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May 7, 2004

Carolyn M. Clancy, M.D.
Director, Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

Re: Docket 2004S-0170; Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 1013: Suggest Priority Topics for Research

Dear Dr. Clancy:

On behalf of its 22.5 million volunteers, the American Heart Association (AHA) is pleased to submit the following recommendations in response to the April 23, 2004 notice in the *Federal Register* seeking comments on priorities for research, demonstration and evaluation projects to support and improve Medicare, Medicaid and the State Child Health Insurance Program (SCHIP). Specifically, these recommendations pertain to the request for recommendations by May 7th involving pharmaceutical therapies.

As discussed below, AHA urges the Secretary to pursue the issue of medication adherence under this new statutory authority. Improving the current medication adherence rates in the United States could have a profound positive impact on patient outcomes.

Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the Secretary (acting through the Director of the Agency for Healthcare Research and Quality) to develop priorities for conducting and supporting research regarding: 1) outcomes, comparative clinical effectiveness and appropriateness of health care items and services; and 2) strategies for improving

the efficiency and effectiveness of Medicare, Medicaid and the State Children's Health Insurance Program (SCHIP).

Under Section 1013 of the MMA, the Secretary is directed to focus on items and services that may significantly improve the prevention, treatment or cure of chronic diseases and conditions (including chronic conditions) that impose high costs on patients and the health care system.

The Need to Study and Promote Medication Adherence

Heart disease and stroke are the first and third leading causes of death in the United States. The AHA and other organizations in the medical community have established evidence-based guidelines that provide clear direction regarding how to significantly reduce the risk of heart disease and stroke. Many of these guidelines involve the use of medication therapies, including prescription drug regimens that lower blood pressure or address abnormal blood cholesterol and lipid levels.

Unfortunately, the vast majority of investigators also agree that medication adherence rates in the United States remain unacceptably low across a wide range of drug categories and patient populations.¹ This problem results in significant and preventable mortality and morbidity each day. From a financial perspective, the direct and indirect costs to society of non-adherence in the United States are estimated to exceed \$177 billion each year.²

In general, when medication adherence rates are referenced, the figures often merely refer to the consumption rate of prescription drugs for persons who are prescribed medications. In fact, there are a number of other factors to consider in assessing and measuring medication adherence, including:

- ~~✎~~ not all persons who could benefit from a particular medication are prescribed that medication;
- ~~✎~~ a sizable percentage of persons who receive prescriptions never fill them;

¹ Miller NH, Hill M, Kottke T, Ockene I. The Multilevel Compliance Challenge: Recommendations For A Call To Action. *Circulation*. 1997;95:1085-1090; Avorn J, Monette J, Lacour A, Bohn RL, Monane M, Mogun H, LeLorier J. Persistence Of Use Of Lipid-Lowering Modifications: A Cross-Sectional Study. *JAMA*. 1998;279:1458-1462; Wang TJ, Stafford RS. National Patterns And Predictors Of Beta-Blocker Use In Patients With Coronary Artery Disease. *Arch Intern Med*. 1998;158:1901-1906; Hoerger TJ, Bala MV, Bray JW, Wilcosky TC, LaRosa J. Treatment Patterns And Distribution Of Low-Density Lipoprotein Cholesterol Levels In Treatment-Eligible United States Adults. *Am J Cardiol*. 1998;82:61-65; Simons LA, Levis G, Simons J. Apparent Discontinuation Rates In Patients Prescribed Lipid-Lowering Drugs. *Med J Aust*. 1996;164:208-211; Andrade SE, Walker AM, Gottlieb LK, Hollenberg NK, Testa MA, Saperia GM, Platt R. Discontinuation Of Antihyperlipidemic Drugs—Do Rates Reported In Clinical Trials Reflect Rates In Primary Care Settings? *N Engl J Med*. 1995;332:1125-1131; Bluml BM, McKenny JM, Cziraky MJ. Pharmaceutical Care Services and Results In Project ImPACT: Hyperlipidemia. *J Am Pharm Assoc*. 2003;40:157; Simpson E, Beck C, Richard H, Eisenberg MJ, Pilote L. Drug Prescriptions After Acute Myocardial Infarction: Dosage, Compliance, and Persistence. *Am Heart J*. 2003;145:438-444.

² Ernst FR, Grizzle AJ. Drug Related Morbidity and Mortality: Updating the Cost-of-Illness Model. *J Am Pharm Assoc*. 2001;41:192-199.

~~is~~ a significant number of patients who begin taking a prescription medication for a chronic condition do not persist in taking the medication over time; and
~~is~~ even for those patients who regularly take one or more prescription medications, and even for those who take all of their prescribed medications correctly, many are not attaining the full clinical goals of the therapy (for example, a patient taking medication for hypertension may not be achieving the desired systolic and diastolic blood pressure levels – in this area in particular, under-prescribing appears to be a problem.)

An Important Opportunity under Medicare Part D

The MMA provisions establishing the new Medicare Part D prescription drug benefit include a requirement that all prescription drug plan sponsors establish a medication therapy management program. According to the statute, the program is intended to ensure the appropriate use of Medicare Part D prescription drugs to optimize therapeutic outcomes and reduce risk of adverse events. The statute explicitly states that medication therapy management programs may include elements that promote “increased enrollee adherence with prescription medication regimens.”³

The programs must target Part D-eligible individuals who have multiple chronic conditions, are taking multiple covered Part D drugs and are identified as likely to incur high prescription drug costs. The statute specifically identifies five chronic conditions as examples, three of which are related to cardiovascular disease: hypertension, hyperlipidemia and congestive heart failure.

Section 1013 of the MMA provides an important opportunity to study the potential effectiveness of the various approaches to medication adherence by collecting meaningful data and evaluating alternative approaches. This provision is an opportunity to improve the health care needs of America’s seniors, as well as to take steps that could save the Medicare program significant funds in the future.

The American Heart Association strongly urges the Secretary to study the effectiveness of medication adherence programs as a means of improving the quality, effectiveness and efficiency of health care delivered through the Medicare Part D prescription drug program. Studying medication adherence initiatives will help ensure a meaningful Part D prescription drug benefit. Improving medication adherence may result in a more efficient use of Medicare Part D prescription drug therapies for beneficiaries with chronic diseases. The goals of improving patient outcomes and decreasing costs are consistent with Congress’ intent in enacting Section 1013.

* * * *

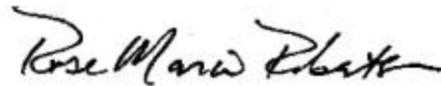
We would be pleased to assist the Secretary in developing and providing guidance on implementing (do we want to say implementing – that seems to imply that we would take federal money) studies or projects investigating the issue of medication adherence

³ MMA § 101, creating Social Security Act § 1860D-4(c)(2).

or other issues involving cardiovascular disease and stroke. Such an initiative would have broad application to other public and private health insurance programs, including Medicaid and SCHIP.

If we can provide any assistance in this or other areas, please do not hesitate to contact us. You may contact Rich Hamburg at 202-785-7909 (richard.hamburg@heart.org) or Renee Smith at 202-785-7913 (renee.smith@heart.org) with any questions regarding this issue. We look forward to working with you and your colleagues.

Sincerely,

A handwritten signature in black ink that reads "Rose Marie Robertson". The signature is written in a cursive style with a large initial "R" and "M".

Rose Marie Robertson, MD, FAHA, FAHA
Chief Science Officer
American Heart Association