreach Strategies

We share the concern raised by CMS regarding low enrollment in MTM programs by special populations of beneficiaries, including those with limited English proficiency or who belong to a racial or ethnic minority group. We concur with CMS's decision to interpret section 1960D-4(c)(2)(D) of the Act as requiring Part D sponsors to establish effective outreach strategies for all beneficiaries – including all at-risk populations.

To improve enrollment in MTM programs, CMS must encourage plans to develop a multifaceted outreach strategy. As the Agency is aware, recent research has shown that high-performing MTM programs leverage multi-pronged and persistent efforts to recruit Medicare beneficiaries to participate. Successful plans also use a diverse set of communication tools, such as person-to-person interactions, phone calls, emails and community contact, to ensure that interventions are appropriate and are ultimately implemented by the patient. All plan sponsors should be strongly encouraged to adopt these tactics. Plans should also explore the Agency's recommendation to analyze fill data to identify pharmacies that at-risk beneficiaries frequent.

We also recommend that CMS conduct further research to identify best practices and share the results with all plan sponsors.

We are optimistic that the proposed changes to the MTM eligibility criteria will increase both the number of eligible beneficiaries and the utilization of MTM services. By clarifying and streamlining the eligibility criteria, the Agency has taken an important step toward eliminating the variation in program design that has, to date, restricted access to these valuable services, while still providing plans the flexibility to innovate based on their specific patient population. We look forward to seeing CMS implement these changes and we urge the Agency to closely monitor how plans design their MTM programs to determine if additional changes are necessary.

Drug Categories or Classes of Clinical Concerns and Exceptions

As noted above, CMS intends to remove immunosuppressants from the list of categories or classes of clinical concern. If this change is finalized, Medicare Advantage and Part D Prescription Drug Plans would no longer have to include all or substantially all of these drugs on their formularies.

[7] Ibid. 17.

According to the proposed rule, CMS proposed this change after reviewing treatment guidelines for organ transplant and finding that "treatment guidelines recommend subclasses of drugs rather than specific, individual drugs."[8] Because the treatment guidelines refer to drug subclasses instead of specific drug names, the Agency determined that coverage of all immunosuppressant drugs is not necessary; instead, coverage of each class or subclass is sufficient. We disagree with this assessment.

Treatment guidelines are intended to provide health care providers with guidance based on the best scientific evidence available, but the actual drug or combination of drugs that is most appropriate for an individual may vary based on patient-specific factors and the clinical scenario. With transplant drugs in particular, there are a number of factors that have to be taken into consideration, including the type of transplant, patient's race and gender, comorbidities, an individual patient's tolerability to a given drug, and history of frequency and severity of rejection. Providers and patients must also consider how to balance the risk of organ rejection with the risk of infection due to a suppressed immune system and the need to minimize toxicity or cancer risk associated with individual agents. For transplant patients, there is no "one size fits all" approach; no one immunosuppressive regimen will work for every patient. Thus, we caution the Agency against assuming that the lack of a specific drug name in a treatment guideline indicates that any drug within the recommended drug class or subclass may be used.

We also note that the Agency's review of treatment guidelines appears to have been limited. Only one treatment guideline on liver transplant was specifically referenced by the CMS Protected Class Review Panel. According to the review panel, that guideline document recommended the use of multiple immunosuppressants from different drug classes, but did not recommend specific drugs within each class. However, we are aware that other treatment guidelines, such as the KDIGO Clinical Practice Guideline for the Care of Kidney Transplant Recipients[9] do make specific drug recommendations. While other guidelines such as the ISHLT Guidelines for the Care of Heart Transplant Recipients include a mixture of drug subclass and drug specific recommendations depending on the clinical scenario.[10] These guidelines appear to counter the Agency's assertion that treatment guidelines only recommend drug classes or subclasses and do not recommend one drug over another in the same class. Yet as discussed above, even when a guideline recommends a specific drug or a "standard treatment", some patients will have unique needs and require different treatment options; hence the need for access to all immunosuppressive therapies.

We also have concerns with the economic rationale CMS provides for removing immunosuppressants (as well as antidepressants and antipsychotics) from the protected class list. According to the Agency, requiring plan sponsors to cover all or substantially all of these drugs "substantially limits Part D sponsors' ability to negotiate price concessions."[11] CMS anticipates that removing this requirement will lead to increased price competition and may result in future savings for the Part D program and for Medicare beneficiaries. While we

[8] FR 79 at 1945.
[9] See http://www.kdigo.org/clinical_practice_guidelines/pdf/TxpGL_publVersion.pdf.
[10] See http://download.journals.elsevierhealth.com/pdfs/journals/1053-2498/PIIS105324981000358X.pdf.
[11] FR 79 at 1937.

understand that economic factors play a role in the development of formularies, we do not believe they should be a primary factor.[12]

We also are concerned that this change may not result in the savings CMS anticipates, but will actually lead to increased costs for the Medicare program and Medicare beneficiaries. If transplant recipients are not properly managed with the appropriate immunosuppressive therapy, they may incur unnecessary and costly physician visits and hospitalizations, require expensive escalated anti-rejection therapies in the hospital setting such as intravenous immunoglobulins, plasmapheresis, and photopheresis, or need a replacement transplant due to graft failure, all of which will increase costs to the Medicare program. Preserving patient access to all immunosuppressant agents may prove to be more cost-effective in the long run.

Finally, we do not believe that providing coverage for all immunosuppressant therapies would be too difficult or costly for plan sponsors. Unlike drug therapies for conditions such as blood pressure, cholesterol, or diabetes where there are multiple options to consider, the number of immunosuppressant therapies on the market is relatively small. In addition, the number of Medicare beneficiaries who receive a transplant, and therefore will require these drugs, is also small; for example, there are only 2,000 hearts transplanted in the United States each year, on average. The limited patient population and limited number of available therapies will help contain the cost of providing coverage for all of these drugs, especially since several of the more common immunosuppressive agents are already available in less costly generic form.

We urge CMS to withdraw its proposal and to maintain immunosuppressants on the list of protected classes. Immunosuppressive therapy is the lifeline for transplanted patients; without proper immunosuppressive therapy, patients are at high risk for graft failure, organ rejection and death. Because immunosuppressant drugs are not interchangeable, and they are prescribed in combinations tailored to meet the needs of each individual patient, health care providers and their patients must have access to all immunosuppressive therapies. A lapse in access to these therapies in any organ transplant recipient is a major risk for rejection and its associated organ failure complications including death. We should prevent this consequence at all costs.

Thank you for consideration of our comments. If you have any questions, please contact Susan K. Bishop, Senior Advisor of Regulatory Affairs, at (202) 785-7908 or susan.k.bishop@heart.org.

Sincerely,

Mariell Jessup, MD, FAHA
President
American Heart Association

[12] American Heart Association Statement on Formularies. See http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_435977.pdf.