American Heart Association | American Stroke Association
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March 25, 2016

The Hon. Sylvia Matthews Burwell
Secretary of Health and Human Services
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

The Hon. Jack Lew
Secretary of the Treasury
U.S. Department of Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

The Hon. Thomas E. Perez
Secretary of Labor
U.S. Department of Labor
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Howard Shelanski
Administrator
Office of Information and
Regulatory Affairs
Attention: CMS Desk Officer
725 17th Street, NW
Washington, DC 20503

RE: Document Identifiers: CMS–10407; Summary of Benefits and Coverage and Uniform Glossary Information Collection Request

Submitted via email to OIRA_submission@omb.eop.gov

Dear Secretary Burwell, Secretary Lew, Secretary Perez, and Administrator Shelanski:

On behalf of the American Heart Association/American Stroke Association, thank you for the opportunity to provide these comments to the Department of Health and Human Services, Department of Labor, and Department of Treasury (Departments) on the revised Summary of Benefits and Coverage (SBC) template, the Uniform Glossary (Glossary) and accompanying guidance. We thank the Departments for your continued work to implement the Affordable Care Act (ACA) and make quality, affordable health insurance available to millions more Americans, including many people with heart disease or stroke or at-risk for developing cardiovascular disease (CVD). Heart disease and stroke are the No. 1 and No. 5 killers of Americans, respectively, and exact an enormous health and economic toll on patients, their families, and our nation as a whole.

The Association has been a strong supporter of the SBC because of its critical value to patients and other consumers. Because of the ACA's requirements that the SBC be provided in a uniform manner in consumer-friendly language, in practical terms the SBC is the most important document consumers obtain to allow them to make "apples to apples" comparisons of health plans, select the plan that best meets their needs, and better understand their health insurance coverage.

As you know from our previous comments, we are concerned that the SBC, while an improvement over other types of health insurance marketing materials and disclosures available to consumers, is not as helpful to consumers as it needs to be. We therefore worked collaboratively with the National Association of Insurance Commissioner's (NAIC) Consumer Information Subgroup during 2015 on the development of a revised SBC template, insurer instructions, and Glossary that reflected the findings of consumer testing and made important improvements to enhance the value of these documents for patients and consumers.

Given the amount of time and effort that went into revising these documents, we were disappointed to learn this past December that the Departments had determined that the statutory 4-page limit for the SBC required condensing of the NAIC's October 2015 template. We believe that the page limitation is both unnecessary and will have an adverse impact on consumers. Important consumer information is being omitted for the sake of meeting this page limitation, and it results in an SBC that is very dense in terms of the information presented. The page limitation has also resulted in the elimination of important design elements that consumer testing revealed were necessary, in particular, for consumers with low health coverage literacy.

Moreover, consumers and patients need to realize the benefit of the improved SBC template as soon as possible, so we are very disappointed in the delayed implementation for most carriers. At one point, the Departments had proposed an applicability date of September 1, 2015 so that patients and consumers could have the benefit of a revised SBC in 2016. Given that implementation has now effectively been delayed until 2018, we strongly oppose any further delay.

We also want to stress the importance of the Departments working to improve the SBC after the currently proposed template and instructions are finalized. Improving the SBC should be a continual process, based on consumer testing and feedback from patient and consumer groups. The Departments should ask the NAIC's Consumer Information Subgroup to play a continuing role in updating the SBC going forward by making annual or biennial recommendations to the Departments for changes to the SBC and Glossary. Future plans should provide adequate time to allow the NAIC's Subgroup to undertake robust consumer testing at the beginning of the process, to inform a thoughtful and collaborative discussion with stakeholders, as well as at the conclusion, to affirm and validate the overall performance of the revised SBC.

This type of process would ensure that the final product reflects strong consumer-oriented content and design elements, both of which will directly benefit consumers across the country. For example, we continue to believe that additional coverage examples should be added to the SBC during the next update. Consumer testing has consistently found the examples to be extremely valuable to consumers. An example illustrating a very serious and expensive medical condition, such as heart attack or stroke, also helped crystallize the fundamental concept of insurance for many consumers, who otherwise approached their shopping task as an effort to acquire pre-paid health care. Indeed, helping to illustrate the value of insurance when faced with a devastating illness or condition was one of the most helpful parts of the SBC for many consumers.

Although, as noted above, we believe that the NAIC's October 2015 SBC template is preferable, we acknowledge your efforts to keep many of the NAIC's recommendations in the template released in February 2016, such as more clearly denoting when specific services are subject to a separate deductible and further instructions on how tiered network information should be displayed. While being mindful of the length constraints that are being imposed, we make the following additional recommendations for changes to the SBC, its accompanying instructions, and the Glossary that we strongly urge the Departments to incorporate when finalizing these documents.

Proposed SBC Template and Proposed Instructions for Completing the SBC

II) Important Questions/Answers/Why This Matters Chart

B. 1. What is the overall deductible?:

Consumer testing and feedback has found considerable confusion about how family deductibles apply. Without better information on family deductibles, consumers could face thousands of dollars in unexpected medical costs. The proposed instructions for describing family coverage with an embedded deductible in the *"Why This Matters"* column of the *"What is the overall deductible?"* row is not clear enough. We strongly support the following consensus language to better explain this difficult topic:

> "Generally, the plan will only begin to pay its share of the cost of covered services that an individual family member receives once that family member's individual deductible has been met. Other family members must pay the full cost of covered services until they meet their own individual deductible or until the total amount of deductible expenses paid by family members meets the overall family deductible."

B. 2. Are there services covered before you meet your deductible?:

The NAIC is suggesting adding the following optional language to the individual and group instructions for the *"Why this matters"* column of the important question *"Are there services covered before you meet your deductible?"* to address health savings account plans and similarly configured plans that apply a deductible to all services. This optional language must make it clear that preventive services are excluded from the deductible even for these types of plans, as follows: "You must meet the deductible for all services *except preventive services* [emphasis added], unless stated as "no charge" and then any applicable copayment or coinsurance may apply."

B. 6. Will you pay less if you use a network provider?

The inclusion of a web address to access the provider directory is an important aspect of the SBC. Unfortunately, the current and proposed instructions are not adequate to ensure the web address provided go directly to plan-specific information. Web addresses for plan networks often take consumers to an insurance company's landing page for all the issuer's networks. As a result, some consumers may inadvertently choose a network for the wrong plan. Issuers should be required to provide a web address that is a direct URL to a provider directory specific to the plan.

III) Common Medical Event, Services You May Need, What You Will Pay, Limitations & Exceptions Chart

B. 1. If you visit a health care provider's office or clinic:

The current structure of the SBC is misleading because it suggests that preventive services are restricted to a provider's office or clinic. Some covered preventive services do not occur at a provider's office. For example, immunizations and nicotine replacement therapies for tobacco cessation may be provided through pharmacies, not a provider's office. Likewise, tobacco cessation or obesity counseling may be provided through an outpatient hospital setting. In both examples, consumers may not understand from the SBC that they can access preventive service without cost-sharing outside of a provider's office. In addition, many preventive services fit into other common medical events on the SBC, which furthers the confusion that may occur by including it only under the *"provider's office"* row. Consumers may expect cost sharing for services such as cholesterol screening to be addressed as a *"Diagnostic test"* under *"If you have a test"* or for nicotine replacement therapy to be included under *"If you need drugs…".*

To address this concern, the Departments should create a new row under *"Common Medical Event"* to explain coverage of preventive services, as proposed below. We believe this change can be made without lengthening the template.

Common Medical Event	Services You May Need	What You Will Pay		Limitations, Exceptions, & Other Important Information
		Network Provider (You will pay the least)	Out-of-Network Provider (You will pay the most)	
If you need a preventive service	Preventive care/ screenings/immunization, /patient counseling	No charge for covered services	[provide cost-sharing information or insert "Not covered" if there is no out-of-network benefit]	You may have to pay for services that aren't preventive. Ask your provider if the services you need are preventive. Then check what your plan will pay for.

B.2. If you need drugs to treat your illness or condition:

As with provider network information, it is important that patients and consumers have access to the plan's formulary. Under the "*Common Medical Events"* column, we urge you to modify the instructions to require issuers to include a direct formulary drug list URL link.

B.7. Information on Rehabilitation and Habilitation Services

The information that is currently found in SBCs related to the coverage of rehabilitation and habilitation services is very inconsistent from plan to plan, making it difficult for consumers to make accurate comparisons of coverage for those services. The proposed SBC template is helpful in delineating rehabilitation and habilitation as separate categories of benefits under

"If you need help recovering or have other special health needs." Moreover, we appreciate that the instructions now require issuers to list physical therapy, speech therapy, and occupational therapy in the *"Limitations, Exceptions, and Other Important Information"* column, along with any quantitative limits that apply. However, further instructions are needed to provide additional important information for consumers about rehabilitative coverage in the *"Rehabilitation services"* row for the "*Limitations, Exceptions, and Other Important Information"* column as follows:

- The sample template appears to allow a joint limitation of rehabilitation and habilitation services listed under *"Limits, Exceptions, & Other Important Information."* Under the February 2015 final rule *HHS Notice of Benefit and Payment Parameters for 2016*, plans required to provide Essential Health Benefits must not impose combined limits on habilitative and rehabilitative services and devices for plan years beginning on or after January 1, 2017.[1] We request that the Departments modify the template to have separate limitations for rehabilitation and habilitation services.
- Issuers should be further instructed to specify whether quantity limits apply to each type of therapy separately or are a combined limit.
- Issuers should be required to also include inpatient rehabilitation services on the chart, along with any limitations on coverage.
- Issuers should be required to specifically list cardiac rehabilitation as included or excluded, and if included, any quantity limits should also be listed. In a recent review commissioned by the association of 2015 SBCs for qualified health plans in all 50 states, only 23 percent of SBCs specifically referenced cardiac rehabilitation – leaving it unclear to consumers whether this type of therapy is covered, and if so, whether there are any limits.

IV) Disclosures

A. Excluded Services and Other Covered Services:

As you know, Section 2709 of the Public Health Service Act, as added by the ACA, requires all non-grandfathered individual and group health plans to provide coverage for the routine costs associated with participation in clinical trials for the prevention, detection, and treatment of cancer or other life-threatening diseases or conditions. Yet despite this important new protection taking effect on January 1, 2014, we continue to hear from eligible patients who are inappropriately being denied this coverage, and many more patients may not even realize that their plan is required to provide this coverage because it is often not listed in the SBC as either a covered service or, in the case of a grandfathered plan, as an excluded service.

Knowing that their plan will cover the routine costs of participating in a clinical trial is an important consideration for many patients when deciding whether to participate in a research study. Therefore, we request that the Departments make the following change to the individual and group instructions and update the proposed SBC Sample Completed Template accordingly:

[1] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10750, 10871 (February 27, 2015).

> Add "Routine clinical trial costs" to the list of required services that issuers must include in either the *"Other Covered Services"* box or the *"Services Your Plan Generally Does Not Cover"* box, as appropriate according to the policy provisions.

This is a simple but important step that the Departments can take to help support the goals of the National Cancer Moonshot Initiative. As Vice President Biden has pointed out, only 5 percent of cancer patients end up in in a clinical trial, and one of the goals of the initiative is to "increase access to information for everyone in the cancer community."[2] This information is equally helpful and important to patients with other life-threatening diseases and conditions, including heart attack, heart failure, and stroke and to advancing the fight against these costly and burdensome diseases.

E. Language Access Services, taglines, culturally and linguistically appropriate requirements:

While the individual and group instructions appropriately reference the need for language access services and the obligation to provide the SBC in a culturally and linguistically appropriate manner, nothing addresses providing the SBC to people with disabilities in alternate formats such as Braille, large print or electronic disc. There are also potentially software or web designs that could be implemented to address accessibility issues. We encourage the Departments to consider revising the instructions to provide further guidance to issuers on meeting their obligation to make the SBC available to enrollees or potential enrollees with disabilities.

V) Coverage Examples

The coverage example for managing type 2 diabetes is a relevant example for millions of Americans and we support its continued inclusion in the SBC. We applaud the Departments for adding a statin drug to the diabetes treatment scenario and also for requiring plans to calculate the diabetes coverage example assuming no participation in a wellness program, as we previously recommended. However, we note that while the sample completed SBC template and individual and group instructions make it clear that cost-sharing shown assumes the enrollee does not participate in a wellness program, the *"Proposed Guide for Coverage Examples Calculations"* mistakenly lists as a standard assumption the following: "If the plan has a wellness program that varies the deductibles, copayments, coinsurance, or coverage for any of the services listed in a treatment scenario, the plan must complete the calculations for that treatment scenario assuming that the patient is participating in the wellness program." This document should be updated to be consistent with the sample template and instructions.

In addition, we believe the way that deductibles are presented in the type II diabetes and simple fracture coverage examples will be confusing for many consumers. The sample coverage examples provide for a $500 overall deductible, but the deductible paid is $800 for Joe and $700 for Mia. While the extra deductibles apparently stem from separate deductibles for specific services (such as a separate prescription drug deductible), the Departments should remain mindful of the potential for confusion in this area and consider how this could be made clearer for consumers.

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[2] The White House. "Inspiring a New Generation to Defy the Bounds of Innovation: A Moonshot to Cure Cancer." Jan 2016. Available online at: https://www.whitehouse.gov/the-press-office/2016/01/12/inspiring-new-generation-defy-bounds-innovation-moonshot-cure-cancer.

We also continue to have concerns that the coverage examples calculator is less accurate, can mask cost-sharing differences between plans, and makes the coverage examples less useful for consumers. Since the Departments plan to continue its use for the next several years, at a minimum we recommend that the calculator for the diabetes example be updated so that it does not assume generic cost-sharing for insulin, given that there is no generic form of insulin.

Proposed Uniform Glossary

Definition of "Rehabilitation Services"

We are concerned that the current definition of "Rehabilitation Services" in the Uniform Glossary excludes cardiac and pulmonary rehabilitation. While we recognize that it may not be possible to list every type of rehabilitation service in the definition in the glossary, we believe it is very important to revise the definition to include cardiac rehabilitation (CR) and pulmonary rehabilitation. These services are very important to maximizing recovery for the substantial number of patients with cardiovascular or lung disease and should be considered a core rehabilitation service. Unfortunately, these evidence-based services that are shown to reduce recurrent events and hospitalizations are underutilized across all types of patients who could benefit from them. Specifically including them in the definition in the glossary can help educate patients and consumers about the availability of these services.

In addition, we recommend explicitly adding devices to the definition of rehabilitation services in the glossary, since devices are specifically included in the statute.

Therefore, we recommend the definition be revised as follows (changes in italics):

> Rehabilitation Services *and Devices*: Health care services *and devices* that help a person keep, get back or improve skills and functioning for daily living that have been lost or impaired because a person was sick, hurt or disabled. These services may include physical and occupational therapy, speech-language pathology, *cardiac rehabilitation, pulmonary rehabilitation,* and psychiatric rehabilitation services in a variety of inpatient and/or outpatient settings.

Definition of "Habilitation Services"

We applaud HHS for adopting our recommendations to implement a standard definition of habilitation services and explicitly add devices to this definition as part of the final HHS Notice of Benefit and Payment Parameters for 2016. For consistency, we encourage the Departments to likewise add "and devices" to the definition of habilitation services in the glossary.

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Thank you for this opportunity to submit recommendations on improving the SBC, its accompanying instructions, and the Uniform Glossary and making these tools even more helpful to patients. We look forward to continuing to work with the Departments to ensure consumers have accurate and complete information about their health coverage. If you have any questions about our comments, please contact Stephanie Mohl, senior government relations advisor in our Office of Federal Advocacy, at Stephanie.Mohl@heart.org or 202-785-7909.

Sincerely,

Mark A. Creager, MD, FAHA
President