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January 30, 2012

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

RE: Essential Health Benefits Bulletin

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 offer our comments on the regulatory approach described in the Essential Health Benefits (EHB) Bulletin (Bulletin) released on December 16, 2011.

An estimated 68 million Americans will obtain insurance coverage that must meet the EHB requirements. In addition, the EHB requirements have implications for the implementation of many other important protections in the Affordable Care Act (ACA), such as the ban on annual dollar limits on EHB services and the establishment of out-of-pocket limits. Therefore, we view the defining of the EHB package as among the most important regulatory tasks required by the ACA. We understand the difficulties you face balancing many competing interests – comprehensiveness of coverage versus cost, the need for certainty for consumers versus states' desire for flexibility, to name just two. We want to share our concerns in order to strike the appropriate balance on these complex issues.

Intended Regulatory Approach

The proposed regulatory approach outlined in the Bulletin allows each state to define EHB services under Section 1302 of the ACA by choosing one benchmark plan from 10 potential plans in four designated categories. AHA believes that deferring the definition of the EHB to the states rather than having a nationally defined set of EHB services is a missed opportunity for several reasons.

First, this approach will make it more difficult to promote value and evidence-based cardiovascular disease (CVD) care to all Americans. A national definition of EHB services would have created a mechanism to promote evidence-based care and compare outcomes across health care providers and health plans throughout the country. We strongly encourage you to strive to promote evidence-based decision-making as part of future rulemaking on the EHB, as recommended by the Institute of Medicine (IOM).

Second, under this approach, it will be much more difficult for consumers to compare plans inside the Exchange with other plans offered by issuers in their state, particularly if the chosen benchmark plan is a type of coverage they are not familiar with. Consumers already have a difficult time comparing the features of different plan options and making informed decisions about coverage. Rather than making this task simpler for consumers as the ACA envisioned, by requiring a national standard set of essential benefits, this approach will mean that consumers will continue to face a confusing array of options. Also, if consumers live in one state and work in another state, the benchmark EHB plan in the state of their employment will be different from the EHB benchmark where they live, creating further confusion and complexity as they try to select the appropriate coverage.

Finally, this approach leaves many questions unanswered. While we understand that additional information and guidance may be forthcoming, we encourage you to provide as much additional clarity as possible through regulation, rather than through guidance, since the latter lacks the force of law. For example, we assume that the benchmark plan that will be chosen is a snapshot of coverage at a date certain; will EHBs change when the underlying benchmark plan changes from year to year? Limits on the number of visits covered for a particular service are common; how will such limits apply to the EHB benchmark? Regulatory action is required to address these issues, and we urge HHS to issue proposed rules as soon as possible.

Four Benchmark Plan Types

We understand HHS's decision to adopt the recommendations of the Institute of Medicine (IOM) regarding state flexibility, but we are very concerned that the intended approach of allowing each state to choose a single benchmark plan from among 10 options will result in significant variations state-to-state. It will also be difficult to assess whether the options for benchmarks are equivalent and adequate in each and every state without more information about what plans meet the benchmark criteria. While we appreciate that HHS has provided some additional information about small group products in each state and nationally available Federal Employees Health Benefits Program (FEHBP) plans, more information is necessary. Specifically, HHS needs to provide a list of the other potential state benchmark plans as well as a comprehensive comparison of the benefits, limitations and exclusions for all of the benchmark options so that the plans can be accurately compared by stakeholders involved in selecting the state benchmark. For example, transplantation services for heart, lung and other organs may be excluded from some benchmark plans, even though the coverage may be evidence-based, medically necessary and crucial for a small number of people.

It is critically important for HHS to ensure that there is an open and transparent process at the state level for choosing the benchmark plan, so that the public can evaluate the benchmarks and serve as fully informed participants in the selection process. The Evidence of Coverage, benefit summaries and other relevant plan documents for the 10 potential benchmark plans should be made available to the public in advance, and the states should conduct open and public meetings to select the benchmark plan. At a minimum, HHS should also publish information about how HHS plans to:

- Ensure that all consumers, employers, health care providers and others can participate in the selection of the benchmark plan in their particular state;
- Assure that the selected benchmark plan provides essential coverage in the 10 designated categories and addresses the needs of diverse and disparate populations;
- Establish a baseline for the benefits and services that must be covered in the EHB plan; and

- Monitor, evaluate, update and revise the 50 state benchmark plans over time based on changes in benefit design, clinical evidence, the standard of care and the availability of effective new treatments.

The Bulletin also requested comments on what the benchmark plan should be in a State that doesn't select one. AHA supports using the FEHBP plan with the largest enrollment as the default benchmark plan for States that don't select a plan. The FEHBP operates in all 50 states and using the FEHBP will facilitate more uniformity in the EHBs offered throughout the country.

Defraying the Cost of Additional Benefits

Since states are required to defray the costs of state-mandated benefits in excess of the EHB for individuals enrolled in a qualified plan in the individual or small group market (Section 1311(d)(3)(B) of the ACA), HHS should evaluate the benchmark approach for calendar years 2016 and beyond and determine whether mandates in the states' EHBs are evidence-based. Benefit mandates that are not evidence-based should be excluded.

We acknowledge that there will be cases where the evidence-based clinical guidelines or recommendations are not clear or where sufficient evidence isn't available to draw a conclusion. In those situations, the HHS Secretary should, at a minimum, set standards rather than leaving these standards to individual states or especially, issuer interpretation. When trustworthy clinical practice guidelines are available that meet the standards set out by the IOM, they should be used to evaluate mandates in the state EHB.

Benchmark Plan Approach and 10 Benefit Categories

HHS has noted that ensuring coverage of all 10 categories of services set forth in section 1302(b)(1) of the ACA is one of the challenges of the benchmark plan approach. While we agree that HHS should assure that every benchmark plan covers the required 10 categories of service, we have concerns about the proposal described in the Bulletin for allowing States to supplement the missing categories using benefits from any other benchmark option or using the default option of the largest plan in the benchmark type for the following reasons:

- It creates a variety of benefit designs when the overall goal is to move toward uniform benefit descriptions by encouraging descriptions that are at least similar in all states.
- It is too complex and will be difficult for the Exchanges and insurers to administer year after year because the benefits will change in the various benchmark plans and as a result, the benefits derived from other benchmark plans may have to be serially modified.
- It will be very difficult for the public to understand.

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 throughout the country in each state's benchmark plan. Because traditional plans do not always categorize their services within the same benefit categories or use the same terminology contained in the ACA, it is unclear how the EHB package could be compared to potential benchmark plans to ensure that it complies with the ACA. This is particularly important for those categories of services that are not common (or for which the terminology is not common) in commercial insurance, such as "habilitative services" and "chronic disease management."

As an alternative for addressing missing categories of services, AHA recommends using benefit language from a FEHBP plan or Medicaid to define missing benefit categories -- for example

rehabilitative or habilitative services, prescription drugs, or vision services -- and requiring all states to use the same definition. If the benefit is covered in the FEHBP, it is more likely to be substantially equivalent across types of plans – for example, HMO and PPO plans and across all states since the FEHBP operates in all 50 states. This approach will provide a uniform definition for missing benefits and new benefits that can be used in all states and establishes a process for developing more uniform benefits going forward.

While all 10 categories of services are important, the Bulletin expressly requests comments on particular categories of services where there is greater uncertainty about how that category should be defined. With respect to habilitative services, AHA again recommends using benefit language from the FEHBP or Medicaid to establish a specific floor for the specific services to be covered. If HHS does not adopt this approach, AHA prefers option 1 proposed in the Bulletin, whereby habilitative services would be offered at parity with rehabilitative services. We do not support option 2, allowing plans to decide which habilitative services to cover and reporting on that coverage to HHS.

We also support including the concept of maintenance of function, as well as restoring and creating skills and functions, in defining habilitative services. 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 issue is particularly important to stroke patients, both adults and children.

With respect to preventive services, Section 2713 of the ACA requires all plans except “grandfathered” plans to cover designated preventive services without cost sharing. HHS needs to make it clear in future regulations that preventive services are required to be covered without cost-sharing in plans required to comply with the EHB, even in instances where a state may choose an EHB benchmark plan that is “grandfathered” and therefore doesn’t offer Section 2713 preventive services with no additional cost-sharing.

Benefit Design Flexibility

HHS’s intended approach of allowing health plans to meet the EHB coverage standard by offering benefits that are “substantially equal” to the benchmark plan selected by the state and modified to reflect the 10 coverage categories will, once again, make it more difficult for consumers to understand their coverage and evaluate whether it meets their needs. Permitting insurance carriers to deviate from the benchmark benefits chosen by the state would significantly weaken the ACA’s EHB provision. The EHB standard is intended to ensure a consistent, minimum level of benefits across all non-grandfathered, fully-insured plans in the individual and small group insurance markets so that consumers can make an apples-to-apples comparison of plan options and to prevent insurers from adopting benefit designs intended to attract healthier people and deter enrollment by those in poorer health. The proposal for “benefit design flexibility” would undermine these goals, regardless of whether variation is allowed within benefit categories or across benefit categories. Allowing each state to set a different benchmark EHB standard already provides significant flexibility; it is unclear what, if any benefit the proposal for giving insurers additional flexibility to substitute benefits would have for consumers. Final guidance and regulations should prohibit such unwarranted flexibility and require insurers to adhere to the applicable benchmark benefits in a given state.

In the Bulletin, HHS proposes using “the same measures defined in [the Children’s Health Insurance Program] CHIP” (42 CFR 457.431) to ensure that any of the proposed benefit flexibility that is exercised by insurers meets actuarial equivalence tests. However, the approach suggested

by HHS is actually quite different from the framework in CHIP, and HHS should clarify exactly how its proposal for benefit design flexibility would be similar to CHIP. In particular, it is significant that a benchmark or benchmark-equivalent plan selected by a state for CHIP is *uniform across the state* and is provided by all CHIP plans in the state (after being approved by HHS). Individual insurers cannot deviate from this standard. In the case of the EHB, HHS is proposing multiple variations *within* a state, at the insurer's discretion. If HHS persists in allowing greater benefit design flexibility, the approach should mirror that used in CHIP.

Updating Essential Health Benefits

HHS has requested comments on approaches to evaluating and updating the EHBs and allowing health insurance issuers to update their benefits on an annual basis to reflect improvements in the quality and practice of medicine. AHA recommends the use of the benchmark framework as a temporary approach. For 2016 and beyond, HHS should define a national set of EHBs that becomes more specific and evidence-based over time, as recommended by the IOM. AHA supports the creation of an ongoing advisory committee or council that would monitor the EHB implementation and make recommendations to the Secretary on updating the EHB package to address gaps in coverage and evaluate benefit designs and service trends. This panel should include experts with a wide range of medical expertise that represent the health care needs of diverse segments of the population.

When HHS issues a future EHB rule, it should establish ongoing mechanisms to regularly track access to health care services, and in particular, whether patients covered under qualified health plans have difficulty accessing needed services for reasons of coverage or cost.

The non-discrimination provision of the ACA requires HHS to "ensure that there are no incentives for coverage decisions, cost sharing or reimbursement rates to discriminate impermissibly against individuals because of their age, disability, or expected length of life." The Bulletin does not suggest how HHS will evaluate benchmark plans to ensure that non-discrimination standards are being met. As part of its statutory obligation to periodically review and update the EHB package, HHS should ensure that a mechanism is in place to monitor for discrimination and enforce non-discrimination requirements. We encourage HHS to provide more guidance in future EHB rulemaking about how it will monitor and enforce the non-discrimination provisions.

Successful implementation of the EHBs in plans throughout the country is critical to making affordable, high-quality health insurance coverage available to millions of Americans, including those with heart disease and stroke and those at risk for CVD. We believe that stronger federal action on essential benefits is imperative. We hope to work closely with you to ensure that the EHB benefits fulfill this promise and meet the needs of all patients and consumers. Thank you again for this opportunity to share our comments. If you have any questions, please contact Stephanie Mohl, Government Relations Manager, at Stephanie.Mohl@heart.org or 202-785-7909.

Sincerely,



Gordon F. Tomaselli, MD, FAHA
President