American Heart Association | American Stroke Association
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Sylvia Matthews Burwell
Secretary of Health and Human Services
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

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

Tom Perez
Secretary of Labor
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20201

RE: Notice of Proposed Rulemaking for Summary of Benefits and Coverage and Uniform Glossary

Dear Secretary Burwell, Secretary Lew and Secretary Perez:

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 Summary of Benefits and Coverage (SBC) and Uniform Glossary proposed rule 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. However, 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. In short, it is still not as readily accessible, consistent, and accurate as it should be to ensure that consumers are able to make well-informed health plan choices. To that end, we submit comments on the proposed SBC regulations and accompanying guidance, including the proposed SBC templates and proposed instructions for completing the SBC, that are meant to ensure accuracy, transparency, and clarity of the SBC.

Proposed SBC Template and Proposed Instructions for Completing the SBC

1) Important Questions/Answers/Why This Matters Chart

The current and proposed instructions to plans for completing the SBC are inadequate to ensure plans provide clear information about family deductibles. Without better information on family deductibles, consumers could face thousands of dollars in unexpected medical costs. The Departments should ensure that the information on family deductibles is consistent across plans so that consumers are able to make true "apples-to-apples" comparisons of their options.

There are two types of family deductibles: embedded and aggregate. An embedded family deductible embeds the individual deductible with each member of the family, so that once a member of the family pays total covered costs equaling the individual deductible, that member has met his or her deductible for the plan year. Once any combination of family members pays total covered costs equaling the family deductible, the entire family has met the deductible for the plan year. In contrast, the individual deductible is completely irrelevant to a family enrolled in a plan with an aggregate deductible. An aggregate deductible functions as a single family deductible, so that none of the family members meet the deductible until the family has paid total covered costs equal to the family deductible.

The current instructions require plans to show both the individual and family deductible if "there is a separate deductible amount for each individual and the family."[1] These instructions do not provide any guidance for differentiating between an embedded deductible and an aggregate deductible. The instructions must require health plans to explain how deductibles apply to family coverage. We are concerned that without such a requirement, families may not understand key differences in their health plan choices and could face thousands of dollars in unexpected costs because they expect that each member of the family only needs to meet the individual deductible.

The following changes to the SBC would clarify how the deductible applies in family coverage and establish consistency for when the deductible applies to services.

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[1] U.S. Department of Labor, What This Plan Covers and What it Costs: Instruction Guide for Group Coverage (proposed Dec. 2014), *available at:* http://www.dol.gov/ebsa/pdf/sbcinstructionsgroupproposed.pdf; U.S. Department of Labor, What This Plan Covers and What it Costs: Instruction Guide for Individual Health Insurance Coverage (proposed Dec. 2014), *available at*: http://www.dol.gov/ebsa/pdf/sbcinstructionsindividualproposed.pdf.

- The instructions should provide language that plans must include in the Why This Matters column for "What is the overall deductible?" The language must explain, in simple terms, whether the individual deductible applies for enrollees in family coverage (embedded deductible) or if a family must meet the family deductible before the plan pays claims for covered services (aggregate deductible). For example:

  > If aggregate: *If you are enrolled in family coverage, once the family has met the family deductible ($ZZZZ), the plan pays claims for covered services. The individual deductible does not apply in family coverage.*
  > If embedded: *If you are enrolled in single/individual coverage, you must meet the individual deductible ($XXXX) before the plan pays claims for covered services. If you are enrolled in family coverage, the plan begins paying claims for an individual family member once he/she meets the individual deductible ($XXXX). Once the family has met the family deductible ($ZZZZ), the plan pays claims for all members of the family for covered services.*

2) Common Medical Event, Services, Cost Sharing, Limitations & Exceptions Chart

a) Preventive Services

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 or via telemedicine. 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 the category. 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:

Common Medical Event	**Services You May Need**	**Your Cost If You Use an In-network Provider**	**Your Cost If You Use an Out-of-network Provider**	**Limitations & Exceptions**
If you need a preventive service	Listed preventive screenings, check-ups, patient counseling, and services	No cost for listed services; deductible does not apply	[provide cost-sharing information]	See full list of preventive services covered without cost-sharing at [website].

In addition, plans should note in the "Limitations and Exceptions" column under additional categories, e.g., "If you need drugs" or "If you have a test," that there are preventive services without cost sharing.

Further, the SBC should include a web address that has a comprehensive, up-to-date list of all required preventive services, including United States Preventive Services Task Force A and B recommendations, HRSA Women's Preventive Services Guidelines, Bright Futures recommendations, and the Advisory Committee on Immunization Practices recommendations for vaccines. A comprehensive list allows consumers to know which preventive services their plan must cover. Ideally, plans should include this web address with the new category specifying coverage of preventive services. However, if the Departments do not create a new category, they should still require plans to include a web address for a comprehensive list of preventive screenings on the SBC to ensure consumers know how to find the full range of preventive services they are entitled to without cost-sharing.

b) Facility Charges and Facility Fees

Patients face two types of costs that are not reflected in the existing or proposed SBC regulations and accompanying guidance. These costs can result in patients facing unexpected cost sharing or charges. The first cost is a type of cost sharing charged by the health insurance plan, sometimes called a facility charge, for services received at a higher-cost facility, such as outpatient services provided at a hospital, hospital campus, or hospital-owned facility. An individual relying on an SBC may receive care from a physician on a hospital campus and incur an additional unexpected cost. Plans must disclose patient cost-sharing responsibilities for facility charges, or similar cost sharing for medical services provided at certain facilities, in the "Limitations and Exceptions" column by stating "Additional $X per visit for services received [insert description of facilities].

The second cost is a facility fee the health care provider charges for the use of the health care facility. Facility fees are billed charges in addition to the health care service that a specific health insurance plan may or may not cover. These provider charges can undermine the preventive services benefits in plans that do not cover facility fees billed by in-network providers for preventive services. The proposed SBC regulations and proposed instructions do not require plans to disclose whether or not they cover facility fees for preventive services (or other services). The Departments must require plans to state, in the "Limitations and Exceptions" columns for preventive services, office visits, and outpatient surgery, if the plan does not cover facility fees or has different cost-sharing requirements for these costs.

c) 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 very difficult for consumers to make accurate comparisons of coverage for those services. The sample 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." However, further instructions are needed to inform plans about how to address specific therapy types.

For example, some SBCs only describe coverage for outpatient rehabilitation, making it unclear whether inpatient rehabilitation services are also covered and if so, whether there are any limits. SBCs also vary significantly on whether they list specific types of therapy, such as physical therapy, cardiac rehabilitation, or cognitive therapy. 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. Therefore, we recommend that HHS revise the instructions to direct plans to specifically list the core types of covered therapies. Core types of therapies under the categories of rehabilitation and habilitation (physical and occupational therapy, speech-language pathology, psychiatric rehabilitation, cardiac rehabilitation, and pulmonary rehabilitation) should always be listed in the SBC if they are in fact covered, so that it is clear to consumers when any of those therapies are not covered. In addition, if there are any limitations on coverage of those services (such as quantity limits), the SBC should continue to clearly specify that limit in the "Limitations & Exceptions" column for each type of service.

d) Information on Deductibles

The proposed instructions for the Common Medical Event table do not provide a strong enough standard for when deductibles do or do not apply to services. As a result, consumers do not always have all of the information about cost sharing and may be comparing SBCs with different levels of detail. This could lead to misunderstandings about how the deductible applies to services. For instance, a consumer may enroll in a plan because it has a low deductible, but not understand that an alternative plan applies the deductible to fewer services. The Departments should require plans to use consistent language to explain plan deductibles. The language should simply state whether or not the deductible applies; plans should include "after deductible" or "deductible does not apply" either in each row under the cost columns for both in-network and out-of-network providers or in the "Limitations and Exceptions" column.

e) Network and Formulary Information

The inclusion of web addresses to access the provider directory and formulary is an important aspect of the SBC. Unfortunately, the current and proposed requirements are not adequate to ensure the web addresses provided go directly to plan specific information. Web addresses for plan networks and formularies often take consumers to an insurance company's home page or a landing page for all the issuer's networks or formularies. Consumers often must click through multiple pages to get to the network or formulary information and, during that process, may have to choose from a list of various networks or formularies. As a result, some consumers may not find the network or formulary information and other consumers may inadvertently choose a network or formulary for the wrong plan. Plans must be required to:

- Provide a network web address that is a direct URL to a provider directory specific to the plan.

- Provide a formulary web address that is a direct URL to a formulary specific to the plan.

f) Additional Benefits in "Other Covered Services" or "Excluded Services"

Plans should be required to provide a web address to the coverage policy or group certificate of coverage following the statement "Check your policy or plan document for other excluded services." The proposed regulations already recommend that such a web address be provided on the SBC by issuers. Including the web address at this location will ensure that health care consumers know how to access the full list of excluded services, beyond those services listed on the SBC. The underlying plan documents may also provide further detail about exclusions that are included in the SBC, such as if services are excluded or only covered in limited circumstances. The inclusion of the web address at this location should not replace including the web address in another location that will be obvious to consumers looking for additional plan information unrelated to exclusions.

3) Coverage Examples

a) Additional Coverage Examples

Consumer testing of the prototype coverage examples back in 2011 found the examples to be extremely valuable to consumers.[2] They provided a sense of how much the plan would pay for certain conditions – information that consumers couldn't calculate on their own. An example illustrating a very serious and expensive medical condition 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 form for many consumers. While we acknowledge that the Departments are proposing to add an additional coverage example for "Simple fracture," we recommend that the Departments require inclusion of additional medical scenarios in the SBC beginning as soon as possible.

When selecting the treatment scenarios to include as coverage examples in the SBC, the Departments should choose examples that are relevant to as wide and diverse a population as possible. Specifically, we urge the Departments to take into account the following factors:

- Prevalence of conditions in the population overall and in subpopulations.
- The seriousness of the medical condition and the potential for catastrophic medical costs if consumers forego coverage.
- Scenarios that illustrate differences in how health insurance coverage varies for different types of care. Typically health plans apply different coverage

[2] See, for example, *Early Consumer Testing of Coverage Facts Labels: A New Way of Comparing Health Insurance*, Kleimann Group and Consumers Union, August 2011. http://prescriptionforchange.org/wordpress/wp-content/uploads/2011/08/A_New_Way_of_Comparing_Health_Insurance.pdf

rules, limits, and cost sharing for certain types of benefits – hospitalization, outpatient prescription drugs, rehabilitative services, etc. Selection of coverage illustrations should show consumers how these coverage differences work under each plan.

A number of cardiovascular conditions meet the statutory criteria for "serious or chronic medical conditions," meet the factors recommended above and would be very appropriate for selection as coverage examples. For example, the following conditions have evidence-based clinical practice guidelines available through the National Guideline Clearinghouse and affect a substantial number of Americans, including both men and women of varying ages, races, and ethnicities. We strongly recommend that you consider including at least one of the following conditions as coverage examples:

- Myocardial infarction (heart attack): A heart attack is a serious, potentially life-threatening condition that generally requires immediate emergency care and hospitalization, as well as follow-up care and cardiac rehabilitation to prevent additional attacks and adverse consequences. Approximately 735,000 individuals experience a new or recurrent heart attack each year in the United States, and a total of about 7.6 million American adults have experienced a heart attack at some point in their lives.[3] According to 2012 prevalence data, about 64 percent of individuals who have had a heart attack are male and 36 percent are female.
- Ischemic stroke: Stroke is a leading cause of death and serious long-term disability and generally requires immediate emergency care, hospitalization, rehabilitation, and follow-up care to maximize recovery and prevent additional strokes. Each year, about 795,000 people experience a new or recurrent stroke, and 87 percent of these strokes are of the ischemic type (caused by a blockage in an artery in the brain).[4] African-Americans are nearly twice as likely to experience a stroke. Overall, an estimated 6.6 million adults in the United States have had a stroke; 55 percent of them are female and 45 percent are male.
- Hypertension (high blood pressure): High blood pressure is a serious chronic condition that can lead to heart attack, stroke, kidney failure and other consequences, particularly if not adequately treated and controlled. One in 3 U.S. adults – an estimated 80 million people -- has high blood pressure. Overall, about 52 percent of those adults with high blood pressure are female and 48 percent are male. Two out of every 5 African-American adults has high blood pressure. According to 2009-2012 data, 76 percent of those with hypertension were under current treatment for the condition, indicating that a coverage example for hypertension would be personally relevant to a significant portion of the population shopping for coverage.

We urge the Departments to add coverage examples for the above common conditions, and pledge that the American Heart Association stands ready to work with you to develop the medical scenarios.

[3] Mozaffarian, D., et al. Heart Disease and Stroke Statistics-2015 update: A Report From the American Heart Association. *Circulation*. 2015; 131(4): e29-e322.
[4] *Ibid.*

b) Management of Type II Diabetes Coverage Example

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. However, we recommend a number of changes to how the example is calculated and presented.

First, we recommend that a statin drug be added to the diabetes treatment scenario. Both the American Heart Association's and the American Diabetes Association's guidelines recommend that, for patients with diabetes over age 40 without overt CVD, clinicians should consider using statin therapy, in addition to emphasizing lifestyle modification. Thus, for the 52 year old patient with diabetes in the diabetes treatment scenario, use of a statin would be indicated.

Second, we recommend that the Departments require plans to calculate the diabetes coverage example assuming no participation in a wellness program (i.e., incentives are not earned). If a plan has a wellness program that varies deductibles, copayments, coinsurance or coverage for any of the services listed in a treatment scenario, the plan is currently instructed to complete the calculations for that treatment scenario assuming the patient is participating in the wellness program. The coverage example for managing type 2 diabetes includes a wellness program disclaimer for plans to use which notes "these numbers assume the patient is participating in the plan's diabetes wellness program. If you have diabetes and do not participate in the wellness program, your costs may be higher." For the consumer, this disclaimer seems to add a layer of confusion and ambiguity to the diabetes example. For individuals comparing plans who might have difficulty participating in or meeting any required outcomes for the diabetes wellness program, the out-of-pocket cost estimates assuming participation in the wellness program could provide consumers with an artificially low impression of out-of-pocket costs under the plan. It also confounds the goal of being able to make "apples to apples" comparisons between plans.

Therefore, by requiring plans to assume no participation in the wellness program, the higher cost sharing that enrollees may be subject to would be reflected in the diabetes coverage example. Making this change would be consistent with how the Departments have treated wellness program cost variations for non-tobacco related programs in other regulations. Specifically, regulations for determining whether an individual eligible for employer-sponsored coverage is exempt from the shared responsibility payment because he/she lacks affordable coverage assume that non-tobacco related wellness program incentives are not earned.[5]

In accordance with our recommendation above, language in the disclaimer that plans are permitted to use in the diabetes coverage example (if they have a wellness program

[5] 26 CFR 1.5000A-3(e)(3)(ii)(F). Nondiscriminatory wellness program incentives, within the meaning of §54.9802-1(f) of this chapter, offered by an eligible employer-sponsored plan that affect premiums are treated as earned in determining an employee's required contribution for purposes of affordability of an eligible employer-sponsored plan to the extent the incentives relate exclusively to tobacco use. Wellness program incentives that do not relate to tobacco use or that include a component unrelated to tobacco use are treated as not earned for this purpose. For purposes of this section, the term *wellness program incentive* has the same meaning as the term *reward* in §54.9802-1(f)(1)(i) of this chapter.

that varies cost sharing) should be changed to say, "If you have diabetes and participate in our wellness program, your costs may be lower." We further recommend consumer testing the wellness disclaimer in order to assess whether it provides any added benefit for consumers or if it creates confusion.

c) Coverage Examples Calculator

We are very concerned that the proposed rule allows continued use of the Coverage Examples Calculator. In past comments with other groups, we have raised concerns about the accuracy of the calculator, which was initially intended as a temporary safe harbor. Issues with the calculator have been documented by others but have not been resolved.[6] The calculator allows plans to take shortcuts by using simplified assumptions. We are concerned the calculator is less accurate, can mask cost-sharing differences between plans and make the coverage examples less useful for consumers. For instance, a particular concern with the Coverage Examples Calculator for the diabetes example is the cost-sharing rules for generic drugs are assumed to apply to all prescription drugs — even though there is no generic form of insulin. As another example, the calculator assumes all diabetes equipment and supplies are covered under the durable medical equipment (DME) benefit but in reality plans may cover these supplies differently (such as under the prescription drug benefit) and have different cost sharing.

We urge the Departments to set an end date for use of the Coverage Examples Calculator. The SBC has the potential to help people better understand relative generosity of coverage when comparing plans, but only if it accurately reflects the plan's coverage. Since plans have had to comply with the SBC for several years now and have experience with the coverage examples, we do not see the need for allowing a safe harbor that can impact the accuracy of the coverage examples.

If the Departments move forward with the proposal to keep the Coverage Examples Calculator in the short term, at minimum we urge revising the calculator to: 1) eliminate the option to allow generic cost-sharing rules for all drugs and instead only allow it for those drugs where generics are actually available, and 2) require plans to calculate coverage for the medical equipment and supplies in the diabetes example according to how the plan actually covers them (for example, under the prescription drug benefit or as DME). This would at least improve the likelihood that the estimates in the diabetes example more closely reflect the plan's coverage. But even these changes do not address all the shortcomings in the calculator and therefore should only be a short-term fix allowed for no longer than one year before use of the Coverage Examples Calculator is prohibited.

Proposed Uniform Glossary

[6] Karen Pollitz. Transparency and Complexity. Kaiser Family Foundation website. August 3, 2012. Available at: http://kff.org/health-reform/perspective/transparency-and-complexity/

1) 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.

We understand the intent of the glossary terms as plain-language descriptions of services meant to facilitate informed decision-making by consumers as they shop for coverage and *not* as legally-binding definitions of covered benefits. However, as we have commented previously, we see a strong need to more clearly define for issuers what types of services should be covered under the category of rehabilitation services and devices. Therefore, in future regulations defining coverage requirements, limitations, and exclusions of coverage benefits, we further urge the Departments to adopt more robust, inclusive definitions for these terms.

Specifically, we strongly urge you to clarify that cardiac rehabilitation is required to be covered as a rehabilitative service. CR has received a class I recommendation in the American College of Cardiology Foundation/American Heart Association guidelines (which means the treatment is useful and effective and should be performed) for patients following heart attack, coronary artery bypass surgery, heart failure, or other cardiac events. CR helps restore and enhance cardiac function, slows or even reverses the progression of cardiovascular disease, and reduces the risk of a future cardiac event. Despite the proven benefit of CR, it is often unclear whether it is covered under the rehabilitative benefit. As we discussed above, the vast majority of SBCs we sampled are silent on whether CR is covered under rehabilitation services or under another category of coverage and whether there are any limits on this coverage. It is important that heart disease patients know when choosing a plan whether CR is covered and under what conditions.

2) 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 recently-released 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.

Other Issues in Proposed Rule

1) Applicability Date

We support the proposed applicability date of September 1, 2015 for changes to the SBC. The proposed regulations and accompanying guidance, with our recommendations, make improvements to the SBC that will improve consumers' access to information about their health insurance coverage. These changes should be instituted as quickly as possible. Requiring an applicability date of September 1, 2015 will ensure that patients and consumers have SBCs meeting the new requirements for plans with plan years starting in 2016.

We also encourage the Departments to work to improve the SBC after these proposed rules are finalized. Improving the SBC should be a continual process, based on consumer testing and feedback from patient and consumer groups. The Departments could ask the NAIC's Consumer Information Working Group to play a continuing role in updating the SBC going forward by making annual recommendations to the Departments for changes to the SBC and glossary. However, we do not believe finalizing the current rule should be delayed, given the need to make improvements to the SBC for the 2016 plan year.

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Thank you for this opportunity to submit recommendations on improving the SBC and 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.

Sincerely,

Elliott M. Antman, MD, FAHA
President