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Internal Revenue Service

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Employee Benefits Security Administration

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CMS-9982-F

45 CFR Part 147

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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.

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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 2724² (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 beneficiary⁹ 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 NAIC²⁰ 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.

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 understanding²⁸ 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 guidance²⁹ 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.

Nonetheless, consistent with Executive Orders 12866 and 13563, the Departments have provided an assessment of the potential benefits and the costs associated with this final regulation.

The Departments have updated the cost estimates from what was presented in the proposed regulations. Since publication of the proposed regulations, the Departments have continued to refine assumptions and estimates to take into account policy decisions made in the final regulations and to incorporate better data. The estimates presented in this rule are a result of those efforts and represent the Departments' best estimate. Discussion of the public comments and the updates to the Departments' estimates are included in the relevant sections of the impact analysis. While the Departments believe the estimates in these final regulations represent the Departments' best estimate, the Departments emphasize there is considerable uncertainty, as is common with regulations implementing new policies, and the discussion throughout the impact analysis reflects this.

1. Current Regulatory Framework

Health plan sponsors and issuers do not currently uniformly disclose information to consumers about benefits and coverage in a simple and consistent way. ERISA-covered group health plans are required to describe important plan information concerning eligibility, benefits, and participant rights and responsibilities in a summary plan description (SPD). But as these documents have increased in size and complexity – for example, due to the insertion of more legalistic language that is designed to mitigate the employer's risk of litigation – they have become more difficult for participants and

beneficiaries to understand.³⁰ Indeed, a recent analysis of SPDs from 40 employer health plans from across the United States (varying based on geography, firm size, and industry sector) found that, on average, SPDs are generally written at a first year college reading level (with readability ranging from a 9th grade reading level to nearly a college graduate reading level).³¹ Moreover, the formats of existing SPDs are not standardized. For example, while these documents could be dozens of pages long, there is no requirement that they include an executive summary. Additionally, group health plans not covered by ERISA, such as plans sponsored by State and local governments, are not required to comply with such disclosure requirements.

In the individual market, health insurance issuers are subject to various, diverse State disclosure laws. For example, States like Massachusetts,³² New York,³³ Rhode Island,³⁴ Utah³⁵ and Vermont³⁶ have established minimum standards for disclosure of health insurance information. However, even within such States, consumer disclosures vary widely with respect to their required content. Additionally, some State disclosure laws are limited to current enrollees, so that individuals shopping for coverage do not

³⁰ ERISA Advisory Council. Report of the Working Group on health and Welfare Benefit Plans' Communication. November 2005. Available at: http://www.dol.gov/ebsa/publications/AC_1105c_report.html.

³¹ "How Readable Are Summary Plan Descriptions For Health Care Plans?" Employee Benefit Research Institute (EBRI) Notes. October 2006, Vol. 27, No. 10. Available at: http://www.ebri.org/pdf/notespdf/EBRI_Notes_10-20061.pdf.

³² M.G.L.A. 176Q § 5 (2010).

³³ NY Ins. Law § 3217-a (2010).

³⁴ Office of the Health Insurance Commissioner Regulation 5: Standards for Readability of Health Insurance Forms, State of Rhode Island and Providence Plantations, August 21, 2010.

³⁵ Utah Code § 31A-22-613.5 (2010).

³⁶ Division of Health Care Administration, Rule 10.000: Quality Assurance Standards and Consumer Protections for Managed care Plans, State of Vermont, September 20, 1997.

receive information about health insurance coverage options. Other State disclosure requirements only extend to managed care organizations, and not to other segments of the market.³⁷

2. Need for Regulatory Action

Congress added new PHS Act section 2715 through the Affordable Care Act to ensure that plans and issuers provide benefits and coverage information in a more uniform format that helps consumers to better understand their coverage and better compare coverage options. These final regulations are necessary to provide standards for a summary of benefits and coverage (SBC) and a uniform glossary of terms used in health coverage. This approach is consistent with Executive Order 13563, which directs agencies to “identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. These approaches include... disclosure requirements as well as provision of information to the public in a form that is clear and intelligible.”

The current patchwork of consumer disclosure requirements makes the process of shopping for coverage an inefficient, difficult, and time-consuming task. Consumers incur significant search costs while trying to locate reliable cost, coverage and benefit

³⁷ For example, New York requires Health Maintenance Organizations to provide to prospective members, as well as policyholders, information on cost-sharing, including out-of-network costs, limitations and exclusions on benefits, prior authorization requirements, and other disclosures such as appeal rights. NY Ins. Law section 3217-a (2010). Utah requires each insurer issuing a health benefit plan to provide all enrollees, prior to enrollment in the health benefit plan, written disclosure of restrictions or limitations on prescription drugs and biologics, coverage limits under the plan, and any limitation or exclusion of coverage. Utah Code section 31A-22-613.5 (2010). Rhode Island requires all health insurance forms to meet minimum readability standards. Office of the Health Insurance Commissioner Regulation 5: Standards for Readability of Health Insurance Forms, State of Rhode Island and Providence Plantations, August 21, 2010.

data.³⁸ Such search costs arise, in part, due to a lack of uniform information across the various coverage options, particularly in the individual and small group markets, but also in large employer plans. Although not directly comparable, in Medigap, a market with standardized benefits, the average per-beneficiary search cost was estimated at \$72 —far higher than in other insurance markets, such as auto insurance.³⁹

In addition to individual consumers, employers, especially small business employers, also face a daunting search process when they shop for health coverage. A 2011 study of the commercial health insurance market found that many employers, especially small businesses, lack the necessary knowledge, sophistication, and information to efficiently choose appropriate health plans to purchase on behalf of their employees. This lack of knowledge, sophistication, and information requires health insurers to spend more money on marketing to target small business employers. Health insurers then pass the extra marketing costs on to employers in the form of higher premiums. The study determined that in 1997, this inefficiency cost consumers in the fully insured market \$34.4 billion. Employers' lack of knowledge, sophistication, and information also produces incentives for health insurers to charge different prices for identical products to different customers, depending upon the customer's negotiating skills. This price variability causes 64 percent more turnover in plan membership, than

³⁸ M. Susan Marquis *et al.*, "Consumer Decision Making in the Individual Health Insurance Market," 25 *Health Affairs* w.226, w.231-w.232 (May 2006). Available at: <http://content.healthaffairs.org/content/25/3/w226.full.pdf+html>.

³⁹ Nicole Maestas *et al.*, "Price Variation in Markets with Homogenous Goods: The Case of Medigap," National Bureau of Economic Research (January 2009).

would otherwise occur. High levels of turnover discourage health insurers from promoting healthy lifestyles and investing in the future health of their policyholders.⁴⁰

Given this difficulty in obtaining comparable information across and within health insurance markets, consumers may not always make informed purchase decisions that best meet the health and financial needs of themselves, their families, or their employees. Similarly, workers may overestimate or underestimate the value of employer-sponsored health benefits, and thus their total compensation; and health insurance issuers and employers may face less pressure to compete on price, benefits, and quality, leading to inefficiency in the health insurance and labor markets.

Furthermore, research suggests that many consumers do not understand how health coverage works. Oftentimes, contracts and benefit descriptions are written in technical language that requires a sophisticated level of literacy that many people do not have.⁴¹ One study found that consumers have particular difficulty understanding cost sharing and tend to underestimate their coverage for mental health, substance abuse and prescription drug benefits, while overestimating their coverage for long-term care.⁴²

3. Summary of Impacts

Table 1 below depicts an accounting statement summarizing the Departments' assessment of potential benefits, costs, and transfers associated with this regulatory

⁴⁰ Cebul, Randall D., James B. Rebitzer, Lowell J. Taylor, and Mark E. Votruba. 2011. "Unhealthy Insurance Markets: Search Frictions and the Cost and Quality of Health Insurance." *American Economic Review*, 101 (August 2011): 1842-1871.

⁴¹ For example, as discussed earlier, the average Summary Plan Description is written at a first-year college reading level. See Employee Benefit Research Institute, October 2006.

⁴² D.W. Garnick, A.M. Hendricks, K.E. Thorpe, J.P. Newhouse, K. Donelan and R.J. Blendon. "How well do Americans understand their health coverage?" *Health Affairs*, 12(3). 1993:204-12. Available at: <http://content.healthaffairs.org/content/12/3/204.full.pdf>.

action. The Departments have limited the period covered by the RIA to 2012–2013. Estimates are not provided for subsequent years, because there will be significant changes in the marketplace in 2014, including those related to the offering of new individual and small group plans through the Affordable Insurance Exchanges, and new market reforms outside of the new Exchanges, and the wide-ranging scope of these changes makes it difficult to project results for 2014 and beyond.

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 allow consumers choosing coverage to more easily compare coverage options. As a result, consumers may make better coverage decisions, which more closely match 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 would 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 would incur costs to compile and provide the summary of benefits and coverage disclosures and a uniform glossary of health coverage and medical terms. The Departments estimate that the annualized cost may be around \$73 million, although there is considerable uncertainty arising from general data limitations and the degree to which economies of scale exist for disclosing this information. The Departments' annualized cost estimates for the final regulation are higher than the estimated annualized cost of \$50 million, which was set forth in the proposed regulations, because, among other things, the Departments now

have narrowed the cost estimate period from 2011-2013 to 2012-2013. This change reflects the fact that the Departments issued guidance on November 17, 2011 providing that, until final regulations are issued and applicable, plans and issuers are not required to comply with PHS Act section 2715, and the fact that these final regulations are being published in 2012.⁴³ Nonetheless, these final regulations lower overall administrative costs compared to the proposed regulations because of several policy changes, notably the omission of premium or cost of coverage information from SBCs, the provision of only two coverage examples, and provisions allowing greater flexibility for electronic disclosures prior to enrollment in coverage.

The Departments anticipate that the provisions of these final regulations will help consumers, including employers, make better health coverage choices and more easily understand their coverage. In accordance with Executive Orders 12866 and 13563, the Departments believe that the benefits of this regulatory action justify the costs.

Table 1. Accounting Table

Benefits:				
Qualitative: Improved information will enable consumers, including applicants, enrollees, and policyholders, to more easily and efficiently understand and compare coverage, and as a result, make better choices.				
Costs:	Estimate	Year Dollar	Discount Rate Percent	Period Covered
Annualized Monetized (\$ millions/year)	\$73	2012	7	2012-2013
	\$73	2012	3	2012-2013

⁴³ 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.

4. Benefits

In developing these final regulations, the Departments carefully considered their potential effects, including costs, benefits, and transfers. Because of data limitations, the Departments did not attempt to quantify expected benefits of these final regulations. Nonetheless, the Departments were able to identify several benefits, which are discussed below.

These final regulations could generate significant economic and social welfare benefits to consumers. Under these final regulations, health insurance issuers and group health plans would provide clear and consistent information to consumers. Uniform disclosure is anticipated to benefit individuals shopping for, or enrolled in, group and individual health insurance coverage and group health plans. The direct benefits of these final regulations come from improved information, which will enable consumers to better understand the coverage they have and allow consumers choosing coverage to more easily compare options. As a result, consumers will make better coverage decisions, which more closely match 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 would also benefit consumers by reducing the time they spend searching for and compiling health plan and coverage information. As stated above, consumers in the individual market, as well as consumers in some large employer-sponsored plans, have a number of coverage options and must make a choice using disclosures and tools that vary widely in content and format. A growing body of decision-making research suggests that the abundance and complexity of information can

overwhelm consumers and create a significant non-price barrier to coverage.⁴⁴ For example, a RAND study of California's individual market found that reducing barriers to information about health insurance products would lead to increases in purchase rates comparable to modest price subsidies.⁴⁵ By ensuring consumers have access to readily available, concise, and understandable information about their coverage options, these final regulations could reduce consumers' cost of obtaining information and may increase health insurance purchase rates and satisfaction with the plan purchased.

Furthermore, greater transparency in pricing and benefits information will allow consumers to make more informed purchasing decisions, resulting in cost-savings for some value-conscious consumers who today pay higher premiums because of imperfect information about benefits.⁴⁶ In particular, the use of coverage examples called for by these final regulations would better enable consumers to understand how key coverage provisions operate in the context of recognizable health care situations and more meaningfully compare the level of financial protection offered by a plan or coverage, resulting in potential cost-savings.^{47, 48} The Departments therefore expect that uniform

⁴⁴ Judith H. Hibbard and Ellen Peters, "Supporting Informed Consumer Health Care Decisions: Data Presentation Approaches that Facilitate the Use of Information in Choice," *24 Annu. Rev. Public Health* 413, 416 (2003).

⁴⁵ M. Susan Marquis et al., "Consumer Decision Making in the Individual Health Insurance Market," *25 Health Affairs* w.226, w.231-w.232 (May 2006). Available at: <http://content.healthaffairs.org/content/25/3/w226.full.pdf+html>.

⁴⁶ A study of California's individual market found that 25 percent of consumers chose products with premiums that were more than 30 percent higher than the median price for an actuarially equivalent product for a similar person. Melinda Beeuwkes Buntin et al., "Trends and Variability In Individual Insurance Products," *Health Affairs* w3.449, w3.457 (2003), available at <http://content.healthaffairs.org/content/early/2003/09/24/hlthaff.w3.449.citation>.

⁴⁷ Shoshanna Sofaer et al., "Helping Medicare Beneficiaries Choose Health Insurance: The Illness Episode Approach," *30 The Gerontologist* 308-315 (1990).

disclosures under these final regulations will enable consumers to derive more value from their health coverage and enhance the ability of plan sponsors, particularly small businesses, to purchase products that are appropriate to both their needs and the health and financial needs of their employees.

Finally, these final regulations are expected to facilitate consumers' ability to understand their coverage. As stated above, research suggests that consumers do not understand how coverage works or the terminology used in health insurance policies. Consequently, consumers may face unexpected medical expenses if they become seriously ill. They may also become confused by a coverage or payment decision made by their plan or issuer, leading to inefficiency in the operation of employee benefit plans and health insurance coverage. By making it easier for consumers to understand the key features of their coverage, these final regulations would enhance consumers' ability to use their coverage. Additionally, the uniform format will make it easier for consumers who change jobs or insurance coverage to see how their new plan or coverage benefits are similar to and different from their previous coverage.

5. Costs

Section 2715 of the PHS Act and these final regulations direct group health plans and health insurance issuers to compile and provide an SBC and a uniform glossary of health coverage and medical terms. The Departments have attempted to quantify one-time start-up costs as well as maintenance costs associated with these requirements.

However, there is considerable uncertainty arising from general data limitations and the

⁴⁸ Michael Schoenbaum *et al.*, "Health Plan Choice and Information about Out-of-Pocket Costs: An Experimental Analysis," 38 *Inquiry* 35-48 (Spring 2001).

degree to which economies of scale can be realized to reduce costs for issuers and third party administrators (TPAs).

In the proposed regulations, the Departments estimated total administrative costs to be \$25 million in 2011, \$73 million in 2012, and \$58 million in 2013. The Departments now estimate that issuers and TPAs will incur approximately \$90 million in one-time costs and maintenance costs in 2012, and \$55 in maintenance costs in 2013. These costs and the methodology used to estimate them are discussed below, and presented in Tables 2-6 below.

General Assumptions

In order to assess the potential administrative costs relating to these final regulations, the Departments consulted with several industry experts, including individuals at large health insurance issuers and representing a TPA association, individuals who formerly worked at health insurance companies, and insurance market researchers, to gain insight into the tasks and level of resources required. The discussions focused on estimating the costs that would be start-up versus maintenance, and determining which functions or departments of an insurance company or TPA would be involved in implementing the provision. In addition, we reviewed the analyses of other Affordable Care Act regulations that impose new requirements on health insurance issuers and TPAs, to determine appropriate work levels and categories for this regulation. Particularly, we analyzed the Medical Loss Ratio (MLR) interim final rule (75 FR 74918). Based on these discussions, the Departments estimate that there will be two categories of principal costs associated with the standards in these final regulations: one-time start-up costs and ongoing maintenance costs. The one-time start-up costs include

costs to develop teams to review the new standards and costs to implement workflow and process changes, particularly the development of information technology (IT) systems interfaces that would generate SBC disclosures through data housed in a number of different systems. The maintenance costs include costs to maintain and update IT systems in compliance with the final standards; to produce, review, distribute, and update the SBC disclosures; to produce and distribute notices of modifications; and to provide the glossary in paper form upon request.

With respect to the individual market, issuers are responsible for generating, reviewing, updating, and distributing SBCs. With respect to employer-sponsored coverage, the Departments assume that fully-insured plans will rely on health insurance issuers, and self-insured plans will rely on TPAs, to perform these functions. Some commenters stated that some employers internally prepare plan materials and do not rely on TPAs. While the Departments acknowledge that some plans may internally prepare the SBC disclosures, the Departments do not have sufficient data to develop separate estimates for such plans. Therefore, the Departments continue to make this simplifying assumption because most plans appear to rely on issuers and TPAs for the purpose of administrative duties such as enrollment and claims processing.⁴⁹ Thus, the Departments have used health insurance issuers and TPAs as the units of analysis for the purposes of estimating administrative costs in this regulatory impact analysis.

As discussed in the MLR interim final rule, the Departments estimate there are about 440 firms offering comprehensive coverage in the individual, small, or large group

⁴⁹ See, for example, the Department of Labor's March 2011 report to Congress on self-insured health plans, available at <http://www.dol.gov/ebsa/pdf/ACAReportToCongress032811.pdf>.

markets, and 75 million covered lives therein.⁵⁰ The number of covered lives includes individuals in the individual market as well as those in insured group health plans.

With respect to the self-insured market, the Departments estimate there are 77 million individuals in self-insured ERISA-covered plans and approximately 14 million individuals in self-insured non-Federal governmental plans.⁵¹ The Departments note that, according to 2007 Economic Census data, there are 2,243 TPAs providing administrative services for health and/or welfare funds. However, there is some uncertainty as to whether all of those TPAs serve self-insured plans; many issuers, for example, have subsidiary lines of business through administrative services only (ASO) contracts through which they perform third-party administrative functions for self-insured plans.⁵² Based on conversations with a national TPA association, the Departments assume that about one-third of the total number of TPAs, or about 748 TPAs, are relevant for purposes of this analysis. However, given the considerable overlap between issuers and TPAs, the Departments recognize there may be fewer affected TPAs, so these estimates should be considered an upper bound of burden estimates.

Because the SBC disclosures are closely related to disclosures that issuers and TPAs provide today as a part of their normal operations (for example, covered benefits

⁵⁰ The NAIC data actually indicate 442 issuers and 74,830,101 covered lives. But the Departments have limited these values to only two significant figures given general data uncertainty. For example, the NAIC data do not include issuers regulated by California's Department of Managed Health Care (DMHC) as well as small, single-State issuers that are not required by State regulators to submit NAIC annual financial statements.

⁵¹ U.S. Department of Labor, EBSA calculations using the March 2009 Current Population Survey Annual Social and Economic Supplement and the 2009 Medical Expenditure Panel Survey; see also interim final rule for internal claims and appeals and external review processes (75 FR 43330, 43345).

⁵² See, for example, the Department of Labor's March 2011 report to Congress on self-insured health plans, available at <http://www.dol.gov/ebsa/pdf/ACAReportToCongress032811.pdf>.

and cost sharing), the Departments estimate that the incremental costs of compiling and providing such readily available information in the final, standardized format is estimated to be modest.⁵³ The regulated community has taken exception to this assumption, and it has stated in written comments, and discussions with the Departments, that information will need to be pulled from multiple sources. However, an opposite conclusion appears to have been reached by a November 2011 survey related to the regulated community's preparedness for SBCs. Particularly, the survey noted that existing communications practices and technology would allow affected entities to be in compliance even by the statutory compliance date of March 23, 2012.⁵⁴ The results of this survey are also consistent with comments indicating that timely compliance is feasible.

The per-issuer or per-TPA cost will largely be determined by size (based on annual premium revenues) and current practices—most importantly, whether the issuer or TPA maintains a robust information technology infrastructure, including a plan benefits design database. Moreover, with regard to issuers, administrative costs may be related to the number of markets in which a company operates (that is, individual, small group, or

⁵³ For example, issuers in the individual and small group markets already report some of the SBC information to HHS for display in the plan finder on the HealthCare.gov website. Issuers have been reporting data to HHS since May 2010 and have refreshed that data on a quarterly basis. These reporting entities have demonstrated that they have the capacity to report information on plan benefit design. See <http://finder.healthcare.gov/>. Further, ERISA-covered plans already report some of the SBC information in summary plan descriptions (SPDs).

⁵⁴ See December 13, 2011 news release for HighRoads Pulse Study, available at <http://newsroom.highroads.com/hr-compliance-connection/highroads-study-shows-employers-will-not-eliminate-benefits-coverage-due-to-health-care-reform>. Among other things, the study's author noted, "SBCs have not caused a great concern among organizations... This is partly a reflection of current communications practices—many employers are already providing a level of communication close to that required by the SBC regulations—and partly a reflection of HR departments embracing technology. By using automation to leverage existing data, they are better able to respond to required changes. That will enable timely compliance once the new deadline is determined."

large group market); the number of policies it offers; and the number of States and licensed entities through which it offers coverage.

To account for variations among issuers, the Departments classify them by size as small, medium, and large issuers based on 2009 premium revenue for individual, small group, and large group comprehensive coverage.⁵⁵ Consistent with the assumptions that were used in the MLR interim final rule, small issuers are defined as those earning up to \$50 million in annual premium revenue; medium issuers as those earning between \$50 million and \$1 billion in annual premium revenue; and large issuers as those earning more than \$1 billion in annual premium revenue. Based on these assumptions, the Departments estimate there are 140 small, 230 medium, and 70 large issuers.

To account for variations among TPAs, the Departments applied the proportions of small, medium, and large issuers to the estimated 750 TPAs. The Departments acknowledge that issuers and TPAs are different and may not have the same size variation. Nonetheless, given general data limitations, the Departments have adopted this methodology, and, on its basis, estimate that there are 240 small, 390 medium, and 120 large TPAs. Table 2 below summarizes the estimated number of issuers and TPAs.

Table 2. Issuer and TPA size classification

	Small	Medium	Large
Issuers	140	230	70
TPAs	240	390	120

⁵⁵ The premium revenue data come from the 2009 NAIC financial statements, also known as “Blanks,” where insurers report information about their various lines of business.

Staffing Assumptions

Table 5 below summarizes the Departments' staffing assumptions, including the estimated number of hours for each task for a small, medium, or large issuer/TPA as well as the percentage of time that different professionals devote to each task. The following assumptions are based on the best information available to the Departments at this time. Particularly, the following series of assumptions are based on conversations with industry experts, the Departments' understanding of the regulated community, and previous analysis in the MLR interim final rule.

IT Systems and Workflow Process Changes

In the proposed regulations, the Departments estimated that it would take a large issuer/TPA about 960 hours to implement IT systems and workflow process changes, based on discussions with a large issuer. These final regulations incorporate policy changes designed to reduce administrative burden. The Departments estimate that the administrative burden to implement IT systems and workflow process changes would be reduced, at least, by about 10 percent.⁵⁶ Accordingly, the Departments are reducing the 960 hours time burden downward, by 10 percent, to 864 hours. The Departments continue to assume that IT systems and workflow process changes would be implemented only by IT professionals. Furthermore, the Departments continue to assume that a medium issuer/TPA would need about 75 percent of a large issuer's/TPA's time, and a small issuer would need about 50 percent of a large issuer's/TPA's time, to implement IT

⁵⁶ A 10 percent is a conservative estimate of the reduction in administrative burden. A national association of insurance companies informed the Departments that premium information alone may account for 10 percent of compliance costs. Given that the omission of premium information from SBCs is one of several policy changes in these final regulations, we conclude that there could be, at a minimum, a 10 percent reduction in administrative burden.

systems and workflow process changes. These estimates are based on the assumption that medium and smaller issuers and TPA's have fewer products/clients that need to come into compliance.

In the proposed regulations, the Departments estimated that it would take a large issuer/TPA about 160 hours to develop teams to analyze the new standards in relation to their current workflow processes. These final regulations incorporate policy changes designed to reduce administrative burden. The Departments estimate that the administrative burden to develop teams would be reduced by about 10 percent. Accordingly, the Departments are revising the 160 hours time burden downward, by 10 percent, to 144 hours. The Departments continue to assume teams would be comprised of IT professionals (45 percent), benefits/sales professionals (50 percent), and attorneys (5 percent), based on technical analysis presented in the MLR interim final rule. The Departments also continue to scale down the burden for medium and small issuers/TPAs by assuming the same relative proportion as above (that is, 75 percent and 50 percent, respectively).

In the proposed regulations, the Departments assumed that, in 2013, each issuer/TPA would incur a separate maintenance cost to maintain IT systems and address changes in regulatory provisions. The Departments assumed the maintenance cost would equal 15% of the total one-time burden noted above (for example, the Departments assumed it will take a large issuer 15% of 1008 hours, or 151 hours). The Departments further assumed that the teams to implement the maintenance tasks would be comprised of IT professionals (55%), benefits/sales professionals (40%), and attorneys (5%). The Departments maintain these assumptions in these final regulations.

The Departments continue to assume that the one-time and maintenance costs to implement IT systems changes and address regulatory requirements would be split between the costs to produce SBCs and the costs to produce the coverage examples (CEs).

Production and Review of SBCs and CEs

In the proposed regulations, the Departments estimated that each issuer/TPA would need 3 hours to produce, and 1 hour to review, SBCs (not including CEs) for all products. Some commenters thought this time burden was an underestimate. However, these commenters did not provide data that could allow the Departments to adjust their estimates. Accordingly, in these final regulations, the Departments are retaining their original estimates. The Departments also continue to assume that the 3 hours needed to produce SBCs would be equally divided between IT professionals and benefits/sales professionals. The Departments also continue to assume that the 1 hour needed to review SBCs would be equally divided between financial managers for benefits/sales professionals and attorneys, based on previous analyses related to the MLR regulation.

In the proposed regulations, the Departments estimated it would take each issuer/TPA about 90 hours to produce, and about 30 hours to review, CEs related to three benefits scenarios for all applicable products, based on the MLR regulation. However, under the guidance document published elsewhere in this issue of the **Federal Register**, issuers and TPAs will need to produce a CE related to only two benefits scenarios in 2012 and 2013. Accordingly, in these final regulations, the Departments are adjusting the time burden downward by one-third. The Departments now estimate that each issuer/TPA would need about 60 hours to produce, and about 20 hours to review, two

CEs for all products. The Departments continue to assume that the 60 hours to produce the two CEs would be equally divided between IT professionals and benefits/sales professionals. The Departments also continue to assume that the 20 hours to review the two CEs would be equally divided between financial managers and attorneys.

For each individual who receives the SBC in paper form, the Departments estimate that printing and distributing the paper disclosures would take clerical staff about 1 minute (0.02 hours) in the group markets and about 2 minutes (0.03 hours) in the individual market. The Departments assume that the individual market has lower economies of scale and, thus, increased distribution costs.

Labor Cost Assumptions

Table 7 below presents the Departments' hourly labor cost assumptions (stated in 2012 dollars) for each staff category based on Bureau of Labor Statistics (BLS) data. The Departments use mean hourly wage estimates from the BLS May 2010 National Occupational Employment and Wage Estimates (accessed at http://www.bls.gov/oes/current/oes_nat.htm#00-0000) for computer systems analysts (Occupation Code 15-1121), insurance underwriters (Occupation Code 13-2053), financial managers (Occupation Code 23-1011), executive secretaries and administrative assistants (Occupation Code 43-6011), and attorneys (Occupation Code 23-1011) as the basis for estimating labor costs for 2012 through 2013 and adjust the hourly wage rate to include a 33 percent fringe benefit estimate for private sector employees.⁵⁷

Distribution Assumptions

⁵⁷ See the Technical Appendix to the MLR interim final rule, available at <http://cciiio.cms.gov>

The Departments make the following assumptions regarding the distribution of the SBC disclosures (including CEs).⁵⁸ These assumptions are based on the best information available to the Departments at this time. Particularly, the following series of assumptions are based on conversations with industry experts, the Departments' understanding of the regulated community, and previous analysis in the MLR interim final rule. The distribution assumptions are as follows:

- The SBCs would be limited to one per household for family members located at the same residence. According to one large issuer, there are 2.2 covered lives per family.
- The number of individuals who would receive an SBC before enrolling in the plan or coverage equals 20 percent of the number of enrollees at any point during the course of a year.⁵⁹
- In 2012 and 2013, respectively, about 2.5 percent and 5 percent of covered individuals who receive a paper SBC would receive a paper glossary from issuers and TPAs. The Departments assume that the burden and cost of providing paper glossaries would be proportional to the burden and cost of providing papers SBCs, excluding coverage examples. The Departments also assume that individuals who do not request a paper copy of the glossary will access it electronically using the Internet address provided in the SBC. These assumptions,

⁵⁸ Although CEs are an integral component of SBCs, the costs associated with CEs are different from the rest of the SBC, and, thus, are separately calculated within this analysis.

⁵⁹ Based on this assumption, the Departments make the following estimate. Prior to enrollment in a given year, 180,000 individuals would receive SBCs from small issuers or TPAs; 3,700,000 individuals would receive SBCs from medium issuers or TPAs; 11,000,000 individuals would receive SBCs from large issuers or TPAs.

presented here in these final regulations, have not changed from the proposed regulations.

- In 2013, about 2 percent of covered individuals would receive a notice of modifications.⁶⁰ Further, the burden and cost of providing such notices would be proportional to the combined burden and cost of providing the SBCs, including CEs. In 2012, the first year of implementation, the number of notices of modifications would be negligible.
- In the proposed regulations, the Departments estimated that electronic distribution would account for 38 percent of all disclosures in the group market and 70 percent of all disclosures in the individual market. The estimate for the group market was based on the methodology used to analyze the cost burden for the Department of Labor's claims procedure regulation (OMB Control Number 1210-0053).⁶¹
- In these final regulations, the Departments are revising upward their estimate of electronic distribution in the group market to 50 percent for pre-enrollment disclosures. This upward revision is justified, because, for participants and beneficiaries who are eligible but not enrolled for coverage, these final regulations

⁶⁰ ERISA section 104(b) requires ERISA-covered plans to furnish participants and beneficiaries with a Summary of Material Modifications (SMM) no later than 210 days after the end of the plan year in which the material change was adopted or in the case of a material reduction in covered services or benefits, no later than 60 days after adoption of the modification or change. As part of its analysis for the Department of Labor's SPD/SMM regulations (29 CFR 2520.104b-3), the Department estimated that about 20 percent of health plans would need to distribute SMM in a given year due to plan amendments. However, almost all of these modifications occur between plan years -- not during a plan year; therefore, the modifications would be required to be disclosed in a SBC that is distributed upon renewal of coverage. The Departments, thus, expect that only two percent of plans will need to issue a notice of modification in the middle of a plan year, because mid-year changes that would result in an update to the SBC are very rare, based on the Department of Labor's experience with ERISA plans. For purposes of simplification, the Departments extend this assumption to the individual market as well.

⁶¹ See the ERISA e-disclosure rule at 29 CFR 2520.104b-1.

- permit the SBC to be provided electronically if the format is readily accessible and a paper copy is provided free of charge upon request.
- The estimate for the group market remains the same for post-enrollment disclosures. The estimate for the individual market also remains the same, and is based on statistics set forth by the National Telecommunications and Information Administration, which indicate that 30 percent of Americans do not use the Internet.⁶²
 - SBC disclosures would be distributed with usual marketing and enrollment materials, thus, costs to mail the documents will be negligible. However, paper glossaries and notices of modifications would require mailing and supply costs as follows: \$0.45 postage cost per mailing and \$0.05 supply cost per mailing. The postage costs have increased by \$0.01 from the \$0.44, as set forth in the proposed regulations, to reflect new first-class postage rates effective January 22, 2012.
 - Printing costs \$0.03 per side of a page. The Departments estimate that it would cost \$0.18 to print a complete SBC (which is six sides of a page based on the length of the NAIC sample completed SBC) and \$0.12 to print the uniform glossary (which is four sides of a page, based on the length of the NAIC recommended uniform glossary). This cost burden is in addition to the time it would take clerical staff to print and distribute the SBC or glossary.

Cost Estimate

⁶² U.S. Department of Commerce, National Telecommunications and Information Administration, *Digital Nation* (February 2010), available at http://www.ntia.doc.gov/reports/2010/NTIA_internet_use_report_Feb2010.pdf.

The Tables below present costs and burden hours for issuers and TPAs associated with the final disclosure requirements of PHS Act section 2715. Tables 3-4 contain cost estimates for 2012 and 2013, derived from the labor hours presented in Table 5 and the hourly rate estimates presented in Table 6, as well as estimates of non-labor costs. Labor hour estimates were developed for each one-time and maintenance task associated with analyzing requirements, developing IT systems, and producing SBCs (that include CEs).

TABLE 3. 2012 Hour Burden, Equivalent Cost, and Cost Burden - 2012 Dollars

	Number of Affected Entities	Hour Burden	Equivalent Cost	Cost Burden (non-labor)	Number of Disclosures
SBC Requirements - Issuers	440	570,000	\$21,000,000	\$2,700,000	570,000
SBC Requirements – TPAs	750	760,000	\$30,000,000	\$3,600,000	760,000
Coverage Example Requirements – Issuers	440	193,000	\$10,500,000	\$1,400,000	193,000
Coverage Example Requirements – TPAs	750	330,000	\$17,900,000	\$1,800,000	330,000
Glossary Requests – Issuers	440	10,000	\$310,000	\$350,000	10,000
Glossary Requests – TPAs	750	12,000	\$380,000	\$460,000	12,000
Subtotal		1,900,000	\$80,000,000	\$10,000,000	1,900,000
Total 2012 Costs			\$90,000,000		

TABLE 4. 2013 Hour Burden, Equivalent Cost, and Cost Burden - 2012 Dollars

	Number of Affected Entities	Hour Burden	Equivalent Cost	Cost Burden (non-labor)	Number of Disclosures
SBC Requirements - Issuers	440	430,000	\$14,000,000	\$2,700,000	41,000,000
SBC Requirements – TPAs	750	540,000	\$18,000,000	\$3,600,000	49,000,000

TPAs					
Coverage Example Requirements – Issuers	440	59,000	\$3,300,000	\$1,400,000	41,000,000
Coverage Example Requirements – TPAs	750	100,000	\$5,600,000	\$1,800,000	49,000,000
Notice of Material Modifications – Issuers	440	8,900	\$290,000	\$310,000	820,000
Notice of Material Modifications – TPAs	750	11,000	\$380,000	\$400,000	990,000
Glossary Requests – Issuers	440	20,000	\$630,000	\$710,000	1,100,000
Glossary Requests – TPAs	750	25,000	\$760,000	\$920,000	1,500,000
Subtotal		1,200,000	\$43,000,000	\$12,000,000	94,000,000
Total 2013 Costs			\$55,000,000		

TABLE 5. Estimated Staffing Hours for Small, Medium, and Large Issuers and TPAs

STAFFING HOUR ASSUMPTIONS	Percent of Hours by Task	Hours		
		Small Issuer/TPA	Medium Issuer/TPA	Large Issuer/TPA
<i>IT Development and Workflow Process Change</i>				
One-Time				
Develop Teams / Analyze Requirements (IT, underwriting / sales)				
IT Professionals	45%	32	49	65
Benefits / Sales Professionals	50%	36	54	72
Attorneys	5%	4	5	7
Implementing Systems Changes (IT and workflow)				
IT Professionals	100%	432	648	864
Maintenance				
Updating to Address Changes in Requirements				
		76	113	151

STAFFING HOUR ASSUMPTIONS	Percent of Hours by Task	Hours		
		Small Issuer/ TPA	Medium Issuer/ TPA	Large Issuer/ TPA
IT Professionals	55%	42	62	83
Benefits / Sales				
Professionals	40%	30	45	60
Attorneys	5%	4	6	8
SBC Requirement				
(maintenance)				
Producing SBCs		3	3	3
IT Professionals	50%	1.5	1.5	1.5
Benefits / Sales				
Professionals	50%	1.5	1.5	1.5
Internal Review of SBCs		1	1	1
Financial Managers –				
Benefits / Sales		0.5	0.5	0.5
Professionals	50%			
Attorneys	50%	0.5	0.5	0.5
Producing and Distributing Paper Version of SBCs (Group Markets)				
Clerical Staff	100%	0.02	0.02	0.02
Producing and Distributing Paper Version of SBCs (Individual Market)				
Clerical Staff	100%	0.03	0.03	0.03
CE Requirement				
(maintenance)				
Producing CEs		60	60	60
IT Professionals	50%	30	30	30
Benefits / Sales				
Professionals	50%	30	30	30
Internal Review of CEs		20	20	20
Financial Managers –				
Benefits / Sales	50%	10	10	10
Professionals				
Attorneys	50%	10	10	10

TABLE 6. Estimated Loaded Hourly Wages for Staff Categories

Staff Category	BLS Code	Loaded
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TABLE 6. Estimated Loaded Hourly Wages for Staff Categories

		Hourly Wage (2012 Dollars)
IT Professionals	Computer Systems Analysts (Occupation Code 15-1121)	\$54.52
Financial Professionals - Benefits / Sales	Insurance Underwriters (Occupation Code 13-2053)	\$43.76
Financial Manager	Financial Managers (Occupation Code 11-3031)	\$78.50
Attorneys	Lawyers (Occupation Code 23-1011)	\$86.86
Clerical Staff	Executive Secretaries and Administrative Assistants (Occupation Code 43-6011)	\$30.78

The Departments received many comments stating that the preliminary cost analysis underestimated the one-time start-up costs as well as maintenance costs. For example, one commenter did a survey of its members (hereinafter “regulated community survey”), wherein 36 member companies responded to questions regarding implementation and maintenance costs. The commenter extrapolated the survey results to all enrollees with coverage in the United States. Accordingly, the commenter projected that one-time implementation costs would be \$188 million and maintenance costs would be \$194 million per year. The commenter stated that a significant cost driver was the March 23, 2012 deadline to switch from current benefit descriptions to the new uniform SBCs. Accordingly, the commenter estimated that there could be a savings of 23

percent with an 18-month extension of the implementation timeline. The commenter also stated that additional factors affecting costs were, among other things, the proposed regulations' requirement to provide premium information; the number and complexity of coverage examples; the renewal process and timeframe to provide SBCs; the number of variations of SBCs to be delivered to each applicant or enrollee; paper delivery of SBCs to most group enrollees; and insufficient flexibility in the SBC template. As discussed elsewhere in this preamble, the Departments have taken steps to ease administrative burden related to most of these factors, and therefore believe that these estimates do not reflect the policies in the final rule.

Because the regulated community survey, as well other commenters' cost estimates, did not provide specific, detailed cost information, it is difficult for the Department to acquire more than a general understanding of the differences between the Departments' cost estimates and the commenters' cost estimates. Accordingly, the Departments continue to believe that there is considerable uncertainty arising from general data limitations and the degree to which economies of scale are achievable.

Even if the Departments were to utilize the regulated community survey, or other commenters' cost estimates, it would be necessary for the Departments to discount those projected costs to account for policy changes in these final regulations. Particularly, these final regulations now omit premium or cost of coverage information from SBCs, provide for only two coverage examples, and allow greater flexibility for electronic disclosures prior to enrollment in coverage.

6. Regulatory Alternatives

Several provisions in these final regulations involved policy choices. A first policy choice involved the applicability date of these final regulations. The Departments received many comments indicating that the proposed March 23, 2012 applicability date was not practical for compliance. Accordingly, in these final regulations, the Departments are delaying the applicability of these provisions by six months to provide plans and issuers additional time to comply. As discussed elsewhere in this preamble, for disclosures to plans, and to individuals and dependents in the individual market, these final regulations apply to health insurance issuers beginning September 23, 2012. Similarly, for the group market, for disclosures with respect to participants and beneficiaries who enroll or re-enroll through an open enrollment period (including re-enrollees and late enrollees), these final regulations apply beginning on the first day of the first open enrollment period that begins on or after September 23, 2012. For disclosures with respect to participants and beneficiaries who enroll other than through an open enrollment period (including individuals who are newly eligible for coverage and special enrollees), these final regulations apply on the first day of the first plan year that begins on or after September 23, 2012. This approach to implementation should lessen administrative burden on the regulated community.

A second policy choice involved whether to include premium or cost of coverage information in the SBC. The Departments received many comments that expressed concerns about the complexity of conveying such information in both the individual and group markets. As noted above in the preamble to these final regulations, the Departments believe that premium information can be more efficiently and effectively provided in documentation other than the SBC. Therefore, the Departments are not

requiring plans and issuers to include premium or cost of coverage information in the SBC. Accordingly, this policy choice should also lessen administrative burden on the regulated community.

A third policy choice involved the number of coverage examples that plans issuers must provide in the SBC. The Departments received a number of comments about the potential cost and burden associated with providing coverage examples. To address these concerns, the guidance document published elsewhere in this issue of the **Federal Register** clarifies that for the first year of applicability, the SBC will include only two coverage examples – having a baby (normal delivery) and routine maintenance of well-controlled type 2 diabetes. Additional coverage examples will be added in later years. This policy choice should also lessen administrative burden on the regulated community.

A fourth policy choice involved determining how to minimize the burden of providing the SBC to individuals shopping for health insurance coverage. The Departments recognize it may be difficult for issuers to provide accurate information about the terms of coverage prior to underwriting. Accordingly, these final regulations provide that if individual health insurance issuers provide the information required by these final regulations and as specified in guidance published by the Secretary to the HHS Secretary's Web portal (HealthCare.gov), as established by 45 CFR 159.120, then they will be deemed to have satisfied the requirement to provide an SBC to individuals who request summary information about coverage prior to submitting an application. The Departments determined this approach promotes regulatory efficiency, minimizing the

administrative burden on health insurance issuers without significantly lessening the protections under PHS Act section 2715.

A fifth policy choice related to electronic distribution of SBCs. The Departments received comments about the electronic transmission of SBCs to participants and beneficiaries in the group market. Specifically, some comments requested that plans and issuers be permitted to provide SBCs to participants and beneficiaries in a manner other than those set forth by the Department of Labor's electronic disclosure safe harbor requirements at 29 CFR 2520.104b-1(c). These final regulations retain the proposed requirements, but 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, and will help reduce the burden of providing the SBC to participants and beneficiaries prior to enrollment.

A sixth policy choice related to whether, in the case of covered individuals residing at the same address, one SBC would satisfy the disclosure requirement with respect to all such individuals, or whether multiple SBCs would be required to be provided. Under these final regulations, a single SBC may be provided to a family unless any individuals are known to reside at a different address. Separate SBCs will therefore need to be provided only in limited circumstances.

A seventh policy choice related to how many SBCs a participant or beneficiary would automatically receive from a group health plan at renewal. The final regulations would further limit burden by requiring a plan or issuer to provide, at renewal, a new

SBC for only the benefit package in which a participant or beneficiary is enrolled. That is, if the plan offers multiple benefits packages, an SBC is not required for each benefit package offered under the group health plan, which the Departments believe would otherwise create an undue burden during open season. Participants and beneficiaries would be able to receive upon request an SBC for any benefits package for which they are eligible. The Departments believe this balanced approach addresses the needs of plans, issuers, and consumers, at renewal.

An eighth policy choice related to the interpretation of the PHS Act section 2715(d)(4), which requires notice of any material modification in any of the terms of the plan or coverage that is not reflected in the most recently provided SBC. The Departments note that a material modification, within the meaning of section 102 of ERISA and its implementing regulations at 29 CFR 2520.104b-3, is broadly defined to include any modification to the coverage offered under the plan or policy, that independently, or in conjunction with other contemporaneous modifications or changes, would be considered by the average plan participant to be an important change in covered benefits or other terms of coverage under the plan or policy. The final regulations interpret this provision as requiring notice only for a material modification 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 renewal or reissuance of coverage (that is, a mid-plan or –policy year change). This approach is consistent with the language of PHS Act section 2715(d)(4) and is more narrowly focused on what we interpret to be the purpose of that provision.

B. Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a final rule has a significant impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of “small entity.”) The Departments use as their measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

As discussed in the Web Portal interim final rule (75 FR 24481), HHS examined the health insurance industry in depth in the Regulatory Impact Analysis that HHS prepared for the final rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis, HHS determined that there were few if any insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for “small” business established by the SBA. Currently, the SBA size threshold is \$7 million in annual receipts for both health insurers (North American Industry Classification System, or NAICS, Code 524114) and TPAs (NAICS Code 524292).

Additionally, as discussed in the Medical Loss Ratio interim final rule (75 FR 74918), HHS used a data set created from 2009 National Association of Insurance

Commissioners (NAIC) Health and Life Blank annual financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and group markets. For purposes of that analysis, HHS used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. HHS estimated that there were 28 small entities with less than \$7 million in A&H earned premiums offering individual or group comprehensive major medical coverage; however, this estimate may overstate the actual number of small health insurance issuers offering such coverage, since it does not include receipts from these companies' other lines of business. These 28 small entities represent about 6.4 percent of the approximately 440 health insurers that are accounted for in this RIA. Based on this calculation, the Departments assume that there are an equal percentage of TPAs that are small entities. That is, 48 small entities represent about 6.4 percent of the approximately 750 TPAs that are accounted for in this RIA.

The Departments estimate that issuers and TPAs earning less than \$50 million in annual premium revenue, including the 76 small entities mentioned above, would incur costs of approximately \$33,000 and \$10,000 per issuer/TPA in 2012 and 2013, respectively. Numbers of this magnitude do not approach the amounts necessary to be considered a "significant economic impact" on firms with revenues in the order of millions of dollars. Additionally, as discussed earlier, the Departments believe that these estimates overstate the number of small entities that will be affected by the requirements in this final regulation, as well as the relative impact of these requirements on these entities, because the Departments have based their analysis on the affected entities' total A&H earned premiums (rather than their total annual receipts). Accordingly, the

Departments have determined and certify that these final regulations will not have a significant economic impact on a substantial number of small entities, and that a regulatory flexibility analysis is not required.

C. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury it has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these final regulations. It is hereby certified that the collections of information contained in this Treasury decision will not have a significant impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Section 54.9815-2715 of the final regulations requires both group health insurance issuers and group health plans to distribute an SBC and notice of any material modifications to the plan that affect the information required in the SBC. Under these final regulations, if a health insurance issuer satisfies the obligations to distribute an SBC and a notice of modifications, those obligations are satisfied not just for the issuer but also for the group health plan. For group health plans maintained by small entities, it is anticipated that the health insurance issuer will satisfy these obligations for both the plan and the issuer in almost all cases. For this reason, these information collection requirements will not impose a significant impact on a substantial number of small entities. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief

Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

D. Unfunded Mandates Reform Act—Department of Labor and Department of Health and Human Services

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 that agencies assess anticipated costs and benefits before issuing any final rule that includes a Federal mandate that could result in expenditure in any one year by State, local or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars updated annually for inflation. In 2011, that threshold level is approximately \$136 million. These final regulations include no mandates on State, local, or Tribal governments. These final regulations include directions to produce standardized consumer disclosures that will affect private sector firms (for example, health insurance issuers offering coverage in the individual and group markets, and third-party administrators providing administrative services to group health plans), but we conclude that these costs will not exceed the \$136 million threshold. Thus, we conclude that these final regulations do not impose an unfunded mandate on State, local or Tribal governments or the private sector. Regardless, consistent with policy embodied in UMRA, this notice of final rulemaking has been designed to be the least burdensome alternative for State, local and Tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

E. Paperwork Reduction Act

1. Department of Labor and Department of the Treasury

Section 2715 of the PHS Act directs the Departments, in consultation with the National Association of Insurance Commissioners (NAIC) and a working group comprised of stakeholders, to “develop standards for use by a group health plan and a health insurance issuer in compiling and providing to applicants, enrollees, and policyholders and certificate holders a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage.” For disclosures to plans, and to individuals and dependents in the individual market, these final regulations apply to health insurance issuers beginning September 23, 2012. Similarly, for the group market, for disclosures with respect to participants and beneficiaries who enroll or re-enroll through an open enrollment period (including re-enrollees and late enrollees), these final regulations apply beginning on the first day of the first open enrollment period that begins on or after September 23, 2012. For disclosures with respect to participants and beneficiaries who enroll other than through an open enrollment period (including individuals who are newly eligible for coverage and special enrollees), these final regulations apply on the first day of the first plan year that begins on or after September 23, 2012.

To implement this provision, collection of information requirements relate to the provision of the following:

- Summary of benefits and coverage.
- Coverage examples (as components of each SBC).
- A uniform glossary of health coverage and medical terms (uniform glossary).
- Notice of modifications.

A copy of the ICR may be obtained by contacting the PRA addressee: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Room N-5718, Washington, DC 20210. Telephone: (202) 693-8410; Fax: (202) 219-4745. These are not toll-free numbers. E-mail: ebesa.opr@dol.gov. ICRs submitted to OMB also are available at [reginfo.gov](http://www.reginfo.gov/public/do/PRAMain) (<http://www.reginfo.gov/public/do/PRAMain>).

The Departments estimate 858 respondents each year from 2012-2013. This estimate reflects approximately 220 issuers offering comprehensive major medical coverage in the small and large group markets, and approximately 638 third-party administrators (TPAs).⁶³

To account for variation in firm size, the Departments estimate a weighted burden on the basis of issuer's 2009 total earned premiums for comprehensive major medical coverage.⁶⁴ The Departments define small issuers as those with total earned premiums less than \$50 million; medium issuers as those with total earned premiums between \$50 million and \$999 million; and large issuers as those with total earned premiums of \$1 billion or more. Accordingly, the Departments estimate approximately 70 small, 115 medium, and 35 large issuers. Similarly, the Departments estimate approximately 204 small, 332 medium, and 102 large TPAs.

⁶³ The Departments estimate that there are 440 issuers and 750 TPAs. Because the Department of Labor and the Department of the Treasury share the hour and cost burden for issuers and TPAs with the Department of Health and Human Services, the burden to produce the SBCs including Coverage Examples for group health plans is calculated using half the number of issuers (220) and 85 percent of the TPAs (638). While the group health plans could prepare their own SBCs, the Departments assume that SBCs would be prepared by service providers, *i.e.*, issuers and TPAs.

⁶⁴ The premium revenue data come from the 2009 NAIC financial statements, also known as "Blanks," where insurers report information about their various lines of business

2012 Burden Estimate

In 2012, the Departments estimate a one-time administrative burden of about 620,000 hours with an equivalent cost of about \$34,000,000 across the industry to prepare for the provisions of these final regulations. This calculation is made assuming issuers and TPAs will need to implement two principal tasks: (1) develop teams to analyze current workflow processes against the new rules and (2) make appropriate changes to IT systems and processes.

With respect to task (1), the Departments estimate about 88,000 burden hours with an equivalent cost of about \$4,500,000. The Departments calculate these estimates as follows:⁶⁵

Task 1: Analyze Current Workflow and New Rules

	Hourly Wage Rate	Small Issuer / TPA		Medium Issuer/TPA		Large Issuer/TPA	
		Hours	Equivalent Cost	Hours	Equivalent Cost	Hours	Equivalent Cost
IT Professionals	\$54.52	32	\$1,800	49	\$2,600	65	\$3,500
Benefits/Sales Professionals	\$43.76	36	\$1,600	54	\$2,400	72	\$3,200
Attorneys	\$86.86	4	\$310	5	\$500	7	\$630
Total per issuer/TPA		72	\$3,700	108	\$5,500	144	\$7,300
Total for all issuers/TPAs		20,000	\$1,000,000	48,000	\$2,500,000	20,000	\$1,000,000

With respect to task (2), the Departments estimate about 530,000 burden hours with an equivalent cost of about \$29,000,000. The Departments calculate these estimates as follows:

⁶⁵ For the purposes of these and other estimates in this section IV.E, the Departments again use the assumptions outlined above in section IV.A.5.

Task 2: IT Changes

	Hourly Wage Rate	Small Issuer/TPA		Medium Issuer/TPA		Large Issuer/TPA	
		Hours	Equivalent Cost	Hours	Equivalent Cost	Hours	Equivalent Cost
IT Professionals	\$54.52	432	\$24,000	648	\$35,000	864	\$47,000
Total per issuer/TPA		432	\$24,000	648	\$35,000	864	\$47,000
Total for all issuers/TPAs		120,000	\$6,600,000	290,000	\$16,000,000	120,000	\$6,400,000

In addition to the one-time administrative costs mentioned above, the Departments assume that plans and issuers will incur additional administrative burden. With regard to this administrative burden, the estimated hour and cost burden for the collections of information in 2012 are as follows:

- The Departments estimate that there will be about 77,000,000 SBCs.
- The Departments assume 50 percent of the total number of SBCs would be sent electronically prior to enrollment, and 38 percent would be sent electronically after enrollment, in the small and large group markets. Accordingly, the Departments estimate that about 31,000,000 SBCs would be electronically distributed, and about 46,000,000 SBCs would be distributed in paper form. The Departments assume there are costs only for paper disclosures, but no costs for electronic disclosures.

Task 3: SBCs – The estimated hour burden for preparing the SBCs is about 780,000 hours with an equivalent cost of about \$24,000,000, and a cost burden of about \$5,500,000. The Departments calculate these estimates as follows:

Task 3: Equivalent Costs for Producing SBCs (Except Coverage Examples)

	Hourly Wage Rate	Small Issuer/TPA		Medium Issuer/TPA		Large Issuer/TPA	
		Hours	Equivalent Cost	Hours	Equivalent Cost	Hours	Equivalent Cost

IT Professionals	\$54.52	1.5	\$82	1.5	\$82	1.5	\$82
Benefits/Sales Professionals	\$43.76	1.5	\$66	1.5	\$66	1.5	\$66
Financial Managers	\$78.50	0.5	\$39	0.5	\$39	0.5	\$39
Attorneys	\$86.86	0.5	\$43	0.5	\$43	0.5	\$43
Total per issuer/TPA		4	\$230	4	\$230	4	\$230
Total for all issuers/TPAs		1,100	\$63,000	1,800	\$100,000	500	\$32,000

Task 3: Equivalent Costs for Distributing SBCs

	Hourly Wage Rate	Hours per SBC	Total Number of SBCs	Total Hours	Total Equivalent Cost
Clerical Staff	\$30.78	0.017	46,000,000	780,000	\$24,000,000

Task 3: Cost Burden for Printing SBCs

	Cost per SBCs	Total Number of SBCs	Total Cost Burden
Printing Costs	\$0.12	46,000,000	\$5,500,000

Task 4: Two Coverage Examples – The estimated hour burden for producing and printing coverage examples is about 69,000 hours with an equivalent cost of about \$4 million, and a cost burden of about \$2,800,000. The Departments calculate these estimates as follows:

Task 4: Equivalent Costs for Producing Coverage Examples

	Hourly Wage Rate	Small Issuer/TPA		Medium Issuer/TPA		Large Issuer/TPA	
		Hours	Equivalent Cost	Hours	Equivalent Cost	Hours	Equivalent Cost
IT Professionals	\$54.52	30	\$1,640	30	\$1,640	30	\$1,640
Benefits/Sales Professionals	\$43.76	30	\$1,310	30	\$1,310	30	\$1,310
Financial Managers	\$78.50	10	\$780	10	\$780	10	\$780
Attorneys	\$86.86	10	\$870	10	\$870	10	\$870

Total per issuer/TPA		80	\$4,600	80	\$4,600	80	\$4,600
Total for all issuers/TPAs		21,900	\$1,260,000	36,000	\$2,100,000	11,000	\$630,000

Task 4: Cost Burden for Printing Coverage Examples

	Printing Cost Per CE Set	Total CE Sets Printed	Total Cost Burden
Printing Costs	\$0.06	46,000,000	\$2,800,000

Task 5: Glossary Requests –The Departments assume that, in 2012, issuers and TPAs will begin responding to glossary requests from covered individuals, and that 2.5 percent of covered individuals, who receive paper SBCs, will request glossaries in paper form. The Departments estimate that the hour and cost burden of providing the notices to be 2.5 percent of the hour and cost burden of distributing paper SBCs, plus an additional cost burden of \$0.50 for each glossary (including \$0.45 for first-class postage and \$0.05 for supply costs). Accordingly, in 2012, the Departments estimate an hour burden of about 24,000 hours with an equivalent cost of about \$740,000 and a cost burden of about \$740,000 associated with about 1,200,000 glossary requests.

The total 2012 burden estimate is about 1,500,000 hours with an equivalent cost of about \$63,000,000 and cost burden of about \$9,000,000.

2013 Burden Estimate

Task 1: SBCs – The number of disclosures is assumed to remain constant at about 77,000,000. Accordingly, in 2013, the Departments again estimate a burden of about 780,000 hours with an equivalent cost of about \$5,500,000 and a cost burden of about \$24,000,000 for preparing and distributing SBCs.

Task 2: Two Coverage Examples – The Departments again estimate about 69,000 hours with an equivalent cost of about \$4,000,000 and a cost burden of about \$2,800,000 for producing and printing coverage examples.

Task 3: Notices of Modifications – The Departments assume that, in 2013, issuers and TPAs would send notices of modifications to covered individuals, and that two percent of covered individuals would receive such notice. The Departments estimate that the hour and cost burden of providing the notices to be two percent of the combined hour and cost burden of providing the SBCs including the coverage examples, plus an additional cost burden of \$0.50 for each paper notice (including \$0.45 for first-class postage and \$0.05 for supply costs). Accordingly, in 2013, the Departments estimate an hour burden of about 17,000 hours with an equivalent cost of \$570,000 and a cost burden of about \$630,000 associated with preparing and distributing about 1,500,000 notices of modification.

Task 4: Glossary Requests – The Departments assume that, in 2013, issuers and TPAs will again respond to glossary requests from covered individuals, and that five percent of covered individuals, who receive paper SBCs, will request glossaries in paper form. The Departments estimate that the burden and cost of providing the glossaries to be five percent of the hour and cost burden of distributing paper SBCs, plus an additional cost burden for \$0.50 for each glossary (including \$0.45 for first-class postage and \$0.05 for supply costs). Accordingly, in 2013, the Departments estimate an hour burden of about 39,000 hours with an equivalent cost of about \$1,200,000 and a cost burden of about \$1,400,000 associated with 2,300,000 glossary requests.

Task 5: Maintenance Administrative Costs – In 2013, the Departments assume that issuers and TPAs will need to make updates to address changes in standards, and, thus, incur 15 percent of the one-time administrative burden. Accordingly, the estimated hour burden is about 93,000 hours, with an equivalent cost of about \$4,800,000. The Departments calculate these estimates as follows:

	Hourly Wage Rate	Small Issuer/TPA		Medium Issuer/TPA		Large Issuer/TPA	
		Hours	Equivalent Cost	Hours	Equivalent Cost	Hours	Equivalent Cost
IT Professionals	\$54.52	42	\$2,300	62	\$3,400	83	\$4,500
Benefits / Sales Professionals	\$43.76	30	\$1,300	45	\$2,000	60	\$2,600
Attorneys	\$86.86	4	\$350	6	\$520	8	\$690
Total per issuer/TPA		76	\$4,000	113	\$5,900	151	\$7,800
Total for all issuers/TPAs		21,000	\$1,100,000	51,000	\$2,600,000	21,000	\$1,100,000

The total 2013 burden estimate is about 1,000,000 hours with an equivalent cost of nearly \$35,000,000 and a cost burden of \$10,000,000.

Estimates are not provided for subsequent years, because there will be significant changes in the marketplace in 2014, including those related to the offering of new individual and small group plans through the Affordable Insurance Exchanges, and new market reforms outside of the new Exchanges, and the wide-ranging scope of these changes makes it difficult to project results for 2014 and beyond.

The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.

The 2012-2013 paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: Affordable Care Act Uniform Explanation of Coverage Documents

OMB Number: 1210-0147; 1545–2229.

Affected Public: Business or other for profit; not-for-profit institutions.

Total Respondents: 858.

Total Responses: 79,500,000.

Frequency of Response: On-going.

Estimated Total Annual Burden Hours (two year average): 620,000 hours (Employee Benefits Security Administration); 620,000 hours (Internal Revenue Service).

Estimated Total Annual Cost Burden (two year average): \$4,800,000 (Employee Benefits Security Administration); \$4,800,000 (Internal Revenue Service).

2. Department of Health and Human Services

ICRs Related to the Summary of Benefits and Uniform Glossary (45 CFR 147.200)

The Department estimates 333 respondents each year from 2012-2013. This estimate reflects the approximately 220 issuers offering comprehensive major medical coverage in the individual market and to fully-insured non-federal governmental plans, and 113 TPAs acting as service providers for self-insured non-federal governmental plans.⁶⁶

⁶⁶ The Department estimates that there are 440 issuers and 750 TPAs. Because the Department shares the hour and cost burden for issuers with the Department of Labor and the Department of the Treasury, the burden to produce the SBCs including coverage examples for non-federal governmental plans and issuers in the individual market is calculated using half the number of issuers (221) and 15% of TPAs (113). While non-federal governmental plans could prepare their own SBCs, the Department assumes that SBCs would be prepared by service providers, *i.e.*, issuers and TPAs.

To account for variation in firm size, the Department estimates a weighted burden on the basis of issuers' 2009 total earned premiums for comprehensive major medical coverage.⁶⁷ The Department defines small issuers as those with total earned premiums less than \$50 million; medium issuers as those with total earned premiums between \$50 million and \$999 million; and large issuers as those with total earned premiums of \$1 billion or more. Accordingly, the Department estimates approximately 70 small, 115 medium, and 35 large issuers. Similarly, the Department estimates approximately 36 small, 59 medium, and 18 large TPAs.

2012 Burden Estimate

In 2012, the Department estimates a one-time administrative burden of about 230,000 hours with an equivalent cost of about \$13,000,000 across the industry to prepare for the provisions of these final regulations. This calculation is made assuming issuers and TPAs will need to implement two principal tasks: (1) develop teams to analyze current workflow processes against the new standards and (2) make appropriate changes to IT systems and processes.

With respect to task (1), the Department estimates about 34,000 burden hours with an equivalent cost of about \$1,800,000. The Department calculates these estimates as follows:⁶⁸

Task 1: Analyze Current Workflow and New Rules

⁶⁷ The premium revenue data come from the 2009 NAIC financial statements, also known as "Blanks," where insurers report information about their various lines of business

⁶⁸ For the purposes of these and other estimates in this section IV.E, the Department again use the assumptions outlined above in section IV.A.5.

	Hourly Wage Rate	Small Issuer / TPA		Medium Issuer/TPA		Large Issuer/TPA	
		Hours	Equivalent Cost	Hours	Equivalent Cost	Hours	Equivalent Cost
IT Professionals	\$54.52	32	\$1,800	49	\$2,600	65	\$3,500
Benefits/Sales Professionals	\$43.76	36	\$1,600	54	\$2,400	72	\$3,200
Attorneys	\$86.86	4	\$310	5	\$500	7	\$600
Total per issuer/TPA		72	\$3,700	108	\$6,000	144	\$7,000
Total for all issuers/TPAs		7,600	\$390,000	19,000	\$1,000,000	7,600	\$370,000

With respect to task (2), the Department estimates about 200,000 burden hours with an equivalent cost of about \$11,000,000. The Department calculates these estimates as follows:

Task 2: IT Changes

	Hourly Wage Rate	Small Issuer/TPA		Medium Issuer/TPA		Large Issuer/TPA	
		Hours	Equivalent Cost	Hours	Equivalent Cost	Hours	Equivalent Cost
IT Professionals	\$54.52	432	\$24,000	648	\$35,000	864	\$50,000
Total per issuer/TPA		432	\$24,000	648	\$35,000	864	\$50,000
Total for all issuers/TPAs		46,000	\$2,500,000	110,000	\$6,100,000	46,000	\$2,700,000

In addition to the one-time administrative costs mentioned above, the Department assumes that plans and issuers will incur additional administrative burden. With regard to this administrative burden, the estimated hour and cost burden for the collections of information in 2012 are as follows:

- The Department estimates that there will be about 13,000,000 SBCs.
- The Department assumes 50 percent of the total number of SBCs would be sent electronically prior to enrollment, and 38 percent would be sent electronically after

enrollment, in the small and large group markets. The Department further assumes 70 percent of SBCs would be sent electronically in the individual market.

Accordingly, the Department estimates that about 7,100,000 disclosures would be electronically distributed, and about 6,200,000 disclosures would be distributed in paper form. The Department assumes there are costs only for paper disclosures, but no costs for electronic disclosures

Task 3: SBCs – The estimated hour burden is about 130,000 hours with an equivalent cost of about \$4,200,000, and a cost burden of about \$740,000. The Department calculates these estimates as follows:

Task 3: Equivalent Costs for Producing SBCs (Except Coverage Examples)

	Hourly Wage Rate	Small Issuer		Medium Issuer		Large Issuer	
		Hours	Equivalent Cost	Hours	Equivalent Cost	Hours	Equivalent Cost
IT Professionals	\$54.52	1.5	\$82	1.5	\$82	1.5	\$82
Benefits/Sales Professionals	\$43.76	1.5	\$66	1.5	\$66	1.5	\$66
Financial Managers	\$78.50	0.5	\$39	0.5	\$39	0.5	\$39
Attorneys	\$86.86	0.5	\$43	0.5	\$43	0.5	\$43
Total per issuer		4	\$230	4	\$230	4	\$230
Total for all issuers		420	\$24,000	700	\$40,000	210	\$12,000

Task 3: Equivalent Costs for Distributing SBCs (Including Coverage Examples)

	Hourly Wage Rate	Hours per SBC	Total Number of SBCs	Total Hours	Total Equivalent Cost
Clerical Staff, Individual Market	\$30.78	0.033	1,700,000	56,000	\$1,700,000
Clerical Staff, Group Market	\$30.78	0.017	4,500,000	77,000	\$2,400,000
Total			6,200,000	130,000	\$4,100,000

Task 3: Cost Burden for Printing SBCs (Except Coverage Examples)

	Cost per SBC	Total SBCs	Cost Burden
Printing Costs	\$0.12	6,200,000	\$740,000

Task 4: Two Coverage Examples – The estimated hour burden for producing and printing coverage examples is about 27,000 hours with an equivalent cost of about \$1,500,000, and a cost burden of about \$370,000. The Department calculates these estimates as follows:

Task 4: Equivalent Costs for Producing Coverage Examples

	Hourly Wage Rate	Small Issuer/TPA		Medium Issuer/TPA		Large Issuer/TPA	
		Hours	Equivalent Cost	Hours	Equivalent Cost	Hours	Equivalent Cost
IT Professionals	\$54.52	30	\$1,640	30	\$1,640	30	\$1,640
Benefits/Sales Professionals	\$43.76	30	\$1,310	30	\$1,310	30	\$1,310
Financial Managers	\$78.50	10	\$780	10	\$780	10	\$780
Attorneys	\$86.86	10	\$870	10	\$870	10	\$870
Total per issuer/TPA		80	\$4,600	80	\$4,600	80	\$4,600
Total for all issuers/TPAs		8,500	\$490,000	14,000	\$800,000	4,200	\$240,000

Task 4: Cost Burden for Printing Coverage Examples

	Printing Cost Per CE Set	Total CE Sets Printed	Total Cost Burden
Printing Costs	\$0.06	6,200,000	\$370,000

Task 5: Glossary Requests – The Department assumes that, in 2012, issuers and TPAs will begin responding to glossary requests from covered individuals, and that 2.5 percent of covered individuals, who receive paper SBCs, will request glossaries in paper

form. The Department assumes that the hour and cost burden of providing the glossaries to be 2.5 percent of the hour and cost burden of distributing paper SBCs, plus an additional cost burden of \$0.50 for each glossary (including \$0.45 for first-class postage and \$0.05 for supply costs). Accordingly, in 2012, the Department estimates an hour burden of about 2,700 hours with an equivalent cost of about \$82,000 and a cost burden of about \$99,000 associated with about 160,000 glossary requests.

The total 2012 burden estimate is about 390,000 hours, or 1,200 hours per respondent, with an equivalent cost of about \$19,000,000, or \$57,000 per respondent, and cost burden of about \$1,200,000, or \$3,600 per respondent.

2013 Burden Estimate

Task 1: SBCs – The number of disclosures is assumed to remain constant at 13,000,000. Thus, in 2013, the Department again estimates an hour burden of about 130,000 hours with an equivalent cost of about \$4,200,000 and cost burden of about \$740,000.

Task 2: Two Coverage Examples – The Department again estimates an hour burden of about 27,000 hours with an equivalent cost of about \$1,500,000 and cost burden of about \$370,000 for producing and printing coverage examples.

Task 3: Notices of Modifications – The Department assumes that, in 2013, issuers will begin sending notices of modifications to covered individuals, and that two percent of covered individuals would receive such notice. The Department estimates that the hour and cost burden of providing the notices to be two percent of the combined hour and cost burden of providing the SBCs including the coverage examples, plus an additional cost burden of \$0.50 for each paper notice (including \$0.45 for first-class

postage and \$0.05 for supply costs). Accordingly, in 2013, the Department estimates an hour burden of about 3,100 hours with an equivalent cost of about \$118,000 and a cost burden of about \$22,000 associated with about 260,000 notices of modification.

Task 4: Glossary Requests – The Department assumes that, in 2013, issuers and TPAs will again respond to glossary requests from covered individuals, and that five percent of covered individuals, who receive paper SBCs, will request glossaries in paper form. The Department estimates that the hour and cost burden of providing the glossaries to be 5 percent of the hour and cost burden of distributing paper SBCs, plus an additional cost burden of \$0.50 for each glossary (including \$0.45 for first-class postage and \$0.05 for supply costs). Accordingly, in 2013, the Department estimates an hour burden of about 5,300 hours with an equivalent cost of \$160,000 and a cost burden of about \$190,000 associated with 310,000 glossary requests.

Task 5: Maintenance Administrative Costs – In 2013, the Department assumes that issuers and TPAs will need to make updates to address changes in standards, and, thus, incur 15 percent of the one-time administrative burden. Accordingly, the estimated hour burden is about 36,000 hours with an equivalent cost of about \$1,800,000. The Department calculates these estimates as follows:

	Hourly Wage Rate	Small Issuer/TPA		Medium Issuer/TPA		Large Issuer/TPA	
		Hours	Equivalent Cost	Hours	Equivalent Cost	Hours	Equivalent Cost
IT Professionals	\$54.52	42	\$2,300	62	\$3,400	83	\$4,500
Benefits / Sales Professionals	\$43.76	30	\$1,300	45	\$2,000	60	\$2,600
Attorneys	\$86.86	4	\$350	6	\$520	8	\$690
Total per issuer/TPA		76	\$4,000	113	\$5,900	151	\$7,800
Total for all issuers/TPAs		8,100	\$420,000	20,000	\$1,000,000	8,000	\$410,000

The total 2013 burden estimate is about 200,000 hours, or about 600 hours per respondent, with an equivalent cost of about \$7,800,000, or \$23,000 per respondent, and cost burden of about \$1,400,000, or \$4,200 per respondent.

Estimates are not provided for subsequent years, because there will be significant changes in the marketplace in 2014, including those related to the offering of new individual and small group plans through the Affordable Insurance Exchanges, and new market reforms outside of the new Exchanges, and the wide-ranging scope of these changes makes it difficult to project results for 2014 and beyond.

The Department notes that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.

The 2012-2013 paperwork burden estimates are summarized as follows:

Type of Review: New collection (Request for a new OMB Control Number).

Agency: Department of Health and Human Services.

Title: Affordable Care Act Uniform Explanation of Coverage Documents

CMS Identifier (OMB Control Number): CMS-10407 (0938-1146).

Affected Public: Business; State, Local, or Tribal Governments.

Total Respondents: 333.

Total Responses: 13,000,000.

Frequency of Response: On-going.

Estimated Total Annual Burden Hours (two year average): 300,000 hours.

Estimated Total Annual Cost Burden (two year average): \$1,300,000.

ICRs Related to Deemed Compliance Reporting (45 CFR 147.200(a)(4)(iii)(C))

Under 45 CFR 147.200(a)(4)(iii)(C), if individual health insurance issuers provide information required by these final regulations to the HHS Secretary's Web portal (HealthCare.gov), as established by 45 CFR 159.120, then they will be deemed to have satisfied the requirement to provide an SBC to individuals who request information about coverage prior to submitting an application for coverage. Individual health insurance issuers already provide most SBC content elements to HealthCare.gov, except for five data elements related to patient responsibility for each coverage example: deductibles, co-payments, co-insurance, limits or exclusions, and the total of all four cost-sharing amounts.

Accordingly, the additional burden associated with the requirements under §147.200(a)(4)(iii)(C) is the time and effort it would take each of the 220 issuers in the individual market to enter the five additional data elements into an Excel spreadsheet. We estimate that it will take these issuers about 110 hours, at a total estimated cost of about \$3,300, for each coverage example. For two coverage examples, the burden and cost would be about 220 hours at a cost of about \$6,600.

In deriving these figures, we used the following hourly labor rates and estimated the time to complete each task: \$ 30.78/hr and 0.5 hr/issuer for clerical staff to enter data into an Excel spreadsheet, or about \$15 per respondent per coverage example.

This information collection requirement reflects the clarification in these final regulations that issuers must provide all content required in the SBC, including the information necessary for coverage examples, to Healthcare.gov to be deemed compliant. The aforementioned burden estimates will be submitted for OMB review and approval as

a revision to the information collection request currently approved under OMB control number 0938-1086.

To obtain copies of the supporting statement and any related forms for the final paperwork collections referenced above, access CMS' Web site at <http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage> or email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office at 410-786-1326.

F. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments' view, these final rules have federalism implications, because it would have direct effects on the States, the relationship between national governments and States, or on the distribution of power and responsibilities among various levels of government relating to the disclosure of health insurance coverage information to consumers. Under these final rules, all group health plans and health insurance issuers

offering group or individual health insurance coverage, including self-funded non-federal governmental plans as defined in section 2791 of the PHS Act, would be required to follow uniform standards for compiling and providing a summary of benefits and coverage to consumers. Such Federal standards developed under PHS Act section 2715(a) would preempt any related State standards that require a summary of benefits and coverage that provides less information to consumers than that required to be provided under PHS Act section 2715(a).

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the HIPAA requirements (including those of 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 health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of a Federal standard. The conference report accompanying HIPAA indicates that this is intended to be the “narrowest” preemption of State laws (See House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018). States may continue to apply State law requirements except to the extent that such requirements prevent the application of the Affordable Care Act requirements that are the subject of this rulemaking. Accordingly, States have significant latitude to

impose requirements on health insurance issuers that are more restrictive than the Federal law. However, under these final rules, a State would not be allowed to impose a requirement that modifies the summary of benefits and coverage required to be provided under PHS Act section 2715(a), because it would prevent the application of this final rule's uniform disclosure requirement.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Departments have engaged in efforts to consult with and work cooperatively with affected States, including consulting with, and attending conferences of, the National Association of Insurance Commissioners and consulting with State insurance officials on an individual basis. It is expected that the Departments will act in a similar fashion in enforcing the Affordable Care Act, including the provisions of section 2715 of the PHS Act. Throughout the process of developing these final regulations, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the Affordable Care Act, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this final rule, the Departments certify that the Employee Benefits Security Administration and the Centers for Medicare & Medicaid Services have

complied with the requirements of Executive Order 13132 for the attached final rule in a meaningful and timely manner.

G. Congressional Review Act

This regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to Congress and the Comptroller General for review.

V. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L.104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 3-2010, 75 FR 55354 (September 10, 2010).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Steven T. Miller
Deputy Commissioner for Services and Enforcement,
Internal Revenue Service.

Approved: February 7, 2012

Emily S. McMahon
Acting Assistant Secretary of the Treasury (Tax Policy)

Signed this 7th day of February, 2012.

Phyllis C. Borzi
Assistant Secretary
Employee Benefits Security Administration
Department of Labor

CMS-9982-F

Dated: February 6, 2012

Marilyn Tavenner,
Acting Administrator,
Centers for Medicare & Medicaid Services.

Dated: February 6, 2012

Kathleen Sebelius,
Secretary,
Department of Health and Human Services.

CMS-9982-F

BILLING CODE 4120-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter 1

Accordingly, the Internal Revenue Service amends 26 CFR Parts 54 and 602 as follows:

PART 54--PENSION EXCISE TAXES

Paragraph 1. The authority citation for Part 54 is amended by adding an entry for §54.9815-2715 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805. ***

Section 54.9815-2715 also issued under 26 U.S.C. 9833.

Par. 2. Section 54.9815-2715 is added to read as follows:

§ 54.9815-2715 Summary of benefits and coverage and uniform glossary.

(a) Summary of benefits and coverage--(1) In general. A group health plan (and its administrator as defined in section 3(16)(A) of ERISA), and a health insurance issuer offering group health insurance coverage, is required to provide a written summary of benefits and coverage (SBC) for each benefit package without charge to entities and individuals described in this paragraph (a)(1) in accordance with the rules of this section.

(i) SBC provided by a group health insurance issuer to a group health plan--(A) Upon application. A health insurance issuer offering group health insurance coverage must provide the SBC to a group health plan (or its sponsor) upon application for health coverage, as soon as practicable following receipt of the application, but in no event later than seven business days following receipt of the application.

(B) By first day of coverage (if there are changes). If there is any change in the information required to be in the SBC that was provided upon application and before the first day of coverage, the issuer must update and provide a current SBC to the plan (or its sponsor) no later than the first day of coverage.

(C) Upon renewal. If the issuer renews or reissues the policy, certificate, or contract of insurance (for example, for a succeeding policy year), the issuer must provide a new SBC as follows:

(1) If written application is required (in either paper or electronic form) for renewal or reissuance, the SBC must be provided no later than the date the written application materials are distributed.

(2) If renewal or reissuance 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 an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(D) Upon request. If a group health plan (or its sponsor) requests an SBC or summary information about a health insurance product from a health insurance issuer offering group health insurance coverage, an SBC must be provided as soon as practicable, but in no event later than seven business days following receipt of the request.

(ii) SBC provided by a group health insurance issuer and a group health plan to participants and beneficiaries--(A) In general. A group health plan (including its administrator, as defined under section 3(16) of ERISA), and a health insurance issuer offering group health insurance coverage, must provide an SBC to a participant or beneficiary (as defined under sections 3(7) and 3(8) of ERISA), and consistent with paragraph (a)(1)(iii) of this section, with respect to each benefit package offered by the plan or issuer for which the participant or beneficiary is eligible.

(B) Upon application. 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 or issuer does not distribute written application materials for enrollment, the SBC must be distributed no later than the first date on which the participant is eligible to enroll in coverage for the participant or any beneficiaries.

(C) By first day of coverage (if there are changes). If there is any change to the information required to be in the SBC that was provided upon application and before 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.

(D) Special enrollees. The plan or issuer must provide the SBC to special enrollees (as described in §54.9801-6) no later than the date by which 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.

(E) Upon renewal. If the plan or issuer requires participants or beneficiaries to renew in order to maintain coverage (for example, for a succeeding plan year), the plan or issuer must provide a new SBC when the coverage is renewed, as follows:

(1) If written application is required for renewal (in either paper or electronic form), the SBC must be provided no later than the date on which the written application materials are distributed.

(2) If renewal 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 an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(F) Upon request. A plan or issuer must provide the SBC to participants or beneficiaries 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.

(iii) Special rules to prevent unnecessary duplication with respect to group health coverage--(A) An entity required to provide an SBC under this paragraph (a)(1) with respect to an individual satisfies that requirement if another party provides the SBC, but only to the extent that the SBC is timely and complete in accordance with the other rules of this section. Therefore, for example, in the case of a group health plan funded through an insurance policy, the plan satisfies the requirement to provide an SBC with respect to an individual if the issuer provides a timely and complete SBC to the individual.

(B) If a single SBC is provided to a participant and any beneficiaries at the participant's last known address, then the requirement to provide the SBC to the participant and any beneficiaries is generally satisfied. 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.

(C) With respect to a group health plan that offers multiple benefit packages, the plan or issuer is required to provide a new SBC automatically upon renewal only with respect to the benefit package in which a participant or beneficiary is enrolled; SBCs are not required to be provided automatically upon renewal with respect to benefit packages in which the participant or beneficiary is not enrolled. However, if a participant or beneficiary requests an SBC with respect to another benefit package (or more than one other benefit package) for which the participant or beneficiary is eligible, the SBC (or SBCs, in the case of a request for SBCs relating to more than one benefit package) must be provided upon request as soon as practicable, but in no event later than seven business days following receipt of the request.

(2) Content – (i) In general. Subject to paragraph (a)(2)(iii) of this section, the SBC must include the following:

(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, in accordance with guidance as specified by the Secretary;

(B) A description of the coverage, including cost sharing, for each category of benefits identified by the Secretary in guidance;

(C) The exceptions, reductions, and limitations of the coverage;

(D) The cost-sharing provisions of the coverage, including deductible, coinsurance, and copayment obligations;

(E) The renewability and continuation of coverage provisions;

(F) Coverage examples, in accordance with paragraph (a)(2)(ii) of this section;

(G) With respect to coverage beginning on or after January 1, 2014, a statement about whether the plan or coverage provides minimum essential coverage as defined under section 5000A(f) 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, certificate, or contract of insurance should be consulted to determine the governing contractual provisions of the coverage;

(I) Contact information for questions and obtaining a copy of the plan document or the insurance policy, certificate, or contract of insurance (such as a telephone number for customer service and an Internet address for obtaining a copy of the plan document or the insurance policy, certificate, or contract of insurance);

(J) For plans and issuers that maintain one or more networks of providers, an Internet address (or similar contact information) for obtaining a list of network providers;

(K) For plans and issuers that use a formulary in providing prescription drug coverage, an Internet address (or similar contact information) for obtaining information on prescription drug coverage; and

(L) An Internet address for obtaining the uniform glossary, as described in paragraph (c) of this section, as well as a contact phone number to obtain a paper copy of the uniform glossary, and a disclosure that paper copies are available.

(ii) Coverage examples. The SBC must include coverage examples specified by the Secretary in guidance that illustrate benefits provided under the plan or coverage for

common benefits scenarios (including pregnancy and serious or chronic medical conditions) in accordance with this paragraph (a)(2)(ii).

(A) Number of examples. The Secretary may identify up to six coverage examples that may be required in an SBC.

(B) Benefits scenarios. For purposes of this paragraph (a)(2)(ii), a benefits scenario is a hypothetical situation, consisting of a sample treatment plan for a specified medical condition during a specific period of time, based on recognized clinical practice guidelines as defined by the National Guideline Clearinghouse, Agency for Healthcare Research and Quality. The Secretary will specify, in guidance, the assumptions, including the relevant items and services and reimbursement information, for each claim in the benefits scenario.

(C) Illustration of benefit provided. For purposes of this paragraph (a)(2)(ii), to illustrate benefits provided under the plan or coverage for a particular benefits scenario, a plan or issuer simulates claims processing in accordance with guidance issued by the Secretary to generate an estimate of what an individual might expect to pay under the plan, policy, or benefit package. The illustration of benefits provided will take into account any cost sharing, excluded benefits, and other limitations on coverage, as specified by the Secretary in guidance.

(iii) Coverage provided outside the United States. 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. In any case, the plan or

issuer must provide an SBC in accordance with this section that accurately summarizes benefits and coverage available under the plan or coverage within the United States.

(3) Appearance. A group health plan and a health insurance issuer must provide an SBC in the form, and in accordance with the instructions for completing the SBC, that are specified by the Secretary in guidance. The SBC must be presented in a uniform format, use terminology understandable by the average plan enrollee, not exceed four double-sided pages in length, and not include print smaller than 12-point font.

(4) Form – (i) An SBC provided by an issuer offering group health insurance coverage to a plan (or its sponsor), may be provided in paper form. Alternatively, the SBC may be provided electronically (such as by email or an Internet posting) if the following three conditions are satisfied –

- (A) The format is readily accessible by the plan (or its sponsor);
- (B) The SBC is provided in paper form free of charge upon request; and
- (C) If the electronic form is an Internet posting, the issuer timely advises the plan (or its sponsor) in paper form or email that the documents are available on the Internet and provides the Internet address.

(ii) An SBC provided by a group health plan or health insurance issuer to a participant or beneficiary may be provided in paper form. Alternatively, the SBC may be provided electronically (such as by email or an Internet posting) if the requirements of this paragraph (a)(4)(ii) are met.

(A) With respect to participants and beneficiaries covered under the plan, the SBC may be provided electronically if the requirements of 29 CFR 2520.104b-1 are met.

(B) With respect to participants and beneficiaries who are eligible but not enrolled for coverage, the SBC may be provided electronically if--

(1) The format is readily accessible;

(2) The SBC is provided in paper form free of charge upon request; and

(3) In a case in which the electronic form is an Internet posting, the plan or issuer timely notifies the individual in paper form (such as a postcard) or email that the documents are available on the Internet, provides the Internet address, and notifies the individual that the documents are available in paper form upon request.

(5) Language. A group health plan or health insurance issuer must provide the SBC in a culturally and linguistically appropriate manner. For purposes of this paragraph (a)(5), a plan or issuer is considered to provide the SBC in a culturally and linguistically appropriate manner if the thresholds and standards of § 54.9815-2719T(e) are met as applied to the SBC.

(b) Notice of modification. If a group health plan, or health insurance issuer offering group health insurance coverage, makes any material modification (as defined under section 102 of ERISA) in any of 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, the plan or issuer must provide notice of the modification to enrollees not later than 60 days prior to the date on which the modification will become effective. The notice of modification must be provided in a form that is consistent with paragraph (a)(4) of this section.

(c) Uniform glossary – (1) In general. A group health plan, and a health insurance issuer offering group health insurance coverage, must make available to participants and

beneficiaries the uniform glossary described in paragraph (c)(2) of this section in accordance with the appearance and the form and manner requirements of paragraphs (c)(3) and (4) of this section.

(2) Health-coverage-related terms and medical terms. The uniform glossary must provide uniform definitions, specified by the Secretary in guidance, of the following health-coverage-related terms and medical terms:

(i) Allowed amount, appeal, balance billing, co-insurance, complications of pregnancy, co-payment, deductible, durable medical equipment, emergency medical condition, emergency medical transportation, emergency room care, emergency services, excluded services, grievance, habilitation services, health insurance, home health care, hospice services, hospitalization, hospital outpatient care, in-network co-insurance, in-network co-payment, medically necessary, network, non-preferred provider, out-of-network co-insurance, out-of-network co-payment, out-of-pocket limit, physician services, plan, preauthorization, preferred provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, reconstructive surgery, rehabilitation services, skilled nursing care, specialist, usual customary and reasonable (UCR), and urgent care; and

(ii) Such other terms as the Secretary determines are important to define so that individuals and employers may compare and understand the terms of coverage and medical benefits (including any exceptions to those benefits), as specified in guidance.

(3) Appearance. A group health plan, and a health insurance issuer, must provide the uniform glossary with the appearance specified by the Secretary in guidance to ensure

the uniform glossary is presented in a uniform format and uses terminology understandable by the average plan enrollee.

(4) Form and manner. A plan or issuer must make the uniform glossary described in this paragraph (c) available upon request, in either paper or electronic form (as requested), within seven business days after receipt of the request.

(d) Preemption. State laws that require a health insurance issuer to provide an SBC that supplies less information than required under paragraph (a) of this section are preempted.

(e) Failure to provide. A group health plan or health insurance issuer that willfully fails to provide information required under this section to a participant or beneficiary is subject to a fine of not more than \$1,000 for each such failure. A failure with respect to each participant or beneficiary constitutes a separate offense for purposes of this paragraph (e).

(f) Effective/Applicability date – (1) This section is applicable to group health plans and group health insurance issuers in accordance with this paragraph (f). (See §54.9815-1251T(d), providing that this section applies to grandfathered health plans.)

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

(ii) For disclosures with respect to participants and beneficiaries who enroll in coverage other than through an open enrollment period (including individuals who are

newly eligible for coverage and special enrollees), this section applies beginning on the first day of the first plan year that begins on or after September 23, 2012.

(2) For disclosures with respect to plans, this section is applicable to health insurance issuers beginning September 23, 2012.

PART 602--OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 3. The authority citation for part 602 continues to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Par. 4. Section 602.101(b) is amended by adding the following entry in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
54.9815-2715	1545-2229
* * * * *	

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons stated in the preamble, the Employee Benefits Security Administration amends 29 CFR part 2590 as follows:

PART 2590 —RULES AND REGULATIONS FOR GROUP HEALTH PLANS

1. The authority citation for Part 2590 continues to read as follows:

Authority:

29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L.104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 3-2010, 75 FR 55354 (September 10, 2010).

Subpart C—Other Requirements

2. Section 2590.715-2715 is added to subpart C to read as follows:

§ 2590.715-2715 Summary of benefits and coverage and uniform glossary.

(a) Summary of benefits and coverage– (1) In general. A group health plan (and its administrator as defined in section 3(16)(A) of ERISA), and a health insurance issuer offering group health insurance coverage, is required to provide a written summary of benefits and coverage (SBC) for each benefit package without charge to entities and individuals described in this paragraph (a)(1) in accordance with the rules of this section.

(i) SBC provided by a group health insurance issuer to a group health plan – (A) Upon application. A health insurance issuer offering group health insurance coverage must provide the SBC to a group health plan (or its sponsor) upon application for health coverage, as soon as practicable following receipt of the application, but in no event later than seven business days following receipt of the application.

(B) By first day of coverage (if there are changes). If there is any change in the information required to be in the SBC that was provided upon application and before the first day of coverage, the issuer must update and provide a current SBC to the plan (or its sponsor) no later than the first day of coverage.

(C) Upon renewal. If the issuer renews or reissues the policy, certificate, or contract of insurance (for example, for a succeeding policy year), the issuer must provide a new SBC as follows:

(1) If written application is required (in either paper or electronic form) for renewal or reissuance, the SBC must be provided no later than the date the written application materials are distributed.

(2) If renewal or reissuance 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 an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(D) Upon request. If a group health plan (or its sponsor) requests an SBC or summary information about a health insurance product from a health insurance issuer offering group health insurance coverage, an SBC must be provided as soon as practicable, but in no event later than seven business days following receipt of the request.

(ii) SBC provided by a group health insurance issuer and a group health plan to participants and beneficiaries – (A) In general. A group health plan (including its administrator, as defined under section 3(16) of ERISA), and a health insurance issuer offering group health insurance coverage, must provide an SBC to a participant or beneficiary (as defined under sections 3(7) and 3(8) of ERISA), and consistent with paragraph (a)(1)(iii) of this section, with respect to each benefit package offered by the plan or issuer for which the participant or beneficiary is eligible.

(B) Upon application. 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 or issuer does not distribute written application materials for enrollment, the SBC must be distributed no later than the first date on which the participant is eligible to enroll in coverage for the participant or any beneficiaries.

(C) By first day of coverage (if there are changes). If there is any change to the information required to be in the SBC that was provided upon application and before 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.

(D) Special enrollees. The plan or issuer must provide the SBC to special enrollees (as described in § 2590.701-6 of this Part) no later than the date by which 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.

(E) Upon renewal. If the plan or issuer requires participants or beneficiaries to renew in order to maintain coverage (for example, for a succeeding plan year), the plan or issuer must provide a new SBC when the coverage is renewed, as follows:

(1) If written application is required for renewal (in either paper or electronic form), the SBC must be provided no later than the date on which the written application materials are distributed.

(2) If renewal 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 an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(F) Upon request. A plan or issuer must provide the SBC to participants or beneficiaries 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.

(iii) Special rules to prevent unnecessary duplication with respect to group health coverage – (A) An entity required to provide an SBC under this paragraph (a)(1) with respect to an individual satisfies that requirement if another party provides the SBC, but only to the extent that the SBC is timely and complete in accordance with the other rules

of this section. Therefore, for example, in the case of a group health plan funded through an insurance policy, the plan satisfies the requirement to provide an SBC with respect to an individual if the issuer provides a timely and complete SBC to the individual.

(B) If a single SBC is provided to a participant and any beneficiaries at the participant's last known address, then the requirement to provide the SBC to the participant and any beneficiaries is generally satisfied. 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.

(C) With respect to a group health plan that offers multiple benefit packages, the plan or issuer is required to provide a new SBC automatically upon renewal only with respect to the benefit package in which a participant or beneficiary is enrolled; SBCs are not required to be provided automatically upon renewal with respect to benefit packages in which the participant or beneficiary is not enrolled. However, if a participant or beneficiary requests an SBC with respect to another benefit package (or more than one other benefit package) for which the participant or beneficiary is eligible, the SBC (or SBCs, in the case of a request for SBCs relating to more than one benefit package) must be provided upon request as soon as practicable, but in no event later than seven business days following receipt of the request.

(2) Content – (i) In general. Subject to paragraph (a)(2)(iii) of this section, the SBC must include the following:

(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, in accordance with guidance as specified by the Secretary;

(B) A description of the coverage, including cost sharing, for each category of benefits identified by the Secretary in guidance;

(C) The exceptions, reductions, and limitations of the coverage;

(D) The cost-sharing provisions of the coverage, including deductible, coinsurance, and copayment obligations;

(E) The renewability and continuation of coverage provisions;

(F) Coverage examples, in accordance with paragraph (a)(2)(ii) of this section;

(G) With respect to coverage beginning on or after January 1, 2014, a statement about whether the plan or coverage provides minimum essential coverage as defined under section 5000A(f) of the Internal Revenue 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, certificate, or contract of insurance should be consulted to determine the governing contractual provisions of the coverage;

(I) Contact information for questions and obtaining a copy of the plan document or the insurance policy, certificate, or contract of insurance (such as a telephone number for customer service and an Internet address for obtaining a copy of the plan document or the insurance policy, certificate, or contract of insurance);

(J) For plans and issuers that maintain one or more networks of providers, an Internet address (or similar contact information) for obtaining a list of network providers;

(K) For plans and issuers that use a formulary in providing prescription drug coverage, an Internet address (or similar contact information) for obtaining information on prescription drug coverage; and

(L) An Internet address for obtaining the uniform glossary, as described in paragraph (c) of this section, as well as a contact phone number to obtain a paper copy of the uniform glossary, and a disclosure that paper copies are available.

(ii) Coverage examples. The SBC must include coverage examples specified by the Secretary in guidance that illustrate benefits provided under the plan or coverage for common benefits scenarios (including pregnancy and serious or chronic medical conditions) in accordance with this paragraph (a)(2)(ii).

(A) Number of examples. The Secretary may identify up to six coverage examples that may be required in an SBC.

(B) Benefits scenarios. For purposes of this paragraph (a)(2)(ii), a benefits scenario is a hypothetical situation, consisting of a sample treatment plan for a specified medical condition during a specific period of time, based on recognized clinical practice guidelines as defined by the National Guideline Clearinghouse, Agency for Healthcare Research and Quality. The Secretary will specify, in guidance, the assumptions, including the relevant items and services and reimbursement information, for each claim in the benefits scenario.

(C) Illustration of benefit provided. For purposes of this paragraph (a)(2)(ii), to illustrate benefits provided under the plan or coverage for a particular benefits scenario, a plan or issuer simulates claims processing in accordance with guidance issued by the Secretary to generate an estimate of what an individual might expect to pay under the

plan, policy, or benefit package. The illustration of benefits provided will take into account any cost sharing, excluded benefits, and other limitations on coverage, as specified by the Secretary in guidance.

(iii) Coverage provided outside the United States. 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. In any case, the plan or issuer must provide an SBC in accordance with this section that accurately summarizes benefits and coverage available under the plan or coverage within the United States.

(3) Appearance. A group health plan and a health insurance issuer must provide an SBC in the form, and in accordance with the instructions for completing the SBC, that are specified by the Secretary in guidance. The SBC must be presented in a uniform format, use terminology understandable by the average plan enrollee, not exceed four double-sided pages in length, and not include print smaller than 12-point font.

(4) Form – (i) An SBC provided by an issuer offering group health insurance coverage to a plan (or its sponsor), may be provided in paper form. Alternatively, the SBC may be provided electronically (such as by email or an Internet posting) if the following three conditions are satisfied –

- (A) The format is readily accessible by the plan (or its sponsor);
- (B) The SBC is provided in paper form free of charge upon request; and
- (C) If the electronic form is an Internet posting, the issuer timely advises the plan (or its sponsor) in paper form or email that the documents are available on the Internet and provides the Internet address.

(ii) An SBC provided by a group health plan or health insurance issuer to a participant or beneficiary may be provided in paper form. Alternatively, the SBC may be provided electronically (such as by email or an Internet posting) if the requirements of this paragraph (a)(4)(ii) are met.

(A) With respect to participants and beneficiaries covered under the plan, the SBC may be provided electronically if the requirements of 29 CFR 2520.104b-1 are met.

(B) With respect to participants and beneficiaries who are eligible but not enrolled for coverage, the SBC may be provided electronically if:

(1) The format is readily accessible;

(2) The SBC is provided in paper form free of charge upon request; and

(3) In a case in which the electronic form is an Internet posting, the plan or issuer timely notifies the individual in paper form (such as a postcard) or email that the documents are available on the Internet, provides the Internet address, and notifies the individual that the documents are available in paper form upon request.

(5) Language. A group health plan or health insurance issuer must provide the SBC in a culturally and linguistically appropriate manner. For purposes of this paragraph (a)(5), a plan or issuer is considered to provide the SBC in a culturally and linguistically appropriate manner if the thresholds and standards of § 2590.715-2719(e) of this Part are met as applied to the SBC.

(b) Notice of modification. If a group health plan, or health insurance issuer offering group health insurance coverage, makes any material modification (as defined under section 102 of ERISA) in any of 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, the plan or issuer must provide notice of the modification to enrollees not later than 60 days prior to the date on which the modification will become effective. The notice of modification must be provided in a form that is consistent with paragraph (a)(4) of this section.

(c) Uniform glossary – (1) In general. A group health plan, and a health insurance issuer offering group health insurance coverage, must make available to participants and beneficiaries the uniform glossary described in paragraph (c)(2) of this section in accordance with the appearance and form and manner requirements of paragraphs (c)(3) and (4) of this section.

(2) Health-coverage-related terms and medical terms. The uniform glossary must provide uniform definitions, specified by the Secretary in guidance, of the following health-coverage-related terms and medical terms:

(i) Allowed amount, appeal, balance billing, co-insurance, complications of pregnancy, co-payment, deductible, durable medical equipment, emergency medical condition, emergency medical transportation, emergency room care, emergency services, excluded services, grievance, habilitation services, health insurance, home health care, hospice services, hospitalization, hospital outpatient care, in-network co-insurance, in-network co-payment, medically necessary, network, non-preferred provider, out-of-network co-insurance, out-of-network co-payment, out-of-pocket limit, physician services, plan, preauthorization, preferred provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, reconstructive surgery, rehabilitation services, skilled nursing care, specialist, usual customary and reasonable (UCR), and urgent care; and

(ii) Such other terms as the Secretary determines are important to define so that individuals and employers may compare and understand the terms of coverage and medical benefits (including any exceptions to those benefits), as specified in guidance.

(3) Appearance. A group health plan, and a health insurance issuer, must provide the uniform glossary with the appearance specified by the Secretary in guidance to ensure the uniform glossary is presented in a uniform format and uses terminology understandable by the average plan enrollee.

(4) Form and manner. A plan or issuer must make the uniform glossary described in this paragraph (c) available upon request, in either paper or electronic form (as requested), within seven business days after receipt of the request.

(d) Preemption. See § 2590.731 of this part. In addition, State laws that require a health insurance issuer to provide an SBC that supplies less information than required under paragraph (a) of this section are preempted.

(e) Failure to provide. A group health plan that willfully fails to provide information required under this section to a participant or beneficiary is subject to a fine of not more than \$1,000 for each such failure. A failure with respect to each participant or beneficiary constitutes a separate offense for purposes of this paragraph (e).

(f) Applicability date – (1) This section is applicable to group health plans and group health insurance issuers in accordance with this paragraph (f). (See §2590.715-1251(d), providing that this section applies to grandfathered health plans.)

(i) For disclosures with respect to participants and beneficiaries who enroll or re-enroll through an open enrollment period (including re-enrollees and late enrollees), this

section applies beginning on the first day of the first open enrollment period that begins on or after September 23, 2012; and

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

(2) For disclosures with respect to plans, this section is applicable to health insurance issuers beginning September 23, 2012.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subtitle A

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

2. The authority citation for part 147 continues to read as follows:

Authority: Sections 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

3. Add § 147.200 to read as follows:

§ 147.200 Summary of benefits and coverage and uniform glossary.

(a) Summary of benefits and coverage– (1) In general. A group health plan (and its administrator as defined in section 3(16)(A) of ERISA), and a health insurance issuer offering group or individual health insurance coverage, is required to provide a written summary of benefits and coverage (SBC) for each benefit package without charge to entities and individuals described in this paragraph (a)(1) in accordance with the rules of this section.

(i) SBC provided by a group health insurance issuer to a group health plan – (A) Upon application. A health insurance issuer offering group health insurance coverage must provide the SBC to a group health plan (or its sponsor) upon application for health coverage, as soon as practicable following receipt of the application, but in no event later than seven business days following receipt of the application.

(B) By first day of coverage (if there are changes). If there is any change in the information required to be in the SBC that was provided upon application and before the first day of coverage, the issuer must update and provide a current SBC to the plan (or its sponsor) no later than the first day of coverage.

(C) Upon renewal. If the issuer renews or reissues the policy, certificate, or contract of insurance (for example, for a succeeding policy year), the issuer must provide a new SBC as follows:

(1) If written application is required (in either paper or electronic form) for renewal or reissuance, the SBC must be provided no later than the date the written application materials are distributed.

(2) If renewal or reissuance 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 an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(D) Upon request. If a group health plan (or its sponsor) requests an SBC or summary information about a health insurance product from a health insurance issuer offering group health insurance coverage, an SBC must be provided as soon as practicable, but in no event later than seven business days following receipt of the request.

(ii) SBC provided by a group health insurance issuer and a group health plan to participants and beneficiaries – (A) In general. A group health plan (including its administrator, as defined under section 3(16) of ERISA), and a health insurance issuer offering group health insurance coverage, must provide an SBC to a participant or beneficiary (as defined under sections 3(7) and 3(8) of ERISA), and consistent with paragraph (a)(1)(iii) of this section, with respect to each benefit package offered by the plan or issuer for which the participant or beneficiary is eligible.

(B) Upon application. 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 or issuer does not distribute written application materials for enrollment, the SBC must be distributed no later than the first date on which the participant is eligible to enroll in coverage for the participant or any beneficiaries.

(C) By first day of coverage (if there are changes). If there is any change to the information required to be in the SBC that was provided upon application and before 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.

(D) Special enrollees. The plan or issuer must provide the SBC to special enrollees (as described in 45 CFR 146.117) no later than the date by which 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.

(E) Upon renewal. If the plan or issuer requires participants or beneficiaries to renew in order to maintain coverage (for example, for a succeeding plan year), the plan or issuer must provide a new SBC when the coverage is renewed, as follows:

(1) If written application is required for renewal (in either paper or electronic form), the SBC must be provided no later than the date on which the written application materials are distributed.

(2) If renewal 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 an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(F) Upon request. A plan or issuer must provide the SBC to participants or beneficiaries 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.

(iii) Special rules to prevent unnecessary duplication with respect to group health coverage – (A) An entity required to provide an SBC under this paragraph (a)(1) with respect to an individual satisfies that requirement if another party provides the SBC, but only to the extent that the SBC is timely and complete in accordance with the other rules of this section. Therefore, for example, in the case of a group health plan funded through an insurance policy, the plan satisfies the requirement to provide an SBC with respect to an individual if the issuer provides a timely and complete SBC to the individual.

(B) If a single SBC is provided to a participant and any beneficiaries at the participant's last known address then the requirement to provide the SBC to the participant and any beneficiaries is generally satisfied. 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.

(C) With respect to a group health plan that offers multiple benefit packages, the plan or issuer is required to provide a new SBC automatically upon renewal only with respect to the benefit package in which a participant or beneficiary is enrolled; SBCs are not required to be provided automatically upon renewal with respect to benefit packages in which the participant or beneficiary is not enrolled. However, if a participant or beneficiary requests an SBC with respect to another benefit package (or more than one other benefit package) for which the participant or beneficiary is eligible, the SBC (or SBCs, in the case of a request for SBCs relating to more than one benefit package) must be provided upon request as soon as practicable, but in no event later than seven business days following receipt of the request.

(iv) SBC provided by a health insurance issuer offering individual health insurance coverage -- (A) Upon application. A health insurance issuer offering individual health insurance coverage must provide an SBC to an individual covered under the policy (including every 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.

(B) By first day of coverage (if there are changes). If there is any change in the information required to be in the SBC that was provided upon application and before the first day of coverage, the issuer must update and provide a current SBC to the individual no later than the first day of coverage.

(C) Upon renewal. The issuer must provide the SBC to policyholders annually at renewal. The SBC must reflect any modified policy terms that would be effective on the first day of the new policy year. The SBC must be provided as follows:

(1) If written application is required (in either paper or electronic form) for renewal or reissuance, the SBC must be provided no later than the date on which the written application materials are distributed.

(2) If renewal or reissuance is automatic, the SBC must be provided no later than 30 days prior to the first day of the new policy year; however, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(D) Upon request. A health insurance issuer offering individual health insurance coverage must provide an SBC to any individual or dependent anytime an individual requests an SBC or summary information about a health insurance product as soon as practicable, but in no event later than seven business days following receipt of the request. For purposes of this paragraph (a)(1)(iv)(D), a request for an SBC or summary information about a health insurance product includes a request made both before and after an individual submits an application for coverage.

(v) Special rule to prevent unnecessary duplication with respect to individual health insurance coverage. If a single SBC is provided to an individual and any dependents at the individual's last known address, then the requirement to provide the SBC to the individual and any dependents is generally satisfied. However, if a

dependent's last known address is different than the individual's last known address, a separate SBC is required to be provided to the dependent at the dependents' last known address.

(2) Content – (i) In general. Subject to paragraph (a)(2)(iii) of this section, the SBC must include the following:

(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, in accordance with guidance as specified by the Secretary;

(B) A description of the coverage, including cost sharing, for each category of benefits identified by the Secretary in guidance;

(C) The exceptions, reductions, and limitations of the coverage;

(D) The cost-sharing provisions of the coverage, including deductible, coinsurance, and copayment obligations;

(E) The renewability and continuation of coverage provisions;

(F) Coverage examples, in accordance with paragraph (a)(2)(ii) of this section;

(G) With respect to coverage beginning on or after January 1, 2014, a statement about whether the plan or coverage provides minimum essential coverage as defined under section 5000A(f) of the Internal Revenue 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, certificate, or contract of insurance should be consulted to determine the governing contractual provisions of the coverage;

(I) Contact information for questions and obtaining a copy of the plan document or the insurance policy, certificate, or contract of insurance (such as a telephone number for customer service and an Internet address for obtaining a copy of the plan document or the insurance policy, certificate, or contract of insurance);

(J) For plans and issuers that maintain one or more networks of providers, an Internet address (or similar contact information) for obtaining a list of network providers;

(K) For plans and issuers that use a formulary in providing prescription drug coverage, an Internet address (or similar contact information) for obtaining information on prescription drug coverage; and

(L) An Internet address for obtaining the uniform glossary, as described in paragraph (c) of this section, as well as a contact phone number to obtain a paper copy of the uniform glossary, and a disclosure that paper copies are available.

(ii) Coverage examples. The SBC must include coverage examples specified by the Secretary in guidance that illustrate benefits provided under the plan or coverage for common benefits scenarios (including pregnancy and serious or chronic medical conditions) in accordance with this paragraph (a)(2)(ii).

(A) Number of examples. The Secretary may identify up to six coverage examples that may be required in an SBC.

(B) Benefits scenarios. For purposes of this paragraph (a)(2)(ii), a benefits scenario is a hypothetical situation, consisting of a sample treatment plan for a specified medical condition during a specific period of time, based on recognized clinical practice guidelines as defined by the National Guideline Clearinghouse, Agency for Healthcare Research and Quality. The Secretary will specify, in guidance, the assumptions,

including the relevant items and services and reimbursement information, for each claim in the benefits scenario.

(C) Illustration of benefit provided. For purposes of this paragraph (a)(2)(ii), to illustrate benefits provided under the plan or coverage for a particular benefits scenario, a plan or issuer simulates claims processing in accordance with guidance issued by the Secretary to generate an estimate of what an individual might expect to pay under the plan, policy, or benefit package. The illustration of benefits provided will take into account any cost sharing, excluded benefits, and other limitations on coverage, as specified by the Secretary in guidance.

(iii) Coverage provided outside the United States. 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. In any case, the plan or issuer must provide an SBC in accordance with this section that accurately summarizes benefits and coverage available under the plan or coverage within the United States.

(3) Appearance. A group health plan and a health insurance issuer must provide an SBC in the form, and in accordance with the instructions for completing the SBC, that are specified by the Secretary in guidance. The SBC must be presented in a uniform format, use terminology understandable by the average plan enrollee (or, in the case of individual market coverage, the average individual covered under a health insurance policy), not exceed four double-sided pages in length, and not include print smaller than 12-point font. A health insurance issuer offering individual health insurance coverage must provide the SBC as a stand-alone document.

(4) Form – (i) An SBC provided by an issuer offering group health insurance coverage to a plan (or its sponsor), may be provided in paper form. Alternatively, the SBC may be provided electronically (such as by email or an Internet posting) if the following three conditions are satisfied –

- (A) The format is readily accessible by the plan (or its sponsor);
- (B) The SBC is provided in paper form free of charge upon request; and
- (C) If the electronic form is an Internet posting, the issuer timely advises the plan (or its sponsor) in paper form or email that the documents are available on the Internet and provides the Internet address.

(ii) An SBC provided by a group health plan or health insurance issuer to a participant or beneficiary may be provided in paper form. Alternatively, for non-Federal governmental plans, the SBC may be provided electronically if the plan conforms to either the substance of the ERISA provisions at 29 CFR 2590.715-2715(a)(4)(ii), or the provisions governing electronic disclosure for individual health insurance issuers set forth in paragraph (a)(4)(iii) of this section.

(iii) An issuer offering individual health insurance coverage must provide an SBC in a manner that can reasonably be expected to provide actual notice in paper or electronic form.

- (A) An issuer satisfies the requirements of this paragraph (a)(4)(iii) if the issuer:
 - (1) Hand-delivers a printed copy of the SBC to the individual or dependent;
 - (2) Mails a printed copy of the SBC to the mailing address provided to the issuer by the individual or dependent;

(3) Provides the SBC by e-mail after obtaining the individual's or dependent's agreement to receive the SBC or other electronic disclosures by e-mail;

(4) Posts the SBC on the Internet and advises the individual or dependent in paper or electronic form, in a manner compliant with paragraphs (a)(4)(iii)(A)(1) through (3), that the SBC is available on the Internet and includes the applicable Internet address; or

(5) Provides the SBC by any other method that can reasonably be expected to provide actual notice.

(B) An SBC may not be provided electronically unless:

(1) The format is readily accessible;

(2) The SBC is placed in a location that is prominent and readily accessible;

(3) The SBC is provided in an electronic form which can be electronically retained and printed;

(4) The SBC is consistent with the appearance, content, and language requirements of this section;

(5) The issuer notifies the individual or dependent that the SBC is available in paper form without charge upon request and provides it upon request.

(C) Deemed compliance. A health insurance issuer offering individual health insurance coverage that provides the content required under paragraph (a)(2) of this section, as specified in guidance published by the Secretary, to the federal health reform Web portal described in 45 CFR 159.120 will be deemed to satisfy the requirements of paragraph (a)(1)(iv)(D) of this section with respect to a request for summary information about a health insurance product made prior to an application for coverage. However,

nothing in this paragraph should be construed as otherwise limiting such issuer's obligations under this section.

(5) Language. A group health plan or health insurance issuer must provide the SBC in a culturally and linguistically appropriate manner. For purposes of this paragraph (a)(5), a plan or issuer is considered to provide the SBC in a culturally and linguistically appropriate manner if the thresholds and standards of §147.136(e) of this chapter are met as applied to the SBC.

(b) Notice of modification. If a group health plan, or health insurance issuer offering group or individual health insurance coverage, makes any material modification (as defined under section 102 of ERISA) in any of 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, the plan or issuer must provide notice of the modification to enrollees (or, in the case of individual market coverage, an individual covered under a health insurance policy) not later than 60 days prior to the date on which the modification will become effective. The notice of modification must be provided in a form that is consistent with paragraph (a)(4) of this section.

(c) Uniform glossary – (1) In general. A group health plan, and a health insurance issuer offering group health insurance coverage, must make available to participants and beneficiaries, and a health insurance issuer offering individual health insurance coverage must make available to applicants, policyholders, and covered dependents, the uniform glossary described in paragraph (c)(2) of this section in accordance with the appearance and form and manner requirements of paragraphs (c)(3) and (4) of this section.

(2) Health-coverage-related terms and medical terms. The uniform glossary must provide uniform definitions, specified by the Secretary in guidance, of the following health-coverage-related terms and medical terms:

(i) Allowed amount, appeal, balance billing, co-insurance, complications of pregnancy, co-payment, deductible, durable medical equipment, emergency medical condition, emergency medical transportation, emergency room care, emergency services, excluded services, grievance, habilitation services, health insurance, home health care, hospice services, hospitalization, hospital outpatient care, in-network co-insurance, in-network co-payment, medically necessary, network, non-preferred provider, out-of-network co-insurance, out-of-network co-payment, out-of-pocket limit, physician services, plan, preauthorization, preferred provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, reconstructive surgery, rehabilitation services, skilled nursing care, specialist, usual customary and reasonable (UCR), and urgent care; and

(ii) Such other terms as the Secretary determines are important to define so that individuals and employers may compare and understand the terms of coverage and medical benefits (including any exceptions to those benefits), as specified in guidance.

(3) Appearance. A group health plan, and a health insurance issuer, must provide the uniform glossary with the appearance specified by the Secretary in guidance to ensure the uniform glossary is presented in a uniform format and uses terminology understandable by the average plan enrollee (or, in the case of individual market coverage, an average individual covered under a health insurance policy).

(4) Form and manner. A plan or issuer must make the uniform glossary described in this paragraph (c) available upon request, in either paper or electronic form (as requested), within seven business days after receipt of the request.

(d) Preemption. For purposes of this section, the provisions of section 2724 of the PHS Act continue to apply with respect to preemption of State law. In addition, State laws that require a health insurance issuer to provide an SBC that supplies less information than required under paragraph (a) of this section are preempted.

(e) Failure to provide. A health insurance issuer or a non-federal governmental health plan that willfully fails to provide information required under this section is subject to a fine of not more than \$1,000 for each such failure. A failure with respect to each covered individual constitutes a separate offense for purposes of this paragraph (e). HHS will enforce these provisions in a manner consistent with 45 CFR 150.101 through 150.465.

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

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

(ii) For disclosures with respect to participants and beneficiaries who enroll in coverage other than through an open enrollment period (including individuals who are

newly eligible for coverage and special enrollees), this section applies beginning on the first day of the first plan year that begins on or after September 23, 2012.

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

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