DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 54 and 602

TD 9575

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DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB52

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CMS-9982-F

45 CFR Part 147

RIN 0938-AQ73

Summary of Benefits and Coverage and Uniform Glossary

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: Final rule.

SUMMARY: This document contains final regulations regarding the summary of benefits and coverage and the uniform glossary for group health plans and health insurance coverage in the group and individual markets under the Patient Protection and

Affordable Care Act. This document implements the disclosure requirements under section 2715 of the Public Health Service Act to help plans and individuals better understand their health coverage, as well as other coverage options. A guidance document published elsewhere in this issue of the **Federal Register** provides further guidance regarding compliance.

DATES: Effective date. These final regulations are effective [**INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER**].

Applicability date. The requirements to provide an SBC, notice of modification, and uniform glossary under PHS Act section 2715 and these final regulations apply for disclosures to participants and beneficiaries who enroll or re-enroll in group health coverage through an open enrollment period (including re-enrollees and late enrollees) beginning on the first day of the first open enrollment period that begins on or after September 23, 2012. For disclosures to participants and beneficiaries who enroll in group health plan coverage other than through an open enrollment period (including individuals who are newly eligible for coverage and special enrollees), the requirements under PHS Act section 2715 and these final regulations apply beginning on the first day of the first plan year that begins on or after September 23, 2012. For disclosures to plans, and to individuals and dependents in the individual market, these requirements are applicable to health insurance issuers beginning on September 23, 2012.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Heather Raeburn, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080;

Jennifer Libster or Padma Shah, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (301) 492-4222.

SUPPLEMENTARY INFORMATION:

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 website (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) website (http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp) and information on health reform can be found at http://www.healthcare.gov.

I. Executive Summary

A. Purpose of the Regulatory Action

1. Need for Regulatory Action

Under section 2715 of the Public Health Service Act (PHS Act), as added by the Patient Protection and Affordable Care Act (Affordable Care Act), the Departments of Health and Human Services, Labor, and the Treasury (the Departments) are to develop standards for use by group health plans and health insurance issuers offering group or individual health insurance coverage in compiling and providing a summary of benefits and coverage (SBC) that "accurately describes the benefits and coverage under the applicable plan or coverage." PHS Act section 2715 also calls for the "development of standards for the definitions of terms used in health insurance coverage."

This regulation establishes the standards required to be met under PHS Act section 2715. Among other things, these standards ensure this information is presented in clear language and in a uniform format that helps consumers to better understand their coverage and better compare coverage options. The current patchwork of non-uniform consumer disclosure requirements makes shopping for coverage inefficient, difficult, and time-consuming, particularly in the individual and small group market, but also in some large employer plans in which workers may be confused about the value of their health benefits as part of their total compensation. As a result of this confusion, health insurance issuers and employers may face less pressure to compete on price, benefits, and quality, contributing to inefficiency in the health insurance and labor markets.

The statute is detailed but not self-implementing, contains ambiguities, and specifically requires the Departments to develop standards, consult with the National Association of Insurance Commissioners, and issue regulations. Therefore these consumer protections cannot be established without this regulation.

2. Legal Authority

The substantive authority for this regulation is generally PHS Act section 2715, which is incorporated by reference into Employee Retirement Income Security Act (ERISA) section 715 and the Internal Revenue Code (Code) section 9815. PHS Act section 2792, ERISA section 734, and Code section 9833 also provide rulemaking authority. (For a fuller discussion of the Departments' legal authority, see section V. of this preamble.)

B. Summary of the Major Provisions of This Regulatory Action

Paragraph (a) of the final regulations implements the general disclosure requirement and sets forth the standards for who provides an SBC, to whom, and when. The regulations outline three different scenarios under which an SBC will be provided: (1) by a group health insurance issuer to a group health plan; (2) by a group health insurance issuer and a group health plan to participants and beneficiaries; and (3) by a health insurance issuer to individuals and dependents in the individual market. For each scenario, an SBC must be provided in several different circumstances, such as upon application for coverage, by the first day of coverage (if information in the SBC has changed), upon renewal or reissuance, and upon request. The final regulations also include special rules to prevent unnecessary duplication in the provision of an SBC with respect to group health coverage and individual health insurance coverage.

The final regulations set forth a list of requirements for the SBC that generally mirror those set forth in the statute. There are a total of 12 required content elements under the regulations, including uniform standard definitions of medical and health coverage terms, which will help consumers better understand their coverage; a description of the coverage including the cost sharing requirements such as deductibles, coinsurance, and co-payments; and information regarding any exceptions, reductions, or limitations under the coverage. The final regulations also require inclusion of coverage examples, which illustrate benefits provided under the plan or coverage for common benefits scenarios. In addition, the regulations specify requirements related to the appearance of the SBC, which generally must be presented in a uniform format, cannot exceed four double-sided pages in length, and must not include print smaller than 12-point font. These requirements are detailed further in a Notice published elsewhere in

today's Federal Register providing additional guidance related to PHS Act section 2715 and these final regulations.

PHS Act section 2715 and the final regulations also require that plans and issuers provide notice of modification in any of the terms of the plan or coverage involved that would affect the content of the SBC, that is not reflected in the most recently provided SBC, and that occurs other than in connection with a renewal or reissuance of coverage.

Finally, the statute directs the Departments to develop standards for definitions for certain insurance-related and medical terms, as well as other terms that will help consumers understand and compare the terms of coverage and the extent of medical benefits (including any exceptions and limitations). Group health plans and health insurance issuers must provide the uniform glossary in the appearance specified by the Departments, so that the glossary is presented in a uniform format and uses terminology understandable by the average plan enrollee or individual covered under an individual policy. A guidance document published elsewhere in today's **Federal Register** provides further guidance with respect to the uniform glossary.

The requirements to provide an SBC, notice of modification, and uniform glossary under PHS Act section 2715 and these final regulations apply for disclosures with respect to participants and beneficiaries who enroll or re-enroll in group health coverage through an open enrollment period (including re-enrollees and late enrollees), beginning on the first day of the first open enrollment period that begins on or after September 23, 2012. For disclosures to participants and beneficiaries who enroll in group health plan coverage other than through an open enrollment period (including individuals who are newly eligible for coverage and special enrollees), the requirements

under PHS Act section 2715 and these final regulations apply beginning on the first day of the first plan year that begins on or after September 23, 2012. For disclosures to plans, and to individuals and dependents in the individual market, these requirements apply to health insurance issuers beginning on September 23, 2012.

C. Costs and Benefits

The direct benefits of these final regulations come from improved information, which will enable consumers, both individuals and employers, to better understand the coverage they have and make better coverage decisions, based on their preferences with respect to benefit design, level of financial protection, and cost. The Departments believe that such improvements will result in a more efficient, competitive market. These final regulations will also benefit consumers by reducing the time they spend searching for and compiling health plan and coverage information.

Under the final regulations, group health plans and health insurance issuers will incur costs to compile and provide the summary of benefits and coverage and uniform glossary of health coverage and medical terms. The Departments estimate that the annualized cost may be around $73 million. As is common with regulations implementing new policies, there is considerable uncertainty arising from general data limitations and the degree to which economies of scale exist for disclosing this information. Nonetheless, the Departments believe that these final regulations lower overall administrative costs from the proposed regulations because of several policy changes, notably flexibility in the instructions for completing the SBC, the omission of premium (or cost of coverage) information from the SBC, the reduction in the number of

coverage examples required from three to two, and provisions allowing greater flexibility for electronic disclosure.

In accordance with Executive Orders 12866 and 13563, the Departments believe that the benefits of this regulatory action justify the costs.

II. Background

The Patient Protection and Affordable Care Act, Pub. L. 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act, Pub. L. 111-152, was enacted on March 30, 2010 (these are collectively known as the "Affordable Care Act"). The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term "group health plan" includes both insured and self-insured group health plans.[1] The Affordable Care Act 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 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. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes.

[1] The term "group health plan" is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term "health plan," as used in other provisions of title I of the Affordable Care Act. The term "health plan" does not include self-insured group health plans.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA by section 715). The preemption provisions of ERISA section 731 and PHS Act section 2724[2] (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of part 7 of ERISA and title XXVII of the PHS Act, as amended by the Affordable Care Act, are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of provisions added to the PHS Act by the Affordable Care Act. Accordingly, State laws with stricter health insurance issuer requirements than those imposed by the PHS Act will not be superseded by those provisions. (Preemption and State flexibility under PHS Act section 2715 are discussed more fully below under section III.D.)

The Departments of Health and Human Services (HHS), Labor, and the Treasury (the Departments) are taking a phased approach to issuing regulations implementing the revised PHS Act sections 2701 through 2719A and related provisions of the Affordable Care Act. These final regulations are being published to implement the disclosure requirements under PHS Act section 2715. As discussed more fully below, a document containing further guidance for compliance is published elsewhere in this issue of the **Federal Register**.

[2] Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

III. Overview of the Final Regulations

A. Summary of Benefits and Coverage

1. In General

Section 2715 of the PHS Act, added by the Affordable Care Act, directs the Departments to develop standards for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage in compiling and providing a summary of benefits and coverage (SBC) that "accurately describes the benefits and coverage under the applicable plan or coverage." PHS Act section 2715 also calls 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 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."[3] On July 29, 2011, the NAIC provided its final recommendations to the Departments regarding the SBC. On August 22, 2011, the Departments published in the **Federal Register** proposed regulations (76

[3] The NAIC convened a working group (NAIC working group) comprised of a diverse group of stakeholders. This working group met frequently each month for over one year while developing its recommendations. In developing its recommendations, the NAIC considered the results of various consumer testing sponsored by both insurance industry and consumer associations. Throughout the process, NAIC working group draft documents and meeting notes were displayed on the NAIC's website for public review, and several interested parties filed formal comments. In addition to participation from the NAIC working group members, conference calls and in-person meetings were open to other interested parties and individuals and provided an opportunity for non-member feedback. See www.naic.org/committees_b_consumer_information.htm.

FR 52442) and an accompanying document with templates, instructions, and related materials (76 FR 52475) for implementing the disclosure provisions under PHS Act section 2715. The proposed regulations and accompanying document adhered to the recommendations of the NAIC. After consideration of all the comments received on the proposed regulations and accompanying document, the Departments are publishing these final regulations. In conjunction with these final regulations, the Departments are also publishing a guidance document elsewhere in this issue of the **Federal Register** that contains further guidance for compliance, including information on how to obtain the SBC template (with instructions and sample language for completing the template) and the uniform glossary. All of these items are displayed at www.dol.gov/ebsa/healthreform and www.cciio.cms.gov.

2. Providing the SBC

Paragraph (a) of the final regulations implements the general disclosure requirement and sets forth the standards for who provides an SBC, to whom, and when. PHS Act section 2715 generally requires that an SBC be provided to applicants, enrollees, and policyholders or certificate holders. PHS Act section 2715(d)(3) places the responsibility to provide an SBC on "(A) a health insurance issuer (including a group health plan that is not a self-insured plan) offering health insurance coverage within the United States; or (B) in the case of a self-insured group health plan, the plan sponsor or designated administrator of the plan (as such terms are defined in section 3(16) of

ERISA)."[4] Accordingly, the final regulations interpret PHS Act section 2715 to apply to both group health plans and health insurance issuers offering group or individual health insurance coverage. In addition, consistent with the statute, the final regulations hold the plan administrator of a group health plan responsible for providing an SBC. Under the final regulations, the SBC must be provided in writing and free of charge.

Several commenters argued that large group health plans or self-insured group health plans should be exempt from the requirement to provide the SBC. Many of these commenters noted that such plans already provide a wealth of useful information, including a summary plan description and open season materials that accurately describe the plan and any coverage options. However, the statute includes no such exemption for large or self-insured plans. Moreover, the Departments believe that the SBC's uniform format and appearance requirements will allow individuals to easily compare coverage options across different types of plans and insurance products, including those offered through Affordable Insurance Exchanges (Exchanges) beginning in 2014.

Several commenters asked whether the SBC is required to be provided with respect to all group health plans, including certain account-type arrangements such as health flexible spending arrangements (health FSAs)[5], health reimbursement arrangements (HRAs)[6], and health savings accounts (HSAs)[7]. An SBC need not be provided for plans, policies, or benefit packages that constitute excepted benefits. Thus,

[4] ERISA section 3(16) defines an administrator as: (i) the person specifically designated by the terms of the instrument under which the plan is operated; (ii) if an administrator is not so designated, the plan sponsor; or (iii) in the case of a plan for which an administrator is not designated and plan sponsor cannot be identified, such other person as the Secretary of Labor may by regulation prescribe.
[5] See Code section 106(c)(2).
[6] See IRS Notice 2002-45, 2002-2 C.B. 93.
[7] See Code section 223.

for example, an SBC need not be provided for stand-alone dental or vision plans or health FSAs if they constitute excepted benefits under the Departments' regulations.[8] If benefits under a health FSA do not constitute excepted benefits, the health FSA is a group health plan generally subject to the SBC requirements. For a health FSA that does not meet the criteria for excepted benefits and that is integrated with other major medical coverage, the SBC is prepared for the other major medical coverage, and the effects of the health FSA can be denoted in the appropriate spaces on the SBC for deductibles, copayments, coinsurance, and benefits otherwise not covered by the major medical coverage. A stand-alone health FSA must satisfy the SBC requirements independently.

An HRA is a group health plan. Benefits under an HRA generally do not constitute excepted benefits, and thus HRAs are generally subject to the SBC requirements. A stand-alone HRA generally must satisfy the SBC requirements (though many of the limitations that apply under traditional fee-for-service or network plans do not apply under stand-alone HRAs). An HRA integrated with other major medical coverage need not separately satisfy the SBC requirements; the SBC is prepared for the other major medical coverage, and the effects of employer allocations to an account under the HRA can be denoted in the appropriate spaces on the SBC for deductibles, copayments, coinsurance, and benefits otherwise not covered by the other major medical coverage.

HSAs generally are not group health plans and thus generally are not subject to the SBC requirements. Nevertheless, an SBC prepared for a high deductible health plan

[8] See 26 CFR 54.9831-1(c), 29 CFR 2590.732(c), 45 CFR 146.145(c).

associated with an HSA can mention the effects of employer contributions to HSAs in the appropriate spaces on the SBC for deductibles, copayments, coinsurance, and benefits otherwise not covered by the high deductible health plan.

There are three general scenarios under which an SBC will be provided: (1) by a group health insurance issuer to a group health plan; (2) by a group health insurance issuer and a group health plan to participants and beneficiaries; and (3) by a health insurance issuer to individuals and dependents in the individual market. In general, the proposed regulations directed that, in each of these scenarios, the SBC be provided when an employer or individual is comparing health coverage options, including prior to purchasing or enrolling in a particular plan or policy.

Some commenters asserted that certain timing requirements in the proposed regulations could be administratively difficult for plans and issuers to meet under certain conditions, such as when negotiations of policy terms are ongoing less than 30 days before renewal, making the proposed timeframe for providing the SBC difficult or impossible to achieve. In response to public comments, the final regulations streamline and harmonize the rules for providing the SBC, while ensuring that individuals and employers have timely and complete information under all three scenarios in which an SBC might be provided. Moreover, in certain circumstances, the final regulations provide plans and issuers with additional time to provide the SBC. For example, under the proposed regulations, an SBC would have been required to be provided as soon as practicable following an application for health coverage or a request for an SBC, but in no event later than seven days following the application or request. For all three scenarios under which an SBC might be provided, the final regulations substitute a seven

business day period for the seven calendar day period in the proposed regulations in each place it appeared.

The Departments also received comments regarding issuance of an SBC at renewal or reissuance of coverage. The proposed regulations would have required that, if written application materials are required for renewal, the SBC must be provided no later than the date on which the materials are distributed. This requirement has been retained without change in the final regulations. In addition, upon an automatic renewal of coverage (that is, when written application materials are not required for renewal), the proposed regulations would have required a new SBC to be provided no later than 30 days prior to the first day of coverage under the new plan or policy year. The final regulations require that, in general, if renewal or reissuance of coverage is automatic, the SBC must be provided no later than 30 days prior to the first day of the new plan or policy year. However, with respect to insured coverage, in situations in which the SBC cannot be provided within this timeframe because, for instance, the issuer and the purchaser have not yet finalized the terms of coverage for the new policy year, the final regulations provide an exception. Under that circumstance, the SBC must be provided as soon as practicable, but in no event later than seven business days after the issuance of the policy, certificate, or contract of insurance (for simplicity, referred to collectively as a "policy" in the remainder of this preamble), or the receipt of written confirmation of intent to renew, whichever is earlier. The regulations provide this flexibility only when the terms of coverage are finalized in fewer than 30 days in advance of the new policy year; otherwise, the SBC must be provided upon automatic renewal no later than 30 days prior to the first day of coverage under the new plan or policy year.

a. Provision of the SBC by an Issuer to a Plan

Paragraph (a)(1)(i) of the final regulations requires a health insurance issuer offering group health insurance coverage to provide an SBC to a group health plan (including, for this purpose, its sponsor) upon an application by the plan for health coverage. The SBC must be provided as soon as practicable following receipt of the application, but in no event later than seven business days following receipt of the application. If there is any change to the information required to be in the SBC before the first day of coverage, the issuer must update and provide a current SBC to the plan no later than the first day of coverage. If the information is unchanged, the SBC does not need to be provided again in connection with coverage for that plan year, except upon request. As noted later in this preamble, the final regulations, in contrast to the proposed regulations, do not include premium or cost of coverage information as a required element of the SBC. In many cases, the only change to the information the proposed regulations required to be in the SBC between application for coverage and the first day of coverage is the premium or cost of coverage information. Because these final regulations eliminate the requirement to include premium or cost of coverage information in the SBC, the Departments anticipate that the number of circumstances in which issuers will have to provide a second SBC will be significantly fewer under the final regulations than they would have been under the proposed regulations.

b. Provision of the SBC by a Plan or Issuer to Participants and Beneficiaries

Under paragraph (a)(1)(ii) of the final regulations, a group health plan (including the plan administrator), and a health insurance issuer offering group health insurance

coverage, must provide an SBC to a participant or beneficiary[9] with respect to each benefit package offered by the plan or issuer for which the participant or beneficiary is eligible.[10] Some commenters stated that SBCs should only be provided to participants, not beneficiaries, or that the SBC should only be provided to beneficiaries upon request. The statutory language, which refers to "applicants" and "enrollees," could be interpreted to support either interpretation. These final regulations retain the requirement that the SBC be provided to both participants and beneficiaries. However, as described below, the final regulations include an anti-duplication rule under which a single SBC may be provided to a family unless any beneficiaries are known to reside at a different address. Accordingly, separate SBCs need to be provided to beneficiaries only in limited circumstances.

The SBC must be provided as part of any written application materials that are distributed by the plan or issuer for enrollment. If the plan does not distribute written application materials for enrollment, the SBC must be distributed no later than the first date the participant is eligible to enroll in coverage for the participant or any beneficiaries. If there is any change to the information required to be in the SBC between

[9] ERISA section 3(7) defines a participant as: any employee or former employee of an employer, or any member or former member of an employee organization, who is or may become eligible to receive a benefit of any type from an employee benefit plan which covers employees of such employers or members of such organization, or whose beneficiaries may be eligible to receive any such benefit. ERISA section 3(8) defines a beneficiary as: a person designated by a participant, or by the terms of an employee benefit plan, who is or may become entitled to a benefit thereunder.

[10] With respect to insured group health plan coverage, PHS Act section 2715 generally places the obligation to provide an SBC on both a plan and issuer. As discussed below, under section III.A.2.d., "Special Rules to Prevent Unnecessary Duplication With Respect to Group Health Coverage", if either the issuer or the plan provides the SBC, both will have satisfied their obligations. As they do with other notices required of both plans and issuers under Part 7 of ERISA, Title XXVII of the PHS Act, and Chapter 100 of the Code, the Departments expect plans and issuers to make contractual arrangements for sending SBCs. Accordingly, the remainder of this preamble generally refers to requirements for plans or issuers.

the application for coverage and the first day of coverage, the plan or issuer must update and provide a current SBC to a participant or beneficiary no later than the first day of coverage.

Under the final regulations, the plan or issuer must also provide the SBC to special enrollees.[11] The proposed regulations would have required that the SBC be provided within seven calendar days of a request for special enrollment. One commenter stated that special enrollees should not be distinguished from other enrollees with such expedited disclosure, particularly since they have already enrolled in coverage and are no longer comparing coverage options. The final rule provides that special enrollees must be provided the SBC no later than when a summary plan description is required to be provided under the timeframe set forth in ERISA section 104(b)(1)(A) and its implementing regulations, which is 90 days from enrollment. The revised timing requirement related to providing an SBC in connection with special enrollment is expected to reduce administrative costs for providing SBCs to these individuals, who have already chosen the plan, policy, or benefit package in which to enroll. To the extent individuals who are eligible for special enrollment and are contemplating their coverage options would like to receive SBCs earlier, they may always request an SBC with respect to any particular plan, policy, or benefit package and the SBC is required to be provided as soon as practicable, but in no event later than seven business days following receipt of the request (as discussed more fully below).

c. Provision of the SBC Upon Request in Group Health Coverage

[11] Regulations regarding special enrollment are available at 26 CFR 54.9801-6, 29 CFR 2590.701-6, and 45 CFR 146.117.

As discussed earlier in this preamble, a health insurance issuer offering group health insurance coverage must provide the SBC to a group health plan (and a plan or issuer must provide the SBC to a participant or beneficiary) upon request for an SBC or summary information about the health coverage, as soon as practicable, but in no event later than seven business days following receipt of the request. The Departments received several comments addressing the requirement to provide the SBC upon request. Many comments were supportive of this approach, especially with regards to participants and beneficiaries needing information about their coverage in the middle of a plan year after life changes. Other comments suggested that providing SBCs to employers and individuals who are only "shopping" for coverage and not yet enrolled is unnecessary and will require multiple SBCs to be provided as employers and individuals go through underwriting.

The final regulations retain the requirement that the SBC be provided upon request to participants, beneficiaries and employers, including prior to submitting an application for coverage, because the SBC provides information that not only helps consumers understand their coverage, but also helps consumers compare coverage options prior to selecting coverage. The Departments believe it is essential for employers, participants, and beneficiaries to have this information to help make informed coverage decisions and believe that the modifications to the SBC template, including the removal of premium information, adequately addresses the concerns that health insurance issuers will have to provide multiple SBCs to employers and individuals prior to underwriting.

Health insurance issuers offering individual market coverage must also provide the SBC to individuals upon request, to allow consumers reviewing coverage options the same ability to compare coverage options in the individual market, as well in the Exchanges and the group markets.

d. Special Rules to Prevent Unnecessary Duplication With Respect to Group Health Coverage

The proposed regulations provided three rules to streamline provision of the SBC and prevent unnecessary duplication with respect to group health plan coverage. Paragraph (a)(1)(iii) of the final regulations retains these special rules, with some modifications. The first states that the requirement to provide an SBC generally will be considered satisfied for all entities if it is provided by any entity, so long as all timing and content requirements are satisfied. The second states that a single SBC may be provided to a participant and any beneficiaries at the participant's last known address. However, if a beneficiary's last known address is different than the participant's last known address, a separate SBC is required to be provided to the beneficiary at the beneficiary's last known address. Finally, under the special rule providing that SBCs are not required to be provided automatically upon renewal for benefit packages in which the participant or beneficiary is not enrolled, a plan or issuer generally has up to seven business days (rather than seven calendar days, as specified in the proposed regulation) to respond to a request to provide the SBC with respect to another benefit package for which the participant or beneficiary is eligible.

Many commenters pointed out the potential duplication and confusion that can result with carve-out arrangements, which is generally when a plan or issuer contracts

with an administrative service provider (such as a pharmacy benefit manager or managed behavioral health organization) to manage prescribed functions such as managed care and utilization review. Plans and issuers should coordinate with their service providers, and with each other, to ensure that the SBCs they provide are accurate.

e. Provision of the SBC by an Issuer Offering Individual Market Coverage

Under these final regulations, the Secretary of HHS sets forth standards applicable to individual health insurance coverage about who provides an SBC, to whom, and when. The provisions of the final regulations for individual market coverage parallel the group market requirements described above, with only those changes necessary to reflect the differences between the two markets, and the provisions of the final regulations are intended to more clearly reflect the similarity between the two sets of rules. For example, individuals and dependents in the individual market are comparable to group health plan participants and beneficiaries. Accordingly, an issuer offering individual health insurance coverage must provide an SBC to an individual or dependent upon receiving an application for any health insurance policy, as soon as practicable following receipt of the application, but in no event later than seven business days following receipt of the application. If there is any change in the information required to be in the SBC between the application for coverage and the first day of coverage, the issuer must update and provide a current SBC to an individual or dependent no later than the first day of coverage.[12] Additionally, an issuer must provide the SBC to any individual or dependent

[12] As noted elsewhere in this preamble, the final regulations, in contrast to the proposed regulations, do not include premium information as a required element of the SBC. Because, in many cases, the only change to the information required to be in the SBC before the first day of coverage is the premium, the

upon request for an SBC or summary information about a health insurance product as soon as practicable, but in no event later than seven business days following the request. Similar to the group market, a request for an SBC or summary information includes a request made at any time, including prior to applying for coverage.

The final regulations retain the individual market anti-duplication rule, similar to the group health coverage anti-duplication rule, for individual health insurance coverage that covers more than one individual (or an application for coverage that is being made for more than one individual). In that case, as under the proposed regulations, a single SBC may generally be provided to one address, unless any dependents are known to reside at a different address.

3. Content

PHS Act section 2715(b)(3) generally provides that the SBC must include:

a. Uniform definitions of standard insurance terms and medical terms so that consumers may compare health coverage and understand the terms of (or exceptions to) their coverage;

b. A description of the coverage, including cost sharing, for each category of benefits identified by the Departments;

c. The exceptions, reductions, and limitations on coverage;

d. The cost-sharing provisions of the coverage, including deductible, coinsurance, and copayment obligations;

e. The renewability and continuation of coverage provisions;

Departments anticipate that the number of circumstances in which issuers will have to provide a second SBC before the first day of coverage will significantly decrease under the final regulation.

f. A coverage facts label that includes examples to illustrate common benefits scenarios (including pregnancy and serious or chronic medical conditions) and related cost sharing based on recognized clinical practice guidelines;

g. A statement about whether the plan provides minimum essential coverage as defined under section 5000A(f) of the Code, and whether the plan's or coverage's share of the total allowed costs of benefits provided under the plan or coverage meets applicable requirements;

h. A statement that the SBC is only a summary and that the plan document, policy, or certificate of insurance should be consulted to determine the governing contractual provisions of the coverage; and

i. A contact number to call with questions and an Internet web address where a copy of the actual individual coverage policy or group certificate of coverage can be reviewed and obtained.

The proposed regulations generally mirrored the content elements set forth in the statute, with four additional elements recommended by the NAIC: (1) for plans and issuers that maintain one or more networks of providers, an Internet address (or similar contact information) for obtaining a list of the network providers; (2) for plans and issuers that maintain a prescription drug formulary, an Internet address where an individual may find more information about the prescription drug coverage under the plan or coverage; (3) an Internet address where an individual may review and obtain the uniform glossary; and (4) premiums (or cost of coverage for self-insured group health plans). The proposed regulations solicited comments on these additional four content elements. In addition, the proposed regulations solicited comments on whether the SBC

should include a disclosure informing individuals of their right to receive a paper copy of the glossary upon request.

These final regulations retain the first two proposed additional content elements without change, modify the third, and delete the fourth. The final regulations retain: (1) the inclusion of an Internet address (or other contact information) for obtaining a list of the network providers, and (2) the inclusion of an Internet address (or similar contact information) where an individual may find more information about the prescription drug coverage under the plan or coverage. The final regulations also retain the requirement of the inclusion of an Internet address where an individual may review and obtain the uniform glossary, with a modification. The Departments received several comments regarding the inclusion of information concerning the uniform glossary including a suggestion that individuals be informed of their right to request a paper copy of the uniform glossary. Commenters noted that the omission of such a disclosure would deny important information to some individuals who are most in need of this information. After review and consideration of the comments, the final regulations require information for obtaining copies of the uniform glossary, which includes an Internet address where an individual may review the uniform glossary, a contact phone number to obtain a paper copy of the uniform glossary, and a disclosure that paper copies of the uniform glossary are available. It is important to note that the definitions in the glossary are solely for the purpose of these regulations; they do not, for example, apply to Medicare coverage policy nor the Secretary of Health and Human Services' definition of essential health benefits.

The final regulations do not require the SBC to include premium or cost of coverage information. The Departments received numerous comments on this issue.

Comments supporting the inclusion of premium information stated that this information was essential for consumers to make meaningful coverage comparisons, and it was necessary for consumers to make coverage comparisons and understand their total financial exposure, as well as useful to encourage competition in the markets on both price and value. One comment stated that employees also need this information to know if the coverage offered by an employer meets the Affordable Care Act's affordability test,[13] which determines the eligibility of employees for premium tax credits with respect to qualified health plans purchased on an Exchange.[14] Comments opposing this additional content requirement stated that this requirement would be administratively burdensome in the group market, where health insurance issuers do not have information on employer contributions, and would not be able to provide accurate cost of coverage information to employees. In addition, some comments noted that it would not be possible to provide an accurate premium estimate prior to medical underwriting. Some comments recommended that premium information be provided in a separate document, for example, a premium table.

After considering all of the comments, the final regulations do not require the SBC to include premium or cost of coverage information. The Departments understand that it is administratively and logistically complex to convey this information to individuals in an SBC in divergent circumstances in both the individual and group markets, including, for example, when premiums differ based on family size and when, in

[13] See Code section 36B(c)(2)(C)(i)(II), as added by section 1401 of the Affordable Care Act.
[14] Providing information in the SBC for individuals relating to Exchanges and the premium tax credit is addressed in the document containing further compliance guidance that is published elsewhere in this issue of the **Federal Register**.

the group market, employer contributions impact cost of coverage. The Departments recognize that the inclusion of premium information in the SBC could result in numerous SBCs being required to be provided to individuals. However, if premium information is not required, only a single SBC might be necessary. The Departments believe that premium information can be more efficiently and effectively provided by means other than the SBC. For example, in the individual market, the Departments note that some of this information may be available through the Federal health care reform Web portal, HealthCare.gov,[15] to individuals shopping for coverage. Furthermore, the Departments anticipate that premium information for qualified health plans will be made widely available through Exchanges for coverage effective beginning in 2014.

With respect to the uniform definitions required by the statute, the Departments proposed to follow the NAIC's recommended two-part approach, requiring provision of – (1) a uniform glossary, which includes definitions of health coverage terminology, to be provided in connection with the SBC, and (2) a "Why this Matters" column for the SBC template (with instructions for plans and issuers to use in completing the SBC template).[16] The Departments retain this approach in the final regulations. The guidance document published elsewhere in today's **Federal Register** addresses comments received on the SBC and related materials (including the uniform glossary) and details the changes from the initial proposal.

[15] Established pursuant to 45 CFR 159.120 (75 FR 24470).
[16] National Association of Insurance Commissioners, Consumer Information Working Group, December 17, 2010, Final Package of Attachments. Available at http://www.naic.org/documents/committees_b_consumer_information_ppaca_final_materials.pdf.

The statute also directs that the SBC include a statement about whether a plan or coverage provides minimum essential coverage, as defined under section 5000A(f) of the Code, (minimum essential coverage statement) 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 (minimum value statement).[17] However, this content is not relevant until other elements of the Affordable Care Act are implemented. Therefore, the final regulations require the minimum essential coverage and minimum value statements to be included in SBCs with respect to coverage beginning on or after January 1, 2014.[18] Future guidance will address the minimum essential coverage and minimum value statements.

The statute also requires that an SBC contain a "coverage facts label." For ease of reference, the proposed regulations used the term "coverage examples" in place of the statutory term. The Departments received many comments regarding the coverage examples. Some comments supported the general approach in the proposed regulations and indicated that coverage examples would be a valuable comparison tool for consumers. Other comments expressed concerns that the coverage examples would cause confusion for consumers, as the examples do not represent the actual treatment plan for

[17] PHS Act section 2715(b)(3)(G) provides that this statement must indicate whether the plan or coverage (1) provides minimum essential coverage (as defined under section 5000A(f) of the Code) and (2) ensures that the plan's or coverage's share of the total allowed costs of benefits provided under the plan or coverage is not less than 60 percent of such costs. The minimum essential coverage and minimum value requirements are part of a larger set of health coverage reforms that take effect on January 1, 2014.

[18] In the Notice providing compliance guidance published separately in today's Federal Register, the Departments state that the SBC template (with instructions, samples, and a guide for coverage example calculations to be used in completing the SBC template) does not provide language to comply with these requirements because the Notice authorizes these documents only with respect to the first year of applicability. Information on the minimum essential coverage statement and the minimum value statement will be provided in future guidance.

any particular individual, or might not represent the actual costs that an individual might incur for a similar cost of treatment. Some such comments urged the Departments to take a different approach to the coverage examples, such as providing an actual cost calculator. The Departments also received comments on the number of coverage examples that should be required, as well as which benefit scenarios should be included in the final regulations. Comments varied with regards to the number of recommended coverage examples, ranging from one to more than six.

These final regulations retain the general approach to the coverage examples that was proposed.[19] Consumer testing performed on behalf of the NAIC[20] 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 very 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 individuals prior to enrollment, making it difficult for individuals and employers to make coverage comparisons.

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[19] The Departments are making one technical change in these final regulations. The proposed regulations stated that the underlying benefits scenario for a coverage example must be based on recognized clinical practice guidelines "available through" the National Guideline Clearinghouse (NGC), Agency for Healthcare Research and Quality. The Departments believe that the proposed regulations would have inadvertently excluded recognized clinical practice guidelines available through other sources, such as the National Comprehensive Cancer Network. Accordingly, these final regulations provide that a benefits scenario must be based on recognized clinical guidelines "as defined by" the NGC. Currently, the NGC uses a definition set forth by the Institute of Medicine. The current definition of clinical practice guidelines adopted by NGC is available at http://www.guideline.gov/about/inclusion-criteria.aspx.

[20] 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.

Nonetheless, as discussed in the guidance document issued elsewhere in this issue of the **Federal Register**, the Departments are taking a phased approach to implementing the coverage examples and intend to consider additional feedback from consumer testing in the future.

To the extent a plan's terms that are required to be 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 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 the effects of a health FSA or an HRA are being described, or if a plan provides different cost sharing based on participation in a wellness program.

Finally, the Departments solicited comments on whether any special rules are necessary to accommodate expatriate plans and received comments related to adjustments needed for expatriate plan coverage. Some commenters noted that PHS Act section 2715(d)(3) refers to a health insurance issuer "offering health insurance coverage within the United States."[21] Other commenters suggested that coverage information that is particularly important to expatriates (such as medical evacuation, repatriation benefits, and country-appropriate care) be exempt from the requirements under PHS Act section

[21] The Departments note that, in the context of group health plan coverage, section 4(b)(4) of ERISA provides that a plan maintained outside the United States primarily for the benefit of persons substantially all of whom are nonresident aliens is exempt from ERISA title I, including ERISA section 715.

2715. These final regulations include a special provision that provides that, in lieu of summarizing coverage for items and services provided outside the United States, a plan or issuer may provide an Internet address (or similar contact information) for obtaining information about benefits and coverage provided outside the United States. Also, to the extent the plan or policy provides coverage available within the United States, the plan or issuer is still required to provide an SBC in accordance with PHS Act section 2715 that accurately summarizes benefits and coverage available within the United States.

4. Appearance

PHS Act section 2715 sets forth standards related to the appearance of the SBC. Specifically, the statute provides that the SBC is to be presented in a uniform format, utilizing terminology understandable by the average plan enrollee, that does not exceed four pages in length, and does not include print smaller than 12-point font. The final regulations retain the interpretation from the proposed regulations that the four-page limitation is four double-sided pages.[22]

The proposed regulations requested comments regarding the requirement to provide the SBC as a stand-alone document. Specifically, comments were requested about whether the SBC should be allowed to be included in a summary plan description (SPD) if it is intact and prominently displayed and the timing requirements for delivery of the SBC are met. The Departments received many comments in response to this request.

[22] PHS Act section 2715(b)(1) does not prescribe whether the four pages are four single-sided pages or four double-sided pages. The SBC template transmitted by NAIC exceeded four single-sided pages. After considering the extent of statutorily-required content in PHS Act section 2715(b)(3), as well as the appearance and language requirements of PHS Act sections 2715(b)(1) and (2), the Departments are interpreting four pages to be four double-sided pages, in order to ensure that this information is presented in an understandable and meaningful way.

Some comments opposed allowing the SBC to be included alongside or within an SPD, noting that SPDs tend to be lengthy documents and allowing this would be contrary to the purpose of requiring a short summary document. However, many comments supported this approach, indicating that permitting this option would reduce burdens and costs associated with printing and disseminating the SBC documents.

Paragraph (a)(3) of these final regulations requires plans and issuers to provide the SBC in the form specified by the Secretaries in guidance and completed in accordance with the instructions for completing the SBC that are specified by the Secretaries in guidance. A guidance document published elsewhere in this issue of the **Federal Register** provides such guidance. The Notice specifies that SBCs provided in connection with group health plan coverage may be provided either as a stand-alone document or in combination with other summary materials (for example, an SPD), if the SBC information is intact and prominently displayed at the beginning of the materials (such as immediately after the Table of Contents in an SPD) and in accordance with the timing requirements for providing an SBC. For health insurance coverage offered in the individual market, the SBC must be provided as a stand-alone document, but HHS notes that it can be included in the same mailing as other plan materials. This guidance regarding appearance may be modified for years after the first year of applicability.

5. Form

a. Group health plan coverage

To facilitate faster and less burdensome disclosure of the SBC, and to be consistent with PHS Act section 2715(d)(2), which permits disclosure in either paper or electronic form, the proposed regulations set forth rules to permit greater use of electronic

transmittal of the SBC. Those proposed regulations generally permitted issuers to provide the SBC to plans electronically (such as an e-mail or Internet posting) if certain conditions were met, and required plans and issuers providing the SBC to participants and beneficiaries to comply with the Department of Labor's electronic disclosure safe harbor requirements at 29 CFR 2520.104b-1(c). In all circumstances, the proposed regulations permitted plans and issuers to provide SBCs in paper form.

Comments generally supported permitting provision of the SBC electronically; however, some comments also asked for more flexibility with regard to electronic provision to participants and beneficiaries. These comments generally requested the rule for provision to participants and beneficiaries mirror the rule for provision to plans, and suggested this change would reduce costs and burdens associated with delivery. Other comments raised concerns about decreased consumer protection if the rules for providing an electronic SBC are too flexible. Some commenters also asked to extend to the group market the option available to individual market issuers to provide information to HealthCare.gov to be in compliance with the requirement to provide the SBC upon request for information about coverage prior to submitting an application.

After taking into account all of the comments, these final regulations generally retain the approach from the proposed regulations with respect to an SBC provided electronically by an issuer to a plan. For SBCs provided electronically by a plan or issuer to participants and beneficiaries, these final regulations make a distinction between a participant or beneficiary who is already covered under the group health plan, and a participant or beneficiary who is eligible for coverage but not enrolled in a group health plan. This distinction should provide new flexibility in some circumstances, while also

ensuring adequate consumer protections where necessary. For participants and beneficiaries who are already covered under the group health plan, these final regulations permit provision of the SBC electronically if the requirements of the Department of Labor's regulations at 29 CFR 2520.104b-1 are met. (Paragraph (c) of those regulations includes an electronic disclosure safe harbor.[23]) For participants and beneficiaries who are eligible for but not enrolled in coverage, these final regulations permit the SBC to be provided electronically if the format is readily accessible and a paper copy is provided free of charge upon request. Additionally, if the electronic form is an Internet posting, the plan or issuer must timely advise the individual in paper form (such as a postcard) or email that the documents are available on the Internet, provide the Internet address, and notify the individual that the documents are available in paper form upon request. The Departments note that the rules for participants and beneficiaries who are eligible for but not enrolled in coverage are substantially similar to the requirements for an issuer providing an electronic SBC to a plan. Finally, as in the proposed regulations, plans, and participants and beneficiaries (both covered, and eligible but not enrolled) have the right to receive an SBC in paper format, free of charge, upon request.

b. Individual health insurance coverage

The Departments received several comments on the proposed regulations, which generally required paper delivery of the SBC and set forth certain circumstances in which

[23] On April 7, 2011, the Department of Labor published a Request for Information regarding electronic disclosure at 76 FR 19285. In it, the Department of Labor stated that it is reviewing the use of electronic media by employee benefit plans to furnish information to participants and beneficiaries covered by employee benefit plans subject to ERISA. Because these regulations adopt the ERISA electronic disclosure rules by cross-reference, any changes that may be made to 29 CFR 2520.104b-1 in the future would also apply to the SBC.

electronic disclosure is permissible. Some comments recommended the SBC for individual market coverage be provided in paper form by default, unless the individual explicitly elects electronic delivery. These comments cautioned against assuming individuals have regular access to a computer or a requisite level of computer literacy simply because an individual submits a request online. Instead, they argued individuals should be able to specify the form in which they prefer to receive the SBC.

Other comments recommended greater flexibility for electronic delivery to reduce the costs of compliance, including eliminating the requirement to acknowledge receipt of an SBC provided through electronic delivery methods. These comments urged the Departments to adopt broader standards that reflect the current state of technology. Specifically, they recommended extending the electronic delivery rules that apply to disclosure from the issuer to the plan in paragraph (a)(4)(i) of the final regulations, to disclosure in the individual market. Some comments also suggested that plans provide in their enrollment materials a notice of the individual's right to receive a paper copy of the SBC upon request, and a telephone number or other contact information for making such request.

The Departments determined it is appropriate to amend the individual market standards in the proposed regulations related to the form and manner of delivery. Rather than specifying the circumstances making paper or electronic appropriate, these final regulations establish the general standard that an issuer offering individual health insurance coverage must provide the SBC in a manner that can reasonably be expected to provide actual notice regardless of the format. These final regulations provide several examples of methods of delivery that may satisfy this requirement. For instance, an issuer

may reasonably expect an individual or dependent to receive actual notice if the issuer provides the SBC by e-mail to an individual who has agreed to receive the SBC (or other electronic disclosures) by e-mail from the issuer and who has provided an e-mail address for that purpose. Or, if the SBC is posted on the Internet, an individual may reasonably be expected to receive actual notice if the issuer timely advises the individual in paper form (such as a postcard) that the documents are available on the Internet and includes the applicable Internet address.

These final regulations substantially retain the safeguards for electronic disclosure in the proposed regulations. Under these final regulations, an issuer providing the SBC electronically must ensure that the format is readily accessible; the SBC is placed in a location that is prominent and readily accessible; the SBC is provided in an electronic form that is consistent with the appearance, content, and language requirements of these final regulations; and that the issuer notifies the individual or dependent that the SBC is available from the issuer in paper form without charge upon request. These final regulations remove the "acknowledge receipt" requirement. However, the regulations also require that the SBC be provided in an electronic form which can be electronically retained and printed. These final regulations provide standards for the form and manner of providing the SBC that balance the objective of protecting consumers by providing accessible information with the goal of simplifying information collection burdens on issuers.

Finally, the final regulations clarify the provision that would deem health insurance issuers in the individual market to be in compliance with the requirement to provide the SBC to an individual requesting information about coverage prior to

submitting an application if the issuer provides the information to HealthCare.gov. The final regulations clarify that a health insurance issuer offering individual health insurance coverage must provide all of the content required under paragraph (a)(2), as specified in guidance by the Secretary, to HealthCare.gov to be deemed compliant with the requirement to provide an SBC to an individual requesting summary information prior to submitting an application for coverage. The final regulations further clarify that any SBC furnished pursuant to a request for an SBC, at the time of application or subsequently, would be required to be provided in a form and manner consistent with the rules described above. The Departments determined that this provision is consistent with the standards for electronic disclosure and reduces the burden of providing an SBC to individuals shopping for individual health insurance coverage.

The Departments received comments in support of this approach which stated HealthCare.gov provides useful summary information about health insurance products that are available to both individuals and small employers shopping for coverage and recommended the final regulations similarly extend the "deemed compliance" provision to the small group market. At this time, the Departments are reviewing comments requesting that the regulations extend the deemed compliance provision to the small group market and may issue future guidance on this issue.

6. Language

PHS Act section 2715(b)(2) provides that standards shall ensure that the SBC "is presented in a culturally and linguistically appropriate manner." The final regulations retain the approach of the proposed regulations and provide that, to satisfy the requirement to provide the SBC in a culturally and linguistically appropriate manner, a

plan or issuer follows the rules for providing notices with respect to claims and appeals in a culturally and linguistically appropriate manner under PHS Act section 2719, and paragraph (e) of its implementing regulations.[24] Note, nothing in these final regulations should be construed as limiting an individual's rights under Federal or State civil rights statutes, such as Title VI of the Civil Rights Act of 1964 (Title VI) which prohibits recipients of Federal financial assistance, including issuers participating in Medicare Advantage, from discriminating on the basis of race, color, or national origins. To ensure non-discrimination on the basis of national origin, recipients are required to take reasonable steps to ensure meaningful access to their programs and activities by limited English proficient persons. For more information, see, "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," available at http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/policyguidancedocument.html. While the Departments received several comments regarding the thresholds set forth in the claims and appeals regulations, the Departments are not making any changes to those standards through these final regulations. Any changes suggested will be considered as part of future rulemakings related to the regulations under PHS Act section 2719, so that the two rules remain consistent.

B. Notice of Modification

PHS Act section 2715(d)(4) directs that a group health plan or health insurance issuer offering group or individual health insurance coverage must provide notice of any

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

material modification if it makes a material modification (as defined under ERISA section 102) in any of the terms of the plan or coverage involved that is not reflected in the most recently provided SBC. The comments generally supported the standards regarding the notice of modification in the proposed regulations, which are adopted as final regulations without change.

However, some comments requested clarification concerning the requirement to provide a notice of modification. For example, several comments requested clarification on what changes in the terms of coverage would rise to the level of a material modification. For purposes of PHS Act section 2715, the proposed and final regulations interpret the statutory reference to the SBC to mean that only a material modification in the terms of the plan or coverage that would affect the content of the SBC; that is not reflected in the most recently provided SBC; and that occurs other than in connection with a renewal or reissuance of coverage would trigger the notice. In these circumstances, the notice would be required to be provided to enrollees (or, in the individual market, covered individuals) no later than 60 days prior to the date on which such change will become effective. A material modification, within the meaning of section 102 of ERISA, includes any modification to the coverage offered under a plan or policy that, independently, or in conjunction with other contemporaneous modifications or changes, would be considered by an average plan participant (or in the case of individual market coverage, an average individual covered under a policy) to be an important change in covered benefits or other terms of coverage under the plan or

policy.[25] A material modification could be an enhancement of covered benefits or services or other more generous plan or policy terms. It includes, for example, coverage of previously excluded benefits or reduced cost-sharing. A material modification could also be a material reduction in covered services or benefits, as defined in 29 CFR 2520.104b-3(d)(3) of the Department of Labor' regulations, or more stringent requirements for receipt of benefits. As a result, it also includes changes or modifications that reduce or eliminate benefits, increase cost-sharing, or impose a new referral requirement.[26] (However, changes to the information in the SBC resulting from changes in the regulatory requirements for an SBC are not changes to the plan or policy requiring the mid-year provision of a notice of modification, unless specified in such new requirements.)

The Departments also received comments seeking clarification on when a notice of modification must be provided. Several comments suggested that this notice must also be provided for modifications effective for new plan or policy years. The final regulations require that this notice be provided only for changes other than in connection with a renewal or reissuance of coverage. At renewal, plans and issuers must provide an updated SBC in accordance with the requirements otherwise applicable to SBCs. PHS Act section 2715 and paragraph (b) of the final regulations specify the timing for providing a notice of modification in situations other than in connection with a renewal or reissuance of coverage. To the extent a plan or policy implements a mid-year change that

[25] See DOL Information Letter, Washington Star/Washington-Baltimore Newspaper Guild to Munford Page Hall, II, Baker & McKenzie (February 8, 1985).
[26] See, e.g., Ward v. Maloney, 386 F.Supp.2d 607, 612 (M.D.N.C. 2005), which discusses judicial interpretations of when an amendment is and is not a material modification.

is a material modification, that affects the content of the SBC, and that occurs other than in connection with a renewal or reissuance of coverage, the final regulations require a notice of modification to be provided 60 days in advance of the effective date of the change. Comments generally supported the flexibility provided in the proposed regulations, which permitted plans and issuers to either provide an updated SBC reflecting the modifications or provide a separate notice describing the material modifications. Plans and issuers continue to have this flexibility under these final regulations.

For ERISA-covered group health plans subject to PHS Act section 2715, this notice is required in advance of the timing requirements under the Department of Labor's regulations at 29 CFR 2520.104b-3 for providing a summary of material modification (SMM) (generally not later than 210 days after the close of the plan year in which the modification or change was adopted, or, in the case of a material reduction in covered services or benefits, not later than 60 days after the date of adoption of the modification or change). In situations where a complete notice is provided in a timely manner under PHS Act section 2715(d)(4), an ERISA-covered plan will also satisfy the requirement to provide an SMM under Part 1 of ERISA.

C. Uniform Glossary

Section 2715(g)(2) of the PHS Act directs the Departments to develop standards for definitions for at least the following insurance-related terms: co-insurance, co-payment, deductible, excluded services, grievance and appeals, non-preferred provider, out-of-network co-payments, out-of-pocket limit, preferred provider, premium, and UCR (usual, customary and reasonable) fees. Section 2715(g)(3) of the PHS Act directs the

Departments to develop standards for definitions for at least the following medical terms: durable medical equipment, emergency medical transportation, emergency room care, home health care, hospice services, hospital outpatient care, hospitalization, physician services, prescription drug coverage, rehabilitation services, and skilled nursing care. Additionally, the statute directs the Departments to develop standards for such other terms as will help consumers understand and compare the terms of coverage and the extent of medical benefits (including any exceptions and limitations).

The final regulations adopt the approach of the proposed regulations with respect to the uniform glossary. This includes the adoption of the NAIC recommendation to include the following additional terms in the uniform glossary: allowed amount, balance billing, complications of pregnancy, emergency medical condition, emergency services, habilitation services, health insurance, in-network co-insurance, in-network co-payment, medically necessary, network, out-of-network co-insurance, plan, preauthorization, prescription drugs, primary care physician, primary care provider, provider, reconstructive surgery, specialist, and urgent care.

The Departments received a number of comments on the proposed uniform glossary. Several comments recommended that the final glossary include additional terms. In general, these comments recommended additional terms to provide consumers with additional information to help them better understand their coverage and the content of the SBC. These comments suggested the glossary include additional terms that may appear in the SBC and that may cause confusion, including specialty drugs, mental health services and behavioral health, cosmetic surgery, and preventive care. In addition, some commenters recommended including definitions for complex or potentially confusing

insurance terms, including explanations of plan types (such as health maintenance organizations or ERISA plans) and terms such as actuarial value and cost-sharing. Other commenters warned against making the uniform glossary too long.

Some commenters recommended modifications to certain definitions in the uniform glossary. For example, several comments recommended modification to the term "medical necessity." In developing the final uniform glossary, the Departments were very cognizant of the consumer testing performed by the NAIC with respect to the uniform glossary included in the proposed regulations and the need to convey in concise, easy-to-understand language basic medical and coverage terms.[27] Accordingly, very minor changes were made in the final uniform glossary, and it continues to include a disclaimer that the terms and definitions of terms in particular plans or policies may differ from those contained in the glossary, together with information on how to get a copy of the actual policy or plan document.

Some commenters requested flexibility to use their own, plan-specific or policy-specific terms in the glossary. PHS Act section 2715(g) is titled "Development of Standard Definitions." The NAIC developed the uniform glossary to provide generalized, plain-English definitions for common coverage and medical terms. The document was intended to help consumers understand the basics of insurance. At the same time, the document specifically cautions that it is intended to be a general educational tool and that individual plan terms may differ (and refers consumers to the

[27] 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 SBC template and the uniform glossary is available at: http://www.commonwealthfund.org/Publications/Issue-Briefs/2011/Feb/Making-Health-Insurance-Cost-Sharing-Clear.aspx.

SBC for information on how to get an accurate description of their actual plan or policy terms). A guidance document published elsewhere in this issue of the **Federal Register** announces the availability of the final uniform glossary. The SBC may be used by plans and issuers to convey more accurate descriptions, where appropriate.

Like the proposed regulations, the final regulations direct a plan or issuer to make the uniform glossary available upon request within seven business days. A plan or issuer satisfies this requirement by complying with the content requirement described in paragraph (a)(2)(i)(L) of the final regulations, which requires that the SBC include an Internet address where an individual may review and obtain the uniform glossary, a contact phone number to obtain a paper copy of the uniform glossary, and a disclosure that paper copies are available upon request. The Internet address may be a place where the document can be found on the plan's or issuer's website, or the website of either the Department of Labor or HHS. However, a plan or issuer must make a paper copy of the glossary available within seven business days upon request. Group health plans and health insurance issuers must provide the uniform glossary in the appearance specified by the Departments, so that the glossary is presented in a uniform format and uses terminology understandable by the average plan enrollee or individual covered under an individual policy.

D. Preemption

Section 2715 of the PHS Act is incorporated into ERISA section 715, and Code section 9815, and is subject to the preemption provisions of ERISA section 731 and PHS Act section 2724 (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)). Under these provisions, the requirements of part 7 of ERISA and part A of title XXVII of the

PHS Act, as amended by the Affordable Care Act, are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of part A of title XXVII of the PHS Act. Accordingly, State laws that impose requirements on health insurance issuers that are stricter than those imposed by the Affordable Care Act will not be superseded by the Affordable Care Act. Moreover, PHS Act section 2715(e) provides that the standards developed under PHS Act section 2715(a), "shall preempt any related State standards that require [an SBC] that provides less information to consumers than that required to be provided under this section, as determined by the [Departments]."

Reading these two preemption provisions together, the final regulations do not prevent States from imposing separate, additional disclosure requirements on health insurance issuers.

The Departments received several comments seeking clarification on the preemption of State disclosure standards. These comments indicate that many States have existing disclosure requirements that may be duplicative and noted consumers could be confused by multiple disclosures. These final regulations retain the preemption standard as stated in the proposed regulations. However, the Departments take note of the concerns about the potential for consumer confusion, and encourage States to take steps to harmonize existing State requirements with these Federal consumer disclosure requirements. The Departments will work with States to clarify the requirements, potential differences, and options.

In addition, some comments requested clarification that States may not require the modification of the SBC or uniform glossary in their own disclosure standards. Comments stated that any State modifications to these documents would defeat the purpose of having an SBC template and uniform glossary, and one comment requested that any State law modifications to these documents be preempted, and that any additional content required by State law be limited to an addendum to the SBC. If States require health insurance issuers to provide information not contained in the SBC or uniform glossary, then they may require issuers to provide that information only if it is provided in a document that is separate from the SBC. This separate document can, however, be provided at the same time as the SBC.

E. Failure to Provide

PHS Act section 2715(f), incorporated into ERISA section 715 and Code section 9815, provides that a group health plan (including its administrator), and a health insurance issuer offering group or individual health insurance coverage, that "willfully fails to provide the information required under this section shall be subject to a fine of not more than $1,000 for each such failure." In addition, under PHS Act section 2715(f), a separate fine may be imposed for each individual or entity for whom there is a failure to provide an SBC. Due to the different enforcement jurisdictions of the Departments, as well as their different underlying enforcement structures, the mechanisms for imposing the new penalty vary slightly, as discussed below.

1. Department of HHS

Enforcement of Part A of Title XXVII of the PHS Act, including section 2715, is generally governed by PHS Act section 2723 and corresponding regulations at 45 CFR

150.101 et seq. Under those provisions, a State has the discretion to enforce the provisions against health insurance issuers in the first instance, and the Secretary of HHS only enforces a provision after the Secretary determines that a State has failed to substantially enforce the provision. If a State enforces a provision such as PHS Act section 2715, it uses its own enforcement mechanisms. If the Secretary enforces, the statute provides for penalties of up to $100 per day for each affected individual.

PHS Act section 2715(f) provides that an entity that willfully fails to provide the information required under PHS Act section 2715 shall be subject to a fine of not more than $1,000 for each such failure. Such failure constitutes a separate offense with respect to each enrollee. This penalty can only be imposed by the Secretary.

Paragraph (e) of the final regulations clarifies that States have primary enforcement authority over health insurance issuers for any violations, whether willful or not, using their own remedies and that PHS Act section 2715 does not limit the Secretary's authority to impose penalties for willful violations regardless of State enforcement. However, the Secretary intends to use enforcement discretion if the Secretary determines that the State is adequately addressing willful violations.

The Secretary of HHS has direct enforcement authority for violations by non-Federal governmental plans, and will use the appropriate penalty for violations of section 2715, depending on whether the violation is willful. Paragraph (e) of the HHS final regulations cross references the enforcement regulations at 45 CFR 150.101 et seq., and states that they relate to any failure, regardless of intent, by a health insurance issuer or non-Federal governmental plan, to comply with any requirement of PHS Act section 2715.

2. Departments of Labor and the Treasury

The Department of Labor enforces the requirements of part 7 of ERISA with respect to ERISA-covered group health plans (generally, plans other than church plans or plans maintained by a governmental entity) and the Department of the Treasury enforces the requirements of chapter 100 of the Code with respect to group health plans maintained by an entity that is not a governmental entity. On April 21, 1999, pursuant to section 104 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, the Secretaries entered into a memorandum of understanding[28] that, among other things, established a mechanism for coordinating enforcement and avoiding duplication of effort for shared jurisdiction. The memorandum of understanding applies, as appropriate, to health legislation enacted after April 21, 1999 over which at least two of the Departments share jurisdiction, including PHS Act section 2715 as incorporated into ERISA and the Code. Therefore, in enforcing PHS Act section 2715, the Departments of Labor and the Treasury will coordinate to avoid duplication in the case of group health plans that are not church plans and that are not maintained by a governmental entity.

a. Department of Labor

The Department of Labor will issue separate regulations in the future describing the procedures for assessment of the civil fine provided under PHS Act section 2715(f) as incorporated by section 715 of ERISA. In accordance with ERISA section 502(b)(3), 29

[28] See 64 FR 70164 (December 15, 1999).

U.S.C. 1132(b)(3), the Secretary of Labor is not authorized to assess this fine against a health insurance issuer.

b. Department of the Treasury

If a group health plan (other than a plan maintained by a governmental entity) fails to comply with the requirements of chapter 100 of the Code, an excise tax is imposed under section 4980D of the Code. The excise tax is generally $100 per day per individual for each day that the plan fails to comply with chapter 100 with respect to that individual. Numerous rules under section 4980D reduce the amount of the excise tax for failures due to reasonable cause and not to willful neglect. Special rules apply for church plans. Taxpayers subject to the excise tax under section 4980D are required to report the failures under chapter 100 and the amount of the excise tax on IRS Form 8928. See 26 CFR 54.4980D-1, 54.6011–2, and 54.6151–1.

Section 2715(f) of the PHS Act subjects a plan sponsor or designated administrator to a fine of not more than $1,000 for each failure to provide an SBC. Unless and until future guidance provides otherwise, group health plans subject to chapter 100 of the Code should continue to report the excise tax of section 4980D on IRS Form 8928 with respect to failures to comply with PHS Act section 2715. The Secretaries of Labor and the Treasury will coordinate to determine appropriate cases in which the fine of PHS Act section 2715(f) should be imposed on group health plans that are in the jurisdiction of both Departments.

F. Applicability

PHS Act section 2715 provides that the requirement for group health plans and health insurance issuers to provide an SBC applies not later than 24 months after the date

of enactment of the Affordable Care Act (which is March 23, 2012). PHS Act section 2715 also provides that group health plans and health insurance issuers shall provide the SBC pursuant to standards developed by the Departments. The proposed regulations proposed an applicability date beginning March 23, 2012. At the same time, the Departments invited comments generally, as well as on a range of discrete issues, including the timing of the application of the SBC requirement. On November 17, 2011, the Departments issued guidance[29] providing that, until final regulations are issued and applicable, plans and issuers are not required to comply with PHS Act section 2715.

The Departments received numerous comments on the applicability date of the regulations. Several comments stated plans and issuers would need time to make changes to their systems and workflow processes and could not come into compliance by March 23, 2012 without incurring significant cost and administrative challenges. Some comments recommend delaying applicability for 12 months, noting that PHS Act section 2715 contemplates that plans and issuers would have 12 months from the date the Secretary develops standards to begin providing the SBC, while others recommended delaying applicability for 18 to 24 months to allow sufficient time for group health plans to revise and coordinate service vendor agreements. Other comments stated the requirements should apply beginning with a plan's open enrollment period to avoid disruption during the plan year. Still others recommended phasing in the requirements by market segment, starting with the individual market initially and broadening over time to

[29] See FAQs About Affordable Care Act Implementation Part VII and Mental Health Parity Implementation, available at www.dol.gov/ebsa/faqs/faq-aca7.html and cciio.cms.gov/resources/factsheets/aca_implementation_faqs7.html.

include the group market. These commenters emphasized the complexity in the group market of coordinating between the plan and the issuer (and perhaps across multiple issuers and/or service providers) and the greater need for standardized information in the individual market (where there are no other Federal requirements to provide summary information). Finally, some comments expressed support for the proposed March 23, 2012 applicability date, arguing individuals and employers should receive the consumer protections of PHS Act section 2715 no later than the date intended by statute.

Following review of the comments submitted on this issue and further consideration of the administrative and systems changes required to implement these requirements, the Departments have determined it would not be feasible to require plans and issuers to comply with the standards in the final regulations beginning March 23, 2012 and have delayed the applicability date for six months from that which was proposed to provide sufficient time for plans and issuers to come into compliance with these provisions. The Departments agree that implementing these provisions to coincide with employers' typical open enrollment processes in the group market will reduce confusion for current enrollees who typically make enrollment decisions during annual open enrollment periods and will avoid unnecessary cost to group health plan sponsors of producing these materials off-cycle. The final regulations provide that the requirements to provide an SBC, notice of modification, and uniform glossary under PHS Act section 2715 and these final regulations apply for disclosures with respect to participants and beneficiaries who enroll or re-enroll in group health coverage through an open enrollment period (including re-enrollees and late enrollees), beginning on the first day of the first open enrollment period that begins on or after September 23, 2012. For administrative

simplicity, with respect to disclosures to participants and beneficiaries who enroll in group health plan coverage other than through an open enrollment period (including individuals who are newly eligible for coverage and special enrollees), PHS Act section 2715 and these final regulations apply on the first day of the first plan year that begins on or after September 23, 2012. For disclosures to plans, and to individuals and dependents in the individual market, these requirements are applicable to health insurance issuers beginning September 23, 2012.

IV. Economic Impact and Paperwork Burden

A. Executive Orders 12866 and 13563—Department of Labor and Department of Health and Human Services

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). As discussed below, the Departments have concluded that these final regulations would not have economic impacts of $100 million or more in any one year or otherwise meet the definition of an "economically significant rule" under Executive Order 12866.