American Heart Association | American Stroke Association

February 21, 2013

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-2334-P
PO Box 8016
Baltimore, MD 21244-8016

RE: File Code CMS-2334-P (Medicaid Essential Health Benefits, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing)

Dear Secretary Sebelius:

On behalf of the American Heart Association (AHA), including its American Stroke Association (ASA) division, and more than 22 million volunteers and supporters, we appreciate this opportunity to submit comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule, "Essential Health Benefits in Alternative Benefit Plans, Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and Children's Health Insurance Program (CHIP), and Medicaid Premiums and Cost Sharing."

The AHA/ASA has long advocated for all Americans to have access to affordable, adequate, quality health insurance coverage, regardless of their source of coverage. We also have set an ambitious goal to prevent as many heart attacks and strokes as possible, as well as the risk factors for these conditions. Although this proposed rule covers many important topics, we have focused our specific comments below on a number of issues that we believe are particularly critical to people with heart disease or stroke or needed to prevent these conditions:

Children's Health Insurance Program Changes – CHIP Waiting Periods (§457.805)

CHIP is an important source of health coverage for children born with congenital heart disease and stroke. We are pleased the proposed rule recognizes the need to revise the use of waiting periods in CHIP. Beginning in 2014, children as well as adults will be required to have coverage under the Affordable Care Act's (ACA) minimum coverage requirement. Moreover, we believe the vast majority of parents want the financial security and peace of mind that health insurance for their children provides. The ACA prohibits the use of waiting periods longer than 90 days in group and non-group coverage, and we do not believe Congress intended for children eligible for CHIP to be the only population still subject to excessive waiting periods. For these reasons, AHA believes waiting periods are no longer needed in CHIP and supports eliminating the permissibility of waiting periods starting in 2014.

If HHS believes waiting periods will still be necessary in certain circumstances, AHA supports the proposal in the rule to prohibit CHIP waiting periods that exceed 90 days. This proposed revision would align the use of waiting periods in CHIP with those permitted in the group market. We also support HHS's proposal that all states waive the imposition of waiting periods in certain situations that may result in a child becoming eligible for CHIP coverage, such as an employer ending the offer of coverage for dependents or a child losing coverage due to death or divorce of a parent. This proposal will help to ensure consistency in enrollment and continuity of coverage for children.

Essential Health Benefits in Alternative Benefit Plans

The recent proposed rule requires that Medicaid benchmark plans, now called Alternative Benefit Plans, cover all 10 categories of Essential Health Benefits (EHB). In general, we believe that this requirement, combined with other protections provided for Medicaid enrollees, will go a long way toward ensuring that patients in Medicaid will have adequate health care coverage.

However, just as we commented with respect to the defining of EHBs in private health insurance, we continue to be concerned that clear definitions of each of the 10 categories has not been provided. We believe HHS should precisely define the scope and services within each of the 10 benefit categories to ensure that the covered services are at a minimum the same and provide a level of guaranteed coverage. This type of additional definition is necessary to ensure that there is adequate coverage within a category and that there is balance between the categories, as required by the law. Without clear definitions, it will be impossible to determine if Alternative Benefit Plans are equivalent to the EHB package or to ensure that they comply with the ACA.

We also have the following comments about the application of specific categories of Essential Health Benefits in Medicaid:

<u>Defining Habilitative Services for Medicaid (§440.347(d))</u>

HHS has requested comments about how a habilitation benefit should be defined for Medicaid. Access to appropriate habilitative and rehabilitative therapy is a critical element of care that minimizes disability and promotes the productivity of patients with many different conditions. This category of benefits is particularly important to stroke patients, both adults and children.

We recognize that many states have been struggling with how to provide for this coverage in a way that meets the care and treatment needs of people living with chronic conditions and disabilities. In its report, "Essential Benefits: Balancing Coverage and Cost," the Institute of Medicine found that, while habilitation services are often not covered by the typical employer plan today, the same is not true for Medicaid programs. Medicaid programs already offer comprehensive coverage of habilitative services for children under the Early and Periodic Screening, Diagnosis and Treatment (ESPDT) benefit and they also provide coverage of habilitation services for individuals with disabilities, particularly developmental disabilities. As a matter of fact, the Medicaid statute includes a definition of habilitation. Therefore, there is no need for states to separately define habilitative services for Medicaid for Alternative Benefit Plan purposes; in fact, the IOM recommended that HHS look to state Medicaid programs as a guide for defining what habilitation services should be covered under the Essential Health Benefits.

Given this history, we recommend HHS incorporate a minimum model habilitative benefit into Section 440.347(d) for adoption by states. For a definition, HHS should consider Medicaid's long

history with habilitation[1], as well as the National Association of Insurance Commissioners' (NAIC) definition of habilitative services: "health care services that help a person keep, learn, or improve skills and functioning for daily living. Examples include therapy for a child who isn't walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings" (NAIC Glossary of Terms for the ACA). HHS's definition can then serve as a floor for states to cover habilitation services under their Alternative Benefit Plans using the same definition they currently use for traditional Medicaid benefits. This approach will ensure continuity in services and eliminate the need for states to have multiple definitions within Medicaid.

When establishing minimum federal standards for a habilitative benefit, HHS should require that states follow these parameters:

- Cover habilitation services and devices which help a person keep, learn or improve skills and functioning, as defined by the HHS Summary of Benefits and Coverage regulation;
- Cover habilitation separate and distinct from rehabilitation. For example, the plan cannot substitute rehabilitation for habilitation or apply only a single visit limit to both benefits.[2] Each benefit must be based upon medical necessity, and not be subject to an arbitrary cap on the number of visits;
- Cover habilitative services without age restrictions. Some children will continue to need habilitative services as they move into adulthood to retain the skills they acquired as a child; and
- Cover habilitative devices without arbitrary restrictions and caps that limit the effectiveness of the benefit;

Coverage of Preventive Services (§440.347(a) and §440.130)

Preventing disease before it occurs is our best opportunity for reducing the long-term health care costs of cardiovascular disease. For this reason, the AHA/ASA has strongly supported policies and efforts to improve access to evidence-based preventive services that help keep people healthy. Research shows that even small co-pays can significantly deter people from getting screenings. For example, one study showed that Medicaid beneficiaries subject to a $1 co-pay per service used fewer physician services and received fewer preventive services, compared to those not subject to the co-pay.[3]

Unfortunately, however, the rule as proposed would permit barriers to life-saving screenings by allowing for the imposition of co-pays for preventive services in Alternative Benefit Plans. We believe that it was not the intent of Congress for the lowest income Americans to pay co-pays for their preventive care, while those with higher incomes are able to receive their preventive care at no cost under Section 2713 of the ACA. This proposed rule creates an untenable situation in which patients with non-grandfathered private insurance and Medicare do not have to pay a co-pay for

[1] The Medicaid program defines habilitation as "services designed to assist individuals in acquiring, retaining and improving the self-help, socialization, and adaptive skills necessary to reside successfully in home and community based settings." Social Security Act, Section 1915 3(c)(5)(A).

[2] Numerous states appear to have base-benchmarks that apply a single, existing rehabilitation visit limit to both the rehabilitation and habilitation benefit. For the majority of states choosing this option, this has meant a 20-visit limit for PT and OT combined whether it is rehabilitation or habilitation. This so severely limits the availability of the therapies and would discourage enrollment by anyone in need of these medical services.

[3] Hudman, J. & O'Malley, M. (2003). Health insurance premiums and cost-sharing: findings from the research on low-income populations. The Kaiser Commission on Medicaid and the Uninsured. Available at: http://www.kff.org/kcmu.

their preventive services, while many of the poorest, most vulnerable Americans would have to pay for their preventive screenings.

We ask that CMS clarify that all of Section 2713 of the ACA, including the requirement that preventive services be provided with no cost-sharing, apply to the Essential Health Benefits in the Alternative Benefit Plans. Without such clarification, millions of our most vulnerable Americans may forgo life-saving preventive screenings, and disparities in heart disease and stroke mortality and morbidity will continue to persist.

We also encourage CMS to provide greater definition with respect to what preventive services states are required to cover in order to meet the Essential Health Benefits requirement. In our efforts to determine what preventive benefits state Medicaid programs currently cover, it was often very difficult to find out specifically what preventive health services are covered and what the scope and limits on this coverage may be. For instance, while all or virtually all states seem to provide coverage for medically necessary cholesterol tests, it is less clear whether states are providing such coverage routinely for screening purposes.

Current coverage of tobacco cessation further helps illustrate our point about why further definition of preventive services is needed to ensure that comprehensive services are available. Nearly one-third of the estimated 443,000 deaths each year that are caused by smoking-related illnesses are CVD-related. Quitting tobacco use leads to increased employee productivity, less disability and chronic disease, and less medical expenditures. Increasing the number of successful attempts to stop tobacco use will have an important effect on health and health care costs. Tobacco users vary in what tobacco products they use, how much, how often, and in what coexisting medical conditions they may have. When quitting, they need access to a range of treatments, both medication and counseling, to find the most effective tools that work for them. The covered benefit should include all over-the-counter (OTC) and prescription medications approved by FDA (including combination use) and multiple face-to-face counseling sessions conducted by a qualified health professional. Given that people on Medicaid currently smoke at rates significantly higher than the population overall (36.5 percent versus 22.7 percent), it is critically important that Medicaid beneficiaries have access to the full range of cessation services.

Despite the evidence that supports coverage of tobacco cessation and the fact that the USPSTF recommendation covers both pharmacotherapy and counseling for tobacco cessation, a 2011 report from the American Lung Association reveals continued unevenness in coverage of tobacco cessation services by state Medicaid programs. For example, two states, Alabama and Georgia, do not cover any tobacco cessation treatments for all Medicaid enrollees. Nine states cover all seven medications but no counseling.[4] Without greater specificity from CMS about what tobacco cessation and other preventive services states are required to cover in their Alternative Benefit Plans, it is unlikely that Medicaid enrollees will actually receive the full range of preventive services recommended by the U.S. Preventive Services Task Force.

Finally, we support the clarification in Section 440.130 that defines preventive services as those "*recommended by* a physician or other licensed practitioner." This revision is an important step towards ensuring that Medicaid and CHIP beneficiaries have access to available, recommended preventive services. We were also pleased to see that a February 1, 2013 CMS letter to State Medicaid Directors confirms our interpretation of this proposed revision. We strongly urge you to preserve this important revision in the final rule.

[4] American Lung Association. "Helping Smokers Quit: Tobacco Cessation Coverage 2011." December, 2011. Accessed online at: http://www.lung.org/assets/documents/publications/smoking-cessation/helping-smokers-quit-2011.pdf.

Prescription drug coverage and cost-sharing

The proposed rule also ensures that patients in Alternative Benefit Plans have access to a comprehensive formulary of drugs. Access to the full spectrum of prescriptions is especially important for patients with complex and chronic diseases like heart disease and stroke. The rule requires that Alternative Benefit Plans follow the same requirements and include all drugs that participate in the Medicaid drug rebate program. We applaud CMS for ensuring that the formulary for the Alternative Benefit Plans covers the medicines necessary for patients with chronic diseases.

However, we are concerned with some of the cost-sharing levels that may be imposed on individuals not exempt from these costs. The proposed rule allows a 20 percent coinsurance on non-preferred prescription drugs for those individuals who are above 150 percent of the Federal Poverty Level (FPL). Although the calculation of the coinsurance is restricted to the price paid by the agency through the Medicaid rebate program, a 20 percent coinsurance for some lifesaving drugs may still be too high. Further, the rule permits the co-pay for non-preferred drugs to increase to up to $8 for those individuals under 150 percent FPL. The average adult with heart disease fills 30 prescriptions per year, and for low income individuals these co-pays could quickly add up to unaffordable amounts. According to a 2010 study, low-income Americans are at particularly high risk of cost-related non-adherence to their prescription medicines. More than one-third (34%) of low-income Americans in 2007 reported not filling prescriptions or skipping doses during the past 12 months.[5] Many of the prescriptions used by heart disease patients are to treat risk factors such as high blood pressure and high cholesterol, which if not controlled can lead to more costly heart attacks, strokes and other adverse events.

Further, the proposed rule continues to allow states to impose arbitrary and inadequate service limits on prescriptions drugs (i.e., a limit to the number of prescriptions per month a patient may have in the program). We understand that such utilization management methods provide states with an ability to manage their pharmaceutical spending. However, if these types of limits are permitted to continue in the final rule, we suggest requiring the states to provide an emergency appeals process for patients.

Medicaid Premiums and Cost-Sharing

The Secretary's proposal to simplify the rules for nominal cost sharing will help eliminate confusion for beneficiaries and providers and reduce the administrative burden on states. For those services where nominal co-payments are appropriate, AHA generally supports the proposed move to flat dollar amounts for maximum allowable cost-sharing, in lieu of percentages.

The proposed rule does not propose changes to the current cost-sharing rules for institutional (i.e. inpatient hospital) care but seeks comments on whether the maximum allowable cost sharing should be revised. We are concerned about the current rules, which allow cost sharing for institutional care of up to 50 percent of the cost for the first day for individuals with incomes below 100% of FPL. For individuals with family income between 101 percent and 150 percent of FPL, cost-sharing for an inpatient stay can be even higher. Although we recognize that a beneficiary's total cost-sharing is capped at 5 percent of the family's monthly or quarterly income, these cost-

[5] Morgan S and Kennedy J. "Prescription Drug Accessibility and Affordability in the United States and Abroad." The Commonwealth Fund; June, 2010. Accessed online at: http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2010/Jun/1408_Morgan_Prescription_drug_accessibility_US_intl_ib.pdf.

sharing levels create a significant financial burden on individuals and families with few resources to pay their share of costs and can be significantly higher than the cost-sharing that is applicable in private insurance plans. We support the option under consideration of applying a flat copayment for inpatient services and suggest $50 as an appropriate maximum level.

Cost Sharing for Emergency Department Services (§447.54)

We are deeply concerned that allowing state Medicaid programs to impose co-payments on Emergency Department (ED) services – even for those that turn out to be non-emergent -- will deter patients from seeking emergency care when needed. As you are well aware, heart attack and stroke are serious, potentially life-threatening conditions that require immediate emergency care. The good news is that, thanks to tremendous advances in treatment, prompt emergency care can greatly reduce long-term disability and even death. To that end, we devote a great deal of resources to educating the general public about the warning signs of heart attack and stroke and encouraging them to call 9-1-1 immediately if they or someone nearby is experiencing any of these symptoms. Likewise, a number of HHS agencies have also launched similar initiatives to urge individuals to learn the warning signs of heart attack and stroke and call 9-1-1 if they think they may be having a heart attack or stroke, such as the Office of Women's Health's "Make the Call, Don't Miss a Beat" campaign[6] and the National Institute of Neurological Disorders and Stroke's "Know Stroke. Know the Signs. Act in Time." campaign[7].

When patients do experience a symptom of a heart attack or stroke, such as acute chest pain, shortness of breath, a sudden, severe headache, or difficulty seeing, they should not try to self-diagnose their condition or worry that they can't afford to seek care. Instead, they must have access to quick diagnosis and treatment in the ED. In some cases, these patients may ultimately be diagnosed with a non-emergency medical condition, but they should not be penalized because they followed the instructions of public campaigns and sought emergency treatment.

The imposition of co-payments on ED services seems intended, at least in part, to reduce non-urgent use of the emergency room. In reality, however, only a small percentage (10%) of ED visits in 2007 were considered non-urgent, according to Centers for Disease Control and Prevention data.[8] While non-elderly Medicaid beneficiaries were more likely to have had at least one ED visit in a 12-month period, compared to their counterparts who had private insurance or were uninsured, this disparate use may be explained by the fact that Medicaid beneficiaries are among the sickest individuals in our health care system.

In addition, research suggests such efforts may not result in the intended cost-savings. While there is mixed evidence on whether co-payments for the population generally result in less utilization of services without an increase in unfavorable outcomes, research does suggest that low-income individuals served by Medicaid are more price sensitive compared to others, more likely to go without needed care, and more likely to experience longer term adverse outcomes.[9] A study of enrollees in Oregon's Medicaid program demonstrated that implementation of a co-pay on

[6] See the Office of Women's Health at http://www.womenshealth.gov/heartattack/.
[7] See the NINDS website at http://stroke.nih.gov/.
[8] Garcia TC, Bernstein AB, Bush MA. Emergency department visitors and visits: Who used the emergency room in 2007? NCHS data brief, no 38. Hyattsville, MD: National Center for Health Statistics. 2010. Accessed online at: http://www.cdc.gov/nchs/data/databriefs/db38.htm.
[9] See for example: Chernew M, Gibson TB, Yu-Isenberg K, Sokol MC, Rosen AB, Fendrick AM. Effects of increased patient cost sharing on socioeconomic disparities in health care. J Gen Intern Med. 2008. Aug; 23(8):1131-6. Ku, L and Wachino, V. "The Effect of Increased Cost-Sharing in Medicaid: A Summary of Research Findings." *Center on Budget and Policy Priorities* (July 2005), available at http://www.cbpp.org/5-31-05health2.htm.

emergency services resulted in decreased utilization of such services but did not result in the intended cost savings because of subsequent use of more intensive and expensive services, suggesting the policy may cause inappropriate delays in needed care.[10]

CMS seeks comment on approaches to successfully distinguish between emergency and non-emergency services. We strongly support maintaining the use of the "prudent layperson" definition of an emergency. Under this standard, Medicaid is required to cover visits to EDs based on an average person's belief that they may be suffering a medical emergency due to the symptoms they are experiencing, not a final diagnosis. Even if the final diagnosis is not a medical emergency, the individual cannot be charged cost-sharing because they met the prudent layperson standard. We appreciate CMS's acknowledgment in the preamble that chest pain, for example, could easily be considered an emergency condition under the prudent layperson standard. While the prudent layperson standard certainly provides an important level of protection, we remain concerned that more subtle symptoms of heart attack (such as women in particularly frequently experience) or stroke may not be considered to meet the prudent layperson standard. Given the difficulty in distinguishing between emergency and non-emergency services, we oppose the imposition of co-payments for ED care. However, if cost-sharing for non-emergency services is permitted in the final rule, we agree that a CPT code alone is not a sufficient basis for distinguishing between emergency and non-emergency care, and we ask CMS to prohibit this approach.

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Thank you again for the opportunity to share our comments on these issues related to Medicaid and CHIP eligibility, benefits, and cost-sharing. If you have any questions, please feel free to contact Stephanie Mohl, Government Relations Manager, at Stephanie.Mohl@heart.org or 202-785-7909.

Sincerely,

Donna K. Arnett, PhD, BSN, FAHA
President

[10] Wallace NT, McConnell KJ, et al. How Effective Are Copayments in Reducing Expenditures for Low-Income Adult Medicaid Beneficiaries? Experience from the Oregon Health Plan. Health Serv Res. 2008 April; 43(2): 515–530.