

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 54 and 602

[REG-140038-10]

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DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB52

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CMS-9982-P

45 CFR Part 147

RIN 0938-AQ73

Summary of Benefits and Coverage and the 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: Notice of proposed rulemaking

SUMMARY: This document contains proposed regulations regarding disclosure of 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 to help plans and individuals better understand their health coverage, as well as other coverage options. The templates and instructions to be used in making these disclosures are being issued separately in today's Federal Register.

DATES: Comment date. Comments are due on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING:** Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB52, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Email: E-OHPSCA2715.EBSA@dol.gov.
- Mail or Hand Delivery: Office of Health Plan Standards and Compliance

Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Attention: RIN 1210—AB52.

Comments received by the Department of Labor will be posted without change to <http://www.regulations.gov> and <http://www.dol.gov/ebsa>, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code CMS-9982-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-9982-P,
P.O. Box 8016,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9982-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of

the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, please call (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security

Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-140038-10, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: CC:PA:LPD:PR (REG-140038-10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- Hand or courier delivery: Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-140038-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW, Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Heather Raeburn, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Jennifer Libster or Padma Shah, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (301) 492-4252.

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>.

SUPPLEMENTARY INFORMATION:

I. 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

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.

law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes.

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 that 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 II.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 proposed regulations propose standards for implementing PHS Act section 2715. As discussed more fully below, templates and instructions for meeting the

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.

disclosure requirements of PHS Act section 2715 are being issued separately in today's Federal Register.

II. Overview of the Proposed 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 in compiling and providing a summary of benefits and coverage (SBC) that “accurately describes the benefits and coverage under the applicable plan or coverage.” The statute directs the Departments, in developing such standards, to “consult with the National Association of Insurance Commissioners” (referred to in this preamble 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.” 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.³ Throughout the process, NAIC working group draft documents and

³ In developing its recommendations, the NAIC considered the results of various consumer testing sponsored by both insurance industry and consumer associations. Specifically, the draft SBC template, including the coverage examples, and the draft uniform glossary underwent consumer testing to assist in determining adjustments to ensure the final product was consumer friendly. Summaries of this testing are available at: http://www.naic.org/documents/committees_b_consumer_information_101012_ahip_focus_group_summary.pdf; http://www.naic.org/documents/committees_b_consumer_information_110603_ahip_bcbsa_consumer_testing.pdf;

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. The Departments have received transmittals from the NAIC that include a recommended template for the SBC (with instructions and samples to be used in completing the template) and a recommended uniform glossary.⁴

These regulations generally propose standards for group health plans (and their plan administrators), and health insurance issuers offering group or individual health insurance coverage, that will govern who provides an SBC, who receives an SBC, when the SBC will be provided, and how it will be provided. The Departments invite comment on the standards of the proposed regulations.

In conjunction with these proposed regulations, the Departments are publishing a document today that provides the proposed template for the SBC (with proposed instructions and sample language for completing the template) and the proposed uniform glossary that are identical to the documents that were developed and agreed to by the entire NAIC working group and then voted on and approved by the full NAIC. Instead of proposing possible changes to the NAIC's proposed SBC template and related materials,

http://www.naic.org/documents/committees_b_consumer_information_101014_consumers_union.pdf (a more detailed summary of which is accessible at: http://prescriptionforchange.org/pdf/CU_Consumer_Testing_Report_Dec_2010.pdf); and http://www.naic.org/documents/committees_b_consumer_information_110603_consumers_union_testing.pdf.

⁴ Information on the NAIC working group, including drafts of SBC materials and other supporting documents developed for compliance with PHS Act section 2715, working group membership lists, and meeting minutes, is available at: http://www.naic.org/committees_b_consumer_information.htm.

the document published today incorporates all of the NAIC working group's recommended materials (with the exception of a sample coverage example⁵) and invites public comment. The Departments recognize that changes to the SBC template may be appropriate to accommodate various types of plan and coverage designs, to provide additional information to individuals, or to improve the efficacy of the disclosures recommended by the NAIC. In addition, the SBC template and related documents were drafted by the NAIC primarily for use by health insurance issuers.⁶

In general, the Departments have heard concerns about the potential redundancies and additional cost associated with elements of the SBC requirement – including the uniform glossary and the coverage facts labels – particularly for those plans and group health insurance issuers that already provide a Summary Plan Description (SPD) under 29 CFR 2520.104b-2. Comments are solicited on whether the SBC should be allowed to be provided within an SPD if the SBC is intact and prominently displayed at the beginning of the SPD (for example, immediately after a cover page and table of contents), and if the timing requirements for providing the SBC (described in paragraph (a) of the proposed regulations) are satisfied. The Departments also welcome further comments on ways the SBC might be coordinated with other group health plan disclosure

⁵ The Appendices do not include a sample coverage example calculation for breast cancer in the individual market that was transmitted by the NAIC. Upon review, it appeared that some of the data in the example might be subject to copyright protection. Moreover, the sample coverage example provided by NAIC was limited to breast cancer in the individual market and did not address the other two coverage examples – maternity coverage and diabetes. Finally, particular coding information and pricing information included in the sample would change annually, which would result in the data included in the sample becoming outdated relatively quickly. Accordingly, HHS is publishing on its website (at <http://cciiio.cms.gov>), the coding and pricing information necessary to perform coverage example calculations for all three coverage examples. HHS will update this information annually.

⁶ National Association of Insurance Commissioners, Consumer Information Working Group, December 17, 2010 Letter to the Secretaries. Available at http://www.naic.org/documents/committees_b_consumer_information_ppaca_letter_to_sebelius.pdf.

materials (e.g., application and open season materials) to communicate effectively with participants and beneficiaries about their coverage and make it easy for them to compare coverage options while also avoiding undue cost or burden on plans and group health insurance issuers.

Consistent with the goals of balancing effective communication and ease of comparison for individuals with minimization of cost and duplication, other sections of this preamble outline and invite comment on potential approaches to major elements of the SBC – the statutorily-required uniform glossary and the coverage examples – in the interest of streamlining standards and making implementation of these components as helpful and user-friendly for individuals, and as workable and efficient as possible.

As discussed below, PHS Act section 2715 generally directs group health plans and health insurance issuers to comply with the SBC requirements beginning on or after March 23, 2012. Comments are requested regarding factors that may affect the feasibility of implementation within this time frame. After the public comment period on these documents, the Departments will finalize the SBC template and instructions. Consistent with PHS Act section 2715(c), the Departments will periodically review and update the documents as appropriate, taking into account public comments.

2. Providing the SBC

Paragraph (a) of the proposed regulations implements the general disclosure requirement and sets forth the proposed standards for who provides an SBC, to whom, and when. PHS Act section 2715 generally sets forth 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).”⁷ Accordingly, these proposed regulations would 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, these proposed regulations would make a plan administrator of a group health plan responsible for providing an SBC. Under the proposed regulations, the SBC would be provided in writing free of charge.

In general, the proposed rules direct that the SBC be provided when a plan or individual is comparing health coverage options. If the information in the SBC changes between the time of application, when the coverage is offered, and when a policy is issued (often the case only for individual market coverage), the proposal would require that an updated SBC be provided. If the information is unchanged, the SBC does not need to be provided again, except upon request. This general approach is explained more fully below.

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

Paragraph (a)(1)(i) of the proposed regulations provides that a health insurance issuer offering group health insurance coverage provide the SBC to a group health plan (including, for this purpose, its sponsor) upon an application or request for information

⁷ 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.

by the plan about the health coverage (see section II.A.2.c. of this preamble, below, for a discussion of this proposal). Under this proposal, the SBC must be provided as soon as practicable following the request, but in no event later than seven days following the request. If an SBC is provided upon request for information about health coverage and the plan subsequently applies for health coverage, a second SBC will be provided automatically only if the information in the SBC has changed. If there is a change to the information in the SBC before the coverage is offered, or before the first day of coverage, the issuer must update and provide a current SBC to the plan no later than the date of the offer (or no later than the first day of coverage, as applicable). The Departments recognize that often the only change to the SBC is a final premium quote (usually in the individual health insurance market or the small group market). The Departments request comments on whether, in such circumstances, premium information can be provided in another way that is easily understandable and useful to plan sponsors and individuals, other than by sending a new, full SBC.

An issuer also must provide a new SBC if and when the policy, certificate, or contract (for simplicity, referred to collectively as a “policy” in the remainder of this preamble) is renewed or reissued. In the case of renewal or reissuance, if the issuer requires written application materials for renewal (in either paper or electronic form), it must provide the SBC no later than the date the materials are distributed. 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.

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

Under paragraph (a)(1)(ii) of the proposed 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 beneficiary⁸ with respect to each benefit package offered for which the participant or beneficiary is eligible.⁹ 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 and any beneficiaries. If there is any change to the information required to be in the SBC 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.

The plan or issuer must also provide the SBC to special enrollees within seven days of a request for enrollment pursuant to a special enrollment period.¹⁰ Additionally, the plan or issuer must provide a new SBC if and when the coverage is renewed.

Specifically, if written application materials are required for renewal (in either paper or electronic form), the SBC must be provided no later than the date the materials are

⁸ 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 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.

⁹ 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 II.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.

¹⁰ Regulations regarding special enrollment can be found at 26 CFR 54.9801-6, 29 CFR 2590.701-6, and 45 CFR 146.117.

distributed. If renewal is automatic, the proposed rules provide that the SBC must be provided no later than 30 days prior to the first day of coverage in the new plan year.

c. Provision of the SBC Upon Request

The regulations propose that a health insurance issuer offering group health insurance coverage provide the SBC to a group health plan (and a plan or issuer must provide the SBC to a participant or beneficiary) upon request, as soon as practicable, but in no event later than seven days following the request. Although PHS Act section 2715 does not specifically reference furnishing SBCs on request, PHS Act section 2715(a) authorizes the Departments to develop standards for providing the SBC to applicants, enrollees, policyholders, and certificate holders. The Departments believe that this provision recognizes that plans and individuals may need or desire the information provided in the SBC at times other than those set forth in the statute to ensure that the plans and individuals have continuous access to coverage and cost information to make informed choices about health coverage.¹¹ In addition, while the “upon request” provision may result in some additional administrative work for plans and issuers, the Departments have used discretion elsewhere in these proposed regulations to create special rules for avoiding duplication and also propose to reduce burden by facilitating electronic transmittal of the SBC, where appropriate. Accordingly, the Departments have sought to balance providing consumer access to SBCs with minimizing burdens on employers and insurers.

¹¹ Moreover, this provision is consistent with requirements under ERISA section 104(b)(4), which requires ERISA-covered group health plans to provide to participants and beneficiaries, upon request, copies of the instruments under which the plan is established or operated.

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

The Departments propose, in paragraph (a)(1)(iii), three rules to streamline provision of the SBC and prevent unnecessary duplication with respect to group health plan coverage. First, the requirement to provide an SBC will be considered satisfied for all entities if the SBC is provided by any entity, so long as all timing and content requirements are also satisfied. For example, if a health insurance issuer offering group health insurance coverage provides a complete, timely SBC to the plan's participants and beneficiaries, the plan's requirement to provide the SBC will be satisfied.

Second, if a participant and any beneficiaries are known to reside at the same address, providing a single SBC to that address will satisfy the obligation to provide the SBC for all individuals residing at that address. However, if a beneficiary's last known address is different than the participant's last known address, a separate SBC must be provided to the beneficiary at the beneficiary's last known address.

Finally, to further reduce unnecessary duplication with respect to a group health plan that offers multiple benefit packages, in connection with renewal, the plan and issuer only need to automatically provide a new SBC with respect to the benefit package in which a participant or beneficiary is enrolled. SBCs are not required to be provided automatically 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 for which the participant or beneficiary is eligible, the SBC must be provided as soon as practicable, but in no event later than seven days following the request.

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

Under these regulations, the Secretary of HHS sets forth proposed standards applicable to individual health insurance coverage for who provides an SBC, to whom, and when. The intent is to parallel the proposed group market requirements described above, with only those changes necessary to reflect the differences between the two markets. For example, individual policyholders 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 as soon as practicable after receiving a request for application or a request for information, but in no event later than seven days after receipt of the request. If an individual later applies for the same policy, a second SBC is required to be provided only if the information in the SBC has changed.

An issuer that makes an offer of coverage must provide an updated SBC only if it has modified the terms of coverage for the individual (including as a result of medical underwriting) that are required to be reflected in the SBC. Similarly, when an individual accepts the offer of coverage, if any terms are modified before the first day of coverage, an updated SBC must again be provided no later than the first day of coverage. A health insurance issuer will provide an SBC annually at renewal, no later than 30 days before the start of the new policy year, reflecting any changes effective for the new policy year.

Finally, similar to the group health coverage rules, 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), if all those individuals are known to reside at the same address, a single SBC may be provided to that address. This single SBC will

satisfy the requirement to provide the SBC for all individuals residing at that address.

However, if an individual's last known address is different than the last known address of the individual requesting coverage, the policyholder, or a dependent of either, a separate SBC must be provided to that individual at the individual's last known 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;
- 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 parallel the content elements set forth in the statute. As discussed above, the Departments are issuing a document that proposes to use the NAIC's recommended SBC template and instructions to satisfy the SBC content and appearance requirements of PHS Act section 2715.

A few of the content elements included in the NAIC's recommendations warrant further explanation and discussion. The template developed by the NAIC working group and transmitted to the Departments includes four elements not specified in the statute. Consistent with the Departments' approach of including all of the NAIC's recommended materials, the proposed regulations include these additional recommended elements. The four additional elements are: (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 Departments have included these elements in the proposed regulation consistent with the NAIC's recommendations. PHS Act section 2715(a) requires the Departments to develop regulations for provision of an SBC that accurately describes benefits and coverage, which includes the statutory content elements listed above, but the Departments believe they are not limited to them. The statute also requires the Departments to consult with the NAIC on the development of the standards for the SBC, which includes content. The Departments' proposal includes all of the NAIC's recommendations, including the additional content, and the Departments invite comments on this approach and the four additional SBC content elements. For example, with respect to the requirement to include an Internet address that may be used to obtain a copy of the uniform glossary, the Departments invite comments on whether the SBC also should disclose the option to receive a paper copy of the uniform glossary upon request.

The NAIC instructions provide that the premium generally is the premium as charged by the issuer (which may be evidenced in a rate table attached to the SBC),¹² or the cost of coverage in the case of self-insured plans. The NAIC instructions further provide that, in the case of a group health plan, a participant or beneficiary should consult the employer for information regarding the actual cost of coverage net of any employer subsidy. This raises issues regarding the ability to compare premium or cost information between coverage options. The Departments request comments regarding whether the SBC should include premium or cost information and if so, the extent to which such information should reflect the actual cost to an individual net of any employer

¹² See page 4 of the NAIC Draft Instruction Guide for Group Policies (available at http://www.naic.org/documents/committees_b_consumer_information_hhs_dol_submission_1107_inst_grp.pdf).

contribution, as well as the extent to which the cost information should include costs for different tiers of coverage (for example, self-only, family). The Departments also request comments on how this information can be provided in a way that allows individuals and plan sponsors to make meaningful comparisons about the cost of their coverage options.

With respect to the definitions, the Departments propose to follow an approach consistent with the recommendations received from the NAIC.¹³ Specifically, PHS Act section 2715(b)(3)(A) requires plans and issuers to include in the SBC “uniform definitions” of common health insurance terms that are consistent with the standards developed under section 2715(g). PHS Act section 2715(g) directs the Departments to “provide for the development of standards for the definitions of terms used in health insurance coverage,” including specified insurance-related terms and medical terms, as well as other terms the Departments determine are important to define.

The NAIC working group adopted a two-part approach to the definitions. First, it drafted a consumer-friendly uniform glossary, which includes definitions of health coverage terminology, to be provided in connection with the SBC. The NAIC’s uniform glossary provides simple, general, descriptive definitions designed to help consumers understand terms and concepts commonly used in health coverage. For example, “out-of-pocket limit” is defined in the NAIC’s uniform glossary as:

The most you pay during a policy period (usually a year) before your health insurance or plan begins to pay 100 % of the allowed amount. This limit never includes your premium, balance-billed charges or health care your health insurance or plan doesn’t cover. Some health insurance or plans don’t count all of

¹³ National Association of Insurance Commissioners, Consumer Information Working Group, December 17, 2010 Letter to the Secretaries. Available at http://www.naic.org/documents/committees_b_consumer_information_ppaca_letter_to_sebelius.pdf.

your co-payments, deductibles, co-insurance payments, out-of-network payments or other expenses toward this limit.

In these proposed regulations, and as described more fully below under section II.C. of this preamble under the heading “Uniform Glossary”, the Departments propose that the NAIC uniform glossary be used to satisfy the requirements of PHS Act 2715(g).

At the same time, these generic glossary definitions, alone, would not necessarily help consumers understand what terms mean under a given plan or policy, nor would they support meaningful comparison of coverage options under PHS Act section 2715(b)(3)(A) because the generic terms used in the glossary are not plan- or policy-specific and would not enable consumers to understand what the terms actually mean in the context of a specific contract. Therefore, in addition to the uniform glossary, the NAIC working group also developed a “Why this Matters” column for the draft SBC template (with instructions for plans and issuers to use in completing the SBC template).¹⁴ The instructions specify how plans and issuers must describe each coverage component in the SBC. For example, the instructions indicate what information must be provided about a plan’s out-of-pocket limit on cost sharing, including whether copayments, out-of-network coinsurance, and deductibles are subject to this limit.

In the Departments’ proposal, the “Why this Matters” column in the SBC template, together with the instructions for completing this column, constitute the definitions required to be provided under PHS Act section 2715(b)(3)(A). This approach allows plans and issuers flexibility in how they design benefits and coverage features, but

¹⁴ 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.

proposes that benefits and features be described in a consistent way so that individuals and employers will understand them and appreciate differences from one plan or policy to the next.

With respect to the element of the SBC regarding a statement about whether a plan or coverage 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 minimum value requirements (minimum essential coverage statement),¹⁵ because this content is not relevant until other elements of the Affordable Care Act are implemented, this statement is not in the NAIC recommendations. For the same reason, these proposed regulations provide that the minimum essential coverage statement is not required to be in the SBC until the plan or coverage is required to provide an SBC with respect to coverage beginning on or after January 1, 2014.¹⁶

Starting in 2014, certain individuals who purchase health insurance coverage through the new Affordable Insurance Exchanges ("Exchanges") may be eligible for a premium tax credit to help pay for the cost of that coverage. In general, individuals offered affordable minimum essential coverage under an employer-sponsored plan will not be eligible to receive a premium tax credit. Correctly establishing whether an

¹⁵ 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.

¹⁶ 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. The Departments' proposal recognizes this effective date and the need for additional guidance with respect to these requirements and is consistent with the recommendation in the transmittal letter from the NAIC. The NAIC will continue to work to develop a recommendation for this SBC requirement and will submit it to the Departments at a later date.

employer is offering affordable minimum essential coverage is important to individuals, employers, and Exchanges and necessitates the verification of certain information about employer coverage, including the information in the minimum essential coverage statement. The Departments are exploring several reporting options under the Affordable Care Act and other applicable statutory authorities¹⁷ to determine how information about employer-provided coverage can be provided and verified in a manner that limits the burden on individuals, employers, and Exchanges. Because the statutory SBC elements include the information in the minimum essential coverage statement, the Departments invite comments on how employers might provide this information to employees and the Exchanges in a manner that minimizes duplication and burden. The Departments also recognize that some of the plan level information that is required to be provided in the SBC is also required to be provided under section 6056 of the Code (requiring employers to report to the IRS specific information related to employer-sponsored health coverage provided to employees) and are coordinating their efforts to determine how and whether the same data can be used for multiple purposes. To help develop a simple, efficient system for employers, the Treasury Department and the IRS intend to request comments on employer information reporting required under section 6056 of the Code.

The last SBC content item that merits further discussion is the coverage facts label. The statute requires that an SBC contain a “coverage facts label.” For ease of reference, the regulations propose to use “coverage examples,” the term recommended by

¹⁷ In addition to section 2715 of the PHS Act, these authorities include, but are not limited to, section 6056 of the Code, as added by section 1514 of the Affordable Care Act (requiring employers to report to the Internal Revenue Service specific information related to employer-sponsored health coverage provided to employees); and section 18B of the Fair Labor Standards Act, as added by section 1512 of the Affordable Care Act (requiring employers to disclose to employees information regarding Exchange coverage options).

the NAIC, in place of the statutory term. As specified in the statute, the proposed regulations provide that the coverage examples illustrate benefits provided under the plan or coverage for common benefits scenarios, including pregnancy and serious or chronic medical conditions. The coverage example would estimate what proportion of expenses under an illustrative benefits scenario might be covered by a given plan or policy. Consumers then could use this information to compare their share of the costs of care under different plan or coverage options to make an informed purchasing decision.

Under the proposed regulations, consistent with the recommendations of the NAIC working group, 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 available through the National Guideline Clearinghouse.¹⁸ A benefits scenario would include the information needed to simulate how claims would be processed under the scenario to generate an estimate of cost sharing a consumer could expect to pay under the benefit package. The document published contemporaneously with these proposed regulations includes specific instructions and an HHS website with specific information necessary to simulate benefits covered under the plan or policy for specified benefits scenarios.¹⁹

¹⁸ The National Guideline Clearinghouse, within the Agency for Healthcare Research and Quality (AHRQ), publishes systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances, available at <http://www.guideline.gov/>.

¹⁹ A general instruction guide for completing the coverage examples portion of the SBC, which is identical to that transmitted by the NAIC, is included in the document published today by the Departments. These instructions, together with specific assumptions for coding data and reimbursement rates published today on HHS's website comprise the Departments' instructions for completing the coverage examples portion of the SBC. See <http://cciio.cms.gov>. http://www.naic.org/documents/committees_b_consumer_information_hhs_dol_submission_1107_template_blank.xls. The coding and reimbursement rate assumptions were developed by HHS and are also open for public comment.

These proposed regulations provide that the Departments may identify up to six coverage examples that may be required in an SBC. A maximum of six coverage examples was discussed by the NAIC working group, so that consumers may easily read, understand, and compare how benefits are provided for different common medical conditions. In future years, the SBC may include coverage examples in addition to the three proposed now. The Departments propose to limit the number of coverage examples to no more than six to limit the burden on plans and issuers and to ensure that there is adequate space in the SBC to present coverage examples in a manner that is easy to read and useful for individuals. A document published contemporaneously with these proposed regulations adopts a phase-in approach to the coverage examples, and uses the three coverage examples recommended by NAIC for inclusion first – having a baby (normal delivery), treating breast cancer, and managing diabetes.²⁰

The Departments invite comments on the proposed coverage examples, whether additional benefits scenarios would be helpful and, if so, what those examples should be. The Departments also invite comments on the benefits and costs associated with developing multiple coverage examples, as well as how multiple coverage examples might promote or hinder the ability to understand and compare terms of coverage. It is anticipated that any additional coverage examples will only be required to be provided prospectively, and that plans and issuers will be provided with adequate time for compliance. Additionally, the Departments invite comments on whether and how to phase in the implementation of the requirement to provide coverage examples. For

²⁰ See http://www.naic.org/documents/committees_b_consumer_information_final_coverage_ex.pdf.

example, one option would provide that in 2012, coverage examples would only need to be provided for the SBCs with respect to a subset of all benefits packages offered by group health plans or health insurance issuers, with coverage examples required to be provided for all benefits packages in later years. Comments are invited on these issues.

Comments are also requested on whether it would be feasible or desirable to permit plans and issuers to input plan- or policy-specific information into a central Internet portal, such as the Federal health care reform website (www.healthcare.gov), that would use the information to generate the coverage examples for each plan or policy. The examples would then be available on the Internet portal for access by individuals. Alternatively, some have suggested that plans and issuers might provide individuals, in a convenient format in the SBC, the several items of plan- or policy-specific information necessary to generate the coverage examples and a reference to the Internet portal, so that individuals could input the information into the Internet portal to generate the coverage examples for the plan or policy. The Departments note that the NAIC considered and rejected the idea of a “cost calculator” or similar tool. The Departments solicit comments on the cost and benefits of these alternatives, including whether such approaches would provide an efficient and effective method for individuals, plans, and issuers to generate or access the coverage examples and how any such approaches could adequately serve individuals who do not have regular access to the Internet (for example, by disclosing in the SBC the option to obtain paper copies of coverage examples generated by the plan or issuer).

4. Appearance.

Section 2715 of the PHS Act sets forth the appearance for 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 proposed regulations, consistent with the NAIC recommendation, interpret the four-page limitation as four double-sided pages.²¹ The Departments' view is that this approach will enable group health plans, participants and beneficiaries, and individuals in the individual insurance market to receive enough information to shop for, compare, and make informed decisions regarding various coverage options that may be available to them.²² The Departments seek comments on this approach.

Consistent with the NAIC recommendations provided to the Departments,²³ under these proposed regulations, a group health plan or a health insurance issuer will provide the SBC as a stand-alone document in the form authorized by the Departments and completed in accordance with the instructions and guidance for completing the SBC that are authorized by the Departments. As noted earlier in this preamble, comments are invited on whether and how the SBC might best be coordinated with the SPD and other group health plan disclosure materials.

²¹ 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.

²² PHS Act sections 2715(b)(3)(A) and (g)(2) clearly reference consumers comparing coverage and PHS Act section 2715(b)(1) requires a uniform format, to enable shopping and comparing health coverage options.

²³ National Association of Insurance Commissioners, Consumer Information Working Group, December 17, 2010 Letter to the Secretaries. Available at http://www.naic.org/documents/committees_b_consumer_information_ppaca_letter_to_sebelius.pdf.

5. Form and Manner

a. Group health plan coverage

To facilitate faster and less burdensome disclosure of the SBC, and consistent with PHS Act section 2715(d)(2), the proposed regulations set forth rules to facilitate electronic transmittal of the SBC, where appropriate. Specifically, an SBC provided by a plan or issuer to a participant or beneficiary may be provided in paper form.

Alternatively, for plans and issuers subject to ERISA or the Code, the SBC may be provided electronically if the requirements of the Department of Labor's electronic disclosure safe harbor at 29 CFR 2520.104b-1(c) are met.²⁴ For non-Federal governmental plans, the regulations propose that the SBC may be provided electronically if either the substance of the provisions of the Department of Labor's electronic disclosure rule are met, or if the provisions governing electronic disclosure in the individual health insurance market (described below) are met.

With respect to an SBC provided by an issuer to a plan, the SBC may be provided in paper form or electronically (such as email transmittal or an Internet posting on the issuer's website or on www.healthcare.gov). For electronic forms, the format must be readily accessible by the plan; the SBC must be provided in paper form free of charge upon request; and for Internet postings, the plan must be notified by paper or email that the documents are available on the Internet, and given the web address. The Departments

²⁴ 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.

invite comments on whether any clarifications are needed with respect to the “readily accessible” standard (for example, whether the requirements for passwords or special software create a sufficient burden that the documents are not “readily accessible”). The Departments also invite comment on whether modifications or adaptations of the SBC are necessary to facilitate or improve electronic disclosure.

b. Individual health insurance coverage

With respect to the individual market, the proposed regulations set forth the circumstances in which an issuer offering individual health insurance coverage may provide an SBC in either paper or electronic form. Specifically, under these proposed regulations, unless specified otherwise by an individual, an issuer would be required to provide an SBC (and any subsequent SBC) in paper form if, upon the individual’s request for information or request for an application, the individual makes the request in person, by phone or by fax, or by U.S. mail or courier service; or if, when submitting an application, the individual completes the application for coverage by hand, by phone or by fax, or by U.S. mail or courier service. As an alternative, the Departments seek comments on whether it might be appropriate to allow issuers to fulfill an individual’s request in electronic form, unless the individual requests a paper form.

Under this proposed rule, an issuer may provide an SBC (and any subsequent SBC) in electronic form (such as through an Internet posting or via electronic mail) if an individual requests information or requests an application for coverage electronically; or, if an individual submits an application for coverage electronically.

To ensure actual receipt of an SBC provided in electronic form, these proposed regulations would set forth certain safeguards for electronic disclosure in the individual

market. Under the proposed regulations, an issuer that provides the SBC electronically must:

- Request that an individual acknowledge receipt of the SBC;
- Make the SBC available in an electronic format that is readily usable by the general public;
- If the SBC is posted on the Internet, display the SBC in a location that is prominent and readily accessible to the individual and provide timely notice, in electronic or non-electronic form, to each individual who requests information about, or an application for, coverage, that apprises the individual the SBC is available on the Internet and includes the applicable Internet address;
- Promptly provide a paper copy of the SBC upon request without charge, penalty, or the imposition of any other condition or consequence, and provide the individual with the ability to request a paper copy of the SBC both by using the issuer's Web site (such as by clicking on a clearly identified box to make the request) and by calling a readily available telephone line, the number for which is prominently displayed on the issuer's Web site, policy documents, and other marketing materials related to the policy and clearly identified as to purpose; and
- Ensure an SBC provided in electronic form is provided in accordance with the appearance, content, and language requirements of this section.

The Departments welcome comments as to whether these or other safeguards are appropriate.

Finally, consistent with the standards for electronic disclosure, these proposed regulations seek to reduce the burden of providing an SBC to individuals shopping for

coverage. Specifically, these proposed regulations provide that a health insurance issuer that complies with the requirements set forth at 45 CFR 159.120 (75 FR 24470) for reporting to the Federal health care reform insurance Web portal would be deemed to comply with the requirement to provide the SBC to an individual requesting information about coverage prior to submitting an application. Any SBC furnished at the time of application or subsequently, however, would be required to be provided in a form and manner consistent with the rules described above.

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.” These proposed regulations 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 appeals notices in a culturally and linguistically appropriate manner under PHS Act section 2719, and paragraph (e) of its implementing regulations.²⁵ In general, those rules provide that, in specified counties of the United States, plans and issuers must provide interpretive services, and must provide written translations of the SBC upon request in certain non-English languages. In addition, in such counties, English versions of the SBC must disclose the availability of language services in the relevant language.²⁶ The counties in which this must be done are those in which at least ten percent of the population residing in the county is literate only in the same non-English language, as determined in

²⁵ See 75 FR 43330 (July 23, 2010), as amended by 76 FR 37208 (June 24, 2011).

²⁶ The SBC template, as recommended by the NAIC, does not include this statement; however, these proposed regulations would require that plans and issuers include it.

guidance. The Departments welcome comments on whether and how to provide written translations of the SBC in these non-English languages. (Note, nothing in these proposed 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 origin. 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>.)

B. Notice of Modifications

Section 2715(d)(4) of the PHS Act directs that a group health plan or health insurance issuer offering group or individual health insurance coverage to provide notice of a material modification if it makes a material modification (as defined under ERISA section 102, 29 U.S.C. 1022) in any of the terms of the plan or coverage involved that is not reflected in the most recently provided SBC. The proposed regulations interpret the statutory reference to the SBC to mean that only a material modification that would affect the content of the SBC would require plans and issuers to provide this notice. In these circumstances, the notice must be provided to enrollees (or, in the individual market, policyholders) no later than 60 days prior to the date on which such change will become

effective, if it is not reflected in the most recent SBC provided and occurs other than in connection with a renewal or reissuance of coverage. 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.²⁷ 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), or more stringent requirements for receipt of benefits. As a result, it also includes changes or modifications that reduce or eliminate benefits, increase premiums and cost-sharing, or impose a new referral requirement.

PHS Act section 2715 and these proposed regulations describe the timing for when a notice of material modification must be provided in situations other than upon renewal at the end of a plan or policy year when a new SBC is provided under the rules of paragraph (a) of the proposed rules. To the extent a plan or policy implements a mid-year change that 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, paragraph (b) of the proposed regulations would require a notice of modifications to be provided 60

²⁷ See DOL Information Letter, Washington Star/Washington-Baltimore Newspaper Guild to Munford Page Hall, II, Baker & McKenzie (February 8, 1985).

days in advance of the effective date of the change. This notice could be satisfied either by a separate notice describing the material modification or by providing an updated SBC reflecting the modification. For ERISA-covered group health plans subject to PHS Act section 2715, this notice is in advance of the timing under the Department of Labor's regulations set forth at 29 CFR 2520.104b-3 that require the provision of 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), of course, an ERISA-covered plan will also satisfy the requirement to provide an SMM under Part 1 of ERISA. The Departments invite comments on this expedited notice requirement, including whether there are any circumstances where 60-day advance notice might be difficult. The Departments also solicit comments on the format of the notice of modification, particularly for plans and issuers not subject to 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 that will help consumers understand and compare the terms of coverage and the extent of medical benefits (including any exceptions and limitations).

The NAIC working group recommended,²⁸ and the Departments are proposing to adopt for this purpose, inclusion of 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 uniform glossary proposed by the Departments is being issued in a document published elsewhere in today's Federal Register.

The Departments invite comments on the uniform glossary, including the content of the definitions and whether there are additional terms that are important to include in the uniform glossary so that individuals and employers may understand and compare the terms of coverage and the extent of medical benefits (or exceptions to those benefits). For example, the Departments are considering whether glossary definitions of any of the following terms would be helpful: claim, external review, maternity care, preexisting condition, preexisting condition exclusion period, or specialty drug. It is anticipated that

²⁸ National Association of Insurance Commissioners, Consumer Information Working Group, December 17, 2010 Letter to the Secretaries. Available at http://www.naic.org/documents/committees_b_consumer_information_ppaca_letter_to_sebelius.pdf.

any additional terms would be included in the uniform glossary prospectively, and that plans and issuers would be provided adequate time for compliance.

The proposed regulations direct a plan or issuer to make the uniform glossary available upon request within seven days. The timing of disclosure is intended to be generally consistent with the proposed requirement, described in section II.A.2.c of this preamble. A plan or issuer may satisfy this disclosure requirement by providing an Internet address where an individual may review and obtain the uniform glossary, as described in section II.A.3 of this preamble. This Internet address may be a place the document can be found on the plan's or issuer's website. It may also be a place the document can be found on the website of either the Department of Labor or HHS. However, a plan or issuer must make a paper copy of the glossary available upon request. Group health plans and health insurance issuers will provide the uniform glossary in the appearance authorized 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)). These provisions apply so that 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 on health insurance issuers requirements 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, these proposed regulations would not prevent States from imposing separate, additional disclosure requirements on health insurance issuers. The Departments recognize the need to balance States’ interest in information disclosure regarding insurance coverage with the primary objective of PHS Act section 2715 (as stated in the section title) of providing for the development and use of a short, uniform explanation of coverage document so that consumers may make apples-to-apples comparisons of plan and coverage options.

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 may 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 C.F.R. 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 with respect to each enrollee constitutes a separate offense. This penalty can only be imposed by the Secretary.

Paragraph (e) of the regulations proposed by HHS clarifies that States have primary enforcement authority over health insurance issuers for any violations, whether willful or not, using their own remedies. These proposed regulations also clarify 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. Proposed paragraph (e) of the HHS 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 section 2715 of the PHS Act.

2. Departments of Labor and the Treasury

The Department of Labor enforces the requirements of part 7 of ERISA 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. Generally the enforcement authority under these provisions applies to all nongovernmental group health plans, but the Department of Labor does not enforce the requirements of part 7 of ERISA with respect to church plans.

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 understanding²⁹ 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 section 2715 of the PHS Act as incorporated into ERISA and the Code. Therefore, in

²⁹ See 64 FR 70164 (December 15, 1999).

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 502(b)(3), 29 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 section 2715(f) should be imposed on group health plans that are not maintained by a governmental entity.

F. Applicability

PHS Act section 2715 directs that the requirement for group health plans and health insurance issuers to provide an SBC “prior to any enrollment restriction” applies not later than 24 months after the date of enactment (*i.e.*, beginning on or after March 23, 2012).³⁰ As noted earlier, the statute also directs the Departments to consult with the NAIC in developing the SBC standards. The Departments are appreciative of the detailed and valuable work the NAIC and its working group has performed in developing recommended standards and materials, including the NAIC’s extensive efforts to involve numerous stakeholder groups in that process for over a year and to provide drafts of its evolving materials to the Departments periodically. Accordingly, as noted, the Departments are appending to the document accompanying these proposed regulations the NAIC’s SBC work product for public comment.

The NAIC transmitted its final materials to the Departments on July 29, 2011. In recognition of existing disclosure requirements under 29 CFR 2520.104b-2 for those group health plans that already provide SPDs to participants and concerns raised about providing SBCs by the statutory deadline, comments are solicited on whether and, if so, how practical considerations might affect the timing of implementation. In coordination

³⁰ Section 2715 is applicable to both grandfathered and non-grandfathered health plans. See 26 CFR 54.9815-1251(d), 29 CFR 2590.715-1251(d), and 45 CFR 147.120(d).

with the request for comment elsewhere in this preamble on a potential phase-in of the implementation of the requirement to provide coverage examples, comments are invited also on how any potential phase-in of those requirements could or should be coordinated with the timing of the effectiveness of the general SBC standards.

The Departments also request comments on whether any special rules are necessary to accommodate expatriate plans. 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. At the same time, in the Department of HHS's interim final regulations relating to medical loss ratio (MLR) provisions published at 75 FR 74864, a special rule was included for expatriate insurance policies. The Departments invite comments on whether any adjustments are needed under PHS Act section 2715 for expatriate plans and, if so, for what types of coverage.

III. 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 proposed 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 proposed regulation. The Departments invite comment on this assessment.

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 plan sponsors 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.³¹ Indeed, a recent analysis of SPDs from 40 employer health plans from across the United States (varying based on geography, firm size, and industry

³¹ 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.

sector) found that, on average, SPDs are generally written at a first year college reading level (with readability ranging from 9th grade reading level to nearly a college graduate reading level).³² 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,³³ New York,³⁴ Rhode Island,³⁵ Utah³⁶ and Vermont³⁷ have established minimum standards for disclosure of health insurance information but 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 receive information about health insurance coverage options. Other State disclosure

³² “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.

³³ M.G.L.A. 176Q § 5 (2010).

³⁴ NY Ins. Law § 3217-a (2010).

³⁵ 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.

³⁶ Utah Code § 31A-22-613.5 (2010).

³⁷ Division of Health Care Administration, Rule 10.000: Quality Assurance Standards and Consumer Protections for Managed care Plans, State of Vermont, September 20, 1997.

requirements only extend to managed care organizations, and not to other segments of the market.³⁸

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 proposed regulations are necessary to provide standards for a summary of benefits and coverage 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 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

³⁸ 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 § 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 § 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.³⁹ Such search costs arise, in part, due to a lack of uniform information across the various coverage options, particularly in the individual market but also in some 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.⁴⁰

Given this difficulty in obtaining relevant information, 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 insurance works. Oftentimes, health insurance contracts and benefit descriptions are written in technical language that requires a sophisticated level of health insurance literacy 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

³⁹ 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>.

⁴⁰ Nicole Maestas *et al.*, “Price Variation in Markets with Homogenous Goods: The Case of Medigap,” National Bureau of Economic Research (January 2009).

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.

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 action. The Departments have limited the period covered by the RIA to 2011–2013. Estimates are not provided for subsequent years, because there will be significant changes in the marketplace in 2014 related to the offering of new individual and small group plans through the Affordable Insurance Exchanges, and the wide-ranging scope of these changes makes it difficult to project results for 2014 and beyond.

The direct benefits of these proposed 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 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 proposed regulations would also benefit consumers by reducing the time they spend searching for and compiling health plan and coverage information.

Under the proposed regulations, group health plans and health insurance issuers would incur costs to compile and provide the summary of benefits and coverage

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>.

disclosures (that includes coverage examples (CEs)) and a uniform glossary of health coverage and medical terms. The Departments estimate that the annualized cost may be around \$50 million, although there is uncertainty arising from general data limitations and the degree to which economies of scale exist for disclosing this information. The costs estimates employ assumptions that we believe fully capture expected issuer and third-party administrator (TPA) costs, and perhaps overestimate them if, for example, economies of scale are achievable.

The Departments anticipate that the provisions of these proposed regulations will help consumers 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 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)	\$51	2011	7	2011-2013
	\$47	2011	3	2011-2013

4. Benefits

In developing these proposed 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

proposed regulations. Nonetheless, the Departments were able to identify several benefits, which are discussed below.

These proposed regulations could generate significant economic and social welfare benefits to consumers. Under these proposed 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 proposed 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 proposed 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.⁴³ For

⁴³ 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).

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.⁴⁴ By ensuring consumers have access to readily available, concise, and understandable information about their coverage options, these proposed regulations could reduce consumers’ cost of obtaining information and may increase health insurance purchase rates.

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.⁴⁵ In particular, the use of coverage examples⁴⁶ called for by these proposed 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 disclosures under these proposed regulations would enable consumers to derive

⁴⁴ 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>.

⁴⁵ 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>.

⁴⁶ The NAIC recommends that the term “coverage examples” be used as reference to the statutory term “coverage facts labels,” and the Departments concur with this recommendation.

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

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

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 proposed 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 proposed 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 proposed regulations direct group health plans and health insurance issuers to compile and provide a summary of benefits and coverage (SBC) (that includes coverage examples (CEs)) 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. However, there is uncertainty arising from general data limitations and the degree to which economies of scale can be realized to reduce costs for issuers and TPAs. The costs estimates employ assumptions that we believe more than fully capture expected issuer and third-party administrator costs, and

perhaps overestimate them if, for example, economies of scale are achievable. On the basis of such assumptions, the Departments estimate that issuers and TPAs will incur approximately \$25 million in costs in 2011, \$73 million in costs in 2012, and \$58 million in costs in 2013. These costs and the methodology used to estimate them are discussed below, and presented in Tables 2-5 below.

General Assumptions

In order to assess the potential administrative costs relating to these proposed regulations, the Departments consulted with industry experts to gain insight into the tasks and level of resources required. Based on these discussions, the Departments estimate that there will be two categories of principal costs associated with the standards in these proposed regulations: one-time start-up costs and 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 proposed standards; to produce, review, distribute, and update the SBC disclosures;⁴⁹ 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

⁴⁹ Plans and issuers subject to ERISA or the Code may provide SBCs electronically only if the requirements of the Department of Labor's electronic disclosure safe harbor at 29 CFR 2520.104b-1 are met. Otherwise, by default, plans and issuers must use paper versions of SBCs.

coverage, the Departments assume fully-insured plans will rely on health insurance issuers, and self-insured plans will rely on TPAs, to perform these functions. While plans may prepare the SBC disclosures internally, the Departments 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.⁵⁰ Thus, the Departments use health insurance issuers and TPAs as the unit of analysis for the purposes of estimating administrative costs.

As discussed in the Medical Loss Ratio (MLR) interim final rule (75 FR 74918), the Departments estimate there are about 440 firms offering comprehensive coverage in the individual, small, or large group markets, and 75 million covered lives therein.⁵¹ 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.⁵² 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

⁵⁰ 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>.

⁵¹ 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.

⁵² 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).

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.⁵³ Based on conversations with one 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. These estimates may be adjusted proportionally in the final regulations based upon additional information about the number of TPAs serving self-insured plans.

Because the SBC disclosures are closely related to disclosures that issuers and TPAs provide today as a part of their normal operations (e.g., information on premiums, covered benefits, and cost sharing), the incremental costs of compiling and providing such readily available information in the proposed, standardized format is estimated to be modest.⁵⁴ The per-issuer or -TPA cost will largely be determined by its 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

⁵³ 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>.

⁵⁴ 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).

the number of markets in which it operates (that is, individual, small group, or 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 provides a synopsis of the 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 6 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. We welcome comments that provide better information or data about any of the following assumptions.

IT Systems and Workflow Process Changes

The Departments estimate 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. The Departments assume that these IT systems and workflow process changes would be implemented only by IT professionals. Furthermore, the Departments assume that a medium issuer/TPA would need about 75% of large issuer's/TPA's time, and a small issuer would need about 50% of a large issuer's/TPA's time, to implement IT systems and workflow process changes.

The Departments estimate 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. The Departments assume such teams would be comprised of IT professionals (45%), benefits/sales professionals (50%), and attorneys (5%). We 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).

The Departments assume that each issuer/TPA would incur a maintenance cost to maintain IT systems and address changes in regulatory requirements. The Departments assume the maintenance cost would equal 15% of the total one-time burden noted above (for example, the Departments assume it will take a large issuer 15% of 1120 hours, or 168 hours). The Departments further assume that the teams to implement the maintenance tasks would be comprised of IT professionals (55%), benefits/sales professionals (40%), and attorneys (5%).

The Departments assume that the one-time and maintenance costs to implement IT systems changes and to address these regulations would be split between the costs to produce SBCs (50%) and the costs to produce the CEs (50%).

Production and Review of SBCs and CEs

The Departments estimate that each issuer/TPA would need 3 hours to produce, and 1 hour to review, SBCs (not including CEs) for all products. The Departments assume that the 3 hours needed to produce the SBCs would be equally divided between IT professionals and benefits/sales professionals. The Departments assume that the 1 hour needed to review the SBCs would be equally divided between financial managers for benefits/sales professionals and attorneys.

In 2012 and 2013, issuers and TPAs would produce CEs for three benefits scenarios. The Departments estimate it will take each issuer/TPA 90 hours to produce, and 30 hours to review, CEs for all applicable products. The Departments assume that the 90 hours to produce the CEs would be equally divided between IT professionals and benefits/sales professionals. The Departments also assume that the 30 hours to review

the CEs would be equally divided between financial managers for benefits/sales professionals and attorneys.

The Departments assume that in 2012 and 2013, respectively, issuers and TPAs would provide, upon request, a paper copy of the uniform glossary to 2.5% and 5% of covered individuals who receive a glossary. The Departments 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.

For each individual who receives the SBC or uniform glossary 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 2011 dollars) for each staff category based on BLS data. The Departments use mean hourly wage estimates from the Bureau of Labor Statistics' (BLS) May 2009 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 15-1051), 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 2011 through 2013 and adjust the hourly wage rate to include a 33% fringe benefit estimate for private sector employees.⁵⁶

Distribution Assumptions

The Departments make the following assumptions regarding the distribution of the SBC disclosures (including CEs).⁵⁷ 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% of the number of enrollees at any point during the course of a year.⁵⁸
- In 2013, about 2% of covered individuals would receive a notice of modifications.⁵⁹ Further, the burden and cost of providing such notices would be

⁵⁶ See the Technical Appendix to the MLR interim final rule, available at <http://ccio.cms.gov>

⁵⁷ 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.

⁵⁸ Based on this assumption, the Departments estimated that small issuers or TPAs have about 180,000 shoppers in a given year, medium issuers or TPAs have 3,700,000 shoppers in a given year, and large issuers or TPAs have 11,000,000 shoppers in a given year.

⁵⁹ 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. As part of its analysis for the Department of Labor's SPD/SMM

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.

- Electronic distribution will 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 is based on the methodology used to analyze the cost burden for the DOL claims procedure regulation (OMB Control Number 1210–0053).⁶⁰ The estimate for the individual market is based on statistics set forth by the National Telecommunications and Information Administration, which indicate that 30% of Americans do not use the Internet.⁶¹
- SBC disclosures would be distributed with usual marketing and enrollment materials, thus, costs to mail the documents will be negligible. However, notices of modifications would require mailing and supply costs as follows: \$0.44 postage cost per mailing and \$0.05 supply cost per mailing.
- Printing costs \$0.03 cents per side of a page. Thus, 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 cents to print the uniform glossary (which is

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 modification 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, expects that only two percent of plans will need to issue an updated SBC mid-year, because mid-year changes that would result in an update to the SBC are very rare. For purposes of simplification, the Departments extend this assumption to the individual market as well.

⁶⁰ See the ERISA e-disclosure rule at 29 CFR 2520.104b-1.

⁶¹ 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.

four sides of a page, based on the length of the NAIC recommended uniform glossary). This cost burden is in addition to the 1 minute or 2 minutes it would take clerical staff to print and distribute the SBC or glossary.

Cost Estimate

The Tables below present costs and burden hours for issuers and TPAs associated the proposed disclosure requirements of PHS Act section 2715. Tables 3-5 contain cost estimates for 2011, 2012, and 2013, derived from the labor hours presented in Table 3 and the hourly rate estimates presented in Table 7, 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. 2011 Hour Burden, Equivalent Cost, and Cost Burden - 2011 Dollars

	Number of Affected Entities	Hour Burden	Equivalent Cost
SBC Requirements – Issuers – One Time	440	88,000	\$4,600,000
SBC Requirements – TPAs – One-Time	750	150,000	\$7,800,000
Coverage Example Requirements – Issuers – One Time	440	88,000	\$4,600,000
Coverage Example Requirements – TPAs – One-Time	750	150,000	\$7,800,000
Total		240,000	\$25,000,000

TABLE 4. 2012 Hour Burden, Equivalent Cost, and Cost Burden - 2011 Dollars

	Number of Affected Entities	Hour Burden	Equivalent Cost	Cost Burden (non-labor)	Number of Disclosures
SBC Requirements - Issuers	440	540,000	\$18,000,000	\$2,900,000	41,000,000
SBC Requirements - TPAs	750	660,000	\$23,000,000	\$3,700,000	49,000,000
Coverage Example Requirements - Issuers	440	140,000	\$7,600,000	\$1,500,000	41,000,000
Coverage Example Requirements - TPAs	750	240,000	\$13,000,000	\$1,800,000	49,000,000
Glossary Requests - Issuers	440	11,000	\$330,000	\$370,000	610,000
Glossary Requests - TPAs	750	13,000	\$370,000	\$470,000	770,000
Subtotal		1,600,000	\$62,000,000	\$11,000,000	91,000,000
Total 2012 Costs			\$73,000,000		

TABLE 5. 2013 Hour Burden, Equivalent Cost, and Cost Burden - 2011 Dollars

	Number of Affected Entities	Hour Burden	Equivalent Cost	Cost Burden (non-labor)	Number of Disclosures
SBC Requirements - Issuers	440	480,000	\$15,000,000	\$2,900,000	41,000,000
SBC Requirements - TPAs	750	560,000	\$17,000,000	\$3,700,000	49,000,000
Coverage Example Requirements – Issuers	440	79,000	\$4,300,000	\$1,500,000	41,000,000
Coverage Example Requirements – TPAs	750	130,000	\$7,200,000	\$1,800,000	49,000,000
Notice of Material Modifications – Issuers	440	10,000	\$320,000	\$330,000	820,000
Notice of Material Modifications - TPAs	750	12,000	\$400,000	\$400,000	1,000,000
Glossary Requests –	440	23,000	\$660,000	\$700,000	1,200,000

Issuers					
Glossary Requests - TPAs	750	26,000	\$750,000	\$900,000	1,500,000
Subtotal		1,300,000	\$46,000,000	\$12,000,000	95,000,000
Total 2013 Costs			\$58,000,000		

TABLE 6. 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%	36	54	72
Benefits / Sales Professionals	50%	40	60	80
Attorneys	5%	4	6	8
Implementing Systems Changes (IT and workflow)				
IT Professionals	100%	480	720	960
Maintenance				
Updating to Address Changes in Requirements				
IT Professionals	55%	46.20	69.30	92.40
Benefits / Sales Professionals	40%	33.60	50.40	67.20
Attorneys	5%	4.20	6.30	8.40
<i>SBC Requirement (maintenance)</i>				
Producing SBCs				
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

STAFFING HOUR ASSUMPTIONS	Percent of Hours by Task	Hours		
		Small Issuer/ TPA	Medium Issuer/ TPA	Large Issuer/ TPA
Financial Managers – Benefits / Sales Professionals	50%	0.5	0.5	0.5
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	0.02
CE Requirement (maintenance)				
Producing 3 CEs		90	90	90
IT Professionals	50%	45	45	45
Benefits / Sales Professionals	50%	45	45	45
Internal Review of 3 CEs		30	30	30
Financial Managers – Benefits / Sales Professionals	50%	15	15	15
Attorneys	50%	15	15	15

TABLE 7. Estimated Loaded Hourly Wages for Staff Categories

Staff Category	BLS Code	Loaded Hourly Wage (2011 Dollars)
IT Professionals	Computer Systems Analysts (Occupation Code 15-1051)	\$53.26
Financial Professionals - Benefits / Sales	Insurance Underwriters (Occupation Code 13-2053)	\$41.94

TABLE 7. Estimated Loaded Hourly Wages for Staff Categories

Financial Manager	Financial Managers (Occupation Code 11-3031)	\$75.32
Attorneys	Lawyers (Occupation Code 23-1011)	\$85.44
Clerical Staff	Executive Secretaries and Administrative Assistants (Occupation Code 43-6011)	\$29.15

6. Regulatory Alternatives

Several provisions in these proposed regulations involved policy choices. A first policy choice involved determining how to minimize the burden of providing the SBC to individuals and employers 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, the proposed regulations provide that issuers offering health insurance coverage in connection with the individual market that make information for their standard policies available on the Secretary of HHS’s Web portal (HealthCare.gov), in compliance with 45 CFR 159.120, will have satisfied the requirement to provide an SBC to individuals who request information about coverage. The Departments believe this approach promotes regulatory efficiency, minimizing the administrative burden on health insurance issuers without lessening the protections under PHS Act section 2715.

A second 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 the proposed regulations, the Departments allow a plan or issuer to provide a single SBC in circumstances in which a participant and any beneficiaries (or, in the individual market, the primary subscriber and any covered dependents) are known to reside at the same address.

In the group market, the proposed 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.

A third policy choice related to the interpretation of the PHS Act section 2715(d)(4), which requires notice of any material modification (as defined for purposes of section 102 of ERISA) 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 proposed regulations would interpret this provision as requiring notice only for a material modification that (1) affects the information in the SBC; and (2) 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 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 proposed 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 we prepared for the proposed 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 \$15,000, \$26,000, and \$15,000 per issuer/TPA in 2011, 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 proposed 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 proposed rules 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 notice of proposed rulemaking 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 proposed regulations. It is hereby certified that the collections of information contained in this notice of proposed rulemaking 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 proposed regulations would require 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 proposed 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, this regulation has been 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 proposed 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 proposed regulations include no mandates on State, local, or Tribal governments. These proposed 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 tentatively conclude that these costs will not exceed the \$136 million threshold. Thus, we tentatively conclude that these proposed 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 proposed 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.” Plans and issuers are required to begin providing the disclosure (herein referred to as a “summary of benefits and coverage” or SBC) no later than March 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.

In developing these collections of information, the Departments have incorporated the documents recommended by the NAIC, including the SBC template (with instructions, samples and a guide for coverage examples calculations to be used in completing the template) and the uniform glossary. These collection instruments were

developed over a period of several months and agreed to by the entire NAIC working group and recommended to the Departments by the NAIC.

Currently, the Departments are soliciting public comments for 60 days concerning these disclosures. The Departments have submitted a copy of these interim final regulations to OMB in accordance with 44 U.S.C. 3507(d) for review of the information collections. The Departments and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, for example, by permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Attention: Desk Officer for the Employee Benefits Security Administration either by fax to (202) 395-5806 or by e-mail to oir_submission@omb.eop.gov. 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:

ebsa.opr@dol.gov. ICRs submitted to OMB also are available at [reginfo.gov](http://www.reginfo.gov) (<http://www.reginfo.gov/public/do/PRAMain>).

The Departments estimate 858 respondents each year from 2011-2013. 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).⁶²

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.⁶³ 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.

2011 Burden Estimate

While the disclosures in these proposed regulations are not required until March 2012, the Departments estimate a one-time administrative cost of about \$36,000,000

⁶² 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% of the TPAs (638). While the group health plans could prepare their own SBCs including coverage examples, the Departments assume that SBCs including coverage examples would be prepared by service providers, *i.e.*, issuers and TPAs.

⁶³ 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

across the industry and a total of about 680,000 burden hours to prepare for the provisions of these proposed 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 97,000 burden hours and an equivalent cost of about \$4,800,000. The Departments calculate these estimates as follows:⁶⁴

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	\$53.26	36	\$1,900	54	\$2,900	72	\$3,800
Benefits/Sales Professionals	\$41.94	40	\$1,700	60	\$2,500	80	\$3,400
Attorneys	\$85.44	4	\$340	6	\$510	8	\$680
Total per issuer/TPA		80	\$3,900	120	\$5,900	160	\$7,900
Total for all issuers/TPAs		22,000	\$1,100,000	53,000	\$2,600,000	22,000	\$1,100,000

With respect to task (2), the Departments estimate about 580,000 burden hours and an equivalent cost of about \$31,000,000. The Departments calculate 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	Hours	Equivalent

⁶⁴ For the purposes of these and other estimates in this section III.E, the Departments again use the assumptions outlined above in section III.A.5.

					Cost		Cost
IT Professionals	\$53.26	480	\$26,000	720	\$38,000	960	\$51,000
Total per issuer/TPA		480	\$26,000	720	\$38,000	960	\$51,000
Total for all issuers/TPAs		130,000	\$7,100,000	320,000	\$17,000,000	130,000	\$7,000,000

The Departments assume the total one-time administrative burden will be divided equally between 2011 and 2012. Thus, in 2011, the Departments estimate a one-time administrative cost of about \$18,000,000 across the industry and about 340,000 hours. The Departments assume issuers and TPAs will incur no other costs in 2011 related to the proposed collection of information.

2012 Burden Estimate

The estimate 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 SBC responses.
- The Departments assume that of the total number of SBC responses, 38 % would be sent electronically in the small and large group markets. Accordingly, the Departments estimate that about 29,000,000 SBCs would be electronically distributed, and about 48,000,000 SBCs would be distributed in paper form. The Departments assume there are no costs associated with electronic disclosures; there are costs only with regard to paper disclosures.

Summary of Benefits and Coverage (not including coverage examples) – The

estimated hour burden is about 820,000 hours, and the estimated total cost is about \$30,000,000. The Departments calculate these estimates as follows:

Task 1: Equivalent Costs for Producing SBCs

	Hourly Wage Rate	Small Issuer/TPA		Medium Issuer/TPA		Large Issuer/TPA	
		Hours	Equivalent Cost	Hours	Equivalent Cost	Hours	Equivalent Cost
IT Professionals	\$53.26	1.5	\$80	1.5	\$80	1.5	\$80
Benefits/Sales Professionals	\$41.94	1.5	\$63	1.5	\$63	1.5	\$63
Financial Managers	\$75.32	0.5	\$38	0.5	\$38	0.5	\$38
Attorneys	\$85.44	0.5	\$43	0.5	\$43	0.5	\$43
Total per issuer/TPA		4	\$220	4	\$220	4	\$220
Total for all issuers/TPAs		1100	\$61,000	1800	\$100,000	550	\$31,000

Task 2: Equivalent Costs for Distributing SBCs

	Hourly Wage Rate	Hours per SBC	Total Number of SBCs	Total Hours	Total Equivalent Cost
Clerical Staff	\$29.15	0.017	48,000,000	820,000	\$24,000,000

Task 1: Cost Burden for Printing SBCs

	Cost per SBC	Total SBCs	Total Cost Burden
Printing Costs	\$0.12	48,000,000	\$5,800,000

Task 2: Coverage Examples – The estimated hour burden is about 100,000 hours, and the estimated total cost is about \$8,700,000. The Departments calculate these estimates as follows:

Task 2: 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	\$53.26	45	\$2,400	45	\$2,400	45	\$2,400
Benefits/Sales Professionals	\$41.94	45	\$1,900	45	\$1,900	45	\$1,900

Financial Managers	\$75.32	15	\$1,100	15	\$1,100	15	\$1,100
Attorneys	\$85.44	15	\$1,300	15	\$1,300	15	\$1,300
Total per issuer/TPA		120	\$6,700	120	\$6,700	120	\$6,700
Total for all issuers/TPAs		33,000	\$1,900,000	53,000	\$3,000,000	16,000	\$900,000

Task 2: Cost Burden for Printing Coverage Examples

	Printing Cost Per CE	Total CEs Printed	Total Cost Burden
Printing Costs	\$0.06	48,000,000	\$2,900,000

Task 3: Glossary Requests –The Departments assume that in 2012, issuers and TPAs will begin responding to glossary requests to covered individuals, and that 2.5% of covered individuals, who receive paper SBCs, will request glossaries. The Departments further estimate that the burden and cost of providing the notices to be 2.5% of the burden and cost of distributing paper SBCs, plus an additional cost burden of \$0.49 for each glossary (including \$0.44 for first-class postage and \$0.05 for supply costs). Accordingly, in 2012, the Departments estimate a total cost of about \$1,300,000 and 21,000 burden hours associated with about 1,200,000 glossary requests.

Task 4: One-Time Administrative Costs – As mentioned above, the Departments estimate a one-time administrative cost of about \$36,000,000 across the industry and a total of about 680,000 burden hours, and assume this burden will be equally divided between 2011 and 2012. Thus, in 2012, the Departments estimate a one-time administrative cost of about \$18,000,000 across the industry and about 340,000 burden hours.

The total 2012 burden estimate is about \$58,000,000. The total number of burden hours is about 1,300,000.

2013 Burden Estimate

Task 1: Summary of Benefits and Coverage (not including coverage examples) – The number of SBC responses is assumed to remain constant. Thus, in 2013, the Departments again estimate a total cost of about \$30,000,000 and about 820,000 burden hours for SBCs (not including coverage examples).

Task 2: Coverage Examples – The Departments again estimate a total cost of about \$8,700,000 and 100,000 burden hours for 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 2% of covered individuals would receive such notice. The Departments further estimate that the burden and cost of providing the notices to be 2% of the combined burden and cost of the SBCs including the coverage examples, plus an additional cost burden for \$0.49 for each paper notice (including \$0.44 for first-class postage and \$0.05 for supply costs). Accordingly, in 2013, the Departments estimate a total cost of about \$1,400,000 and 18,000 burden hours associated with 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 to covered individuals, and that 5% of covered individuals, who receive paper SBCs, will request glossaries. The Departments further estimate that the burden and cost of providing the glossaries to be 5% of the burden and cost of distributing paper SBCs, plus an additional cost burden for \$0.49 for each glossary (including \$0.44 for first-class postage and \$0.05 for supply costs).

Accordingly, in 2013, the Departments estimate a total cost of about \$2,700,000 and 41,000 burden hours associated with 2,400,000 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% of the one-time administrative burden. Accordingly, the estimated hour burden is about 100,000 hours, and the estimated total cost is about \$5,400,000. 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	\$53.26	46.2	\$2,500	69.3	\$3,700	92.4	\$4,900
Benefits / Sales Professionals	\$41.94	33.6	\$1,800	50.4	\$2,700	67.2	\$3,600
Attorneys	\$85.44	4.2	\$220	6.3	\$340	8.4	\$450
Total per issuer/TPA		84	\$4,500	126	\$6,700	168	\$8,900
Total for all issuers/TPAs		23,000	\$1,200,000	56,000	\$3,000,000	23,000	\$1,200,000

The total 2013 cost estimate is about \$48,000,000. The total number of burden hours is about 1,100,000 hours.

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: XXXX–XXX; XXXX–XXXX.

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

Total Respondents: 858.

Total Responses: 80,000,000.

Frequency of Response: On-going.

Estimated Total Annual Burden Hours: 600,000 hours (Employee Benefits Security Administration); 600,000 hours (Internal Revenue Service).

Estimated Total Annual Burden Cost: \$5,100,000 (Employee Benefits Security Administration); \$5,100,000 (Internal Revenue Service).

2. Department of Health and Human Services

The Department estimates 333 respondents each year from 2011-2013. 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.⁶⁵

To account for variation in firm size, the Department estimates a weighted burden on the basis of issuer's 2009 total earned premiums for comprehensive major medical

⁶⁵ 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 including Coverage Examples, the Department assumes that SBCs including coverage examples would be prepared by service providers, *i.e.*, issuers and TPAs.

coverage.⁶⁶ 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.

2011 Burden Estimate

While the disclosures in these proposed regulations are not required until March 2012, the Department estimates a one-time administrative cost of about \$14,000,000 across the industry and 270,000 burden hours to prepare for the provisions of these proposed 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 38,000 burden hours, and an equivalent cost of about \$1,900,000. The Department calculates these estimates as follows:⁶⁷

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	\$53.26	36	\$1,900	54	\$2,900	72	\$3,800

⁶⁶ 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

⁶⁷ For the purposes of these and other estimates in this section III.E, the Departments again use the assumptions outlined above in section III.A.5.

Benefits/Sales Professionals	\$41.94	40	\$1,700	60	\$2,500	80	\$3,400
Attorneys	\$85.44	4	\$340	6	\$510	8	\$680
Total per issuer/TPA		80	\$3,900	120	\$5,900	160	\$7,900
Total for all issuers/TPAs		8,500	\$420,000	21,000	\$1,000,000	8,500	\$450,000

With respect to task (2), the Department estimates 230,000 burden hours, and an equivalent cost of out \$12,000,000. 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	\$53.26	480	\$26,000	720	\$38,000	960	\$51,000
Total per issuer/TPA		480	\$26,000	720	\$38,000	960	\$51,000
Total for all issuers/TPAs		51,000	\$2,700,000	125,000	\$6,700,000	51,000	\$ 2,700,000

The Department assumes the total one-time administrative burden will be divided equally between 2011 and 2012. Thus, in 2011, the Department estimates a one-time administrative cost of about \$7,000,000 across the industry and 135,000 burden hours. The Department assumes issuers and TPAs will incur no other costs in 2011 related to the proposed collection of information.

2012 Burden Estimate

The hour and cost burden for the collections of information are as follows:

- The Department estimates that there will be about 13,000,000 SBC responses in 2012.
- The Department assumes that 38 percent of the SBCs would be sent electronically in the group market, and 70 percent of the SBCs would be sent electronically in the individual market. Accordingly, the Department estimates that about 5,900,000 SBCs would be electronically distributed, and about 7,400,000 SBCs would be distributed in paper form. The Department assumes there are no costs associated with electronic disclosures, and there are costs only with regard to paper disclosures.

Task 1: Summary of benefits and coverage (not including coverage examples)

– The estimated hour burden is about 170,000 hours, and the estimated total cost is about \$5,900,000. The Department calculates these estimates as follows:

Task 1: Equivalent Costs for Producing SBCs

	Hourly Wage Rate	Small Issuer/TPA		Medium Issuer/TPA		Large Issuer/TPA	
		Hours	Equivalent Cost	Hours	Equivalent Cost	Hours	Equivalent Cost
IT Professionals	\$53.26	1.5	\$80	1.5	\$80	1.5	\$80
Benefits/Sales Professionals	\$41.94	1.5	\$63	1.5	\$63	1.5	\$63
Financial Managers	\$75.32	0.5	\$38	0.5	\$38	0.5	\$38
Attorneys	\$85.44	0.5	\$43	0.5	\$43	0.5	\$43
Total per issuer/TPA		4	\$220	4	\$220	4	\$220
Total for all issuers/TPAs		420	\$24,000	700	\$39,000	200	\$12,000

Task 1: Equivalent Costs for Distributing SBCs

	Hourly Wage Rate	Hours per SBC	Total Number of SBCs	Total Hours	Total Equivalent Cost
Clerical Staff, Individual Market	\$29.15	0.033	2,700,000	89,000	\$2,600,000

Clerical, Group Market	\$29.15	0.017	4,700,000	80,000	\$2,300,000
Total			7,400,000	170,000	\$4,900,000

Task 1: Cost Burden for Printing SBCs

	Cost per SBC	Total SBCs	Cost Burden
Printing Costs	\$0.12	7,400,000	\$890,000

Task 2: Coverage Examples – The estimated hour burden is about 40,000 hours, and the estimated total cost is about \$2,700,000. The Department calculates these estimates as follows:

Task 2: 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	\$53.26	45	\$2,400	45	\$2,400	45	\$2,400
Benefits/Sales Professionals	\$41.94	45	\$1,900	45	\$1,900	45	\$1,900
Financial Managers	\$75.32	15	\$1,100	15	\$1,100	15	\$1,100
Attorneys	\$85.44	15	\$1,300	15	\$1,300	15	\$1,300
Total per issuer/TPA		120	\$6,700	120	\$6,700	120	\$6,700
Total for all issuers/TPAs		13,000	\$710,000	21,000	\$1,200,000	6,400	\$350,000

Task 2: Cost Burden for Printing Coverage Examples

	Printing Cost Per CE	Total CEs Printed	Total Cost Burden
Printing Costs	\$0.06	7,400,000	\$440,000

Task 3: Glossary Requests – The Department assumes that in 2012, issuers and TPAs will begin responding to glossary requests to covered individuals, and that 2.5% of

covered individuals, who receive paper SBCs, will request glossaries. The Departments further estimate that the burden and cost of providing the glossaries to be 2.5% of the burden and cost of distributing paper SBCs, plus an additional cost burden of \$0.49 for each glossary (including \$0.44 for first-class postage and \$0.05 for supply costs). Accordingly, in 2012, the Department estimates a total cost of about \$240,000 and 4,300 burden hours associated with about 190,000 glossary requests.

Task 4: One-Time Administrative Costs: As mentioned above, the Department estimates a one-time administrative cost of about \$14,000,000 across the industry and a total of 270,000 burden hours, and assumes this burden will be equally divided between 2011 and 2012. Thus, in 2012, the Department estimates a one-time administrative cost of about \$7,000,000 across the industry and 135,000 burden hours.

The total 2012 burden estimate is about \$16,000,000. The total number of burden hours is 350,000.

2013 Burden Estimate

Task 1: Summary of benefits and coverage (not including coverage examples)
– The number of SBC responses is assumed to remain constant. Thus, in 2013, the Department again estimates a total cost of about \$5,900,000 and 170,000 burden hours for SBCs (not including coverage examples).

Task 2: Coverage Examples – In 2013, the Department again estimates a total cost of about \$2,700,000 and 40,320 burden hours for 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 2% of covered individuals will receive such notice. The Department further estimates that the

burden and cost of providing the notices to be 2% of the combined burden and cost of the SBCs including the coverage examples, plus an additional cost burden for \$0.49 for each paper notice (including \$0.44 for first-class postage and \$0.05 for supply costs).

Accordingly, in 2013, the Department estimate a total cost of about \$300,000 and 4,200 burden hours 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 to covered individuals, and that 5% of covered individuals, who receive paper SBCs, will request glossaries. The Department further estimates that the burden and cost of providing the glossaries to be 5% of the burden and cost of distributing paper SBCs, plus an additional cost burden of \$0.49 for each glossary (including \$0.44 for first-class postage and \$0.05 for supply costs).

Accordingly, in 2013, the Department estimates a total cost of \$470,000 and 8,500 burden hours associated with 370,000 glossary requests.

Task 5: Maintenance Administrative Costs – In 2013, the Department assume that issuers and TPAs will need to make updates to address changes in standards, and, thus, incur 15% of the one-time administrative burden. Accordingly, the estimated hour burden is about 40,000 hours, and the estimated total cost is about \$2,000,000. 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	\$53.26	46.2	\$2,500	69.3	\$3,700	92.4	\$4,900
Benefits / Sales Professionals	\$41.94	33.6	\$1,800	50.4	\$2,700	67.2	\$3,600
Attorneys	\$85.44	4.2	\$220	6.3	\$340	8.4	\$450
Total per issuer/TPA		84	\$4,500	126	\$6,700	168	\$8,900

Total for all issuers/TPAs		8,900	\$470,000	22,000	\$1,100,000	8,900	\$470,000
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The total 2013 cost estimate is about \$11,000,000. The total number of burden hours is about 260,000 hours.

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.

Agency: Department of Health and Human Services.

Title: Affordable Care Act Uniform Explanation of Coverage Documents

OMB Number: 0938-New.

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: 310,000 hours.

Estimated Total Annual Burden Cost: \$1,600,000.

To obtain copies of the supporting statement and any related forms for the proposed 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.

If you comment on this information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS-9982-P

Fax: 202-395-5806; or

E-mail: OIRA_submission@omb.eop.gov

E. 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed rule in a meaningful and timely manner.

IV. Statutory Authority

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

The Department of Labor proposed regulations are proposed to be 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 proposed regulations are proposed to be 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.

Sarah Hall Ingram
Acting Deputy Commissioner for Services and
Enforcement,
Internal Revenue Service.

Signed this _____ 15th _____ day of _____ August _____, 2011.

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

CMS-9982-P

Dated: July 28, 2011

Donald Berwick,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: August 9, 2011

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

CMS-9982-P

BILLING CODE 4120-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR Parts 54 and 602 are proposed to be amended 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) By a group health insurance issuer to a group health plan – (A) A health insurance issuer offering group health insurance coverage must provide the SBC to a group health plan (or its sponsor) upon application or request for information about the health coverage as soon as practicable following the request, but in no event later than seven days following the request. If an SBC is provided upon request for information about health coverage and the plan (or its sponsor) subsequently applies for health

coverage, a second SBC must be provided under this paragraph (a)(1)(i)(A) only if the information required to be in the SBC has changed.

(B) If there is any change in the information required to be in the SBC before the coverage is offered, or 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 date of the offer (or no later than the first day of coverage, as applicable).

(C) 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 when the policy, certificate, or contract is renewed or reissued.

(1) In the case of renewal or reissuance, if written application is required for renewal (in either paper or electronic form), the SBC must be provided no later than the date the 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.

(D) If a group health plan (or its sponsor) requests an SBC from a health insurance issuer offering group health insurance coverage, it must be provided as soon as practicable, but in no event later than seven days following the request for an SBC.

(ii) By a group health insurance issuer and a group health plan to participants and beneficiaries – (A) 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 the rules of 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) 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.

(C) If there is any change to the information required to be in the SBC 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) The plan or issuer must provide the SBC to special enrollees (as described in § 54.9801-6) within seven days of a request for enrollment pursuant to a special enrollment right.

(E) 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.

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

(2) If renewal is automatic, the SBC must be provided no later than 30 days prior to the first day of coverage under the new plan year.

(F) A plan or issuer must provide the SBC to participants or beneficiaries upon request, as soon as practicable, but in no event later than seven days following the request.

(iii) Special rules to prevent unnecessary duplication with respect to group health coverage – (A) An entity required to provide an SBC under paragraph (a)(1) of this section 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 participant and any beneficiaries are known to reside at the same address, and a single SBC is provided to that address, the requirement to provide the SBC is satisfied with respect to all individuals residing at that address. 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 with respect to benefit packages in which the participant or beneficiary are 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 in accordance with the rules of paragraph (a)(1)(ii) of this section, which

requires the SBC to be provided as soon as practicable, but in no event later than seven days following the request.

(2) Content – (i) In general. 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;

(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 the rules of 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, or certificate 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;

(L) An Internet address for obtaining the uniform glossary, as described in paragraph (c) of this section; and

(M) Premiums (or in the case of a self-insured group health plan, cost of coverage).

(ii) Coverage examples. The SBC must include coverage examples that illustrate benefits provided under the plan or coverage for common benefits scenarios (including pregnancy and serious or chronic medical conditions) that are identified by the Secretary in accordance with the following:

(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 section, 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 available through the National Guideline Clearinghouse, Agency for Healthcare Research and Quality. The Secretary will specify, in guidance, the types of

services, dates of service, applicable billing codes, and allowed charges for each claim in the benefits scenario.

(C) Demonstration of benefit provided. To demonstrate benefits provided under the plan or coverage, a plan or issuer simulates how claims would be processed under the scenarios provided by the Secretary to generate an estimate of cost sharing a consumer could expect to pay under the benefit package. The demonstration of benefits will take into account any cost sharing, excluded benefits, and other limitations on coverage, as described by the Secretary in guidance.

(3) Appearance. A group health plan and a health insurance issuer must provide an SBC as a stand-alone document in the form authorized by the Secretary and completed in accordance with the instructions for completing the SBC that are authorized 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 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 plan or issuer to a participant or beneficiary may be provided in paper form. Alternatively, the SBC may be provided electronically if the requirements of 29 CFR 2520.104b-1 are met.

(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 modifications. 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 such modification will become effective. The notice of modification must be provided in a form that is consistent with the rules of 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 format requirements of paragraphs (c)(3) and (c)(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, for 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 authorized in guidance, ensuring that the uniform glossary is presented in a uniform format and utilizes 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 days of the request. (Under the rules of paragraph (a) of this section, the form authorized in guidance for the SBC will disclose to participants and beneficiaries their rights to request a copy of the uniform glossary.)

(d) Preemption. With respect to the standards for providing an SBC required under paragraph (a) of this section, 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) Applicability date. This section is applicable beginning March 23, 2012. See § 54.9815-1251T(d), providing that this section applies to grandfathered health plans.

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.

* * * * *

54.9815-27151545-

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DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR Part 2590 is proposed to be amended 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) By a group health insurance issuer to a group health plan – (A) A health insurance issuer offering group health insurance coverage must provide the SBC to a group health plan (or its sponsor) upon application or request for information about the

health coverage as soon as practicable following the request, but in no event later than seven days following the request. If an SBC is provided upon request for information about health coverage and the plan (or its sponsor) subsequently applies for health coverage, a second SBC must be provided under this paragraph (a)(1)(i)(A) only if the information required to be in the SBC has changed.

(B) If there is any change in the information required to be in the SBC before the coverage is offered, or 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 date of the offer (or no later than the first day of coverage, as applicable).

(C) 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 when the policy, certificate, or contract is renewed or reissued.

(1) In the case of renewal or reissuance, if written application is required for renewal (in either paper or electronic form), the SBC must be provided no later than the date the 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.

(D) If a group health plan (or its sponsor) requests an SBC from a health insurance issuer offering group health insurance coverage, it must be provided as soon as practicable, but in no event later than seven days following the request for an SBC.

(ii) By a group health insurance issuer and a group health plan to participants and beneficiaries – (A) 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 the rules of 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) 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.

(C) If there is any change to the information required to be in the SBC 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) The plan or issuer must provide the SBC to special enrollees (as described in § 2590.701-6 of this Part) within seven days of a request for enrollment pursuant to a special enrollment right.

(E) 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.

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

(2) If renewal is automatic, the SBC must be provided no later than 30 days prior to the first day of coverage under the new plan year.

(F) A plan or issuer must provide the SBC to participants or beneficiaries upon request, as soon as practicable, but in no event later than seven days following the request.

(iii) Special rules to prevent unnecessary duplication with respect to group health coverage – (A) An entity required to provide an SBC under paragraph (a)(1) of this section 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 participant and any beneficiaries are known to reside at the same address, and a single SBC is provided to that address, the requirement to provide the SBC is satisfied with respect to all individuals residing at that address. 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 with respect to benefit packages in which the participant or beneficiary are 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 in accordance with the rules of paragraph (a)(1)(ii) of this section, which requires the SBC to be provided as soon as practicable, but in no event later than seven days following the request.

(2) Content – (i) In general. 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;

(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 the rules of 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, or certificate 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;

(L) An Internet address for obtaining the uniform glossary, as described in paragraph (c) of this section; and

(M) Premiums (or in the case of a self-insured group health plan, cost of coverage).

(ii) Coverage examples. The SBC must include coverage examples that illustrate benefits provided under the plan or coverage for common benefits scenarios (including pregnancy and serious or chronic medical conditions) that are identified by the Secretary in accordance with the following:

(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 section, 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 available through the National Guideline Clearinghouse, Agency for Healthcare Research and Quality. The Secretary will specify, in guidance, the types of services, dates of service, applicable billing codes, and allowed charges for each claim in the benefits scenario.

(C) Demonstration of benefit provided. To demonstrate benefits provided under the plan or coverage, a plan or issuer simulates how claims would be processed under the scenarios provided by the Secretary to generate an estimate of cost sharing a consumer could expect to pay under the benefit package. The demonstration of benefits will take into account any cost sharing, excluded benefits, and other limitations on coverage, as described by the Secretary in guidance.

(3) Appearance. A group health plan and a health insurance issuer must provide an SBC as a stand-alone document in the form authorized by the Secretary and completed in accordance with the instructions for completing the SBC that are authorized 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 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 plan or issuer to a participant or beneficiary may be provided in paper form. Alternatively, the SBC may be provided electronically if the requirements of 29 CFR 2520.104b-1 are met.

(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 modifications. 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 such modification will become effective. The notice of modification must be provided in a form that is consistent with the rules of 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 format requirements of paragraphs (c)(3) and (c)(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, for 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 authorized in guidance, ensuring that the uniform glossary is presented in a uniform format and utilizes 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 days of the request. (Under the rules of paragraph (a) of this section, the form authorized in guidance for the SBC will disclose to participants and beneficiaries their rights to request a copy of the uniform glossary.)

(d) Preemption. See § 2590.731 of this Part. In addition, with respect to the standards for providing an SBC required under paragraph (a) of this section, 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. This section is applicable beginning March 23, 2012. See § 2590.715-1251(d) of this Part, providing that this section applies to grandfathered health plans.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subtitle A

The Department of Health and Human Services proposes to amend 45 CFR part 147 as follows:

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

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

Authority: Sections 2710 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.

2. 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) By a group health insurance issuer to a group health plan – (A) A health insurance issuer offering group health insurance coverage must provide the SBC to a group health plan (or its sponsor) upon application or request for information about the health coverage as soon as practicable following the request, but in no event later than seven days following the request. If an SBC is provided upon request for information about health coverage and the plan (or its sponsor) subsequently applies for health

coverage, a second SBC must be provided under this paragraph (a)(1)(i)(A) only if the information required to be in the SBC has changed.

(B) If there is any change in the information required to be in the SBC before the coverage is offered, or 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 date of the offer (or no later than the first day of coverage, as applicable).

(C) 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 when the policy, certificate, or contract is renewed or reissued.

(1) In the case of renewal or reissuance, if written application is required for renewal (in either paper or electronic form), the SBC must be provided no later than the date the 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.

(D) If a group health plan (or its sponsor) requests an SBC from a health insurance issuer offering group health insurance coverage, it must be provided as soon as practicable, but in no event later than seven days following the request for an SBC.

(ii) By a group health insurance issuer and a group health plan to participants and beneficiaries – (A) 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 the rules of 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) 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.

(C) If there is any change to the information required to be in the SBC 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) The plan or issuer must provide the SBC to special enrollees (as described in 45 CFR 146.117) within seven days of a request for enrollment pursuant to a special enrollment right.

(E) 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.

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

(2) If renewal is automatic, the SBC must be provided no later than 30 days prior to the first day of coverage under the new plan year.

(F) A plan or issuer must provide the SBC to participants or beneficiaries upon request, as soon as practicable, but in no event later than seven days following the request.

(iii) Special rules to prevent unnecessary duplication with respect to group health coverage – (A) An entity required to provide an SBC under paragraph (a)(1) of this section 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 participant and any beneficiaries are known to reside at the same address, and a single SBC is provided to that address, the requirement to provide the SBC is satisfied with respect to all individuals residing at that address. 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 with respect to benefit packages in which the participant or beneficiary are 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 in accordance with the rules of paragraph (a)(1)(ii) of this section, which

requires the SBC to be provided as soon as practicable, but in no event later than seven days following the request.

(iv) By a health insurance issuer offering individual health insurance coverage --
(A) Individuals prior to coverage. A health insurance issuer offering individual health insurance coverage must provide an SBC to an individual upon receiving an application for, or a request for information about, any health insurance policy, as soon as practicable following the application or request, but in no event later than seven days following the application or request.

(1) If an SBC is provided upon request for information about a particular health insurance policy and the individual subsequently submits an application for the same policy, a second SBC must be provided under this paragraph (a)(1)(iv)(A) only if the information required to be in the SBC has changed.

(2) If the issuer modifies the terms of coverage after receiving an application for any health insurance policy (including modifications as a result of medical underwriting) so that the information required to be in the SBC has changed, the issuer must provide an updated SBC that reflects these changes to the terms of coverage to the applicant, for each policy for which an application was received, as soon as practicable, but in no event later than the date on which the offer of coverage is made.

(B) Individuals covered under individual health insurance coverage -- (1) A health insurance issuer offering individual health insurance coverage must generally provide an SBC to an individual who accepts an offer of coverage no later than the first day of coverage. However, if the SBC is provided upon request for information about health insurance coverage or at the time that an offer of coverage is made under paragraph

(a)(1)(iv)(A) of this section, the SBC must be provided under this paragraph (a)(1)(iv)(B) only if the information required to be in the SBC has changed.

(2) The issuer must provide the SBC to policyholders annually at renewal, no later than 30 days prior to the first day of coverage under the new policy year. The SBC must reflect any modified policy terms that would be effective on the first day of the new policy year.

(C) Upon request. A health insurance issuer offering individual health insurance coverage must provide an SBC to any policyholder or covered dependent, upon request, as soon as practicable, but in no event later than seven days following the request.

(v) Special rule to prevent unnecessary duplication with respect to individual health insurance coverage. If the policy covers more than one individual (or if an application for coverage is being made for more than one individual); all those individuals are known to reside at the same address; and a single SBC is provided to that address, then the requirement to provide the SBC is satisfied with respect to all individuals residing at that address. If an individual's last known address is different than the last known address of the policyholder, the issuer is required to provide an SBC to the individual at the individual's last known address.

(2) Content – (i) In general. 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;

(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 the rules of 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, or certificate 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;

(L) An Internet address for obtaining the uniform glossary, as described in paragraph (c) of this section; and

(M) Premiums (or in the case of a self-insured group health plan, cost of coverage).

(ii) Coverage examples. The SBC must include coverage examples that illustrate benefits provided under the plan or coverage for common benefits scenarios (including pregnancy and serious or chronic medical conditions) that are identified by the Secretary in accordance with the following:

(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 section, 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 available through the National Guideline Clearinghouse, Agency for Healthcare Research and Quality. The Secretary will specify, in guidance, the types of services, dates of service, applicable billing codes, and allowed charges for each claim in the benefits scenario.

(C) Demonstration of benefit provided. To demonstrate benefits provided under the plan or coverage, a plan or issuer simulates how claims would be processed under the scenarios provided by the Secretary to generate an estimate of cost sharing a consumer could expect to pay under the benefit package. The demonstration of benefits will take into account any cost sharing, excluded benefits, and other limitations on coverage, as described by the Secretary in guidance.

(3) Appearance. A group health plan and a health insurance issuer must provide an SBC as a stand-alone document in the form authorized by the Secretary and completed in accordance with the instructions for completing the SBC that are authorized 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 a health insurance policy), 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 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 plan or 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 2520.104b-1, or the provisions governing electronic disclosure for individual health insurance issuers set forth in paragraph (a)(4)(iii)(B) of this section.

(iii) With respect to an SBC provided by an issuer offering individual health insurance coverage, the SBC may be provided in either electronic or paper form.

(A) Paper disclosure. Unless specified otherwise by an individual, an issuer must provide an SBC (and any subsequent SBC) in paper form if:

(1) Upon the individual's request for information or request for an application for coverage, the individual makes the request in person, by phone, or by mail; or

(2) When submitting an application for coverage, the individual completes the application by phone or mail.

(B) Electronic disclosure—(1) An issuer may provide an SBC (and any SBC provided thereafter) in electronic form (such as through an Internet posting or via electronic mail) if:

(i) Upon an individual's request for information or request for an application for coverage, the individual makes a request electronically; or

(ii) When submitting an application, an individual completes an application for coverage electronically.

(2) If an issuer provides an SBC in electronic form, the issuer must:

(i) Request that an individual acknowledge receipt of the SBC;

(ii) Make the SBC available in an electronic format that is readily usable by the general public;

(iii) If the SBC is posted on the Internet, display the SBC in a location that is prominent and readily accessible to the individual and provide timely notice, in electronic or non-electronic form, to each individual who requests information or applies for coverage that apprises the individual the SBC is available on the Internet and includes the applicable Internet address;

(iv) Promptly provide in accordance with the rules of paragraph (iii), without charge, penalty, or the imposition of any other condition or consequence, a paper copy of the SBC upon request. An issuer must provide an individual with the ability to request a paper copy of the SBC both by using the issuer's Web site (such as by clicking on a clearly identified box to make the request) and by calling a readily available telephone line, the number for which is prominently displayed on the issuer's Web site, policy documents, and other marketing materials related to the policy and clearly identified as to purpose; and

(v) Ensure an SBC provided in electronic form is provided in accordance with the appearance, content, and language requirements of this section.

(C) Deemed compliance. A health insurance issuer offering individual health insurance coverage that complies with the requirements set forth at 45 CFR § 159.120 (relating to the federal health reform Web portal) is deemed to comply with the requirement to provide the SBC to an individual requesting information prior to applying for coverage. However, an issuer must provide any SBC provided at the time of application or subsequently in a form and manner compliant with the requirements of paragraphs (a)(4)(iii)(A) and (a)(4)(iii)(B) of 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 modifications. 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, 29 U.S.C. 1022) 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 a health insurance policy), not later than 60 days prior to the date on which such modification will become effective. The notice of modification must be provided in a form that is consistent with the rules of 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 format requirements of paragraphs (c)(3) and (c)(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, for 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 authorized in guidance, ensuring that the uniform glossary is presented in a uniform format and utilizes 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 days of the request. (Under the rules of paragraph (a) of this section, the form authorized in guidance for the SBC will disclose to participants, beneficiaries, and individuals covered under an individual policy their rights to request a copy of the uniform glossary.)

(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, with

respect to the standards for providing an SBC required under paragraph (a) of this section, 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. This section is applicable beginning March 23, 2012. See §147.140(d) of this chapter, providing that this section applies to grandfathered health plans.

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