

separate offense for purposes of this paragraph (e). HHS will enforce these provisions in a manner consistent with 45 CFR 150.101 through 150.465.

(f) *Applicability date*—(1) This section is applicable to group health plans and group health insurance issuers in accordance with this paragraph (f). (See § 147.140(d), providing that this section applies to grandfathered health plans.)

(i) For disclosures with respect to participants and beneficiaries who enroll or re-enroll through an open enrollment period (including re-enrollees and late enrollees), this section applies beginning on the first day of the first open enrollment period that begins on or after September 23, 2012; and

(ii) For disclosures with respect to participants and beneficiaries who enroll in coverage other than through an open enrollment period (including individuals who are newly eligible for coverage and special enrollees), this section applies beginning on the first day of the first plan year that begins on or after September 23, 2012.

(2) For disclosures with respect to plans, and to individuals and dependents in the individual market, this section is applicable to health insurance issuers beginning September 23, 2012.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[CMS–9982–FN]

45 CFR Part 147

Summary of Benefits and Coverage and Uniform Glossary—Templates, Instructions, and Related Materials; and Guidance for Compliance

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Guidance for compliance and notice of availability of templates, instructions, and related materials.

SUMMARY: The Departments of Health and Human Services, Labor, and the Treasury are simultaneously publishing in the **Federal Register** this guidance document and final regulations under the Patient Protection and Affordable Care Act to implement the disclosure for group health plans and health insurance issuers of the summary of benefits and coverage (SBC), notice of modifications, and the uniform glossary. This guidance document provides guidance for compliance with section 2715 of the Public Health Service Act and the Departments' final regulations, including a template for the SBC, instructions, sample language, a guide for coverage example calculations, and the uniform glossary.

FOR FURTHER INFORMATION CONTACT:

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Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) Web site (http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp) and information on health reform can be found at <http://www.healthcare.gov>.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Departments of Health and Human Services (HHS), Labor, and the Treasury (the Departments) are taking a phased approach to issuing regulations and guidance implementing the revised Public Health Service Act (PHS Act) sections 2701 through 2719A and related provisions of the Patient Protection and Affordable Care Act (Affordable Care Act).¹ Section 2715 of

the PHS Act directs the Departments to develop standards for use by a group health plan and a health insurance issuer in compiling and providing a summary of benefits and coverage (SBC) that “accurately describes the benefits and coverage under the applicable plan or coverage.” Section 2715 of the PHS Act also directs the Departments to provide for the development of “standards for the definitions of terms used in health insurance coverage.” The statute directs the Departments, in developing such standards, to “consult with the National Association of Insurance Commissioners” (referred to in this guidance document as the “NAIC”), “a working group composed of representatives of health insurance-related consumer advocacy organizations, health insurance issuers, health care professionals, patient advocates including those representing individuals with limited English proficiency, and other qualified individuals.”

After consultation with the NAIC,² on August 22, 2011, the Departments published proposed regulations to implement PHS Act section 2715,³ as well as a companion document that proposed an SBC template (with instructions, sample language, and a guide for coverage examples calculations to be used in completing the SBC template) and a uniform glossary.⁴ HHS also published on its Web site (at <http://cciiio.cms.gov>, and accessible via hyperlink from www.dol.gov/ebsa/healthreform) the coding and pricing information necessary to perform calculations for the three proposed coverage examples. Comments were solicited on these materials.

Final regulations under PHS Act section 2715 are being published elsewhere in this issue of the **Federal Register** (final regulations). This guidance document provides guidance for compliance with PHS Act section 2715 and the final regulations, including information on how to obtain the SBC template (with instructions and sample language for completing the template) and the uniform glossary. These items are displayed at www.dol.gov/ebsa/healthreform and www.cciiio.cms.gov.

provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans.

² A summary of the NAIC's work can be found at 76 FR 52476–77, August 22, 2011.

³ 76 FR 52442, August 22, 2011.

⁴ 76 FR 52475, August 22, 2011.

¹ The Affordable Care Act also adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the

II. Guidance

A. Documents Authorized for the First Year of Applicability

This guidance document authorizes an SBC template (with instructions, samples, and a guide for coverage example calculations to be used in completing the SBC template), and the uniform glossary, to comply with the disclosure requirements of PHS Act section 2715, pursuant to paragraph (a)(3) of the final regulations.⁵ These documents are authorized with respect to group health plan coverage and group and individual health insurance coverage for SBCs and uniform glossaries provided with respect to coverage beginning before January 1, 2014 (referred to in this guidance document as “the first year of applicability”).

The materials described in this guidance document are authorized by the Departments for the first year of applicability only; the Departments intend to issue updated materials for later years. Specifically, these documents do not provide language to comply with paragraph (a)(2)(i)(G) of the final regulations, requiring a statement in the SBC about whether a plan or coverage provides minimum essential coverage and whether the plan’s or coverage’s share of the total allowed costs of benefits provided under the plan or coverage meets applicable minimum value requirements, because the final regulations do not require this material to be included in the first year of applicability. In addition, the Departments recognize that, beginning January 1, 2014, new market reforms⁶ will take effect, which are expected to prompt additional changes to the SBC (for example, annual limits will no longer be permissible).

Finally, the documents described in this guidance document contain information for two coverage examples—having a baby (normal delivery) and managing type 2 diabetes (routine maintenance of a well-controlled condition). This approach differs from the documents published in connection with the proposed regulations, which included three coverage examples (relating to having a baby (normal delivery), breast cancer, and diabetes). The Departments

received many comments asserting that the necessary calculations for the coverage examples would be costly and complicated. Commenters asked the Departments to add flexibility in use of the coverage examples and expressed concerns about misleading consumers about the costs of the health care services associated with the coverage examples. The Departments also received a number of comments that expressed concern about the high variability in treatment plans for patients with breast cancer and diabetes. Therefore, the Departments have modified the coverage examples requirements and will continue to evaluate these coverage examples, as well as others suggested by commenters.⁷ Consumer testing performed on behalf of the NAIC⁸ demonstrated that the coverage examples facilitated individuals’ understanding of the benefits and limitations of a plan or policy and helped them make more informed choices about their options. Such testing also showed that individuals were able to comprehend that the examples were only illustrative. Additionally, while some plans provide useful coverage calculators to their enrollees to help them make health care decisions, they are not uniform across all plans and most are not available to shoppers, making it difficult for consumers to make coverage comparisons. Future guidance will add coverage examples and make other changes (including those described above) for SBCs required to be provided after the first year of applicability.

In addition to the materials described in this guidance document, HHS is providing (at <http://ccio.cms.gov>, also accessible via hyperlink from www.dol.gov/ebsa/healthreform) the specific information necessary to simulate benefits covered under the plan or policy for the coverage example portion of the SBC (including relevant medical items and services, dates of service, billing codes, and allowed charges), pursuant to paragraph (a)(2)(ii) of the final regulations. This information must be used for SBCs

provided during the first year of applicability. Future guidance will make changes to this information for SBCs required to be provided after the first year of applicability.

B. Appearance

The Departments’ 2011 proposed regulations would have required that a group health plan and a health insurance issuer provide an SBC as a stand-alone document. This requirement was eliminated with respect to group health plan coverage in the final regulations (as discussed more fully in the preamble to the final regulations). Instead, the final regulations provide for the Secretaries to issue guidance for the form of the SBC. Consistent with the authority set forth in paragraph (a)(3) of the final regulations, with respect to group health plan coverage, the Departments authorize the SBC to be provided either as a stand-alone document or in combination with other summary materials (for example, a summary plan description), if the SBC information is intact and prominently displayed at the beginning of the materials (such as immediately after the Table of Contents in a summary plan description). For health insurance coverage provided in the individual market, the SBC must be provided as a stand-alone document. The Departments will review and monitor SBCs provided as part of other plan materials and may modify their guidance as to appearance for SBCs required to be provided after the first year of applicability in response to plan and issuer practices.

The NAIC stated in its December 2010 transmittal letter that the NAIC working group intentionally designed the layout and color of the SBC template. The Departments noted in the document published contemporaneously with the proposed regulations, however, that color printing may be costly and proposed that a plan or issuer would be compliant with the requirement to provide the SBC if it used either the color version as recommended by the NAIC or the grayscale version. The Departments are retaining that approach in this guidance document, and will allow the SBC to be provided either in color or grayscale.

C. Special Rule

For group health plans and health insurance issuers in the group and individual markets, use of the full SBC template authorized by this guidance document is required, including for the first year of applicability. To the extent a plan’s terms that are required to be described in the SBC template cannot

⁵ This guidance makes references to various paragraphs of the final regulations. The final regulations are codified at 26 CFR 54.9815–2715, 29 CFR 2590.715–2715, and 45 CFR 147.200. However, for simplicity, this guidance refers only to the relevant paragraph of the three regulations instead of using three parallel, full citations.

⁶ See Subpart I of Part A of Title XXVII of the PHS Act.

⁷ Examples suggested by comments included prostate cancer, colorectal cancer, hypertension, heart attack, stroke, major depression, and chronic kidney disease, among others.

⁸ A summary of the focus group testing done by America’s Health Insurance Plans is available at: http://www.naic.org/documents/committees_b_consumer_information_101012_ahip_focus_group_summary.pdf, a summary of the focus group testing done by Consumers Union on the coverage examples is available at: http://prescriptionforchange.org/wordpress/wp-content/uploads/2011/08/A_New_Way_of_Comparing_Health_Insurance.pdf.

reasonably be described in a manner consistent with the template and instructions, the plan or issuer must accurately describe the relevant plan terms while using its best efforts to do so in a manner that is still consistent with the instructions and template format as reasonably possible. Such situations may occur, for example, if a plan provides a different structure for provider network tiers or drug tiers than is contemplated by the template and these instructions, if a plan provides different benefits based on facility type (such as hospital inpatient versus non-hospital inpatient), in a case where a plan is denoting the effects of a related health flexible spending arrangement or a health reimbursement arrangement, or if a plan provides different cost sharing based on participation in a wellness program. The Departments intend to update the template instructions for SBCs required to be provided after the first year of applicability. Whether the need for a special rule becomes moot in light of additional instructions, or whether the need continues to exist, will be addressed in future guidance.

D. Language

PHS Act section 2715 requires group health plans and health insurance issuers to provide the SBC in a culturally and linguistically appropriate manner. Paragraph (a)(5) of the final regulations provides that a plan or issuer satisfies this requirement by following the rules for providing claims and appeals notices in a culturally and linguistically appropriate manner under PHS Act section 2719, and paragraph (e) of its implementing regulations, as applied to the SBC.⁹ Under those rules, plans and issuers must provide notices in a culturally and linguistically appropriate manner when 10 percent or more of the population residing in the claimant's county are literate only in the same non-English language, as determined based on American Community Survey data published by the United States Census Bureau. At the time of publication of this guidance document, 255 U.S. counties (78 of which are in Puerto Rico) meet this threshold. The overwhelming majority of these are Spanish; however, Chinese, Tagalog, and Navajo are present in a few counties, affecting five states (specifically, Alaska, Arizona, California, New Mexico, and Utah).¹⁰

⁹ See 75 FR 43330 (July 23, 2010), as amended by 76 FR 37208 (June 24, 2011).

¹⁰ The Departments publish guidance on their Web site with a list of the counties that meet this threshold. This information is available at www.dol.gov/ebsa/healthreform and <http://cciio.cms.gov/>.

To help plans and issuers meet the language requirements of paragraph (a)(5) of the final regulations, as requested by commenters, HHS will provide (at <http://cciio.cms.gov>, also accessible via hyperlink from www.dol.gov/ebsa/healthreform) written translations of the SBC template, sample language, and uniform glossary in Spanish, Tagalog, Chinese, and Navajo. HHS may also make these materials available in other languages to facilitate voluntary distribution of SBCs to other individuals with limited English proficiency.

III. Templates, Instructions, and Related Materials

As stated above, this guidance document authorizes documents to comply with the disclosure requirements of PHS Act section 2715, pursuant to paragraph (a)(3) of the final regulations. The Departments received comments in response to the previous guidance and proposed templates, instructions, and related materials.¹¹ These comments addressed specific issues related to the SBC template, instructions, samples, and the uniform glossary. After consideration of these comments, the Departments are announcing the availability of the following documents, available at <http://cciio.cms.gov> and www.dol.gov/ebsa/healthreform:

1. *SBC template.* The document is available in modifiable format (MS Word), as suggested by commenters for ease of use.

2. *Sample completed SBC.* This document was completed using information for sample health coverage and provides a general illustration of a completed SBC.

3. *Instructions.* For assistance in completing the SBC template, separate instructions are available for group health coverage and for individual health insurance coverage.

4. *Why This Matters language.* The SBC instructions include language that must be used when completing the "Why This Matters" column on the first page of the SBC template. Two language options are provided depending on whether the answer in the applicable row is "yes" or "no", according to the terms of the plan or coverage.

5. *Coverage examples.* This guidance document, together with information provided in Microsoft Excel format by HHS at <http://cciio.cms.gov> and accessible via hyperlink from www.dol.gov/ebsa/healthreform, provides all the information necessary

to perform the coverage example calculations.

6. *Uniform glossary.* The uniform glossary of health coverage and medical terms may not be modified by plans or issuers.

In revising the proposed template, instructions, and other materials, the Departments made several changes that were suggested in comments. Some of these changes were made at the request of self-insured plans, which commented that terminology in the SBC template was appropriate only for insured coverage. For example, terms such as "policy" and "insurer" have been changed to "coverage" and "plan", respectively. In addition, because rights to continue coverage vary based on many factors (including plan size, whether the plan is insured or self-insured, and State law), the description of rights to continue coverage has been modified to reference Federal and State protections more generally and include contact information for questions. Additionally, the data element in the proposed template labeled as "Policy Period" has been revised to be labeled as "Coverage Period." The instructions for this data element have also been updated, to allow for situations in which there is no known end date to the coverage period when the SBC is prepared, and for situations in which an updated SBC is being provided to satisfy the requirements of paragraph (b) of the final regulations, relating to notice of a modification. The Departments also revised the disclaimer language at the beginning of the uniform glossary, to make clear that the glossary is intended to be educational in nature and that the definitions contained in the glossary may not be the same as the definitions used by a particular plan or issuer.

Certain changes were also made to the SBC template and instructions for completing the template to conform to changes made in the final regulations. The final regulations eliminated premiums from the required content for the SBC document. Therefore, the row for communicating premium information has been removed from the SBC template document and the instructions for completing this section have also been removed. Additionally, language was added to the instructions to address expatriate plans and policies. Specifically, the new instruction allows an expatriate plan or policy to include a reference on the SBC template in the "Other Covered Services" box regarding where to find information about coverage provided outside of the United States.

Additional flexibility was also added to the instructions for completing the

¹¹ 76 FR 52475 (August 22, 2011).

SBC template. The instructions specify that, to the extent a plan's terms that are required to be described in the SBC template cannot reasonably be described in a manner consistent with the template and instructions, the plan or issuer must accurately describe the relevant plan terms while using its best efforts to do so in a manner that is still as consistent with the instructions and template format as reasonably possible.

The Departments also reduced the number of coverage examples required for SBCs issued during the first year of applicability to two examples, having a baby (normal delivery) and managing type 2 diabetes (routine maintenance of a well-controlled condition). The breast cancer example has been removed from the template and HHS will be providing treatment and reimbursement information only to complete the coverage examples relating to having a baby and managing diabetes. Additionally, the Departments modified some of the language to clarify that the coverage examples are not intended to demonstrate costs for an actual, specific person (for example the "You Pay" language was changed to "Patient Pays").

Modifications were also made to the benefits scenarios. First, the underlying benefits scenarios were modified to more accurately reflect current accepted standards of care. For example, the proposed maternity scenario included two ultrasounds during the early stages of pregnancy, which is not necessary for a routine pregnancy, so the final

scenario includes one ultrasound at 20 weeks. In addition, the final maternity scenario no longer includes some services that are clinically appropriate, but not clinically required, such as circumcision. In the proposed diabetes scenario, the metformin dosage was 1000 mg twice daily, which may not be appropriate for well-controlled type 2 diabetes. The final scenario now states that metformin dosage is 500 mg twice daily. In addition, the proposed diabetes scenario included two podiatrist office visits, which has been reduced to one annual visit, which is clinically appropriate for well-controlled type 2 diabetes. The pricing data in both scenarios (allowed amounts) has been refined to more closely reflect reimbursement rates in the private health insurance markets. The benefits scenario has also been updated to reflect correct coding practices, and HHS is now providing both ICD-9 and ICD-10 codes for the maternity scenario, in anticipation of the October 1, 2013 transition to ICD-10.

IV. Paperwork Reduction Act

According to the Paperwork Reduction Act of 1995 (Pub. L. 104-13) (PRA), no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The Departments note that a Federal agency cannot conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and displays a currently valid OMB control number,

and the public is not required to respond to a collection of information unless it displays a currently valid OMB control number. *See* 44 U.S.C. 3507. Also, notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number. *See* 44 U.S.C. 3512.

This document relates to the information collection request (ICR) contained in final regulations titled "Summary of Benefits and Coverage and the Uniform Glossary," which is published elsewhere in this issue of the **Federal Register**. For a discussion of the hour and cost burden associated with the ICR, please see those final regulations.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Signed this 7th day of February 2012.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: February 6, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: February 6, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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